Abstract

Objective: We conducted a well-designed prevalence study in a rural population of Haryana in Mullana rural area to find out the latest prevalence of essential hypertension, the prescription pattern of antihypertensive drugs and the associated risk of new onset of diabetes.

Methods: A retrospective study was carried out on the patient data (2672 patients) from the years 2009 to 2013 at OPD of M. M. University hospital, Mullana to find the previous year’s prevalence of different diseases, including essential hypertension, new onset of diabetes and associated risk factors, prescription pattern of antihypertensive drug therapy. Based on the above results, a prospective study was conducted from January 2015 to December 2016 and total 510 patients (270 essential hypertension and 240 essential hypertension with new onset of diabetes) and 270 normal individuals were recruited in the study.

Results: The retrospective study, a total of 2672 patients’ data was evaluated which showed 41.21% prevalence of essential hypertension, 11.83% new onset of diabetes in Essential hypertension patients and 15.87% diabetic patients. Antihypertensive monotherapy was prescribed to 59.85% patients and combination therapy to 40.15% patients while that of a prospective study showed 40.37% patients of monotherapy and 59.63% of combination therapy. The prospective study also showed that different anthropometric parameters were significantly associated with risk of hypertension and new onset of diabetes except for age and height.

Conclusion: An increase in the prevalence of essential hypertension and associated risk factors was observed when compared with previous studies and retrospective study. It is clearly seen by the change in drug therapy pattern and different anthropometric parameters. Implementation of a large scale awareness program is needed to combat these metabolic diseases.

Keywords: Anthropometric Parameters, Antihypertensive Therapy, Essential Hypertension, New Onset of Diabetes, Prevalence Study, Rural Area

Introduction

Chronic diseases like hypertension and diabetes mellitus are prevailing at an epidemic scale throughout the world due to continuous chronic change in the lifestyle pattern of mankind which then further lead to high mortality rates [1, 2]. Even in India, hypertension affected 25% of urban and 33% of rural populations. The data suggested that among the essential hypertension affected population, only 38% of urban and 25% of the rural population are being treated for hypertension [3]. By the year 2025, the global load of hypertension is expected to increase from 1 billion to 1.56 billion, which will further worsen the conditions [4]. Hypertension alone is considered as the risk factor for many cardiovascular diseases, including new onset of diabetes. Many studies found a close association of essential hypertension with diabetes mellitus as both share a common metabolic pathway and also both affect the pathophysiology of one another [5, 6]. Around one-third hypertensive patients are reported to develop diabetes in later stages of hypertension [7]. Co-existence of hypertension and diabetes at a single time in an individual is 75% more dangerous than either a single disease which increases the risk of another cardiovascular disease such as coronary heart disease, nephropathy, retinopathy and stroke [8, 9]. In addition, certain antihypertensive therapies (especially beta-blockers (BBs), diuretics, angiotensin-converting enzyme inhibitors (ACEIs) and calcium channel blockers (CCBs)) on prolonged use (for 3 y or more) are also reported to induce type 2 diabetes or glucose dysregulation in hypertensive patients under the influence of polymorphic alleles of certain genes [10]. Even it is very hard to control hypertension in patients who have developed diabetes and a combination of antihypertensive therapies is needed to take control over high blood pressure [11]. This may further complicate the situation of glycemic dysregulation due to excessive use of antihypertensive drugs. Hence, it is better to diagnose and treat diabetes in hypertensive patients at an early stage to avoid such complications. Therefore, identification of the type of hypertensive patients (based on certain clinical markers, genetic markers ethnic markers and certain other markers) who are more prone to develop diabetes may also help to combat metabolic complexities and reduce the mortality associated with these diseases.

Haryana is a northern state of India with people from diverse ethnic and cultural groups. An earlier study (in 2011) found a higher (30.2%) prevalence of hypertension (59.2% males and 40.8% females) in a rural population of Haryana [12]. Therefore, in the present study, we tried to find out the current prevalence of different diseases, including hypertension, diabetes mellitus and new onset of diabetes in hypertensive patients along with the different drug therapies in the same rural population of this area.

Materials and Methods

Ethics

The study was approved (IEC/670) by the Institutional Ethics Committee of M. M. University and a prior written consent was obtained from all the participants.

Study design

The present study was carried out on the 38,500 inhabitants residing in a 30-kilometer radius of Mullana block in the Ambala district of Haryana State. A retrospective analysis (on the previous year’s patient data) was done to find out the previous five years data.
on the prevalence of different diseases, including essential hypertension and Essential hypertension with new onset of diabetes and a prospective study was conducted to assess the risk factors associated with essential hypertension and new onset of diabetes in these patients. The detailed study design is discussed as given below:

**Retrospective study**

The retrospective study was conducted in M. M. Institute of Medical Science and Research, Mullana (Haryana) on total 2672 patients visiting the OPD of the hospital during the years from 2009 to 2013. The retrospective data were collected from the patient data center of the university hospital to find out the prevalence of different diseases, including essential hypertension and essential hypertension with new onset of diabetes in this rural population.

**Prospective study**

The data from our retrospective study suggested that a sufficient number of patients are available within the hospital to conduct a prospective study on the same area population to assess the risk factors associated with essential hypertension and the associated new onset of diabetes. The prospective study was conducted on patients visiting the medicine OPD of a university hospital from January 2015 to December 2016. A sample size of 164 patients would be sufficient to represent the essential hypertension population residing in the rural area under investigation with a power of 80% and a P-value of 0.05. We have selected 510 patients (270 essential hypertension patients and 240 essential hypertension with new onset of diabetes patients) who visited regularly in hospital OPD. Patients who agree to participate were explained the nature and the objectives of the study and informed consent were obtained individually. In order to make a comparison with normal individuals, we have selected normal individuals with age and sex-matched from the same place and denoted as a normotensive group.

**Data collection**

Various parameters like age, sex, body mass index (BMI), height, weight, waist circumference (WC), hip circumference (HC), systolic blood pressure (SBP), diastolic blood pressure (DBP), fasting blood glucose level (FBG), W/H ratio, education, and family history were recorded in a given questionnaire only after taking the patient consent. The information about patient's identity was not included with other data and the only physician had the access to this information.

**Inclusion criteria**

The below-given selection criteria were followed and essential hypertension patients of both sexes between the age group of 18 to 75y were included in the study. Patients on treatment with selective antihypertensive medication (diuretics, BBs, CCBs) for about 3 y or more either as monotherapy and combination therapy (for essential hypertension group), essential hypertension patients with new onset of diabetes patients (as diagnosed by the physician) (for essential hypertension with new onset of diabetes group) and normal individuals without any history of essential hypertension and diabetes and without any drug therapy were included.

**Exclusion criteria**

The exclusion criteria indicated that all individuals with the age below 18 y and above 75 y, essential hypertension patients who were on antihypertensive drugs other than diuretics, BBs, and CCB, patients with irregular dosing of antihypertensive therapy, patients with secondary cause of hypertension, pregnant and lactating mothers, non-cooperative and disabled patients were also excluded from the study.

**Blood pressure measurements**

The blood pressure recordings were taken by the physicians in OPD. An appropriately sized cuff (suff bladerr encircling at least 80 percent of the arm) was used to ensure accuracy in the palpatory obliteration of radial pulse pressure was obtained before auscultating for blood pressure (BP) measurement. Patients were made to sit quietly for at least 15 min on a chair and smoking and intake of any kind of drugs (which may affect blood pressure) was avoided for at least 30 min prior to the BP measurement. Three readings were taken at 5 min interval, and the average was recorded. By auscultatory method appearance and disappearance of Korotkoff sound were taken as indicative of SBP and DBP, respectively [13].

**Blood glucose monitoring**

The FBG level of each recruited patient was monitored to find out the essential hypertension patients with new onset of diabetes after chronic therapy of diuretics, BBs and CCBs.

**Statistical analysis**

Data analysis was done with the help of an SPSS version 14.5. Continuous variables were expressed as means ±SD. Intergroup comparisons were made using student t-test. Allele frequencies were calculated from genotype frequencies and were compared using chi-squared (χ²) statistics. P value<0.05 was considered statistically significant.

**RESULTS**

**Retrospective study**

Total of 2672 patients was included in the study that consists of 1560 (58.38%) male and 1112 (41.62%) female patients. The prevalence rates of different diseases among male and female populations are given in below table 1.

**Table 1: Gender wise prevalence of different disease in the rural population of Haryana during the y 2009 to 2013**

| Disease                                      | Male n (%) | Female n (%) | Total n (%) |
|----------------------------------------------|------------|--------------|-------------|
| Essential hypertension                       | 577 (21.59)| 524 (19.61)  | 1101 (41.21)|
| Diabetes mellitus                            | 242 (9.06) | 182 (6.81)   | 424 (15.87) |
| Essential hypertension with new onset of diabetes | 122 (4.57)| 194 (7.26)   | 316 (11.83) |
| Cardiovascular disease                       | 411 (15.38)| 150 (5.61)   | 561 (21)    |
| COPD                                         | 175 (6.55) | 49 (1.83)    | 224 (8.38)  |
| Other diseases                               | 33 (1.24)  | 13 (0.49)    | 46 (1.72)   |
| Total                                        | 1560 (58.38)| 1112 (41.62)| 2672 (100)  |

n (%)=number of total individuals (value in percentage)

From the above table, a very high prevalence of essential hypertension (41.21%) was found followed by CVDs (21%), diabetes mellitus (15.87%), essential hypertension with new onset of diabetes (11.83%), COPD (8.38%) and other non-serious seasonal disease (1.72%) of the total population (Fig. 1).

The male patient population of this rural area showed a high prevalence for both essential hypertension (21.59%) and diabetes (9.06%) as compared to females (19.61% and 6.81% respectively). Essential hypertension with new onset of diabetes was more prevalent in females (7.26%) than males (4.57%) among those visited the university hospital. CVDs, COPD and other diseases were more prevalent in male patients as compared to females.

This data showed that female patients were more prone to develop diabetes and hypertension along with their coexistence (Fig. 2).
Antihypertensive therapy prescription pattern

Out of total 1101 essential hypertension patients, 59.85% patients were prescribed monotherapy and 40.15% were prescribed as combination therapy (24.98% on the two-drug combination and 15.17% of multiple drug combination therapy) as given in table 2.

Gender wise prescription data revealed that the more number of female patients (30.33%) were prescribed with antihypertensive monotherapy than male patients (29.52%). However, two drug combinations and multiple drug therapies were more prescribed in males (14.90% and 7.99%, respectively) than females (10.08% and 7.18%, respectively) (fig. 3).

Table 2: Prescription pattern of anti-hypertensive therapy among the patients visited the medicine OPD of university hospital from 2009 to 2013

| Pattern               | Number of prescriptions | Total n (%) |
|-----------------------|-------------------------|-------------|
|                       | Male n (%)   | Female n (%)|               |
| Monotherapy           | 325 (29.52) | 334 (30.33) | 659 (59.85) |
| Combination therapy   | 164 (14.90) | 111 (10.08) | 275 (24.98) |
| Two drugs             | 88 (7.99)   | 79 (7.18)   | 167 (15.17) |
| Multiple drugs        | 577 (52.41) | 524 (47.59) | 1101 (100.00) |

n (%)=number of total individuals (value in percentage)
The drug wise data showed that among male patients 28.31% were prescribed with BBs, 5.54% with ACEI, 27.08% with CCB, 12.92% with diuretics and 26.15% with ARB. While among female patients 33.23% were prescribed with BB, 8.68% with ACEI, 20.06% with CCB, 17.66% with diuretics and 20.36% with ARB (fig. 4). Data revealed that female patients were most prescribed with BB followed by diuretics and ACEI while male patients were mostly prescribed with CCB followed by ARB.

Prospective study
Total of 510 patients was recruited for the study and categorized in two groups, i.e. essential hypertension patients (n=270) and essential hypertension with new onset of diabetes patients (n=240). Individuals without any history of hypertension, diabetes, essential hypertension with new onset of diabetes or any other metabolic diseases were selected as normal control (n=270).

Patient information including the history of disease, prescription pattern, anthropometric parameters, BP and FBG level measurements were taken and discussed in below table 3.

Table 3: Comparative demographic data of normal, essential hypertension and essential hypertension with new onset of diabetes groups

| Parameters           | Normal          | Essential hypertension | Essential hypertension with new onset of diabetes | Overall p-value |
|----------------------|-----------------|------------------------|---------------------------------------------------|-----------------|
| M/F                  | 150/120         | 95/175                 | 80/160                                            | -               |
| Age (y)              | 51.82±11.91     | 53.4±10.86             | 54.92±9.29                                        | 0.0054<sub>a</sub>=<sub>b</sub><sup>**</sup> 0.001<sub>a</sub>=<sub>b</sub><sup>***</sup> |
| SBP (mmHg)           | 123.3±4.99      | 152.59±10.24           | 155.4±8.17                                        | 0.000<sub>c</sub>=<sub>d</sub><sup>***</sup> |
| DBP (mmHg)           | 81.5±3.73       | 91.8±2.62              | 92.3±2.47                                         | 0.0001<sub>a</sub>,<sub>b</sub>,<sub>c</sub><sup>***</sup> |
| FBG (mg/dl)          | 97.18±6.61      | 107.20±7.85            | 207.29±81.02                                      | 0.0001<sub>a</sub>,<sub>b</sub><sup>***</sup> |
| Weight (kg)          | 63.4±8.87       | 71.96±7.54             | 75.94±8.64                                        | 0.0004<sub>a</sub>,<sub>b</sub><sup>***</sup> |
| Height (cm)          | 158.53±9.33     | 156.89±8.71            | 158.02±8.36                                      | 0.0001<sub>a</sub>,<sub>b</sub>,<sub>c</sub><sup>***</sup> |
| BMI (kg/m<sup>2</sup>) | 76.3±7.52       | 94.13±7.08             | 103.13±11.35                                      | 0.0001<sub>a</sub>,<sub>b</sub><sup>***</sup> |
| WC (cm)              | 90.5±7.14       | 105.57±10.22           | 104.92±12.67                                      | 0.0001<sub>a</sub>,<sub>b</sub><sup>***</sup> |
| W/H Ratio            | 0.85±0.08       | 0.90±0.06              | 0.99±0.05                                         | 0.0001<sub>a</sub>,<sub>b</sub><sup>***</sup> |
| Duration of HTN (y)  | -               | 4.70±4.11              | 7.91±4.52                                         | -               |
| Duration of diabetes (y) | -             | -                     | 5.72±4.32                                         | -               |

Statistical analysis of data was carried by one-way ANOVA followed by Tukey's Multiple Range Test. The values are mean±SD for each group, “normal v/s essential hypertension, “normal v/s essential hypertension with new onset of diabetes, “essential hypertension v/s essential hypertension with new onset of diabetes, “Highly significant, “Moderate significant, “Non significant
The mutual comparison of the demographic details of normal, essential hypertension and essential hypertension with new onset of diabetes groups revealed that the age was moderately significant for normal v/s essential hypertension with new onset of diabetes comparison only ($p<0.01$) and was non-significant for another group comparison ($p>0.05$). Likely, height was also non-significant when compared among these three groups ($p>0.05$). However, all other anthropometric and clinical parameters were highly significant among the three comparison groups ($p<0.0001$).

In socio-demographic data comparison (table 4), in all groups, smokers and drinkers were lesser in number than non-smokers and non-drinkers. Similarly, vegetarian individuals were higher in number as compared to non-vegetarian among disease groups. The majority of the patients were belonging to the illiterate and non-working category having a sedentary lifestyle in both the groups. The lower number of patients was having a family history profile.

**Pattern of anti-hypertensive drug therapy among the essential hypertension patients**

Out of total 270 essential hypertension patients, monotherapy was prescribed to 109 (40.37%) patients while combination drug therapy was prescribed to 161 (59.63%) patients (fig. 5).

### Table 4: The socio-demographic details of the populations under study

| Parameters | Normotensive n (%) | Essential hypertension n (%) | Essential hypertension with new onset of diabetes n (%) |
|------------|--------------------|-------------------------------|-------------------------------------------------------|
| **Gender** |                    |                               |                                                       |
| Male       | 150 (55.5)         | 95 (35.1)                     | 80 (33.4)                                             |
| Female     | 120 (44.5)         | 175 (72.9)                    | 160 (66.6)                                            |
| **Smoking**|                    |                               |                                                       |
| Smoker     | 108 (40)           | 60 (22.2)                     | 20 (8.4)                                              |
| Non smoker | 212 (60)           | 210 (77.7)                    | 220 (91.6)                                            |
| **Drinking**|                  |                               |                                                       |
| Drinker    | 60 (22.3)          | 50 (18.5)                     | 20 (8.4)                                              |
| Non drinker| 210 (77.7)         | 220 (81.4)                    | 220 (91.6)                                            |
| **Food habits**|              |                               |                                                       |
| Vegetarian | 126 (46.7)         | 170 (62.9)                    | 165 (68.7)                                            |
| Non-vegetarian |            | 100 (37.1)                     | 75 (31.2)                                             |
| **Occupation**|               |                               |                                                       |
| Own business| 72 (26.6)          | 40 (14.8)                     | 35 (14.5)                                             |
| Farming    | 78 (28.8)          | 25 (9.2)                      | 40 (16.6)                                             |
| Non-workers| 36 (13.3)          | 140 (51.8)                    | 150 (62.5)                                            |
| Workers    | 54 (20)            | 55 (20.3)                     | 15 (6.25)                                             |
| Students   | 30 (11.11)         | 0                             | 0                                                     |
| **Education**|                |                               |                                                       |
| Illiterate | 96 (35.5)          | 125 (46.2)                    | 100 (41.6)                                            |
| Primary    | 36 (13.3)          | 50 (18.5)                     | 55 (22.9)                                             |
| Secondary  | 54 (20)            | 55 (20.3)                     | 45 (18.7)                                             |
| Higher education | 84 (31.1) | 40 (14.8)                     | 40 (16.6)                                             |
| **Family History**|          |                               |                                                       |
| Yes        | 90 (33.3)          | 55 (20.3)                     | 85 (35.4)                                             |
| No         | 180 (66.6)         | 215 (79.6)                    | 155 (64.6)                                            |

n(%)=number of total individuals (value in percentage)

Out of total 109 monotherapy patients, BB and diuretics were equally prescribed in 32 (29.36%) patients followed by CCB in 45 (41.28%) patients (table 5).

The gender wise data showed that out of total 37 monotherapy male patients, BB (29.73%) and a diuretic (29.73%) were most prescribed drug therapy followed by CCBs (40.54%). Out of total
72 female patients, the almost same trend was observed for BB (29.17%), diuretics (29.17%) and CCBs (41.66%) (fig. 6). Surprisingly, ACEIs and ARBs were not prescribed to a single patient as monotherapy.

Table 5: Prescription pattern of monotherapy among the essential hypertensive patients

| Monotherapy | Male n (%) | Female n (%) | Total n (%) |
|-------------|------------|--------------|-------------|
| BB          | 11 (29.73) | 21 (29.17)   | 32 (29.36)  |
| Diuretics   | 11 (29.73) | 21 (29.17)   | 32 (29.36)  |
| CCB         | 15 (40.54) | 30 (41.66)   | 45 (41.28)  |
| Total       | 37 (100.00)| 72 (100.00)  | 109 (100.00)|

n (%)=number of total individuals (value in percentage)

Among total 240 Essential hypertension with new onset of diabetes patients, 80 (33.33%) were male and 160 (66.67%) were females. Mono drug therapy was prescribed to 78 (32.50%) patients; whereas combination therapy was given to 162 (67.50%) patients (fig. 7).

Hypertension and diabetes are interrelated diseases, the combination of which becomes lethal to the mankind. Not only hypertension is considered as one of the risk factors for developing diabetes but also antihypertensive therapy also been found associated with new onset of diabetes in essential hypertension patients [10]. Therefore, a high prevalence of hypertension is dangerous in either way and poses health problems in the mankind.

In India, the prevalence of hypertension and diabetes is increasing at an alarming rate with the development of the country. Availability of an exact data of a particular area about the prevalence of hypertension, diabetes and other related diseases may help the healthcare system to serve in an efficient way and combat the diseases effectively. Therefore, in the present study, we tried to assess the prevalence of essential hypertension, the prescription pattern of antihypertensive drugs, and risk factors for new onset of diabetes in hypertensive patients.

From the retrospective study, we found a very high prevalence of essential hypertension (41.21%) and diabetes (15.87%) in the overall population (table 1) which is slightly higher than the previous study conducted in the same population area by Gupta et al., 2011 [12]. The gender wise data revealed that the prevalence of hypertension was more in male (21.59%) than females (19.61%). Similarly, the prevalence of diabetes was more in males (9.06%) than females (6.81%). While the prevalence of essential hypertension with new onset of diabetes patients showed that the prevalence of new onset of diabetes in hypertensive female patients (7.26%) was more than male patients (4.57%). The Antihypertensive therapy prescription pattern showed that monotherapy was prescribed to about 59.85% patients and a combination therapy to 40.15% patients during the year 2009 to 2013 (table 2). Among which, BBs were the most prescribed drugs followed by CCBs and ARBs.

In prospective study, mutual comparison of different anthropometric parameters among normal, essential hypertension...
and essential hypertension with new onset of diabetes group patients (table 3) suggested that the comparative p-value for age and height parameters were non-significant (p=0.05) which indicated that these two parameters were not the risk factor for essential hypertension and new onset of diabetes. But other parameters such as SBP, DBP, FBG level, BMI, WC, HC and W/H ratio were differing significantly which clearly indicated these parameters as the risk factors for essential hypertension which further may be associated with new onset of diabetes. From the socio-demographic data, it is evident that illiterate people living in sedentary conditions, with elevated BP and family history of diabetes were at higher risk of hypertension and further diabetes [15, 16].

A significant shift in the pattern of antihypertensive drug therapy from monotherapy to a combination therapy was observed in the prospective study (fig. 5) when it was compared with that from the retrospective study (table 2). Over these years, more patients were shifted to combination drug therapy (59.63%) and a reduction in monotherapy patients (40.37%) was observed. The same scenario of the antihypertensive therapy prescription pattern was observed for essential hypertension with new onset of diabetes patients. This indicated the severity of the diseases and their pace with which these are spreading. CCBs were most prescribed drugs in the prospective study followed by BBs and diuretics, but surprisingly, ACEIs and ARBs were not prescribed to even a single patient. Therefore, from our data, it was found that the prescription pattern of the antihypertensive therapy shifted from monotherapy to combination therapy from 2009-2013 data to 2016 data which suggest the severity of the disease.

CONCLUSION

Our study suggests that essential hypertension is the most prevalent disease in the rural population of Haryana in both males and females. However, essential hypertension with new onset of diabetes was more prevalent in the female population. The severity of the disease increased from 2009 to 2016 which resulted in the shift of the prescription pattern of the antihypertensive from monotherapy to combination therapy in the majority of the patients. Different anthropometric parameters are the indicator of risk factors associated with essential hypertension and new onset of diabetes in these patients. Person’s lifestyle pattern also indicated the risk factor for essential hypertension and new onset of diabetes. An illiterate person living in sedentary lifestyle is at most risk.

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AUTHORS CONTRIBUTIONS

The corresponding author (Dr. Sumeet Gupta) is the principal author and guided the project, first author (Vikas Jhawat) carried out the complete experimental work, Dr. Bimal Kumar Agarwal helped in identification, selection and recruitment of appropriate patients and collection of samples and Dr. Partha Roy and Dr. Vipin Saini helped in the study protocol designing and editing and further analysis.

CONFLICT OF INTERESTS

Declared none

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