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ABSTRACT

Diabetes and associated metabolic non communicable diseases (NCDs) including hypertension, obesity etc are no longer a disease of affluent developed nations, the prevalence rates of diabetes and metabolic NCDs is steadily increasing in developing countries like India. The epidemiological transition occurring in the India, as a result of rapid urbanization and economic development, has perhaps made it one of the epicentres of the diabetes epidemic. Currently, in India, there are large data deficits on diabetes and associated metabolic NCDs with regards to their prevalence and disease outcomes. The national Indian Council of Medical Research–India Diabetes (ICMR–INDIAB) study was designed to provide accurate and comprehensive state- and national-level data on the prevalence of diabetes and other metabolic NCDs in India. Phase I results of the ICMR-INDIAB study was conducted in four regions (Tamil Nadu, Maharashtra, Jharkhand and Chandigarh) between 2008 and 2010. The results of the ICMR-INDIAB study shows that of the four regions studied, the prevalence of diabetes was highest in Chandigarh followed by Tamilnadu, Maharashtra and Jharkhand. The glycemic control among self-reported diabetic subjects is poor in India, with less than a third of subjects exhibiting good glycemic control. In addition, India has a huge burden of hypertension, obesity and dyslipidemia and poor levels of physical activity, which may predispose to even larger increases in NCDs in the future. Thus, the results from ICMR-INDIAB study helps not only in earlier detection of diabetes/prediabetes through screening, it also lays the foundation for effective NCD prevention and control in India.

BURDEN OF DIABETES IN INDIA

The alarming increase in the prevalence of diabetes globally, has made it a major public health and economic problem. Diabetes and associated metabolic non communicable diseases (NCDs) including hypertension, obesity etc are no longer a disease of affluent, developed nations, as the prevalence of diabetes is increasing disproportionately in developing countries¹ and India is not exempted from it. Indeed, nearly two thirds of the world's population with diabetes currently lives in low- and middle-income regions.² Type 2 diabetes can be considered the prototype of chronic NCDs. While type 1 diabetes and other types account for 5% to 10% of all cases of diabetes, type 2

diabetes remains by far, the most common form of diabetes and has attained epidemic proportions worldwide.. The second highest number of people with diabetes in the world currently is in India (69.2 million) and these numbers are expected to increase to 123.5 million by 2040.³ The majority of NCDs including diabetes occur due to the combined effects of behavioral risk factors including physical inactivity, unhealthy diets, tobacco consumption and the harmful use of alcohol. The greatest effects of these risk factors are unfortunately observed in developing countries, and in poorer people within all countries, mirroring the underlying socioeconomic determinants (poverty, illiteracy, social inequality and poor health infrastructure). Given that there is a growing epidemic of diabetes and associated metabolic NCDs in India, reliable and informative epidemiological data is vital to quantify impacts and predictors of disease and to facilitate formulation of prevention/ control strategies.

Currently, in India, there are large data deficits on diabetes and associated metabolic NCDs with regards to the distribution, trends, determinants and disease outcomes. Even where data is available, there is considerable heterogeneity within regions and the variable quality of the data limits their value. In the last two decades several epidemiological studies have been done in India to estimate the magnitude of diabetes, hypertension, obesity and other NCDs. However, the earlier studies conducted in India suffer from several limitations; they are mostly regional, have small sample sizes, low response rates, use of varied diagnostic criteria, problems with sample design, lack of standardization, measurement errors and incomplete reporting of results.⁴ This results in a lot of available information either not being used or being presented in an incomplete way, thereby providing inaccurate projections for policy makers. Thus there was a need for a large representative population-based study that will provide state-wise and rural–urban estimates of diabetes and other related NCDs including obesity, hypertension and dyslipidemia. The Indian Council of Medical Research–India Diabetes (ICMR–INDIAB) study directly addresses this need and provides accurate and comprehensive state- and national-level data on the prevalence of diabetes and other metabolic NCDs in India.

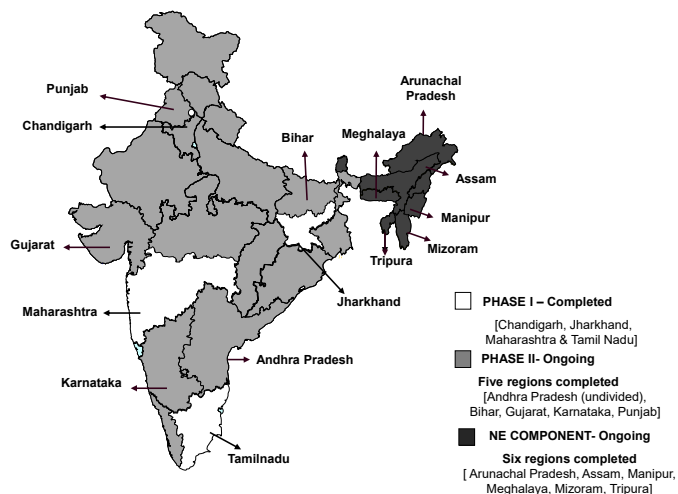


Fig. 1: Phases of the ICMR-INDIAB Study and completed regions

MULTICENTRE EARLIER STUDIES

There have been very few multicentre studies on the prevalence of diabetes in India. In early 1970's, the Indian Council of Medical Research (ICMR), conducted a systematic collaborative study on diabetes in 34,194 individuals aged > 15 years in 6 different parts of the country using uniform methodology and sampling techniques.⁵ Capillary blood glucose was used for diagnosis of diabetes. This study reported an overall prevalence of 2.1 % in urban areas and 1.5% in rural areas, while in those above 40 years of age, the prevalence was 5% in urban and 2.8% in rural areas. The National Urban Diabetes Survey⁶ showed an overall age-standardized prevalence of 12.1% for diabetes and 14% for impaired glucose tolerance (IGT) in six large metropolitan cities. The Prevalence of Diabetes in India Study conducted in 49 urban and 59 rural areas⁷ reported diabetes prevalence of 5.9% and 2.7% in small towns and rural areas respectively. The Five City Study Group⁸ reported that 33.5% of the urban dwellers had BMI ≥ 25 -29.9 kg/m². The WHO-ICMR NCD Risk Factor Surveillance Study conducted in urban and rural areas of six different states (44,523 individuals aged 15-64 years) between 2003-2005, reported an overall prevalence of self-reported diabetes of 4.5%.⁹ In another cross-sectional survey conducted among the employees and their family members of 11 medium-to-large industries from 5 urban sites including Delhi, Hyderabad, Bangalore, Chennai and Trivandrum, reported an overall diabetes prevalence of 10.1%.¹⁰

After nearly 30 years, the Indian Council of Medical Research (ICMR), New Delhi and the Department of Health Research (DHR), Government of India took up the large multicentre "ICMR- India Diabetes [INDIAB] Study, which is nationally coordinated by the Madras Diabetes Research Foundation, Chennai, while the Northeast component is coordinated by the Regional Medical Research Centre, Dibrugarh.

THE ICMR-INDIAB STUDY

The ICMR-INDIAB Study, is an ongoing nationwide cross-sectional, door-to-door survey conducted in adults of either gender, aged ≥ 20 years and above from all 28 states

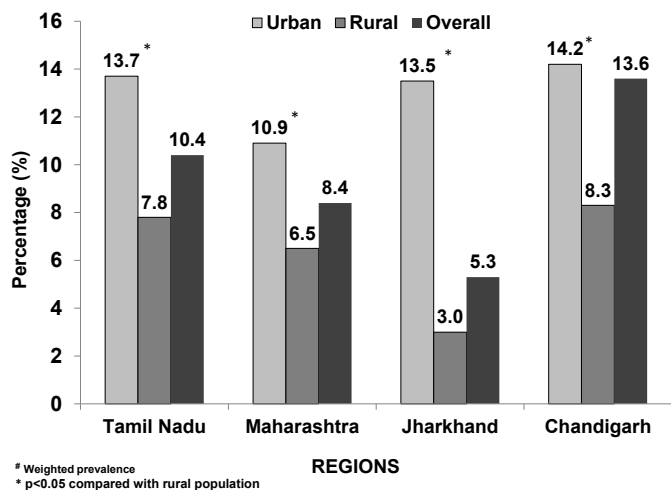
(now 29 States), National Capital territory (NCT) of New Delhi and 2 union territories (UTs) namely Chandigarh and Puducherry in the mainland of India in a phased manner.¹¹ Each state, the National Capital Territory and the Union Territories will have an urban component (towns including metros, wherever applicable) and a rural component (villages). A stratified multi-stage sampling design has been adopted and from each state, 4,000 individuals [2,800 individuals in rural areas and 1,200 individuals in urban areas] are being studied. Thus the total sample size for the study is estimated to be 1,24,000 individuals. The primary objectives of the study are to determine the prevalence of diabetes mellitus and prediabetes in India by estimating the state-wise prevalence of the same and to compare the prevalence rates in urban and rural areas across the country. The additional objectives of the study are to determine the prevalence of metabolic NCDs including hypertension, dyslipidemia, obesity and coronary artery disease (CAD) among subjects with and without diabetes and to assess the level of glycemic control among individuals with self-reported diabetes.

In view of the complexity of the study and the logistics involved, the study has been planned in phases. The different phases of the study are presented in Figure 1. The first phase of the study which has been completed in 4 regions of India, which includes three states randomly selected to represent the south (Tamil Nadu), west (Maharashtra) and east (Jharkhand) of India and one UT representing northern India (Chandigarh) has already provided authentic epidemiological data on diabetes, hypertension, dyslipidemia and obesity in the country till date. Currently the North East component, which includes 8 north eastern states namely Sikkim, Assam, Meghalaya, Tripura, Mizoram, Manipur, Nagaland and Arunachal Pradesh is underway. Phase II, which includes 17 states, the National Capital territory of New Delhi and 1 union territory is also in progress. Currently, fifteen states/UT have been surveyed and the lessons learnt from Phase I (involving four regions), conducted from November 2008 to April 2010, are presented here.

LESSONS LEARNT FROM PHASE I OF THE ICMR-INDIAB STUDY

Diabetes and prediabetes

In Phase I, of the 16,607 individuals (5112 urban and 11,495 rural) selected for the study, 14,277 (4186 urban and 10,091 rural) participated, of whom 13,055 gave blood samples. In all study subjects, an interviewer-administered questionnaire was used to obtain demographic, behavioral, medical information and knowledge of diabetes. Weight, height, and waist circumference were measured and body mass index (BMI) was calculated. Blood pressure was recorded using an electronic instrument as the mean of two readings taken five minutes apart. Fasting and 2 hour post glucose capillary blood glucose (CBG) was used for diagnosis of diabetes, as CBG has been shown to be a feasible alternative for screening of diabetes and IGT in epidemiological studies in developing countries where



* Weighted prevalence

* p<0.05 compared with rural population

Fig. 2: Prevalence[#] of diabetes (self-reported, newly diagnosed and overall diabetes) in urban and rural population

obtaining venous samples is difficult or even impossible in some situations.¹² In addition, in every fifth subject (n=2,042), a fasting venous sample was collected and lipids (total cholesterol, triglycerides and HDL cholesterol) were measured. Glycemic control among subjects with self-reported diabetes was assessed by measurement of glycated hemoglobin (HbA1c).

Diabetes was defined as individuals diagnosed by a physician and on glucose-lowering medications (self-reported) and/or those who had a fasting CBG ≥ 126 mg/dl and/or a 2 h post glucose CBG value ≥ 220 mg/dl.¹³ The overall weighted prevalence of diabetes was 10.4% (Tamil Nadu: Urban-13.7: Rural- 7.8%), 8.4% (Maharashtra: Urban-10.9%:Rural-6.5%), 5.3% (Jharkhand: Urban-13.5%: Rural- 3.0%) and 13.6% (Chandigarh: Urban-14.2%: Rural-8.3%) [Figure 2]. The prevalence of self reported diabetes among urban residents of Tamil Nadu, Maharashtra, Jharkhand and Chandigarh were 8.5%, 3.7%, 8.4% and 6.6% while that among rural residents was 4.1%, 1.7%, 0.7% and 3.1% respectively. The prevalence of newly diagnosed diabetes among urban residents of Tamil Nadu, Maharashtra, Jharkhand and Chandigarh were 5.2%, 7.2%, 5.1% and 7.6% and that among rural residents, 3.8%, 4.9%, 2.3% and 5.2% respectively. This translated to 4.8 million individuals with diabetes in Tamil Nadu. In Maharashtra, an estimated 6.0 million had diabetes, Jharkhand, 0.96 million and in Chandigarh 0.12 million had diabetes in 2011. The ICMR-INDIAB study estimated the number of individuals with diabetes in India in 2011 to be 62.4 million.¹⁴ The figure for diabetes from the ICMR-INDIAB study was accepted by the International Diabetes federation (IDF) for India in 2011, which reported a figure of 61.3 million people with diabetes in India in the age group of 20-79 years.¹⁵

One of the points of concern is that the take-off point in prevalence of diabetes was at 25–34 years with a decline after age 65. At every age interval, the prevalence of diabetes in urban areas was higher compared with rural areas. Age, male gender, family history of diabetes, urban residence, abdominal obesity, generalized obesity,

Table 1: Distribution of glycated hemoglobin (HbA1c) among individuals with self reported diabetes

HbA1c levels (%)	Area wise		Gender wise		Overall
	Urban	Rural	Male	Female	
<7	31.3	30.8	30.9	31.3	31.0
7.0-7.9	17.4	15.7	16.6	16.6	16.6
8.0-8.9	17.9	15.7	19.8	12.9	16.8
9.0-9.9	9.7	10.8	10.6	9.8	10.3
>10	23.6	27	22.1	29.4	25.3

hypertension and income status were significant risk factors associated with diabetes.¹⁴

The overall weighted prevalence of 'prediabetes' defined as individuals with impaired fasting glucose [IFG] or impaired glucose tolerance [IGT] or both in Tamil Nadu, Maharashtra, Jharkhand and Chandigarh were 8.3%, 12.8%, 8.1% and 14.6% respectively. Among urban residents it was 9.8% (Tamil Nadu), 15.2% (Maharashtra), 10.7% (Jharkhand) and 14.5% (Chandigarh). Among rural residents the corresponding prevalence of prediabetes was 7.1%, 11.1%, 7.4% and 14.7% respectively. This study reported that in 2011, Maharashtra have 9.2 million individuals with prediabetes, Tamil Nadu, 3.9 million, Jharkhand, 1.5 million and Chandigarh 0.13 million individuals, with prediabetes. Extrapolated to the whole country, these estimates translated to 77.2 million with prediabetes in India. The risk factors associated with prediabetes were age, family history of diabetes, abdominal obesity, hypertension and income status.¹⁴

In Phase I of the ICMR-INDIAB study, self-reported diabetes was reported in 480 subjects. The mean HbA1c levels among them were highest in Chandigarh (9.1%), followed by Tamil Nadu (8.2%), Jharkhand (8.2%), and Maharashtra (8.0%).¹⁶ The study reported that there was no significant difference in the mean HbA1c among urban and rural dwellers in any of the regions studied. Overall, good glycemic control (HbA1c <7%) was observed only in 31.0% and 25.3% had an HbA1c level of >10.0%. There was significant difference in the glycemic control among urban and rural as well as male and female population in the regions studied (Table 1). This study showed that levels of glycemic control in India remain unacceptably poor. Nearly 70% of subjects fail to meet the recommended HbA1c goal of <7%. More than 60% of the individuals in both urban and rural areas reported that they had not checked their HbA1c in the past year. The various risk factors associated with poor glycemic control were younger age, duration of diabetes, insulin use, and high triglyceride levels.¹⁶

There is evidence to show that increasing knowledge regarding diabetes and its complications has significant benefits including increase in compliance to treatment, thereby decreasing the complications associated with diabetes.¹⁷ Although there have been small regional studies on the subject of diabetes awareness in India, the

Table 2: Gender and areawise knowledge regarding diabetes in the 4 regions studied

Have you heard of a condition called diabetes? - YES					
	Tamil Nadu	Maharashtra	Jharkhand	Chandigarh	Overall
Gender					
Male	64.2*	54.4*	32.7*	33.5*	46.7*
Female	57.2	43.3	20.5	34.3	39.6
Area					
Urban	72.3 [#]	56.5 [#]	52.3 [#]	50.8 [#]	58.4 [#]
Rural	55.8	45.2	16.5	27.6	36.8

* p<0.001 compared to females; [#] p<0.001 compared to rural area

Table 3: Prevalence of overweight and obesity in the four regions studied-ICMR-INDIAB study (Phase I)

Regions	Overweight ^a			Generalized Obesity (%) ^b			Abdominal obesity (%) ^c			Combined obesity (%) ^d		
	Urban	Rural	Overall	Urban	Rural	Overall	Urban	Rural	Overall	Urban	Rural	Overall
Tamil Nadu	16.5	14.6*	15.2	35.7	20.0*	24.6	37.4	22.1*	26.6	28.8	15.3*	19.3
Maharashtra	13.6	10.3*	11.3	26.1	12.2*	16.6	26.7	15.0*	18.7	20.2	9.7*	13.0
Jharkhand	13.1	5.7*	7.8	30.4	4.3*	11.8	37.2	8.7*	16.9	26.3	3.1*	9.8
Chandigarh	18.9	14.8*	15.9	40.3	27.9*	31.3	46.6	32.1*	36.1	34.0	24.0*	26.6

^a BMI ≥ 23 kg/m² but < 25 kg/m² for both genders; ^b BMI ≥ 25 kg/m² for both genders; ^c Waist circumference ≥ 90 cm for men and ≥ 80 cm for women; ^d Individuals with both generalized and abdominal obesity.

*p<0.001 compared to urban areas

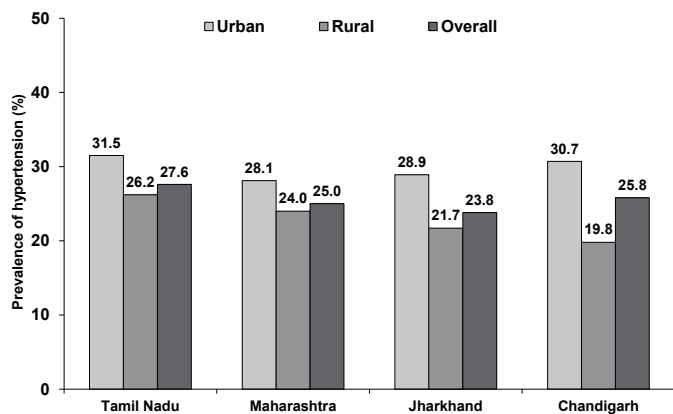
ICMR-INDIAB study provides data at a national level or indeed even in a whole state of India on the awareness about diabetes. Awareness and knowledge about diabetes were also assessed in the general population, as well as in individuals with diabetes in Phase I.¹⁸ Overall, only 43.2% of the study population had heard about a condition called diabetes. Awareness of diabetes was higher among urban residents compared to their rural counterparts (58.4% vs. 36.8%) [Table 2]. Urban residents had better awareness rates than rural residents in all four regions, with highest rates in Tamil Nadu followed by Maharashtra, Jharkhand and Chandigarh. Overall 46.7% of males and 39.6% of females reported that they knew about a condition called diabetes. This study reported that males had better awareness rates about diabetes than females in all regions, except Chandigarh as shown in Table 2.

Of the general population, 41.5% knew about a condition called diabetes and among them, over 80.0% knew that the prevalence of diabetes was increasing. Among the self-reported diabetic population, 93.0% knew that the prevalence of diabetes was increasing. Among the general and diabetic population, 56.3% and 63.4%, were aware that diabetes could be prevented and 51.5% and 72.7% respectively knew that diabetes could affect other organs. Among the general population who answered in the affirmative for the question "Do you think diabetes can affect other organs?", the most common organs reported were the feet (54.0%), eyes (52.3%), kidneys (36.3%), heart (33.6%) and nerves (18.7%). While, among individuals with diabetes, the knowledge of diabetic complications was comparatively better (eyes – 73.5%, feet – 61.3%,

kidneys – 47.9%, heart – 45.1% and nerve problems – 26.8%). It is disturbing that even among subjects with diabetes; this basic knowledge was still so poor.¹⁸

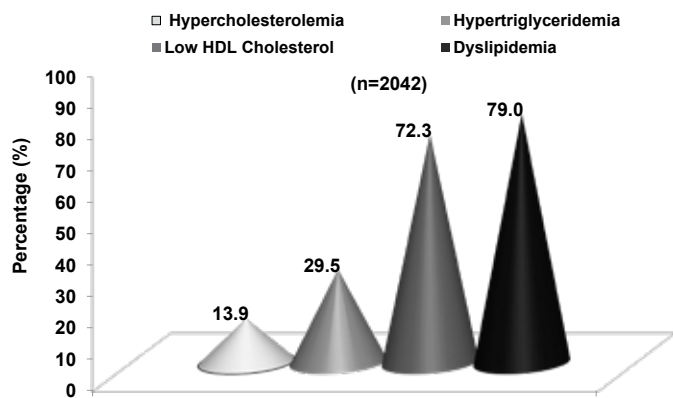
PREVALENCE OF OTHER METABOLIC NCDS IN INDIAB STUDY Obesity

India, being the second most populous country in the world is currently experiencing rapid epidemiological transition. Industrialization and urbanization also contribute to increased prevalence of obesity. Studies from different parts of India have provided evidence on the rising prevalence of obesity.^{19,20} The prevalence of generalized obesity (GO) defined as BMI ≥ 25 kg/m² for both genders²¹ abdominal obesity (AO) defined as a waist circumference ≥ 90 cm for men and ≥ 80 cm for women²² and combined obesity (CO) defined as individuals with both GO and AO were assessed in the ICMR-INDIAB study in both urban and rural areas (Table 3).²³ The prevalence of overweight was highest in Chandigarh (15.9%) followed by Tamil Nadu (15.2%), Maharashtra (11.3%) and Jharkhand (7.8%). The prevalence of GO was 24.6, 16.6, 11.8 and 31.3 per cent among residents of Tamil Nadu, Maharashtra, Jharkhand and Chandigarh. The prevalence of AO and CO also followed the same trend as that of overweight. The prevalence of GO, AO and CO were significantly higher among urban residents compared to rural residents in all the four regions studied. The various risk factors associated with GO, AO and CO were female gender, hypertension, diabetes, higher socio-economic status, physical inactivity and urban residence. In all the



Note: No significant difference among urban and rural areas in all the four regions studied

Fig. 3: Age standardized prevalence of hypertension in four regions of India



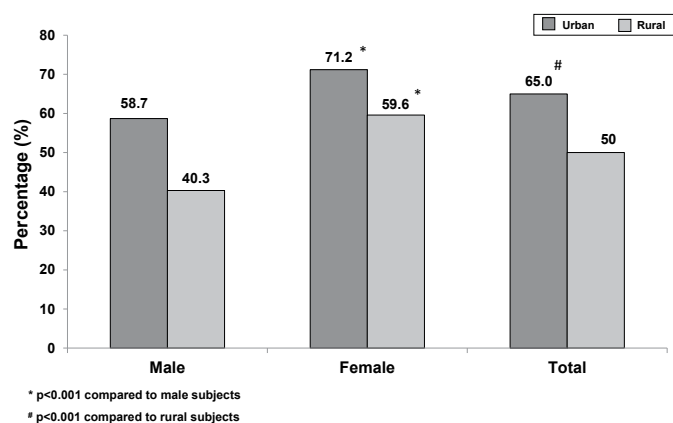
Hypercholesterolemia- Cholesterol ≥ 200 mg/dl; Hypertriglyceridemia-Triglycerides ≥ 150 mg/dl ; Low HDL cholesterol -HDL-C < 40 (m); < 50 mg/dl (f); Dyslipidemia -any one lipid abnormality

Fig. 4: Prevalence of different components of dyslipidemia (n=2042)

four regions studied age was significantly associated with AO and CO, but not with GO.

Hypertension

High blood pressure is ranked as the third most important risk factor for attributable burden of disease in south Asia.²⁴ The prevalence of hypertension is also rising in India. In the ICMR-INDIAB study, the overall, age standardized prevalence of hypertension defined using Joint National Committee 7 Criteria²⁵ in the four regions studied was 26.3% (self-reported: 5.5%; newly detected: 20.8%).²⁶ The age-standardized prevalence of hypertension (Figure 3) was highest in Tamilnadu: 27.6% followed by Chandigarh: 25.8%, Maharashtra: 25.0% and Jharkhand: 23.8%. The prevalence of hypertension was higher in urban areas compared to rural areas and newly diagnosed HTN was higher than self-reported HTN across all three states and the UT. In the four regions studied, the ratio of newly diagnosed to self-reported hypertension was 3.8:1. The prevalence of hypertension increased with increasing age, even in the age group of 20–24 years, the prevalence of hypertension ranged from 5.4–13.9% in urban and from 9–10% in rural areas. Salt intake ≥ 6.5 g per day, conferred 1.4 times higher risk for hypertension even after adjusting for confounding variables.



* p<0.001 compared to male subjects

p<0.001 compared to rural subjects

Fig. 5: Physical inactivity levels in the urban and rural population of India

Dyslipidemia

Asian Indians are known to have a unique pattern of dyslipidemia with lower HDL cholesterol, increased triglyceride levels and higher proportion of small dense LDL cholesterol.²⁷ In the ICMR-INDIAB study, in every 5th subject (n= 2042), lipids were measured to assess the pattern and prevalence of dyslipidemia in India.²⁸ Overall, prevalence of dyslipidemia, defined using National Cholesterol Education Programme (NCEP) guidelines (at least one lipid abnormality),²⁹ was 79% in the 4 regions studied, with highest rates found in Chandigarh (82.9%), followed by Jharkhand (80%), Maharashtra (77%) and Tamilnadu (76.9%). Hypercholesterolemia (serum cholesterol levels ≥ 200 mg/dl) was observed in 13.9% and hypertriglyceridemia (serum triglycerides levels ≥ 150 mg/dl) in 29.5%. Low HDL-C (HDL cholesterol levels < 40 mg/dl for men and < 50 mg/dl for women) was the most common lipid abnormality (72.3%) in all the four regions studied [Figure 4]; in 44.9% of subjects, it was present as an isolated abnormality. High LDL-C levels were observed in 11.8%. There were no urban rural differences observed in any of the four regions studied. In the population studied, 7.7% had all three lipid abnormalities (hypercholesterolemia + hypertriglyceridemia + low HDL-C) and 4.8% of the population had all four lipid abnormalities (hypercholesterolemia + hypertriglyceridemia + low HDL-C + high LDL-C). Of the studied population, only 21.1% had no lipid abnormality. The significant risk factors for dyslipidemia included obesity, diabetes, and dysglycemia.²⁸

PHYSICAL INACTIVITY AS A RISK FACTOR FOR NCDs

The majority of NCDs occur due to the synergistic effects of behavioral risk factors such as physical inactivity, unhealthy diets, tobacco consumption and the harmful use of alcohol. The rising prevalence of NCDs can be attributed, at least in part, to two of the most important modifiable risk factors including increasing levels of physical inactivity and unhealthy diets.³⁰ ICMR-INDIAB study assessed the reports on the levels of physical activity and inactivity in India using Global Physical Activity Questionnaire (GPAQ).³¹ Overall, 54.4% of the population were inactive (males: 41.7%), while 31.9% (males: 58.3%)

were active and 13.7% (males: 61.3%) were highly active.³² **Figure 5** presents the physical inactivity levels in the urban and rural areas studied in Phase I of the ICMR-INDIAB study. Subjects were more inactive in urban, compared to rural, areas (65.0% vs. 50.0%) and female subjects were significantly more inactive than their male counterparts. Physical inactivity was highest in Chandigarh (66.8%) followed by Tamilnadu (60.0%), Maharashtra (55.2%) and Jharkhand (34.9%). Absence of recreational activity was reported by 88.4%, 94.8%, 91.3% and 93.1% of the subjects in Chandigarh, Jharkhand, Maharashtra and Tamilnadu respectively. Most of the time spent in moderate to vigorous intensity activity was at the workplace. Even among those who reported recreational physical activity (8.1%), the time spent in moderate to vigorous intensity activity was overall <20 mins/day.

SUMMARY

In summary, the Phase I results of the ICMR-INDIAB study shows that of the four regions studied, the prevalence of diabetes was highest in Chandigarh followed by Tamilnadu, Maharashtra and Jharkhand. Again, the prevalence of prediabetes was highest in Chandigarh followed by Maharashtra, Tamilnadu and Jharkhand. The glycemic control among self-reported diabetic subjects is poor in India, with less than a third of subjects exhibiting good glycemic control. Knowledge and awareness about diabetes in India, particularly in rural areas, is abysmally low. In addition, the prevalence of other metabolic NCDs including obesity, hypertension and dyslipidemia are higher in both urban and rural areas of India compared with earlier studies. With greater urbanization and longevity, we can expect huge increases in the numbers of people with diabetes and other metabolic NCDs in India in the future. This phase of the study also reports that nearly half of the population in the four regions studied was inactive, with fewer than 10% engaging in recreational physical activity. Hence it is recommended to improve overall physical activity, at least 150 minutes of moderate-intensity aerobic PA or at least 75 minutes of vigorous-intensity aerobic activities throughout the week to reduce the risk of various NCDs. Thus, the results from ICMR-INDIAB study helps not only in earlier detection of diabetes/prediabetes through screening, it also lays the foundation for effective NCD prevention and control in India.

ACKNOWLEDGEMENT

The authors acknowledge the Indian Council of Medical Research, New Delhi, for the financial support for the study. This is the tenth paper from the ICMR-INDIAB Study (ICMR –INDIAB -10).

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