AWARENESS, TREATMENT, AND CONTROL OF HYPERTENSION OR DIABETES IN INDIA: THE IMPACT OF PUBLIC HEALTH PROMOTION

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PUBLISHED IN: Frontiers in Public Health

frontiers Research Topics

frontiers

ISSN 1664-8714
ISBN 978-2-88976-226-2
DOI 10.3389/978-2-88976-226-2

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Citation: Thankappan, K. R., Daivadanam, M., Thirunavukkarasu, S., Mini, G. K., Joshi, R., eds. (2022). Awareness, Treatment, and Control of Hypertension or Diabetes in India: The Impact of Public Health Promotion.
Lausanne: Frontiers Media SA. doi: 10.3389/978-2-88976-226-2

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frontiers | Frontiers in Public Health

EDITORIAL
published: 02 May 2022
doi: 10.3389/fpubh.2022.906862

Editorial: Awareness, Treatment, and Control of Hypertension or Diabetes in India: The Impact of Public Health Promotion

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Keywords: awareness, treatment, control, hypertension, diabetes, health promotion, India

Editorial on the Research Topic

Awareness, Treatment, and Control of Hypertension or Diabetes in India: The Impact of Public Health Promotion

In India, recent estimates show that there are 207 million people with hypertension (1) and 74 million people with diabetes (2). A nationally representative study among 1.3 million Indian adults aged 18 years and above reported a hypertension prevalence of 25.3% and a diabetes prevalence of 7.5% in 2012–14 (3). Despite the high prevalence, the awareness (men:32%, women:42%), treatment (men:25%, women:35%) and control (men:11%, women:18%) rates of hypertension in the country are low (4). Similar data for diabetes are not available from a representative sample in India and one of the articles included in this special issue fills this gap.

India is a country with huge variations in health and development indicators between states (5), consequently the prevalence of hypertension and diabetes vary across states. For example, diabetes prevalence among women aged 18 years and above ranges from 2.3% in Madhya Pradesh to 16.4% in Goa and among men, the respective figures are 2.7 and 17.9% (3). Hypertension prevalence among women ranges from 13.5% in Chhattisgarh to 36.3% in Daman and Diu, whereas in men they vary from 17.1 to 43.5%, respectively (3). Similar variation in awareness, treatment and control is also reflected in a few articles included in this issue.

The low rates of awareness, treatment and control of hypertension and diabetes are likely to lead to increased vascular and renal complications in the population (6). Thus, there is an urgent need for improved detection and treatment of these conditions through task-sharing, regular supply of medications, and strategies to improve healthier diet and physical activity (7). An intervention using mobile phone based clinical decision support system in primary care in India was effective in improving hypertension and diabetes control (8). A school based educational intervention in Kerala was found to be effective in improving hypertension control rates among teachers (9). However, unless these studies in controlled settings are scaled up the control rates are likely to be poor.

In this special issue, 11 manuscripts were submitted, and of which nine articles were published; four on hypertension, three on diabetes, one study on hypertension and diabetes, and another study on doctor-patient relationship among hospitalized patients.

OPEN ACCESS

Edited and reviewed by:
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Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: *29 March 2022*
Accepted: *13 April 2022*
Published: *02 May 2022*

Citation:
Thankappan KR, Daivadanam M, Mini GK, Joshi R and Sathish T (2022) Editorial: Awareness, Treatment, and Control of Hypertension or Diabetes in India: The Impact of Public Health Promotion. Front. Public Health 10:906862. doi: 10.3389/fpubh.2022.906862

Bhatia et al. analyzed the nationally representative data of about 72,000 adults (aged $\geq$ 45 years) and reported a hypertension prevalence of 45%. The states with a higher proportion of people below poverty line had a lower performance in the diagnosis of hypertension and states with a greater availability of doctors had a better performance of treatment-seeking behavior.

Thakur and Nangia reported a hypertension prevalence of 40% in Punjab and 26% in Haryana and a diabetes prevalence of 14 and 15%, respectively. The awareness, treatment and control rates of hypertension were 48, 31, and 18%, respectively in Punjab and 33, 26, and 12% in Haryana. These rates for diabetes were 34, 28, and 14%, respectively in Punjab and 29, 22, and 14% in Haryana.

Cao et al. explored factors associated with awareness, treatment, and control of hypertension among adults in Kerala state. The authors reported that psychosocial factors, better engagement with health services in hypertension management, as well as giving more attention to body fat control and largely male-related behaviors such as alcohol consumption are likely to improve hypertension management.

Sreedevi et al. reported the need for control of hypertension among diabetes patients in Kerala state. Most of the diabetes patients in the study did not achieve the target blood pressure control. They suggested effective and stringent screening measures to control hypertension in this population.

Jebasingh and Thomas emphasized the need for physicians to be aware of low birth weight (LBW) as a potential cause for early-onset hypertension and the importance to elicit this history from the mother of the patient. The authors also suggest that LBW babies need to be provided with adequate nutrition and should not be overfed with additional calories which could result in early-onset hypertension.

Mathur et al. provided the prevalence, awareness, treatment and control of diabetes and associated factors amongst adults using a nationally representative sample of 10,659 adults in India. A prevalence of 9% and low rates of awareness (56%), treatment (36%), and control (16%) of diabetes were reported. The authors emphasized the need for continuous monitoring and surveillance of diabetes and the role of comprehensive health promotion and management interventions to achieve the World Health Organization global non-communicable disease voluntary targets by 2025.

Rahul et al. studied the level of glycaemic control among patients with diabetes using a standardized modular based training including the importance of adherence to antidiabetic medication delivered through front line health workers in a randomized controlled trial in Kerala state. The study reported promising results on improving glycaemic control at 6 months after the intervention. These findings emphasize the benefits of utilizing existing health service personnel to control diabetes.

Using a randomized controlled trial, Joshi et al. reported the findings of a pilot study on the development, testing and integration of a multidisciplinary program targeted to address the co-management of tuberculosis and diabetes in a rural primary healthcare setting in Andhra Pradesh. Even though the awareness about diabetes and tuberculosis (TB) and cardiovascular risk increased among non-physician health workers over 8 months, there was no significant variation in the mean blood glucose level in the control and intervention groups. The study findings suggest that co-management of TB and diabetes within the existing health care systems is likely to be feasible.

Gala et al. explored experiences, perceptions and expectations of doctor-patient relationship among recently hospitalized patients in Karnataka state of India. They reported a more positive doctor-patient relationship for those with primary care providers, which is important for improving hypertension and diabetes care.

In summary, the studies published in this special issue reiterate that the prevalence of hypertension and diabetes is high in India, but the rates of awareness, treatment and control are unacceptably low. These findings clearly emphasize the importance of health promotion and other evidence-based interventions to improve these rates to reduce complications related to these health conditions in India.

AUTHOR CONTRIBUTIONS

All authors listed have made a substantial, direct, and intellectual contribution to the work and approved it for publication.

ACKNOWLEDGMENTS

We thank all the authors who contributed to this Research Topic.

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frontiers in Public Health

ORIGINAL RESEARCH
published: 29 October 2021
doi: 10.3389/fpubh.2021.766458

Diagnosis and Treatment of Hypertension Among People Aged 45 Years and Over in India: A Sub-national Analysis of the Variation in Performance of Indian States

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Introduction: Cardiovascular disease (CVD) is the single largest contributor to non-communicable disease (NCD) deaths, with hypertension contributing to a significant proportion of these deaths. This study aims to provide estimates of the prevalence, awareness, treatment and control of hypertension at sub-national levels in India and identifies well and under-performing states with respect to the diagnosis and treatment of hypertension.

Methods: The study utilises data from the Longitudinal Study of Ageing in India (LASI), a nationally representative survey of more than 72,000 individuals. Age-sex adjusted prevalence rates of self-reported hypertension was calculated using the direct standardisation method. Multivariable logistic regression was performed to assess the association of self-reported hypertension with the various individual co-morbidity, lifestyle, and household factors. Self-reported prevalence was compared with an objective measure of hypertension for each state, and funnel plots were constructed to assess the performance of states.

Results: Our findings suggest that the overall prevalence of age-sex adjusted self-reported hypertension was 25.8% in India with significant variation among states. Results based on logistic regression confirm that those individuals who are elderly, obese, belong to a higher socio-economic group and have associated co-morbidities are at increased odds of reporting hypertension. Overall, 4 out of 10 adults over 45 years of age in India are not aware of their hypertensive condition, and of those who are aware, 73% are currently taking medication, and only 10% of these have their hypertension under control. Based on the performance, states were classified into high and low performing categories. States with an increased proportion of population below the poverty line had significantly lower performance with respect to the diagnosis of hypertension, whereas states with higher literacy rates and greater availability of specialist doctors at community health centres (CHCs) had significantly better performance with respect to treatment-seeking behaviour.

OPEN ACCESS

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Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: *29 August 2021*
Accepted: *07 October 2021*
Published: *29 October 2021*

Citation:
Bhatia M, Kumar M, Dixit P and Dwivedi LK (2021) Diagnosis and Treatment of Hypertension Among People Aged 45 Years and Over in India: A Sub-national Analysis of the Variation in Performance of Indian States. Front. Public Health 9:766458. doi: 10.3389/fpubh.2021.766458

Conclusion: The findings of this study and its policy implications are discussed. Based on state performance, strategies are proposed in terms selective targeting vs. population-based strategies. High impact states and sub-groups are identified where intense efforts are needed to tackle the growing menace of hypertension in India.

Keywords: hypertension, awareness, diagnosis, treatment, variation in performance, India

INTRODUCTION

Non-communicable diseases (NCDs) are a leading cause of mortality worldwide and disproportionately affect low and middle income countries. According to the World Health Organisation (WHO), NCDs account for 71% of all deaths globally, and 77% of these deaths occur in low and middle income countries (1). Cardiovascular disease (CVD) is the single largest contributor with over 44% of all NCD deaths (1). Not only are CVDs rising rapidly in low and middle income countries, but unlike the west, these diseases are affecting younger age groups that are economically productive. For example, 30% of NCD-related deaths in low income countries occur under the age of 60, whereas in high income countries, the proportion is only 13% (2). India is no exception to this trend. According to the Global Burden of Disease (GBD) Study, disability adjusted life years (DALYs) as a result of NCDs have increased from 29.2% in 1990 to 57.9% in 2019 (3).

NCDs are not only a major burden on already weak public health care systems further weakened by COVID, but also contribute significantly to financial hardship in households in many low and middle income countries. The economic burden of NCDs is enormous. A study estimated that the economic loss due to NCDs over the next two decades would represent 75% of global Gross Domestic Product (GDP) (4). It is therefore not surprising to note efforts by the global community to reduce the burden of NCDs. For example, the United Nations (UN) sustainable development goal 3 (SDGs) aims to reduce premature mortality from NCDs by a third by 2030 (5).

Hypertension (HT) is one of the commonest NCD, and a major public health concern accounting for 19% of all NCD deaths globally (1). In South Asia, HT is estimated to be the third leading cause of death and disability, after household air pollution and tobacco smoking (6). In addition, it is an independent risk factor for coronary heart disease; the asymptomatic nature of HT contributes to a lack of awareness of this condition, thus being labelled a "silent killer disease." If undiagnosed or uncontrolled, HT can significantly contribute to unnecessary death and disability due to coronary heart disease. Hence, it is crucial that the basic principle of levels of prevention in public health is adhered to, including early diagnosis and prompt treatment.

India is the second most populous nation, contributing to 18% of the world's population (7), and is one of the fastest growing economies in the world. The country ranked 131 among 188 countries in the SDG progress indicators (8), with widespread diversity among regions and states of India. Health in India is a state subject, in that the responsibility of financing and delivering health care lies with the respective states. However, there is considerable variation among the states in terms of their population coverage, human development index (HDI), the level of demographic and epidemiological transition taking place, and health system capacity including supply side constraints, all of which have an impact on the prevalence of disease and the quality of health service that the state is able to provide to its population. For example, states like Kerala and Goa, with an HDI of over 7.5, experience health indicators comparable to Sri Lanka and China, whereas states like Jharkhand, Uttar Pradesh and Bihar with an HDI below 6 experience health indicators comparable to Kenya, Cambodia and the Republic of Congo (9). This relationship is reversed in the case of NCDs and HT, where more developed states with a higher HDI, and urbanisation experience higher HT prevalence rates (10).

There have been number of studies reporting on the prevalence of HT across various geographical regions in India (11–16) and occupational status groups (17–19). According to a recent study based on a national-level blood pressure survey, the prevalence of HT among individuals aged 18+ and 65+ years was nearly 30 and 52%, respectively (20). Moreover, a meta-analysis based on 142 communities-based studies in India observed significant differences in the prevalence of HT across the Indian regions, where HT prevalence in rural regions varies between 14.5% (North) and 31.7% (East), while in urban regions it varies between 28.8% (North) and 35.8% (West) (21). This region-wide variation demands updated state-level estimates for the prevalence, awareness, treatment and control of HT based on nationally representative data for older Indian adults. In addition, although there are few studies reporting on the prevalence of HT in which individual socio-economic characteristics were analysed, there are hardly any studies that have analysed the variation in state performance with respect to the diagnosis and treatment of HT on a nationally representative survey.

Given the decentralised health care system in India and considerable variation in access to health care, varying levels of access to government health facilities and high out of pocket payments, a disaggregate analysis providing estimates of performance of states with respect to the diagnosis and treatment of HT would benefit sub-national policy makers to identify and target priority states and sub-groups within the states where intense efforts are needed to effectively plan interventions and strategies related to tackling the burden of HT. Such research is all the more necessary, as a study over two decades has concluded that, in spite of a significant increase in the prevalence of HT in India, there has been no improvement in the management of HT during this time (22).

This study therefore aims to identify the characteristics of those who have been diagnosed as hypertensive and are taking treatment, and to assess the performance of states with respect to diagnosis and treatment of HT. Through the use of maps, logistic regression and funnel plots, in addition to undertaking a disaggregate analysis at the sub-national level, the present study contributes to the existing literature by providing current estimates of the prevalence, awareness, treatment and control of HT, and identifies well- and under-performing states with respect to the diagnosis and treatment of HT. Furthermore, the study investigates the possible determinants of the prevalence and treatment of HT among older adults aged 45 years and above and the causes for the variation in performance by linking it to state development, supply side constraints, public health system capacities and the role of the private sector. Finally, by identifying high impact states and sub-groups, this paper makes policy recommendations to ensure government policies, programmes and limited resources are better targeted to key states and high risk groups where intense efforts are needed in order to reduce the mortality and morbidity associated with HT in India.

MATERIALS AND METHODS

Data Source and Study Population

We used data from the Longitudinal Ageing Survey of India (LASI, 2017–18) which is a national representative survey of over 72,000 older adults aged 45 years and above (including spouses irrespective of their age) across all states and UTs in India, except Sikkim. The main objective of the LASI survey was to provide scientific evidence on demographics, household economic status, chronic health conditions, functional and mental health, biomarkers, health care utilisation, work and employment, etc. LASI adopted a multistage stratified area probability cluster sampling design to arrive at the eventual units of observations: a three-stage sampling design in rural areas and a four-stage sampling design in urban areas. The detailed methodology, with the complete information on the survey design and data collection, was published in the survey report (23). The present study was based on the eligible older adults aged 45 years and above, and the effective sample size was 65,562.

Measures

Self-reported HT was assessed by asking the question, "*Has any health professional ever told you that you have HT or high blood pressure?*" The participants who responded "Yes" to this question were considered hypertensive. Only self-identified hypertensive participants were further asked about their treatment-seeking behaviour: "*In order to control your blood pressure or HT, are you currently taking any medication?*" In the biomarker measurements section, LASI also provides the blood pressure measurements of older adults. HT was defined as the average of the last two readings of systolic blood pressure (SBP) $\geq$ 140 mmHg or/and diastolic blood pressure (DBP) $\geq$ 90 mmHg. The prevalence of 'overall HT' is defined as the proportion of hypertensive older adults either by self-reported or biometric measurement. Controlled HT is defined as SBP $<$ 140 mmHg or DBP $<$90 mmHg and currently taking anti-hypertensive medication (24).

Covariates

Socio-Demographic Variables

Various demographic variables such as gender (male, female), age (45–54, 55–64, 65–74, or 75+ years), education (no education, primary, secondary, or higher), working status (never worked, currently working or not currently working), and marital status (currently married, widowed or divorced/separated/deserted) were included in the analysis. LASI collected information from households about their spending on food (a reference period of 7 days) and non-food items (reference periods of 30 and 365 days). After standardising the food and non-food expenditure to a 30-day reference period, the monthly per capita consumption expenditure (MPCE) was computed and used as the summary measure of consumption: poorest, poorer, middle, richer, and richest. Various other household factors, including caste (scheduled tribe, scheduled caste, other backward class, or other), religion (Hindu, Muslim, Christian, or other), and place of residence (rural or urban), and region (North, Central, East, Northeast, West, and South) of residence were included in the analysis.

Health Status

Body mass index (BMI) was recoded as underweight ($<$18.5), normal (18.5–24.9), overweight (25–29.9) or obese (30 and above); we have combined overweight and obese for analytical purposes. We have included three self-reported chronic diseases (diabetes, arthritis and stroke) diagnosed by a health professional. Functional health was assessed by basic and instrumental activities of daily living (ADLs). Six basic ADLs (BADLs) include dressing, indoor mobility, bathing, eating difficulties, getting in or out of bed and using the toilet, and seven instrumental ADLs (IADLs) include food preparation, shopping for groceries, taking medication, making telephone calls, doing work around the house or garden, ability to handle finances and getting around or finding an address in unfamiliar places. We created two variables for assessing the functional limitations: difficulty in ADLs (at least one difficulty in six BADLs) and difficulty in IADLs (at least one difficulty in seven IADLs).

Lifestyle Behaviours

In LASI, the participants were asked about their tobacco use status (smoking and smokeless). Based on the information, we have classified the participants as: never, former or current tobacco users. Alcohol drinking status was assessed with a yes/no question. To assess the level of physical activities among older adults, LASI collected information on moderate (*washing clothes, cleaning the house, fetching water, drawing water from a well, gardening, walking at a moderate pace, bicycling at a regular pace, and floor or stretching exercises*) and vigorous (*swimming, running or jogging, going to health centre/gym, cycling, digging with a spade or shovel, heavy lifting, chopping, farm work, fast bicycling, and cycling with a load*) physical activities. The possible responses for moderate and vigorous physical activities were: every day, more than once a week, once a week, one to three times per month

TABLE 1 | Unadjusted and age-sex adjusted prevalence of self-reported and its treatment, India, LASI, 2017–18.

	Unadjusted % (95% CI)		Adjusted % (95% CI)	
	Self-reported HT	**Taking treatment for HT**	**Self-reported HT**	**Taking treatment for HT**
State/UT				
Jammu and Kashmir	40.6 (38.1, 43.1)	85.3 (82.4, 88.2)	37.7 (34.6, 40.9)	82.5 (76.9, 88.1)
Himachal Pradesh	32.9 (30.3, 35.5)	63.7 (59.0, 68.5)	30.4 (27.4, 33.4)	60.1 (53.6, 66.6)
Punjab	42.8 (40.6, 45.0)	73.9 (71.0, 76.9)	40.7 (38.0, 43.4)	73.0 (68.8, 77.2)
Chandigarh	39.6 (36.4, 42.7)	80.7 (76.7, 84.7)	37.9 (34.4, 41.4)	76.8 (71.5, 82.1)
Uttarakhand	26.6 (24.2, 29.1)	56.6 (51.3, 61.8)	25.2 (22.5, 27.9)	56.0 (49.3, 62.7)
Haryana	38.4 (36.2, 40.7)	55.2 (51.4, 59.0)	37.0 (34.4, 39.5)	53.0 (48.3, 57.7)
Delhi	35.8 (33.0, 38.5)	68.1 (63.5, 72.8)	35.8 (32.2, 39.5)	63.4 (57.2, 69.5)
Rajasthan	27.3 (25.4, 29.2)	59.7 (55.7, 63.7)	25.6 (23.5, 27.7)	57.4 (52.1, 62.7)
Uttar Pradesh	20.0 (18.8, 21.2)	57.5 (54.2, 60.7)	19.5 (18.1, 20.9)	56.0 (52.0, 60.1)
Bihar	25.1 (23.6, 26.6)	49.2 (45.8, 52.6)	23.7 (21.6, 25.8)	44.1 (39.4, 48.8)
Arunachal Pradesh	22.6 (20.0, 25.2)	31.7 (25.2, 38.2)	23.0 (19.2, 26.7)	34.0 (25.7, 42.4)
Nagaland	15.8 (13.8, 17.9)	60.5 (52.8, 68.2)	15.5 (10.2, 20.8)	61.5 (48.5, 74.6)
Manipur	28.7 (26.2, 31.2)	69.9 (64.9, 74.8)	27.1 (23.8, 30.3)	64.6 (57.5, 71.7)
Mizoram	24.0 (21.5, 26.5)	43.7 (37.8, 49.6)	21.8 (18.7, 25.0)	40.6 (32.8, 48.3)
Tripura	30.4 (27.6, 33.2)	68.0 (62.8, 73.2)	29.4 (26.5, 32.4)	66.2 (60.2, 72.1)
Meghalaya	25.9 (23.0, 28.8)	78.1 (72.6, 83.6)	23.3 (20.3, 26.3)	73.1 (64.4, 81.9)
Assam	31.1 (29.1, 33.1)	64.7 (60.9, 68.5)	30.5 (28.4, 32.7)	61.6 (57.2, 65.9)
West Bengal	29.6 (28.0, 31.1)	74.6 (72.1, 77.2)	28.0 (26.0, 30.1)	72.2 (68.0, 76.3)
Jharkhand	21.7 (20.0, 23.4)	64.1 (59.8, 68.4)	20.2 (18.4, 22.0)	61.7 (56.4, 67.0)
Odisha	20.4 (18.9, 21.9)	67.7 (63.8, 71.6)	19.2 (17.6, 20.7)	64.5 (59.6, 69.4)
Chhattisgarh	16.5 (14.8, 18.2)	68.8 (63.6, 74.1)	16.3 (14.5, 18.1)	66.0 (60.1, 71.9)
Madhya Pradesh	20.0 (18.5, 21.5)	64.2 (60.2, 68.2)	19.3 (17.0, 21.6)	58.3 (52.1, 64.6)
Gujarat	25.7 (23.9, 27.6)	69.2 (65.2, 73.1)	24.2 (22.1, 26.3)	63.9 (58.5, 69.4)
Daman and Diu	32.9 (29.9, 36.0)	79.8 (75.1, 84.4)	31.2 (27.4, 35.0)	75.8 (68.6, 83.0)
Dadra and Nagar Haveli	17.0 (14.7, 19.3)	69.4 (61.8, 76.9)	16.9 (14.1, 19.7)	68.9 (60.4, 77.5)
Maharashtra	28.9 (27.4, 30.3)	86.4 (84.4, 88.5)	26.0 (24.3, 27.8)	82.8 (79.2, 86.4)
Andhra Pradesh	34.9 (33.0, 36.9)	88.3 (86.2, 90.5)	33.3 (31.3, 35.3)	86.6 (83.8, 89.4)
Karnataka	32.7 (30.7, 34.7)	91.7 (89.3, 94.1)	31.1 (23.3, 38.9)	89.5 (82.2, 96.9)
Goa	44.1 (41.4, 46.8)	94.7 (92.8, 96.6)	40.8 (37.4, 44.1)	93.0 (89.7, 96.3)
Lakshadweep	35.5 (32.6, 38.4)	76.7 (72.6, 80.8)	33.3 (29.6, 36.9)	74.3 (68.0, 80.7)
Kerala	41.0 (39.0, 43.1)	87.6 (85.5, 89.7)	36.6 (33.7, 39.6)	81.0 (76.2, 85.8)
Tamil Nadu	26.3 (24.8, 27.9)	76.7 (74.0, 79.4)	24.6 (22.7, 26.4)	75.1 (71.1, 79.1)
Puducherry	32.7 (30.1, 35.3)	87.8 (84.9, 90.8)	29.8 (26.8, 32.7)	84.7 (79.8, 89.6)
Andaman and Nicobar Islands	41.2 (38.3, 44.1)	78.8 (75.0, 82.6)	40.4 (36.2, 44.6)	76.4 (70.7, 82.1)
Telangana	31.0 (29.1, 32.9)	87.6 (85.2, 90.0)	28.7 (26.7, 30.8)	87.7 (84.9, 90.6)
India	**27.4 (27.1, 27.7)**	**73.0 (72.4, 73.6)**	**25.8 (24.9, 26.7)**	**70.1 (68.2, 72.0)**

HT, hypertension.

and hardly ever or never. Based on these responses, we classified the respondent as physically active (more than once a week) and physically inactive (engagement of once a week or less often) for both moderate and vigorous activities.

In addition, macro-level secondary data, which may affect self-reported HT prevalence and treatment among Indian older adults, was collected for different covariates to explain state level variations in performance. Information about the state-wise HDI and percentage of persons below the poverty line (BPL) was obtained from Indiastat.com. Data for the variables, including doctors available at primary health centres (PHCs), specialists available at community health centres (CHCs), and per capita health expenditure were obtained from India's National Health Profile report (25). Information about state-wise literacy rates was obtained from the Census of India (2011). Moreover, the Longitudinal Ageing Survey in India report (23) was used to derive the data for state-wise out-of-pocket expenditure (OOPE).

Statistical Analysis

We calculated the age-sex adjusted prevalence rates of self-reported HT and treatment of HT for all states and Union Territories (UTs) using the direct standardisation method.

The age-sex structure of the national population from Census 2011 was used as the reference population for carrying out the standardisation. We assessed the diagnosis-based performance of all the states defined as the ratio of older adults who are aware of their HT status and overall HT. We further constructed funnel plots to observe the variation in diagnosis-based performance, HT treatment, and controlled HT between states. The national average of diagnosis-based performance, HT treatment, and controlled HT (indicated by a solid line parallel to the x-axis) was used as the baseline reference. The 95 and 99% confidence bands were also created on the funnel plots. We used multivariable logistic regression to assess the association of self-reported HT and treatment of HT with the various individual (i.e., age, education, working status and marital status), morbidities (i.e., diabetes, stroke and arthritis), lifestyle (i.e., smoking status, chewing tobacco, drinking alcohol, moderate and vigorous activities) and household (i.e., MPCE quintile, religion, caste and residence) factors. Finally, a regression model using select state level covariates was performed to explain the variation in state performance with respect to the diagnosis and treatment of HT.

RESULTS

As observed in **Table 1**, the prevalence of unadjusted self-reported HT subjects had a 1.6 percentage point greater prevalence than adjusted self-reported HT subjects (27.4 vs. 25.8%). The results indicate that the sex and age-adjusted prevalence of self-reported HT varied greatly between states and UTs, with a prevalence of about 16% in Chhattisgarh, Nagaland, and Dadra and Nagar Haveli to prevalence of 41% in Punjab, Goa and Andaman and Nicobar Islands. Interestingly, the prevalence of self-reported adjusted HT was highest in the states belonging to the northern region, namely Jammu and Kashmir (37.7%), Chandigarh (37.9%), Haryana (37%), Delhi (35.8%), and Kerala (36.6%) from the southern region. On the contrary, self-reported prevalence of HT was relatively low in states belonging to the central region such as Uttar Pradesh (19.5%), Madhya Pradesh (19.3%) and Odisha (19.2%) from the eastern part of India.

The unadjusted current treatment seeking for HT was 2.9 percentage points greater than adjusted treatment seeking (73 vs. 70.1%). Adjusted treatment seeking among those aged 45 years and above varied significantly across the states and UTs in India, from about 34% in Arunachal Pradesh to 93% in Goa. It is important to note that Goa was one of the states where adjusted self-reported HT was also highest among all the states. Mostly high treatment seeking was observed in southern states like Karnataka (89.5%), Telangana (87.7%), Andhra Pradesh (86.6%), Puducherry (84.7%) and Kerala (81%) and was low in Mizoram (40%), and Bihar (44%).

Table 2 shows the adjusted odds ratios (AOR) for self-reported HT separately for men and women. A range of individual variables, presence of co-morbidities, lifestyle factors and household factors were included in the model. The results show that increasing age positively affected HT in both genders, and currently working men and women were less likely to report HT compared to individuals who never worked. Compared with individuals with a normal BMI, individuals who were overweight or obese were more likely to suffer with HT [AOR (95%CI): ranging from 1.68 (1.56–1.80) in men to 1.79 (1.69–1.90) in women]. All the morbidity-related factors like presence of diabetes, stroke, arthritis and difficulty in ADL and IADL were positively related to HT prevalence in both men and women. Among the lifestyle factors, if women were moderately active and men were vigorously active, then they had less chance of having HT relative to inactive individuals. Household characteristics were also significantly associated with the risk of self-reported HT. Individuals who belonged to poorer to the richest households (compared with the poorest households), or belonged to other religion (compared with Hindu) and from an urban area (compared with rural) were associated with an increased risk of HT. However, the AORs of the individual from scheduled tribe (compared to scheduled caste) and from the central and western regions (compared with the northern region) were significantly less likely to report HT.

The AORs of current treatment seeking behaviour for HT using multivariable logistic regression analysis are given in **Table 3**. In the multivariable analysis, the odds for treatment seeking of HT increased with age and was highest among the age groups 75 years and older (among men AOR: 2.18; 95% CI 1.44–3.31 and among women AOR: 2.27; 95% CI 1.68–3.06). In men, education was not significantly associated with treatment seeking, but in women, if they had a secondary level education, they were more likely to take treatment compared to less educated women. In both men and women, if they were overweight/obese, their chances of taking treatment increased. Those with diabetes had higher odds of treatment seeking (among men AOR: 1.84; 95% CI 1.45–2.33 and among women AOR: 1.92; 95% CI 1.55–2.38). Men suffering from stroke were significantly associated with treatment seeking.

Table 4 depicts the state-wise performance of self-reported HT, undiagnosed HT (newly diagnosed cases or measured at the time of survey), total prevalence (addition of self-reported HT and undiagnosed HT), currently taking medicine (treated), and controlled HT (on treatment and had a normal BP). At the national level, 27.4% of individuals had self-reported HT and 17.8% were not aware about their HT condition and learned of it at the time of survey. This indicates that about four out of 10 adults aged 45 years and older are suffering from HT and only 60% are aware of their hypertensive status. Among hypertensive individuals, 73% reported currently taking treatment, and only 10.4% had a normal BP. **Table 4** also shows considerable variation among states and UTs in the proportion of all these indicators, as total HT was highest in Lakshadweep (66.1%) and lowest in Uttar Pradesh (34.7%) and Mizoram (34.8%). Undiagnosed HT cases varied from 9.7% in Jammu and Kashmir to 38.5% in Nagaland and 28.6% in Chhattisgarh; and those diagnosed out of total HT cases varied from 29.2% in Nagaland and 36.6% in Chhattisgarh to 80.7% in Jammu and Kashmir; treated HT cases ranged from 31.7% in Arunachal Pradesh to 94.7% in Goa; and controlled BP varied from 1.1% in Nagaland to 23.5% in Goa. It is important to note that Jammu and Kashmir, Chandigarh, Haryana and Goa performed better in comparison to other states as the proportion of self-reported HT out of total HT was higher,

TABLE 2 | Logistic regression results for self-reported hypertension among older adults, India, LASI, 2017–18.

	AOR (Overall)	95% CI	AOR (Men)	95% CI	AOR (Women)	95% CI
Individual factors						
Age groups						
45–54	Ref.		Ref.		Ref.	
55–64	1.39***	(1.32, 1.46)	1.41***	(1.30, 1.53)	1.41***	(1.32, 1.50)
65–74	1.76***	(1.66, 1.87)	1.88***	(1.71, 2.07)	1.81***	(1.68, 1.96)
75+	1.80***	(1.66, 1.95)	2.07***	(1.82, 2.34)	1.85***	(1.66, 2.07)
Education level						
No education	Ref.		Ref.		Ref.	
Primary	1.13***	(1.07, 1.19)	1.18***	(1.09, 1.29)	1.25***	(1.16, 1.34)
Secondary	1.06	(0.99, 1.12)	1.25***	(1.14, 1.37)	1.09	(1.00, 1.19)
Higher	1.11*	(1.02, 1.20)	1.42***	(1.27, 1.59)	0.98	(0.86, 1.11)
Working status						
Never worked	Ref.		Ref.		Ref.	
Currently working	0.69***	(0.66, 0.73)	0.81*	(0.69, 0.95)	0.79***	(0.74, 0.85)
Not currently working	0.97	(0.92, 1.02)	1.13	(0.96, 1.33)	1.05	(0.98, 1.12)
Marital status						
Currently married	Ref.		Ref.		Ref.	
Widowed	1.29***	(1.23, 1.36)	0.97	(0.87, 1.08)	1.30***	(1.23, 1.39)
D/S/D/Others[a]	1.00	(0.89, 1.12)	0.85	(0.70, 1.02)	1.10	(0.95, 1.28)
BMI categories						
Normal	Ref.		Ref.		Ref.	
Underweight	0.64***	(0.60, 0.68)	0.63***	(0.58, 0.70)	0.64***	(0.59, 0.70)
Overweight/obese	1.77***	(1.69, 1.85)	1.68***	(1.56, 1.80)	1.79***	(1.69, 1.90)
Morbidities						
Diabetes						
No	Ref.		Ref.		Ref.	
Yes	3.51***	(3.32, 3.72)	3.61***	(3.33, 3.92)	3.46***	(3.20, 3.74)
Stroke						
No	Ref.		Ref.		Ref.	
Yes	3.32***	(2.85, 3.87)	3.62***	(2.97, 4.40)	3.03***	(2.37, 3.88)
Arthritis						
No	Ref.		Ref.		Ref.	
Yes	1.39***	(1.30, 1.49)	1.32***	(1.17, 1.48)	1.42***	(1.30, 1.54)
Difficulty in ADL[b]						
No	Ref.		Ref.		Ref.	
Yes	1.20***	(1.13, 1.27)	1.27***	(1.15, 1.41)	1.16***	(1.07, 1.25)
Difficulty in IADL[c]						
No	Ref.		Ref.		Ref.	
Yes	1.17***	(1.11, 1.22)	1.15***	(1.06, 1.25)	1.13***	(1.06, 1.20)
Lifestyle factors						
Moderate activities						
Inactive	Ref.		Ref.		Ref.	
Active	0.97	(0.92, 1.01)	0.95	(0.89, 1.02)	0.90***	(0.85, 0.95)
Vigorous activities						
Inactive	Ref.		Ref.		Ref.	
Active	0.91***	(0.86, 0.96)	0.90**	(0.83, 0.96)	0.97	(0.90, 1.04)
Smoking tobacco						
Never	1.00	(1.00, 1.00)	1.00	(1.00, 1.00)	1.00	(1.00, 1.00)
Former	1.04	(0.95, 1.15)	1.06	(0.95, 1.18)	1.25	(0.99, 1.58)
Current	0.85***	(0.79, 0.91)	0.91*	(0.84, 0.98)	0.99	(0.85, 1.15)

(Continued)

TABLE 2 | Continued

	AOR (Overall)	95% CI	AOR (Men)	95% CI	AOR (Women)	95% CI
Chewing tobacco						
Never	Ref.		Ref.		Ref.	
Former	1.05	(0.92, 1.19)	1.01	(0.86, 1.20)	1.13	(0.92, 1.40)
Current	0.93**	(0.88, 0.98)	0.89**	(0.82, 0.97)	1.03	(0.95, 1.12)
Alcohol consumption						
No	Ref.		Ref.		Ref.	
Yes	0.95	(0.89, 1.01)	1.06	(0.99, 1.14)	0.86	(0.74, 1.01)
Household factors						
MPCE quintile						
Poorest	Ref.		Ref.		Ref.	
Poorer	1.15***	(1.08, 1.23)	1.08	(0.98, 1.20)	1.19***	(1.09, 1.29)
Middle	1.25***	(1.17, 1.34)	1.16**	(1.04, 1.28)	1.30***	(1.20, 1.42)
Richer	1.37***	(1.28, 1.46)	1.30***	(1.17, 1.44)	1.39***	(1.28, 1.52)
Richest	1.42***	(1.33, 1.52)	1.36***	(1.23, 1.51)	1.43***	(1.30, 1.56)
Religion						
Hindu	Ref.		Ref.		Ref.	
Muslim	1.23***	(1.15, 1.31)	1.12*	(1.01, 1.24)	1.38***	(1.27, 1.50)
Christian	1.03	(0.94, 1.12)	1.00	(0.87, 1.15)	1.05	(0.94, 1.18)
Others[$]	1.26***	(1.15, 1.39)	1.27***	(1.10, 1.47)	1.34***	(1.18, 1.52)
Caste						
Scheduled caste	Ref.		Ref.		Ref.	
Scheduled tribe	0.76***	(0.70, 0.82)	0.78***	(0.69, 0.89)	0.74***	(0.66, 0.82)
OBC[#]	0.99	(0.93, 1.05)	0.98	(0.89, 1.07)	1.00	(0.92, 1.08)
Others	1.04	(0.97, 1.11)	1.07	(0.96, 1.18)	1.02	(0.93, 1.11)
Place of residence						
Rural	Ref.		Ref.		Ref.	
Urban	1.19***	(1.14, 1.25)	1.19***	(1.11, 1.28)	1.18***	(1.11, 1.26)
Region						
North	Ref.		Ref.		Ref.	
Central	0.67***	(0.62, 0.72)	0.69***	(0.61, 0.78)	0.66***	(0.60, 0.73)
East	0.84***	(0.79, 0.91)	0.92	(0.82, 1.03)	0.81***	(0.74, 0.88)
Northeast	1.00	(0.92, 1.10)	1.10	(0.96, 1.26)	0.87*	(0.78, 0.99)
West	0.77***	(0.71, 0.83)	0.83**	(0.74, 0.93)	0.71***	(0.64, 0.78)
South	0.84***	(0.79, 0.90)	0.96	(0.87, 1.06)	0.76***	(0.70, 0.83)

[#]*Other Backward Classes.*

[$]*Includes Sikh, Buddhist/neo-Buddhist, Jain, Parsi/Zoroastrian and others.*

[a]*Divorced, separated, and deserted.*

[b]*Activities of daily living includes dressing, walking across a room, bathing, eating difficulties, getting in or out of bed and toilet use (any one or more).*

[c]*Instrumental Activities of Daily Living (IADL) includes preparing a hot meal, shopping for groceries, making telephone calls, taking medications, doing work around the house or garden, managing money and getting around or finding address in unfamiliar place (any one or more).*

*$p < 0.05$, **$p < 0.01$, ***$p < 0.001$.

BMI, Body Mass Index; AOR, Adjusted Odds Ratio; CI, Confidence Interval.

indicating better performance of the health systems in these states.

Figures 1–3 shows the funnel plots of state performance with respect to diagnosis, treatment, and control of HT. The figures show the states with the lowest prevalence of diagnosed HT, lowest proportion of patients taking treatment, and lowest percentages of controlled HT with the highest percentage of these indicators compared with Indian average figures, as indicated by a solid line parallel to the x-axis. The prevalence of these HT-related indicators at the national level was used as a baseline comparison for each state. Data points closer to the y-axis are states with a smaller population size and those on the right side have larger population size. Data points that are outside the confidence interval (CI) band are pointed out as having a different prevalence of HT-related indicators from the Indian average. Those states outside the 99% CI can be measured as outliers in terms of their performance with respect to the mentioned indicators. States that are above the Indian average are the best-performing states and those below the national average are the worst-performing states in terms of awareness, treatment

TABLE 3 | Logistic regression results for currently taking treatment of hypertension among older adults, India, LASI, 2017–18.

	AOR (overall)	95% CI	AOR (men)	95% CI	AOR (women)	95% CI
Individual factors						
Age groups						
45–54	Ref.		Ref.		Ref.	
55–64	1.65***	(1.42, 1.93)	1.94***	(1.46, 2.57)	1.52***	(1.27, 1.81)
65–74	1.96***	(1.64, 2.34)	2.14***	(1.59, 2.86)	1.82***	(1.44, 2.29)
75+	2.24***	(1.77, 2.85)	2.18***	(1.44, 3.31)	2.27***	(1.68, 3.06)
Education level						
No education	Ref.		Ref.		Ref.	
Primary	1.11	(0.95, 1.29)	1.08	(0.84, 1.37)	1.14	(0.93, 1.40)
Secondary	1.30*	(1.05, 1.60)	1.17	(0.87, 1.57)	1.56**	(1.19, 2.04)
Higher	1.32*	(1.05, 1.67)	1.37	(0.98, 1.91)	1.16	(0.78, 1.73)
Working status						
Never worked	Ref.		Ref.		Ref.	
Currently working	0.78**	(0.65, 0.93)	0.66	(0.40, 1.10)	0.89	(0.72, 1.10)
Not currently working	0.95	(0.81, 1.11)	0.98	(0.61, 1.58)	0.91	(0.76, 1.10)
Marital status						
Currently married	Ref.		Ref.		Ref.	
Widowed	1.22**	(1.05, 1.41)	0.99	(0.70, 1.40)	1.25*	(1.05, 1.49)
D/S/D/Others[a]	0.76	(0.52, 1.10)	0.63	(0.33, 1.23)	0.84	(0.54, 1.30)
BMI categories						
Normal	Ref.		Ref.		Ref.	
Underweight	0.62***	(0.53, 0.73)	0.46***	(0.36, 0.59)	0.76*	(0.62, 0.94)
Overweight/obese	1.61***	(1.40, 1.84)	1.50***	(1.19, 1.90)	1.68***	(1.43, 1.99)
Comorbidities						
Diabetes						
No	Ref.		Ref.		Ref.	
Yes	1.88***	(1.60, 2.21)	1.84***	(1.45, 2.33)	1.92***	(1.55, 2.38)
Stroke						
No	Ref.		Ref.		Ref.	
Yes	1.85***	(1.34, 2.55)	2.12**	(1.33, 3.38)	1.53	(0.98, 2.41)
Arthritis						
No	Ref.		Ref.		Ref.	
Yes	0.99	(0.80, 1.23)	1.13	(0.81, 1.57)	0.94	(0.72, 1.22)
Difficulty in ADL[b]						
No	Ref.		Ref.		Ref.	
Yes	1.20	(0.99, 1.47)	1.15	(0.80, 1.66)	1.23	(1.00, 1.51)
Difficulty in IADL[c]						
No	Ref.		Ref.		Ref.	
Yes	0.98	(0.85, 1.13)	0.87	(0.68, 1.10)	1.04	(0.88, 1.23)
Lifestyle factors						
Moderate activities						
Inactive	Ref.		Ref.		Ref.	
Active	0.85*	(0.74, 0.96)	0.92	(0.74, 1.16)	0.80**	(0.67, 0.94)
Vigorous activities						
Inactive	Ref.		Ref.		Ref.	
Active	0.94	(0.81, 1.10)	0.94	(0.75, 1.18)	0.93	(0.76, 1.13)
Smoking tobacco						
Never	Ref.		Ref.		Ref.	
Former	1.25	(0.96, 1.64)	1.50*	(1.09, 2.07)	0.71	(0.44, 1.14)
Current	0.98	(0.81, 1.19)	1.04	(0.81, 1.32)	0.92	(0.65, 1.30)

(Continued)

TABLE 3 | Continued

	AOR (overall)	95% CI	AOR (men)	95% CI	AOR (women)	95% CI
Chewing tobacco						
Never	Ref.		Ref.		Ref.	
Former	0.83	(0.58, 1.19)	0.73	(0.47, 1.14)	1.00	(0.56, 1.78)
Current	0.93	(0.79, 1.08)	0.80*	(0.64, 1.00)	1.07	(0.86, 1.34)
Alcohol consumption						
No	Ref.		Ref.		Ref.	
Yes	0.76**	(0.64, 0.91)	0.79*	(0.64, 0.98)	0.75	(0.49, 1.17)
Household factors						
MPCE quintile						
Poorest	Ref.		Ref.		Ref.	
Poorer	1.39**	(1.13, 1.71)	1.47*	(1.03, 2.11)	1.36*	(1.07, 1.73)
Middle	1.51***	(1.23, 1.87)	1.37	(0.96, 1.96)	1.63***	(1.29, 2.07)
Richer	1.63***	(1.32, 2.02)	1.66**	(1.16, 2.39)	1.63***	(1.29, 2.06)
Richest	1.81***	(1.45, 2.27)	1.96***	(1.34, 2.85)	1.73***	(1.35, 2.23)
Religion						
Hindu	Ref.		Ref.		Ref.	
Muslim	1.17	(0.97, 1.41)	1.40*	(1.01, 1.94)	1.05	(0.83, 1.33)
Christian	1.08	(0.82, 1.42)	1.02	(0.67, 1.56)	1.12	(0.78, 1.61)
Others[$]	1.24	(0.96, 1.60)	1.38	(0.97, 1.96)	1.19	(0.83, 1.69)
Caste						
Scheduled caste	Ref.		Ref.		Ref.	
Scheduled tribe	0.80	(0.62, 1.03)	0.76	(0.51, 1.14)	0.84	(0.61, 1.16)
OBC[#]	0.92	(0.77, 1.09)	0.88	(0.68, 1.14)	0.98	(0.78, 1.22)
Others	1.03	(0.86, 1.24)	1.00	(0.76, 1.32)	1.08	(0.85, 1.37)
Place of residence						
Rural	Ref.		Ref.		Ref.	
Urban	1.47***	(1.28, 1.69)	1.41**	(1.12, 1.79)	1.50***	(1.26, 1.78)
Region						
North	Ref.		Ref.		Ref.	
Central	0.95	(0.79, 1.15)	0.95	(0.69, 1.31)	0.94	(0.75, 1.20)
East	1.13	(0.95, 1.34)	1.18	(0.89, 1.55)	1.10	(0.88, 1.36)
Northeast	1.40**	(1.12, 1.74)	1.41*	(1.01, 1.97)	1.30	(0.97, 1.74)
West	1.99***	(1.58, 2.51)	2.21***	(1.55, 3.13)	1.84***	(1.37, 2.49)
South	2.77***	(2.27, 3.39)	2.73***	(1.96, 3.81)	2.71***	(2.12, 3.45)

[#]*Other Backward Classes.*

[$]*Includes Sikh, Buddhist/neo-Buddhist, Jain, Parsi/Zoroastrian and others.*

[a]*Divorced, separated, and deserted.*

[b]*Activities of daily living includes dressing, walking across a room, bathing, eating difficulties, getting in or out of bed and toilet use (any one or more).*

[c]*Instrumental Activities of Daily Living (IADL) includes preparing a hot meal, shopping for groceries, making telephone calls, taking medications, doing work around the house or garden, managing money and getting around or finding address in unfamiliar place (any one or more).*

*$p < 0.05$, **$p < 0.01$, ***$p < 0.001$.

BMI, Body Mass Index; AOR, Adjusted Odds Ratio; CI, Confidence Interval.

and controlled HT. Health system performance in Jammu and Kashmir, Goa and states mainly from the northern region were far better than other states, since out of total HT caseload, more than 70% of cases were diagnosed. Conversely, Nagaland, Chhattisgarh and Dadra and Nagar Haveli were the states where only <45% people are aware of their HT condition. **Figure 2** shows variation in treatment seeking for HT, where most of the states in the south and west performed better than east and central regions. This low treatment seeking could be due to unaffordable medication, lack of availability and the accessibility of health centres. Similarly, **Figure 3** illustrates the considerable variation in state performance with respect to controlled HT. Of all the states and UTs, 11 states, namely Uttar Pradesh, Bihar, Odisha, Madhya Pradesh, Jharkhand, Assam, Chandigarh, Nagaland, Arunachal Pradesh, Mizoram and Damn and Diu performed so poorly with respect to controlled HT that they were below the lower limits of the distribution of the funnel plot, which was created at the 99% confidence bands. Mainly 10 states from

TABLE 4 | State-wise prevalence of self-reported, undiagnosed, overall, and controlled hypertension among older adults in India, LASI, 2017–18.

States	Self-reported HT	Total prevalence	Gap (undiagnosed HT)	Performance of state (diagnosis)	Currently taking medicine	Controlled HT
	a	*b*	*c = b-a*	*d = a*100/b*	(e)	(*f*)
Jammu and Kashmir	40.6	50.3	9.7	80.7	85.3	16.5
Himachal Pradesh	32.9	56.1	23.2	58.6	63.7	8.4
Punjab	42.8	62.1	19.2	69.0	73.9	14.5
Chandigarh	39.6	53.5	14.0	73.9	80.7	19.6
Uttarakhand	26.6	48.1	21.5	55.3	56.6	8.4
Haryana	38.5	52.5	14.1	73.2	55.2	12.5
Delhi	35.8	52.5	16.7	68.2	68.2	11.7
Rajasthan	27.3	42.3	15.0	64.5	59.7	9.6
Uttar Pradesh	20.0	34.7	14.7	57.7	57.5	7.0
Bihar	25.1	42.1	17.1	59.5	49.2	6.5
Arunachal Pradesh	22.6	44.8	22.2	50.4	31.7	2.4
Nagaland	15.8	54.3	38.5	29.2	60.5	1.1
Manipur	28.7	45.7	17.0	62.8	69.9	10.2
Mizoram	24.0	34.8	10.8	69.0	43.7	4.7
Tripura	30.4	48.2	17.8	63.1	68.0	10.8
Meghalaya	25.9	50.0	24.0	51.9	78.1	9.5
Assam	31.1	48.1	17.0	64.6	64.7	7.9
West Bengal	29.6	44.4	14.9	66.5	74.6	9.5
Jharkhand	21.7	43.3	21.6	50.1	64.1	6.3
Odisha	20.4	38.1	17.8	53.5	67.7	7.8
Chhattisgarh	16.5	45.1	28.6	36.6	68.8	5.7
Madhya Pradesh	20.0	38.4	18.4	52.1	64.2	7.2
Gujarat	25.7	46.5	20.8	55.3	69.2	10.1
Daman and Diu	32.9	52.6	19.7	62.6	79.8	13.0
Dadra and Nagar Haveli	17.0	40.8	23.8	41.7	69.4	6.6
Maharashtra	28.9	49.1	20.2	58.8	86.4	14.1
Andhra Pradesh	35.0	53.0	18.0	66.0	88.4	15.2
Karnataka	32.7	51.1	18.4	64.0	91.7	15.6
Goa	44.1	57.9	13.8	76.2	94.7	23.5
Lakshadweep	35.5	66.1	30.6	53.7	76.7	9.4
Kerala	41.0	60.3	19.3	68.0	87.6	18.0
Tamil Nadu	26.3	45.2	18.8	58.3	76.7	10.4
Puducherry	32.7	49.3	16.6	66.3	87.8	18.1
Andaman and Nicobar Island	41.2	64.8	23.7	63.5	78.8	10.8
Telangana	31.0	47.3	16.3	65.5	87.6	15.4
Total	**27.4**	**45.2**	**17.8**	**60.6**	**73.0**	**10.4**

the southern, eastern and western regions were above the overall Indian baseline at the 99% band.

Finally, we also attempt to understand the factors that explain the variation in state performance as observed in the funnel plots. The regression results for self-reported HT (Model 1) and treatment (Model 2) are presented in **Table 5**. The results suggest that having a higher proportion of the population below the poverty line was significantly related to lower HT awareness ($p = 0.012$). Total OOPE was significantly associated with an increase in self-reported HT ($p = 0.043$). The literacy rate was positively but not significantly related to HT awareness ($p = 0.313$). Regarding treatment seeking behaviour in Model 2, higher literacy rates ($p = 0.059$) and greater availability of specialist doctors ($p = 0.061$) at CHCs significantly increased the prevalence of treatment for HT at a 10% level of significance.

DISCUSSION

India is a diverse country with considerable variations in terms of socio-economic development, caste, and cultural practises among its population. With increasing urbanisation, improved standards of living due to economic growth, associated lifestyle

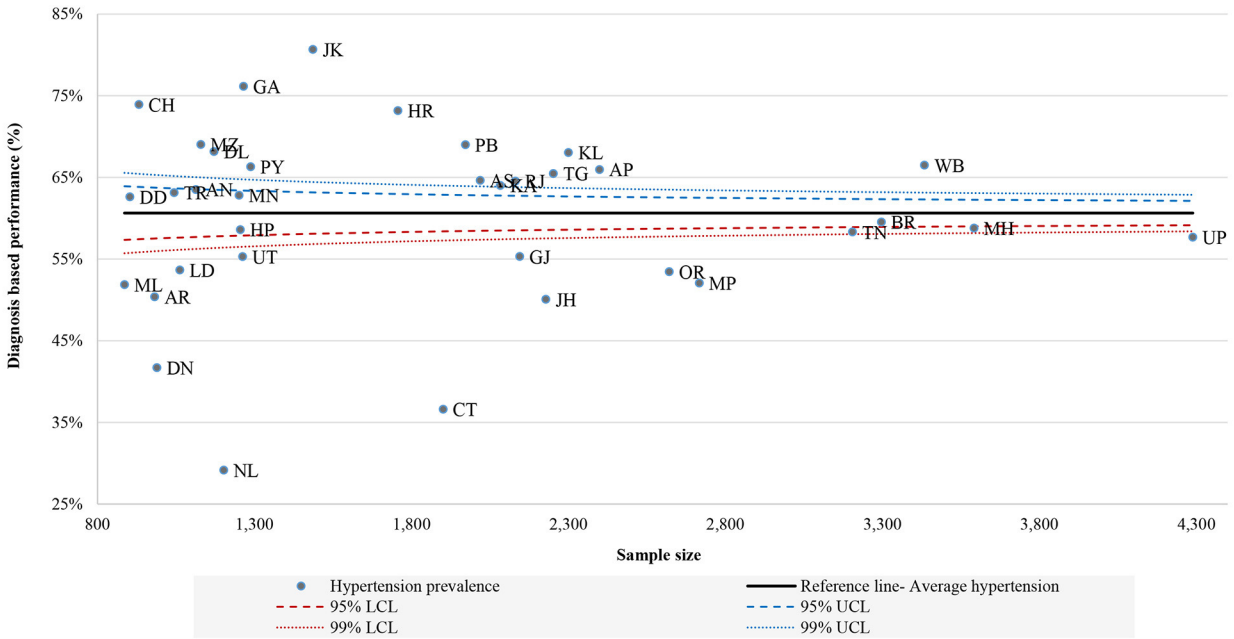

FIGURE 1 | Funnel plot of performance of states: diagnosis of hypertension, LASI (2017–18).

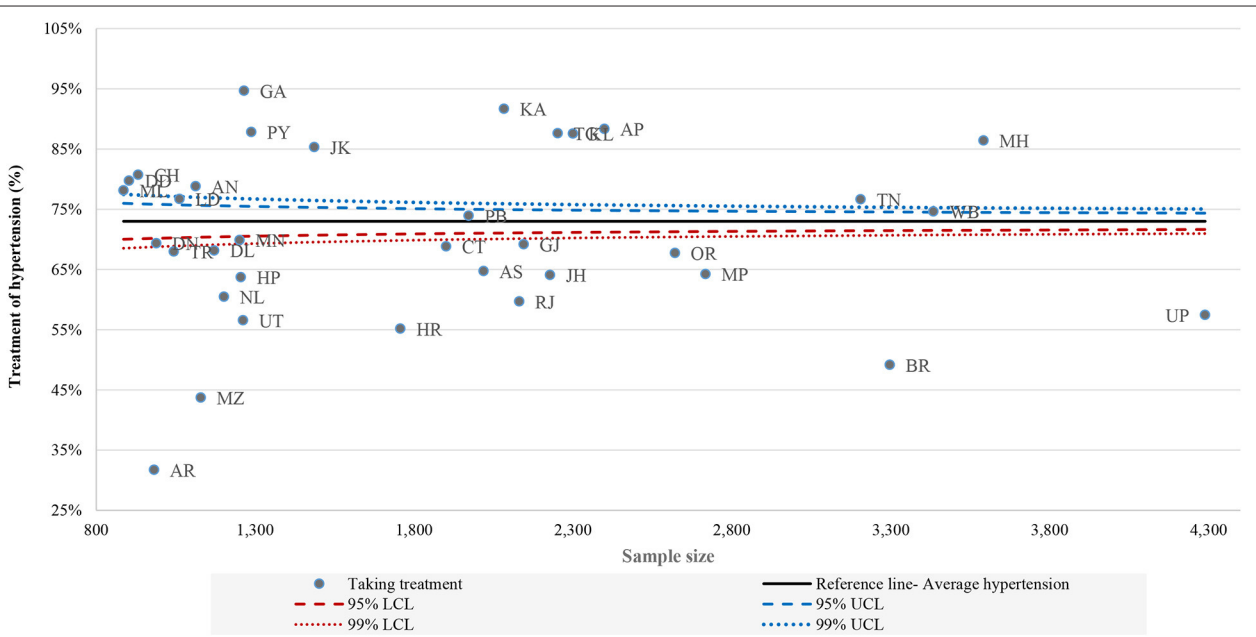

FIGURE 2 | Funnel plot of performance of states: treatment of hypertension, LASI (2017–18).

changes and an increasingly ageing population as a result of increased life expectancy, India is fertile ground for an increasing prevalence of NCDs. In addition, a health transition both in terms of demographic and epidemiological transition is rapidly taking place in India, with a shift from a predominantly young population to an increasingly ageing population, and from high morbidity and mortality due to acute, infectious and communicable diseases in the younger population to chronic non-communicable diseases in the elderly population. For example, disability-adjusted life-years (DALYs) due to NCDs has

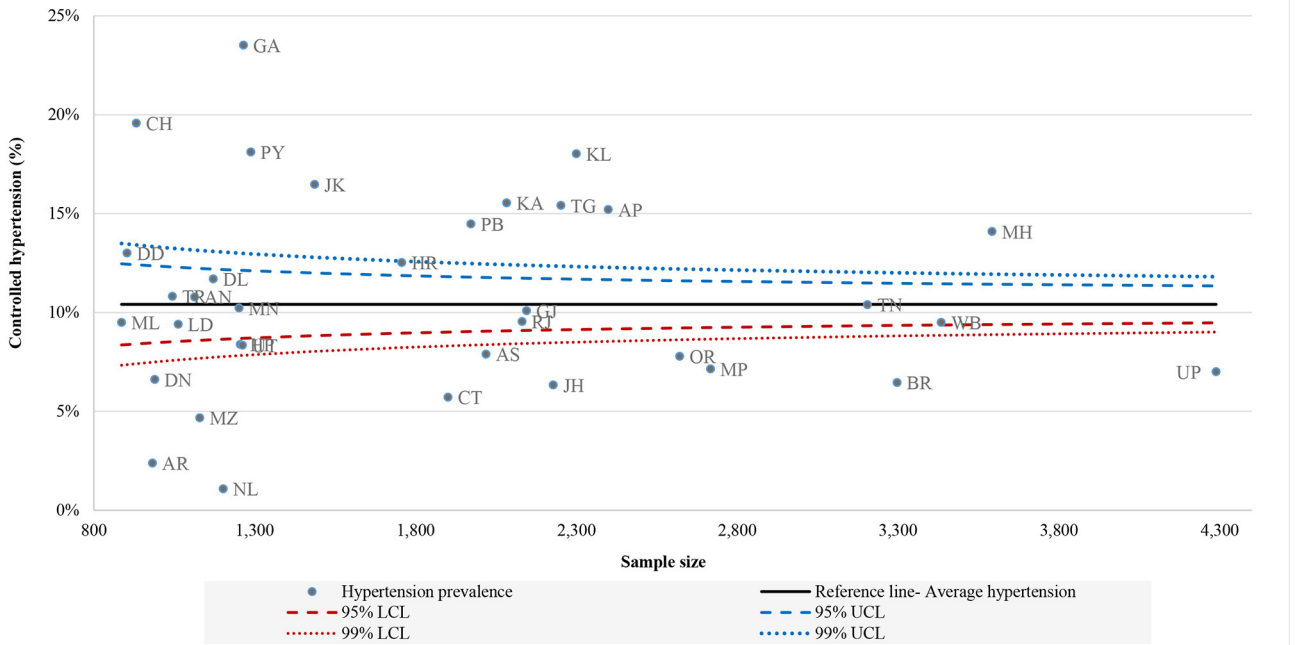

FIGURE 3 | Funnel plot of performance of states: controlled hypertension, LASI (2017–18).

TABLE 5 | Regression results for state performance- self-reported HT and its treatment, 2017–18.

Variables	Self-reported hypertension (model-1)			Treatment for hypertension (model-2)		
	Coeff.	*p*-value	95% CI	Coeff.	*p*-value	95% CI
HDI	6.422	0.842	(−59.23, 72.07)	71.035	0.292	(−65.08, 207.15)
% Population BPL	−0.329	0.012	(−0.579, −0.08)	−0.215	0.398	(−0.732, 0.302)
Literacy rate	0.176	0.313	(−0.177, 0.53)	0.704	0.059	(−0.029, 1.436)
Doctors available at PHCs	0.000	0.918	(−0.005, 0.004)	−0.006	0.216	(−0.015, 0.004)
Specialists available at CHCs	−0.003	0.836	(−0.028, 0.023)	0.051	0.061	(−0.002, 0.104)
OOPE	0.017	0.043	(0.001, 0.033)	−0.001	0.958	(−0.035, 0.033)
Per capita health expenditure	−0.001	0.585	(−0.003, 0.001)	−0.005	0.029	(−0.009, −0.001)
N	32			32		
R^2	57.5			43.7		

HT, Hypertension; Coeff., Coefficient; HDI, Human Development Index; BPL, Below Poverty Line; PHC, Public Health Centre; CHC, Community Health Centre; OOPE, Out-of-Pocket expenditure (includes inpatient and outpatient expenditures).

increased from 29.2% in 1990 to 57.9% in 2019 (3). Similarly, the Global Burden of Diseases study estimates that DALYs attributed to HT almost doubled from 18 to 37 million in the period from 1990 to 2019 (3). However, in spite of the increasing prevalence of HT, there has been no significant improvement in the diagnosis, treatment and control of HT over the years (22).

As healthcare is a state responsibility in India, for effective targeting of health services at the local level, sub-national level planners and policy makers must have a reliable estimate of not only the overall prevalence of HT, but also its distribution and the characteristics of the sub-groups of the population that are aware of their hypertensive status and are taking treatment. In addition, understanding the variation in state performance with respect to the diagnosis and treatment of HT at the sub-national level is necessary for planning effective strategies to control HT.

Our study findings confirm that the overall prevalence of HT among older adults over the age of 45 years is 45.2% (4 in 10) with significant variation among states. Among the hypertensive participants, only 60.6% (6 in 10) were aware of their condition. Although 73.0% (7 in 10) of these participants who were aware of their diagnosis were currently taking treatment at the time of the survey, only 10.4% (1 in 10) had adequately controlled their HT. Comparing our findings with other countries shows that our estimated HT prevalence is lower than that of China

(26) and many developed countries such as the United States (27), Ireland and the Russian Federation (28), but higher than that in many other neighbouring countries (29–31). For example, in a systematic review based on 33 observational studies from seven South Asian countries, the overall prevalence of HT was nearly 27%, ranging from 17.9% in Bangladesh to 33.8% in Nepal (32). Our higher prevalence rate of 45% compared to the South Asian study mentioned above and others can to a large extent be explained by the selection of participants who were above the age of 45 years in our study, whereas other studies considered adults over the age of 18 years.

A study based on multiple national-level surveys on the overall prevalence of HT among older adults aged 50 years and above in select high-income countries (HICs), upper-middle-income countries (UMICs) and lower-middle-income countries (LMICs), estimated the rates of awareness, treatment and control of HT from 78.0, 67.9, and 29.8% in HICs, to 40.3, 31.6, and 7.3% in UMICs, and 43.7, 24.2, and 12.5% in LMICs (28). In comparison, the rates of awareness, treatment and control of HT in our study were 60.6, 44.0, and 10.4%, respectively, with considerable variation among states. There may be number of factors contributing to lack of awareness of HT in states like Chhattisgarh, Bihar, Jharkhand, Madhya Pradesh, Odisha, Himachal Pradesh, Gujarat and Uttarakhand. HT is usually asymptomatic, so many individuals who are hypertensive may not recognise this condition and thus may not be aware of it, may not come in contact with doctors/health facilities, may provide inadequate/incomplete information to doctors or their blood pressure measurements may not have been measured in spite of coming into contact with a doctor/health facility. This represents a missed opportunity in terms of diagnosis, or even after being diagnosed as hypertensive, survey participants may not have remembered at the time of the survey (recall bias). However, it appears that the main reason could be due to issues around access and availability of health facilities and a lack of screening programmes, such that fewer individuals have the opportunity to measure their blood pressure.

As cheap and effective drugs are available for the treatment and control of HT, and the consequences of not treating HT are associated with significant adverse health outcomes, it is unacceptable that India has such low treatment and control rates. Issues around financial barriers resulting in a lack of affordability to purchase anti-hypertensive drugs from the pharmacy and lack of consistent availability of these drugs in the public sector may be important reasons for low treatment rates in states like Rajasthan, Uttar Pradesh, Odisha, Assam, Manipur and Uttarakhand. It is even more of a concern as only 37.2% of India's population is covered under any health insurance (25).

It is also interesting to note that, although the treatment rate of those currently taking medication is similar to that of India, Pakistan has a higher control rate of 22.3% (33). Similarly, our overall treatment rate for all hypertensives was 44% and comparable to Bangladesh at 43%, yet Bangladesh has a much better HT control rate at 22% (34) when compared to our 10% control rate. India's poor performance with respect to HT control rate raises issue around the treatment protocol, adherence regimes and affordability, monitoring and follow-up. Further research may be undertaken to understand the underlying causes for such poor HT control rates in India.

Given poor awareness and low treatment and control rates for HT as per our study findings, it therefore raises the question of the effectiveness of the national CVD control programme and national NCD programme. For instance, the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) was launched in 2010 with the aim of preventing and controlling NCDs through awareness, lifestyle changes and early diagnosis of high risk individuals. However, only 4 million persons attended NCD clinics and were screened for HT in 2018 (25). Our findings in terms of low rates of the treatment and control of HT are similar to other studies in India and elsewhere and raise concerns regarding impending cardiovascular mortality and morbidity (13, 35, 36). The literature suggests that there are significant barriers in terms of access and utilisation of diagnostic services and therefore treatment of HT in India. In a country like India, where OOPE constitute 70% of total health spending (37), financial barriers can be a significant concern as both diagnosis and the purchase of hypertensive drugs may require OOPE by the majority of the population. This is further exacerbated as diagnostic services, doctor consultations or admissions in the private sector are all on a fee-for-service basis. There is evidence to suggest that high OOPE for health care contributes to impoverishment in India (38).

India is home to 17.7% of the world's population and contributes 20% of the global burden of diseases due to NCDs (39). Currently, 60% of hospitals, 75% of dispensaries, and 80% of doctors are in the urban areas serving only 28% of the country's population (40). Whereas, the majority of India's population resides in rural areas where decades of underfunding have resulted in a weak public health care system with inadequate health infrastructure, lack of adequate human resources for health and low availability of drugs, resulting in significant barriers to accessing health services. In addition, the population residing in rural areas has other unfavourable social determinants of health like lower literacy rates and lower socio-economic conditions that further prevent the effective implementation of preventive and promotive health programmes.

Our findings suggest that even more developed states like Karnataka and Kerala have an 11 and 17% shortage of doctors in PHCs and a 67 and 80% shortage of specialist doctors in CHCs in rural areas, respectively. For India as a whole, there is a shortfall of over 78% of specialist doctors at CHCs in rural areas (41). A study published in the Lancet confirms our findings that 83% of surgeon and physician roles are vacant in India's rural areas (42). Similarly, a 72% shortfall has been observed with respect to health assistants (HA) at the PHC level. Although unacceptable, the situation is comparatively better in urban areas than in rural areas. There is a 46% shortfall of auxiliary nurse midwives (ANMs) in urban PHCs, who are a key workers in a number of public health programmes. In addition, there is shortfall of staff including doctors, specialists, nurses, pharmacists and technicians in urban PHCs and CHCs. Thus, it appears that unless large investments are considered, India's existing public health infrastructure will be unable to cope with

the epidemic of NCDs. Unfortunately, the latest budget was a missed opportunity to remedy the situation (43). It is therefore imperative that the meagre government health spending of 1.8% of GDP is raised significantly to improve the public health infrastructure, staffing levels and equipment, and availability of drugs in general, and in particular with respect to screening, diagnostic services, treatment and the management of HT.

Policy makers will have to ensure that this variation among states and sub-groups is minimised and that public health care systems are improved, especially in underperforming states. Lessons could be learnt from well-performing states like Goa, Kerala, Punjab, Karnataka and Chandigarh. A number of reasons can be hypothesised for good performing states in terms of the diagnosis and treatment of HT, including higher HDI, higher literacy rates, a strong public health sector including the primary health care network, and better access to quality health services including the availability of human resources and drugs as compared to underperforming states.

Given the extent of variation in state performance, a one-size-fits-all approach to reducing HT across India may not be an effective strategy. Policy makers may rather adopt a flexible approach depending on a state's development and its performance in terms of the diagnosis and treatment of HT. Policy makers may consider targeting underperforming states as identified by the funnel plot and thus attempt to minimise the variation in performance across the states of India. As per our findings, states with a large population, high prevalence of HT and low performance in terms of the diagnosis and treatment of HT can be identified as high impact states and should be given priority by policy makers, as these states have significant potential for reducing the avoidable mortality and morbidity associated with HT and its consequences. It is proposed that selective targeting of high risk individuals may be adopted as a strategy in states like West Bengal where the prevalence of HT is low but state performance in terms of diagnosis and treatment rate is high. Conversely, states like Himachal Pradesh, Uttarakhand, and Gujarat where the prevalence of HT is high and state performance is low in terms of diagnosis and treatment of HT would benefit from a rapid scale-up of primary level of interventions at a population level.

More generally, India could adopt multipronged strategies that include improved screening and measurement of blood pressure for high risk individuals, health education programmes and free availability of hypertensive drugs in order to improve the diagnosis and treatment rates. Medical staff should be trained to ensure that every contact with the health staff involves opportunistic screening for HT so that appropriate treatment can be initiated at the earliest. Besides opportunistic screening at health facilities, screening should also be undertaken at the community level, especially in high risk states. Given the issues around the affordability of private doctors and the lack of doctors in the public health sector, community health workers could be trained in screening those at risk and referring individuals for further management. Studies have shown that community health workers are effective in a number of public health programmes in various settings (44, 45). In addition, mass screening camps for the early detection of HT cases can be considered in high risk areas with limited health facilities. Such a strategy, based on the primary care level with an emphasis on early diagnosis and prompt treatment of HT, is likely to be highly cost-effective as the economic burden of untreated HT to the individual and the health system can be enormous.

Our study had potential strengths and limitations. The study's main strength was the large sample size and national-level representation of the Indian older adults. Moreover, the present study contributes to the existing literature by not only providing current estimates of the prevalence, awareness, treatment and control of HT at sub-national levels but also provides estimates of performance of states with respect to the diagnosis and treatment of HT. Despite these strengths, all the limitations of cross-sectional survey data apply to this study as it is based on the first wave of the LASI data, thus fails to establish the causal relationship between the observed associations. It may also be noted that the Joint National Committee (JNC) 7 criteria for defining hypertension (i.e., self-reported HT, SBP $\geq$140 or DBP $\geq$90, and currently on medication) (46) was not used in this study. In the context of India, with number of barriers like literacy/awareness, access to health care services, and financial affordability to drugs and treatment, we believe that using the JCN-7 definition would underestimate the true prevalence of HT in the population. Moreover, we did not include the non-pharmacological treatments, dietary habits and life-style changes in the analysis that could impact on the treatment of HT.

Given India's population, its approach to reducing HT in its high impact states will determine the attainment of national NCD targets and global SDG targets.

DATA AVAILABILITY STATEMENT

Publicly available datasets were analysed in this study. This data can be found here: the study uses secondary data which is available on reasonable request through https://www.iipsindia.ac.in/content/lasi-wave-i.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the Indian Council of Medical Research (ICMR) extended the necessary guidelines and ethics approval for undertaking the LASI survey. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

MB conceptualised and designed this study. LKD, MK, and PD were involved in data analysis and statistical methods. All authors contributed to the drafting, reviewing, revising the manuscript, and seen and approved the final version of the manuscript.

FUNDING

This research has received funding from the LSE Covid Impact Fund for Research and Knowledge Exchange.

ACKNOWLEDGMENTS

We would like to thank Proof-Reading-Service.com for their professional proofreading service.

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frontiers in Public Health

ORIGINAL RESEARCH
published: 01 November 2021
doi: 10.3389/fpubh.2021.753070

Factors Associated With Hypertension Awareness, Treatment, and Control Among Adults in Kerala, India

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OPEN ACCESS

Edited by:
Meena Daivadanam, Uppsala University, Sweden

Reviewed by:
Prasanna Mithra, Kasturba Medical College, Mangalore, India
Amutha Ramadas, Monash University Malaysia, Malaysia

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Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: *04 August 2021*
Accepted: *11 October 2021*
Published: *01 November 2021*

Citation:
Cao Y, Sathish T, Haregu T, Wen Y, Mello GTd, Kapoor N and Oldenburg B (2021) Factors Associated With Hypertension Awareness, Treatment, and Control Among Adults in Kerala, India. Front. Public Health 9:753070. doi: 10.3389/fpubh.2021.753070

Background: Hypertension, the most significant risk factor for cardiovascular disease, is an increasing contributor to global health burden, particularly in low- and middle-income countries (LMICs) such as India. While the rates of hypertension awareness, treatment, and control in India have been reported in several studies, the factors associated with these rates are less well-understood. Existing studies are predominantly cross-sectional, and the factors examined are limited. Understanding the predictors associated with these rates, using more rigorous study designs, is crucial for the development of strategies to improve hypertension management.

Aims: To examine a range of factors associated with hypertension awareness, treatment, and control using both cross-sectional and longitudinal analyses.

Methods: Data was derived from a population-based sample of 1,710 participants from Kerala, aged 30–60 years. We examined a comprehensive range of factors, including demographic, behavioral factors, anthropometric, clinical measures, psychosocial factors and healthcare utilization. Multilevel mixed effects logistic regression was used for both cross-sectional and longitudinal analyses (repeated measures for all variables across 2 years) to determine the factors associated with awareness, treatment, and control of hypertension.

Results: A total of 467 (27.3%) participants had hypertension at baseline. Among those, the rates of awareness, treatment, and control of hypertension were 54.4, 25.5, and 36.4%, respectively. Being male (OR 0.27, 95% CI 0.14–0.53) and consumption of alcohol (OR 0.49, 95% CI 0.31–0.80) were significant predictors of poorly controlled hypertension (longitudinal analysis). Depression (OR 2.04, 95% CI 1.15–3.61) and fair-to-poor self-perceived health status (OR 1.87, 95% CI 1.15–3.04) were associated with increased hypertension awareness, whereas anxiety (OR 1.97, 95% CI 1.04–3.71) was associated with increased hypertension treatment (cross-sectional analysis). Seeking outpatient service in the past 4 weeks was associated with higher awareness

(OR 1.09, 95% CI 1.27–2.87), treatment (OR 1.73, 95% CI 1.20–2.50) and control (OR 1.96, 95% CI 1.37–2.80) (longitudinal analysis).

Conclusion: Our findings suggest the importance of considering psychosocial factors and better engagement with health services in hypertension management, as well as giving more attention to body fat control and largely male-related behaviors such as alcohol consumption, taking into account of some Indian specific attributes.

Keywords: hypertension, awareness, treatment, control, risk factors, longitudinal, India

INTRODUCTION

Hypertension remains one of the most important modifiable risk factors for the morbidity and mortality associated with cardiovascular disease (1). While hypertension control has improved over the past few decades globally, the prevalence has increased in low- and middle-income countries (LMICs), with low proportions of hypertension awareness, treatment, and control (2). In India, there has been a big increase in the prevalence of hypertension over the past two decades (23–42.2% in urban and 11.2–28.9% in rural areas), with no substantial improvement in the rates of hypertension awareness, treatment, and control (3).

Improved awareness and treatment of hypertension can lead to improved control of hypertension (4, 5). Understanding which factors are associated with these rates is very important for developing appropriate strategies to improve hypertension control. Studies conducted in LMICs have investigated demographic and behavioral factors that can be associated with hypertension awareness, treatment, and control. Some of these studies suggest that, being a female, overweight or obese, non-smoker and non-drinker are associated with higher rates of hypertension awareness and/or treatment or control (6, 7). Others have found higher waist-to-height ratio and having co-morbidities (e.g., diabetes and other chronic conditions) are associated with higher rates of hypertension awareness or treatment (8); physical inactivity was associated with higher levels of treatment, and higher percent of body fat was associated with higher level of awareness, treatment, and control (9). However, all these studies were cross-sectional; further prospective studies are needed to determine the predictors of these important rates in hypertension management. In addition, investigating other factors in addition to demographic and behavioral factors in relation to hypertension awareness, treatment, and control may also be important to help manage hypertension (10).

There are also psychosocial factors such as anxiety and depression that have been shown to be associated with the development/worsening of hypertension (11, 12), yet, they haven't been extensively explored in relation to awareness, treatment, and control of hypertension. Similarly, health-related quality of life has been shown to be poor in patients with hypertension (13), but it is not clear how it can be important in relation to hypertension awareness, treatment, and control. Social support, including family and friends' ties, was shown to be associated with less uncontrolled hypertension (10). On the other hand, health service utilization factors, including easy access to health services and regular check of BP, were both found to be associated with higher hypertension awareness (9). Taken together, more scrutiny is needed to further examine the role of a wider range of factors that includes not only demographic and behavioral factors, but also psychosocial factors in relation to hypertension awareness, treatment, and control.

In India, several studies have investigated the prevalence of hypertension awareness, treatment, and control (14–16). Factors associated with these rates were only explored in cross-sectional studies and also, only a limited number of potential factors were investigated (9). Considering all potential factors from different aspects mentioned above in relation to hypertension awareness, treatment, and control, not only in cross-sectional, but also in longitudinal studies, could enhance our understanding of the determinants of these rates and how to improve hypertension control in the population. This will help establish stronger evidence-based strategies to reduce the burden of cardiovascular diseases in India and other LMICs.

Our team has established a cohort in Kerala India in 2013, to implement and evaluate a community-based diabetes prevention [Kerala Diabetes Prevention Program (K-DPP)] (17). Despite being an intervention trial, comprehensive information was collected on all study participants, including socio-demographic measures, behavioral measures, psychosocial measures, clinical and biochemical measures, as well as measures of health utilization. This has enabled us to examine a range of factors that could be associated with hypertension awareness, treatment, and control in a population representative sample. Moreover, three repeated measures at baseline, 12 and 24-months means that it is possible to examine such associations longitudinally in order to increase the understanding of the casual relationships between a diverse range of factors and hypertension awareness, treatment, and control.

Therefore, the current study aimed to examine a range of predictors of hypertension awareness, treatment, and control, using both cross-sectional and longitudinal analyses in the cohort of K-DPP. The predictors to examine include demographic variables, behavioral factors, anthropometric and clinical measures, psychosocial factors (i.e., anxiety, depression, chronic stress, social support, and health-related life quality) and measures of health utilization.

MATERIALS AND METHODS

Study Participants

Study participants in this study were a broadly representative, population-based sample from the general population in Kerala, aged from 30 to 60 years, collected in 2013 (18). The detailed information on study design and participants screening and recruitment have been previously published (17, 19). Detailed recruitment information is presented in **Figure 1**.

After first step of excluding IDRS <60 ($n = 1{,}057$) and those who were not willing to have OGTT ($n = 320$), 1,209 participants underwent the OGTT to assess the presence of diabetes. A total of 1,007 participants who were free of diabetes at baseline were included in the K-DPP trial (intervention group 500, control group 507). For those who with IDRS <60 ($n = 1{,}057$), a random selection of participants ($n = 501$) were recruited. All measures for these 501 participants were done as were for the trial population. For the purpose of this study, to include more general population, we included K-DPP trial participants ($n = 1{,}007$), those who had diabetes at baseline ($n = 202$), and those who with IDRS <60 at baseline (randomly selected $n = 501$), resulting in a total study sample of 1,710 at baseline for analysis (**Figure 1**).

Data Collection and Measurements

A range of variables were measured including socio-demographic measures, behavior measures, clinical measures, psychosocial measure and cost-effective measures, which have been published previously (17). Data collection was performed by trained staff, using standard questionnaire, in accordance with WHO STEPS protocol (21). Anthropometric measures were performed using standard protocols (22), including height, weight, waist and hip circumferences, and body composition. Blood pressure (BP) was recorded three times using the Omron automatic BP monitor (model IA2) with an interval of at least 3 min between the readings. BP monitors are calibrated weekly using a sphygmomanometer. The average of the second and third BP readings was used in the current analysis. Standard protocols were followed for collection of fasting glucose, OGTT, HbA1c, and lipids (17). Blood samples are centrifuged within 30 min at the clinic and transported to a laboratory accredited by the National Accreditation Board for Laboratories (NABL) (23) for processing. Family history of CVD was also assessed by the question: "Do you have any family history of cardiovascular disease (heart disease or stroke)?".

We defined hypertension as mean systolic BP (average of second and third measures) $\geq$ 140 mmHg or diastolic BP $\geq$90 mmHg based on the JNC 8 classification of hypertension (24), or currently under anti-hypertensive medication or self-reported hypertension. In order to better understand the stages of hypertension in this sample, we have further checked prehypertension (systolic BP between 120 and 139 mmHg or diastolic BP between 80 and 89 mmHg); stage 1 hypertension

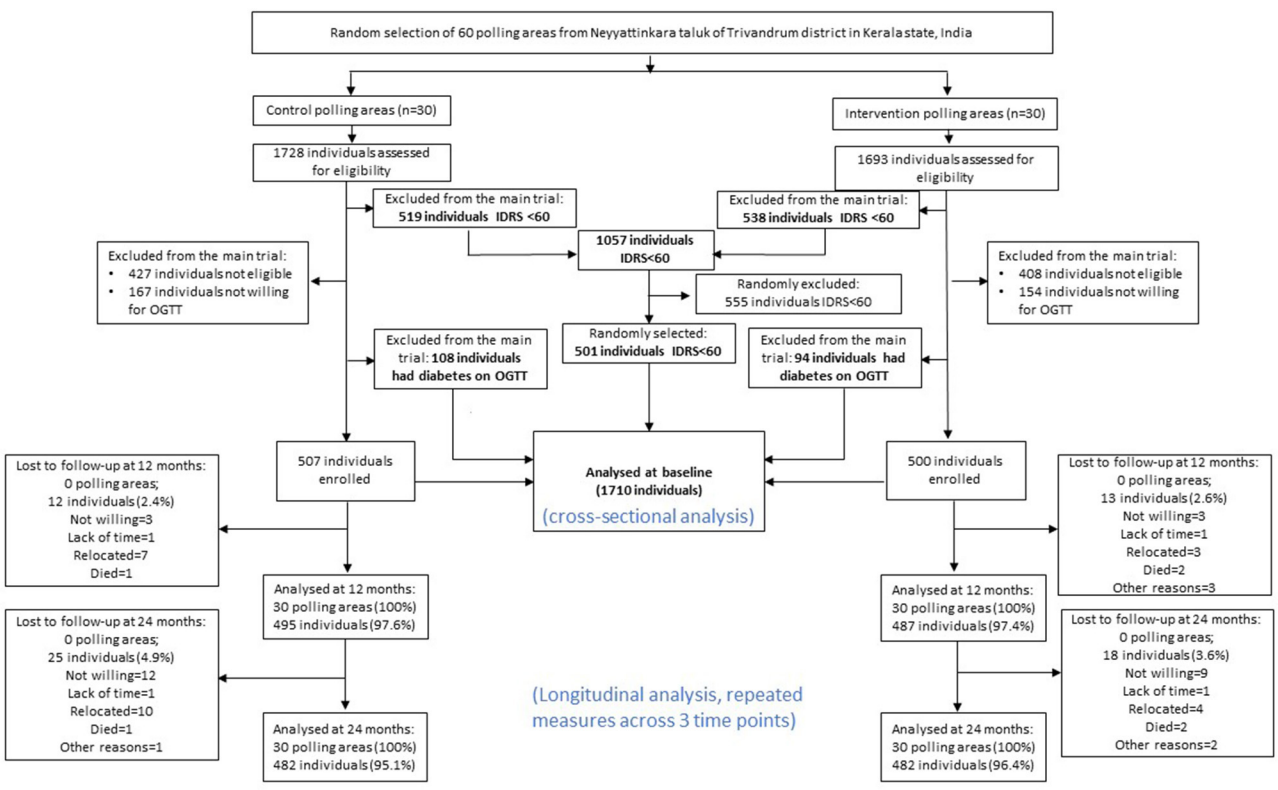

FIGURE 1 | Flow chart of the present study, adapted from previous K-DDP publications (20). IDRS, Indian Diabetes Risk Score; OGTT, oral glucose tolerance test.

(systolic BP between 140 and 159 mmHg, or diastolic BP between 90 and 99); stage 2 hypertension (systolic BP between 160 and 179 mmHg, or diastolic BP between 100 and 109); and stage 3 hypertension (systolic BP $\geq$ 180 mmHg, or diastolic BP $\geq$ 110 mmHg) (24). We defined hypertension awareness as self-reported previous diagnosis of hypertension by a physician among those with hypertension. Similarly, we defined hypertension treatment as currently taking anti-hypertension medication. Controlled hypertension was defined as systolic BP $<$ 140 mmHg and diastolic BP $<$ 90 mmHg among those hypertensive participants (regardless of receiving treatment) based on the definition mentioned above.

Behavioral Factors

Tobacco use was assessed by asking the question "Did you use any of the following tobacco products (smoking: cigarettes, bidis, cigars and hookah; smokeless: snuff, betel with tobacco, khaini and gutka) in the last 30 days?" Fruits and vegetable intake were assessed using Food Frequency Questionnaire adapted from PROLIFE study (25). Alcohol consumption was assessed by asking the question "Did you consume an alcoholic drink (such as beer, wine, whiskey, toddy) in the last 30 days?" Self-reported levels of physical activity were measured using the Global Physical Activity Questionnaire (26).

Psychosocial Factors

Anxiety was measured using the General Anxiety Disorder scale (27). Depression was measured using Patient Health Questionnaire-9 amended in line with CURES-65 study (28). Chronic stress was measured by Chronic stress scale used in MESA study (29). Self-perceived health status was measured using Short Form-36 (30).

Social support was measured by the ENRICHED social support scale (31), consisting of 7 items with 5 scale (total score = 35), with higher score indicating higher level of social support. Health-related quality of life was assessed using the 36-item Short-Form (SF-36) health survey (30).

Health Utilization

Health utilization was assessed by asking the questions "Did you have any out-patient services during the past 4 weeks (including specialist, community health services, nurses etc.) and "Did you have any in-patient services in the last 1 year?"

Statistical Analysis

Descriptive statistics were used to present participant characteristics in general and by hypertension awareness, treatment, and control. Mean (SD) and proportions (%) were used to summarize for continuous and categorical variables, respectively. Chi-square test was used to compare difference between proportions, and ANOVA was used to compare differences in continuous variables between groups. Multilevel mixed logistic regression (25) was performed for both cross-sectional and longitudinal analyses, considering polling areas (clusters) as the second level in the model. Odds ratios were obtained by exponentiating the estimated regression coefficients were presented. For the longitudinal analysis, repeated measures for all variables (predictors and outcome variables) at all three time points (waves) among trial participants detected with hypertension were included in the model, adjusting for wave and study arm. Variables tested in the univariate analysis include demographic factors, behavioral factors, anthropometric and clinical measures (including the family history of CVD), and health utilization. Variables selected in the final multivariable analysis for each of the outcome variables was decided based on evidence from previous studies and significant results of univariate analysis. All analyses were conducted using STATA16.0 (College Station, TX: StataCorp LLC).

RESULTS

In total, there were 1,710 participants included in this study at baseline (62% male, mean age 45 years, SD 7.9 years). The prevalence of hypertension was 27.3% (n = 467, including 170 with controlled hypertension) at baseline. Characteristics of participants with hypertension at baseline (n = 467) were presented in **Table 1**. The prevalence of hypertension awareness, treatment, and control is presented in **Table 2**. In brief, among all hypertensive participants (n = 467), 54.4% were aware of their hypertension [indicating 45.6% (213 participants) were newly diagnosed with hypertension], 25.5% were receiving treatment and 36.4% had their BP controlled at baseline. Among those who were aware of their hypertension, about 47% were receiving treatment, and among those with treatment, about 69% had their BP controlled. Among those with uncontrolled hypertension (n = 297), 72.5, 20.9, and 7.1% had stage 1, stage 2, and stage 3 hypertension, respectively.

There was a significant difference in hypertension awareness, treatment, and control by sex. On average, women had better hypertension management, compared to men. Even among those who had controlled hypertension but not on treatment, women were more than twice as likely to have their hypertension controlled, as compared to men (43.7 vs. 17.6%) (**Table 2**). The trends of these rates over 2 years based on repeated measures (n = 1,007) are presented in **Figure 2**. In brief, there was no change in the prevalence of hypertension over 2 years. However, there was a significant improvement in hypertension awareness (54% at baseline, 66% at year 1 and 70% at year 2, p for trend $<$0.001). Although no significant trends found for the other rates across 2 years, there was a significant increase in treatment and control rates from baseline to year 1 (27.4–34.4% and 38–42.6%, respectively). There was a modest increase of these rates from year 1 to year 2, without significant differences (**Figure 2**).

Baseline characteristics of hypertensive participants by hypertension awareness, treatment, and control are shown in **Table 3**. Men, those who did skilled/unskilled jobs, and who consumed alcohol were more likely to be unaware of their hypertension, and less likely to be receiving treatment or to have their BP controlled. On the other hand, those who with higher body fat, depressive symptoms, anxiety symptoms, chronic stress, poor to fair self-perceived health status and those who sought outpatient service in the last 4 weeks, were more likely to be aware and receive treatment

TABLE 1 | Characteristics of participants with hypertension at baseline ($n = 467$).

Factors	*n* (%)
Demographic factors	
Age (years), mean (SD)	47.6 (8.0)
Men	308 (66.0)
Marital status, *n* (%)	
Married	451 (96.6)
Not married (separated/ divorced/widowed/never married)	16 (3.4)
Education, *n* (%)	
Up to primary school	142 (30.4)
Secondary school	263 (56.3)
Tertiary and above	62 (13.3)
Occupation, *n* (%)	
Skilled/unskilled	348 (74.5)
Homemaker/unemployed/retired	119 (25.5)
Behavioral factors	
Leisure-time physical activity, *n* (%)	
Inactive	375 (80.3)
Active	92 (19.7)
Fruits and vegetable servings[a], *n* (%)	
≥5 servings per day	317 (68.5)
<5 servings per day	146 (31.5)
Alcohol consumption, *n* (%)	141 (30.2)
Tobacco use[b], *n* (%)	118 (25.3)
Anthropometric measures	
BMI categories[c], *n* (%)	
Normal weight (<23 kg/m^2)	125 (26.8)
Overweight (≥23.0 and < 25 kg/m^2)	115 (24.7)
Obese (≥25 kg/m^2)	226 (48.5)
Waist circumference in cm, mean (SD)	89.6 (9.6)
Fat percent (%), mean (SD)	29.1 (8.5)
Psychosocial factors	
Anxiety[d], *n* (%)	
No	347 (74.8)
Yes	117 (25.2)
Depression[e], *n* (%)	
No	314 (69.2)
Yes	140 (30.8)
Chronic stress[f], *n* (%)	
None	158 (35.7)
Low	160 (36.3)
High	125 (28.2)
Self-perceived health status[f], *n* (%)	
Good-excellent	163 (34.9)
Fair-poor	304 (65.1)
Social support score[g], *n* (%)	23.6 (4.8)
Clinical measures	
Family history of CVD	116 (24.8)
Systolic BP in mmHg, mean (SD)	141.1 (19.5)
Diastolic BP in mmHg, mean (SD)	85.6 (12.5)
Fasting plasma glucose (mmol/L), mean (SD)	6.7 (2.3)
Two-hour plasma glucose (mmol/L), mean (SD)	7.9 (4.5)
Total cholesterol (mmol/l), mean (SD)	227.1 (42.7)
LDL cholesterol (mmol/l), mean (SD)	159.6 (36.9)
Health utilization	
Outpatient services in the last 4 weeks	132 (28.3)

(Continued)

TABLE 1 | Continued

[a] *One serving of fruit equals a medium-sized fruit or two small-sized fruits or half a glass of fruit juice or a bowl of grapes. One serving of vegetables (including tubers) equals 80 g.*
[b] *Tobacco use include smoke and smokeless (chewing tobacco and snuff) in the past 30 days.*
[c] *BMI was categorized according to the Indian guideline (32).*
[d] *Anxiety was measured using the General Anxiety Disorder scale (27).*
[e] *Depression was measured using Patient Health Questionnaire-9 amended in line with CURES-65 study (28).*
[f] *Self-perceived health status was measured using Short Form-36 (30).*
[g] *Social support was measured by the ENRICHED social support scale (31). It consists of 7 items with 5 scale (total score = 35), higher score indicates higher level of social support. SD, standard deviation; BMI, body mass index; Percentages may not add up to 100% due to rounding.*

TABLE 2 | Awareness, treatment, and control of hypertension among individuals with hypertension by sex at baseline ($n = 467$)[a].

	Total ($n = 467$)	Men ($n = 308$)	Women ($n = 159$)	*P*-value[b]
Awareness, *n* (%)	254 (54.4)	144 (46.8)	110 (69.2)	0.000
Treatment, *n* (%)				
Among those were aware	119 (46.9)	63 (43.8)	56 (50.9)	0.257
Among all cases	119 (25.5)	63 (20.5)	56 (35.2)	0.001
Control, *n* (%)				
Among those who were treated[c]	82 (68.9)	40 (63.5)	42 (75)	0.176
Among those with no treatment[d]	88 (25.3)	43 (17.6)	45 (43.7)	0.000
Among all cases	170 (36.4)	83 (26.9)	87 (54.7)	0.000

[a] *Data shown was among those with hypertension, defined as either systolic BP ≥ 140 mmHg or diastolic BP ≥ 90 mmHg or having anti-hypertension drugs, or self-reported having hypertension (n = 467).*
[b] *P-values are based on Chi square test between men and women.*
[c] *There were 119 participants were treated (63 men and 56 women).*
[d] *There were 348 participants were hypertensive but not receiving treatment (245 men and 103 women).*

and control their hypertension. Surprisingly, participants with higher social support were less likely to have their hypertension controlled as compared to those with lower level of social support.

The cross-sectional results of correlates of hypertension awareness, treatment, and control are presented in **Table 4**. Participants with higher age (OR 0.96, 95% CI 0.94–0.99) and being men (OR 0.34, 95% CI 0.14–0.83) were less likely to have their hypertension controlled. Homemakers/unemployed/retired (OR 2.67, 95% CI 1.33–5.40) were more likely to be receiving

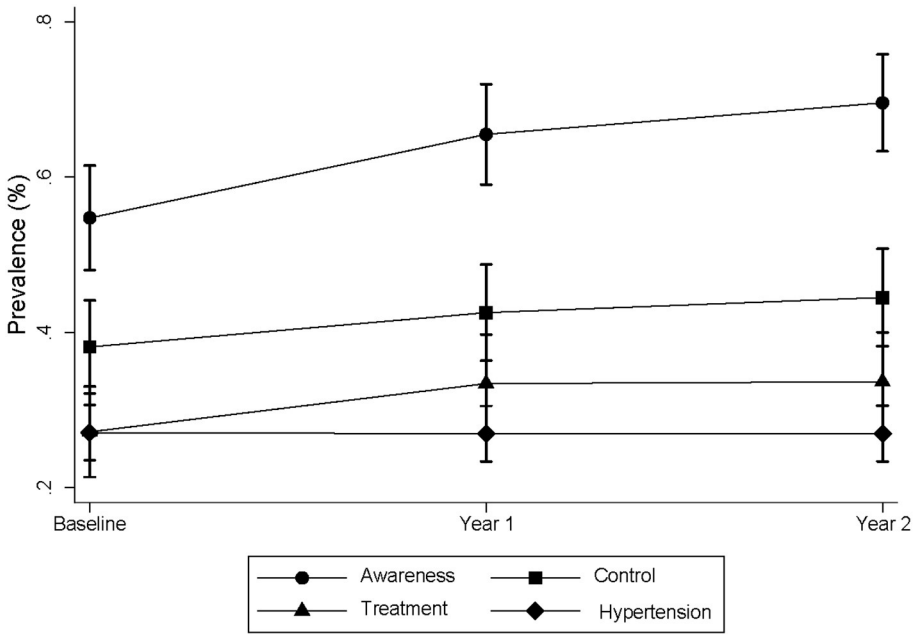

FIGURE 2 | Trends of prevalence of hypertension awareness, treatment and control cross 2 years. The data was obtained from the K-DPP participants with repeated measures. There were 1,007 participants at baseline, 981 at year 1 and 962 at year 2. For hypertension, there were 274 at baseline, 265 at year 1 and 260 at year 2. The prevalence of awareness, treatment, and control were calculated among those who were hypertensive per definition at each time point.

hypertension treatment. Alcohol consumption (OR 0.49, 95% CI 0.27–0.87) were associated with uncontrolled hypertension. Psychosocial factors such as depression (OR 2.04, 95% CI 1.15–3.61) and fair to poor self-perceived health status (OR 1.87, 95% CI 1.15–3.04) were associated with increased hypertension awareness, whereas anxiety (OR 1.97, 95% CI 1.04–3.71) was associated with increased hypertension treatment. Social support (OR 0.95, 95% CI 0.90–1.00) was associated with uncontrolled hypertension. Seeking outpatient service within last 4 weeks was consistently associated with hypertension awareness (OR 3.78, 95% CI 2.19–6.53), treatment (OR 2.69, 95% CI 1.55–4.65), and control (OR 3.67, 95% CI 2.23–6.03).

Longitudinal associations between these factors and hypertension awareness, treatment, and control revealed similar results (**Table 5**), including (1) being homemakers/unemployed/retired (OR 2.09, 95% CI 1.25–3.47) were more likely to receive treatment; (2) those who consumed alcohol (OR 0.49, 95% CI 0.31–0.80) was associated with uncontrolled hypertension; (3) fair to poor self-perceived health status (OR 1.87, 95% CI 1.15–3.04) were associated with increased hypertension awareness; (4) seeking outpatient service within last for weeks was consistently associated with better hypertension awareness (OR 1.90, 95% CI 1.27–2.87), treatment (OR 1.73, 95% CI 1.20–2.50) and control (OR 1.96, 95% CI 1.37–2.80). Differently, body fat percent was associated with slightly increased hypertension treatment (OR 1.04, 95% CI 1.00–1.08) and lower hypertension control (OR 0.97, 95% CI 0.94–1.00). No association was found between social support and hypertension control.

DISCUSSION

To our knowledge, this is the first study in India to investigate a comprehensive range of factors in relation to hypertension awareness, treatment, and control, both cross-sectionally and longitudinally. The study has identified the importance of targeting males and alcohol consumption in relation hypertension management, as well as the importance of psychosocial factors and health utilization. Although more than half of the participants in this study with hypertension were aware of their condition, only a quarter of them were receiving treatment. Despite receiving treatment, <70% participants had their hypertension controlled. A quarter of those who were not receiving treatment had their hypertension controlled, leading to more than 50% of those who were controlled of their hypertension was not dependent on treatment ($n = 88$). Addressing key risk behaviors and psychosocial factors as well as health utilization may help better manage hypertension and guide policies and promotion strategies in a country like India in the future.

Compared with previous systematic reviews on the region-specific prevalence of hypertension which found about 25% of rural population and 21% of the South India population had hypertension (33), about 27% of participants in our study (mostly rural residents) were found to have hypertension. The level of hypertension awareness, treatment, and control in previous studies conducted in Kerala varies across districts and age groups, with lower awareness found in Trivandrum (16.8%) (34), Kannur district (38.7%) (14), and higher in

TABLE 3 | Characteristics of participants by hypertension awareness, treatment, and control groups among those with hypertension at baseline ($n = 467$)[a].

	Awareness[b]			Treatment[c]			Control[d]		
	Yes ($n = 254$)	No ($n = 213$)	*p*-value	Yes ($n = 119$)	No ($n = 348$)	*p*-value	Yes ($n = 170$)	No ($n = 297$)	*p*-value
Demographic factors									
Age (years), mean (SD)	47.4 (8.2)	47.7 (7.9)	0.76	49.1 (8.0)	47.0 (8.0)	0.017	47.0 (8.2)	47.9 (7.9)	0.24
Men, *n* (%)	144 (56.7)	164 (77.0)	<0.001	63 (52.9)	245 (70.4)	<0.001	83 (48.8)	225 (75.8)	<0.001
Marital status, *n* (%)			0.88			0.53			0.93
Married	245 (96.5)	206 (96.7)		116 (97.5)	335 (96.3)		164 (96.5)	287 (96.6)	
Not married (separated/divorced/widowed/ never married)	9 (3.5)	7 (3.3)		3 (2.5)	13 (3.7)		6 (3.5)	10 (3.4)	
Education, *n* (%)			0.52			0.75			0.29
Up to primary school	76 (29.9)	66 (31.0)		33 (27.7)	109 (31.3)		54 (31.8)	88 (29.6)	
Secondary school	148 (58.3)	115 (54.0)		69 (58.0)	194 (55.7)		99 (58.2)	164 (55.2)	
Tertiary and above	30 (11.8)	32 (15.0)		17 (14.3)	45 (12.9)		17 (10.0)	45 (15.2)	
Occupation, *n* (%)			<0.001			<0.001			<0.001
Skilled/unskilled	170 (66.9)	178 (83.6)		70 (58.8)	278 (79.9)		109 (64.1)	239 (80.5)	
Homemaker/unemployed/retired	84 (33.1)	35 (16.4)		49 (41.2)	70 (20.1)		53 (31.2)	50 (16.8)	
Behavioral factors									
Leisure time physical active, *n* (%)	43 (16.9)	49 (23.0)	0.10	19 (16.0)	73 (21.0)	0.24	26 (15.3)	66 (22.2)	0.070
≥5 servings of vegetables and fruits/per day[e], *n* (%)	73 (29.0)	73 (34.6)	0.19	32 (27.1)	114 (33.0)	0.23			
Alcohol consumption, *n* (%)	60 (23.6)	81 (38.0)	<0.001	22 (18.5)	119 (34.2)	0.001	30 (17.6)	111 (37.4)	<0.001
Current tobacco use[f], *n* (%)	56 (22.0)	62 (29.1)	0.080	21 (17.6)	97 (27.9)	0.027	37 (21.8)	81 (27.3)	0.19
Anthropometrics									
Waist circumference (cm), mean (SD)	89.5 (10.3)	89.7 (8.7)	0.84	89.8 (10.3)	89.5 (9.3)	0.77	88.7 (10.6)	90.1 (8.9)	0.15
BMI categories[g], *n* (%)			0.072			0.038			0.039
Normal weight (<23 kg/m^2)	61 (24.1)	64 (30.0)		29 (24.4)	96 (27.7)		42 (24.7)	83 (28.0)	
Overweight (≥23.0 and < 25 kg/m^2)	57 (22.5)	58 (27.2)		21 (17.6)	94 (27.1)		33 (19.4)	82 (27.7)	
Obese (≥25 kg/m^2)	135 (53.4)	91 (42.7)		69 (58.0)	157 (45.2)		95 (55.9)	131 (44.3)	
Body fat percent (%), mean (SD)	30.5 (8.9)	27.4 (7.8)	<0.001	31.4 (9.3)	28.3 (8.1)	<0.001	31.3 (9.0)	27.8 (8.0)	<0.001
Psychosocial factors									
Anxiety[h], *n* (%)			<0.001			<0.001			<0.001
No	169 (67.1)	178 (84.0)		70 (59.3)	277 (80.1)		107 (63.7)	240 (81.1)	
Yes (mild-severe)	83 (32.9)	34 (16.0)		48 (40.7)	69 (19.9)		61 (36.3)	56 (18.9)	
Depression[i], *n* (%)			<0.001			<0.001			
No	145 (58.7)	169 (81.6)		62 (54.9)	252 (73.9)		99 (60.7)	215 (73.9)	0.004
Yes (mild-severe)	102 (41.3)	38 (18.4)		51 (45.1)	89 (26.1)		64 (39.3)	76 (26.1)	
Chronic stress[j], *n* (%)			0.004			0.017			0.10
None	76 (31.1)	82 (41.2)		35 (30.7)	123 (37.4)		49 (30.1)	109 (38.9)	
Low	84 (34.4)	76 (38.2)		35 (30.7)	125 (38.0)		60 (36.8)	100 (35.7)	
High	84 (34.4)	41 (20.6)		44 (38.6)	81 (24.6)		54 (33.1)	71 (25.4)	
Self-perceived health status[k], *n* (%)			<0.001			0.15			0.022
Good-excellent	71 (28.0)	92 (43.2)		35 (29.4)	128 (36.8)		48 (28.2)	115 (38.7)	
Poor-fair	183 (72)	121 (56.8)		84 (70.6)	220 (63.2)		122 (71.8)	182 (61.3)	
Social support score[l], mean (SD)	23.4 (4.9)	23.9 (4.7)	0.21	23.6 (4.5)	23.6 (4.9)	0.94	22.9 (5.0)	24.1 (4.6)	0.011
Clinical measures									
Family history of CVD, *n* (%)	72 (28.3)	44 (20.7)	0.055	32 (26.9)	84 (24.1)	0.55	49 (28.8)	67 (22.6)	0.13
Systolic BP (mmHg), mean (SD)	133.8 (21.0)	149.8 (13.0)	<0.001	134.4 (18.9)	143.3 (19.2)	<0.001	122.2 (10.9)	151.9 (14.5)	<0.001
Diastolic BP (mmHg), mean (SD)	81.8 (13.4)	90.2 (9.6)	<0.001	81.3 (12.3)	87.1 (12.2)	<0.001	74.9 (8.0)	91.8 (10.3)	<0.001
Fasting plasma glucose (mmol/L), mean (SD)	6.7 (2.2)	6.8 (2.3)	0.59	6.8 (2.4)	6.7 (2.2)	0.46	6.5 (1.8)	6.9 (2.5)	0.065
Two-hour plasma glucose (mmol/L), median (SD)	7.8 (4.3)	8.0 (4.6)	0.49	8.3 (4.7)	7.8 (4.4)	0.30	7.6 (4.0)	8.1 (4.7)	0.32

(Continued)

TABLE 3 | Continued

	Awareness[b]			Treatment[c]			Control[d]		
	Yes ($n = 254$)	No ($n = 213$)	*p*-value	Yes ($n = 119$)	No ($n = 348$)	*p*-value	Yes ($n = 170$)	No ($n = 297$)	*p*-value
Total cholesterol (mg/dl), mean (SD)	224.3 (40.7)	230.5 (45.0)	0.15	220.8 (41.7)	229.2 (43.0)	0.095	219.7 (41.7)	231.5 (42.8)	0.008
LDL cholesterol (mg/dl), mean (SD)	158.1 (36.5)	161.4 (37.3)	0.38	155.4 (38.8)	161.0 (36.2)	0.20	154.6 (37.9)	162.6 (36.0)	0.040
Health utilization									
Outpatient service within last 4 wks, *n* (%)	102 (40.2)	30 (14.1)	<0.001	53 (44.5)	79 (22.7)	<0.001	75 (44.1)	57 (19.2)	<0.001

[a] *Hypertension was defined as mean systolic BP ≥ 140 mmHg or diastolic BP ≥ 90 mmHg based on the JNC 7 classification of hypertension, or currently under anti-hypertensive medication or self-reported hypertension.*

[b] *Awareness was defined as self-reported previous diagnosis of hypertension by a physician among those with hypertension (refer to #a).*

[c] *Treatment was defined as currently prescribed anti-hypertension medication.*

[d] *Controlled was defined as systolic BP < 140 mmHg and diastolic BP < 90 mmHg among those hypertensive participants (refer to #a).*

[e] *One serving of fruit equals a medium-sized fruit or two small-sized fruits or half a glass of fruit juice or a bowl of grapes. One serving of vegetables (including tubers) equals 80 g.*

[f] *Tobacco use include smoke and smokeless (chewing tobacco and snuff) in the past 30 days.*

[g] *BMI was categorized according to the Indian guideline (32).*

[h] *Anxiety was measured using the General Anxiety Disorder scale (27).*

[i] *Depression was measured using Patient Health Questionnaire-9 amended in line with CURES-65 study (28).*

[j] *Chronic stress was measured by Chronic stress scale used in MESA study (29).*

[k] *Self-perceived health status was measured using Short Form-36 (30).*

[l] *Social support was measured by the ENRICHED social support scale (31). It consists of 7 items with 5 scale (total score = 35), higher score indicates higher level of social support.*

SD, standard deviation; BMI, body mass index; Percentages may not add up to 100% due to rounding.

Ernakulam district with older age groups (78%) (15), comparing to 54% found in our study in rural Kerala. Compared with one of the earliest cohorts in Kerala to study the incidence of hypertension (35), we found slightly higher rates of awareness (54.4 vs. 42.9%) and treatment (25.5 vs. 22.9%). Interestingly, all these studies found higher treatment rates than control rates among all hypertensive participants; however, we found a lower rate of treatment (25.5%), than control (36.4%). The reason could be that in our study, more than 50% of controlled hypertension were not using any anti-hypertensive treatment, leading to a possible higher rate of control than treatment. This is an important finding, because most studies that reported controlling hypertension, have been among those with treatment. However, ignoring those who have been able to control their hypertension without treatment may underestimate the importance of non-pharmaceutical management in hypertension, including lifestyle modification and psychosocial factors (36).

Men were found to have poorer hypertension control, compared to women. This is consistent with the results from 44 LMICs that men are less likely to reach each step of hypertension care cascade, (37) as well as other studies (8, 38). The possible reasons for this difference might be due to sex norms and maternal health focused services in LMICs. Interestingly, one study in Nepal found although women were more likely to be aware and treated for hypertension, they had lower control rates compared to men, which might be partly due to inequality issues in hypertension management (39). In our study, even among those who were not on treatment, but had their hypertension controlled, women were twice likely to control their hypertension, compared to men. This indicates that women may manage non-pharmaceutical related factors (e.g., lifestyle factors) better than men or that there are some other important sex specific factors.

Alcohol consumption was found to be associated with uncontrolled hypertension in both cross-sectional and longitudinal analyses. Different physiological mechanisms of alcohol in raising BP have been demonstrated in the literature previously (40). Meta-analysis of intervention trials have confirmed a dose-dependent manner between alcohol reduction and blood pressure reduction (41). The findings of the meta-analysis indicated the necessity of prioritizing reducing alcohol consumption in countries with substantial alcohol-attributable risk in hypertension management and health promotion. In addition, sex-specific alcohol consumption and hypertension incidence has been suggested in a systematic review of high quality cohorts (42), that found a dose relationship between alcohol consumption (any level) and incidence of hypertension in men but not women. In our study, alcohol consumption was very uncommon for women, which has identified the importance of addressing men related risk behaviors in hypertension management in countries like India.

Besides alcohol consumption, body fat percent was found to be positively associated with hypertension treatment, but uncontrolled hypertension in the longitudinal analysis. This indicates that although patients with a higher fat distribution are likely to get treatment, the treatment doesn't necessarily lead to an optimal control of hypertension. This is different from the other study, where body fact percent was found to be positively associated across all hypertension outcomes, including controlled hypertension (9). However, the authors did not discuss the potential mechanisms, and given the cross-sectional study design, the results need to be confirmed in prospective studies. In fact, there are different pathophysiological mechanisms

TABLE 4 | Factors associated with hypertension awareness, treatment, and control at baseline (cross-sectional analysis among hypertensive participants, $n = 467$)[a].

	Awareness OR (95% CI)	Treatment OR (95% CI)	Control OR (95% CI)
Demographic factors			
Age (years)	0.99 (0.96, 1.02)	1.03 (0.10, 1.06)	**0.96 (0.94, 0.99)**
Men	0.77 (0.30, 1.93)	2.31 (0.85, 6.31)	**0.34 (0.14, 0.83)**
Occupation			
Skilled/unskilled	1.00	1.00	1.00
Homemaker/ unemployed/ retired	1.81 (0.88, 3.71)	**2.67 (1.33, 5.40)**	1.25 (0.67, 2.34)
Behavioral factors			
Alcohol consumption			
No	1.00	1.00	1.00
Yes	0.74 (0.44, 1.29)	0.57 (0.28, 1.14)	**0.49 (0.27, 0.87)**
Tobacco use			
No		1.00	1.00
Yes	–	0.66 (0.30, 1.46)	–
Body fat percent	1.01 (0.97, 1.06)	1.03 (0.98, 1.08)	0.98 (0.94, 1.02)
Psychosocial factors			
Anxiety			
No	1.00	1.00	1.00
Yes (mild-severe)	1.08 (0.58, 2.03)	**1.97 (1.04, 3.71)**	1.63 (0.93, 2.86)
Depression			
No	1.00	1.00	1.00
Yes (mild-severe)	**2.04 (1.15, 3.61)**	1.30 (0.72, 2.35)	0.92 (0.54, 1.56)
Chronic stress			
None	1.00	1.00	1.00
Low	0.99 (0.59, 1.68)	0.69 (0.38, 1.28)	–
High	1.10 (0.59, 2.05)	0.93 (0.47, 1.82)	–
Self-perceived health status			
Good-excellent	1.00	1.00	1.00
Fair-poor	**1.87 (1.15, 3.04)**	–	1.25 (0.77, 2.01)
Social support score	–	–	**0.95 (0.90, 1.00)**
Heath utilization			
Outpatient service within last 4 weeks			
No	1.00	1.00	1.00
Yes	**3.78 (2.19, 6.53)**	**2.69 (1.55, 4.65)**	**3.67 (2.23, 6.03)**

[a]*Results obtained from multi-level mixed logistic regression model, considering (cluster as level 2) among hypertensive participants at baseline.*
Bold values indicate statistically significant at $p<0.05$.
Variables selected in each model was based on the results of univariate analyses, some variables were included in one model but not in others, therefore represented as "–."

TABLE 5 | Factors associated with hypertension awareness, treatment, and control over 2-year follow-up among hypertensive participants[a].

	Awareness OR (95% CI)	Treatment OR (95% CI)	Control OR (95% CI)
Demographic factors			
Age (years)	**0.97 (0.95, 1.00)**	**1.04 (1.01, 1.06)**	0.98 (0.96, 1.00)
Men	0.70 (0.33, 1.47)	1.77 (0.86, 3.63)	**0.27 (0.14, 0.53)**
Occupation			
Skilled/unskilled	1.00	1.00	1.00
Homemaker/ unemployed/ retired	1.72 (0.98, 3.02)	**2.08 (1.25, 3.47)**	1.28 (0.80, 2.04)
Behavioral factors			
Alcohol consumption			
No	1.00	1.00	1.00
Yes	0.82 (0.51, 1.29)	0.91 (0.54, 1.52)	**0.49 (0.31, 0.80)**
Tobacco use			
No		1.00	1.00
Yes	–	0.70 (0.37, 1.35)	–
Body fat percent	1.01 (0.97, 1.05)	**1.04 (1.00, 1.08)**	**0.97 (0.94, 1.00)**
Psychosocial factors			
Anxiety			
No	1.00	1.00	1.00
Yes (mild-severe)	1.20 (0.70, 2.07)	1.47 (0.89, 2.24)	0.99 (0.62, 1.58)
Depression			
No	1.00	1.00	1.00
Yes (mild-severe)	1.48 (0.91, 2.42)	1.17 (0.74, 1.86)	0.90 (0.58, 1.38)
Chronic stress			
None	1.00	1.00	1.00
Low	0.76 (0.50, 1.15)	0.72 (0.48, 1.09)	–
High	0.96 (0.57, 1.62)	1.05 (0.65, 1.70)	–
Self-perceived health status			
Good-excellent	1.00	1.00	1.00
Fair-poor	**1.80 (1.23, 2.62)**	–	1.37 (0.96, 1.94)
Social support score	**–**	**–**	1.01 (0.97, 1.04)
Heath utilization			
Outpatient service within last 4 weeks			
No	1.00	1.00	1.00
Yes	**1.90 (1.27, 2.87)**	**1.73 (1.20, 2.50)**	**1.96 (1.37, 2.80)**

[a]*Results obtained from multi-level mixed logistic regression model, considering (cluster as level 2) in K-DPP trial participants among hypertensive participants over 2-year period. With missing observations at each time point, the number of participants with hypertension were 274 at baseline, 265 at year one and 260 at year two, respectively.*
Bold values indicate statistically significant at $p < 0.05$.
Variables selected in each model was based on the results of univariate analyses, some variables were included in one model but not in others, therefore represented as "–."

have been established in obesity induced hypertension (43). Maintaining a healthy body weight and reasonable body fat percent are important in hypertension control.

Anxiety and depressive symptoms were found to be strongly associated with higher level of hypertension awareness and treatment, respectively, although only from the cross-sectional analysis. Previous studies have also found a higher level of psychological distress in participants who were aware of their hypertension (44). It might be that those who were more distressed were more likely to worry about their health, so they were more likely to seek health advice. However, we did not find this association in the longitudinal analysis. Unexpectedly, we also found anxiety was associated with a higher chance of getting hypertension treated, which was inconsistent with previous studies that found anxiety was associated with non-adherence to hypertension treatment (45). However, such association supports the finding that people with anxiety were more likely to be aware of their hypertension, because they were more likely to get

hypertension treated once they were aware of their hypertension. Alternatively, this might also be an inverse association due to the cross-sectional nature that people who got treated were more likely to get anxious due to unsatisfactory outcomes. Nevertheless, as about 25–30% of hypertensive participants had anxiety or depression in our study, addressing mental health in hypertension management may further help to understand each step of the cascade care of hypertension particularly in settings like India, where mental health has been suggested to be integrated in cardiovascular diseases management (46).

Similar association was found between poor to fair self-perceived health status and a higher awareness of hypertension. It is known that people with hypertension were more likely to have lower satisfaction of their health status than normotensive counterparts (13). So such association could also be an inverse association observed in the cross-sectional manner. However, the same direction was confirmed in the longitudinal analysis as well, which may indicate that the potential role of self-perceived health in early hypertension awareness and diagnosis. Longer follow-up studies are needed to confirm such association.

Although higher social support was associated with uncontrolled hypertension, this was not supported by the findings from longitudinal analysis. Social factors have been suggested to be associated with better hypertension diagnosis and control (47). Interestingly, in an Albanian study that included multi-level of social and community determinants found that children's support was associated with uncontrolled hypertension, but support from friends was associated with controlled hypertension (10). The authors concluded that this may be partly due to traditional "familism" and children's support, which may present unwanted responsibility and potential conflicts. Nevertheless, the inverse association between social support and hypertension control may also be due to inverse causation, that people who with uncontrolled hypertension were getting more social support. In fact, social support seemed to be associated with controlled hypertension from longitudinal analysis, despite non-significant result.

Another finding from this study was that seeking outpatient service was consistently associated with hypertension awareness, treatment, and control from both cross-sectional and longitudinal analyses. Frequently seeking health service was reported to be associated with better awareness and treatment of hypertension in another India study (9). It is likely that frequent outpatient service did play a role in improving hypertension awareness, treatment, and control. This again provides some evidence of the importance of providing access to outpatient services in rural settings to improve hypertension management.

One of the key strengths of this study is that we were able to conduct longitudinal analysis of the participants from K-DPP trial, which enabled us to identify potential predictors of hypertension awareness, treatment, and control. Another strength is that we have included a comprehensive range of factors, including more traditional demographic and behavioral factors, as well as psychosocial factors and health utilization variables. Despite these strengths, there were some limitations. Firstly, longitudinal study results are from K-DPP trial participants, who had been identified as having an elevated risk of diabetes. However, those participants had been randomly selected from the community and their socio demography (age, education, occupation, marital status and household size) were very similar to the general population of rural Kerala (48). Secondly, we did not have information on community and societal level factors such as quality of health care and perception of safety. Lastly, we do not have information on the duration of hypertension, but we were able to detect newly diagnosed hypertension in this study.

In conclusion, our findings highlight the potentially important role of psychosocial factors and health service utilization in hypertension management. It is probably also important to give more attention to alcohol consumption in Indian males as well as body fat control. These factors need to be considered in future health promotion strategies directed at the prevention and control of hypertension in India. Furthermore, more longitudinal studies in the general population and studies in other states of India on the determinants of hypertension management are needed, as the current findings in Kerala might be a harbinger of the situation in the rest of India over the coming years. In addition, our findings need to be interpreted properly, considering Indian specific attributes such as the high prevalence of hypertension patients self-medication, healthcare policy and financial burden in patients, as well as quality of health care. These can be further studied in future studies to facilitate policy makings related to hypertension management in India.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the SreeChitra Tirunal Institute for Medical Sciences and Technology, Trivandrum in India (SCT/IEC-333/May 2011), Monash University (CF11/0457-2011000194), and the University of Melbourne in Australia (1441736). The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

YC and TS contributed to conceptualization of the study. YC carried out the data analyses and wrote the manuscript. TS contributed to critically reviewing the analysis. TS, TH, NK, GM, YW, and BO contributed to critically review of the manuscript and approved for the final version of the study. All authors contributed to the article and approved the submitted version.

FUNDING

This research was supported by funding from the National Health and Medical Research Council, Australia (1005324) and (1160283) for the original and follow-up study of the K-DPP study respectively.

ACKNOWLEDGMENTS

We also acknowledge all the participants of the K-DPP study, including peer leaders and community trained staff at the Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology in Trivandrum.

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frontiers in Public Health

ORIGINAL RESEARCH
published: 16 November 2021
doi: 10.3389/fpubh.2021.747065

Effectiveness of a Non-pharmacological Intervention to Control Diabetes Mellitus in a Primary Care Setting in Kerala: A Cluster-Randomized Controlled Trial

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OPEN ACCESS

Edited by:
Kavumpurathu Raman Thankappan, Central University of Kerala, India

Reviewed by:
Devarsetty Praveen, George Institute for Global Health, India
Manickam Ponnaiah, National Institute of Epidemiology (ICMR), India
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Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: *25 July 2021*
Accepted: *19 October 2021*
Published: *16 November 2021*

Citation:
Rahul A, Chintha S, Anish TS, Prajitha KC and Indu PS (2021) Effectiveness of a Non-pharmacological Intervention to Control Diabetes Mellitus in a Primary Care Setting in Kerala: A Cluster-Randomized Controlled Trial. Front. Public Health 9:747065. doi: 10.3389/fpubh.2021.747065

Background: Despite being the first Indian state with a dedicated Non-Communicable Disease (NCD) program, glycemic control among a large proportion of patients is low in Kerala. This study tries to find evidence for a standardized non-pharmacological strategy delivered through Junior Public Health Nurses (JPHNs) in achieving and maintaining glycemic control among diabetic patients registered with NCD clinics of primary health care settings.

Design: A cluster randomized controlled trial was conducted among adult patients with Diabetes Mellitus attending NCD clinics of primary care settings of South Kerala, India. JPHNs of the intervention group received additional module-based training while standard management continued in the control group. Sequence generation was done by random permuted blocks method and a cluster of 12 patients was selected from each of the 11 settings by computer-generated random numbers. Patients were followed up for 6 months with monthly monitoring of Fasting Blood Sugar (FBS), Post-Prandial Blood Sugar (PPBS), blood pressure, Body Mass Index (BMI), and health-related behaviors. Knowledge and skills/practice of JPHNs were also evaluated. Analysis of Covariance was done to study the final outcome adjusting for the baseline values and a model for glycemic control was predicted using multilevel modeling.

Results: We analyzed 72 participants in the intervention group and 60 participants in the control group according to the intention-to-treat principle. The intervention was associated with a significant reduction in FBS ($p < 0.001$) and PPBS ($p < 0.001$) adjusting for the baseline values. The achievement of glycemic control was 1.5 (95% CI: 1.05–2.3) times better with intervention and they showed a better trend of maintenance of glycemic control (FBS, $p = 0.003$ and PPBS, $p = 0.039$). Adjusting for clustering and the baseline values, the intervention showed a significant effect on FBS ($B = -3.1$, $SE = 0.57$; $p < 0.001$) and PPBS ($B = -0.81$, $SE = 0.3$; $p < 0.001$) with time. Drug adherence score ($p < 0.001$), hours of physical activity ($p < 0.001$), BMI ($p = 0.002$), fruit intake ($p = 0.004$),

and green leafy vegetable intake ($p = 0.01$) were the major predictors of FBS control. The practice/skills score of the JPHNs significantly improved with intervention ($p < 0.001$) adjusting for baseline values.

Conclusion: A well-designed health worker intervention package incorporated into the existing health system can translate into attitude change and skill development in the health workers which can reflect in the improvement of glycemic control among the patients.

Trial registration: [URL: http://www.ctri.nic.in], identifier [CTRI/2017/11/010622].

Keywords: diabetes mellitus, primary care, non-pharmacological intervention, cluster randomized controlled trial, public health workers

INTRODUCTION

Diabetes is a huge threat to the public health systems, at the global, national, and family levels, in terms of morbidity, mortality, and the economic burden it imposes directly and indirectly. Kerala is the state with the highest burden of diabetes in India and is the first state with a State-funded dedicated Non-Communicable Disease (NCD) Control Programme, of which control of Diabetes mellitus is a major component (1, 2). Non-communicable Disease (NCD) clinics are conducted every week at the health sub-centers (most peripheral and the first contact point between the primary health care system and the community) as a part of the NCD control program of the Government aiming at early detection, delivery of adequate health education to the patients and improving access for NCD care and drugs. However, the glycemic control among a large proportion of diabetic patients is reported to be low even among the patients who receive treatment (3–5). Understanding that primary care optimization is an effective tool toward the achievement of health system objectives (6), researches to develop contextually appropriate and resource-sensitive approaches at the primary care level become important to ensure glycemic control among patients with diabetes.

The role of non-pharmacological interventions alone and along with medications in glycemic control is well-documented elsewhere (7–10). However, there is a scarcity of evidence on the effectiveness of non-pharmacological interventions through field-level health workers, who represent an important link between patients and the health system (11). This study tries to find evidence for a standardized non-pharmacological strategy delivered through field-level health workers in improving glycemic control among known diabetic patients. The trial primarily aims to study the effectiveness of a non-pharmacological intervention delivered through Junior Public Health Nurses (JPHNs) in achieving a reduction of fasting blood glucose among diabetic patients registered with NCD clinics of primary health care settings of Southern Kerala. Secondly, changes in post-prandial blood glucose and maintenance of glycemic control were studied along with other clinical parameters like blood pressure and body mass index, and health-related behaviors. The effectiveness of standardized module-based training in improving the knowledge and skills of Junior Public Health Nurses was also studied.

METHODS

The study details and results are reported in accordance with the CONSORT statement for randomized trials of Non-Pharmacologic Treatments (NPTs) (12).

Study Oversight

A cluster randomized control trial was conducted in the 11 health sub-centers functioning under the urban and rural health training centers of a tertiary teaching institute in south Kerala. The trial was approved by the Human ethics committee of the institute (IEC No. 12/01/2017/MCT) and was registered with the Clinical Trial Registry of India (CTRI), registration number-CTRI/2017/11/010622. The baseline data collection was done in July and August 2018 and participants were followed up for a period of 6 months.

Health sub-centers (HSC) are the most peripheral units of the health system in India and they carry out public health activities in a defined population. Each HSC in the study setting caters to a population of 7,000–11,000. The field-level health workers known as Junior Public Health Nurses (JPHNs) and Junior Health Inspectors (JHI) in Kerala are the key personnel in every HSC and are recruited through Kerala Public Service Commission. They provide comprehensive primary care services varying from promotive, preventive, curative, rehabilitative, and palliative services. The JPHNs have an educational qualification of a higher secondary degree along with an Auxillary Nurse Midwife (ANM) certificate. They discharge activities related to Maternal and Child health, communicable disease surveillance, and conduct weekly Non-Communicable Disease (NCD) clinics in the HSC. Around 50–70 patients attend the sub-center NCD clinics monthly.

Participant Eligibility and Sample Size

Adult patients (above 18 years of age) with diabetes mellitus registered at the NCD clinics were included. Patients who were unwilling, pregnant, bedridden, suffering from malignancy, renal/hepatic disease, had cardiac events in the past year, and those with cognitive impairment were excluded. The sample

size was calculated based on a study by Goldhaber et al. which reported a decrease of 19 ± 55 mg/dl in the fasting blood sugar value of the intervention group and an increase of 16 ± 78 mg/dl in the control group (13). The two-sided probability of type I error was fixed at 5% and power at 80% to calculate a minimum required sample size of 58 in each group. Since the exact intracluster correlation (ICC) between the HSCs in FBS values of patients was unknown and a high level of ICC was not expected for a non-communicable disease at the HSC level, the sample size was inflated by 10%. It was decided to enroll patients from all 11 selected HSCs as clusters of size 12.

Randomization and Blinding

The HSCs were randomized into intervention and control groups by random permuted blocks method (block size four). The sequence generation was done by a statistician (who had no prior knowledge regarding the HSCs) and the allocation was concealed from the researchers till the day of intervention using an opaque sealed envelope. Since there were only 11 clusters for randomization, the 12th code was neglected. The eligible participants were selected from each HSC by simple random method using computer-generated random numbers. No blinding of participants was done owing to the nature of the study. Outcome assessors and data analysis was blinded.

Intervention and Outcome Measures

Preparation of a Module to Train the JPHNs

A module was prepared to train JPHNs with a key focus on improving their knowledge, attitude, and skills in diabetes management at the primary health care level with due focus on a healthy diet, adequate exercise, compliance to treatment and follow-up, cessation of smoking, and alcohol intake. The module content was validated qualitatively with the help of experts by the modified Delphi technique (14). The panel included State Nodal Officer of NCD division (Government of Kerala), Deputy Director of planning (Directorate of health services), Administrative Medical Officers of the primary health centers under the study, an epidemiologist, a diabetologist, and a social scientist.

Content of the Training Module

The module consisted of a 1-day training to be conducted in three sessions targeting the improvement in knowledge, attitude, and skills in counseling patients with diabetes. The module was prepared in the local language, Malayalam.

1. Knowledge (Duration 1.5 h)

This session consisted of a short lecture based on andragogy principles using a PowerPoint presentation. The slides were prepared after a comprehensive literature review and expert advice regarding non-communicable disease burden, diabetes—its risk factors, complications, prevention, and control. The role of lifestyle modification in controlling diabetes was highlighted with due focus on a healthy diet, adequate physical activity, cessation of smoking and alcoholism, drug compliance, and regular follow-up.

2. Attitude (Duration 2 h)

This session involved attitude building in JPHNs through discussion of different case scenarios related to diabetes in a primary health setting. The participants were seated in a circle and a clinical scenario from the training module was read out by a participant to the group. Each participant was given a chance to discuss their views and the advice that they would offer in the scenario. The investigator acted as a facilitator for the discussion. Following this, the instructor discussed the best instructions and action plan for patients in each scenario. Flexible approaches to facilitate sustainability of behavioral changes like maintenance of a health diary, setting up of community walking groups, vegetable/fruit gardening at home, etc. were highlighted.

3. Practice/Skills (Duration 2.5 h)

This session involved hands-on training for the JPHNs simulating diabetes care in a primary care setting with diabetic patients. The participants were given two patients each and allotted a time of 30 min to gather history regarding their illness, monitor the clinical parameters, and offer counseling on diabetes care. The activities were monitored and scored by the investigators. The participants were encouraged to take feedback from the patients and identify the barriers to behavioral change. Finally, a group discussion was conducted with the JPHNs and the investigators to share their experiences and feedback from the patients. The investigators discussed the possible ways to aid effective and successful counseling through a better understanding of barriers and flexibility of approaches.

Training JPHNs

A 6-h training was conducted for the JPHNs in the intervention group involving discussions, role play, and hands-on sessions based on the module. Pre and post-intervention evaluation of JPHNs was done using a structured questionnaire for the assessment of knowledge and a checklist for the assessment of skills and practice.

Implementation at HSCs

Study participants were recruited to the respective study groups after obtaining informed consent. Their demographic and behavioral characteristics (diet, physical activity, smoking, and alcohol intake) and baseline values of blood sugar, Body Mass Index, and blood pressure were noted by the investigators. Baseline compliance to treatment was measured using the Medication Adherence Questionnaire (MAQ). A 3–5 min counseling was offered by the JPHNs of the intervention group to every patient attending the NCD clinic during their monthly visit (followed for 6 months) with a focus on diet modification, exercise, improving drug compliance, regular medical check-ups, and cessation of smoking and alcohol intake in addition to the standard treatment. The patients in the control group received standard management according to the Directorate of Health Services (Government of Kerala) guidelines (15).

Monitoring and Follow up

Participants were followed up for 6 months with monthly monitoring of FBS, PPBS, BMI, and Blood pressure by the JPHNs, and the values were recorded in the data collection sheets

provided. Data on drug adherence, dietary patterns, physical activity, and habits of smoking and alcoholism were also collected at the end of the follow-up. All the data recorded were verified by research assistants. At the end of the trial, all patients who did not turn up for follow-up were contacted over the phone by the investigators and advised to report at the HSC on the specified date.

Outcomes and Definitions

All participant assessments took place at the HSC during the follow-up visits. Fasting blood sugar was the primary outcome under study. As secondary outcomes, post-prandial blood sugar, glycemic control status, and other clinical parameters like blood pressure, BMI, and health-related habits like drug adherence, dietary pattern, physical activity, and habits of smoking and alcoholism were studied. The improvement in knowledge and skills/practice of the JPHNs and patient perception of services delivered at the HSCs were also studied.

We defined glycemic control status as per the targets recommended by the American Diabetes Association (ADA) for the treatment of Diabetes (16). Controlled fasting blood sugar was defined as FBS value between 80 and 130 mg/dl and controlled postprandial blood sugar as PPBS $<$ 180 mg/dl. Achieving total glycemic control required optimum control of FBS and PPBS. Adequacy of physical activity was defined as at least 150 min of moderate-intensity physical activity throughout the week, or at least 75 min of vigorous-intensity physical activity throughout the week, or an equivalent combination of moderate and vigorous-intensity physical activity as per the World Health Organization (17). Classification of BMI was done as per WHO-recommended cut-offs for the Asian population. A BMI of 23–24.9 kg/m^2 was considered overweight and BMI $\geq$ 25 kg/m^2 was considered obesity (18). Preparation of food frequency table and quantification of food items including portion size estimation (wherever applicable) was done based on the common food materials consumed in India as reported by the Indian Council of Medical Research (National Institute of Nutrition) guidelines modified with inputs from the Kerala State Nutrition Office. Medication adherence was assessed using Morisky, Green and Levine Adherence Scale (also known as Medication Adherence Questionnaire) (19).

Statistical Methods and Data Analysis

Statistical analysis was performed using IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp. Baseline characteristics of the participants were summarized using mean and standard deviation (SD) or median and interquartile range (IQR) for continuous variables and frequency and percentage for categorical variables. The primary analysis was planned to study the effect of the intervention on the FBS values at the end of 6 months adjusting for the baseline values based on the intention-to-treat principle. This was to prevent bias due to the expected missing values considering the nature of the intervention and data collection. Analysis of Covariance (ANCOVA) was used to compare the final blood sugar levels adjusting for the baseline values after assessing the assumption of linearity using residuals. The model was also adjusted for the potentially confounding sociodemographic and baseline values. Similarly, ANCOVA was used to compare the PPBS, blood pressure, and BMI values at the end of follow-up adjusting for baseline values. Glycemic control status at the end of follow-up was compared between the intervention and control group by chi-square test and the trend of glycemic control across the 6 months of follow-up was analyzed using chi-square for trend.

Multiple imputation of missing monthly glycemic values using iterative Markov Chain Monte Carlo (MCMC) method was done to create 10 imputed datasets. The imputation model was supplemented with auxiliary variables identified in preliminary analyses to be related to attrition and the pooled estimates were analyzed. Repeated measure ANOVA was done to study the change in FBS and PPBS values over the months of follow-up (Mauchy's test of sphericity indicated a violation of the assumption of sphericity and therefore a Greenhouse-Geisser correction was used).

Multilevel modeling (MLM) using the random intercepts model was done to assess the effect of the intervention over the study period on FBS and PPBS values adjusting for the clustering at the HSC level with time interaction. Adjustments for the sociodemographic and baseline variables between the two groups were also done in the model. MLM was conducted in STATA data analyses software, version 15.0. Study group (intervention or control), time point (baseline and 6 months of follow-up), and a study group-timepoint interaction were specified as fixed effects in the model. The significance of intervention was tested using the study group-time frame interaction. Intra-Class Correlation (ICC) coefficient of each model and its 95% confidence interval was calculated as the proportion of variance in the outcome that is explained by the grouping structure of the hierarchical model ($\rho = {\sigma_{u0}}^2/{\sigma_{u0}}^2 + {\sigma_e}^2$, where ${\sigma_{u0}}^2$ is the variance of the level-2 residuals and ${\sigma_e}^2$is the variance of the level-1 residuals).

A model for individual factors in the intervention package as predictors of glycemic control was built adjusting for sociodemographic variables, and baseline values of drug adherence, dietary habits, physical activity, alcoholism, and smoking frequency using Generalized Estimating Equations (GEE). The post-training improvement in knowledge and skills of JPHN was assessed using ANCOVA. The threshold of statistical significance was defined at $P < 0.05$ for all analyses.

Ethics

Written Informed consent was obtained from all study participants. The information of the participants was coded to ensure confidentiality. The trial followed good clinical practice and did not interfere with any existing treatment. Following trial completion and generation of evidence on the effectiveness of the intervention, the health workers in the control group were also given training based on the module.

RESULTS

Overview of Enrolment and Data Completeness

We recruited 72 participants to the intervention group and 60 participants to the control group and at the end of

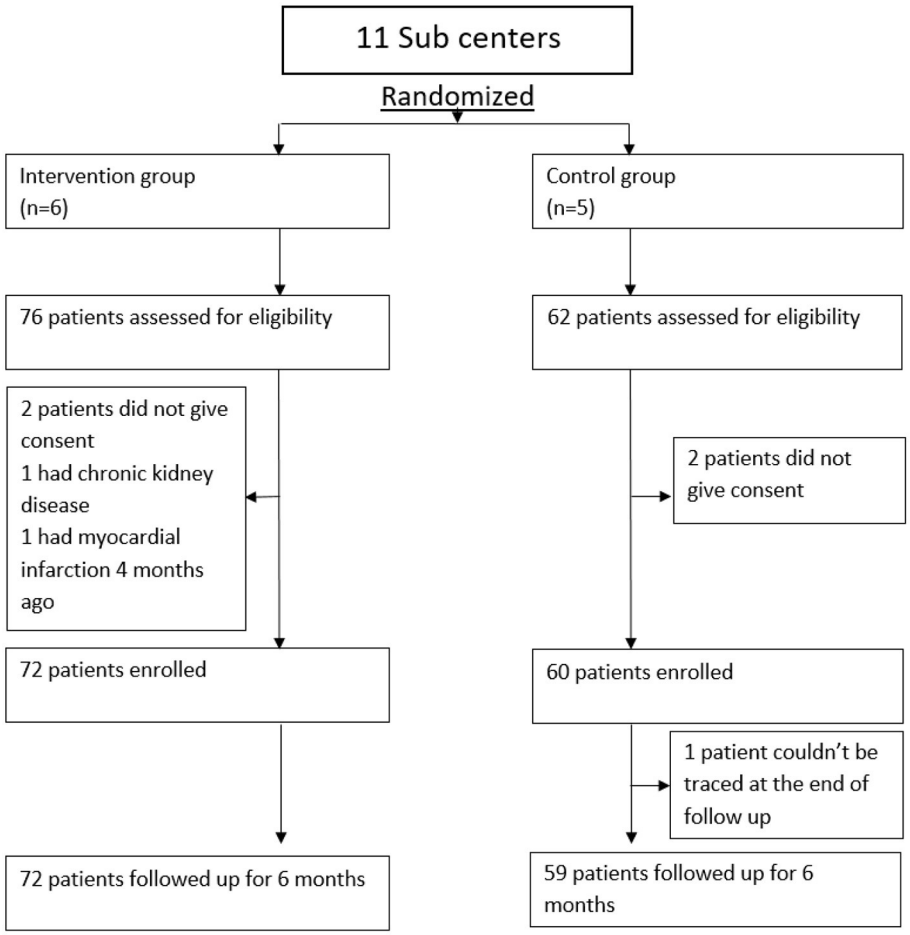

FIGURE 1 | Study enrolment profile.

follow-up, all except one participant could be traced by the investigators (**Figure 1**). An intention-to-treat analysis was done including all recruited cases. Since follow-up attendance was a variable under study, the completeness of follow-up data was different in both groups and the investigators did not interfere in it.

Baseline Characteristics of the Study Participants

Around three fourth of the participants were aged above 55 years and more than 70% were females in both groups. At the initiation of the trial, 32 (44.4%) participants in the intervention group and 32 (53.3%) participants in the control group had their FBS levels under control whereas the PPBS control was seen in 26.4 and 28.3% of participants, respectively. The baseline sociodemographic and clinical characteristics of the intervention and control group are summarized in **Table 1** and the baseline dietary habits are given in **Table 2**. The baseline parameters in the two groups appear to be potentially imbalanced for some variables including gender, socioeconomic status, diagnosed comorbidities, blood glucose parameters, and smoking status.

Outcomes

At the end of 6 months, mean fasting blood sugar values dropped in both groups, the drop being higher in the intervention group. Adjusting for the baseline FBS values, FBS at the 6th month was 123.7 ± 1.71 (95% CI: 120.3–127.1) mg/dl in the intervention group and 135.4 ± 1.89 (131.6–139.1) mg/dl in the control group. The intervention was associated with a significant reduction in FBS at the end of 6-month follow-up after controlling for the effect of baseline FBS, $F_{(1,130)} = 20.8$, $p < 0.001$.

The model was further adjusted for age, gender, socioeconomic status, diagnosed comorbidities, years since diagnosis of diabetes, baseline FBS value, and smoking status. The adjusted mean 6th-month FBS value was 125.1 (±15.9) mg/dl in the intervention group and 133.6 (±23.9) mg/dl in the control group. The FBS values were significantly lower in the intervention group, $F_{(1,121)} = 14.1$, $p < 0.001$, and the adjusted model showed a 10.3 (±2.6) mg/dl decline in FBS values with the intervention compared to the control group.

Adjusting for the baseline PPBS values, PPBS at the 6th month was 179.7 ± 3.59 (172.6–186.8) mg/dl in the intervention group and 210.1 ± 3.97 (202.3–217.9) mg/dl in the control group.

TABLE 1 | Baseline characteristics of the study participants.

Variables		Intervention group *n* = 72 (%)	Control group *n* = 60 (%)
Age in years, mean ± SD		60.99 ± 9.6	62.77 ± 9.3
Gender	Male	21 (29.2)	11 (18.3)
	Female	51 (70.8)	49 (81.7)
Socio-economic status*	Lower class	4 (5.6)	1 (1.7)
	Upper lower	33 (45.8)	25 (41.7)
	Lower middle	31 (43.1)	26 (43.3)
	Upper middle	3 (4.2)	8 (13.3)
	Upper class	1 (1.4)	0 (0)
Diagnosed hypertension		57 (79.2)	51 (85)
Diagnosed hyperlipidemia		19 (26.4)	20 (33.3)
Diagnosed thyroid disease		6 (8.3)	8 (13.3)
Family history of Diabetes mellitus		46 (63.9)	41 (68.3)
Duration of Diabetes in years, median (IQR)		6 (2.5–10)	7 (4–12)
Fasting Blood Sugar (mg/dl), mean ± SD		141 ± 29	134 ± 33
Post prandial blood sugar (mg/dl), mean ± SD		218 ± 55	209 ± 57
Controlled FBS		32 (44.4)	32 (53.3)
Controlled PPBS		19 (26.4)	17 (28.3)
Controlled FBS and PPBS		17 (23.6)	15 (25)
Body Mass Index (kg/m^2), mean ± SD		25.0 ± 4.1	25.5 ± 3.3
Systolic Blood Pressure (mm Hg), mean± SD		132 ± 15	132 ± 14
Diastolic Blood Pressure (mm Hg), mean± SD)		81 ± 7	82 ± 8
Medication adherence score, median (IQR)		1 (1–3)	1 (1–3)
Adequate physical activity		12 (16.7)	8 (13.3)
Alcohol use		6 (8.3)	5 (8.3)
Smoking		8 (11.1)	4 (6.7)
Vegetable garden at home		7 (9.7)	8 (13.3)
Fruit garden at home		8 (11)	4 (6.7)

**Classified based on modified Kuppuswami scale.*

TABLE 2 | Baseline dietary habits[#].

Food item	Mean ± SD	
	Intervention group *n* = 72	Control group *n* = 60
Oil use (grams/day)*	21.1 ± 3.2	20.4 ± 3.9
Salt use (grams/day)*	10.9 ± 3.4	11 ± 3.1
Sugar use (grams/day)*	12.6 ± 4.5	11.9 ± 5
Coconut use (grams/day)*	86 ± 26	91 ± 30
Red meat (days/month)	0.3 ± 0.5	0.5 ± 0.7
Other meat (days/month)	1.6 ± 1	2.0 ± 1.3
Fish (days/month), median (IQR)	27 (20–30)	25 (20–30)
Egg (days/month)	4.5 ± 3.7	5.1 ± 4.1
Sweets (days/week)	0.48 ± 0.7	0.7 ± 0.8
Fried snacks (days/week)	1.2 ± 1	1.0 ± 1.0
Sugary drinks (days/week)	0.15 ± 0.3	0.3 ± 0.5
Tea/coffee (times/day)	2.2 ± 0.7	2.1 ± 0.8
Polished rice (times/day)	1.5 ± 0.5	1.6 ± 0.5
Wheat (times/day)	0.3 ± 0.5	0.3 ± 0.5
Oats/ragi (times/day)	0.2 ± 0.4	0.1 ± 0.3
Tubers (days/week)	2 ± 0.7	1.8 ± 0.9
Pickle/pappad (days/week)	1.7 ± 1.8	1.5 ± 1.6
Pulses (days/week)	2.6 ± 0.8	2.5 ± 1
Water (glasses/day)	8 ± 1.7	8.2 ± 1.5
Fruits (grams/week)	95.2 ± 70	111.7 ± 73
Green leafy vegetables (grams/week)	88.6 ± 49.3	90.3 ± 67.7
Other vegetables (grams/week)	363.9 ± 107.9	364 ± 103

[#]Estimated from food frequency questionnaire.
**Estimated using family intake (data on standard intake per person is not available).*

The reduction in PPBS at the end of 6th-month follow-up was significantly better in the intervention group after controlling for the effect of baseline PPBS, $F_{(1,130)} = 32.15$, $p < 0.001$. The PPBS model adjusted for sociodemographic and other baseline variables showed a significant decline of 27.7 (±5.6) mg/dl in the PPBS values in the intervention group compared to the control group, $F_{(1,121)} = 23.9$, $p < 0.001$. The adjusted PPBS values were 182.2 (±42.2) mg/dl and 207 (±49.2) mg/dl in the intervention and control groups, respectively.

At the end of follow-up, 51 (70.8%) participants in the intervention group and 29 (49.2%) participants in the control group had their FBS under control, whereas PPBS control was present in 40 (55.6%) and 22 (37.3%) participants, respectively. The intervention was associated with a 1.73 (1.2–1.9) times incidence of FBS control and 1.6 (1.1–2.1) times incidence of PPBS control compared to the standard management. The achievement of a total glycemic control status (control of both fasting and postprandial blood sugar) was 1.5 (1.05–2.3) times higher in participants who received the intervention.

The intervention group had a significantly better trend of maintenance of glycemic control (**Figure 2**). Chi-square value for linear trend (Extended Mantel Haenszel) was significant at $P = 0.003$ for FBS and $p = 0.039$ for PPBS.

The percentage of missing values of FBS across the 6 months of follow-up ranged between 0 and 11% in the intervention group and 1.3 and 37% in the control group. The percentage of missing PPBS values ranged between 0 and 7% in the intervention group and 1.1 and 32% in the control group. Repeated measures ANOVA analysis (on the imputed data set) showed a statistically significant effect of the intervention on the FBS values over the months, $F_{(3.76,457.3)} = 11.9$, $p < 0.001$. A similar effect of the intervention on the PPBS values over 6 months was noted $F_{(3.77,539.4)} = 11.45$, $p < 0.001$ (**Figure 3**).

Cluster Adjusted Analysis

On adjusting for clustering at the HSC level with time, the intervention was associated with a significant decline in FBS values, with an estimated decline of 3.09 (SE = 0.57) mg/dl with

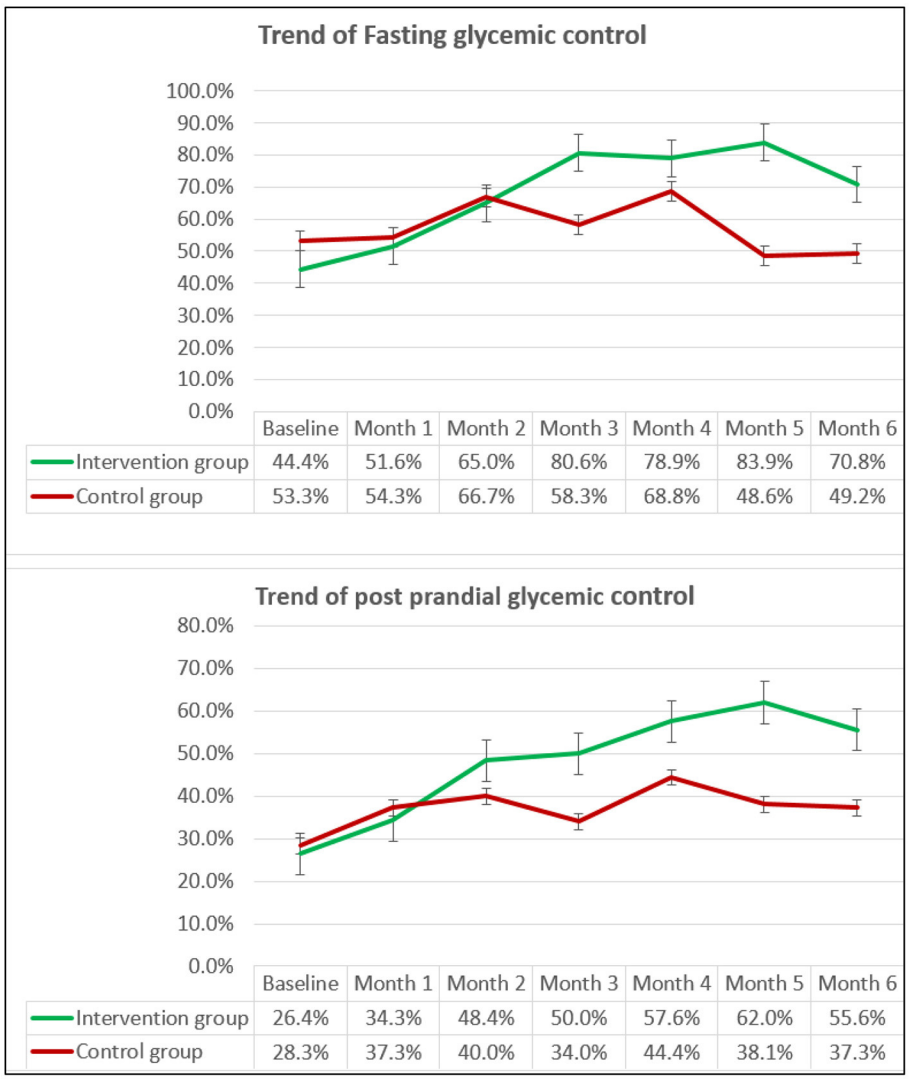

FIGURE 2 | The trend of proportion* of participants with Fasting and Postprandial glycemic control over the follow-up period. *Percentages are calculated excluding the missing values in both groups.

each month of follow-up, $p < 0.001$. A similar cluster adjustment on PPBS values showed a 6.35 (SE = 1.04) mg/dl decline of PPBS values with intervention-time interaction compared to the control group, $p < 0.001$. The ICC calculated for FBS and PPBS values at the HSC level was 0.058 (95% CI: 0.012–0.23) and 0.048 (95% CI: 0.008–0.23), respectively. At the patient level, ICC was 0.601 (95% CI: 0.528–0.671) for FBS and 0.606 (95% CI: 0.53–0.671) for PPBS model.

The model was further adjusted for sociodemographic and baseline parameters, and the intervention-time interaction was found to reduce FBS values by 3.1 (SE = 0.57) mg/dl ($p < 0.001$). In addition, with each year since the diagnosis of diabetes, a 0.81 (SE=0.3) mg/dl increase in the FBS value was shown by the model. A similar hierarchical model for PPBS showed intervention being associated with 6.3 (SE = 1.03) mg/dl reduction of PPBS with every month of follow-up, $p < 0.001$. Years since diagnosis of diabetes ($B = 1.5$, SE = 0.59, and $p = 0.009$), diagnosed hyperlipidemia ($B = 14.3$, SE = 7.19, and $p = 0.046$) and baseline BMI ($B = 2.04$, SE = 0.87, and $p = 0.019$) values were found to be significantly associated with PPBS values. The ICC calculated for the adjusted FBS and PPBS models at the patient level were 0.54 (SE = 0.039) and 0.54 (SE = 0.037), respectively.

Improvement in Other Clinical Parameters

The intervention was associated with a significant change in the systolic and diastolic blood pressure values at the end of follow-up after controlling for the effect of baseline blood pressure values, $F_{(1,130)} = 23.9$, $p < 0.001$ and $F_{(1,130)} = 15.27$, $p < 0.001$, respectively. No significant difference was observed in the Body Mass Index values (**Table 3**).

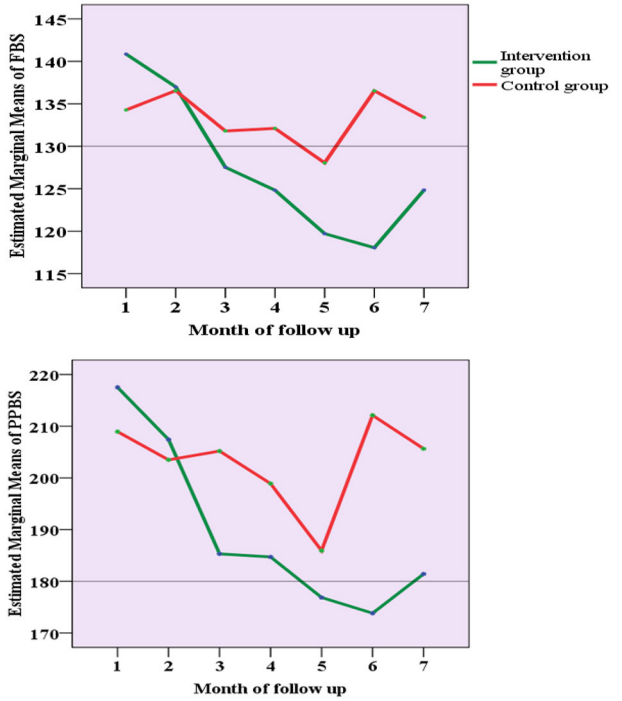

FIGURE 3 | The trend of the estimated marginal mean of FBS and PPBS values over the follow-up period.

Change in the Health-Related Behaviors

The mean number of follow-up visits attended by the participants was 5.8 ± 0.5 and 4.8 ± 1 in the intervention and control groups, respectively. The difference was significant with $t = 6.4$, $p < 0.001$. While the median drug adherence score remained at 1 (1–3) throughout the months of follow-up in the control group, the score improved to 3 (3, 4) in the intervention group. GEE showed a significant change with β = 0.67, Wald chi-square = 8.0, degree of freedom = 1, $p = 0.005$.

After categorizing the patients into poor, moderate, and good drug adherence based on their medication adherence scores, the intervention group had 6 (8.3%) participants with poor drug adherence and 33 (45.8%) participants each with moderate and good drug adherence. In the control group, the proportion of participants with poor, moderate, and good drug adherence were 50.8, 30.5, and 18.6%, respectively. A significant association of intervention with drug adherence was noted, $p < 0.001$. On regrouping the participants into two categories (poor adherence and moderate-high adherence), the control group showed a 1.9 (1.5–2.4) times higher risk of poor drug adherence.

When adjusted for baseline values, the mean hours of physical activity per week was 3.6 ± 0.07 h in the intervention group and 3.0 ± 0.08 h in the control group, $F_{(1,130)} = 9.36$, $p = 0.003$. WHO-recommended adequacy of physical activity was reported only by 16 (22.2%) participants in the intervention group and 10 (16.7%) participants in the control group.

At the baseline, choosing walking as a method of traveling a kilometer distance was preferred by 38 (52.8%) and 40 (66.7%) participants in the intervention and control group, respectively, and this proportions climbed to 86.1% in the intervention group and 69.5% in the control group by the end of 6 months ($p = 0.02$). The number of participants with a self-reported habit of alcoholism remained the same in the control group, whereas three among the six alcoholics reported having stopped the habit of alcohol intake in the intervention group. Among the smokers, one person each from the intervention and control group reported quitting the habit of smoking. A significant reduction in the number of cigarettes smoked per day ($p = 0.03$) and the amount of alcohol consumption per day ($p = 0.002$) was noted in the intervention group adjusting for the baseline values.

Dietary habits at the end of follow-up were assessed after adjusting for the baseline values using one-way ANCOVA. Significant dietary changes between the intervention and control group are shown in **Table 4**. By the end of follow-up, 24 (33.3%) participants in the intervention group and 9 (15.3) participants in the control group had a vegetable garden at home ($p = 0.02$). No significant change was observed in initiating a fruit garden at home.

Role of Individual Factors in the Intervention Package

A General Linear model was built with GEE to study the effect of factors in the intervention package on glycemic control adjusting for the sociodemographic variables, and baseline values of drug adherence, dietary habits, physical activity, alcoholism, and smoking frequency. The model showed drug adherence score ($p < 0.001$), physical activity in hours per week ($p < 0.001$), Body Mass Index ($p = 0.002$), fruit intake ($p = 0.004$), and green leafy vegetable intake ($p = 0.01$) as the major predictors of FBS control (**Table 5**).

Improvement in Service Delivery at the HSCs

Adjusting for the baseline values, the practice/skills score of the JPHNs in the intervention group was 18.2 (95% CI: 16.9–19.4) and in the control group was 7.6 (95% CI: 6.2–8.9), the difference being significant at $p < 0.001$. No significant difference was noted in the knowledge score. At the end of follow up 65 (90.3%) participants in the intervention group reported the quality of services received from their HSC to be good (an increase from a baseline value of 37%) and the remaining reported it to be satisfactory. In the control group, 10 (16.9%), 45 (76.3%), and 4 (6.8%) participants reported the services as good, satisfactory, and poor, respectively. As per the participants, there was a major difference in the counseling services received in each group, with almost all patients in the intervention group having received counseling on a healthy diet, drug adherence, and regular follow-up.

DISCUSSION

The intervention was successful in reducing the Fasting and Postprandial blood glucose of participants, improving their glycemic control and its maintenance. Non-pharmacological

TABLE 3 | Change in clinical parameters adjusted for baseline values.

Variables	Group	Mean value at the end of 6 months (SD)	Adjusted Mean	Standard error	95% Confidence interval	Significance 2 tailed *p*
FBS (mg/dl)	Intervention	125 ± 16	123.7	1.71	120.3 to 127.1	<0.001
	Control	134 ± 24	135.4	1.89	131.6 to 139.1	
PPBS (mg/dl)	Intervention	182 ± 42	179.7	3.59	172.6 to 186.8	<0.001
	Control	207 ± 49	210.1	3.97	202.3 to 217.9	
BMI (kg/m^2)	Intervention	25 ± 4	25.15	.06	25.02 to 25.29	0.08
	Control	26 ± 3	25.33	0.07	25.18 to 25.47	
Systolic BP (mmHg)	Intervention	125 ± 9	125.5	1.24	123.0 to 127.9	<0.001
	Control	135 ± 14	134.5	1.37	131.8 to 137.2	
Diastolic BP (mmHg)	Intervention	80 ± 5	80.2	0.75	78.8 to 81.7	<0.001
	Control	85 ± 8	84.6	0.83	83.0 to 86.2	

TABLE 4 | Dietary habits at end of follow-up adjusting for the baseline values.

Variables	Group	Adjusted Mean	Standard error	95% Confidence Interval	Significance 2 tailed p
Sugar use (grams/day)	Intervention	10.6	0.26	10.1 to 11.2	0.001
	Control	12.0	0.29	11.4 to 12.6	
Fried snacks (days/week)	Intervention	0.59	0.07	0.44 to 0.73	<0.001
	Control	1.3	0.08	1.14 to 1.4	
Sugary drinks (days/week)	Intervention	0.07	0.04	−0.004 to 0.151	<0.001
	Control	0.37	0.04	0.28 to 0.45	
Pickle/pappad (days/week)	Intervention	1.04	0.09	0.87 to 1.21	<0.001
	Control	1.8	0.09	1.6 to 1.98	
Pulses (days/week)	Intervention	2.7	0.06	2.64 to 2.87	0.013
	Control	2.5	0.06	2.40 to 2.66	
Fruits (grams/week)	Intervention	120.6	4.6	111.4 to 129.8	0.022
	Control	104.5	5.1	94.4 to 114.7	
Green leafy vegetables (grams/week)	Intervention	115.6	4.25	107.2 to 124.0	<0.001
	Control	85.0	4.7	755.7 to 94.3	
Other vegetables (grams/week)	Intervention	405.2	6.0	393.4 to 417.0	0.033
	Control	386	6.6	372.9 to 399.0	

interventions have been shown to improve knowledge, health behavior, and glycemic control among diabetics and prediabetics across the globe (13, 20–26). However, there are pragmatic primary care trials that failed to show significant results (27–29). Most studies emphasize the role of nutrition, exercise, and the importance of diabetes self-care including medication adherence and routine follow-up. Evidence of a community-based participatory learning approach in diabetes prevention and management with the help of Community Health Workers was documented in the Indian population as early as 2012 (30). Even after the demonstration of many successful models worldwide, the NCD control statistics fall far below the desired level (31). The complexity including resource intensity and individualized approaches are hindrances behind the implementation. Further, most of the studies were done in academic centers and their emulation at a community level is grueling. Our study is the first randomized controlled trial from India to demonstrate the effectiveness of a community health worker/ multipurpose health worker-led intervention integrated into the health system for diabetes management at the primary care level. Such an intervention can be pivotal as a sustainable tool at the community level.

In this study, the mean fasting blood sugar values showed a reduction of 16 mg/dl in the intervention group whereas no notable difference was observed in the control group. A Community Health Worker based integrated approach to cardiovascular risk reduction from India reported 43.0 ± 83.5 mg/dl FBS reduction in the intervention group and 16.3 ± 77.2 mg/dl reduction in the control group with 2 years of follow up (32). A recent systematic review and meta-analysis on community-based programs for diabetes prevention reported a significant reduction in FBS values along with BMI and waist circumference, however, a significant difference was not demonstrated in 2-h PPBS values and blood pressure

TABLE 5 | Factors associated with glycemic control.

Variables	FBS control			PPBS control		
	B	**Wald chi-square***	***P*-value**	***B***	**Wald chi-square***	***P*-value**
Drug adherence score	0.4	26.5	<0.001	0.59	27.9	<0.001
Physical activity (hours per week)	0.06	13.9	<0.001	0.21	4.6	0.03
Body Mass Index (kg/m^2)	0.1	9.7	0.002	0.14	8.5	0.005
Fruit intake (in grams per week)	0.01	8.5	0.004	0.01	0.11	0.7
Green leafy vegetable intake (in grams per week)	0.01	6.3	0.01	0.01	4.7	0.03

**Degree of freedom = 1.*

The corrected Quasi Likelihood under the independence Model Criterion (QICC) was 633 and 263 for the FBS and PPBS model, respectively.

(33). The Kerala Diabetes Prevention Programme using a community-based peer support lifestyle intervention showed a non-significant reduction in the incidence of diabetes with significant improvement in some cardiovascular factors (34). Besides glycemic control, the present intervention could bring a significant reduction in blood pressure values of participants but not in the BMI. A significant reduction in BMI may require a more intensive intervention strategy or a longer duration of follow-up (35). An intervention study through Community Health Workers among hypertensive patients in a rural community in Kerala demonstrated significant improvement (36).

The study population represented NCD primary care utilization in LMICs with the predominance of elderly, females, and lower-middle-class population. Gender differences in the utilization of primary health services were reported by many studies across the globe (13, 37, 38). The poor baseline diabetes control status in both groups is comparable to the findings reported from the country in nationwide surveys including the ICMR-INDIAB study and the TIGHT study (3, 39). Chronic diseases like diabetes require good patient motivation for long-term therapy adherence, and suboptimal therapy can hinder the control and engender complications. Moreover, Diabetes is difficult to monitor and control compared with hypertension and requires more active self-management by the patients (26). The baseline adherence rates observed in this study is comparable to the WHO estimates of <50% adherence to long-term therapy in LMICs (40).

Though changes in health-related behaviors of the patient and physician behaviors were found to be possible mechanisms of improved glycemic control in many studies, the role of improved medication adherence was hypothesized to be the major contributor (25, 41, 42). In our trial, medication adherence and the number of follow-ups attended showed the most significant improvement. A remarkable upshot of the intervention was a significant increase in the preference of walking a distance of one kilometer instead of using a public or private vehicle and a reduction in the intake of unhealthy food items. Despite a significant increase in the consumption of fruits and vegetables, none of the study participants reported an adequate intake. A pragmatic trial from rural Kerala through neighborhood groups highlighted the difficulty in increasing the fruit and vegetable intake in the community and the need to explore new strategies (43). Due to the nature of the family system in India, explaining a dietary change at the family level requires special attention along with administrative level actions like ensuring the availability of healthy foods and stabilization of prices (24, 44, 45).

Despite the effectiveness of educational interventions in diabetes management, a major challenge across populations is the maintenance of glycemic control (46, 47). We tried to generate evidence on the maintenance of glycemic control through a 6-month follow-up of participants. Sustainability is the arduous part of any lifestyle change intervention and can be made feasible only with system changes, community efforts, and peer reinforcement. The role of social support groups in the maintenance of glycemic control was studied by Ing et al. (46) However, it is not always feasible to involve additional manpower in a resource-poor setting. Our study was a pilot to create a system change at the primary care level involving community participation. Better health worker attitude and skills could bring forth satisfaction and a better understanding of disease control among the patients. Continuance of the lifestyle changes was further ensured through simple measures like vegetable/fruit garden in the house, walking groups, and dairy maintenance. The program can serve as a scalable low-cost model for low-middle income countries in the control of chronic diseases.

International evidence has shown insufficient training and skills to be the major loophole behind the failure of CHW programs (11, 23). Our trial put forth an insight into the gaps in the training process of the health staff at the primary care level. Though the staff had adequate knowledge on diabetes care and non-pharmacological interventions, they failed to demonstrate the necessary attitude and skill in patient counseling which could be improved by the intervention provided. Every training mechanism should target the affective and psychomotor domains of the participants using non-traditional training methods like group discussions, role-play, hands-on training, etc. along with the cognitive domain. The study evaluated the training using all levels of Miller's pyramid, unlike most studies that tried to measure improvement in knowledge. A World Health Organization, 2003 report on medication adherence observed that a negative attitude of nurses and paramedical staff is responsible for 50% of poor drug adherence among patients (40). Positive attitude and commitment of health staff is not a

choice, but a necessity. Attitude building, regular supervision and feedback, non-traditional training methods, and multifaceted interventions can bring a change (48).

The study is a novel attempt to incorporate training on non-pharmacological interventions which can reflect an attitude change among the field-level health workers in the existing primary health system. The minimal loss to follow-up may be attributed to the integration into the preexisting health system. Our study has some limitations. The study was conducted in a limited setting under a medical teaching institution. However, the setting resembles the peripheral health care institutes throughout the state. A major limitation is the possibility of measurement error because of the self-reporting nature of the health-related habits, vulnerable to social desirability. Considering the sustainability of the intervention, the 6-month evaluation period is relatively short and needs further follow-up assessments. We used Fasting and Postprandial blood glucose as a measure of glycemic control instead of HbA1c (which could have been a more robust measure), as the frequency of HbA1c monitoring is poor in our setting and the former may be a more sustainable outcome measure in a pragmatic setting. Moreover, there is increasing recognition of PPBS as an important measure of the overall glycemic burden and a more reliable predictor of cardiovascular disease complications (49, 50). Since the study was done on a small sample, an imbalance of some baseline variables was noted between the two groups and we have tried to adjust for this difference in our analysis. However, a possibility of residual confounding by measured and unmeasured variables cannot be excluded. Since the exact intraclass correlation was not known, our sample size calculation involved inflation of sample size by 10% instead of calculating the design effect. But, we have calculated the ICC from the study data and have adjusted for clustering in the analysis. There exists a possibility of some degree of contamination. This was minimized by informing the intervention group health workers not to discuss the information in the training module with their colleagues throughout the trial period.

CONCLUSION

This trial data brings experimental evidence to the effectiveness of a non-pharmacological intervention through field-level health workers which can be incorporated into the existing health system to improve and maintain glycemic control among diabetic patients in the primary care settings. The study has shown that a well-designed health worker intervention can translate to attitude change and skill development which in turn can reflect in the improvement of glycemic control among the patients. The study emphases the need to reorient training in the health sector to address the affective and psychomotor domain through non-traditional training methods. The study also attempted to elucidate the mechanism by which the intervention improved glycemic control of which improvement in drug adherence, follow-up, physical activity, fruit and vegetable intake by the participants were found to be the major contributors. Despite demonstrating the role of diet and physical activity, the achievement of adequacy in these regards remained very low. More studies need to be planned to incorporate better interventions in the health system.

Recommendations

Task sharing interventions involving counseling on drug adherence, regular follow-up, healthy diet involving fruits and vegetables, adequate physical activity, and smoking and alcohol cessation should become an integral part of non-communicable disease management at the primary care level. Multifaceted health worker interventions including non-traditional training methods and attitude building can help tackle the growing burden of NCDs in low and middle-income countries. Training programs for health workers should be meticulously designed and tested for efficiency. Moreover, every training program should be evaluated for immediate and long-term effects. Researches should be designed to identify barriers to behavior change so that new strategies can be identified in developing and implementing self-management plans for diabetic patients. This includes the identification of decision-making dynamics in diet and physical activity of individuals and families. Specific health system interventions with intersectoral cooperation need to be planned in this regard.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Human Ethics Committee, Government Medical College, Thiruvananthapuram. Ethics clearance number: IEC No. 12/01/2017/MCT. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

AR was the principal investigator, responsible for the oversight of the study, drafted the manuscript, and swears the manuscript to be honest and transparent. AR, SC, TA, and PI contributed to the study design. AR and KP created data collection tools and led data collection. AR, TA, and KP conducted the data analysis and produced figures and tables. The critical review of the manuscript was done by PI, SC, and TA. All authors participated in the interpretation of the results and had full access to the data and affirm integrity.

ACKNOWLEDGMENTS

The authors acknowledge the junior public health nurses for their dedicated service to their patients and the patients for their participation. The authors thank Dr. C. K Jagadeesan, Deputy Director (Planning, Directorate of Health Services), and Dr. Bipin K. Gopal, Nodal Officer, State NCD division, Government of Kerala for their support in module preparation. The authors acknowledge Dr. Ratheesh K. H. and Dr. Jeena Ramesh, the

Administrative Medical Officers of the health centers under which the study was conducted. The authors also acknowledge Malavika Babu, Associate Research Officer (Department of Biostatistics, Christian Medical College Vellore) for the assistance in statistical analysis.

SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2021.747065/full#supplementary-material

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frontiers in Public Health

REVIEW
published: 21 January 2022
doi: 10.3389/fpubh.2021.767545

Barker Hypothesis and Hypertension

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Early onset hypertension is one of many major medical disorders that have evolved over the current millennium across both the developing as well as the developed world. Though various mechanisms have been postulated for the evolution of hypertension in these individuals, one of the most relevant ones is that of low birth weight and its association with hypertension. Barker from historical evidence has postulated the foetal onset adult disease (FOAD) or Thrifty phenotype on Low Birth Weight (LBW) associated hypertension. Later, Brenner highlighted the importance of low nephron mass and future implications. In this review we elaborate the mechanisms that were postulated for LBW-related hypertension as well the potential antihypertensive therapy that may be used in these individuals.

Keywords: low birth weight, Barker hypothesis, Brenner hypothesis, low nephron number, hypertension

OPEN ACCESS

Edited by:
G. K. Mini,
Ananthapuri Hospitals and Research Institute, India

Reviewed by:
Augustine Odili,
University of Abuja, Nigeria
Kavumpurathu Raman Thankappan,
Central University of Kerala, India

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Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: *31 August 2021*
Accepted: *23 December 2021*
Published: *21 January 2022*

Citation:
Jebasingh F and Thomas N (2022) Barker Hypothesis and Hypertension. Front. Public Health 9:767545. doi: 10.3389/fpubh.2021.767545

INTRODUCTION

Hypertension is a leading cause for the global burden of disease across developed and developing countries. Moreover, it is an independent risk factor for the subsequent evolution of coronary artery disease. The prevalence of hypertension among the Indian population has been rising since the turn of the century. This may be attributed to the increase in sedentary lifestyle pattern and increase in body weight (1).

The transition as a result of the free market economic reforms that occurred toward the latter part of the twentieth century, has increased the availability of high calorie food across urban and rural India (2). As per the Fourth National Family Health Survey (NFHS-4), the prevalence of hypertension is as high as 20 percent in most of the rural India (3, 4).

Having said that, it is important to think tangentially of other potential precipitating factors. According to NFHS-4 survey, 18% of new born infants fall into the category of Low Birth weight (LBW) as the per the World Health Organisation (WHO) criteria i.e., birthweight <2.5 kg.

LOW BIRTH WEIGHT COHORTS ACROSS THE GLOBE

The *Helsinki and Hertfordshire cohorts* that were followed up between the 1930s and 1940s, with over 20,000 sample population has shown clear evidence linking poorly developed foetal growth with metabolic syndrome in their adult life (5). Moreover, these effects may be transmitted to subsequent generations as having an increased prevalence of diabetes mellitus, hypertension, and coronary artery disease (6).

However, those foetuses subjected to the *Leningrad famine* during World War II, has shown a decreased prevalence of diabetes, hypertension as well other metabolic problems, after they were on a continuous calorie restriction during their infancy. This is in contrast to the Dutch counterpart that was followed during the early part of twentieth century. These contrasting scenarios in association with low birth weight and the metabolic syndrome have provided a different dimension toward the pathogenesis of the metabolic syndrome and birth weight (7).

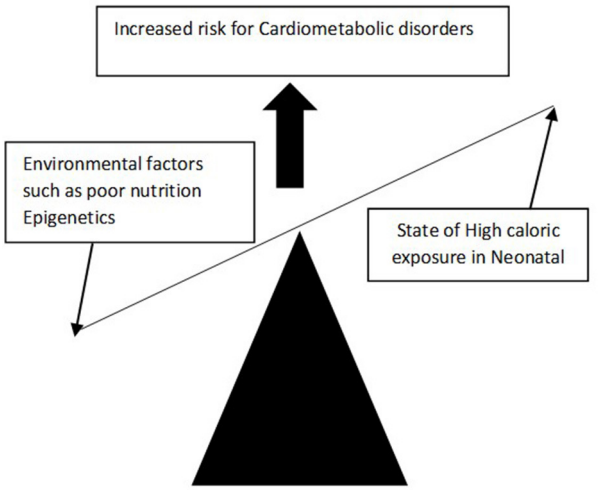

FIGURE 1 | Barker's hypothesis.

Subsequently in 1962, James V Neel proposed the thrifty-genotype hypothesis, stating that "an individual's adaptation to the environment was dependent on genes selected over a long period of time." It proposed that genes that favour survival during prolonged adverse environment in the foetal life, can be detrimental if those same genes are subjected to a state of surplus energy at a later part of life, as was shown in Hertfordshire cohort (8). This was subsequently labelled as the thrifty genotype hypothesis.

However, Hales and Barker later challenged this theory and proposed that the foetus which experiences suboptimal nutritional uptake during intrauterine development, may lead to reprogramming of foetal genes that subsequently alters foetal structure, function as well as metabolic changes. This hypothesis is called the FOAD (Foetal origin of adult disease) or thrifty phenotype or Barker's hypothesis or "developmental origins of adult health and disease" hypothesis (DOHAD) (**Figure 1**). The FOAD hypothesis represents a mismatch between foetal life and neonatal life, thereby increasing the risk for cardiometabolic diseases. Hence low birth weight, which is a surrogate marker of poor foetal growth, is linked to hypertension, diabetes, obesity, and insulin resistance. In addition, a disproportionate catch-up fat growth, in comparison with lean body mass, is one of the major driving factors for the development of cardiometabolic problems among adults with LBW.

In the Indian context of low birth weight and cardiometabolic consequences, studies from Vellore, Pune, and Delhi has highlighted an increased prevalence of cardio-metabolic disorders amongst those born with LBW (9–12).

One of the major risk factors for the low birth weight is maternal age. A U-shaped relationship has been described between maternal age and LBW. Teen age pregnancies on one hand and an increased maternal age on the other hand have been shown to be associated more with LBW (13). Moreover, untreated sexually transmitted disorders such as chlamydia and bacterial vaginosis have been known to precipitate LBW. Moreover, the literature has also cited domestic violence during pregnancy to be associated with LBW (14). Substance abuse such as alcohol, smoking, or using illicit drugs such as heroin or cocaine are also found to be associated with LBW (15). Maternal educational status below the primary school cut off, a reduced birth interval of <2 years, poor maternal weight gain (<4 kg), pregnancy induced hypertension and poor antenatal follow ups have been shown to be associated with LBW in a study done in Southern India (14–16).

Hence, LBW might be prevented through regular antenatal checkups and appropriate therapy for sexually transmitted diseases during pregnancy. More so factors such as teen age pregnancy and substance abuse during pregnancy lead to LBW.

HYPERTENSION AMONGST LOW-BIRTH-WEIGHT INDIVIDUALS

David Baker has demonstrated that low birth weight could cause raised blood pressure in adult life and this has already been established in many studies from different ethnicities. Therefore, lower the birth weight, higher the risk of adult onset of hypertension (13–16). A metanalysis on LBW and hypertension comprising nine studies has shown that there was an odds ratio of 1.21 (95% CI 1.13, 1.30) in developing hypertension among those born with LBW (17).

A retrospective study from Sri Lanka ($N = 122$), that surveyed the hospital records of low birth weight in relation to hypertension in adulthood, found a significant association with high systolic Blood pressure (OR = 2.89; 95% CI: 1.01, 8.25), and hypertension (OR = 3.15; 95% CI: 1.17, 9.35; $P = 0.03$) and no association with diastolic blood pressure after adjusting for other independent factors that may determine adult-onset hypertension (18). Law et al. in his metanalysis has also demonstrated an inverse relationship with birth weight and hypertension in adults (19).

LOW BIRTH WEIGHT, CATCH UP GROWTH, AND BLOOD PRESSURE

Studies have provided enough evidence about the association between LBW in relation to the timing of a foetal nutritional insult during the stages of development. A thin infant at birth with a low Ponderal index is more likely to have had a sustained duration of a nutritional insult in the last trimester. However, a neonate with a small head circumference may have had a nutritional insult through all three trimesters (20). A study by Thomas N et al. has shown the presence of a borderline trend toward high diastolic blood pressure amongst an Asian Indian Low birth weight cohort (12).

It is important to understand that there are two types of catch-up growth in childhood, i.e., skeletal and non-skeletal growth. Skeletal catch-up growth implies the acceleration in growth following a health crisis or illness, to eventually achieve a reasonable final height. Non-skeletal growth implies: either the

weight gained or body mass index (BMI) accrued in relation to the baseline birth weight.

A systematic review of 80 studies has shown that there is an inverse association between birth weight and SBP in adults among those with a high catch-up growth during childhood. However, the review failed to show a significant association between the Ponderal index and high blood pressure. This may suggest that an individual with a sustained intrauterine nutritional insult and a significant non-skeletal catch-up growth during childhood is also at risk for future hypertension (16, 21).

PATHOGENESIS OF LBW AND HYPERTENSION

There are several mechanisms that have been proposed for the association between Low Birth weight and hypertension.

One proposed mechanism was that an increased pressure in foetal circulation, as a compensatory mechanism in maintaining placental perfusion, might persist even after birth (22). Another mechanism that has been proposed: intrauterine growth retardation causing low birth weight may lead to accelerated postnatal growth and thereby, an accelerated rise in blood pressure. This was shown in both mothers with and without hypertension during pregnancy (15, 23).

Gunhild Keller performed autopsy studies and demonstrated that reduced nephron numbers with associated hypertrophy of the glomeruli was common among those with systemic hypertension compared with those without hypertension (median, $6.50 \times 10^3/mm^3$ vs. $2.79 \times 10^3/mm^3$) (24).

Evidence from native Australian Aborigines have demonstrated that there is a strong association between reduction in the nephron numbers and an increased prevalence of adult related hypertension and cardio-renal disorders (25). In addition, this study has also shown that there is a strong link between low birth weight, low nephron numbers, and hypertension at adulthood.

The results from the Dutch famine birth cohort has shown that the variations in presentation were dependent on the type of metabolic disorder and the timing of the intrauterine insult. Those with a first trimester insult resulted in an increased risk of coronary artery events (OR 3.0, 95% CI 1.1–8.1), whereas an insult during the second trimester had shown an increased prevalence of microalbuminuria and a further increase in systolic hypertension (OR 2.1; 95% CI, 1.0–4.3) (26). Amongst those with mid or a third trimester insult, the impact involved an increased prevalence of dysglycemia during adulthood (27).

There was no association between the type of specific nutritional deficiency in foetal life and the onset of hypertension in adulthood. But if the protein intake is restricted to <5 percent it can be one of the major factors for its association (28).

The INTERSALT study has shown that a subject taking a larger quantity of salt and a prolonged ingestion of salt over years, has a greater propensity to develop hypertension, when compared with those counterparts taking diet with low or normal salt intake (29). As per the studies, the average intake of salt is about 11 g per day, which is more than double the WHO's recommended maximum intake of 5 g per day (30). Therefore, a two-hit hypothesis has been proposed by Thomas et al. in their work on the development of hypertension amongst those born LBW (12). The factors that have been proposed in the two hit hypotheses with regards to low birth weight and hypertension include, reduction in the number of nephrons and a subsequent decline in glomerular functions and a high intake of salt when compared to the western population.

According to the Borst Guyton concept, chronic hypertension is due to the imbalance in glomerular pressure and sodium homeostasis in the kidneys (31). The reduced critical mass of nephrons imposes immense workload on the individual nephrons by increasing hyperfiltration. Furthermore, glomerular sclerosis in adult life causes nephron death, thereby initiating a vicious cycle and thereby resulting in end stage renal disease (32). Moreover, obesity increases renal filtration load and the associated insulin resistance further augments the workload on the kidneys. Hence, the imbalance between the triad of low birth with progressive weight gain, reduced nephron mass and an increased load on the kidneys and its related sodium homeostasis induces an early onset hypertension in those born with LBW (33).

The Brenner hypothesis in conjunction with the Barker hypothesis may help interpret the association between the pathogenesis of hypertension amongst individuals born with LBW (27, 34) (**Figure 2**).

PROGRESSION OF HYPERTENSION WITH AGE

There is a clear association between arterial compliance, elastogenesis and hypertension (35). It was proposed by Barker that there is decreased elastin production among neonates with LBW due to poor vasculogenesis *in vitro*. This alteration decreases the arterial compliance that causes hypertension in individuals with LBW (15).

CLINICAL IMPLICATIONS

One should diligently ask for a history of low birth weight among those with obesity, early onset hypertension, diabetes, or coronary artery disease as LBW is a major contributor for the development of cardiovascular diseases (36). The most appropriate way to obtain this is often not from the subject concerned, but the mother of the subject who may be available to give the history of low birth weight.

Singhal et al. followed-up infants with LBW who were given a specific diet for 1 month, after 20 years and found that those who were given a high carbohydrate and high fat diet had elevated pro-insulin levels, suggesting these young adults might develop diabetes in future. Thus, even a brief duration of a nutritional intervention in early infancy may have a major stake in changing the prevalence of future diabetes (37). Lowering the systolic and diastolic blood pressure by 10- and 5-mm Hg, respectively, reduces cardiovascular risk at 65 years of age by 25 percent and strokes by 35% (38).

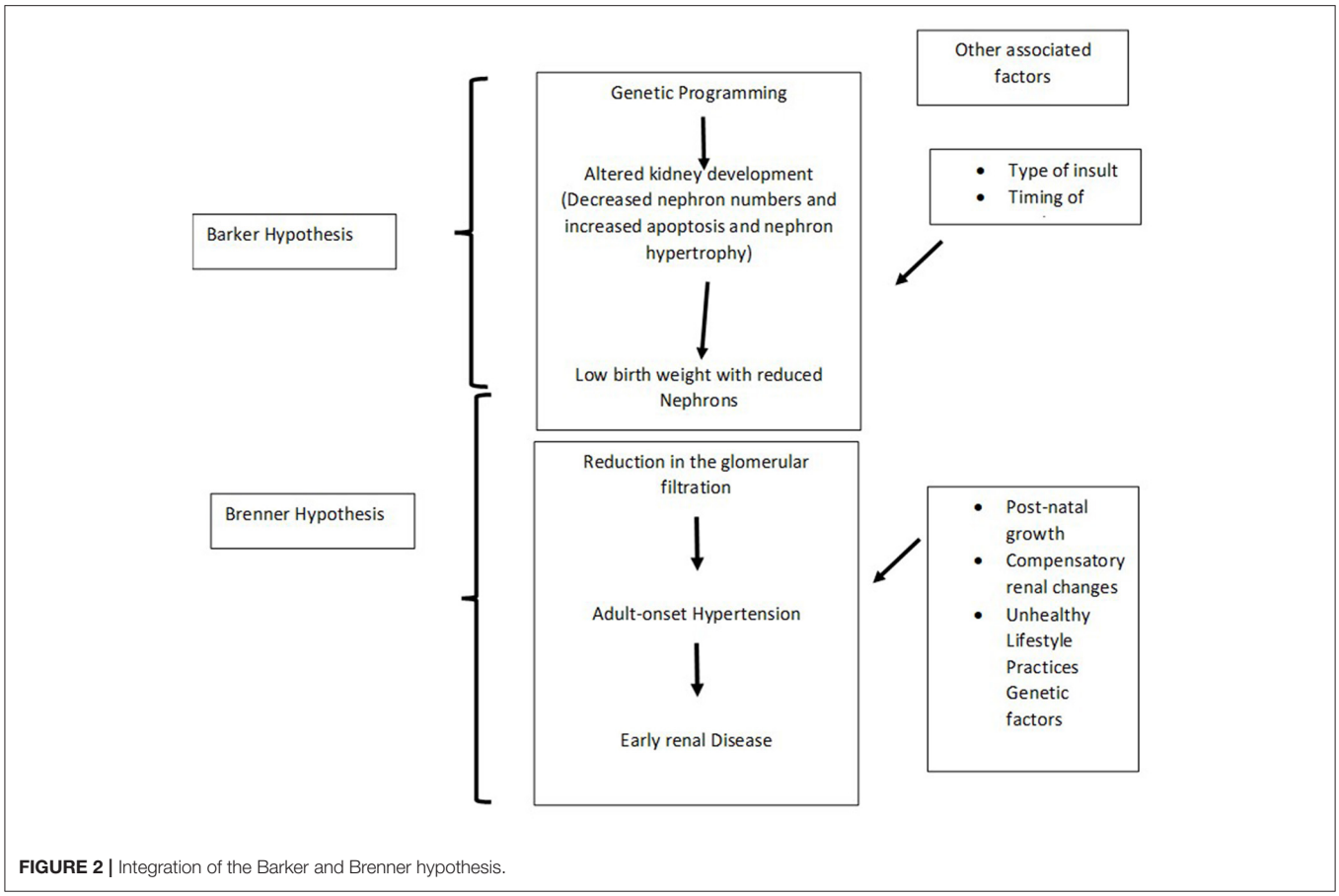

FIGURE 2 | Integration of the Barker and Brenner hypothesis.

After analysing 354 trials, Law and Ward demonstrated that a combination of three antihypertensives at half of their standard dose, reduce two-third of strokes, and half the number of CAD at 60 years of age. Moreover, at the lowest possible doses, these antihypertensives has negligible adverse effects (39). There is evidence of increased glucocorticoid sensitivity in patients with LBW. Moreover, glucocorticoid intake during pregnancy may also induce foetal growth retardation. Evidence suggests that those children who were exposed to glucocorticoids have a subsequently higher prevalence of hypertension. The proposed mechanism is that the glucocorticoids increase the sensitivity of angiotensin converting enzymes and thereby increasing the levels of angiotensin -II. This elevated intraglomerular angiotensin may induce hypertension (40).

The role of the renin-angiotensin-aldosterone pathway as well as early onset proteinuria among those with LBW suggests that ACE-inhibitors or Angiotensin receptor blockers could be a potential medication involved in the therapy of individuals with LBW related adult-onset hypertension (41–45).

Though there are many studies on LBW and metabolic problems across the globe, the studies having LBW as the theme are very limited, in developing countries like India and other African countries. With an increase in the prevalence of Hypertension amongst the developing countries, the cause for early onset hypertension could be multifactorial rather than LBW as a sole factor. More so, the antihypertensives that could be used as first line medications in patients with LBW and early onset hypertension have not been clearly elucidated as yet (46, 47).

CONCLUSION

Many studies have clearly mentioned the association between low birth weight and the subsequent risk of hypertension. This has been demonstrated both in obese as well as non-obese adults. There are several mechanisms that have been postulated in early hypertension among those who were born with LBW. A concise Barker and Brenner hypothesis explains the cause of hypertension in individuals born with LBW. According to the Barker hypothesis, reprogramming of genes in the foetus due to suboptimal nutrition in intrauterine life induces a functional and structural change in the foetus, subsequently leading on to various illnesses, such as hypertension, diabetes, and obesity; particularly when there is unrestricted or increased calorie intake during the neonatal period. Brenner hypothesised that LBW babies tend to have reduced critical nephron related mass that induces a mismatch in the sodium homeostasis in the glomeruli between foetal and adult life due to work load on the kidneys. This leads to an early onset hypertension among those born with LBW. Hence birth weight is inversely proportional to adult-onset hypertension. However, there is no definitive evidence-based

research to suggest as to what antihypertensive therapy may be of use for patients with hypertension and who have been born LBW. Physicians should be aware of LBW as a potential cause for early onset hypertension and should elicit this important history from the mother of the patient. Those born with LBW should be provided with adequate nutrition that may suffice for normal linear growth. They are not to be overfed with additional calories, as through the mechanisms described above, it could result in young onset hypertension.

AUTHOR CONTRIBUTIONS

FJ and NT wrote and reviewed the manuscript. Both authors contributed to the article and approved the submitted version.

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frontiers in Public Health

ORIGINAL RESEARCH
published: 03 February 2022
doi: 10.3389/fpubh.2021.778235

Uncontrolled Blood Pressure and Associated Factors Among Persons With Diabetes: A Community Based Study From Kerala, India

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The coexistence of raised blood pressure (BP) in people with type 2 diabetes mellitus (T2DM) is a major contributor to the development and progression of both macrovascular and microvascular complications. The aim of our study was to determine the prevalence of uncontrolled BP and its associated factors in persons with T2DM in a district in Kerala.

Methods: The study was conducted in Ernakulam district in Kerala, and a total of 3,092 individuals with T2DM were enrolled after obtaining consent. Those with a BP "above or equal to 140 mmHg" and/or "above or equal to 90 mmHg" were thus considered to have uncontrolled BP. If the BP was equal or >140 and/or 90 mmHg, a repeat reading was taken after 30 min and the average of the two was considered. Basic demographic details were enquired along with electronic measurement of BP, HbA1c estimation and screening for diabetic retinopathy, peripheral arterial disease (PAD), and peripheral neuropathy. Quantitative and qualitative variables were expressed as mean (SD) and proportions, respectively. The model for determinants of uncontrolled BP was developed adjusting for age, gender, education, duration of diabetes, occupation, body mass index (BMI) and clustering effect.

Results: The mean age of the study population was 59.51 ± 9.84 years. The mean duration of T2DM was found to be 11.3 ± 6.64 years. The proportion of uncontrolled HTN adjusted for clustering was 60% (95% CI 58 and 62%). Among them, only one in two persons (53.3%) had a history of hypertension. Age >60 years [adjusted odds ratio (aOR) 1.48, 95% CI 1.24, 1.76; $p < 0.001$], unemployment (aOR 1.33, 95% CI 1.01, 1.75; $p < 0.01$), duration of diabetes >11 years (aOR 1.42, 95% CI 1.19, 1.68; $p < 0.001$), and BMI ≥23 (aOR 1.33, 95% CI 1.10, 1.59; $p < 0.002$) were found to be independent determinants of high BP levels when adjusted for the aforementioned variables, gender, education, and cluster effect. The association between complications, such as peripheral neuropathy, PAD, and retinopathy showed a higher risk among those with uncontrolled BP. Retinopathy was 1.35 times more (95% CI 1.02, 1.7, $p < 0.03$), PAD was 1.6 times more (95% CI 1.2, 2.07, $p < 0.001$), and peripheral neuropathy was 1.5 (95% CI 1.14, 1.9, $p < 0.003$) times more compared to their counterparts.

OPEN ACCESS

Edited by:
Kavumpurathu Raman Thankappan, Central University of Kerala, India

Reviewed by:
Brijesh Sathian, Hamad Medical Corporation, Qatar
GK Mini, Ananthapuri Hospitals and Research Institute, India

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Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: *16 September 2021*
Accepted: *23 December 2021*
Published: *03 February 2022*

Citation:
Sreedevi A, Krishnapillai V, Menon VB, Mathew MM, Nair RR, Pillai GS, Numpelil M, Menon J and Marwaha V (2022) Uncontrolled Blood Pressure and Associated Factors Among Persons With Diabetes: A Community Based Study From Kerala, India. Front. Public Health 9:778235. doi: 10.3389/fpubh.2021.778235

Conclusion: Target BP levels were far from being achieved in a good majority of the persons with T2DM. To reduce further macrovascular and microvascular events among people with T2DM, effective awareness and more stringent screening measures need to be employed in this population.

Keywords: type 2 diabetes mellitus, blood pressure, diabetes complications, coexistent disease, diabetic retinopathy, peripheral arterial disease, diabetic neuropathies

INTRODUCTION

Type 2 diabetes mellitus (DM) is a metabolic disorder characterized by insulin resistance and insulin hyposecretion that result in hyperglycaemia. It is estimated that by the year 2030, about 439 million adults (7.7%) will be affected by diabetes, globally (1). According to the Indian Council of Medical Research-India Diabetes (ICMR–INDIAB) study, the overall prevalence of diabetes in India is 7.3% (95% CI 7.0–7.5) (2), which is in tandem with the global estimates. Long-standing diabetes can pave the way for various microvascular and macrovascular complications, dementia, certain cancers, and respiratory disease (3, 4).

Hypertension is defined as a condition where the blood vessels have persistently raised pressure. The coexistence of hypertension or blood pressure (BP) above the target level in patients with type 2 diabetes mellitus (T2DM) is a major contributor to the development and progression of macrovascular and microvascular complications (5). The combined effect of these can seriously affect the health status of the population. Studies have shown that people with diabetes face a 2- to 4-fold increased risk of cardiovascular disease (CVD) when compared to the general population (6). In people with diabetes, coexisting hypertension can triple the risk of coronary artery disease (CAD), double the total mortality and stroke risk, and can be responsible for up to 75% of all CVD events (7). Hypertension has also been shown to accelerate the progression of certain complications, such as diabetic nephropathy, retinopathy, and neuropathy (8–10).

Bringing down BP has proven to be beneficial in reducing complications associated with diabetes. Several studies have shown that treating hypertension in people with diabetes can reduce atherosclerotic cardiovascular disease (ASCVD) events, heart failure, and microvascular complications (11). As per the Joint National Committee (JNC) eight guidelines, among people with diabetes, anti-hypertensive therapy should be initiated when BP is $\geq$140/90 mmHg, and the target BP should be maintained below 140/90 mmHg (12). In the UK Prospective Diabetes Study (UKPDS), compared to individuals in the control group, participants in the tight BP control group had a reduction of 34% and 37% risk of macrovascular diseases and microvascular disease, respectively (13).

However, maintaining the target range of BP is still a challenge. In a European study in 24 countries, a target BP level of <140/90 mmHg was achieved only in 54% of people with diabetes (14). In India, hypertension is still a major public health issue. Although there are significant regional differences, it is estimated that there are more than 200 million hypertensive individuals in the country (15). Studies have shown that among people with diabetes, hypertension often remains undiagnosed (16), thereby delaying therapy. Additional attention to traditional cardiovascular (CV) risk factors, such as high BP, could yield further substantive reductions in CV events and mortality in adults with diabetes (17). Data on hypertension control status among type 2 Diabetes in India are limited. The objectives of this study were to determine the prevalence of uncontrolled BP among persons with diabetes and to assess the associated factors, including.

METHODS

A community-based cross-sectional study was carried out in Ernakulam district in Kerala, India. The district, which is an administrative division in the state, has the highest population density and is the commercial capital of the state. A prevalence of 20.6% (16) was used to calculate the sample size from a previous study on hypertension/uncontrolled BP among persons with diabetes. With a relative precision of 10%, the sample size was calculated to be 1,425. As clusters were taken, a design effect of two was used to arrive at a sample size of 2,850.

A two-stage cluster sampling with population proportionate to size sampling (PPS) was carried out. In the first stage, 33 clusters, which are local self-government areas, were drawn by probability proportional to their size. The population of all the local self-government (LSG) areas was listed. The cumulative population was calculated. The total population was divided by the number of clusters to determine the sampling interval. The first number was picked by the random number table within the sampling interval. The corresponding LSG was selected. The sampling interval was added 33 times to get the 33 LSG areas, which are the clusters. The frontline health worker [accredited social health activist (ASHA)] of each ward provided the list of persons with diabetes to the Primary health centre (PHC). The team at the PPHC chose every third/fourth person from the list. Thus, about 110 persons were provided a referral card and referred considering a non-response rate of 20%.

The first 85–90 participants who came to the camp with diabetes for more than a year were enrolled in the study after obtaining informed consent. Local camps were conducted in the selected LSG areas under the aegis of an international non-government organization (NGO), a tertiary care center, Primary Health Center, and National Health Mission. Thus, a total of 3,092 persons with diabetes were enrolled. The inclusion criteria of the study included adults with type 2 diabetes of at least 1 year of duration. The exclusion

criteria were those who could not respond to the questions with coherence or those who were cognitively impaired, pregnant woman, and above 80 years. However, in order to efficiently utilize resources, the screening for complications, such as retinopathy, peripheral arterial disease (PAD), and peripheral neuropathy, was carried out among persons with more than 5 years of diabetes. About 33 camps were conducted from November 2020 to March 2021 by a multidisciplinary team of community physicians, ophthalmologists, doctors with training in Podiatry, nurses, laboratory technician, optometrists, and medical social workers. Institutional ethical committee approval was obtained vide IEC-AIMS-2020-COMM-186 dated November 9, 2020.

The outcome variable was uncontrolled BP among persons with type 2 diabetes. The BP was considered to be controlled if the systolic and diastolic values were <140 and <90 mmHg. This was also synonymous with having attained target BP. Those with a BP "above or equal to 140 mmHg" and or "above or equal to 90 mmHg" were thus considered to have uncontrolled BP. The BP was measured by the OMRON HEM 7124 automatic blood pressure monitor (Shimogyo-ku, Kyoto, Japan) by measuring upper arm BP. If a level above or equal to 140 and or 90 mmHg was observed, the measurement was repeated after 30 min and the average of the two readings was taken (18). Several guidelines have prescribed a BP target of not more than >140 and >90 mmHg (11) for persons with diabetes. The independent variables collected included sociodemographic details, anthropometric measurements, such as weight and height using standard measurements, self-reported co-morbidity, personal habits, such as tobacco and alcohol, known complications of diabetes, duration of illness, family history of diabetes, and Glycosylated Haemoglobin (HbA1c). HbA1c was measured with a point-of-care device HbA1c HemoCue auto analyzer after validation with the laboratory values. A correlation of 0.9 was obtained with the laboratory values. The targets for glycated hemoglobin were as follows: <7% as ideal, ≥7 to <8 satisfactory, and ≥8 unsatisfactory (19). Assessment of foot complications, such as PAD, peripheral neuropathy in the lower limbs, and retinopathy, was also carried out. Body mass index (BMI) was calculated from the weight in kilogram (kg) and height in metre (m) measurement, and the Asian standards were used for categorization; 18.5–22.9 for normal, 23–27.5 for overweight, and >27.5 for obese.

After lying down and being made comfortable, the vibration perception threshold (VPT) was tested using a biothesiometer. A probe was placed in the palm of patients to familiarize them with the vibration perception. The patient was advised to feel the vibration on his/her feet and slowly vibration intensity was increased. At the point at which the patient felt the vibration, the VPT was recorded in volts and graded. This indicated the threshold voltage that can be perceived by the person. The probe was applied to the big toe and medial malleoli. The vibration intensity was increased gradually by turning the dial. The VPT value was graded as <15 volts as normal (Grade I), 16–20 volts as mild loss of sensation (Grade II), 21–25 volts as moderate loss of sensation (Grade III), and >25 volts as severe and abnormal (Grade IV) (11).

The patient continued to be in the lying posture, and ankle-brachial pressure index was measured to detect PAD. First brachial BP was measured using a sphygmomanometer and handheld Doppler, then the ankle pressure of each leg was measured, and the ratio of ankle pressure to brachial pressure was calculated for the left and right lower limbs. The BP cuff was placed on the arm, with the limb at the level of the heart. The ultrasound gel was applied in the antecubital fossa over the patient's brachial pulse. The transducer of the handheld Doppler was placed over the antecubital fossa on the gel, and the transducer was positioned to maximize the intensity of the signal. The cuff was then inflated to about 10 mmHg above the expected systolic BP of the patient such that, the Doppler signal disappeared. The cuff was then deflated at approximately 1 mmHg/s. When the Doppler signal re-appears, the pressure of the cuff is recorded as brachial systolic pressure. To measure ankle pressure, the cuff was placed immediately proximal to the malleoli. The ultrasound gel was applied on the skin overlying the dorsalis pedis (DP) artery in the foot. The Doppler signal of the DP artery was found slightly lateral to the midline of the dorsum of the foot. Using a standard handheld Doppler probe and the ultrasound gel, the signal was located. The cuff was inflated till the Doppler signal was no longer heard. Then using the same technique, the cuff was deflated until the Doppler signal re-appeared. The measurement was recorded. The Ankle Brachial Index (ABI) was calculated for each leg. The ABI value was determined by taking the higher pressure of the two arteries at the ankle, divided by the brachial arterial systolic pressure. In calculating the ABI, the higher of the two brachial systolic pressure measurements was used. In normal individuals, there should be a minimal (<10 mmHg) interarm systolic pressure gradient during a routine examination. A reading ≥1.3 was considered to be abnormal vessel hardening, 0.9–1.2 to be normal, 0.50–0.79 to be moderate arterial disease, under 0.50 considered as severe arterial disease (11).

Retinopathy was assessed by mydriatic fundus photography and rechecked by indirect ophthalmoscopy. All patients underwent visual acuity examination with available glass correction and pinhole to see if there was any improvement with a further change of glasses. All patients were dilated with tropicamide eye drops and mydriatic retinal photography was performed. All patients also underwent retinal examination with an indirect ophthalmoscopy by a trained ophthalmologist and retinal findings and diagnosis were confirmed. Grading of diabetic retinopathy was done on site and confirmed with viewing the retinal photographs by experts.

The data collected were entered in excel and data analysis was carried out in Statistical Package of Social Sciences (SPSS) (20, 24). For the purposes of this study, multiple morbidities were defined as the presence of more than one morbidity in a person with diabetes, such as heart disease, thyroid disease, and hyperlipidaemia. The quantitative variables have been expressed as mean and SD and the qualitative as proportions. The bivariate analysis was done by the chi-square test. The proportion of uncontrolled HTN adjusted for clustering has been reported. Multiple variable analysis adjusted for clustering (number of camps) along with variables that showed $p < 0.1$ in the univariate analysis was carried out. Age, gender, duration of DM, education,

BMI, and occupation were considered as fixed effects, and cluster was considered as random effect in the logistic regression model. Adjusted odds ratio and 95% CI are reported. This was carried out in STATA 15 (College Station, TX, USA).

RESULTS

The mean age of the study population was 59.51 years ± 9.84, and it ranged from 29 to 80 years. There was an almost equal distribution among persons less than or equal to 60 years, 1,423 (46.2%) and above 1,652 (53.7%). Men constituted only about a third [1,144 (37%)] of the participants and more than three-quarters [2.422 (78.4%)] of the respondents were from rural areas (**Table 1**). However, all study participants were literate and only 111 (6.7%) had more than 12 years of schooling. About half [1,478 (49.5%)] were below the poverty line according to self-reports. The mean duration of diabetes was 11.2 ± 6.64 years. Only 10.8% had an ideal HbA1c below 7. As far as the cardiometabolic risk factors were concerned, only about a quarter [821 (27%)] had a BMI of <23 as per the ideal Asian standards. More than a half (60.1%) had BP equal to or above 140/90 mmHg of which more than a half (966/1,812) (53.3%) were known hypertensives. The proportion of uncontrolled Hypertension (HTN) adjusted for clustering was 60% (95% CI 58 and 62%).

Thus, the target BP for persons with diabetes was achieved by only 1,205 (39.9%) patients. Complications, such as PAD and peripheral neuropathy, were found among about a half [738 (48.5%)] and more than a half [963 (53.5%)], respectively. Retinopathy was found among more than a fourth, i.e., 612 (28.9%).

The BP target level was not attained among 65.5% of those aged more than 60 years compared to 53.5% among those who were <60 years ($p < 0.001$). Women had a significantly higher percentage of uncontrolled BP at 61.7% ($p < 0.019$). Uncontrolled BP was higher among those with a duration of diabetes of more than 11 years ($p < 0.001$). The uncontrolled BP was found to significantly decrease with the improvement of employment status from 66.2 to 54.6% ($p < 0.001$). BP was significantly above the target level in those with a BMI ≥23. Others, such as rural-urban residence, education, socioeconomic status, physical activity, Hba1c, heart disease, and respiratory disease, were not found to be significant (**Table 1**).

The multiple logistic regression was used by the enter method, and the following variables were found to be independent predictors. Age >60 years [adjusted odds ratio (aOR) 1.48, 95% CI 1.24, 1.76; $p < 0.001$], unemployment (aOR 1.33, 95% CI 1.01, 1.75; $p < 0.01$), duration of diabetes (aOR 1.42, 95% CI 1.19, 1.68; $p < 0.001$), BMI ≤23 (aOR 1.33, 95% CI 1.10, 1.59; $p < 0.002$) were found to be independent predictors of high BP levels when adjusted for the aforementioned variables, education, gender, and cluster (**Table 2**). For the final multivariate analysis, 2,588 samples were considered. However, there was a loss of 16% of samples in the analysis for covariates, the reverse calculation of the power for each significant variable was 95%, which is sufficient to establish risk.

The association between complications, such as peripheral neuropathy, PAD, and retinopathy, showed a higher risk among

TABLE 1 | Sociodemographic distribution of the study population.

	Frequency	Percentage
Age (in years)		
≤60	1,423	46.3%
>60	1,652	53.7%
Gender		
Men	1,144	37%
Women	1,948	63%
Place of residence		
Rural	2,422	78.3%
Urban	670	21.7%
Education		
≤12 years of schooling	2,618	92.6%
>12 years of schooling	210	6.8%
*264 missing		
Socioeconomic status		
Non priority group	1,505	50.5
Priority group	1,478	49.5
*109 missing		
Occupation		
Unemployed	619	21
Home maker	1,119	38
Employed / Retired	1,206	41
*148 missing		
	Frequency	**Percentage**
HbA1C(Glycosylated hemoglobin)		
Ideal	302	10.8
Satisfactory	522	18.7
Unsatisfactory	1,968	70.5
Duration of diabetes (in years)		
≤11	1,865	60.3
>11	1,193	38.6
*34 missing		
Body Mass Index (BMI)		
<23	821	27
≥23	2,216	71.7
Blood pressure controlled		
Yes	1,205	39.9
No	1,812	60.1
Known hypertension among those with uncontrolled blood pressure		
Yes	966	53.3
No	846	46.7
Peripheral neuropathy		
Yes	988	53.8
No	847	46.2
Peripheral arterial disease		
Yes	738	48.5
No	783	51.5
Retinopathy		
Yes	612	28.9
No	1,501	71.1

TABLE 2 | Factors associated with uncontrolled blood pressure adjusted for clustering.

	Controlled	Uncontrolled	Unadjusted OR (95% CI)	Adjusted OR (95% CI)	*p*
Age(in years)					
≤60	646 (46.5)	742 (53.5)	1	1	
>60	556 (34.5)	1,056 (65.5)	1.65 (1.42, 1.92)	1.48 (1.24, 1.76)	<0.001
Sex					
Male	476 (43.7)	639 (57.3)	1	1	
Female	729 (38.3)	1,173 (61.7)	1.19 (1.03, 1.39)	1.06 (0.84, 1.34)	0.373
Duration of DM					
<=11.2 yrs	792 (43.5)	1,027 (56.5)	1	1	
>11.2 yrs	400 (34.3)	766 (65.7)	1.47 (1.26, 1.72)	1.42 (1.19, 1.68)	<0.001
Education					
<=12 yrs	1,021 (39.8)	1,541 (60.2)	1	1	
>12 yrs	96 (46.4)	111 (53.6)	0.76 (0.57, 1.02)	0.87 (0.67, 1.12)	0.21
Body mass index					
<23	354 (44.0)	450 (56.0)	1	1	
≥23	838 (38.5)	1,340 (61.5)	1.25 (1.07, 1.48)	1.33 (1.10, 1.59)	<0.002
Occupation					
Employed	536 (45.4)	644 (54.6)	1	1	
Unemployed	204 (33.8)	399 (66.2)	1.62 (1.33, 1.99)	1.33 (1.01, 1.75)	0.005
Home maker	417 (38.1)	678 (61.9)	1.35 (1.14, 1.59)	1.22 (0.92, 1.63)	0.112

TABLE 3 | Association between uncontrolled blood pressure among persons with type 2 diabetes and complications.

Uncontrolled blood pressure						
	Yes	**No**	**Total**	**COR(95% CI)**	**aOR(95% CI)**	**p**
Retinopathy						
Yes	401 (65.5)	211 (34.5)	612	1.45 (1.19, 1.77)	1.35 (1.02, 1.77)	0.03
No	850 (56.6)	651 (43.4)	1,501	1	1	
Peripheral arterial disease						
Yes	503 (68.1)	235 (31.9)	738	1.43 (1.16, 1.76)	1.6 (1.23, 2.07)	0.00
No	469 (59.8)	314 (40.2)	783	1		
Peripheral neuropathy						
Yes	635 (65.8)	328 (34.2)	965	1.37 (1.19, 1.77)	1.48 (1.14, 1.92)	0.003
No	489 (66.3)	348 (33.7)	737	1		

those with uncontrolled BP. Retinopathy was 1.35 times more (95% CI 1.02, 1.7, $p < 0.03$), PAD was 1.6 times more (95% CI 1.2, 2.07, $p < 0.001$), and peripheral neuropathy was 1.5 (95% CI 1.14, 1.9, $p < 0.003$) times more (**Table 3**) compared to their counterparts.

DISCUSSION

Six out of 10 persons with type 2 diabetes in our study had BP above the target level. Age above 60 years, duration of diabetes of more than 11 years, a BMI above or equal to 23, and unemployment were independent determinants of high BP.

There are not many studies in India, which have looked at the control of BP among persons with diabetes. Of a few, some have looked at the coexistence of hypertension and diabetes which was 20% (16), and another hospital-based study has found uncontrolled BP to be high at 70% (21). Global studies in Europe and USA also report uncontrolled BP proportion ranging from 54 (14) to 68.4% (22), respectively, whereas it was only about a third i.e., (34%), in Spain (23). This calls for more attention to control BP particularly among persons with diabetes as there is 1.5–2 times increased occurrence of hypertension among persons with diabetes in India and this coexistence has seen an increase (24). It is also of concern that among those with uncontrolled BP, only a half i.e., (53.3%), were known hypertensives. The complications, such as PAD, diabetic retinopathy, and diabetic neuropathy, have also been found to be significantly higher among those with uncontrolled BP in this study. However, as it is a cross-sectional study, the temporality cannot be determined, as to whether the high BP led to complications or the complications led to higher blood pressure.

The overall prevalence of diabetic retinopathy was 28.7%. Although this is slightly less than the global prevalence of diabetic retinopathy 34.6% reported by Yau et al. (25), a similar prevalence was reported a decade earlier in a smaller population of self-reported diabetics (26). Diabetic retinopathy is one of the leading causes of blindness among persons of working age (27) and hypertension plays a critical role in the occurrence and progression of the microvascular complications, such as diabetic retinopathy and neuropathy (5). The UKPDS study had shown a 34% reduction in the rate of progression of diabetic retinopathy when the BP was kept below the target value of <150/85 mmHg (13). Proper screening and management of hypertension among people with diabetes will help to reduce the burden in the longer run. Around 54% (988) of the individuals had peripheral neuropathy. Several studies in the past had shown a higher prevalence of diabetic neuropathy (28–30). The International Prevalence and Treatment of Diabetes and Depression Study (INTERPRET-DD) (31) that collected data from 14 countries had shown an overall prevalence of 26.7%, though, it was 13.3% in India. However, this may not be representative of India/Kerala

as a sample of only 188 were studied and the area of study is not mentioned. Prevalence of PAD was also on the higher side, with about 48% of people diagnosed with the same in our study. Global estimates of PAD (32) showed a reduced prevalence in low- and middle-income countries, with a majority of them living in southeast Asian region. Both DM and hypertension have been found to be significantly associated with PAD (33). Thus, reducing complications, such as PAD, can be effectively achieved by reaching target BPs in persons with diabetes.

Thus, there is an urgent need to screen the BP of persons with diabetes. However, the metabolic control for persons with diabetes is a BP <140/90 mmHg (19), a large percentage of this diabetic population seem far from achieving it.

Three-quarters of the study population had a BMI ≥23. People with diabetes who had a BMI of more than or equal to 23 were found to have their BP values above the target level. Obesity has long been associated with hypertension (34, 35) and is a major contributor to morbidity and mortality among people with diabetes. Recommendations from the various associations, namely, the ICMR (19), the American Diabetes Association, and the European Association for the Study of Diabetes, have emphasized the management of obesity and hypertension to reduce CV events among people with diabetes (36). Therefore, identifying people with diabetes who are currently leading a sedentary lifestyle is of utmost importance and measures need to be taken to increase physical activity in such individuals.

Individuals aged above 60 years and increasing duration of diabetes were also independent determinants of uncontrolled BP. Age is known to be a major predisposing factor for most of the common degenerative conditions. The risk of hypertension in the general population can double with every 9–10-year age increment (37).

LIMITATIONS

There may be problems with generalizability as people belonging to low- and middle socioeconomic status are more likely to attend these camps than those of high socioeconomic status. As it was a camp, setting the BP could not be measured two times for everybody and could only be measured for those who had a reading ≥140/90 mmHg. This study was conducted during the lull after the first wave of the Coronavirus Disease-2019 (COVID) pandemic and before the second wave started in Kerala. Therefore, it is difficult to ascertain whether COVID may have contributed to higher BP levels.

CONCLUSION

The target levels of BP among people with type 2 diabetes are far from being achieved. This needs emphasis through patient and physician awareness. Increased BP has been associated with micro- and macro-vascular complications, such as retinopathy, neuropathy, and PAD, respectively. Control of BP to below target levels is thus very important for persons with diabetes.

DATA AVAILABILITY STATEMENT

The datasets presented in this article are not readily available because permissions will be required from Amrita Institute of Medical Sciences (Kochi), National Health Mission (Ernakulam) and Lions Clubs International (District 318C) for release of data. Requests to access the datasets should be directed to Amrita Institute of Medical Sciences, Kochi.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by IEC Amrita Institute of Medical Sciences, Kochi. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

AS contributed to study conception, data collection, interpretation of data, and drafting the manuscript. VK contributed to conception, implementation, and editing of manuscript. VMe contributed to conduct, data collection, and editing of manuscript. MM analysed the data. RN contributed to conduct, data collection, and editing of the manuscript. GP contributed to conception, implementation, and data collection. MN contributed to study conception and supported in data collection. JM contributed to conception and editing of the manuscript. VMa contributed to conduct of the study and editing of the manuscript. All authors read and approved the manuscript and critically revised the manuscript for important intellectual content.

FUNDING

This work was funded from Lion Club International Foundation (DIA16895/318-C).

ACKNOWLEDGMENTS

The authors wish to acknowledge the ASHA's, the paramedical team from Amrita, the persons with type 2 diabetes, Primary Health center personnel. Over and above the authors wish to thank Mr. Rajesh Kolarikkal, Mr. Das Mankidy, and Mr. Rajan of Lions DIA16895/318-C for their leadership, support to implement this service project. The authors wish to thank Dr. Sumithra S, St John's Research Institute for her assistance with the statistical calculation and Dr. Joseph Mankidy.

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Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

frontiers in Public Health

ORIGINAL RESEARCH
published: 14 March 2022
doi: 10.3389/fpubh.2022.748157

Prevalence, Awareness, Treatment and Control of Diabetes in India From the Countrywide National NCD Monitoring Survey

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Background: To determine the prevalence, awareness, treatment and control of diabetes mellitus (DM) and associated factors amongst adults (18–69 years) in India from the National Noncommunicable Disease Monitoring Survey (NNMS).

Methods: NNMS was a comprehensive, cross-sectional survey conducted in 2017–18 on a national sample of 12,000 households in 600 primary sampling units. In every household, one eligible adult aged 18–69 years were selected. Information on NCD risk factors and their health-seeking behaviors were collected. Anthropometric measurements, blood pressure and fasting capillary blood glucose were measured. DM was defined as fasting blood glucose (FBG) $\geq$126 mg/dl including those on medication. Awareness, treatment, and control of DM were defined as adults previously diagnosed with DM by a doctor, on prescribed medication for DM, and FBG $<$126 mg/dl, respectively. The weighted data are presented as mean and proportions with 95% CI. We applied the Student *t*-test for continuous variables, Pearson's chi-square test for categorical variables and multivariate regression to determine the odds ratio. For statistical significance, a p-value < 0.05 was considered.

Results: Prevalence of DM and impaired fasting blood glucose (IFG) in India was 9.3% and 24.5% respectively. Among those with DM, 45.8% were aware, 36.1% were on treatment and 15.7% had it under control. More than three-fourths of adults approached the allopathic practitioners for consultation (84.0%) and treatment (78.8%) for diabetes. Older adults were associated with an increased risk for DM [OR 8.89 (95% CI 6.66–11.87) and were 16 times more aware of DM. Better awareness, treatment and control levels were seen among adults with raised blood pressure and raised cholesterol.

Conclusions: The prevalence of DM and IFG is high among adults, while the levels of awareness, treatment and control are still low in India, and this varied notably between the age groups. Multifaceted approaches that include improved awareness, adherence to treatment, better preventive and counseling services are crucial to halt diabetes in India. Also, expanding traditional systems of medicine (Ayurveda, Yoga, Naturopathy, Unani, Siddha, and Homeopathy [AYUSH]) into diabetes prevention and control practices open solutions to manage this crisis.

Keywords: awareness, control, diabetes mellitus, India, prevalence, treatment, surveillance

OPEN ACCESS

Edited by:
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Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: *27 July 2021*
Accepted: *21 January 2022*
Published: *14 March 2022*

Citation:
Mathur P, Leburu S and Kulothungan V (2022) Prevalence, Awareness, Treatment and Control of Diabetes in India From the Countrywide National NCD Monitoring Survey. Front. Public Health 10:748157. doi: 10.3389/fpubh.2022.748157

INTRODUCTION

Diabetes is a rapidly growing health challenge and potential epidemic across the low-and-middle-income countries like India (1). It is projected that by 2025 the number of cases with diabetes in India would be 69.9 million with a vast majority still undiagnosed (1, 2). This is primarily driven by dietary transitions and insufficient or lack of physical activity altering the physiological milieu leading to overweight or obesity and diabetes (1, 2). Care for chronic diseases like diabetes poses challenges characterized by the need for sustained compliance to treatment, prevention or management of associated complications (3). This requires the continuous engagement of health systems in the continuum of care at all stages (3). Diabetes care requires coordination across all tiers of health care systems. Most importantly co-driven by the patient's knowledge, attitudes and perceptions toward awareness, treatment and adherence to the recommendations (3, 4).

The Noncommunicable Disease (NCD) Monitoring Framework targets (10) and indicators (21) set by the Ministry of Health and Family Welfare, Government of India adapted from the Global NCD framework (World Health Organization), calls for a need to halt the rise in diabetes and prevent premature deaths from NCDs by 25% by 2025 (5, 6). Such targets can be met only with effective strategies at multisectoral levels (7). However, an important limitation and quandary for policymakers are that majority of the population might be unaware of their diabetes status and are not adherent to advice (3). Robust empirical data on diabetes prevalence, awareness, treatment, control and adherence is needed to comprehend the impact of initiatives taken to halt the growing burden of diabetes, response of health systems and health-seeking behaviors amongst the population (1). Understanding where diabetics are lost in the care cascade is essential for targeted health interventions. Also, to monitor progress in health system performance for diabetes management over time (8).

In this paper, we present the results on diabetes care cascade among those aged 18–69 years from the large national comprehensive survey, the National NCD Monitoring Survey (NNMS). Additionally, the paper also presents results on the availability of services for diabetes care amongst surveyed public health facilities across the country. The NNMS was undertaken to collect much-needed quality data specific to NCD risk factors in adults and adolescents, health-seeking behaviors and health system responses to NCDs in India (9, 10).

MATERIALS AND METHODS

Sampling Design

The NNMS was a multi-centric, cross-sectional survey done in 2017–18, that addressed NCD specific components at the population level among adults: 18–69 years and adolescents: 15–17 years residing in urban and rural areas; and at the health facility level. The survey was coordinated and implemented by the Indian Council of Medical Research (ICMR)—National Center for Disease Informatics and Research (NCDIR), Bengaluru (9, 10).

The survey followed a multistage cluster sampling design by dividing the country into 10 contiguous zones that approximated 60 clusters and 600 primary sampling (300 rural and 300 urban). The study population was divided into four subgroups/strata urban/rural and men/women (2 x 2). The sample size for adults aged 18–69 years was computed using 9% estimated prevalence of obesity, 15% relative precision, 95% confidence interval, 15% Non-response rate and design effect of 1.5. Since the adolescents (15–17 years) were to be enrolled from the same households, the sample was enlarged to 12,000 households and this was equally allocated to both urban and rural areas (6,000 households each). Twenty households were selected in every PSU to sum up to 12,000 households to represent a national sample. One eligible adult aged 18–69 years from every household was selected by the KISH method thus, totalling a sample of 12,000 adults. For the health facility survey, one each of public primary, community health centers, district hospital and primary private hospitals within and, near the PSUs were included in the survey sample (9–11).

The survey was approved by the ICMR-NCDIR institutional ethics committee (IEC) and the respective survey implementing agencies IECs. The survey obtained all the necessary support and concurrence from local bodies for its implementation. All selected study participants were briefed about the visit and the purpose of the survey. Following their voluntary acceptance to participate, written informed consent was obtained.

Data Collection and Laboratory Methods

Survey data were collected electronically in personal digital assistants through globally standardized questionnaires [WHO-STEPwise approach to noncommunicable disease risk factor surveillance (WHO-STEPS), Integrated disease surveillance project (IDSP)-NCD risk factor survey, and Global Adult Tobacco Survey-India (GATS)] administered by well-trained interviewers in English and eleven local languages through face-to-face interviews at the household (9, 10). Physical measurements of height (SECA 213 portable stadiometer), weight (SECA 803 digital weighing scale), waist circumference (SECA, 201 measuring or tension tape), blood pressure (OMRON HEM−7120 automatic blood pressure machine) were also made at the household level by trained and certified technicians using international standard procedures recommended by WHO-STEPS (9, 10). All measures of privacy and confidentiality were followed to limit any possible bias during data collection. Biochemical testing of fasting blood glucose (FBG) was done as a camp-based approach among consenting adults. During the household interviews, information on socio-demographic characteristics (e.g., education level, occupation, housing type etc.) and risk factors like tobacco use, alcohol consumption, dietary factors (intake of fruits and vegetable intake, dietary salt), levels of physical activity (moderate and vigorous physical activity at workplace or home, during travel and leisure) using Global Physical Activity Questionnaire were collected, including questions on previous diagnosis, treatment of diabetes, hypertension, raised blood cholesterol

and cardiovascular or cerebrovascular accidents (9, 10). The study questionnaires for health-seeking behaviors also included questions on consultation and treatment-seeking behaviors of adults from practitioners of allopathy or alternate system of medicine including those who practised Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH) (9).

All eligible participants were given appointment slips a day before the camp along with instructions for fasting. One place in the PSU was identified based on operational feasibility for setting up the camp. All participants were called to the camp facility early in the morning in an overnight fasting state ($\geq$ 8 h). The date and time of their last meal were noted in the camp activity sheet. On confirmation of fasting status and under aseptic conditions the capillary fasting blood glucose estimation was done using Glucometer *(Gluco spark, Sensa core, Telangana, India)* by teams well-trained in all survey procedures including laboratory procedures, sample handling and waste disposal (9, 10).

Definitions and Statistical Analysis

According to the WHO diagnostic criteria, prevalence of diabetes mellitus (DM) was defined as FBG $\geq$126 mg/dl or self-reported history of diabetes (i.e., if they have ever been diagnosed with DM as told by a doctor or health professional) and impaired fasting blood glucose (IFG) was defined as FBG 100–125 mg/dl (12). Adults who self-reported were considered as previously diagnosed/aware and those who had raised FBG levels $\geq$126 mg/dL on testing during the survey but did not self-report were classified under newly-diagnosed cases of DM. Treatment was defined as the use of anti-diabetic medications (oral hypoglycaemic drugs or insulin) for DM on any one day in the last 2 weeks before the survey. Control was defined as treatment (oral medication or insulin) of DM associated with FBG <126 mg/dl when measured for FBG in the survey (9).

Standard definitions were used for estimating all behavioral and biological indicators (tobacco use, alcohol use, diet, physical activity, BMI, central obesity, raised blood pressure and raised cholesterol). Current tobacco and alcohol use was defined as the use of any form of tobacco (smoked or smokeless) and consumption of alcohol in the last 12 months preceding the survey. Insufficient physical activity in adults was defined as the proportion of adults aged 18–69 years who spent <150 min of moderate-intensity physical activity per week OR <75 min of vigorous-intensity physical activity per week OR an equivalent combination of moderate-and-vigorous intensity physical activity accumulating <600 MET-min per week. BMI was categorized using WHO criteria: underweight: <18.5 Kg/m^2, Normal: 18.5–24.9 Kg/m^2, Overweight: 25.0–29.9 Kg/m^2 and obesity: $\geq$30.0 Kg/m^2. Central obesity was defined as those with a waist circumference of $\geq$90 cm in males and $\geq$80 cm in females (as per South Asia Pacific Guidelines). Raised blood pressure in adults aged between 18 and 69 years with a systolic blood pressure $\geq$140 mmHg and/or diastolic blood pressure $\geq$90 mmHg including those on medication for raised blood pressure. Raised cholesterol was defined as all adults (18–69 years) who reported being diagnosed as having raised blood cholesterol either by a doctor or health worker.

The data collected was cleaned using *IBM Statistical Package for the Social Sciences (SPSS) for Windows version 22.0*. The cleaned data were weighted and analyzed in *STATA 14.1* using complex survey analysis. The survey response rates are provided as weighted numbers and proportions. The weighted results have been presented in descriptive statistics as mean and proportions with 95% confidence interval (CI). The association of variables with diabetes were assessed by the *Student t-test* for continuous variables and the *Pearson's chi-square test* for categorical variables. We performed the logistic regression analysis to determine the risk factors using odds ratio (OR) estimates with 95% CI. A multivariate regression analysis was done with a p-value < 0.05 for statistical significance.

RESULTS

A total of 9,721 adults were surveyed out of which 904 were found to have diabetes based on their FBG measurement and self-reported history of diabetes. Out of these, only 414 were aware of their diabetes status, 326 were under treatment for diabetes and 142 were under control as defined as fasting blood glucose <126 mg/dl (**Figure 1**).

The mean FBG among 18–69 years was 96.7 mg/dl, this was higher in the older age group 50–69 years (107.47 mg/dl) and among urban adults (101.57 mg/dl) (**Supplementary Table S1**).

Overall, 66.2% of adults were normoglycemic and 24.5% had IFG of 100–125 mg/dl. A nearly equal proportion of adults were newly-diagnosed (5.0%) and previously-diagnosed (4.3%) with diabetes. The highest proportion of adults with either IFG, newly-diagnosed or previously-diagnosed diabetes was aged 50–69 years, urban residents, and had metabolic risk factors (overweight, obesity, central obesity, hypertension and raised cholesterol). These findings were statistically significant ($p <$ 0.001) (**Table 1**).

Figure 2 shows the distribution of adults by FBG values across different age categories. The prevalence of IFG (31.6%), previously-diagnosed by a doctor or health professional with diabetes (22.2%) and newly-diagnosed with raised FBG levels during the survey (10.2%) was highest among urban adults aged 50–69 years. The highest proportion of younger men had normal FBG levels (83.1%) (**Figure 2**). The prevalence of IFG was higher with increasing BMI. A higher proportion of adults with raised FBG levels and those previously-diagnosed belonged to the obese BMI category of $\geq$30.0 Kg/m^2. Nearly a quarter proportion of the adults with normal BMI had IFG, 2.9% were previously-diagnosed and 4.3% were newly-diagnosed in the survey (**Figure 3**).

The prevalence of raised FBG was 9.3% and it was highest in adults aged 50–69 years (21.8%), those obese (20.5%), overweight (16.4%) and from urban areas (14.3%) (**Table 2**). The p-value across age groups and BMI categories were statistically significant ($p < 0.001$).

Among those with diabetes (9.3%), nearly half were aware (45.8%), more than one-third were on treatment (36.1%), and only 15.7% had their blood glucose levels under control (**Figure 1**). Significantly higher proportions of adults who were aware and on treatment were older adults, urban residents, men, with metabolic risk factors and who received any level of education. While the control levels were higher in women, rural adults and those without any education though not statistically

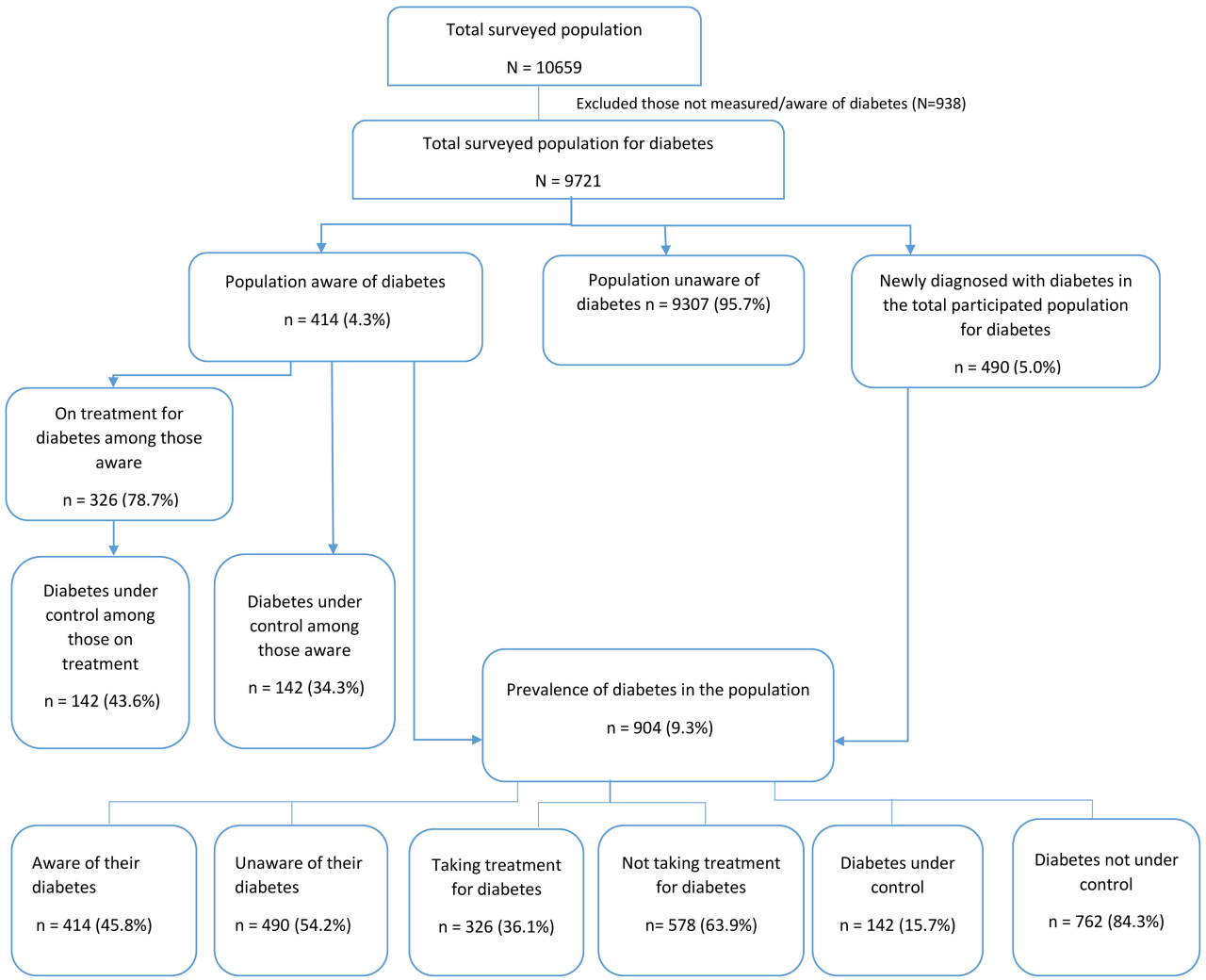

FIGURE 1 | Survey response rates of diabetes care cascade among adults (18–69 years) in India.

significant (**Tables 2**, **3**). Awareness and treatment levels were statistically significant for among those with high BMI (p-value < 0.001) (**Tables 2**, **3**).

In the multivariate analysis, older age, metabolic risk factors namely overweight, obesity, central obesity, raised blood pressure and raised cholesterol were all significantly associated with an increased risk of diabetes ($p < 0.001$). Adults aged 50–69 years had more than 8.89 times higher odds of diabetes. Low physical activity and alcohol use showed risk but were not statistically significant (**Table 2**). Awareness levels of diabetes were 15.77 times higher among adults aged 50–69 years and 3.10 times among 30–49 years. These findings were statistically significant ($p < 0.001$). Adults who reported raised cholesterol had 3.85 times the odds of being aware of diabetes status, while those with central obesity (OR: 2.03) and hypertension (OR: 1.99) were of two times higher odds of being aware. These odds were statistically significant ($p < 0.001$) (**Table 2**). Older adults had higher odds of being on treatment for diabetes among those aware, while the control status was better among younger adults. Similar to awareness, those with increased BMI, central obesity, raised blood pressure and known raised cholesterol were on treatment, though the findings were not statistically significant (**Table 3**).

The majority of the urban adults sought both consultation and treatment from practitioners of the allopathic system of medicine (79.1%). A nearly similar proportion of adults (18–69 years) of their education and area of residence status sought consultation (84.0%) and treatment (78.8%) from allopathic practitioners. Rural residents in a higher proportion had taken consultation (24.6%) and treatment (18.2%) from practitioners of traditional systems of medicine (AYUSH) than urban residents (**Supplementary Table S2**).

Among the surveyed health facilities, more than 90% of public secondary health care facilities provided screening, laboratory and management services for diabetes. While, among the public primary care facilities, screening and management services

TABLE 1 | Distribution (Percentage) of socio-demographic and risk factor profile of Indian adult population (18–69 years) by fasting blood glucose categories.

Variables	*n* (weighted)	Normal fasting blood glucose			Impaired fasting blood glucose			Newly-diagnosed diabetes			Previously-diagnosed diabetes		
		n [%]	95% CI	*p** value	*n* [%]	95% CI	*p* value	*n* [%]	95% CI	*p* value	*n* [%]	95% CI	*p* value
Overall (18–69 years)	9,721	6,438 [66.2]	(63.6–68.8)		2,379 [24.5]	(22.3–26.7)		490 [5.0]	(4.2–6.0)		414 [4.3]	(3.7–5.0)	
Residence													
Urban	3,137	1,791 [57.1]	(52.1–62.0)	**<0.001**	896 [28.6]	(24.6–32.8)	**<0.001**	192 [6.1]	(4.9–7.7)	**0.001**	258 [8.2]	(6.9–9.7)	**<0.001**
Rural	6,584	4,647 [70.6]	(67.6–73.4)		1,483 [22.5]	(20.1–25.2)		298 [4.5]	(3.5–5.7)		156 [2.4]	(1.9–3.0)	
Sex													
Men	5,036	3,509 [69.7]	(67.0–72.2)	**<0.001**	1,100 [21.8]	(19.6–24.3)	**<0.001**	209 [4.2]	(3.4–5.1)	**<0.001**	218 [4.3]	(3.5–5.4)	0.723
Women	4,685	2,929 [62.5]	(59.2–65.7)		1,279 [27.3]	(24.7–30.0)		281 [6.0]	(4.8–7.4)		196 [4.2]	(3.5–5.0)	
Age groups													
18–29 years	2,853	2,264 [79.4]	(76.1–82.2)	**<0.001**	525 [18.4]	(15.8–21.3)	**<0.001**	50 [1.8]	(1.2–2.6)	**<0.001**	14 [0.5]	(0.2–1.1)	**<0.001**
30–49 years	4,681	3,095 [66.1]	(63.0–69.1)		1,222 [26.1]	(23.5–28.9)		243 [5.2]	(4.2–6.4)		121 [2.6]	(2.0–3.4)	
50–69 years	2,187	1,079 [49.3]	(45.6–53.0)		632 [28.9]	(25.9–32.1)		197 [9.0]	(7.3–11.1)		279 [12.8]	(10.9–14.9)	
Education status													
Received education	6,847	4,547 [66.4]	(63.5–69.2)	0.561	1,651 [24.1]	(21.8–26.5)	0.194	330 [4.8]	(4.0–5.8)	0.124	319 [4.7]	(3.9–5.5)	**0.003**
No education	2,874	1,891 [65.8]	(62.2–69.2)		728 [25.3]	(22.4–28.5)		160 [5.6]	(4.3–7.1)		95 [3.3]	(2.5–4.3)	
Behavioral risk factors													
Current tobacco use (any form)													
No	6,513	4,142 [63.6]	(60.6–66.5)	**<0.001**	1,696 [26.0]	(23.7–28.6)	**<0.001**	350 [5.4]	(4.4–6.5)	**0.032**	325 [5.0]	(4.3–5.8)	**<0.001**
Yes	3,208	2,296 [71.6]	(68.4–74.6)		683 [21.3]	(18.7–24.1)		140 [4.4]	(3.3–5.7)		89 [2.8]	(2.1–3.7)	
Current alcohol use													
No	8,164	5,335 [65.3]	(62.5–68.1)	**<0.001**	2,056 [25.2]	(23.0–27.5)	**<0.001**	419 [5.1]	(4.2–6.2)	0.347	354 [4.3]	(3.7–5.1)	0.377
Yes	1,557	1,103 [70.8]	(66.8–74.6)		323 [20.7]	(17.5–24.3)		71 [4.6]	(3.2–6.5)		60 [3.9]	(2.6–5.5)	
Physical activity													
Insufficient	4,002	2,458 [61.4]	(58.1–64.6)	**<0.001**	1,081 [27.0]	(24.4–29.8)	**<0.001**	222 [5.5]	(4.5–6.8)	0.056	241 [6.0]	(5.0–7.2)	**<0.001**
Sufficient	5,719	3,980 [69.6]	(66.7–72.3)		1,298 [22.7]	(20.4–25.2)		268 [4.7]	(3.8–5.8)		173 [3.0]	(2.4–3.8)	
Metabolic risk factors													
BMI categories													
Normal	5,198	3,566 [68.6]	(65.6–71.4)	**<0.001**	1,259 [24.2]	(21.8–26.8)	**<0.001**	222 [4.3]	(3.5–5.2)	**<0.001**	151 [2.9]	(2.3–3.7)	**<0.001**
Underweight	1,863	1,455 [78.1]	(74.8–81.1)		326 [17.5]	(14.8–20.6)		59 [3.2]	(2.3–4.4)		23 [1.2]	(0.6–2.3)	
Overweight	1,895	1,040 [54.9]	(50.5–59.1)		544 [28.7]	(25.2–32.6)		145 [7.7]	(6.0–9.7)		166 [8.8]	(7.4–10.3)	
Obesity	590	257 [43.6]	(38.2–49.2)		212 [35.9]	(30.2–42.0)		59 [10.0]	(6.8–14.4)		62 [10.5]	(8.0–13.7)	
Central obesity													
No	6,492	4,735 [72.9]	(70.3–75.4)	**<0.001**	1,391 [21.4]	(19.2–23.8)	**<0.001**	244 [3.8]	(3.1–4.6)	**<0.001**	122 [1.9]	(1.5–2.4)	**<0.001**
Yes	3,071	1,589 [51.7]	(47.9–55.5)		960 [31.3]	(28.2–34.5)		240 [7.8]	(6.2–9.8)		282 [9.2]	(8.0–10.5)	
Raised blood pressure													
No	6,917	4,822 [69.7]	(67.0–72.3)	**<0.001**	1,644 [23.8]	(21.5–26.2)	**0.011**	295 [4.3]	(3.5–5.2)	**<0.001**	156 [2.3]	(1.8–2.9)	**<0.001**
Yes	2,783	1,600 [57.5]	(53.9–61.0)		730 [26.2]	(23.5–29.2)		195 [7.0]	(5.6–8.7)		258 [9.3]	(7.9–10.9)	
Reported raised cholesterol													
No	9,592	6,411 [66.8]	(64.2–69.4)	**<0.001**	2,334 [24.3]	(22.2–26.6)	0.006	480 [5.0]	(4.2–5.9)	0.156	367 [3.8]	(3.3–4.5)	**<0.001**
Yes	129	27 [20.9]	(13.2–31.2)		45 [34.9]	(25.2–46.1)		10 [7.8]	(3.7–16.0)		47 [36.4]	(26.1–48.0)	

**Chi-square test. P-value < 0.05 is considered statistically significant.*

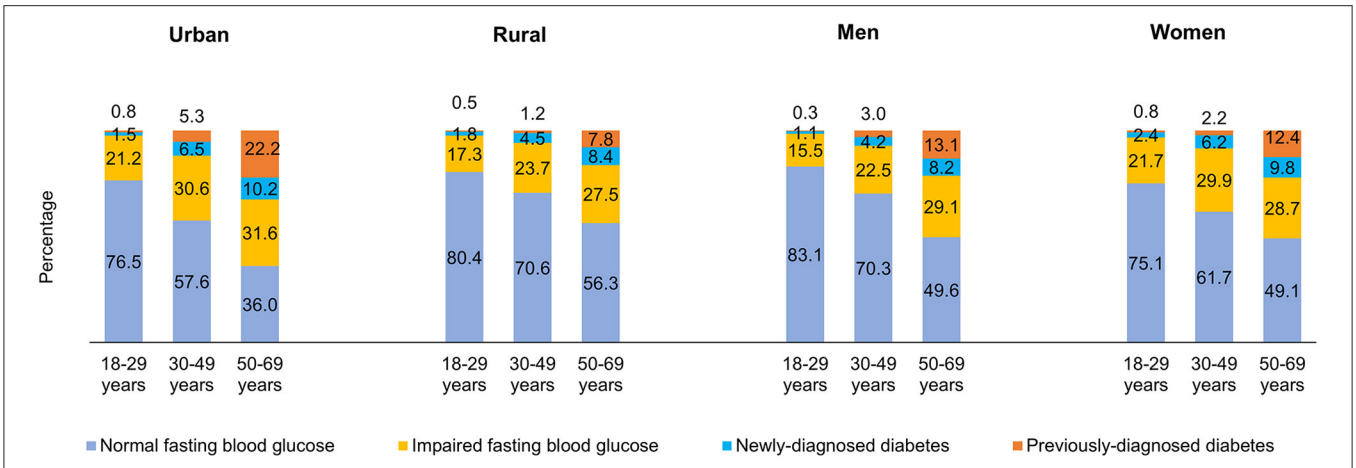

FIGURE 2 | Distribution (Percentage) of fasting blood glucose among adults by area of residence, sex and age categories.

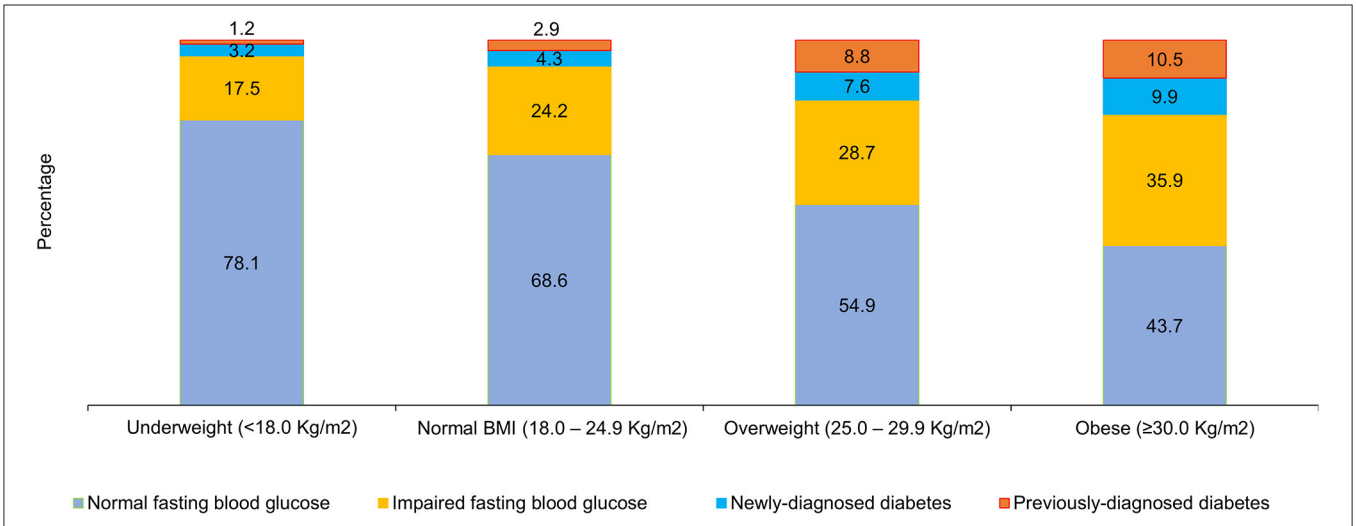

FIGURE 3 | Distribution of fasting blood glucose among adults (18–69 years) by BMI (Percentage).

for diabetes were available in 81.9% and 93.7% of facilities, respectively. Counseling services were available only in one-quarter of public primary (25.1%) and a half (50.8%) of the secondary care facilities (**Supplementary Table S3**).

DISCUSSION

The prevalence of diabetes and impaired glucose tolerance has been estimated to be 9.3% and 24.5%, respectively based on the nationally representative sample of adults aged 18–69-years in the National NCD Monitoring Survey. These findings highlight the impending burden of diabetes especially given the high population base and demographic transition in India. The survey also points out that almost half of diabetics are unaware of their raised fasting glucose status and that early diagnosis and treatment are primary for preventing complications, ensuring longevity and better quality of life. Across the globe, 10.4% of the population from high-income countries, 9.5% from middle-income and 4.0% from low-income countries were diabetic in 2019 (8). The South-East-Asia-Region ranked third in the prevalence of diabetes in 2019 with India ranking second to China (8). The prevalence of diabetes is projected to rise by the year 2045, with a nearly equal proportion from high-income (11.9%) and middle-income (11.8%) countries; and 4.7% in low-income countries (8). Few other recent epidemiological surveys, showed the prevalence of DM in India ranged from 5 to 17% (13–16). This paper findings identify groups that are at a specific disadvantage, highlighting the need for improving access to both preventive and curative health care among these groups. It also provides empirical evidence for policy formulation in the area of NCDs, especially would call for actions to prevent the occurrence of disease as well as to improve the reach of health systems for diabetes care. The study recommends robust data management

TABLE 2 | Determinants (adjusted OR) of awareness and prevalence of diabetes among adults aged 18–69 years in India.

Variables	*N* (weighted)	Awareness				Prevalence			
		Univariate analysis		Multivariable logistic regression		Univariate analysis		Multivariable logistic regression	
		n [%]	*p* value*	OR (95% CI)	*p* value	*n* [%]	*p* value*	OR (95% CI)	*p* value
Residence									
Urban	3,137	258 [8.2]	**<0.001**	1	**<0.001**	450 [14.3]	**<0.001**	1	**<0.001**
Rural	6,584	156 [2.4]		2.04 (1.61–2.59)		454 [6.9]		1.47 (1.25–1.73)	
Sex									
Men	5,036	218 [4.3]	**0.003**	1	0.119	427 [8.5]	**0.004**	1	0.146
Women	4,685	196 [4.2]		0.82 (0.63–1.05)		477 [10.2]		1.14 (0.96–1.36)	
Age groups									
18–29 years	2,853	14 [0.5]	**<0.001**	1		64 [2.2]	**<0.001**	1	
30–49 years	4,681	121 [2.6]		3.10 (1.78–5.40)	**<0.001**	364 [7.8]		2.77 (2.09–3.67)	**<0.001**
50–69 years	2,187	279 [12.8]		15.77 (9.11–27.27)	**<0.001**	476 [21.8]		8.89 (6.66–11.87)	**<0.001**
Education status									
Received education	6,847	319 [4.7]	**0.001**	1	**0.007**	649 [9.5]	0.338	1	**0.002**
No education	2,874	95 [3.3]		0.68 (0.51–0.90)		255 [8.9]		0.75 (0.63–0.90)	
BEHAVIORAL RISK FACTORS									
Current tobacco use (any form)									
No	6,513	325 [5.0]	0.015	1	**0.003**	675 [10.4]	**<0.001**	1	**0.012**
Yes	3,208	89 [2.8]		1.56 (1.17–2.08)		229 [7.1]		1.27 (1.05–1.54)	
Current alcohol use									
No	8,164	354 [4.3]	0.989	1	0.148	773 [9.5]	0.189	1	0.057
Yes	1,557	60 [3.9]		1.29 (0.91–1.82)		131 [8.4]		1.25 (0.99–1.58)	
Physical activity									
Sufficient	5,719	173 [3.0]	**<0.001**	1	0.112	441 [7.7]	**<0.001**	1	0.346
Insufficient	4,002	241 [6.0]		1.20 (0.96–1.50)		463 [11.6]		1.08 (0.92–1.26)	
METABOLIC RISK FACTORS									
BMI									
Normal	5,198	151 [2.9]	**<0.001**	1		373 [7.2]	**<0.001**	1	
Underweight	1,863	23 [1.2]		0.75 (0.47–1.21)	0.242	82 [4.4]		0.81 (0.63–1.05)	0.118
Overweight	1,895	166 [8.8]		1.32 (0.98–1.76)	0.065	311 [16.4]		1.45 (1.18–1.79)	**<0.001**
Obesity	590	62 [10.5]		1.37 (0.93–2.01)	0.108	121 [20.5]		1.65 (1.25–2.18)	**<0.001**
Central obesity									
No	6,492	122 [1.9]	**<0.001**	1	**<0.001**	366 [5.6]	**<0.001**	1	**<0.001**
Yes	3,071	282 [9.2]		2.03 (1.49–2.77)		522 [17.0]		1.48 (1.20–1.82)	
Raised blood pressure									
No	6,917	156 [2.3]	**<0.001**	1	**<0.001**	451 [6.5]	**<0.001**	1	**<0.001**
Yes	2,783	258 [9.3]		1.99 (1.58–2.51)		453 [16.3]		1.48 (1.27–1.73)	
Reported raised cholesterol									
No	9,592	367 [3.8]	**<0.001**	1	**<0.001**	847 [8.8]	**<0.001**	1	**<0.001**
Yes	129	47 [36.4]		3.85 (2.50–5.91)		57 [44.2]		2.80 (1.90–4.13)	

**Chi-square test. P-value < 0.05 is considered statistically significant.*

under the National Program for Control and Prevention of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) for both public and private health facilities. Also, a need for community-based implementation strategies for treatment and control like strengthening counseling services through grassroot health workers like the ASHA, either incentivise or disincentivise schemes for increasing physical activity or reduction of obesity.

This survey reports that the prevalence of DM was two times higher in urban areas (14.3%) than in rural areas (6.9%). Urban areas also showed a high prevalence of IFG. These findings are more robust as the NNMS has the advantages of a national sample equally distributed among both urban and rural areas. Several large epidemiological studies in India have reported similar findings (16–19). The ICMR-INDIAB study reported

TABLE 3 | Determinants (adjusted OR) of treatment and control of diabetes among adults aware of diabetes aged 18–69 years in India.

Variables	*N* (weighted)	Treatment				Control			
		Univariate analysis		Multivariable logistic regression		Univariate analysis		Multivariable logistic regression	
		n [%]	*p* value*	OR (95% CI)	*p* value	*n* [%]	*p* value*	OR (95% CI)	*p* value
Residence									
Urban	258	212 [82.2]	**0.023**	1	0.481	83 [32.2]	0.260	1	
Rural	156	114 [73.1]		1.24 (0.68–2.28)		59 [37.8]		1.12 (0.68–1.86)	0.653
Sex									
Men	218	180 [82.6]	0.074	1		69 [31.7]	0.387	1	
Women	196	146 [74.5]		0.51 (0.25–1.04)	0.063	73 [37.2]		1.18 (0.67–2.05)	0.568
Age groups									
18–29 years	14	3 [21.4]	**<0.001**	1		11 [78.6]	0.110	1	
30–49 years	121	86 [71.1]		3.79 (0.90–15.89)	0.069	36 [29.8]		0.12 (0.03–0.49)	**0.003**
50–69 years	279	237 [84.9]		8.34 (2.03–34.22)	**0.003**	95 [34.1]		0.14 (0.04–0.53)	**0.004**
Education status									
Received education	319	255 [79.9]	0.277	1		103 [32.3]	0.170	1	
No education	95	71 [74.7]		0.94 (0.45–1.97)	0.868	39 [41.1]		1.53 (0.83–2.83)	0.171
BEHAVIORAL RISK FACTORS									
Current tobacco use (any form)									
No	325	252 [77.5]	0.252	1		115 [35.4]	0.317	1	
Yes	89	74 [83.1]		0.83 (0.38–1.82)	0.635	27 [30.3]		1.49 (0.80–2.79)	0.208
Current Alcohol use									
No	354	282 [79.7]	0.398	1		115 [32.5]	0.077	1	
Yes	60	44 [73.3]		0.47 (0.19–1.16)	0.102	27 [45.0]		2.71 (1.33–5.53)	**0.006**
Physical activity									
Sufficient	173	121 [69.9]	**<0.001**	1		49 [28.3]	**0.019**	1	
Insufficient	241	205 [85.1]		1.79 (1.02–3.14)	**0.042**	93 [38.6]		1.94 (1.21–3.11)	**0.006**
METABOLIC RISK FACTORS									
BMI									
Normal	151	118 [78.1]	**0.002**	1		50 [33.1]	0.133	1	
Underweight	23	11 [47.8]		0.40 (0.13–1.20)	0.102	12 [52.2]		1.11 (0.39–3.16)	0.845
Overweight	166	132 [79.5]		0.71 (0.32–1.58)	0.405	60 [36.1]		1.24 (0.68–2.27)	0.490
Obesity	62	53 [85.5]		1.25 (0.46–3.40)	0.661	16 [25.8]		0.75 (0.34–1.66)	0.480
Central obesity									
No	122	84 [68.9]	**0.003**	1		48 [39.3]	0.136	1	
Yes	282	232 [82.3]		1.89 (0.85–4.22)	0.119	91 [32.3]		0.67 (0.35–1.27)	0.215
Raised blood pressure									
No	156	105 [67.3]	**<0.001**	1		53 [34.0]	0.757	1	
Yes	258	221 [85.7]		2.40 (1.38–4.17)	**0.002**	89 [34.5]		0.95 (0.59–1.52)	0.822
Reported Raised cholesterol									
No	367	281 [76.6]	**0.002**	1		127 [34.6]	0.982	1	
Yes	47	45 [95.7]		4.25 (0.92–19.63)	0.064	15 [31.9]		0.92 (0.45–1.86)	0.809

**Chi-square test. P value < 0.05 is considered statistically significant.*

the prevalence of diabetes in urban areas being higher than rural areas, being highest in the age group of 55–64 years (Urban: nearly 25% and rural areas: nearly 10%) (16). Urban predominance of diabetes is an influence of a multitude of factors like rapid urbanization, the prevalence of overweight and obesity in consequence of inactive lifestyle and changing dietary habits (1, 8, 16–19). But the proportions in rural areas are also worrisome, with an equally high prevalence of IFG and raised FBG, reflecting the expanding urbanization. Gupta et al. 2020, discussed the reduction of the conventional rural-urban differences in the prevalence of DM (20). Their study findings on diabetes prevalence in rural areas was similar to urban studies by Goswami et al. in 2016, and Singh et al. in 2012 undertaken in the same geographic locations in India (20–22). This urban-rural narrowing has been reported across the globe (8, 23). The International Diabetes Federation reported, 67.0% of adults living

with diabetes across the world were urban residents, but also notified the rising prevalence of DM in the rural areas (10.8%–Urban vs. 7.2%–Rural) (8). Thus, the emerging challenges with DM in rural India cannot be overlooked, rapid mechanisms are needed to prevent and halt the rise.

The prevalence of IFG was higher than diabetes, specifically most affected were aged 50–69 years, followed by those aged 30–49 years and 18–29 years which constitute to be the most productive years of life. The World Health Organization–IDF reported the 35–64 year age group to be the most prevalent group with diabetes in the developing countries compared to the 65+ years group in the developed countries (2). It is projected that by 2030, this age-wise burden shall only increase with no alteration in its course (2). Thus, amplified efforts of screening, early interventions, awareness and health promotion among the younger adults would help prevent and halt the progression rates from IFG to DM. These findings from our national survey are imperative for aggressive policy planning and action.

The current study showed, the prevalence of IFG and DM being pre-dominant among women. This could be influenced by the sex-related differences in lifestyle and risk factors (1, 16, 18). Women are more likely to be with higher BMI (obese or overweight) than men and thus be expected to have a higher prevalence of DM (1, 16). Both IFG and DM were more prevalent among adults with metabolic risk factors—overweight, obesity, central obesity than those with normal BMI or underweight (16–19, 24). Also, 44.2% with raised cholesterol and 16.3% with hypertension had diabetes thus revealing the cardio-metabolic and co-morbid behavior of DM. As these co-morbid factors share common risk factors, adpating lifestyle alterations like weight management, sufficient physical activity, consumption of adequate servings of fruits and vegetables and other dietary modifications can together benefit their prevention and control (25).

Notably, awareness, treatment and control of DM were better among older adults, men, urban residents and those who received some education. Those with raised cholesterol and raised blood pressure had better awareness levels, were taking anti-diabetic medication and had their blood glucose under control. This could be explained by improved awareness on DM in urban areas; better access and affordability to care; routine screening of blood glucose along other co-morbid factors like blood pressure and cholesterol (1, 3, 16). Poor awareness and treatment levels in women can be attributed to poor access to treatment for women. Also, being educated enables one to understand and be willing to adopt healthy behaviors. A high proportion of adults previously-diagnosed vs. newly-diagnosed DM in both urban and rural areas as well as among older adults, highlights the sustained efforts by the Government of India through the NPCDCS program (26). However, still a large proportion remains undiagnosed and are not adherent to treatment and this is a problem in the low-and-middle-income countries like India (8). Nearly 70% of primary and more than 90% of secondary public health facilities surveyed provided screening, laboratory, and management services for diabetes, but majorly lacked counseling services (public primary−25% and public secondary−51%). Thus, emphasizing the need to expand and strengthen the initiative especially at the primary care level in both urban and rural areas. Also, stronger actions are needed to identify the younger adults and women who are more likely to be missed from diagnosis and or treatment.

More than three-fourth of adults in India sought care for diabetes from allopathic practitioners and more than 10% from AYUSH practitioners and this proportion was higher among rural residents (18.2–24.6% from AYUSH) and older adults. Indicating that the rural residents and older adults are more oriented and receptive to the Indian traditional systems of medicine. This provides a new dimension to policymakers in promoting AYUSH services for preventive and early diabetes care. Also, encouraging and expanding traditional medicine services in urban areas as well as creating awareness among younger adults are better alternatives to lessen the current and future burden on health systems. Amalgamating allopathic and traditional systems as a holistic approach to diabetes and NCD care can help meet the rising burden on health systems (27, 28).

The strengths and limitations of this survey findings include the general strengths and limitations of NNMS that have been described elsewhere (10, 11). Several studies either provide random blood glucose estimates to report the prevalence of diabetes or self-reported history (17, 18, 21). We have used a combination of previously-diagnosed history and fasting blood glucose measurements to report diabetes prevalence in India. However, due to logistic reasons, we used capillary blood glucose for IFG and raised FBG estimations as a standard alternative to venous plasma blood glucose (12). Since it is a cross-sectional survey that recorded behavioral risk factors at the time of the survey and no baseline data, it is difficult to infer if some of these survey participants may have changed behavior after diagnosis of diabetes or possibly other chronic illnesses and therefore their relationship as causal factors are not significant. Our findings provide national estimates that can help inform policies to target populations at risk for diabetes based upon awareness, treatment and control levels. Also, provide a baseline to monitor the NCD targets under the global and national NCD framework to be achieved by 2025.

In conclusion, the level of morbidity and mortality from diabetes and its potential complications are enormous. Despite the presence, some of the persons continue to have behavioral risk factors and thus increasing their chances for complications. Producing periodic prevalence estimates, awareness, treatment and control levels as well as future projections for diabetes is essential to promote its prevention and encourage quality of care. Continuous monitoring and surveillance of diabetes as well as comprehensive health promotive and management interventions among diabetics are crucial in the progress of countries to achieve the WHO Global NCD Voluntary Targets by 2025.

DATA AVAILABILITY STATEMENT

The National Noncommunicable Disease Monitoring Survey (NNMS) report is available at: https://www.ncdirindia.org/nnms/. Further data are available upon request.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Institutional Ethics Committee of the Coordinating Center, Indian Council of Medical Research—National Centre for Disease Informatics and Research, Bengaluru, India. Every implementing agency obtained their ethics approval from their own Institutional Ethics Committee. The patients/participants provided their written informed consent to participate in this study. Approval no: NCDIR/IEC/2017/4 dated 03 Feb 2017.

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SL, VK, and PM contributed to the concept, design of the paper, and involved in revision of the manuscript. VK and SL developed the analysis plan. VK was involved in data management and statistical analyses. SL drafted the manuscript with expert review and inputs from PM and VK. PM reviewed the plan, received funding for the study, and was the principal investigator. All authors were part of the central coordinating unit primarily involved in investigation and approved the final version of the manuscript.

FUNDING

The Ministry of Health and Family Welfare (MoHFW), Government of India, funded this survey. (Dy.No.C-707, dated 06 July 2015). The funders only provided the funds and had no role in the study planning, implementation and preparation of the manuscript.

ACKNOWLEDGMENTS

We acknowledge the support and facilitation provided by the Ministry of Health and Family Welfare, Government of India, New Delhi, Indian Council of Medical Research (ICMR), New Delhi and World Health Organization-South-east-Asia-Region and Regional office in India. We also thank the NNMS–National Technical Working Group experts for their valuable suggestions and scientific input and all the ICMR-NNMS investigators and collaborators.

SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2022.748157/full#supplementary-material

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Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

frontiers in Public Health

ORIGINAL RESEARCH
published: 21 March 2022
doi: 10.3389/fpubh.2022.768471

Prevalence, Awareness, Treatment, and Control of Hypertension and Diabetes: Results From Two State-Wide STEPS Survey in Punjab and Haryana, India

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Background: India which is home to more than one sixth of the world's population, accounts for more than two thirds of total deaths due to non-communicable diseases (NCD). Out of this, hypertension and diabetes are the most common NCDs. Awareness, treatment, and control of hypertension and diabetes remains a major challenge despite various national programs being run to curb the rising burden NCDs. In order to fill the knowledge gap, awareness, treatment, and control of diabetes and hypertension were studied by using data from the STEPS survey among the adult population in two major northern Indian states of Punjab and Haryana.

Methods: Two state-wide NCD risk factors surveys were conducted using WHO STEPS methodology among 5,127 individuals in Punjab and 5,078 individuals in Haryana aged 18–69 years in the year 2014–15 and 2016–18. Standardized questionnaire was used to determine the behavioral risk factors in step one followed by anthropometric measurements for physical risk factors in step two and in the third step serum and urine samples were collected for biochemical risk factors.

Results: The prevalence of hypertension in Punjab was 40.1% while that in Haryana was 26.2%. In Punjab, only 48.3% of the hypertensive were aware of their condition, 30.9% were on treatment while only 18.3% of the cases were controlled. While in Haryana 33.4% of the respondents were aware of their condition, 26.3% are on treatment while only 12% of the cases were controlled. Similarly, the prevalence of diabetes was 14.3 and 15.1% in Punjab and Haryana, respectively. In Punjab 34.2% of diabetics were aware of their condition, 28.2% were on treatment while only 14.2% of the cases were controlled. The awareness and control rates in Haryana were similar to that in Punjab. 29.5% of the respondents were aware of their condition, 22.4% were on treatment while only 13.8% of the cases of diabetes were controlled. Family history of diabetes and hypertension was found to be associated with higher odds of being aware, on treatment and controlled blood glucose and blood pressure levels in both Punjab and Haryana.

Discussion: Hypertension and diabetes are a major public health problem in Punjab and Haryana and awareness, treatment and control rates are low which require specific

OPEN ACCESS

Edited by:
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Reviewed by:
Prabhdeep Kaur, National Institute of Epidemiology (ICMR), India
Prasanna Mithra, Kasturba Medical College, Mangalore, India

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Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: *31 August 2021*
Accepted: *18 February 2022*
Published: *21 March 2022*

Citation:
Thakur JS and Nangia R (2022) Prevalence, Awareness, Treatment, and Control of Hypertension and Diabetes: Results From Two State-Wide STEPS Survey in Punjab and Haryana, India. Front. Public Health 10:768471. doi: 10.3389/fpubh.2022.768471

interventions with a focus on access to treatment, regular follow up for better control. There is an urgent need to effectively implement the existing national NCD programmes in these states in India.

Keywords: awareness, treatment, NCDs, hypertension, diabetes, Punjab, Haryana, STEPS survey

INTRODUCTION

The global burden of non-communicable diseases (NCDs) has a disproportionate impact on low- and middle-income countries (LMICs). An estimated 41 million people worldwide died from NCDs in 2016, of which more than 78% occurred in low- and middle-income countries (1, 2). The burden of hypertension and diabetes has steadily increased over the past 50 years globally, with India contributing a major part of the global burden (3). In India, almost 5.8 million people die every year from NCDs, mainly heart and lung diseases, stroke, cancer and diabetes, meaning a quarter of Indians are at risk of dying from a NCD before the age of 70 years. India has more than one sixth of the world's population, and accounts for more than two thirds of all deaths from non-NCDs (4). Among them, hypertension and diabetes are the most NCDs. The recent epidemiological evidence shows that the incidence and prevalence of the disease in both urban and rural India is on the rise (5, 6).

Early diagnosis and control of hypertension and diabetes can reduce premature mortality and disability (7). However, studies suggest that around half of the population living with hypertension have not been diagnosed while one third of the population with diabetes are unaware of their condition (8, 9). The National Health Policy 2017 of India also aims to increase screening and treatment of 80% of people with diabetes and hypertension to reduce premature deaths from diabetes by 25% by 2025 (10).

Several studies report that patients in rural and urban areas around the world have low levels of awareness of hypertension and diabetes (9, 11, 12). Although a number of national programmes and policies have been introduced to curb the growing burden of NCDs, the awareness, treatment and control of hypertension and diabetes remains a major challenge.

Punjab and Haryana, two major northern Indian states reported a high prevalence of non-communicable diseases in the state-wide risk factor surveys (13, 14). The STEPS survey findings in both the state survey suggests that NCD risk factors are, in general, common and almost uniformly prevalent in the adult population of the two states. The fact that only 1% of the study population in Punjab and 0.2% of the study population in Haryana was found to be free of all studied NCD risk factors is an indication of growing epidemic of NCDs in the two states. The cascade care for NCDs, that is, the proportion of people with related conditions who have been screened, know their diagnosis, are taking medications, and their condition is under control is a useful concept that provides information to design intervention and to evaluate the health system performance. To date, few large-scale population based studies have been conducted in India, reporting the prevalence and control rates of hypertension and diabetes and the point at which people are lost from care (15). To fill the knowledge gap, awareness, treatment, and control of diabetes and hypertension were studied among the adult population in these two major northern Indian states.

METHODOLOGY

Study Design

The data used for the study is from the state-wide NCD risk factors surveys were conducted in Punjab and Haryana, India using the WHO STEPS methodology. The data is state representative and the survey were conducted in 2014–15 and 2016–17, respectively. The detailed methodology of the surveys has been published separately (13, 14). Standardized questionnaire was used to determine the behavioral risk factors in step one followed by anthropometric measurements for physical risk factors in step two and in the third step serum and urine samples were collected for biochemical risk factors.

Sampling

This study reports the results from cross-sectional surveys conducted in two states using a multi-stage stratified sample. The subjects of the survey were 18–69 year-old adult men and women living in urban and rural areas. The estimated value of the total sample size of the two surveys was calculated by summing up the age, gender, and residential strata and adjusting them to a design effect of 1.5 (16). The sample sizes for Punjab 5400 and Haryana 5250 were calculated after considering the response rate of 90%.

The primary sampling units (PSUs) were villages in rural areas and census enumeration blocks in urban areas. In both urban and rural areas, one individual was selected from the selected household following the KISH method (17). The WHO STEPS questionnaire version 3.1 (18), with local adaptations was used in both the surveys.

Data Collection

In both the surveys, socio-demographic and behavioral information was collected in STEP 1. The information on tobacco and alcohol use, health screening, history of chronic conditions and family history of NCDs was collected. For STEP 2, physical measurements such as height, weight, waist circumference, and blood pressure were collected using standard procedures and protocols. The instruments were calibrated periodically during the survey. The standard procedures of measurement have been described in detail previously (13, 14). The blood pressure was measured in sitting position on the right arm supported at the level of the heart using calibrated electronic equipment (OMRON HEM 7120, Omron Cooperation, Japan) (19). Total of three measurements were recorded at 2 min interval each and for the analysis the average of last two readings

were taken. STEP 3, i.e., the biochemical measurements were conducted on serum samples to assess fasting blood glucose STEP 3 was done on a subsample of the total participants. Alternate individuals (50% of the total) were given written instructions regarding fasting and appointment date for blood test. Blood glucose was measured using finger prick blood samples and blood glucose measurement device (Optium H Freestyle) (20).

Operational Definitions

Both surveys used cut-off values recommended in the WHO STEPS approach (18). Current tobacco use was defined as those who smoked and consumed smokeless tobacco in the past 30 days and current alcohol use as those who had consumed alcohol in the last 1 year. Obesity was defined as BMI 27.5 kg/m^2 which is the standard cut-off for Asian population (21). Hypertension was defined as systolic blood pressure (SBP) $\geq$ 140 mm of Hg, or diastolic blood pressure (DBP) $\geq$ 90 mm of Hg or the use of blood pressure-lowering medications for hypertension. Individuals with fasting capillary blood glucose of $\geq$126 mg/dl or on medications for high blood sugar were considered to have diabetes mellitus. Individual was considered on treatment with current use of antihypertensive or antidiabetic medication. Controlled hypertension or diabetes was defined for

TABLE 1 | Socio-demographic and behavioral characteristics of the participants, Punjab and Haryana.

Variable		Punjab (*N* = 5,127) *N* (%)	Haryana (*N* = 5,078) *N* (%)
Age	18–44	3,344 (65)	3,473 (68)
	45–69	1,783 (35)	1,605 (32)
Gender	Male	2,381 (46)	2,294 (45)
	Female	2,746 (54)	2,784 (55)
Residence	Rural	3,096 (60)	3,368 (66)
	Urban	2,031 (40)	1,710 (34)
Education	No formal schooling	1,208 (24)	514 (12)
	Less than primary school	281 (6)	321 (8)
	Primary school completed	987 (19)	743 (17)
	Secondary school completed	760 (15)	878 (21)
	High school completed	1,373 (27)	1,113 (26)
	College/University completed	348 (7)	575 (13)
	Post graduate degree	170 (3)	137 (3)
Social group	SC	1,927 (38)	1,742 (34)
	OBC/others	699 (14)	1,223 (24)
	General	2,410 (47)	2,082 (41)
	Refused	91 (1)	31 (1)
Marital status	Never married	838 (16)	612 (12)
	Currently married	3,875 (76)	4,132 (81)
	Separated	37 (1)	8 (0)
	Divorced	25 (1)	5 (0)
	Widowed	318 (6)	271 (5)
	Refused	35 (0)	50 (1)
Measurement of blood pressure	Never measured	1,998 (39)	2,209 (44)
Measurement of blood sugar	Never measured	3,316 (64)	3,773 (74)
Family history	Hypertension	1,957 (38.3)	2,162 (42.6)
	Diabetes	1,174 (23.2)	1,052 (20.8)
Hypertension status	Prevalence	2,030 (40.3)	1,371 (26.2)
	Aware	980 (48.3)	457 (33.3)
	On treatment	611 (30.1)	361 (26.3)
	Controlled	373 (18.3)	164 (12.0)
		N* = 2,366	***N* = 2,488***
Diabetes status	Prevalence	336 (14.2)	348 (15.5)
	Aware	115 (34.2)	103 (29.5)
	On treatment	95 (28.2)	78 (22.4)
	Controlled	48 (14.2)	48 (13.7)

**Blood glucose was measured on a subsample of the total participants.*

those taking medication for the management of high BP or high blood glucose at the time of the interview and having systolic BP < 140 mmHg and diastolic BP < 90 mmHg and blood glucose <126 mg/dl.

Ethical Considerations

The study was approved by the Ethics Committee of the Postgraduate Institute of Medical Education and Research, Chandigarh. The technical advisory committee of both the surveys approved the research plan and supervised the implementation and execution of the two surveys. Written consent of all survey participants has been obtained. Complete privacy and confidentiality of participants was ensured.

Statistical Analysis

Frequencies (percentages) or means and standard deviations were used to summarize the socio-demographic characteristics, physical measurements, and hypertension and diabetes status of the study participants. The primary outcome variables were awareness, treatment, and control of hypertension and diabetes The strength of associations of socio-demographic associated factors of hypertension and diabetes, awareness, treatment, and control were assessed by Odds-Ratios (OR) estimated in logistic regression models All estimates are presented with 95% confidence intervals (CIs), significance of difference in results between different groups was observed by comparing CIs. The associations were assessed using multivariate models adjusted for the covariates age, gender, residence, education, family history of hypertension and diabetes, current tobacco, and current alcohol status. Significance level was set at $p < 0.05$ for all hypothesis tests. SPSS version 21 (22) was used as the statistical software for analysis.

RESULTS

Socio-Demographic and Behavioral Characteristics

Table 1 gives the socio-demographic and the behavioral characteristics of the study population of the two surveys in Punjab and Haryana. The surveys included a total of 5,127 participants in Punjab and 5,078 participants in Haryana. In Punjab, 54% women and 46% men stratified by age group, sex and place of residence were included. In Haryana, 55% of the total participants were females and 45% were males. Sixty-eight percent of the study sample in Haryana and 65% in Punjab belonged to 18–44 years age group. About 40% of the Punjab population and 44% of the Haryana population have never had their blood pressure measured. In the case of diabetes, the numbers are even higher, as 64% of the Punjab population and 74% of the Haryana population have never had their blood glucose measured. In Punjab, prevalence of current tobacco and alcohol use was 11.3 and 14.5%, respectively. While in Haryana, 23.5% were current tobacco users and 10.5% were current alcohol users.

Prevalence, Awareness, Treatment, and Control of Hypertension

Figure 1 shows the extent of awareness, treatment and control of hypertensive cases in Punjab and Haryana. The prevalence of hypertension in Punjab was 40.1% while that in Haryana was 26.2%. In Punjab, only 48.3% of the hypertensive were aware of their condition, 30.9% are on treatment while only 18.3% of the cases were controlled. While in Haryana 33.4% of the respondents were aware of their condition, 26.3% are on treatment while only 12% of the cases are controlled. The prevalence of hypertension was found to be higher among males in both the states, i.e., 47.4% in Punjab and 29.5% in Haryana.

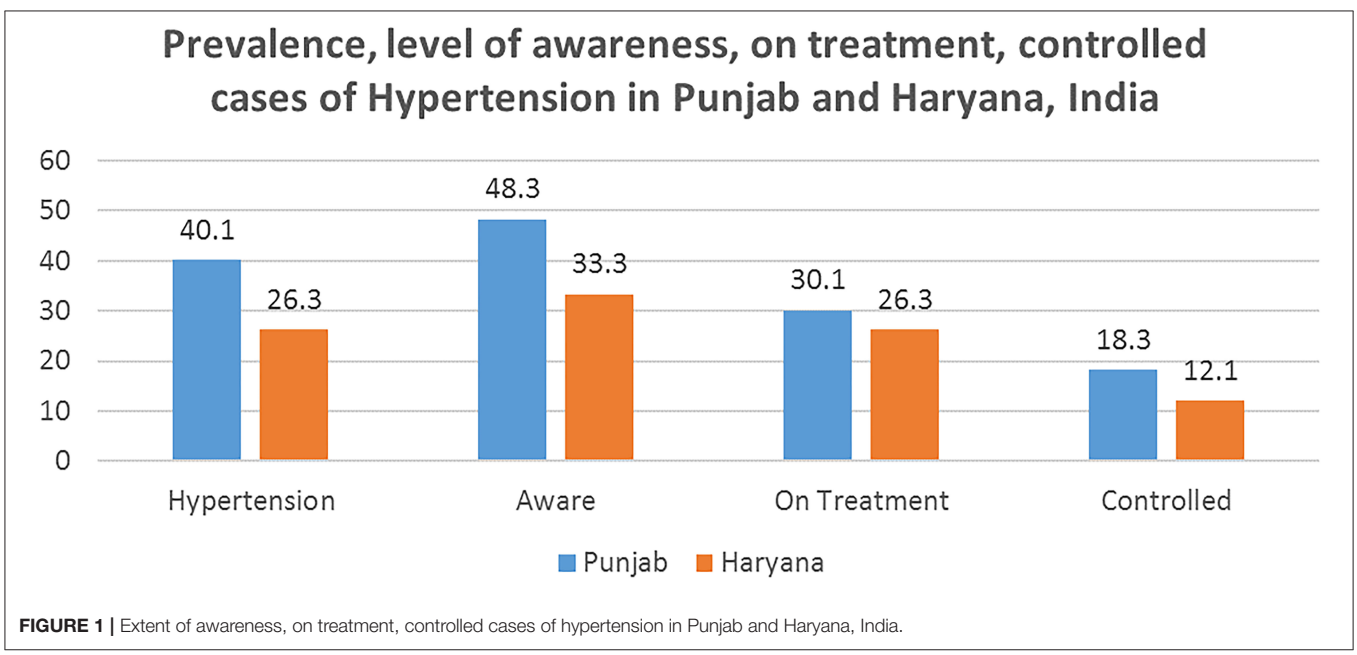

FIGURE 1 | Extent of awareness, on treatment, controlled cases of hypertension in Punjab and Haryana, India.

TABLE 2 | Proportion (%) of hypertension awareness, treatment, and control in Punjab and Haryana, India.

Demographic variables	Punjab, *n* (%)				Haryana, *n* (%)			
	Hypertensnsives (*N* = 5,027)	Aware (*N* = 2,030)	On treatment (*N* = 2,030)	Controlled (*N* = 2,030)	Hypertensives (*N* = 5,078)	Aware (*N* = 1,371)	On treatment (*N* = 1,371)	Controlled (*N* = 1,371)
Gender								
Male	1,093 (47.4)	324 (29.6)	197 (18.1)	100 (9.1)	719 (29.5)	268 (37.2)	121 (16.9)	70 (9.8)
Female	937 (31.5)	656 (70.4)	414 (44.1)	273 (25.3)	652 (22.1)	189 (28.9)	240 (36.8)	94 (14.4)
Residence								
Rural	1,225 (41.1)	590 (48.2)	347 (28.3)	203 (16.6)	851 (24.4)	209 (24.5)	213 (25.1)	106 (12.4)
Urban	805 (38.7)	390 (48.7)	264 (32.8)	170 (21.2)	520 (28.8)	248 (47.7)	148 (28.4)	58 (11.2)
Age (years)								
18–44	979 (30.4)	407 (41.6)	214 (21.9)	149 (15.2)	738 (20.7)	217 (29.4)	159 (21.5)	87 (11.8)
45–69	1,051 (60.6)	573 (54.6)	397 (37.8)	224 (21.3)	633 (39.1)	240 (37.9)	202 (44.2)	77 (12.2)

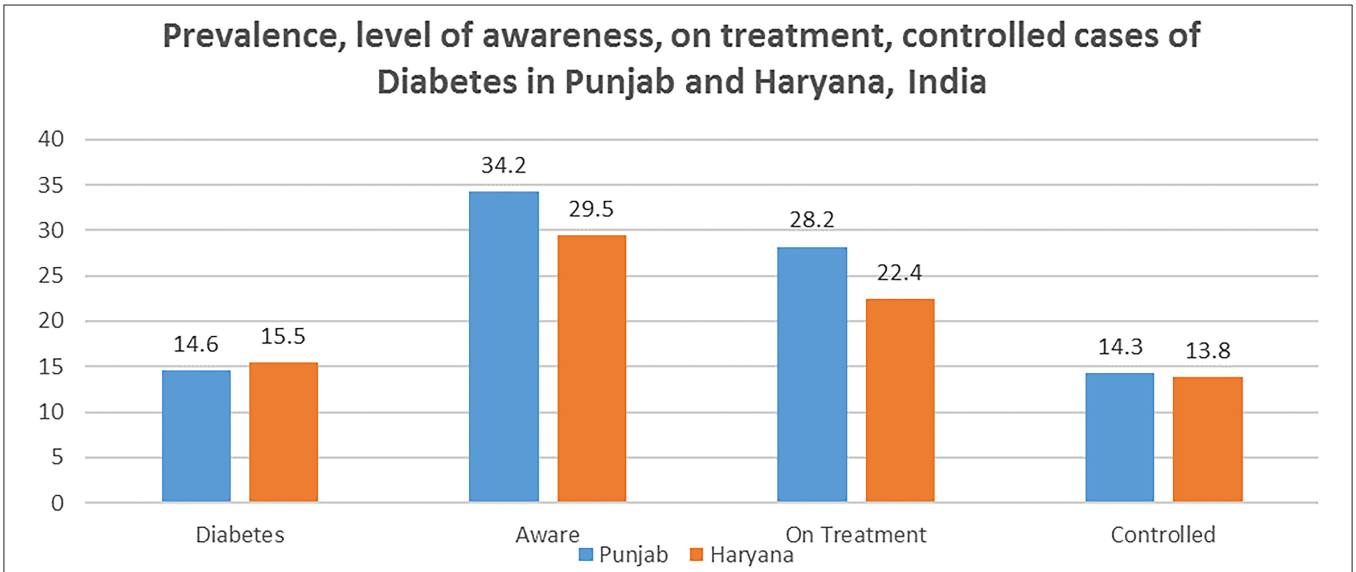

FIGURE 2 | Extent of awareness, on treatment, controlled cases of diabetes in Punjab and Haryana, India.

Further analysis shows that more females were on treatment in both the states in comparison to men. Also, in both the states, higher proportion the urban population were on treatment than the rural population (**Table 2**).

Prevalence, Awareness, Treatment, and Control of Diabetes

The prevalence of diabetes was 14.3 and 15.1% in Punjab and Haryana, respectively. In Punjab 34.2% of diabetics aware of their condition, 28.2% are on treatment while only 14.2% of the cases are controlled. **Figure 2** highlights the awareness and control rates in Haryana were similar to that in Punjab. 29.5% of the respondents were aware of their condition, 22.4% are on treatment while only 13.8% of the cases of diabetes were controlled. **Table 3** highlights that the prevalence of diabetes was higher in rural areas in both Punjab and Haryana. Furthermore, in both the states, higher proportion the urban population were on treatment than the rural population.

Factors Associated With Awareness, Treatment, and Control of Hypertension

Table 4 presents findings from multiple logistic regression that identified factors associated with hypertension awareness, treatment, and control. It highlights that the family history of hypertension is associated with higher odds of being aware, and controlled blood pressure levels in Punjab with OR of 1.1 (95% CI, 0.6–1.8) and OR 0.1 (95% CI, 0.7–1.4). While in Haryana people with family history of hypertension were more likely to be aware, on treatment and had better control rates for hypertension with OR 2.49 (95% CI, 2.3–2.6), 1.6 (95% CI, 1.4–2.8), 2.0 (95% CI, 1.4–2.7)/ No formal schooling was negatively associated with hypertension awareness, treatment, and control in both the states. Also, the current tobacco and alcohol use is related with

TABLE 3 | Proportion (%) of diabetes awareness, treatment, and control in Punjab and Haryana, India.

Demographic Variables	Punjab, *n* (%)				Haryana, *n* (%)			
	(*N* = 2,366)				(*N* = 2,488)			
	Diabetics (*N* = 2,366)	Aware (*N* = 336)	On treatment (*N* = 336)	Controlled (*N* = 336)	Diabetics (*N* = 2,488)	Aware (*N* = 348)	On treatment (*N* = 348)	Controlled (*N* = 348)
Gender								
Male	133 (14.0)	42 (28.6)	50 (44.1)	33 (25.1)	140 (14.2)	62 (33.2)	38 (16.9)	14 (9.8)
Female	203 (14.6)	73 (38.4)	45 (38.1)	15 (9.3)	208 (17.6)	41 (26.9)	40 (28.8)	34 (13.4)
Residence								
Rural	146 (14.0)	39 (48.2)	347 (24.3)	203 (12.6)	189 (12.6)	54 (24.5)	32 (25.1)	26 (9.4)
Urban	190 (14.6)	76 (30.7)	264 (30.8)	170 (16.2)	159 (19.7)	49 (35.7)	46 (28.4)	22 (15.2)
Age (years)								
18–44	98 (8.4)	407 (41.6)	214 (21.9)	149 (15.2)	165 (15.0)	59 (26.4)	27 (21.5)	12 (10.8)
45–69	238 (27.7)	573 (54.6)	397 (37.8)	224 (21.3)	183 (21.3)	44 (35.9)	51 (34.2)	36 (14.2)

TABLE 4 | Multivariable Logistic Regression Model to assess Factors associated with awareness, treatment, and control of hypertension in Punjab and Haryana, India.

		Punjab			Haryana		
		Awareness	Treatment	Control	Awareness	Treatment	Control
		OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)
Education	No formal schooling	0.3 (0.04–1.3)	0.7 (0.3–1.0)	0.3 (0.1–0.6)	0.94 (0.6–1.4)	0.9 (0.5–1.8)	0.4 (0.2–0.9)
	Primary education	0.5 (0.4–1.8)	0.7 (0.4–0.9)	0.8 (0.4–1.2)	1.1 (0.7–1.6)	1.0 (0.8–3.0)	0.7 (0.3–1.1)
	Secondary education	0.6 (0.4–1.9)	0.9 (0.4–1.8)	1 (06–1.6)	0.8 (0.6–1.3)	1.3 (0.7–2.3)	0.8 (0.5–1.4)
	Higher education	1	1	1	1	1	1
Current tobacco use	Yes	1.7** (1.1–2.5)	0.8* (0.6–1.1)	0.9 (0.6–1.7)	1.8** (1.2–2.4)	1.2 (0.7–1.9)	0.8 (0.5–1.3)
	No	1	1	1	1	1	1
Current alcohol use	Yes	0.9 (0.6–1.1)	0.7 (0.5–1.0)	0.8 (0.4–1.2)	0.5* (0.3–0.7)	1.3 (0.7–2.2)	0.9 (0.7–1.8)
	No	1	1	1	1	1	1
Gender	Males	0.2* (0.1–1.7)	0.4* (0.2–0.9)	0.8 (0.4–1.4)	1.27 (0.85–1.9)	0.7* (0.4–1.2)	0.5* (0.3–0.7)
	Females	1	1	1	1	1	1
Age group	18–44	3.6* (3.1–4.1)	1.2 (0.8–1.9)	2.3 (1.8–3.1)	3.2* (2.5–4.1)	1.4 (1.1–2.0)	0.4* (0.3–0.7)
	45–69	1	1	1	1	1	1
Family history of hypertension	Yes	1.1* (0.6–1.8)	0.8 (0.6–0.9)	1.1 (0.7–1.5)	2.49** (2.3–2.6)	1.6* (1.4–2.8)	2.0** (1.4–2.7)
	No	1	1	1	1	1	1
Residence	Rural	1.0 (0.8–1.2)	0.9 (0.5–1.4)	0.8 (0.8–1.4)	1.08 (0.8–1.4)	0.9 (0.7–1.3)	1.1 (0.7–1.3)
	Urban	1	1	1	1	1	1

*$p < 0.05$; **$p < 0.001$.

The variables adjusted include education, residence, age group, family history of hypertension, gender, current tobacco, and current alcohol use.

poor control status of the blood pressure levels while higher awareness and treatment rates in both states.

Factors Associated With Awareness, Treatment, and Control of Diabetes

The multiple logistic regression analysis to find the factors associated with awareness, treatment and control rates of diabetes are given in **Table 5**. Men were more likely to be aware of their diabetes status than women in Punjab and Haryana (OR = 1.1, 95% CI, 0.8–1.9; OR: 1.27, 95% CI, 0.85–1.9).The analysis highlights that the family history of diabetes is associated with higher odds of being aware, treatment, and controlled blood glucose levels in both Punjab and Haryana. Also, the current tobacco and alcohol use is negatively related with control status of the blood glucose levels.

DISCUSSION

The study reports a high prevalence of hypertension and diabetes in Punjab and Haryana, the two major north Indian states. The estimates for diabetes, i.e., 14 and 15.5% are higher than the global average of 9% and that of other South Asian countries (23, 24). The prevalence of hypertension reported in Punjab is also higher than the national average of 29.8% (25). Economic

TABLE 5 | Multivariable Logistic Regression Model to assess Factors associated with awareness, treatment, and control of diabetes in Punjab and Haryana, India.

		Punjab (*N* = 2,366)			Haryana (*N* = 2,488)		
		Awareness	**Treatment**	**Control**	**Awareness**	**Treatment**	**Control**
		OR (95% CI)	**OR (95% CI)**	**OR (95% CI)**	**OR (95% CI)**	**OR (95% CI)**	**OR (95% CI)**
Education	No formal schooling	0.6 (0.6–1.1)	0.1* (0.03–0.4)	0.8 (0.3–1.8)	0.6 (0.4–1.4)	0.8 (0.5–1.8)	0.4 (0.2–0.9)
	Primary education	0.8 (0.7–1.4)	0.3 (0.05–0.8)	0.7 (0.6–2.6)	0.4 (0.3–1.6)	0.8 (0.8–3.0)	0.7 (0.3–1.1)
	Secondary education	0.4 (0.4–1.0)	0.8 (0.3–1.2)	0.9 (0.4–1.9)	0.8 (0.6–1.3)	1.3 (0.7–2.3)	0.9 (0.5–1.4)
	Higher education	1	1	1	1	1	1
Current tobacco use	Yes	1.04 (0.6–1.9)	0.9 (0.7–1.8)	0.7 (0.6–2.0)	0.8** (0.6–2.4)	1.2 (0.7–1.9)	0.6 (0.5–1.3)
	No	1	1	1	1	1	1
Current alcohol use	Yes	1.3 (0.9–1.5)	0.8 (0.4–1.1)	0.4 (0.3–1.3)	0.5* (0.3–0.7)	1.3 (0.7–2.2)	0.7 (0.7–1.8)
	No	1	1	1	1	1	1
Gender	Males	1.1 (0.8–1.9)	1.2 (0.8–2.0)	1.09 (0.4–2.0)	1.27 (0.85–1.9)	0.9 (0.4–1.4)	1.5* (0.3–1.7)
	Females	1	1	1	1	1	1
Age group	18–44	0.2* (0.2–0.4)	3.0* (1.3–4.0)	2.3 (1.4–3.2)	3.2* (2.5–4.1)	1.4 (1.1–2.0)	0.4* (0.3–0.7)
	45–69	1	1	1	1	1	1
Family history of Diabetes	Yes	1.2* (0.9–1.5)	1.1* (0.5–2.5)	0.5 (0.2–1.2)	1.49** (1.3–2.7)	1.6* (1.4–2.8)	0.6** (0.4–2.7)
	No	1	1	1	1	1	1
Residence	Rural	0.8 (0.6–1.1)	1.5 (0.6–2.2)	0.9 (0.4–1.9)	1.0 (0.8–1.4)	0.9 (0.7–1.3)	1.1 (0.7–1.3)
	Urban	1	1	1	1	1	1

*$p < 0.05$; **$p < 0.001$.

The variables adjusted include education, residence, age group, family history of diabetes, gender, current tobacco, and current alcohol status.

development, changes in lifestyle and diet, and an increase in life expectancy may explain the rapidly increasing prevalence of hypertension and diabetes in developing countries (26).

A large proportion of the population in these two states suffers from uncontrolled high blood pressure and diabetes. Eighteen percent of cases of hypertension in Punjab, while only 12% of cases of hypertension in Haryana were under control, which is startling. The results of these two states are consistent with other studies conducted in different states of India. Several previous studies conducted in India reported similar data on blood pressure and diabetes control rates which were alarmingly low. The level of awareness ranges from 26 to 59%, while the control rates are as low as 10–45% (12, 25, 27–32).

A systematic review of population-based studies from 90 countries conducted in 2016, showed that less than half (46.5%) of adults with hypertension were aware of their condition, 36.9% were treated with antihypertensive medication, and only 13.8% had their blood pressure controlled worldwide (9). High-income countries had almost double the proportions of awareness (67.0 vs. 37.9%) and treatment (55.6 vs. 29.0%) and 4 times the proportion of control among patients with hypertension (28.4 vs. 7.7%) in comparison with low- and middle income countries.

The country-level analysis of the hypertension care cascade, however, disguises the large variation in the care cascades among states and population groups (25). In the studies conducted abroad, the percentage of people who were aware of their hypertensive status varied between 24.1 and 81.8%. The proportion of treated population among the aware population was ranged from 36.1 to 82.1%. The percentage of controlled disease varied between 10.6 and 50.7% of the treated population (33–36).

The study also highlights that having a family history of hypertension or diabetes is a predictor for awareness and treatment for the condition. Implications of our findings are that there needs to be substantial investment in health promotion to raise awareness, and changes in healthcare delivery that address treatment and control of diabetes regardless of socio-demographic status.

Hypertension and diabetes are a major public health problem in Punjab and Haryana and awareness, treatment, and control rates are low which require specific interventions with a focus on access to treatment, regular follow up for better control. Despite the screening process which have been undertaken for NCDs including hypertension diabetes being a major component of the National Programme for Control of Cancer, Diabetes, Cardiovascular Diseases, and Stroke (NPCDCS) in India, implementation is abysmal (37, 38). The low levels of awareness and control rates indicate toward the need for aggressive health promotion program under NPCDCS.

The undiagnosed cases of hypertension and diabetes if left untreated are more prone to complications and morbidity including cardiac failure, kidney failure, cerebral stroke, and damage to blood vessels (39, 40). Hence, it is imperative to identify and offer early therapy to these individuals and ensure regular follow up.

At the primary care level, screening for these conditions among asymptomatic persons shall be useful in their early diagnosis and management. Appropriate counseling to improve adherence to treatment and advice is likely to result in better

control of these conditions. While improvements are needed along the entire hypertension and diabetes care cascade, this highlights a particular need for interventions that focus on the awareness and treatment steps of the cascade. There is an urgent need to effectively implement the existing national NCD programmes in these states in India.

Strengths and Limitations of the Study

The strengths of the present study are that it utilizes the data from two state wide representative population based, multistage sample including adults 18–69 years of age. Both the surveys had a high response rate and followed the standard WHO STEPS methodology. One of the limitation of the surveys was drawing the blood sample from a subset of the total population owing to the resource constraints. Also, the blood glucose was measured was through a glucometer instead of glucose measurement on venous blood sample.

DATA AVAILABILITY STATEMENT

The datasets presented in this study can be found in online repositories. The names of the repository/repositories and accession number(s) can be found below: https://doi.org/10.1371/journal.pone.0208872.s005; https://doi.org/10.1371/journal.pone.0157705.s001.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the Institute Ethics Committee, Postgraduate Institute of Medical Education and Research. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

JT: conceptualization, funding acquisition, and resources. RN: data curation and writing – original draft. JT and RN: formal analysis, investigation, methodology, validation, and writing – review and editing. All authors contributed to the article and approved the submitted version.

FUNDING

This study was supported by two state-wide surveys of National Health Mission (State NCD Cell, Punjab and Haryana), Ministry of Health and Family Welfare, Government of India.

ACKNOWLEDGMENTS

The author would like to thank all the members of the Technical Advisory Committee of NCD Risk Factor Survey Punjab and Haryana and the chairperson Prof. S. K. Jindal for the technical support in designing and implementation of the surveys. And also like to thank the Investigators from the participating medical institutes namely Dr. Sanjay Jain, Dr. Rajender Prasad, Dr. Arnab Pal, Dr. K. L. Gupta, Dr. Vivek Kumar, and Dr. Sandeep Grover (Post graduate Institute of Medical Education and Research, Chandigarh); Dr. Shavinder Singh (Christian Medical College, Ludhiana); Dr. Amarjit Singh (Government Medical College, Patiala); Dr. SS Deepti and Dr. Mohan Lal (Government Medical College, Amritsar); Dr. Sanjay Gupta (Guru Gobind Singh Medical College, Faridkot); Dr. Ramesh Verma (Pandit Bhagwat Dayal PGIMS, Rohtak); Dr. Ramnika Aggarwal (Kalpana Chawla Medical College, Karnal); Dr. Mohd. Haroon Khan (Shahid Hassan Khan Mewati Medical College, Mewat); Dr. Tanica Lyngdoh (Indian Institute of Public Health, Public Health Foundation of India, Gurugram); and Dr. Rajiv Saran (University of Michigan, USA) for their active participation and valuable inputs for the surveys.

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Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

frontiers | Frontiers in Public Health

ORIGINAL RESEARCH
published: 06 April 2022
doi: 10.3389/fpubh.2021.768705

Perceptions of the Doctor-Patient Relationship Among Patients in a Private, Secondary-Level Hospital in Southern India

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OPEN ACCESS

Edited by:
Kavumpurathu Raman Thankappan, Central University of Kerala, India

Reviewed by:
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Dorothy Lall, Government Vellore Medical College, India

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Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: 01 September 2021
Accepted: 22 December 2021
Published: 06 April 2022

Citation:
Gala P, Sriram V, Kotian C, Ballala K, Vedanthan R, Perish E, Umakanth S and Meltzer D (2022) Perceptions of the Doctor-Patient Relationship Among Patients in a Private, Secondary-Level Hospital in Southern India. Front. Public Health 9:768705. doi: 10.3389/fpubh.2021.768705

Introduction: An epidemic of non-communicable diseases (NCDs) in India is fueling a growing demand for primary care and hospitalization services. Difficulties in coordinating inpatient and outpatient care create significant barriers to providing high-quality medical care. In this paper, we describe patient experiences, perceptions, and expectations of doctor-patient relationships in a secondary-level private hospital in Karnataka, India.

Methods: We conducted a cross-sectional, mixed-method needs assessment with surveys and in-depth interviews at Dr. TMA Pai Hospital (TMAPH), a secondary-level, private sector hospital in Karnataka, India. Inclusion criteria included all adults over 18 years old hospitalized at TMAPH in the past year. Patients were consecutively recruited from August 2019-October 2019 and asked to rate aspects of their relationship with their primary care provider (PCP). Descriptive statistics and multivariable logistic regression were used to analyze predictors of the doctor-patient relationship. Patients were interviewed regarding their perceptions of care coordination and doctor-patient relationships. General Thematic Analysis was utilized to analyze qualitative data and develop themes. Quantitative and qualitative findings were then merged to interpret the various dimensions of doctor-patient relationships.

Results: A total of 150 patients (47.3% male) enrolled. Ten patients underwent qualitative interviews. The median patient age was 67 years (IQR 56–76). 112 (74.7%) of patients identified a PCP either at or outside of TMAPH. 89% had diabetes and/or hypertension. Compared to patients without a PCP, having a PCP led to a significantly higher adjusted odds of always spending optimal time with their doctors (aOR 2.7, 95% CI 1.1–6.8, $p = 0.04$), and always receiving clear instructions on managing their medical conditions (aOR 2.5, 95% CI 1.0–6.1, $p = 0.04$). The following themes were developed from patient interviews: (1) patients trusted and respected their PCP believing they were receiving high quality care; and (2) despite perceived fragmentation in care, patients spoke favorably of their relationships with their doctors.

Conclusions: Among a sample of recently hospitalized patients, those with a PCP reported more positive doctor-patient relationships, though rates of dissatisfaction with doctors were still high. Further research and strategies are required to optimize continuity of care and doctor-patient relationships across the entire continuum of outpatient and inpatient care.

Keywords: non-communicable diseases, doctor-patient relationship, quality of care, low- and middle-income countries, provider trust

INTRODUCTION

The burden of chronic illness is rapidly increasing in India. 60% of all deaths in India are attributed to non-communicable diseases (NCDs) (1). From 1990 to 2016, mortality attributed to diabetes (DM) and cardiovascular disease (CVD) increased by 250 and 215%, respectively (2, 3). The delivery of quality care to address this growing burden of chronic disease remains a persistent challenge in India (4). Doctor-patient relationships are central to any discussion around quality-of-care for patients. Strong doctor-patient relationships have been shown to improve a wide range of health care outcomes including medication adherence, reduced disease co-morbidity, and mortality (5–8).

Researchers and practitioners in India have observed a deterioration in the doctor-patient relationship, driven by complex systemic and social factors (9, 10). In other low- and middle income countries (LMICs) poor doctor-patient communication, high doctor workload, the inability of patients to return to the same doctor to develop longitudinal relationships, and decreased medical service quality were drivers of lower doctor-patient trust (10–13).

Continuity of care and having a consistent primary care provider have also been used as proxies for the strength of doctor-patient relationships. As defined by primary health care experts, relational continuity as used in our study refers to "a therapeutic relationship between a patient and one or more providers that spans various healthcare events and results in accumulated knowledge of the patient and care consistent with the patient's needs." (14). In other studies, continuity of care has shown to be associated with higher rates of screening of diabetes (DM) and hypertension (HTN) (15), improved physical and mental health (7), and reduced hospitalization, disease-related complications, and mortality in patients with chronic diseases (8, 13).

Anecdotal evidence from Dr. TMA Pai Hospital (TMAPH), Udupi, an urban secondary-level private hospital in Karnataka, India has found that due to steady increases in complex patient populations, physicians are experiencing increasing pressures on their time in the outpatient setting. As a result, care is increasingly fragmented, with a potential to cause adverse outcomes of re-hospitalization, rising costs, and perceived harm to the patient and doctor experiences. There is also a limited understanding of how such changes were impacting doctor-patient relationships and quality of care more broadly. Beyond the immediate relevance of these findings to TMAPH, research on quality of care and improvements to the doctor-patient relationship is urgently needed to address the increased severity, complexity, and need for continuity of patients with diabetes, hypertension and other chronic conditions in India to prevent hospitalizations and adverse healthcare complications.

In this paper, we describe patient experiences, perceptions, and expectations of doctor-patient relationships of patients seeking care at TMAPH.

METHODS

Study Design

We carried out a cross-sectional, mixed-method needs assessment with two components: (1) quantitative surveys of patients hospitalized or seen in the outpatient setting after recent hospitalization at TMAPH; (2) in-depth qualitative interviews with a subset of patients. Quantitative and qualitative arms of the study were conducted concurrently.

Settings and Participants

Udupi is a southern district in the state of Karnataka in India with a population of approximately 1.2 million people. About 28% of the population lives in urban areas (16). The literacy rate ranges from 83.9% (rural) to 92.1% (urban). TMAPH is a private, urban, secondary level hospital located in the city of Udupi (population 144,960) in the district of Udupi which offers services in nearly 15 specialties including general medicine and cardiology. The hospital operates under the umbrella academic institution of Manipal Academy of Higher Education (MAHE) and within the referral network, has close ties to community hospitals and an affiliated tertiary level hospital Kasturba Hospital at Manipal. The Manipal healthcare system is a private hospital system that provides discounts and insurance cards for their patient population. The Manipal Arogya card cuts outpatient patient consultation fees by 50% (17).

Quantitative Methods

Participants

Adult patients admitted to the medical wards or presenting post-discharge at the outpatient clinic at TMAPH were recruited for the study. Eligible participants were those with at least one hospitalization in the medical ward at Udupi (including current hospitalization) in the past year. Exclusion criteria included children <18 years old, pregnant women, patients unable to consent due to altered mental status, patients with active tuberculosis, and patients currently in the intensive care unit.

Sample Size

We aimed to recruit 150 or an estimated 5% of the annual population hospitalized at Udupi for a representative sample.

Study Tool Validation

A survey tool for patients and providers was co-constructed by study investigators and research coordinators at MAHE and the University of Chicago. Trained translators were employed to translate the survey into Kannada. During a pilot phase in July 2019, a sample of five hospitalized patient-participants underwent cognitive interviewing. Surveys were revised accordingly.

Data Collection

From August 2019 to October 2019, patients were recruited consecutively. The research team reviewed the list of patients admitted to TMAPH with the medical team to determine which patients were appropriate to recruit and interview based on inclusion and exclusion criteria and proximity to discharge date. Patients were recruited at or within 24 h of discharge to avoid interference with the provision of medical care for active medical issues. The research team also recruited patients from the outpatient clinic at TMAPH. 150 patients consented and completed quantitative surveys. Tablets were used to record survey data into REDCAP. Data from patients were collected on socio-demographics, self-rated health, satisfaction with outpatient care delivery, and outpatient doctor-patient relationships at TMAPH and outside of TMAPH.

Hall et al. (18) outline five key provider qualities necessary to build strong doctor patient relationships, including *fidelity* (genuine interest in a patient), *honesty, competence* (both knowledge and communication skills), *confidentiality, and global trust.* To assess the outpatient patient-doctor relationship, patients were asked to rate their doctors as always, sometimes, or never for the following elements (previously validated at University of Chicago) (19, 20). A primary care provider (PCP) in this study was defined as a qualified health care provider with either a MBBS degree (MD in United States), internal medicine specialization or family medicine specialization who provides continued care (2+ visits) and is the first provider of contact regardless of health concern (e.g., not limited by organ system or type of health concern) for a patient.

Binary outcomes were categorized as optimal (always) and suboptimal (sometimes, never).

- In the past 12 months, how often was this doctor knowledgeable about your medical history?
- How often did you feel that you could tell your doctor anything, even things you might not tell anyone else?
- How often did the doctor explain things in a way that was easy to understand?
- How often did this doctor spend enough time with you?

Statistical Analysis

Descriptive statistics were used to assess the quantitative data in this study. Multivariable logistic regression was used to determine the patient reported factors that were associated with components of the doctor-patient relationship including having enough time with their doctors, trusting their doctors, receiving clear instructions from their doctors, and having their doctors always being knowledgeable of their medical conditions. Additional factors included underlying medical conditions, and identifying a PCP. STATA v. 15 was used for quantitative data analysis.

TABLE 1 | Qualitative interview guide excerpt.

Interview guide
Domain I: patient needs
Let's start by discussing your healthcare needs.
How would you describe your health right now?
What role does your doctor play in keeping you healthy?
Domain II: Patient expectations of the provider—patient relationship
When you are choosing a doctor, what factors are important to you?
How do these factors change when you have a short-term illness, such as a cough or fever? Where do you seek treatment?
What about chronic conditions, such as diabetes or hypertension? Where do you/would you seek treatment?
How would you describe your relationship with your doctor at Dr. TMA Pai Hospital? (Probe: how well do they know you as a person, your medical history, coordinating with other doctors?)

Qualitative Methods

Participants

Maximum variation sampling—a form of purposive sampling—was utilized to identify participation (21). We identified patients in order to construct a sample consisting of patients with a diverse range of characteristics—age, gender, socioeconomic status, and co-morbidities—but who were all hospitalized at least once within the past year (22). Through this sampling approach and after achieving data saturation, we ultimately recruited ten participants from the quantitative survey phase of the study to participate in a qualitative interview. Exclusion criteria included children <18 years old, pregnant women, patients unable to consent due to altered mental status, patients with tuberculosis and patients currently in the intensive care unit.

Interview Guide Development and Data Collection

The research team at MAHE and University of Chicago developed the interview guide to elicit responses around health care needs, expectations of the doctor-patient relationship, and experiences in the clinic and hospital. **Table 1** outlines a selection of questions from the interview guide. Trained research assistants and members of the research team conducted the interviews. Written informed consent for the quantitative interview included a section on a chance of being selected for a qualitative interview. Interviews were audio-recorded, lasted approximately 30–45 mins and were conducted in Kannada, Tulu, Hindi, and English based on the language preference of the participant. Patient interviews were de-identified, transcribed and translated into English by a contracted transcriber.

Data Analysis

Qualitative data were analyzed using General Thematic Analysis (23). This is an approach that allows for theoretical framework

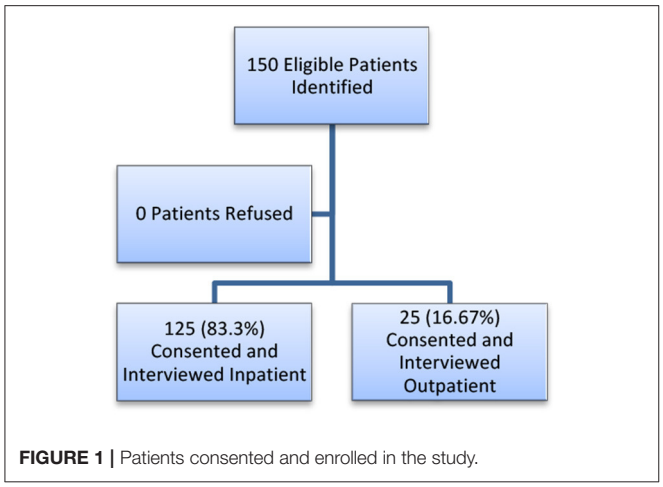

FIGURE 1 | Patients consented and enrolled in the study.

flexibility to arrive at themes that explain people's experiences, perceptions, or representations of a topic. The codebook was developed by VS, CK and PG using an inductive approach, where codes were generated from the data using line-by-line coding with three transcripts. After the codebook was finalized, two analysts (VS, CK) both coded ten patient transcripts manually using Microsoft Word. Analysts discussed reached consensus on points of disagreement through frequent discussions. When all ten transcripts were coded with consensus reached among the coders, one analyst (VS) reviewed the coded data and developed themes by (1) reviewing data from *within* each code in order to understand patterns in patient experiences; (2) by reviewing data *across* codes in order to develop broader themes. Weekly discussions with VS, CK, and PG refined the analysis.

Mixed Method Analysis

Data from both strands were triangulated using a framework from Hall et al. on doctor patient relationships. The research team analyzed findings concurrently and merged in order to bolster interpretation of findings. For example, qualitative data were used to illustrate key findings from the quantitative results from the survey data.

Ethics

The study protocol and all study materials were approved by the institutional review boards of Manipal Academy of Higher Education, Manipal, Karnataka, India, and the University of Chicago, Chicago, IL.

RESULTS

Patient Demographics and Co-morbidities

A total of 150 patients were consecutively recruited, 125 (83.3%) were enrolled from the inpatient setting and 25 (16.7%) were enrolled from the outpatient setting post-discharge. All eligible patients approached by research assistants consented and enrolled in the study (**Figure 1**).

Patients' median age was 67 years (IQR, 56–76 years) and 47% of patients were male. 19.5% of patients completed a high school level of education. 38% held a Below Poverty Line (BPL) card. 12.8% reported being unemployed, not including categories of retired and homemakers. The average number of co-morbidities in this population was 2.4 (SD 1.0). Seventeen (11.3%) patients had no underlying DM/HTN, 41 (27.3%) had HTN alone, 26 (17.3%) had DM alone, and 66 (44%) had both HTN and DM. Patients visited the outpatient clinic an average of 2.1 (SD 1.4) times over the course of 12 months. The average number of hospitalizations in the past 12 months was 1.4 (SD 0.9) and the average number of lifetime hospitalizations was 4.1(SD 4.2) (**Table 2**). 112 (74.7%) patients reported having a primary care provider, and 38 (25.3%) reported having no primary care provider.

Among the ten patients that underwent qualitative interviews, 30% were male and ages ranged from 47–80 years (median 65.5). Most patients were above poverty level (60%), 20% lived in rural areas, 30% in urban areas, 40% in sub-urban areas, and 50%

TABLE 2 | Socio-demographic factors and co-morbidities of patients by PCP status.

	Primary care doctor ($n = 112$)	No primary care doctor ($n = 38$)	Total ($n = 150$)	p value
Age (median)	67 (IQR 53–75.5)	69.5 (IQR 58–76)	67 (IQR 56–76)	
Age over 65	8 (47%)	26 (63%)	88 (59%)	0.07
Gender (male)	51 (46%)	20 (53%)	71 (47%)	0.45
High school diploma	43 (38%)	15 (39%)	58 (39%)	0.91
Unemployed	13 (12%)	6 (16%)	19 (13%)	0.42
Number of co-morbidities	2.3 (1.0)	2.6 (1.1)	2.4 (1.1)	0.18
Below poverty line (BPL) ration card*	33 (35%)	15 (44%)	48 (38%)	0.87
Rural residence	41 (37%)	20 (53%)	61 (41%)	0.08
Number of hospitalizations in past 12 months	1.4 (0.9)	1.5 (1.0)	1.4 (0.9)	0.9
Number of lifetime hospitalizations	4.1 (4.3)	4.3 (3.7)	4.1 (4.2)	0.78
Distance to TMA pai hospital (minutes)	30.9 (2.6)	37.4 (7.9)	32.5 (2.8)	0.31
Yearly median household expenditure on healthcare	16,476 INR (1,772 INR)	8,851 INR (2,435 INR)	14,517 INR (1,883 INR)	0.08
Insurance coverage	89 (79%)	31 (84%)	120 (81%)	0.57
Co-morbidities				
Number of Co-morbidities	2.3 (1.0)	2.6 (1.1)	2.4 (1.1)	0.18
No HTN/DM	13 (12%)	4 (11%)	17 (11%)	0.86
HTN and/or DM	99 (88%)	34 (90%)	133 (89%)	0.86
Hypertension only	30 (27%)	11 (29%)	41 (27%)	0.80
Diabetes only	23 (21%)	3 (0.1%)	26 (17%)	0.08
HTN/DM combined	46 (41%)	20 (53%)	66 (44%)	0.22

**Below Poverty Line is used by the Indian government to identify economically disadvantaged households in need of government assistance. The criteria are varied by state and between rural and urban communities.*

TABLE 3 | Most common reasons for hospitalization.

Most common reasons for hospitalization ($n = 123$) *	Percentage
Infection total	**51.2%**
Respiratory infections ($n = 23$)	18.7%
Urinary tract infections ($n = 13$)	10.5%
Dengue, malaria ($n = 9$)	7.3%
Cellulitis ($n = 8$)	6.5%
Gastrointestinal: vomiting, diarrhea ($n = 5$)	4.1%
Other (dengue, non-specific fever, malaria, sinusitis) ($n = 5$)	4.1%
Exacerbation of chronic disease total	**37.4%**
COPD/Asthma ($n = 19$)	15.4%
Diabetes/hyperglycemia ($n = 19$)	15.4%
Cardiovascular complications (stroke, heart failure, high blood pressure) ($n = 8$)	6.5%
Miscellaneous (hemoptysis, anemia, weakness, liver disease, fainting, sodium deficiency) ($n = 14$)	**11.4%**

**27 missing reasons for hospitalization.*

had an education below high school level. Patients had between 2–5 chronic conditions (median 3), 60% with DM, 90% with HTN, 30% with cardiac disease, and had been hospitalized 1-23 (median 5) times in their lifetimes (**Supplementary Materials**).

Awareness of Diabetes and Hypertension

When compared to diagnoses listed on a patient's medical chart, 94.4% of patients with HTN were aware of having HTN and 96.8% of those with DM were aware of having DM. In comparison, fewer patients (71.1%) with a diagnosis of cardiac disease (heart failure, ischemic heart disease) in their chart were aware of that diagnosis.

Hospitalizations

There was no difference in number of hospitalizations in the past 12 months ($p = 0.78$) or number of lifetime hospitalizations (0.31) between those who had a PCP and those who did not (**Table 2**). Of note, the average number of lifetime hospitalizations was highest in those with co-morbid DM and HTN (No disease: 3.7 vs. HTN: 4.10 vs. DM: 3.16 vs. HTN/DM: 4.6) (**Supplemental Materials**). The most common chief complaints about last or current hospitalization for all patients included infections (51.2%) followed by an acute exacerbation of chronic illness (36.6%) (**Table 3**).

Characterizing the Doctor-Patient Relationship

Compared to patients without a PCP, after controlling for age and gender, having a PCP led to a significantly higher odds of always spending optimal time with their doctors (OR 2.7, 95% CI 1.1–6.8, $p = 0.04$), always trusting their doctor with their medical information (OR 2.7, 95% CI 1.0–7.4, $p = 0.05$), and always receiving clear instructions on managing their medical conditions from their doctors (OR 2.5, 95% CI 1.0–6.1, $p = 0.04$). There was a trend toward significance of a higher odds of those with a PCP always reporting that their doctor was knowledgeable of their medical history (OR 2.3, 95% CI 0.9–5.6, $p = 0.07$) (**Table 4**; **Figure 2**). Amongst those with either DM and/or HTN, those with DM alone reported lower odds of always receiving clear instructions about managing their medical conditions (OR 0.2, 95% CI 0.04–0.9, $p = 0.03$) and lower odds of their doctors always being knowledgeable about their medical conditions (OR: 0.2; CI 0.04–0.99; $p = 0.05$) (**Figure 2**; **Table 4**). See **Supplementary Materials** for a breakdown of each component of the doctor-patient relationship by underlying condition (DM, HTN, DM/HTN, neither) and having a PCP.

Several patients reported respecting and trusting their PCPs, praising their bedside manner, the time they make for patients no matter how busy they might be, and the way they explain medical conditions.

> *An 80-year-old male with DM, HTN, cardiac disease, kidney disease, four lifetime hospitalizations who was retired with a post-graduate education living in an urban setting reported "His [Dr. D] medicines are best. The way Dr. D talks is best and the way this doctor looks after me is best. You cannot find this [quality of care] anywhere."*
>
> *A 64-year-old F with DM and HTN who lived below poverty in a rural setting noted "Yes, we come here only, as Dr. Z [explains], I follow. I won't go anywhere else, I want him only to see me. He'll also treat me only, however busy he might be..."*

While patients complained about long wait lines to see their doctors, there was no mention of having insufficient time with their doctor during a clinic visit.

Continuity of Care With Doctors

While many patients identified individual doctors they saw regularly, there was evidence of fragmented care. Some patients saw multiple doctors due to their high burden of chronic diseases and visits to both generalists (MBBS, internal medicine, family medicine) and specialists.

> *An 80-year-old M with DM, HTN, cardiac disease, and kidney disease reports: "Yeah sometimes I see other doctors also because I go to Manipal KMC… There I had the chance to see many doctors… There are different types of doctors there."*

At times discontinuity was due to doctors leaving TMAPH or having long wait times until the next appointment.

> *A 67-year-old M with DM, HTN, cardiac disease, thyroid disease, kidney disease, and over 20 lifetime hospitalizations commented on seeing a few different primary care physicians over time. "When I [first] came, Dr. Z was here. When she left from here… they gave me an appointment for 3 months to Dr. A, then Dr. B, now Dr. A or Dr. B."*

Some patients did not perceive this as an issue; one patient noted that they would be comfortable with any provider, as each doctor "is like a god." Other patients discuss their preferences for longitudinal care in the hospital and as outpatient with specific

TABLE 4 | Logistic regressions for the perception of the patient-doctor relationship.

Variables	Odds ratio—Time spent*	*p* value	Odds ratio—Knowledge of patient medical history*	*p* value	Odd ratio —Trust*	*p* value	Odds ratio—Clear instructions*	*p* value
Age	1.0 (CI 0.98–1.0)	0.38	1.0 (CI 0.97–1.0)	0.9	1.0 (CI 0.97–1.03)	0.91	1.0 (CI 0.97–1.0)	0.95
Gender	0.6 (CI 0.3–1.4)	0.23	1.2 (CI 0.5–2.5)	0.72	1.5 (CI 0.6–3.4)	0.38	1.1 (CI 0.5–2.4)	0.82
Below poverty line	0.5 (CI 0.2–1.1)	0.08	0.98 (CI 0.4–2.2)	0.97	0.9 (CI 0.3–1.9)	0.78	1.3 (CI 0.6–2.9)	0.53
Having a primary care provider	2.7 (CI 1.1–6.8)	0.04	2.3 (CI 0.9–5.6)	0.07	2.7 (CI 0.997–7.4)	0.051	2.5 (CI 1.0–6.1)	0.04
Hypertension+	0.2 (CI 0.05–0.8)	0.03	0.7 (CI 0.2–2.8)	0.65	0.7 (CI 0.2–2.7)	0.6	0.5 (CI 0.1–1.9)	0.32
Diabetes+	0.08 (CI 0.01–0.4)	0.003	0.2 (CI 0.04–0.99)	0.050	0.2 (CI 0.03–1.02)	0.053	0.2 (CI 0.04–0.9)	0.03
Hypertension and diabetes+	0.3 (CI 0.08–1.3)	0.1	0.8 (CI 0.2–2.9)	0.76	0.8 (CI 0.2–2.8)	0.70	0.8 (CI 0.2–2.9)	0.79

**95% confidence interval.*

+As compared to patients with no diabetes nor hypertension.

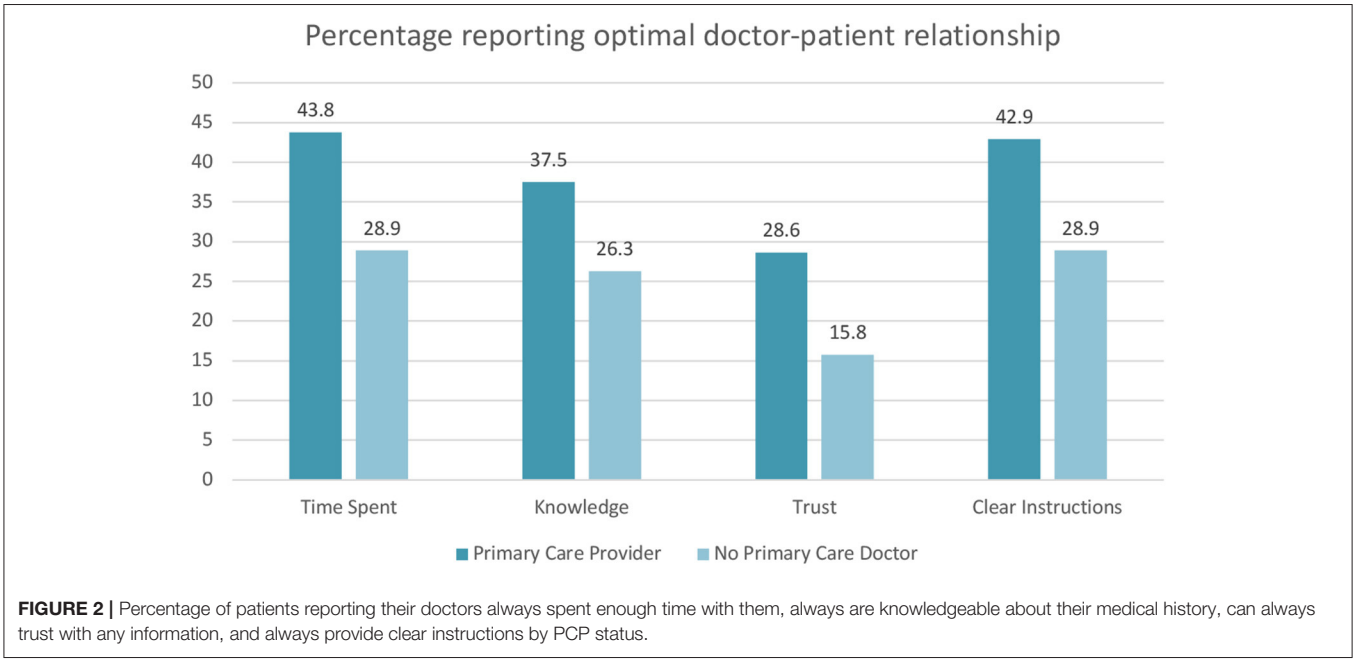

FIGURE 2 | Percentage of patients reporting their doctors always spent enough time with them, always are knowledgeable about their medical history, can always trust with any information, and always provide clear instructions by PCP status.

doctors that they trust. Some patients insisted on continuity of care with those doctors with skepticism to the quality of care they would receive from providers who were not their PCP. For these patients, their PCP provided them with confidence and reassurance.

A 73-year-old female with lung disease, HTN, and liver disease, five hospitalizations and a high school education noted, "We come[mainly] to meet him. We don't go to anyone else. When Dr. C tells me or explains, I feel confident about my health. With others, I think I am not sure I will get the same reassurance. That's why [when] I fall [sick], I don't visit any other doctor. Very rarely."

Additional Factors Affecting the Doctor-Patient Relationship

In the quantitative data, there was no significant difference in perceptions of components of the doctor-patient relationship associated with age, gender, or below poverty line (BPL) status (**Table 4**). In qualitative analyses, some patients more highly educated or with a higher socio-economic status differentiated

between specialist physicians and PCPs, but otherwise there were no clear distinctions when patients described their doctors.

A retired 80-year-old M with a post-graduate education with DM, HTN, cardiac disease, and kidney disease, four lifetime hospitalizations and living APL recalled about his primary care doctor "Though he is not a cardiology doctor, he is quite capable of answering certain questions though [it is not his expertise].

At times a combination of the education of a patient, their health awareness, and age resulted in more doctor communication with family members than the patient.

A 56-year-old F with DM, HTN, and lung disease, two lifetime hospitalizations, and with a BPL card denied discussing her health problems with her doctors:

*"**I:** About your health problems, do they discuss with you about the disease and how is it?*

***P:** No, no.*

***I:** Say nothing? Do they tell your children?*

***P:** Yes, they [tell my] children."*

Finally, patients that identified a primary care doctor had a trend toward higher yearly median household expenditure on healthcare [16,476 INR (221 USD) vs. 8,851 INR (119 USD), $p = 0.08$]. Insurance coverage was similar in both groups of patients (**Table 1**). Patients in qualitative interviews commented on out-of-pocket costs of medical care in the private sector but still preferred TMAPH over other facilities.

A 67-year-old M with five chronic conditions (DM, HTN, cardiac disease, kidney disease, thyroid disease), APL, retired with a higher secondary education living in an urban setting reported compliance with his medications despite it being financially difficult to cover all expenses with his insurance health card, he recognizes the importance of managing for his health. "if it is costly, no problem, [my] health is first."

He continues: "Once I asked here, is there any little low-cost facility…?" …Dr. Y told me, "There is one but I won't advise you [to go there]."… I thought taking some 20% discount losing my health is not a good choice so I canceled that one."

DISCUSSION

There has been a steady rise in the numbers of patients with complex needs (i.e., patients living with multiple chronic conditions) in India. One sub-national study found that nearly a third of patients utilizing primary care presented with multi-morbidities (24). Doctor-patient relationships in the outpatient setting, longitudinal continuity of care, and high-quality care are necessary for adequate disease control for these chronic disease patients.

Our study of a population with high rates of DM and/or HTN showed that having a PCP was associated with a higher odds ratio of patients reporting optimal doctor-patient relationships compared to not having a PCP. Patients highly praised doctors that spent adequate time with them, communicated effectively, and whom they trusted with confidential personal information. However, there were still major gaps. Notably even with a PCP, less than half of this population reported always spending adequate time with their doctors, always receiving clear instructions from their doctors, and only 28.6% of those with a PCP reported always trusting their provider with medical and personal information (**Figure 2**). Having a PCP alone may not be as important as developing doctor-patient relationships built on confidentiality, global trust, fidelity, honesty, communication and medical knowledge competence (18) with any one or multiple doctors involved in a patient's care. In the Indian healthcare system, patients seek out primary care providers for general healthcare concerns as well as prevention (e.g., vaccination). The supply of primary care doctors (and qualifications) is dependent on providers choosing general medicine, internal medicine, or family medicine as their specialty, similar to what exists in many other countries worldwide. More research is needed in India to explore the associations between having a PCP, elements of strong doctor-patient relationships and health outcomes.

Despite low rates of trust, receiving clear instructions, and spending adequate time with PCPs noted in quantitative surveys, patients in this study may have demonstrated a social desirability bias in qualitative interviews. When asked to expand on perceptions of doctors, this patient population may have had a tendency to answer more favorably or positively for multiple reasons. Patients were interviewed in the healthcare setting, which may not have felt like a secure, objective environment for all patients. To counter this, all surveys and interviews were conducted in private settings by research staff not associated with the hospital or outpatient clinic. Additionally, inpatient interviews were conducted on or 24 h prior to the day of discharge to eliminate any fear that participation and their responses would jeopardize their clinical care. This patient population also actively chose to seek care at TMAPH instead of going to local or public facilities due to inherently favorable perceptions of TMAPH.

Our quantitative study showed no difference by age, gender, and below poverty line status on perceptions of the doctor-patient relationship. Our qualitative data suggested that age, gender, education, complexity of medical disease may all impact how doctors interact with patients and a patient's perception of their doctor, which is similar to other studies (25, 26). There are many factors that may explain this discrepancy including the wording and patient understanding of quantitative vs. qualitative questions. The categorical questions in the patient survey may have been insufficient in capturing the nuance of patient perceptions of their doctors, which in this study population seemed to encompass not only how doctors communicate with patients but also how doctors incorporate and communicate with patients' families.

Currently, there is a push to improve quality of care in primary care in LMICs, especially with growing rates of DM, HTN and chronic diseases (27–29). While quality has been measured using the cascade of care of care (30–33) and achievement of guideline-based management and counseling strategies (34, 35), fewer studies in LMICs include the role of longitudinal primary care doctors, empanelment, and the doctor-patient relationship in quality-of-care assessments (36).

Given that research has shown that continuity of care improves medication adherence and patient healthy lifestyle behaviors (37–39), more research is needed on the state of continuity of care in LMICs and the doctor-patient relationship. Interventions targeting strengthening this critical relationship and continuity of care with a PCP need to be tested and evaluated in LMICs (36).

Strengths of this study included a mixed methods methodology and a focus on patient perceptions of their experience of the healthcare system. The adequate management of DM and HTN requires patient activation, autonomy and empowerment. Better understanding the factors that affect patient perceptions and patient empowerment is necessary to designing interventions to better manage DM and HTN.

Limitations to this study include due to timeline and convenience, the recruitment of a larger portion of the study population in the hospital instead of the outpatient clinic after discharge. Given this small sample size, we were unable to evaluate the effect of different locations of recruitment on patient perceptions. Patients recruited in the hospital may have more recall bias regarding their outpatient experiences than patients recruited in the outpatient setting.

Our study had a small sample size of patients reporting no PCP. Our study was not designed to evaluate the relationship between perception of the doctor patient relationship, having a PCP and healthcare outcomes. A larger study is recommended to test the hypothesis that a having a PCP improves the doctor-patient relationship as suggested by this study. In the coming year we plan to implement a comprehensive care program at TMAPH to address some of the barriers we identified in this study and determine if strengthening the doctor-patient relationship in India leads to improved health outcomes in medically complex, chronic disease patients.

Our study is one of few studies in LMICs highlighting the association between having a primary care doctor and the doctor-patient relationship in the context of chronic disease (9, 40, 41) and more research is needed to characterize the facilitators and barriers to strong doctor-patient relationships more broadly. There is an urgent need for better disease control amongst HTN and DM patients in India.

Interventions to date have had inadequate impact and reach and there is a dire need to better understand and strengthen the doctor-patient relationship and continuity of care in India.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by University of Chicago, Manipal Academy of Higher Education. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

PG, VS, KB, EP, SU, and DM were all involved in designing the study. CK was the study coordinator and helped pilot test, edited and revised the surveys, and along with PG and VS developed an implementation strategy. PG analyzed the quantitative data, wrote the first draft of the manuscript with additions from CK and VS, and finalized the manuscript incorporating edits from VS, KB, EP, SU, RV, and DM. CK and VS analyzed the qualitative data. All authors contributed to the article and approved the submitted version.

FUNDING

This project was funded by the Section for Hospital Medicine, Department of Medicine, University of Chicago.

ACKNOWLEDGMENTS

The authors thank the Manipal Academy of Higher Education, the Department of Medicine at Dr. TMA Pai Hospital, and the University of Chicago for their support. We thank the research assistants Kishore, Imthiaz, Mahesh, Prasanna, Savithri, and Deepika for their valuable contributions.

SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2021.768705/full#supplementary-material

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Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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frontiers | Frontiers in Public Health

ORIGINAL RESEARCH
published: 10 May 2022
doi: 10.3389/fpubh.2022.766847

Integrated Management of Diabetes and Tuberculosis in Rural India – Results From a Pilot Study

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Introduction: The World Health Organization and International Union against Tuberculosis (TB) recommends screening patients with TB for Diabetes Mellitus (DM) at the initiation of treatment. There are few pilot studies which screen TB patients for DM, but none of them have documented the feasibility of managing TB patients with DM in the Indian healthcare setting. Operational research is needed to determine the best way to manage individuals with both conditions. This pilot study aimed to develop, and field test an integrated, multidisciplinary program addressing the management of individuals with TB and DM and other associated chronic conditions in the Indian primary healthcare setting.

Methods: This pilot study used a randomized controlled trial design with mixed-methods evaluation and was conducted in Guntur district of Andhra Pradesh, a southern state of India. All the 120 patients newly diagnosed with TB from 10 participating villages were screened for DM and associated cardiovascular risk factors. Non-physician health workers were trained to follow-up patients for a period of 8 months to encourage treatment adherence, monitor treatment response including blood glucose levels and provide lifestyle advice.

Results: The intervention was well-accepted by the providers and patients. However, there were no statistically significant variations observed for mean blood glucose levels (mean [SD]: 5.3 [−23.3 to 33.8]) of patients for both intervention and control group participants in this feasibility study. Awareness about diabetes and tuberculosis comorbidity and cardiovascular risk increased among the non-physician health workers in the intervention arm of the study.

Discussion: The co-management of TB-DM is acceptable to both the health providers and patients. With appropriate training, availability of infrastructure and planned intervention implementation, it is feasible to co-manage TB-DM within the existing primary health care system in India.

Keywords: delivery of health care (MeSH), diabetes mellitus, tuberculosis, primary health care (MeSH), feasibility studies

OPEN ACCESS

Edited by:
Francisco Gonzalez-Salazar, Mexican Social Security Institute (IMSS), Mexico

Reviewed by:
Jeff Bolles, University of North Carolina at Pembroke, United States
Roy William Mayega, Makerere University, Uganda

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Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: *30 August 2021*
Accepted: *21 February 2022*
Published: *10 May 2022*

Citation:
Joshi R, Behera D, Di Tanna GL, Ameer MA, Yakubu K and Praveen D (2022) Integrated Management of Diabetes and Tuberculosis in Rural India – Results From a Pilot Study. Front. Public Health 10:766847. doi: 10.3389/fpubh.2022.766847

INTRODUCTION

There is strong evidence about the epidemiological linkage between tuberculosis (TB) and type 2 diabetes mellitus (DM) (1). Globally, 15% of adult TB cases are estimated to be attributable to DM which is nearly the same for HIV-TB association (2). Having DM increases the risk of getting infected with TB infection by 3-fold (1, 3, 4). Coexistence of TB-DM also interferes with treatment outcomes and exacerbate complications (1). Studies have reported that patient with TB and DM have delayed sputum smear conversion, higher chances of TB relapse, treatment failure and death as compared to those without DM (4–6). Conversely, TB also affects glycemic control leading to hyperglycemia among patients (7, 8).

India has the highest burden of TB-DM comorbidity worldwide (4). In 2017, 27% of estimated global TB patients were living in India, with about 410,000 TB related deaths among non-HIV infected population (9). Simultaneously, a fast-emerging economy, demographic and epidemiological transition, and rapid urbanization have resulted in a dramatic increase in DM prevalence in the country. The International Diabetes Federation estimated that 72.9 million Indians had Dm in 2017 (10) and number is projected to increase to 101.2 million in 2030 (10). The anticipated escalating trend of DM epidemic might impede the achievement of End TB strategy by 2025 (11).

To address this emerging challenge in many countries, the World Health Organization (WHO) and the International Union developed a collaborative framework in 2011 which suggested bidirectional screening and combined approaches of care and control for DM and TB (12). Subsequently, the Indian government mandated bidirectional screening of patients with TB and DM (13). Few studies have reported the feasibility of DM screening among patients with TB (14–16), but none of them have documented combined management within Indian health care setting.

The population based non-communicable disease screening program in India currently requires a basic cardiovascular disease (CVD) risk assessment at the community level by the Accredited Social Health Activists (ASHAs), who are India's community health workers, followed by referral and screening of BP, blood sugar (BS) and some of the common cancers for population above 30 years of age by the auxiliary nurse midwife (ANMs) at the sub-center level (17). The patient is then referred to the closest primary health center for diagnoses and treatment (17). There are also clear guidelines for the management of TB and access to free services under the revised national TB control (RNTCP) program (11). However, the integrated care for patients with TB and DM remains a distant dream. Despite India's national framework for joint TB-DM collaborative activities implemented since 2017, the follow-up and joint intervention activities for TB-DM comorbid patients remains ambiguous (13). Also, the population-based screening process for common NCDs under the National Program for the Prevention and control of Cancer, Diabetes, Cardiovascular Disease and Stroke (NPCDCS) program is recommended to be followed for patients with hypertension and DM annually (18), while patients with TB-DM comorbidity need more frequent screening and follow-up. Hence, an integrated intervention protocol on community-based follow-up and care for patients with TB-DM in India is essential for better management and preventing serious consequences of this deadly comorbidity.

In this pilot study, we assessed the feasibility of integrating the screening and management of DM and related chronic conditions such as CVD within the existing TB program of India. It incorporated key strategies of task-sharing between the primary care physician and the ANM (non-physician health worker) and use of technology in providing evidence-based health care. The aim of the study was to develop and evaluate the feasibility, acceptability, and preliminary effectiveness of a complex intervention for the integrated screening and management of DM and TB at the community level.

MATERIALS AND METHODS

Design, Setting and Randomization

This pilot study used a cluster randomized controlled trial design with mixed-methods evaluation and was conducted in Guntur district of Andhra Pradesh, a southern state of India. Recruitment took place from May-October 2017 with an 8-month follow-up period. The end of study evaluation took place from Jan-June 2018. We invited 10 primary health care centers (PHCs) with co-located functional Directly Observed Treatment Short-term (DOTS) to participate in the study. These PHCs were selected based on the discussion with the district health administration and their proximity to The George Institute's Field Office in the district. Patients meeting the eligibility criteria of being aged 18 years or more and newly diagnosed with TB (defined as diagnosed within the last 4 months) were invited to participate. All ANMs working and reporting to the DOTS centers were also invited to be included in the study. Since this was a pilot study to understand the feasibility and acceptability of the intervention, formal sample size calculation was not carried out. Randomization of all 10 sites was conducted prior to initiation of the intervention. Central computer-based blinded randomisation was conducted and the selected PHCs were allocated to intervention and control arms with five PHCs in each group.

Development and Training of Intervention Tools

SMARThealth application has been developed by the George Institute for Global Health as an electronic decision support system to facilitate guidelines-based assessment and management of cardiovascular disease risk to be used by lay health workers and doctors (19, 20). The SMARThealth platform was adapted to include screening and management protocols for DM and TB based on Indian and international guidelines (21–23), and was validated by domain experts and physicians. The development of the platform involved a process of summarizing the clinical guidelines, converting this into a programmable algorithm, performing clinical validation of the algorithm and developing a user interface. Details for development and validation of the SMARThealth platform are explained elsewhere (20). The SMARThealth intervention for this study was designed to be

used *via* android-based tablets. The ANMs used the tablets to screen patients and receive decision support about referral, management, and follow-up.

Prior to the beginning of intervention, all ANMs working at PHCs of that arm were trained for 2 days on TB, DM, and CVD risk and the use of SMARThealth. The training modules included information on co-morbid disease conditions, use of tablet device to administer the screening tools, interpret the decision support output, refer individuals identified to have DM or CV risk to the PHC; and monitor and promote adherence to any prescribed medications and provide lifestyle advice in these individuals.

Intervention

At the beginning of the pilot study, all patients diagnosed with TB were enlisted and invited to participate in the study. Demographic and anthropometric information was collected from the consented patients along with their blood pressure measurement. This information was used for identification of individuals with high risk of DM and CVD by the ANMs using the SMARThealth decision support tool. As per the national guidelines, the random blood sugar (RBS) values were used to screen individuals for DM. Patients with $\geq$110 mg/dl blood glucose levels were referred to the PHC for confirmation of diagnosis. Those with fasting blood sugar (FBG) levels of $\geq$126 mg/dl were diagnosed to have DM and were referred to the PHC physicians for treatment. ANMs followed up the patients during home visits to enquire about blood glucose lowering treatment initiation, provided medication adherence support, and monitored blood glucose levels during regular DOTS visit in the community. They also educated the individuals and families about the risk factors and advised them about tobacco use, diet, and physical activity. ANMs followed up the patients monthly during the first 3 months, after which they visited them once in 3 months and a final visit after the cessation of the DOTS program (usually coinciding with 8 months post recruitment).

Control

PHCs and participants in the usual care villages were not offered any component of the intervention. The patients continued to receive usual care from their DOTS providers.

Data Collection

Data collection was carried out at baseline and at the end of 8 months by trained research associates who conducted independent interviews, collected anthropometry and blood pressure measurements, and tested random blood sugar levels of the study participants. These data were collected electronically using tablets. In addition, in-depth interviews were carried out with randomly selected patients (six in total, one from each intervention village and one additional participant) and ANMs (five in total, one from each intervention village) to understand the acceptability and patient and provider experience of the intervention and explore the barriers and enablers of the integrated disease management approach. Interviews were conducted by research assistants who used interview guides to facilitate the interviews. Interviews were conducted in Telugu. Qualitative data were audio-recorded which were later transcribed and translated to English. Feasibility was defined as the ease of adoption of the intervention while acceptability was defined as the uptake of the intervention by both ANMs (use of SMARThealth) and individuals with DB and TB (if individuals agreed to share their information and allow the ANM to use SMARThealth for the management of their condition).

Outcomes

The primary outcome of this mixed-method evaluation of the pilot study was to a) define the prevalence of DM in patients with TB (18), b) increase the proportion of individuals with TB screened for DM and associated CVD risk factors by ANMs, c) increase proportion of individuals with DM/TB/high CVD risk on recommended therapies in the intervention arm, d) improved awareness and knowledge among patients about DM and its complications in the intervention arm.

Effectiveness of study intervention were measured in terms of changes in blood glucose, blood pressure, body mass index (BMI) levels, quality of life of patients as well as their risk levels and medication adherence in intervention group as compared to the control group. The feasibility and acceptability of the intervention within the context of routine DOTS program were explored from the user and provider experience information collected through qualitative interviews.

Analysis

Outcome analysis were done at the individual participant level. Descriptive statistics were conducted for sociodemographic characteristics and clinical parameters for intervention and control group. Differences in outcomes between the Intervention and Control arm have been assessed by linear mixed effects models estimated by restricted maximum likelihood with the clusters (PHC) as random effects. Uni- and multi-variable analyses have been performed with a covariate set defined a priori that included age, gender, education, occupation, BMI, smoking and chewing. Statistical analyses have been performed using Stata v16.

All qualitative data were manually analyzed using thematic content analysis method (24). We used an inductive approach to search for patterns from the transcripts. This allowed for themes to develop during the coding process. Two coders (RJ and DB) reviewed the transcripts and discussed the emerging themes with the senior author (DP). We explored two themes relating to the provider and patient experience. The knowledge, training, acceptability and feasibility of using SMARThealth application by the ANMs for screening and follow-up care for DM and other related chronic diseases at the community level were assessed. We also explored for themes relating to barriers in uptake of the intervention.

Ethics Approval

Ethical approval was granted by the Independent Ethics Review Committee of Centre for Chronic Disease Control, New Delhi, India. The study was endorsed by Government health officials at the District level in Guntur. Written informed consent was obtained in the local language from all participants prior to randomization.

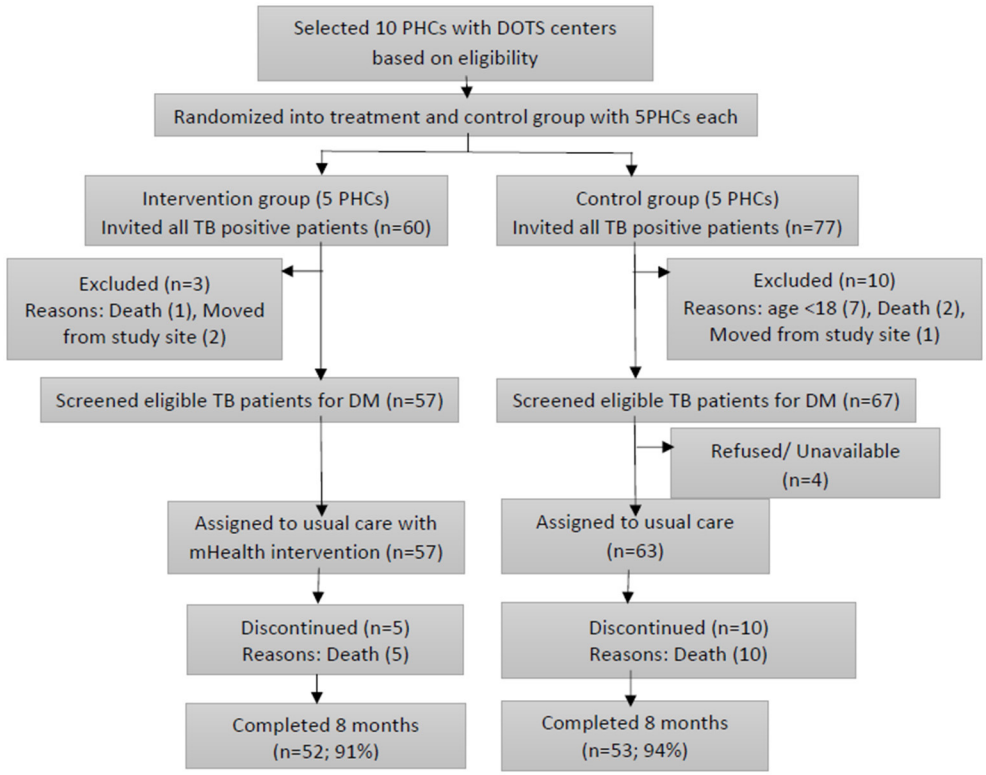

FIGURE 1 | Flowchart of study participants.

RESULTS

Figure 1 depicts the flow chart of randomization and selection of study participants. Ten PHCs participated in the pilot study of which five were randomized to the intervention and five to usual care. All eligible patients (120) gave written informed consent to participate in the study of which 57 were assigned to intervention group and 63 to control group. Thirteen patients were loss to follow up (3 intervention and 10 control arm).

Sample Characteristics

Table 1 provides the baseline characteristics of study participants. The mean age of participants was 44 years (SD = 13.7) in intervention group and 43 years (SD = 14.7) in control group. The age of the participants ranged from 19 to 75 years. About 70% of the study participants were males and the primary occupation was working as laborers in skilled (29.2%), manual (15.8%) or agricultural (33.3%) activities. About 47.4% participants had no education in intervention group as compared to 27% in control group.

Prevalence of DM, CVD Risk, and Other Health Indicators

A total of 19 patients with TB (15.8%) had previously been diagnosed to have DM (19.3% in intervention and 12.7% in control group). No new participants were screen-positive for DM during the study. **Table 1** outlines the baseline characteristics of the study participants. The mean systolic and mean diastolic blood pressure among the study participants were 102.7 mmHg (SD = 22.4) and 72.1 mmHg (SD = 14.4), respectively. Smoking (27.5%) was more common than chewing tobacco (10%). Five patients reported to have HIV (4.2%).

Table 2 shows the comparison of clinical outcome indicators and their variations from baseline to end-of-study for both intervention and control groups. There were no statistically significant variations observed for mean blood glucose levels of patients from the beginning to the end of study for both intervention and control group participants. For systolic blood pressure, there was a significant increase from baseline to end of study in both the intervention (p-value = 0.030) and control groups (p-value = 0.001). But the difference in changes across both groups was found to be not statistically significant (difference = −1.0, 95% CI: −7.5 to 5.5, p-value = 0.758). Similarly, the variations between intervention and control groups in terms of changes in BMI (−0.1, 95% CI:−0.9 to 0.7, p-value = 0.778).

Changes in Risk Factors and Medication Use

The comparison of proportions of risk factors across intervention and control group is provided in **Table 3**. There was decrease in smoking and tobacco chewing rates from baseline to end-of-study in both intervention and control groups. However,

TABLE 1 | Baseline characteristics of study respondents in intervention and control group.

Characteristics	Intervention ($n = 57$)	Control ($n = 63$)	Total ($n = 120$)
Age (years)	Mean: 44.0, SD: 13.7	Mean: 42.9, SD: 14.7	Mean: 43.4, SD: 14.2
Male	40 (70.2)	42 (66.7)	82 (68.3)
Education			
Illiterate	27 (47.4)	17 (27.0)	44 (36.7)
Class 1–9	21 (36.8)	25 (39.7)	46 (38.3)
Class 10 or above	9 (15.8)	21 (33.3)	30 (25.0)
Occupation			
Agricultural laborer	19 (33.3)	21 (33.3)	40 (33.3)
Manual laborer	8 (14.0)	11 (17.5)	19 (15.8)
Skilled laborer	18 (31.6)	17 (27.0)	35 (29.2)
Business	8 (14.0)	7 (11.1)	15 (12.5)
Others	4 (7.0)	7 (11.1)	11 (9.2)
Current Smoker	15 (48.4)	18 (52.9)	33 (50.8)
Current tobacco chewer	8 (61.5)	4 (44.4)	12 (54.6)
Body mass index[#]	Mean: 20.9, SD: 5.7	Mean: 20.9, SD: 7.1	Mean: 20.9, SD: 6.4
Pre-diagnosed diabetics	11 (19.3)	8 (12.7)	19 (15.8)
CVD risk level			
Level 1	44 (77.2)	50 (79.4)	94 (78.3)
Level 2	8 (14.0)	7 (11.1)	15 (12.5)
Level 3 or above	5 (8.8)	6 (9.5)	11 (9.2)
Systolic blood pressure (mmHg)	Mean: 104.7, SD: 24.1	Mean: 100.9, SD: 20.7	Mean: 102.7, SD: 22.4
Diastolic blood pressure (mmHg)	Mean: 73.5, SD: 15.0	Mean: 70.8, SD: 13.8	Mean: 72.1, SD: 14.4
HIV positive	2 (3.5)	3 (4.8)	5 (4.2)
Quality of life[##]			
Very low	4 (7.0)	3 (4.8)	7 (5.8)
Low	17 (29.8)	20 (31.7)	37 (30.8)
Good	36 (63.2)	37 (58.7)	73 (60.8)

Values are mentioned as numbers (percentages) unless otherwise stated.
[#]2 missing cases (n = 62 for control and n = 56 for intervention), Calculated as Weight in kilograms divided by square of height in meters.
[##]3 missing cases in control (n = 60), Calculated using WHO (Five) Well-Being Index and categorized as ≤ 28 as very low, 29-50 as low and >50 as good on a scale of 0–100.

the changes were not statistically significant (p-value > 0.05). Similarly, there was no significant change observed for CVD risk levels over the study period. **Table 4** gives the proportion of patients using necessary medications according to their health condition. Among patients with hypertension, the proportion of people using blood pressure controlling medications increased from 60% to 80% in intervention group. However, the proportion of patients with DM taking glucose lowering medication decreased from 100% to about 91%. At the end-of-the study, all the participants had completed the DOTs course for TB. About 54% patients in the intervention group and 60% in control group were on intensive phase of TB medication at the beginning of study. At the end of 8 months, all had completed the TB treatment.

Provider Experiences

This intervention was acceptable to the ANMs as it increased their knowledge and awareness about the comorbidity. Awareness about DM and TB comorbidity and cardiovascular risk increased among the ANMs in the intervention arm of the study. They felt knowledgeable and empowered to educate people about the risk of developing cardiovascular disease and help them adopt preventive measures.

> *"After this ICDM program has begun, we got to know that TB patient can get diabetes, earlier we didn't know about this association."* – ANM 1

Most of the ANMs thought the training was adequate for them to complete the assigned tasks. However, some felt the need for longer practical training on use of the application, uploading and saving data.

> *"Two days training is not sufficient is what I feel …. another whole day should be for training regarding how to upload…. that way we can learn completely" – ANM 2*

At times, ANMs required re-training on the job and contacted the Field Supervisor for additional support.

> *"If there was any problem, we called the person who had trained us, they've given us instructions and we have followed the same." - ANM 5*

As the intervention was integrated into their routine work, it was feasible for them to undertake this work, though they reported to be overburdened due to non-replacement of personnel whose job were shared with them. They were confident of using tablets since they had prior experience in using android tablets for the Government maternal and antenatal health services. There were no difficulties reported for using SMARThealth application. However, due to slow internet speed in the sample area, sometimes the data saving was problematic or delayed.

The SMARThealth application helped the ANMs to communicate about cardiovascular disease risk and educate the participants and family members about diet, tobacco use and physical activity. The graphical and colorful visual display on the tablet were also very useful for the ANMs to motivate the patients to adhere to medications.

> *"We inform them the necessary precautions to keep their BP and sugar levels in control by regulating diet, walking regularly so that they remain healthy …… the ICDM application also has audio and video, this is helpful. It has 4-5 types of videos, we show them to the patients" – ANM 4*

ANMs were found to be already overburdened with the responsibilities of several community-based health services and disease control programs. In addition, staff attrition and non-replacement of positions, has led to extra burden on remaining workforce.

TABLE 2 | Outcome variables at baseline and end-of-study and differences between intervention and control group at the end of intervention.

Measures	Intervention		Control				
	Baseline *n* (SD)	End-of-study (SD)	Baseline *n* (SD)	End-of-study (SD)	Difference[+] (95% CI)	*P* value	Adj *P* value*
Blood glucose (mg/dl)	139.4 (75.5)	152.3 (89.0)	145.4 (74.2)	151.4 (88.9)	5.3 (-23.3 to 33.8)	0.718	0.467
Systolic blood pressure (mmHg)	104.7 (24.1)	113.4 (21.9)	100.9 (20.7)	107.2 (18.9)	−1.0 (-7.5 to 5.5)	0.758	0.790
Diastolic blood pressure (mmHg)	73.5 (15.0)	77.6 (14.4)	70.8 (13.8)	74.5 (13.7)	−0.3 (-5.2 to 4.5)	0.897	0.674
Body mass index[†]	20.9 (5.7)	22.4 (4.5)	20.9 (7.1)	22.2 (4.9)	−0.1 (-0.9 to 0.7)	0.778	0.536

Values are mentioned as mean (SD) unless otherwise stated.
[+]Mean difference between Baseline to end of study changes comparing Intervention and Control group.
[†]2 missing cases for BMI in Baseline (n = 56 in intervention and n = 62 in control) and 2 missing cases in End line (n = 50 in intervention and n = 53 in control).
**p-value from the fully adjusted (multivariable) model.*

TABLE 3 | Risk factors at baseline and end-of-study.

Measures	Intervention		Control	
	Baseline *n* = 57	End-of-study *n* = 52	Baseline *n* = 63	End-of-study *n* = 53
Current smoking as number (%)	15 (48.4)	13 (65.0)	18 (52.9)	9 (39.1)
Current tobacco chewing as number (%)	8 (61.5)	2 (40.0)	4 (44.4)	2 (40.0)
CVD risk level				
Level 1	44 (77.2)	43 (82.7)	50 (79.4)	44 (83.0)
Level 2	8 (14.0)	3 (5.8)	7 (11.1)	4 (7.5)
Level 3 or above	5 (8.8)	6 (11.5)	6 (9.5)	5 (9.4)

Values are mentioned as number (%).

TABLE 4 | Medication use at baseline and end-of-study.

Medication use	Intervention		Control	
	Baseline	End-of-study	Baseline	End-of-study
Blood pressure medications	3 (5.3)	4 (7.7)	1 (1.6)	3 (5.7)
Lipid lowering medications	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)
Anti-platelet therapy	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)
Glucose lowering medications	11 (19.3)	10 (19.2)	8 (12.7)	6 (11.3)
Tuberculosis medications				
Intensive phase	31 (54.4)	0 (0.0)	37 (58.7)	0 (0.0)
Continuation phase	26 (45.6)	0 (0.0)	25 (39.7)	0 (0.0)
Anti-retroviral therapy	2 (3.5)	0 (0.0)	3 (4.8)	2 (3.8)

Values are mentioned as number (%).

"workload has increased drastically. for every 5000 population there must be two ANMs. currently I'm the one in this subcenter. My senior ANM got promotion and she left, so that post is vacant. I've to take responsibility of 5000 population alone." – ANM 5

Since the ICDM program aligned its visit with the DOTS schedule, the ANMs did not perceive this as inconvenient.

Patient Experience

The intervention was acceptable to the study participants who considered the process helpful for them to receive services on a regular basis at their doorstep. They liked the concept of free screening, education, and support by the ANM at their home, without having to lose daily wages for hospital visits and spending money on medications in a private pharmacy.

"If we go to private hospitals, they will give medicines which cost thousands...private doctors don't counsel us… ANMs do all tests, check their BP, sugar and give them medicines for free and make them sit for 15 min and counsel them.." Patient 3
"Without getting tired and without loss of money, they are coming to our place and conducting regular check-ups and monthly tests. We are not losing our wages." – Patient 5

Watching the video about risk factors and health messages on tablet and graphical presentation of their risk levels comparing from previous visits were motivating for them. They felt good to receive advice and reminders on medication use.

DISCUSSION

WHO's TB-DM collaborative framework 2011 emphasized that implementation of co-management strategies is crucial to curtail the rising TB-DM co-epidemic (1). The framework also recommended research and evaluation studies to be carried out to gather evidence on how local and national health programs and systems can be adapted to achieve effective co-management strategies (1). The study findings suggest feasibility of TB-DM co-management within the existing health care systems of India with sufficient training and properly planned implementation of intervention. This is consistent with findings of other similar studies in Mexico, Tanzania, and Nigeria (2–4). Several other studies have already established the possibility of bidirectional screening of TB-DM within the health programs of many countries including India (5–7).

An Ethiopian study reported good acceptability of the integrated TB-DM care within the TB control program (8). Task sharing approach, digital intervention and door-step free care delivery were found to be the main enablers during this TB-DM co-management intervention. Nevertheless, inadequate awareness, training and overburdened community health workers emerged as the key barriers.

Task sharing with the non-physician health workers have been proven to be feasible, safe, and cost-effective model in various contexts to combat growing burden of diseases (9–11). In this study, task sharing for combined management of TB-DM supported the earlier evidence of being feasible in a community care setting. Delivery of supportive care intervention for DM and other cardiovascular diseases at the patient's doorstep by the community health workers was found to be a key factor in achieving patient satisfaction for this intervention strategy.

Recent studies have demonstrated the effectiveness of computerized clinical decision support systems (CDSS) to screen individuals and provide individualized recommendations for appropriate healthcare delivery (12, 13). This study also reported the use of digital intervention with the SMARThealth application to be acceptable by the community health workers, patients, and their family members in elevating motivation level of patients for better adherence to medications and lifestyle modifications. By viewing the pictorial and graphical presentation of their health indicators during the routine visits of health workers was reported to be enticing for the patients and it kept their motivation up throughout the intervention period.

While there was minimal awareness among the non-physician health workers about TB-DM coexistence at the beginning of the study, interactive training helped in raising their knowledge about this comorbidity, their screening methods and healthier lifestyle behaviors. Community health workers play a pivotal role in most public health programs in India especially for the community level activities, awareness, and care delivery. Lately, they have become overburdened with many programs competing for their time for service implementation as well as extensive documentation of the activities. This study found such complains of work overburden by the community health workers. However, scheduling intervention visits on the days of routine DOTS visits in this study enabled the community health workers to manage both tasks without much inconvenience.

In this study, the prevalence of DM among the TB patients was observed to be 15.8%. This is consistent with a Madhya Pradesh study in 2017 which screened TB patients at DOTS centers and reported the DM prevalence to be 15.4% (14). Other two Indian studies have reported DM prevalence of 11.9 and 8%, respectively among the TB patients (15, 16).

This randomized pilot study was not effective in lowering blood glucose levels of patients in the intervention group. This may be attributed to smaller sample size of this pilot study trial which aimed to demonstrate feasibility over a short intervention period. The study demonstrated a non-significant decline in the prevalence of risky behaviors like smoking and alcohol consumption through the course of the intervention. A similarly unclear result was found for medication adherence in this study.

Additional evidence using large-scale randomized controlled trial design is needed to confirm feasibility of managing TB-DM comorbid patients within the robust TB control program. While the DOTS TB strategy is designed for 6–12 months depending on the severity of infection, management of chronic diseases like DM and cardiovascular diseases (CVDs) require long-term treatment approaches. There is need to institutionalize bi-directional screening of patients with TB and DM and screen individuals for other co-morbidities such as hypertension which would impact the outcomes. WHO's TB-DM collaborative framework and India's TB strategy recommends screening of TB and DM patients (25). The framework also encourages implementation research to contextualize to local health systems. There is a need to invest in robust evidence generation to develop a strong community based integrated care protocol with detailed guide on screening, referral, follow-up, and continued treatment for TB-DM comorbid patients. The presence of TB and DM represents the double burden of disease which needs to be addressed by health systems, especially in LMICs. Primary health systems need to be responsive, and services need to be adapted to address these comorbidities.

The population based non-communicable disease screening program in India currently requires a basic CVD risk assessment at the community level by the ASHAs followed by referral and opportunistic screening of BP, RBS and some of the common cancers of a targeted group of population above 30 years of age by the ANMs at the sub-center level (17). India's national framework for joint TB-DM collaborative activities 2017 mandates bidirectional screening and referral of TB and DM patients in India (26). However, it remains fully clear on the follow-up and joint intervention activities for comorbid patients. Subsequently, the Community Based Assessment Checklist (CBAC) form being used in India still remain standalone in terms of early risk assessment of common NCDs and TB with some referral instructions for TB suspected cases for further diagnosis to the TB care center (18).

While everyone referred to health facilities for further detection and care of the comorbidity may not visit there, the target of providing integrated care for TB-DM remains far from being full-proof. Also, the population based screening process is recommended to be followed for patients with DM once a year by the ANMs (17), whereas patients with TB-DM comorbidity need more frequent screening and follow-up considering their higher susceptibility toward severity and fatality. Hence, a detailed integrated intervention pathway on community-based follow-up and care for patients with TB-DM comorbidity in India is essential for preventing serious consequences of this deadly comorbidity and save lives.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by an Independent Ethics Review Committee of the Centre for Chronic Disease Control, New Delhi, India. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

RJ conceived the idea for the study, its design, and led the writing of the manuscript. DB carried out the qualitative analysis and contributed to the writing of the manuscript. GD carried out the quantitative analysis and contributed to the writing of the manuscript. MA supervised the implementation of the study project. KY contributed to the writing of the manuscript. DP led the design of the study, its implementation, and contributed to the writing of the study. All authors contributed to the article and approved the submitted version.

FUNDING

RJ was funded by an Australian National Heart Foundation Fellowship and UNSW Scientia Fellowship. KY was supported by a UNSW Scientia Scholarship.

ACKNOWLEDGMENTS

The authors would like to acknowledge all the participants of the study.

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