Original Article

Hypertensive Phenotypes and Pattern of Ambulatory Blood Pressure in Patients of Diabetes Mellitus of Kashmir Valley

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Abstract

Background: Patients of diabetes mellitus (DM) with hypertension (HTN) have a fourfold increased risk of cardiovascular disease (CVD) as compared to normotensive nondiabetic controls. However, many patients of DM who are normotensive or have controlled blood pressure on office BP measurement (OBPM) may assume that they do not have increased risk of CVD but may be having HTN or uncontrolled blood pressure on ambulatory blood pressure monitoring (ABPM). **Study Design Objective:** A cross-sectional observational study to compare OBPM with ABPM and thus predict various hypertensive phenotypes like masked hypertension (MH) and white coat hypertension and pattern of blood pressure in diabetic patients of our population. **Materials and Methods:** Two hundred patients of DM with or without HTN were included in this study. The cases were subjected to detailed history, clinical examination, OBPM, and ABPM. **Results:** Out of 200 patients of DM, 32 were normotensives, 46 were hypertensives controlled on antihypertensive treatment, 22 were hypertensives not on anti-hypertensive treatment, and 100 were hypertensives uncontrolled on anti-hypertensive treatment. Among 32 normotensive diabetics, 17 (53%) patients had **MH** on ABPM. Out of these 32 normotensive patients, 7 (21.8%) had **isolated nocturnal hypertension**, 3 (9.3%) had **isolated day-time HTN (IDH)** and 7 (21.8%) had **day-time and nocturnal HTN (DNH)**. Patients with MH had higher BMI, an observation that was statistically significant. Non-dipping pattern was found in 53% of patients of masked HTN. Out of 46 hypertensive diabetics with controlled OBPM on antihypertensive treatment, 26 (56.5%) had **masked effect or masked uncontrolled hypertension** on ABPM. Out of 22 diabetics with treatment naïve HTN, 7 (32%) were found to have **white coat hypertension** on ABPM. Fifteen (15%) patients out of 100 hypertensive diabetics with uncontrolled OBPM despite on anti-hypertensive were found to have **white coat effect** on ABPM. Patients with white coat effect had higher body mass index an observation that was statistically significant ($p = 0.039$). Non-dipping pattern was significantly associated with longer duration of diabetes (≥ 120 months), retinopathy and neuropathy. **Conclusion**: To rely exclusively on OBPM to diagnose HTN and monitor blood pressure may underestimate the CVD risk especially in diabetics. ABPM is a tool that may not only help clinicians in starting anti-HTN treatment perspicuously, but also may help in avoiding unnecessary anti-hypertensive treatment and/or withdrawing anti-hypertensive treatment as indicated and thus avoiding credulity.

Keywords: Ambulatory blood pressure monitoring, hypertension, masked effect, masked hypertension, office blood pressure monitoring, white coat effect, white coat hypertension

Introduction

Diabetes mellitus (DM) is a group of metabolic diseases characterized by hyperglycaemia resulting from either a defect in insulin secretion or insulin action or both.[1] Diabetes accounts for 10.7% of global all-cause mortality in people aged 20–79 years, with nearly one in two deaths occurring in those less than 60 years of age. India home to 72.9 million people with diabetes and another 24 million with impaired glucose tolerance, is expected to become country with the largest population of people with diabetes by 2045 as per the 8th edition of International Diabetes Federation Diabetes Atlas 2017. More than half of these diabetic patients remain undiagnosed

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with approximately 1 million deaths being attributed to this condition.[2,3]

Hypertension (HTN) is seen in one out of every two patients with diabetes. Diabetic patients with HTN have a fourfold increased risk of cardiovascular disease (CVD) as compared to normotensive nondiabetic controls.[4] A retrospective analysis of data from the Framingham original and offspring cohorts explored the risk attributable to HTN in patients with diabetes. The presence of HTN at the time of type 2 diabetes diagnosis in 1,145 Framingham subjects revealed approximately 40% higher all-cause mortality and cardiovascular (CV) events compared to normotensive subjects with type 2 diabetes. Much of the excess risk was attributed to the concomitant presence of HTN in addition to the risk attributed to diabetes.[5]

Since HTN is the strongest driver of CV outcome in patients with diabetes, blood pressure (BP) diagnosis, and control has emerged as the most important intervention in this population. The classic definition of HTN is based on office BP measurements, and most data relating HTN to CV morbidity and mortality are derived from office measurements.[6] The measurements in office may not reflect the true BP level. They may be elevated when the true BP is normal [white coat effect (WCE)], or they may be normal when true BP is elevated (masked hypertension). Office measurements also do not reflect the diurnal variations and nocturnal BP levels. Twenty-four-hour ambulatory blood pressure monitoring (ABPM) is a precise method to quantify BP levels and diagnose HTN and monitor control. Recent studies showed that 24-hr ABPM is more accurate than office measurements in predicting CV morbidity and mortality.[7]

ABPM is particularly important for the management of HTN in diabetic patients, since HTN is a major risk factor for CVD in these patients. Diabetic patients are more likely to be non-dippers, and therefore office BP measurements do not reflect the real CV risk.[8] White coat hypertension (WCH) seems to be less frequent and masked hypertension more frequent in diabetic patients and seems to be associated with increased organ damage.[9]

Since the HTN is particularly devastating in diabetic patients, it seems prudent to perform ABPM in all diabetic patients with high normal BP.[10] In patients with normal office BP and elevated ambulatory BP levels, anti-HTN treatment should be initiated and response should be evaluated by repeated ambulatory BP monitoring. Abnormalities in systolic BP, particularly during the night, could be linked with excess BP-related CV risk of diabetes.

Hence, relying exclusively on office BP measurements may not identify true pattern of BP in diabetic patients making it imperative to supplement patient evaluation with ABPM. A wider use of ABPM in diabetic patients would identify more patients with masked hypertension and patients with nocturnal HTN and would help to improve BP control.

Aims and Objectives

To compare office BP with 24-h ambulatory blood pressure recordings in patients of DM and to determine the pattern of BP.

Materials and Methods

The study was conducted in the department of general medicine at Sheri Kashmir Institute of Medical Sciences (SKIMS) and SKIMS Medical College Hospital, Srinagar. A total number of 200 diabetic subjects were included in the study over a period of two years from August 2017 to July 2019. An ethical clearance was obtained from the institutional ethical committee and informed consent was sought from the patients to participate in the study. The subjects with fever, sepsis, CCF, acute events like stroke and MI, pregnancy were not included in study.

Bio data in the form of name, age, sex, body mass index (BMI), clinical examination esp. related to complications of DM, baseline investigations including Complete blood count (CBC), kidney function test (KFT), liver function test (LFT),Lipid profile, 24 hr urinary protein, HbA!C, fundus examination, electrocardiography, ultrasonography. Details of drugs which patient has been taking, especially antihypertensive and anti-diabetic were also recorded.

Office BP was measured according to standardized procedure with the use of calibrated mercury sphygmomanometer. Mean of the two readings taken 1 min apart was used. The patient was subjected to ABPM within a week of office BP measurement and patient was asked not to change dosing and/or timing of any anti-hypertensive treatment if any he/she has been taking.

ABPM was performed with validated, automated, oscillometric device (Meditech device) programmed to record BP every 15-min interval during the day and 30-min intervals during the night. Day-time interval was set between 6 am and 10 pm and night interval between 10 pm and 6 am. For analysis, mean of all valid readings was used and valid measurements had to fulfil pre-specified quality criteria, including the successful recording of at least 70% of programmed measurements corresponding to 20 day-time and 7 night-time readings during the 24 hr recording period. Reports were generated on all patients in a standard manner and after performing ABPM, categorization of hypertensive phenotypes and sub-categorization was done [Table 1 and 2].

Blood pressure definition in patients not on any antihypertensive treatment

Office BP value of ≥130 mm Hg (SBP) and/or ≥80 mm Hg was considered as HTN and ABPM value of 24-hr average BP≥130/80 mmHg and/or average day-time BP≥125/75 mmHg and/or average night-time BP≥110/65 mmHg was considered HTN as per ABPM results.[11]

Blood pressure goals in DM patients on antihypertensive treatment

Office BP value of ≤130/79 and ABPM average day-time value of BP ≤125/79 was considered as controlled BP and

Table 1: Hypertensive phenotypes based on office BP and ABPM. Elevated ABPM means any of the following elevated average readings of daytime SBP/day-time DBP/ night-time SBP/night-time DBP

	Office BP	ABPM
Normotension	Normal	Normal
Masked HTN	Normal	Elevated
Hypertension controlled	Normal on Anti-hypertensive treatment	Normal
Masked effect	Normal on Anti-hypertensive treatment	Elevated
Hypertension	Elevated	Elevated
White Coat HTN	Elevated	Normal
Uncontrolled HTN	Elevated on Anti-hypertensive treatment	Elevated
White coat effect	Elevated on Anti-hypertensive treatment	Normal

Table 2: Sub-categorization of masked hypertension and masked uncontrolled hypertension. INH: Isolated nocturnal HTN, IDH: Isolated day-time HTN, DNH: Day-time, and nocturnal HTN

	Office BP	Overall ABPM	Day time	Nocturnal
INH	Normal	Normal/ Elevated	Normal	Elevated
IDH	Normal	Normal/ Elevated	Elevated	Normal
DNH	Normal	Elevated	Elevated	Elevated

Table 3: Classifying dipping pattern on the basis of diurnal index

	Pattern	Diurnal Index
1.	Normal dipper	11-20%
2.	Non-dipper	1-10%
3.	Reverse dipper	< 0
4.	Extreme dipper	21-30%

office BP value of SBP ≥131/80 mmHg and ABPM average day-time value of BP ≥126/80 was considered as uncontrolled BP.[12,13]

The dipping status was assessed by calculating diurnal index, which was calculated by dividing the difference between day- and night-time mean BP by mean day-time BP and multiplying the resultant by 100 and patients were classified as per their dipping status [Table 3].

Results and Observations

A total of 200 diabetic patients were included in this study, 71 (34.5%) were males and 129 (64.5%) were females. Among the patients, 39 (19.5%) were smokers and 161 (80.5%) were non-smokers.

Out of 200 DM, patients studied, 32 were normotensives not on any drug, 46 were having controlled office BP on anti-hypertensive medication, 22 had uncontrolled office BP and were not on any treatment and 100 had uncontrolled office BP on anti-hypertensive medications.

- Group 1: DM with controlled office BP without anti-hypertensive treatment. (n = 32)
- Group 2: DM with controlled office BP with anti-hypertensive treatment. (n = 46)
- Group 3: DM with uncontrolled office BP and not on anti-hypertensive treatment. (n = 22)
- Group 4: DM with uncontrolled Office BP and on anti-hypertensive treatment. (n = 100).

Group 1: DM with normal office BP without anti-hypertensive treatment

Out of 32 DM patients who were normotensive on office BP, ABPM revealed masked hypertension in 17 (53%) patients and normal BP in rest 15 (47%) patients. Isolated nocturnal hypertension (INH) was more common than isolated day-time HTN (21.8% vs 9.3%) in patients diagnosed with masked hypertension and non-dipping pattern was a significant observation in patients with masked HTN [Table 4].

There was no significant association of any demographic, clinical, or laboratory variable except BMI which was significantly higher in masked hypertension as compared to normotensive patients (p = 0.027) [Table 5].

Out of 17 patients with masked hypertension, 3 (17.6%) had complicated diabetes, while 2 (13.3%) out of 15 true normotensives had complicated diabetes. There was no significant association of complications of DM with masked hypertension on fisher exact test (p = 1.0).

Group 2: DM and controlled office BP with anti-hypertensive treatment

Out of 46 patients of DM with controlled office BP on anti-hypertensive treatment, 26 (56.5%) patients had uncontrolled BP on ABPM. These patients were labelled as DM with masked effect (ME) or masked uncontrolled HTN (MUCH). There was no significant difference among various demographic, clinical and, laboratory parameters studied between truly controlled and ME group [Table 6]. Patients with ME/MUCH had higher percentage of non-dipping pattern as compared to those with controlled BP on ABPM.

Out of 26 patients with ME, 12 (46.1%) patients had complicated diabetes whereas 11 (55%) out of 20 patients with truly controlled BP had complications of diabetes. However, the association was statistically insignificant (p = 0.402).

Group 3: DM with uncontrolled office BP not on anti-hypertensive treatment

Out of 22 DM patients with uncontrolled office BP not on anti-hypertensive treatment, 7 (32%) were normotensives (white coat hypertension) whereas 15 (68%) patients had sustained HTN on ABPM. There was no significant difference among various variables studied between sustained HTN and WCH [Table 7].

Table 4: Diurnal index pattern among normotensive and masked hypertensive patients

	Normal Dipper	Non-dipper	*P*
Normotensive	13 (86.7%)	2 (13.3%)	0.019
Masked HTN	8 (47.1%)	9 (52.9%)	

Table 5: Demographic, clinical, and laboratory parameters among normotension and masked hypertension in diabetic mellitus patients

Mean±SD	Normotension	Masked Hypertension	*P*
Age (years)	45.8±9.6	47.18±8.9	0.679
BMI (Kg/m^2)	24.02±1.45	26±3.08	0.027
Duration of diabetes (months)	40.2±24.3	53.0±48.2	0.344
HbA1C (%)	9.1±3.3	8.3±1.04	0.338
24 hr urinary protein (gm/24 hr)	0.00 (0.0)	0.00 (0.0)	0.303
Serum creatinine (mg/dl)	0.9±0.16	0.96±0.23	0.437

Table 6: Demographic, clinical, and laboratory parameters among truly controlled and masked effect DM patients

	Controlled BP	Masked effect	*P*
Age (years)	56.5 (12)	50.5 (12)	0.113
BMI (Kg/m^2)	26.1 (6.37)	28 (6.8)	0.929
Duration of diabetes (months)	78 (117)	84 (114)	0.973
HbA1C (%)	8.05 (4.6)	7.75 (1.37)	0.222
24 Hr UP (mg/24 hr)	45 (195)	12.2 (102)	0.361
Creatinine (mg/dl)	0.95 (0.73)	0.85 (0.55)	0.131

Table 7: Demographic, clinical, and laboratory parameters among sustained hypertension and white coat hypertension (WCH) DM patients

	Sustained HTN	White coat HTN	*P*
Age (years)	44 (17)	48 (27)	0.525
BMI (Kg/m^2)	25.4 (4.8)	26.45 (8.76)	0.751
Duration of diabetes (months)	48 (72)	72 (48)	0.254
HbA1C (%)	8.1 (3.9)	7.2 (3)	0.503
24 Hr UP (mg/24 hr)	0.00 (35)	0.00 (60)	0.964
Creatinine (mg/dl)	0.81 (0.36)	0.90 (0.49)	0.435

Group 4: DM with uncontrolled office BP on anti-hypertensive treatment

Fifteen (15%) patients of DM with uncontrolled office BP on anti-hypertensive treatment had normal BP on ABPM, that is, WCE, 85 (85%) patients had uncontrolled BP (truly uncontrolled) on ABPM. Among various variables studied between WCE and uncontrolled BP patients with WCE had higher BMI as compared with truly uncontrolled BP on treatment, an observation that was statistically significant (p = 0.039) [Table 8].

Duration of diabetes ≥120 months, retinopathy and neuropathy were significantly associated with non-dipping pattern of BP whereas proteinuria was not associated with non-dipping pattern of BP in our study [Tables 9-11]. There was no statistically significant association of retinopathy, neuropathy, or proteinuria with any of the hypertensive phenotypes in our study.

Discussion

The aim of our study was to obtain a comprehensive insight into the different BP phenotypes by comparing OBPM and ABPM measurements in the diabetic patients of our population and simultaneously predicting their demographic, clinical, and laboratory associations.

The prevalence of masked hypertension in DM patients with normal office BP while not on any anti-hypertensive treatment in our study was 53% which is in accordance with earlier studies.[14-17] The prevalence of masked hypertension in one of the largest study "The ABPM India study" conducted by Kaul *et al*.[18] was 23% which is much lower than observations made in our study. Also, the prevalence of INH in our study was 21.8% as compared to 11.9% in study conducted by Kaul *et al*.[18] The lower prevalence of masked HTN and INH in a study conducted by Kaul et al. can be explained by the fact that the study subjects were general population and not exclusively patients of DM.[18] A slightly higher prevalence of INH was found in 31.2% of patients of DM in a study conducted by Wijikman *et al*.[19] and obesity was the only factor that was statistically significant in patients with INH. Similar results were also observed by Ozkan & Asayama *et al*.[20,21] In our study, BMI was the only factor that was significantly higher in patients of masked HTN as compared to true normotensives. However, we did not any find association of other factors like age, sex, duration of diabetes, or complications of diabetes as a predictor of masked hypertension as was reported in earlier studies. The other risk factors like sedentary lifestyle, obstructive sleep apnea, and excessive alcohol consumption were not considered in our study.

The prevalence of ME in diabetics with controlled BP on anti-hypertensive drugs was 56.5% in our study which is much higher than 42.5%, an observation made by Franklin *et al*.[15] Isolated uncontrolled nocturnal BP was observed in 17.4% of patients in our study, whereas uncontrolled nocturnal BP was reported in 28% and 23% in patients of DM with controlled office BP by Wijikman *et al.* and Rodriguesa *et al*., respectively.[19,22] In the ABPM study which was conducted on general population by Kaul *et al*.,[18] the prevalence of masked uncontrolled hypertension (MUCH) or ME was reported as 14.8% which is lower than that reported by any study. We did not find association of factors like age, sex, BMI, duration of diabetes, or complication status in patients with ME in our study.

The prevalence of white coat hypertension in diabetics with HTN and not on any anti-hypertensive drug in our study

Table 8: Demographic, clinical, and laboratory parameters among uncontrolled hypertension and white coat effect DM patients

	Uncontrolled BP	WCE	*P*
Age (Years)	55 (12)	54 (14)	0.813
BMI (Kg/m^2)	26.2 (5.4)	30.4 (4.1)	0.005
Duration of diabetes (months)	96 (132)	72 (108)	0.333
HbA1C (%)	8.6 (2.4)	8.1 (3.4)	0.327
24 hr UP (gm/dl)	0.00 (80)	0.00 (90)	0.581
Creatinine (mg/dl)	0.93 (0.4)	0.78 (0.32)	0.618

Table 9: Correlation of fundus examination with dipping pattern of blood pressure in diabetics

	Normal Fundus	Retinopathy	Pearson's Chi-square
Normal dippers	92 (87.6%)	13 (12.4%)	0.012
Non-dippers	70 (73.7%)	25 (26.3%)	

Table 10: Correlation of diabetic neuropathy with dipping pattern of blood pressure in diabetics

	No DSMN	DSMN	Pearson's Chi-square
Normal dippers	96 (91.4%)	9 (8.6%)	0.05
Non-dippers	77 (82.1%)	17 (17.9%)	

Table 11: Correlation of duration of DM with dipping pattern of blood pressure in diabetics

	<120 months	≥120 months	Pearson's Chi-square
Normal dippers	78 (74.3%)	27 (25.7%)	0.014
Non-dippers	55 (57.9%)	40 (42.1%)	

was 32% which is in near agreement with the study by Gorostidi *et al*.[23] where the prevalence of WCH was 33%. The prevalence of WCE in diabetics with uncontrolled BP on anti-hypertensive drug in our study was 15% and a higher BMI was the only factor that was statistically significant in these patients.

Regarding diurnal variation and nocturnal BP pattern among diabetic hypertensive patients, 44% patients were normal dippers, 35.5% were non dippers, 10.5% were reverse dippers, and 10% were extreme dippers. The high prevalence of non-dipping and reverse dipping pattern in our study was in accordance with the study done by Roberto Fogari and Eguchi K which showed it to be 30% and 8.7%, respectively.[24,25] Diabetic retinopathy, neuropathy, and prolonged duration of diabetes were the factors significantly associated with non-dipping pattern on ABPM in our study.

The current study signifies the importance of ABPM in all diabetic hypertensive patients who on office measurement have controlled or uncontrolled BP, as it helps to diagnose nocturnal pattern of hypertension (Masked HTN) which is more common in diabetics and is associated with elevated CV risk.

Conclusion

Relying exclusively on conventional office BP measurement, the true pattern of BP in patients with diabetes may not be identified. ABPM is valuable addition to the techniques which help in both diagnosis and treatment of HTN in patients with diabetes especially who appear to have normal BP recordings on office measurements and thus help in diagnosing masked hypertension. Hence, it is suggested to change the traditional practice to diagnose and manage BP according to office BP monitoring and use 24 hr ABPM more frequently.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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