Original Articles

Prevalence of Diagnosed and Undiagnosed Diabetes and Hypertension in India—Results from the Screening India's Twin Epidemic (SITE) Study

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Abstract

Objective: Despite the rising number of patients with diabetes and hypertension in India, there is a dearth of nationwide, comprehensive prevalence data on these diseases. Our study aimed at collecting data on the prevalence of diabetes and hypertension and the underlying risk factors in various outpatient facilities throughout India.

Methods: This cross-sectional study was planned to be conducted in 10 Indian states, one state at a time. It was targeted to enroll about 2,000 patients from 100 centers in each state. Each center enrolled the first 10 patients ($\geq$18 years of age, not pregnant, signed consent) per day on two consecutive days. "Diabetes" and "hypertension" were defined by the 2008 American Diabetes Association and the Joint National Committee's 7th Report guidelines, respectively. Patient data (demographics, lifestyle factors, medical history, and laboratory diagnostic results) were collected and analyzed.

Results: During 2009–2010, in total, 15,662 eligible patients (54.8% males; mean age, 48.9 ± 13.9 years) from eight states were enrolled. Diabetes was prevalent in 5,427 (34.7%) patients, and 7,212 (46.0%) patients had hypertension. Diabetes and hypertension were coexistent in 3,227 (20.6%) patients. Among those whose disease status was not known at enrollment, 7.2% (793 of 11,028) and 22.2% (2,408 of 10,858) patients were newly diagnosed with diabetes and hypertension, respectively; additionally, 18.4% (2,031 of 11,028) were classified as having prediabetes and 60.1% (6,521 of 10,858) as having prehypertension. A positive association ($P < 0.05$) was observed between diabetes/hypertension and age, familial history of either, a medical history of cardiovascular disorders, alcohol consumption, and diet.

Conclusions: Our study demonstrates that the substantial burden of diabetes and hypertension is on the rise in India. Patient awareness and timely diagnosis and intervention hold the key to limiting this twin epidemic.

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Introduction

HYPERTENSION AND DIABETES, two of the major global risks for mortality,[1] are on a rapid rise in developing nations. In India, as per the 2011 estimates reported by the Indian Council of Medical Research–India Diabetes study, 62.4 and 77.2 million people have diabetes and prediabetes, respectively.[2] It is predicted that by 2030, India's diabetes burden will be almost 87 million people.[3] Additionally, there is an increasing prevalence of hypertension in the Indian population, especially in the urban areas.[4] Elevated blood pressure (BP) has been linked to ischemic heart disease, peripheral vascular diseases, stroke, myocardial infarction, and renal failure.[5] Hypertension and diabetes are important risk factors for cardiovascular disease. Given the increasing rates of coronary artery disease among Indians, especially at a younger age,[6] understanding and successfully managing hypertension and diabetes may hold the key to reducing cardiovascular mortality in India.

Diabetes and hypertension are also known to coexist in patients. The prevalence of hypertension is 1.5–2.0 times more in those with diabetes than in those without diabetes, whereas almost one-third of the patients with hypertension develop diabetes later.[7] This coexistence presents an increased risk and can accelerate vascular complications.[8,9]

Diabetes and hypertension are manageable health conditions and can be controlled by medicinal intervention, exercise, and diet. Moreover, detection of progenitors—prediabetes and prehypertension—through periodic surveillance can allow for early intervention and delay disease progression.

With an increasing burden of these diseases in India, public awareness and disease prevention projects need to be undertaken. Although studies have been carried out over the past few decades to estimate the prevalence of diabetes and hypertension, they were often small-scale and regional or carried out in a particular subset of the diverse Indian population. They also used older guidelines that have ever since been updated based on newer and evolving clinical information. Understanding the prevalence of diabetes and hypertension and their associated risk factors (hyperlipidemia, microalbuminuria, central obesity, etc.) in a larger and more diverse population using the current guidelines is therefore central to any meaningful evaluation of disease epidemiology.

One of the major goals of the Screening India's Twin Epidemic (SITE) study was to determine the prevalence of diabetes and hypertension in India. Toward this aim, the study was conducted in seven of the 10 most populous states in India and the National Capital Territory, so that the study patients are representative of the population at large. In this article, we present the findings on prevalence of known and new cases of diabetes and hypertension and on coexisting risk factors.

Subjects and Methods

Study design

The SITE study was a cross-sectional, multicentric, non-interventional, observational study carried out in India during 2009–2010. It was planned to be conducted in 10 states across five zones—East, West, North, South, and Central. Patients were recruited from one state at a time, with a target of 2,000 patients from 100 centers in each state. The study population was patients visiting their general practitioner. Eligibility criteria included patient's age ≥18 years, not pregnant, willing to undergo screening tests, and providing a signed consent. The first 10 eligible patients visiting the physician for whatever reasons were recruited on two consecutive days. The pilot phase of SITE was conducted in Maharashtra, followed by the remaining states. Additional study details have been reported earlier.[10]

The SITE study was conducted in accordance with the guidelines for Good Epidemiological Practices[11,12] and complied with the recommendations of the 18th World Health Congress (Helsinki, Finland, 1964) and the local laws and regulations in India.

Assessments

Patient data were collected in two steps. During the first visit (V1) to the physician, the data collection form was used to gather information on demographics, personal medical history, family history of diabetes and hypertension, lifestyle practices (smoking, alcohol consumption, and diet), and other parameters pertinent to the study objectives.[10] The patient's BP was also recorded. At the end of the visit, patients received a coupon of identification and were told to report to the nearest predetermined diagnostic center within 2–5 days for further testing (V2).

BP was measured using a sphygmomanometer by the auscultatory method. Two readings were taken in a resting patient at a 5-min interval, and the average of the two readings was reported. In case of a difference of >5 mm Hg in the readings, two more readings were taken in a similar manner, and the average of all readings was reported.

At the diagnostic center, patients' blood samples were analyzed for oral glucose tolerance test (OGTT) or fasting plasma glucose (FPG) levels.

For the pilot study (in Maharashtra), patients were analyzed for random blood sugar (RBS) levels during the physician's visit (V1), and at the subsequent laboratory visit (V2), patients with RBS ≥140 mg/dL were administered the OGTT. For patients recruited from the second state (Delhi), in lieu of RBS analysis at V1 and a consequent OGTT, patients were evaluated for FPG levels when diabetes status was not known. For patients recruited from the third state (Tamil Nadu) onward, irrespective of existing diabetes status, all patients were evaluated for FPG. Study procedures carried out are summarized in Table 1.

Protocol amendment

A high patient dropout rate was observed in the pilot study for the OGTT because of logistic and procedural difficulty. Thus, for confirmation of diabetes from the second state onward, FPG, which can also be used as per American Diabetes Association recommendations,[13] was used instead of OGTT. Given the strong association between lifestyle factors (diet and alcohol consumption) and diabetes and hypertension, these factors were evaluated from the second state onward. FPG levels were estimated in all patients, irrespective of their previous history of diabetes, from the third state onward. This was done in order to simplify the study protocol.

Definition of disease

The American Diabetes Association guidelines[14] were used for diagnosis of "new" diabetes cases. In the pilot phase

Table 1. Data Collection and Diagnostic Tests Conducted

	Wave 1 (Maharashtra)	Wave 2 (Delhi)	Wave 3 onward
Blood pressure	All	All	All
Demographics, familial disease history, cardiovascular medical history, and smoking status	All	All	All
Alcohol consumption	—	All	All
Diet	—	All	All
RBS	All	—	—
OGTT	RBS ≥140 or <200 mg/dL in known cases of diabetes	—	—
FPG	—	Only for "unknown" cases of diabetes	All

FPG, fasting plasma glucose; OGTT, oral glucose tolerance test; RBS, random blood sugar.

conducted in the state of Maharashtra, patients without previously reported diabetes who had RBS ≥200 mg/dL or OGTT ≥200 mg/dL were considered as "new" cases of diabetes mellitus. Patients with missing RBS or OGTT values and without a previous history of diabetes comprised "unknown" cases. Those with "nondiabetes" were the sample remainder minus the "known," "unknown," and "new" cases of diabetes. After the pilot phase, "new" cases were defined as patients who had no previous history but had FPG levels ≥126 mg/dL during testing. "Unknown" and "nondiabetes" were defined as earlier but using FPG levels instead. A patient whose diabetes status was not known and had either RBS/OGTT levels between 140 and <200 mg/dL (for Maharashtra) or FPG levels between 100 and <126 mg/dL was defined as having "prediabetes."

Hypertension, in "known" as well as "new" cases, was classified as per the recommendations of the 7th Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure.[15] Patients without previously reported hypertension who, at the time of V1, had a systolic BP ≥140 mm Hg or a diastolic BP ≥90 mm Hg were considered as "new" cases. Consequently, patients without a previous history of hypertension with systolic BP <140 mm Hg and diastolic BP <90 mm Hg were considered as having "nonhypertension." Patients who had systolic BP 120–139 mm Hg or a diastolic BP 80–89 mm Hg were classified as having "prehypertension." Isolated systolic hypertension (ISH) was defined as systolic BP ≥140 mm Hg and diastolic BP ≤89 mm Hg, whereas isolated diastolic hypertension (IDH) was defined as diastolic BP ≥90 mm Hg and systolic BP ≤139 mm Hg.

Statistical analyses

Based on an expected prevalence of 15% for diabetes[16,17] and a dropout rate of 39%, it was estimated that 2,000 patients per state needed to be enrolled to ensure a 95% confidence on the actual prevalence. Thus, a total of 20,000 patients in 10 states were targeted for recruitment.

Descriptive statistics using mean, SD, and range was used for analyzing continuous variables like age, whereas frequency and percentage were used for describing categorical variables like gender and disease prevalence. Comparative analysis between groups was conducted using two-tailed Student's *t* test and χ^2 test. The Wilcoxon–Mann–Whitney test was used to compare non-normal variables between two groups. A value of $P < 0.05$ was considered to have statistical significance. All statistical analyses were conducted using SPSS version 18 (IBM, New York, NY).

Results

Demographics

The SITE study recruited a total of 15,662 patients from 807 centers in eight states: Maharashtra, Delhi, Tamil Nadu, West Bengal, Karnataka, Andhra Pradesh, Gujarat, and Madhya Pradesh. Of these, 14,192 (90.6%) patients completed the evaluations carried out at V2. Given a lower than anticipated dropout rate as well as time and budget constraints, recruitment was terminated after the eighth state, and the data gathered were deemed to be sufficient and statistically substantial enough to represent the diversity in the general population.

The study population ($n = 15,662$) had more males (54.8%, $n = 8,579$) than females, and mean age was 48.9 ± 13.9 years. About three-fourths (74.2%, $n = 11,622$) of the patients were 40 years or older, and 24.4% ($n = 3,816$) were 60 years and above. The mean systolic and diastolic BP of the patients was 128.8 ± 15.9 mm Hg and 82.5 ± 8.9 mm Hg, respectively.

As shown in Table 2, almost one-fourth of the patients had a familial history of diabetes (24.5%, $n = 3,836$) and hypertension (23.2%, $n = 3,641$). A previous history of ischemic heart disease, myocardial infarction, and stroke was reported in 473 (3.0%), 245 (1.6%), and 132 (0.8%) of the patients, respectively. In total, 1,784 (11.4%) patients were or had been smokers. Alcohol consumption and non-vegetarian diet were reported in 1,514 (11.0%) and 8,502 (61.5%) patients, respectively.

Prevalence of diabetes

In total, 5,427 (34.7%) patients in the study had diabetes with 4634 (29.6%) "known" cases. Among those whose disease status was not known, 7.2% (793 of 11,028) patients were newly diagnosed with diabetes, and 18.4% (2,031 of 11,028) were classified as having prediabetes (Table 2). Mean duration of diabetes in "known" cases was 7.0 ± 6.2 years. The difference in mean duration between males (7.3 ± 6.6 years) and females (6.6 ± 5.6 years) with diabetes was statistically significant ($P = 0.031$). Type 2 diabetes was the most common among the "known" cases, reported in 96.1% (4,452 of 4,634)

TABLE 2. DISEASE PREVALENCE AND DEMOGRAPHIC DATA BY EACH STATE

Disease parameter	Total (n=15,662)	Maharashtra (n=1,842)	Delhi (n=1,980)	Tamil Nadu (n=1,972)	West Bengal (n=1,930)	Karnataka (n=1,979)	Andhra Pradesh (n=1,895)	Gujarat (n=2,161)	Madhya Pradesh (n=1,903)
Diabetes [n (%)]									
Overall	5,427 (34.7)	733 (39.8)	644 (32.5)	795 (40.3)	598 (31.0)	682 (34.5)	710 (37.5)	624 (28.9)	641 (33.7)
Known	4,634 (29.6)	679 (36.9)	601 (30.4)	680 (34.5)	494 (25.6)	581 (29.4)	595 (31.4)	464 (21.5)	540 (28.4)
New (% of not known cases)	793 (7.2%)	54 (4.6%)	43 (3.1%)	115 (8.9%)	104 (7.2%)	101 (7.2%)	115 (8.8%)	160 (9.4%)	101 (7.4%)
Nondiabetes	10,148 (64.8)	1,069 (58.0)	1,315 (66.4)	1,174 (59.5)	1,330 (68.9)	1,295 (65.4)	1,175 (62.0)	1,537 (71.1)	1,253 (65.8)
Unknown	87 (0.6)	40 (2.2)	21 (1.1)	3 (0.2)	2 (0.1)	2 (0.1)	10 (0.5)	0 (0.0)	9 (0.5)
Prediabetes (% of not known cases)	2,031 (18.4)	66 (5.7)	134 (9.7)	333 (25.8)	309 (21.5)	285 (20.4)	268 (20.6)	396 (23.3)	240 (17.6)
Hypertension [n (%)]									
Overall	7,212 (46.0)	1,038 (56.4)	955 (48.2)	779 (39.5)	898 (46.5)	636 (32.1)	937 (49.4)	978 (45.3)	991 (52.0)
Known	4,804 (30.7)	763 (41.4)	627 (31.7)	426 (21.6)	634 (32.8)	448 (22.6)	600 (31.7)	581 (26.9)	725 (38.1)
New cases (% of not known cases)	2,408 (22.2%)	275 (25.5%)	328 (24.2%)	353 (22.8%)	264 (20.4%)	188 (12.3%)	337 (26%)	397 (25.1%)	266 (22.6%)
Nonhypertensive	8,450 (54.0)	804 (43.6)	1,025 (51.8)	1,193 (60.5)	1,032 (53.5)	1,343 (67.9)	958 (50.6)	1,183 (54.7)	912 (47.9)
Prehypertensive (% of not known cases)	6,521 (60.1)	632 (58.6)	775 (57.3)	920 (59.5)	749 (57.8)	1071 (70)	778 (60.1)	869 (55)	727 (61.7)
Coexistence of diabetes and hypertension	3,227 (20.6)	531 (28.8)	418 (21.1)	367 (18.6)	313 (16.2)	345 (17.4)	461 (24.3)	361 (16.7)	431 (22.6)
Family history [n (%)]									
Diabetes	3,836 (24.5)	461 (25.0)	552 (27.9)	434 (22.0)	365 (18.9)	377 (19.1)	583 (30.8)	551 (25.5)	513 (27.0)
Hypertension	3,641 (23.2)	476 (25.8)	505 (25.5)	294 (14.9)	447 (23.2)	275 (13.9)	553 (29.2)	495 (22.9)	596 (31.3)
Medical history [n (%)]									
Ischemic heart disease	473 (3.0)	167 (9.1)	96 (4.8%)	51 (2.6)	13 (0.7)	20 (1.0)	10 (0.5)	77 (3.6)	39 (2.0)
Myocardial infarction	245 (1.6)	69 (3.7)	50 (2.5)	38 (1.9)	1 (0.1)	3 (0.2)	18 (0.9)	47 (2.2)	19 (1.0)
Stroke	132 (0.8)	54 (2.9)	8 (0.4)	27 (1.4)	7 (0.4)	5 (0.3)	7 (0.4)	12 (0.6)	12 (0.6)
Lifestyle factors [n (%)]									
Smoking (past and present)	1,784 (11.4)	131 (7.1)	281 (14.2)	237 (12)	397 (20.6)	249 (12.6)	193 (10.2)	125 (5.8)	171 (9.0)
Alcohol consumption	1514 (11%)	—	342 (17.3)	215 (10.9)	153 (7.9)	258 (13.0)	285 (15.0)	91 (4.2)	170 (8.9)
Diet [n (%)]									
Vegetarian	5,317 (38.5)	—	1,024 (51.7)	303 (15.4)	138 (7.2)	703 (35.5)	416 (22)	1,648 (76.3)	1,085 (57)
Non-vegetarian	8,502 (61.5)	—	955 (48.2)	1,669 (84.6)	1,792 (92.8)	1,276 (64.5)	1,479 (78.0)	513 (23.7)	818 (43.0)

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patients. Maharashtra had the highest percentage of "known" cases (36.9%, $n=679$), whereas Gujarat had the lowest (21.5%, $n=464$). It is interesting that Gujarat had the highest proportion of "newly" diagnosed cases (9.4%, $n=160$). Tamil Nadu had the highest proportion of overall number of subjects with diabetes (40.3%, $n=795$), whereas Gujarat had the lowest (28.9%, $n=624$).

Table 3 shows the comparison between subjects with and without diabetes. With a mean age of 54.5 ± 11.5 years, those with diabetes were significantly older ($P<0.0001$) than those without diabetes, who had a mean age of 45.9 ± 14.1 years. Age distribution of the patients was significantly associated with diabetes status ($P<0.0001$), and the highest number of subjects with diabetes was seen in the age group 50–59 years (32.8%, $n=1,781$). A higher proportion of those with diabetes than those without diabetes had a personal history of ischemic heart disease, myocardial infarction, and stroke and a familial history of diabetes and hypertension, and this difference was significant ($P<0.0001$). A higher proportion of those with diabetes than those without diabetes were consuming a non-vegetarian diet (63.1% vs. 60.6%; $P<0.05$).

Prevalence of hypertension

Almost half (46.0%) of the study patients were hypertensive (Table 2). Of the 7,212 reported cases, 4,804 (30.7%) were "known" cases. Among those whose disease status was not known, 22.2% (2,408 of 10,858) patients were newly diagnosed with hypertension, and 60.1% (6,521 of 10,858) were classified as having prehypertension (Table 2). Mean duration of hypertension in "known" cases was 6.4 ± 5.9 years with no significant difference between males and females. Prevalence of ISH was 7.7% (1,209 patients), 14.5% (693 patients), and 4.8% (516 patients) among the overall population, "known" cases, and "new" cases, respectively. Similarly, prevalence of IDH was 11.4% (1,780 patients), 12.8% (616 patients), and 10.7% (1,165 patients), respectively.

Overall prevalence of hypertension was the highest in Maharashtra (56.4%, $n=1,038$) and the lowest in Karnataka (32.1%, $n=636$). Maharashtra also had the highest proportion of "known" cases of hypertension at 41.4% ($n=763$), whereas the highest percentage of "new" cases was reported in Andhra Pradesh (26.0%, $n=337$). Hypertensive females tended to have a familial history of the disease ($P=0.0002$).

A comparison between those with and without hypertension is provided in Table 4. The mean age of hypertensive patients was 53.8 ± 12.6 years and was significantly older ($P<0.0001$) than that of patients without hypertension (44.7 ± 13.6 years). The age distribution of the patients was also associated ($P<0.0001$) with hypertension status, with highest proportion of hypertension seen in the 50–59-year age group (28.9%, $n=2,081$). A higher proportion of those with

TABLE 3. COMPARISON BETWEEN SUBJECTS WITH AND WITHOUT DIABETES

	With diabetes (n=5,427)	Without diabetes (n=10,148)	P value
Sex [n (%)]			
Male	2,973 (54.8)	5,565 (54.8)	0.964
Female	2,454 (45.2)	4,583 (45.2)	
Age (years) (mean±SD)	54.5±11.5	45.9±14.1	<0.0001
Age categories [n (%)]			
18–29	62 (1.1)	1,336 (13.2)	<0.0001
30–39	455 (8.4)	2,157 (21.3)	
40–49	1,271 (23.4)	2,690 (26.5)	
50–59	1,781 (32.8)	2,018 (19.9)	
60–69	1,253 (23.1)	1,330 (13.1)	
≥70	605 (11.1)	617 (6.1)	
Coexistence of hypertension [n (%)]			
Yes	3,227 (59.5)	3,956 (39.0)	<0.0001
Family history [n (%)]			
Diabetes	2,083 (37.6)	1,788 (17.6)	<0.0001
Hypertension	1,358 (25.0)	2,269 (22.4)	<0.0001
Medical history [n (%)]			
Ischemic heart disease	240 (4.4)	229 (2.3)	<0.0001
Myocardial infarction	127 (2.3)	118 (1.2)	<0.0001
Stroke	71 (1.3)	61 (0.6)	<0.0001
Lifestyle factors [n (%)]			
Smoking (past and present)	650 (1.2)	1,128 (11.1)	0.106
Alcohol consumption	538 (11.5)	970 (10.7)	0.166
Diet [n (%)]			
Vegetarian	1,730 (36.9)	3,577 (39.4)	
Non-vegetarian	2,963 (63.1)	5,502 (60.6)	0.004

TABLE 4. COMPARISON BETWEEN SUBJECTS WITH AND WITHOUT HYPERTENSION

	With hypertension (n =7,212)	Without hypertension (n=8,450)	P value
Sex [n (%)]			
Male	3,968 (55.0)	4,611 (54.6)	0.572
Female	3,244 (45.0)	3,839 (45.4)	
Age (years) (mean±SD)	53.8±12.6	44.7±13.6	<0.0001
Age categories [n (%)]			
18–29	186 (2.6)	1,224 (14.5)	<0.0001
30–39	732 (10.1)	1,898 (22.5)	
40–49	1,725 (23.9)	2,262 (26.8)	
50–59	2,081 (28.9)	1,738 (20.6)	
60–69	1,630 (22.6)	959 (11.3)	
≥70	858 (11.9)	369 (4.4)	
Coexistence of diabetes [n (%)]			
Yes	3,227 (44.7)	2,200 (26.0)	<0.0001
Family history [n (%)]			
Diabetes	2,037 (28.2)	1,799 (21.3)	<0.0001
Hypertension	2,291 (31.8)	1,350 (16.0)	<0.0001
Medical history [n (%)]			
Ischemic heart disease	395 (5.0)	114 (1.3)	<0.0001
Myocardial infarction	171 (2.4)	74 (0.9)	<0.0001
Stroke	95 (1.3)	37 (0.4)	<0.0001
Lifestyle factors [n (%)]			
Smoking (past and present)	841 (11.7)	943 (11.2)	0.326
Alcohol consumption	747 (12.1)	767 (10.0)	0.0001
Diet [n (%)]			
Vegetarian	2,445 (39.6)	2,872 (37.6)	0.014
Non-vegetarian	3,728 (60.4)	4,774 (62.4)	

TABLE 5. CO-PREVALENCE OF DIABETES
AND HYPERTENSION

	With hypertension	Without hypertension	Total
With diabetes	3,227 (20.6%)	2,200 (14.0%)	5,427
Without diabetes	3,956 (25.3%)	6,192 (39.5%)	1,0148
Total	7,183[a]	8,392[b]	15,575[c]

[a]Missing data = 29.
[b]Missing data = 58.
[c]Missing data = 87.

hypertension than those without hypertension had a personal history of ischemic heart disease, myocardial infarction, and stroke and a familial history of diabetes and hypertension, and this difference was significant ($P < 0.0001$). Alcohol consumption was positively associated with hypertension status ($P = 0.0001$) as was a vegetarian diet ($P = 0.014$).

Co-prevalence of diabetes and hypertension

Table 5 shows the co-prevalence of diabetes and hypertension in the SITE study. A total of 3,227 (20.6%) of the study patients had both diabetes and hypertension, with the highest number reported in Maharashtra (28.8%, $n = 531$) (Table 2). Of the 7,212 patients with hypertension, diabetes was coincident in 3,227 (44.7%) patients. In a similar calculation, of the 5,427 patients with diabetes, hypertension was reported in more than half (59.5%) of the patients. When co-prevalent, diabetes and hypertension were preexisting in almost two-thirds (67.6%, $n = 2,182$) of these patients (Table 6). A total of 634 (19.6%) patients had previously reported diabetes and were diagnosed as a "new" case of hypertension. Only a small percentage of the patients (5.6%, $n = 180$) were a "new" case of both disorders.

Discussion

The SITE study was a descriptive registry with the main intention of estimating the prevalence of the twin epidemic of diabetes and hypertension in an urban, primary care, outpatient setting in India. The study was conducted in eight states, and the pooled analyses are from a representative sample of the Indian population.

Recent years have witnessed a rapid rise in the prevalence of diabetes and hypertension in India. This could be attributed to the increasing levels of sedentarism, urbanization, and consumption of energy-dense and fiber/micronutrient-poor food. Additionally, Indians have a high intake of salt. Some ethnic Indian foods like chutneys, papads, and pickles that are regular and popular household dietary choices increase daily

TABLE 6. CO-PREVALENCE OF NEW AND KNOWN
CASES OF DIABETES AND HYPERTENSION

	Known hypertension	New hypertension	Total
Known diabetes	2,182 (67.6%)	634 (19.6%)	2,816
New diabetes	231 (7.2%)	180 (5.6%)	411
Total	2,413	814	3,227

sodium consumption and predispose the population to hypertension.[18]

The prevalence of diabetes, either previously known or newly diagnosed in the course of the SITE study, was 34.7%. Previous epidemiological studies in India have shown an increasing trend in the prevalence of diabetes, with around 1% in 1995 to 13.1% in males and 11.3% in females in 2002.[19–21] This rise has been more pronounced in certain communities. In the Jaipur Heart Watch study, between 2004 and 2007, the incidence of diabetes rose from 17.7% to 25.9% in men and from 14.2% to 21.1% in women of the Punjabi community.[21] Although there was no significant difference in the prevalence of diabetes among males and females in the SITE study, it does bolster the case that diabetes cases are on the rise in India. It must be noted here that the diagnosis of "new" diabetes was made through RBS/OGTT values in the pilot phase, whereas FPG levels were used for the rest of the study. This transition was made for the exclusive purpose of logistic ease of testing and patient convenience and was not thought to have any bearing on the diagnostic capacity of either test. Moreover, either of these tests is recommended by the American Diabetes Association for diagnosis of diabetes.[13] The prevalence of previously known diabetes was different in various states and ranged from 21.5% in Gujarat to 36.9% in Maharashtra. It was interesting to note that the highest number of newly diagnosed cases was from Gujarat (9.4%). Our study also showed a prevalence of prediabetes in 18.4% of the study population. Prediabetes, as defined by an impaired glucose tolerance, has been reported to be 5.2–14.6% in various Indian studies.[2,16,22,23] A recent prospective study showed that about 40% of those with prediabetes progress to full-blown diabetes,[24] underscoring the clinical importance of our finding.

Almost half the patients in our study had hypertension. This corroborates the findings of a previous study,[21] which showed a prevalence of hypertension of 51% in the study population. ISH, a potent risk factor for stroke, cardiovascular disease, and renal failure, represents the most common form of hypertension among the elderly. On the other hand, IDH is generally more pronounced in those with hypertension who are less than 50 years of age. In our study population, we discovered that the prevalence of ISH was at 7.7%, whereas that of IDH was 11.4%. The higher prevalence of IDH can possibly be attributed to the fact that 51.3% of the study population was under the age of 50 years. In contrast, only about one-fourth of the population was over the age of 60 years. Further age-stratified analysis of prevalence of ISH and IDH will lead to a better understanding of the actual scenario.

As seen in subjects with diabetes, the percentage of hypertensive patients varied from state to state, with the highest prevalence of known cases in Maharashtra (41.4%). Various regional studies in India have put the prevalence of prehypertension in the range of 31–54%.[25–28] In accordance with these reports, our study reported prehypertension in 60.1% of patients. This finding is clinically important because those with prehypertension have a greater chance of developing hypertension.[25]

In our registry, diabetes and hypertension were co-prevalent in around one-fifth of the patients. Although this is lesser than previously reported values, which are in the range of 42–62%,[29–31] it is substantial enough when its impact on health outcomes is taken into consideration. Most patients with both diabetes and hypertension were "known" cases,

but the next highest number was that of subjects with known diabetess who were newly diagnosed with hypertension. In accordance with previous reports, almost half of the hypertensive patients had diabetes, whereas more than half of those with diabetes had hypertension.

Familial history has been known to predispose people to diabetes and hypertension. In our study, 37.6% and 25.0% of those with diabetes reported a familial history of diabetes and hypertension, respectively, and these significantly differed from subjects without diabetes. Similarly, the difference between those with and without hypertension reporting a familial history of either diabetes or hypertension was statistically significant. Despite smoking being accepted as a strong risk factor, our study could not discern a significant association between smoking and prevalence of diabetes or hypertension. Alcohol consumption and diet are also established high-risk factors for diabetes and hypertension. In our study, we observed an association between alcohol consumption and hypertension status. It is interesting that with respect to diet, vegetarianism was reported more often in those with hypertension, whereas those with diabetes predominantly had a non-vegetarian diet. An interesting exception to this last observation is the lower than average prevalence of diabetes in patients from West Bengal, who predominantly have a non-vegetarian diet. The Asian Indian diet is predominantly vegetarian, and occasionally, a few times a week, non-vegetarian food like eggs, fish, and chicken is eaten; red meat is rare. The vegetarian Asian Indian diet has a high glycemic index and thus has a higher area under the curve for glucose excursion, with larger postprandial peaks. These factors contribute toward a higher prevalence of diabetes within the Indian population.[32]

The SITE study does have limitations. It is a clinic-based study conducted in urban metropolitan townships. Although, many of the townships cater to patients from rural and tribal India, this would probably account for <5% of the study population. Hence, the observations and conclusions of this study cannot be extrapolated to the general population, especially the one that lives outside urban and semi-urban zones. Additionally, we did not stratify patient recruitment by time blocks: because subjects with diabetes and hypertension have a higher propensity of visiting physicians earlier in the day, this could have led to a bias. These shortcomings of sampling techniques could thus interfere with estimation of accurate prevalence rates. The diagnosis of hypertension was made based on a measurement during a single time point without any confirmation during the second visit. Subjective risk factors like diet, smoking, and alcohol consumption need to be evaluated in depth to impart validity to their observed association to disease conditions. In our study, we only evaluated their coincidence with the disease condition, and thus the association can only be interpreted as general. Despite these shortcomings, the SITE study provides valuable information from a large population representative of India. This can be useful for improving the awareness and management of diabetes and hypertension as well as in formulation of policies and guidelines.

References

1. World Health Organization: Global Health Risks: Mortality and Burden of Disease Attributable to Selected Major Risks. December 2010. www.who.int/healthinfo/global_burden_disease/GlobalHealthRisks_report_full.pdf (accessed June 18, 2011).
2. Anjana RM, Pradeepa R, Deepa M, Datta M, Sudha V, Unnikrishnan R, Bhansali A, Joshi SR, Joshi PP, Yajnik CS, Dhandhania VK, Nath LM, Das AK, Rao PV, Madhu SV, Shukla DK, Kaur T, Priya M, Nirmal E, Parvathi SJ, Subhashini S, Subashini R, Ali MK, Mohan V: Prevalence of diabetes and prediabetes (impaired fasting glucose and/or impaired glucose tolerance) in urban and rural India: Phase I results of the Indian Council of Medical Research-INdia DIABetes (ICMR-INDIAB) study. Diabetologia 2011 Sep 30 [Epub ahead of print]. DOI: 10.1007/s00125-011-2291-5.
3. Shaw JE, Sicree RA, Zimmet PZ: Global estimates of the prevalence of diabetes for 2010 and 2030. Diabetes Res Clin Pract 2010;87:4–14.
4. Gupta R, Gupta VP: Hypertension epidemiology in India: lessons from Jaipur Heart Watch. Curr Sci 2009;97:349–355.
5. Whitworth JA: 2003 World Health Organization (WHO)/International Society of Hypertension (ISH) statement on management of hypertension. J Hypertens 2003;21:1983–1992.
6. Mohan V, Deepa R, Rani SS, Premalatha G: Prevalence of coronary artery disease and its relationship to lipids in a selected population in South India: the Chennai Urban Population Study (CUPS No. 5). J Am Coll Cardiol 2001;38:682–687.
7. Sahay BK: API-ICP guidelines on diabetes 2007. J Assoc Physicians India 2007;55:1–50.
8. Williams G. Hypertension in diabetes. In: Pickup J, Williams G, eds. Textbook of Diabetes. London: Blackwell Scientific Publications, 1991:719–732.
9. Parving HH, Andersen AR, Smidt UM, Oxenboll B, Edsberg B, Christiansen JS: Diabetic nephropathy and arterial hypertension. Diabetologia 1983;24:10–12.
10. Joshi SR, Vadivale M, Dalal JJ, Das KK: The Screening India's Twin Epidemic (SITE)—Study Design and Methodology (SITE-1). Indian J Endocrinol Metab 2011;15(Suppl 4):S390–S395.
11. Andrews EA, Avorn J, Bortnichak EA, Chen R, Dai WS, Dieck GS, Edlavitch S, Freiman J, Mitchell AA, Nelson RC, Neutel CI, Stergachis A, Strom BL, Walker AM: Guidelines for Good Epidemiology Practices for drug, device, and vaccine research in the United States. Pharmacoepidemiol Drug Saf 1996;5:333–338.
12. IEA-European Federation: Good Epidemiological Practice (GEP): IEA Guidelines for Proper Conduct in Epidemiologic Research. www.ieaweb.org/index.php?option=com_content&view=article&id=15&Itemid=43 (accessed June 18, 2011).
13. Standards of medical care in diabetes—2008. Diabetes Care 2008;31(Suppl 1):S12–S54.

14. American Diabetes Association: Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. Diabetes Care 2003;26(Suppl 1):S5–S20.

15. Chobanian AV, Bakris GL, Black HR, Cushman WC, Green LA, Izzo JL Jr, Jones DW, Materson BJ, Oparil S, Wright JT Jr, Roccella EJ; National Heart, Lung, and Blood Institute Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure; National High Blood Pressure Education Program Coordinating Committee: The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: the JNC 7 Report. JAMA 2003;289:2560–2572.

16. Mohan V, Deepa M, Deepa R, Shanthirani CS, Farooq S, Ganesan A, Datta M: Secular trends in the prevalence of diabetes and impaired glucose tolerance in urban South India—the Chennai Urban Rural Epidemiology Study (CURES-17). Diabetologia 2006;49:1175–1178.

17. Ramachandran A, Mary S, Yamuna A, Murugesan N, Snehalatha C: High prevalence of diabetes and cardiovascular risk factors associated with urbanization in India. Diabetes Care 2008;31:893–898.

18. Misra A, Khurana L: Salt intake and hypertension: walking the tight rope. J Assoc Physicians India 2007;55:401–403.

19. Gupta R, Gupta VP, Sarna M, Bhatnagar S, Thanvi J, Sharma V, Singh AK, Gupta JB, Kaul V: Prevalence of coronary heart disease and risk factors in an urban Indian population: Jaipur Heart Watch-2. Indian Heart J 2002;54:59–66.

20. Gupta R, Prakash H, Majumdar S, Sharma S, Gupta VP: Prevalence of coronary heart disease and coronary risk factors in an urban population of Rajasthan. Indian Heart J 1995;47:331–338.

21. Gupta R, Sarna M, Thanvi J, Rastogi P, Kaul V, Gupta VP: High prevalence of multiple coronary risk factors in Punjabi Bhatia community: Jaipur Heart Watch-3. Indian Heart J 2004;56:646–652.

22. Sadikot SM, Nigam A, Das S, Bajaj S, Zargar AH, Prasannakumar KM, Sosale A, Munichoodappa C, Seshiah V, Singh SK, Jamal A, Sai K, Sadasivrao Y, Murthy SS, Hazra DK, Jain S, Mukherjee S, Bandyopadhay S, Sinha NK, Mishra R, Dora M, Jena B, Patra P, Goenka K: The burden of diabetes and impaired fasting glucose in India using the ADA 1997 criteria: Prevalence Of Diabetes in India Study (PODIS). Diabetes Res Clin Pract 2004;66:293–300.

23. Ramachandran A, Snehalatha C, Kapur A, Vijay V, Mohan V, Das AK, Rao PV, Yajnik CS, Prasanna Kumar KM, Nair JD: High prevalence of diabetes and impaired glucose tolerance in India: National Urban Diabetes Survey. Diabetologia 2001;44:1094–1101.

24. Mohan V, Deepa M, Anjana RM, Lanthorn H, Deepa R: Incidence of diabetes and pre-diabetes in a selected urban south Indian population (CUPS-19). J Assoc Physicians India 2008;56:152–157.

25. Yadav S, Boddula R, Genitta G, Bhatia V, Bansal B, Kongara S, Julka S, Kumar A, Singh HK, Ramesh V, Bhatia E: Prevalence & risk factors of pre-hypertension & hypertension in an affluent north Indian population. Indian J Med Res 2008;128:712–720.

26. Shanthirani CS, Pradeepa R, Deepa R, Premalatha G, Saroja R, Mohan V: Prevalence and risk factors of hypertension in a selected South Indian population—the Chennai Urban Population Study. J Assoc Physicians India 2003;51:20–27.

27. Prabhakaran D, Shah P, Chaturvedi V, Ramakrishnan L, Manhapra A, Reddy KS: Cardiovascular risk factor prevalence among men in a large industry of northern India. Natl Med J India 2005;18:59–65.

28. Hazarika NC, Narain K, Biswas D, Kalita HC, Mahanta J: Hypertension in the native rural population of Assam. Natl Med J India 2004;17:300–304.

29. Moore WV, Fredrickson D, Brenner A, Childs B, Tatpati O, Hoffman JM, Guthrie R: Prevalence of hypertension in patients with type II diabetes in referral versus primary care clinics. J Diabetes Complications 1998;12:302–306.

30. Kabakov E, Norymberg C, Osher E, Koffler M, Tordjman K, Greenman Y, Stern N: Prevalence of hypertension in type 2 diabetes mellitus: impact of the tightening definition of high blood pressure and association with confounding risk factors. J Cardiometab Syndr 2006;1:95–101.

31. Dhobi GN, Majid A, Masoodi SR, Bashir MI, Wani AI, Zargar AH: Prevalence of hypertension in patients with new onset type 2 diabetes mellitus. J Indian Med Assoc 2008;106:92, 94–98.

32. Henry CJ, Lightowler HJ, Newens K, Sudha V, Radhika G, Sathya RM, Mohan V: Glycaemic index of common foods tested in the UK and India. Br J Nutr 2008;99:840–845.

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