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Original Research Article

Evaluating blood pressure variability in hypertensive patients with comorbidities: a prospective observational study using 24-hour ambulatory blood pressure monitoring

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ABSTRACT

Background: Blood pressure variability (BPV) is an independent predictor of cardiovascular risk, particularly in patients with hypertension and diabetes. This study aimed to evaluate BPV in hypertensive patients with comorbidities using ambulatory blood pressure monitoring (ABPM) and assess the influence of gender and antihypertensive therapy.
Methods: This prospective observational study included 58 patients (aged 26–85 years) undergoing 24-hour ABPM in Mumbai, India. BPV was assessed using the standard deviation of 24-hour systolic blood pressure (SD 24-h SBP). Patients were categorized based on hypertension and diabetes status, gender, and antihypertensive therapy (monotherapy, dual, or triple therapy). Statistical comparisons were made using t-tests and chi-square tests, with significance set at $p<0.05$.
Results: Patients with diabetes exhibited significantly higher BPV than those without diabetes ($p<0.05$). Gender differences were observed, with females showing greater BPV than males. Among hypertensive patients, those on triple therapy had higher BPV than those on dual therapy, indicating greater difficulty in achieving BP control. Despite antihypertensive and adjunct therapies, BPV remained elevated in some patients, particularly those with diabetes and those requiring multiple antihypertensive agents.
Conclusions: BPV is significantly elevated in patients with diabetes and those on intensive antihypertensive regimens, highlighting the challenges in BP management. The observed gender differences suggest potential influences of hormonal and vascular factors. These findings underscore the need for personalized treatment strategies to improve BP control and reduce cardiovascular risk in high-risk populations.

Keywords: Blood pressure variability, Ambulatory blood pressure monitoring, Hypertension, Diabetes mellitus, Antihypertensive therapy, Gender differences, Cardiovascular risk

INTRODUCTION

Blood pressure variability (BPV) has emerged as an important predictor of cardiovascular outcomes, independent of mean blood pressure levels.[1,2] Elevated BPV is associated with an increased risk of target organ damage, including nephropathy, retinopathy and stroke, particularly in patients with hypertension and diabetes.[3,4]

Ambulatory blood pressure monitoring (ABPM) is a valuable tool for assessing BPV over 24 hours, providing more accurate and reliable data compared to office-based blood pressure measurements.[3]

Patients with diabetes are known to exhibit higher BPV compared to those without diabetes, primarily due to factors such as poor glycaemic control, autonomic dysfunction and endothelial impairment.[5] These factors not only contribute to higher BP fluctuations but also increase the risk of adverse cardiovascular events.[5] Moreover, sex-based differences in BPV have been observed, with studies indicating that females may have greater BPV than males, potentially influenced by hormonal differences, body composition and smoking habits.[6-8]

Despite the availability of antihypertensive therapies, BPV remains a clinical challenge, particularly in patients with comorbid diabetes. Although combination antihypertensive therapies, such as dual or triple regimens, are often used to manage hypertension in complex cases, BP control remains difficult, and BPV can persist.[4,9] Furthermore, adjunct therapies, including statins and antidiabetic drugs, have shown potential in modulating BPV by improving endothelial function and vascular stability.[10]

Given the clinical significance of BPV and its role in cardiovascular risk stratification, this study aims to evaluate BPV using ABPM in hypertensive patients with comorbid diabetes. Additionally, we assess the impact of sex and different antihypertensive regimens on BPV, with the goal of identifying potential gaps in current treatment strategies and informing personalised management approaches for high-risk patients.[9]

METHODS

Study design and period

This prospective, observational study was conducted in the Shyamlata Clinic, Mumbai, Maharashtra, India. The study was carried out over a 12-month period from January 2019 to January 2020.[11]

Sampling technique and sample size

A convenience sampling technique was used. All consecutive patients referred for 24-hour ABPM during the study period and meeting the eligibility criteria were invited to participate.

Because no prior local data existed estimating BPV in this population, a formal sample size calculation was not performed. Instead, the sample size of 58 patients represents the total number of eligible and consenting patients available during the study period. This approach is commonly accepted in exploratory observational studies assessing physiological parameters such as BPV.

Selection criteria

Inclusion criteria

Adults aged 18–85 years, patients referred for 24-hour ABPM, diagnostic evaluation of suspected hypertension, or therapeutic assessment of BP control, patients able to provide informed consent.

Exclusion criteria

Pregnant or lactating women, hospitalised or bedridden patients, individuals with atrial fibrillation, pacemaker implants or significant arrhythmias, patients with major orthopedic problems of the upper limb interfering with cuff placement, individuals unwilling to undergo ABPM

Study procedure

After obtaining written informed consent, baseline demographic and clinical details were recorded, including age, sex, comorbidities, known hypertension status, diabetes status, and current antihypertensive treatment.

Ambulatory blood pressure monitoring

ABPM was performed using a validated oscillometric device.

The cuff was applied to the non-dominant arm unless contraindicated.

Patients were instructed to maintain usual daily activities and avoid vigorous exercise.

BP measurements were automatically recorded: every 30 minutes during daytime, and every 60 minutes during nighttime.

ABPM recordings with at least 80% valid readings were included for analysis.

Parameters measured

24-hour mean systolic (SBP) and diastolic BP (DBP)

Daytime and nighttime mean BP

Blood pressure variability

24-hour standard deviation of SBP (SD 24-h SBP)

24-hour standard deviation of DBP (SD 24-h DBP)

Office BP measurements

Office BP was measured using a calibrated sphygmomanometer following standard guidelines and compared with ABPM results.

Ethical approval

The study was approved by the Conscience Independent Ethics Committee, Ahmadabad, Gujarat, India (Approval number: ECR/233/Indt/GJ/2015). Written informed consent was obtained from all participants.

Statistical analysis

Data were entered and analysed using Microsoft Excel and SPSS version 25. Continuous variables were summarised as mean ± standard deviation (SD). Categorical variables were expressed as frequencies and percentages. Comparison between groups (e.g., hypertensive vs normotensive, male vs female, diabetic vs non-diabetic, monotherapy vs dual vs triple therapy) was performed using: Independent sample t-test for continuous variables Chi-square test for categorical variables. A p-value < 0.05 was considered statistically significant.

RESULTS

In our study, a total of 58 patients with a mean (SD) age of 57.76 (14.99) years were included. The age range was 26-85 years (Table 1). The average (SD) age of male and female patients was 50.05 (15.72) and 55.88 (12.54) years, respectively.

Table 1: Baseline characteristics (n=58).

Parameter	Result
Mean (SD) age in years	51.76 (14.99)
Age range in years	26–85
Gender	
Male	41 (70.69%)
Female	17 (29.31%)
Reasons for ABPM	
Diagnosis	22 (37.93%)
Therapeutic evaluation	36 (62.07%)
Comorbidities	
Yes	33 (56.90%)
No	25 (43.10%)

The study comprised 41 (70.69%) males and 17 (29.31%) females. ABPM was conducted for diagnostic purposes in 22 (37.93%) patients and for therapeutic evaluation in 36 (62.07%) patients. Among the male patients, 19 (46.34%) underwent ABPM for diagnosis, whereas 22 (53.66%) underwent it for evaluation. In contrast, 3 (17.65%) female patients underwent ABPM for diagnosis, and 14 (82.35%) underwent it for evaluation. A significant gender-based difference was found in the purpose of ABPM (p = 0.040).

Comorbidities were present in 33 (56.90%) patients (Figure 1). Among these, 22 (37.93%) had diabetes. Among the patients with diabetes, three had dyslipidemia, two had ischemic heart disease, and one each had deep vein thrombosis, obesity, or a history of hypoglycemia. Other comorbidities included anxiety (2 patients, 3.45%), hypoglycemia (2 patients, 3.45%), dyslipidemia (3 patients, 5.17%), obesity (4 patients, 6.89%), gastroesophageal reflux disease (1 patient, 1.72%) and gout (1 patient, 1.72%).

Table 2: Drug combinations used in dual and triple therapies in this patient group.

Therapy
Dual therapy
Telmisartan, Amlodipine
Metoprolol, Amlodipine
Telmisartan, Chlorthalidone
Olmesartan, Chlorthalidone
Telmisartan, Hydrochlorothiazide
Olmesartan, Amlodipine
Olmesartan, Hydrochlorothiazide
Triple therapy
Telmisartan, Amlodipine, Chlorthalidone
Telmisartan, Hydrochlorothiazide, Metoprolol
Telmisartan, Amlodipine, Metoprolol
Olmesartan, Amlodipine, Chlorthalidone

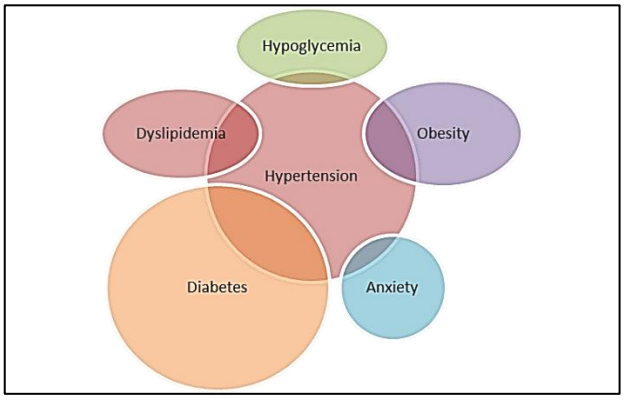

Figure 1: Relationship between comorbidities in the patient group. Individual percentages are given in the text.

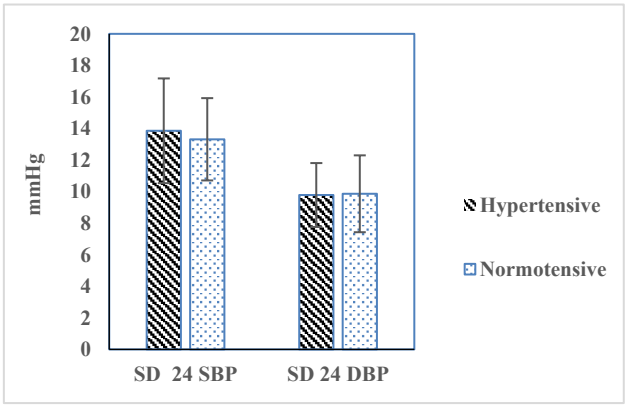

Figure 2: BPV in patients with hypertension vs. normotension with all comorbidities, as labelled by ABPM. Error bars indicate the standard deviation within each group.

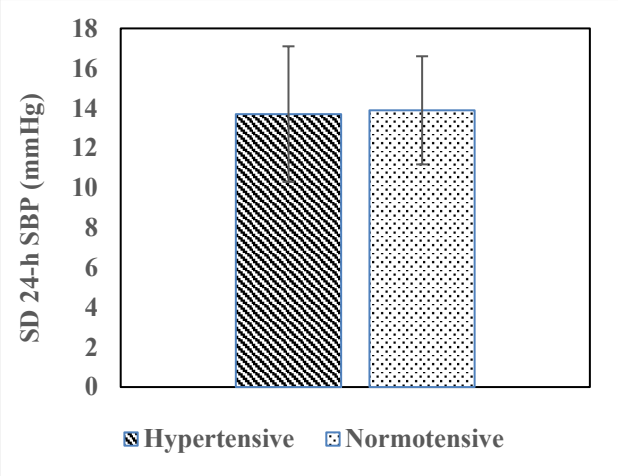

Figure 3: 24-h SD SBP in diabetic patients with hypertension vs. normotension labelling via ABPM. Error bars indicate SD within each group.

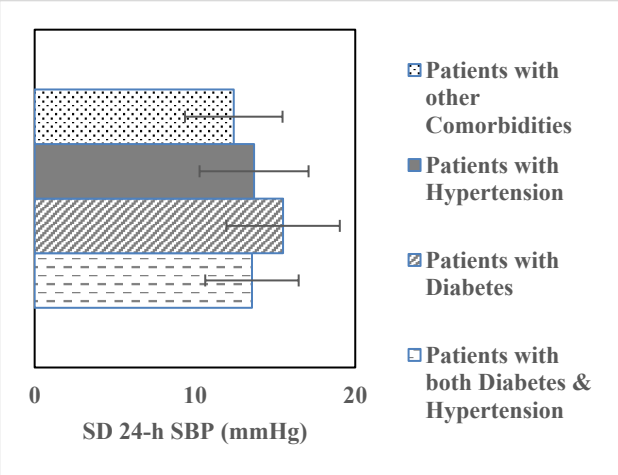

Figure 4: BPV in terms of 24-h SD SBP in patients with various comorbidities. Error bars indicate the variability within each group.

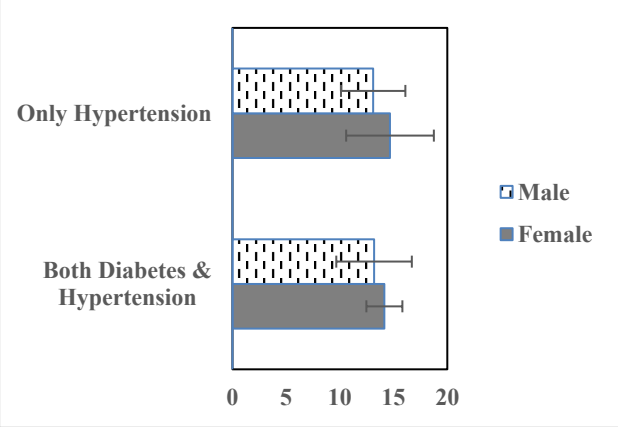

Figure 5: BPV in male and female patients with hypertension alone and with both diabetes and hypertension. Error bars indicate the SD within each group.

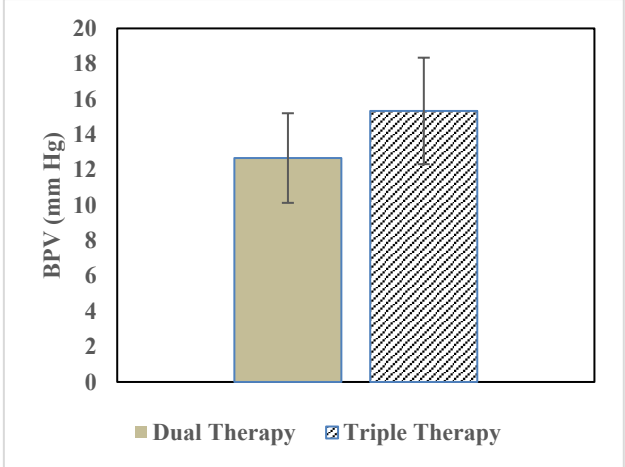

Figure 6: BPV in dual and triple therapy of antihypertensive drugs in patients with diabetes using ABPM. Please refer to Table 2 for the drug combinations used in this patient group. Error bars indicate the SD within each group.

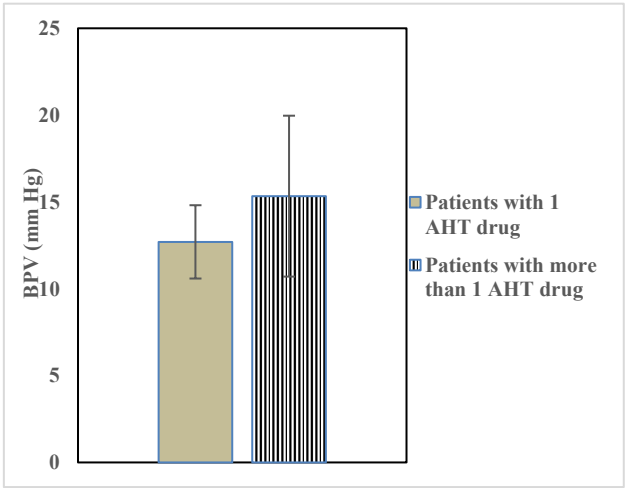

Figure 7: BPV in patients with hypertension with 1 or more than 1 antihypertensive drug. Error bars indicate the SD within each group.

Diabetes was found in 12 (29.27%) male and 10 (58.82%) female patients, with a statistically significant difference (p=0.035). Among the 36 known hypertensive patients, 12 (33.33%) were on monotherapy, 17 (47.22%) were on dual therapy, 6 (16.67%) were on triple therapy and 1 (1.72%) was on four-drug therapy.

Office BP measurements revealed that 35 (64.81%) patients had hypertension, whereas 19 (35.19%) were normotensive. In contrast, ABPM identified hypertension in 32 (59.26%) patients, and 22 (40.74%) patients were classified as normotensive. The 24-hour systolic and diastolic blood pressures (SBP and DBP) were compared between patients with hypertension and normotension, as classified by ABPM (Figure 2). In Figure 3, the 24-hour systolic blood pressure variability (SD SBP) is shown for diabetic patients categorized as hypertensive and

normotensive based on ABPM. Figure 4 compares BPV in patients with other comorbidities, patients with hypertension and diabetes, hypertension alone, diabetes alone and those with both. Figure 5 presents the 24-hour SD SBP in male and female patients across two groups: those with hypertension alone and those with both diabetes and hypertension. The variability values are displayed separately for each subgroup, with error bars indicating the standard deviation. In our study, patients on dual therapy had lower 24-h SD SBP (12.7±2.5 mmHg) compared to those on triple therapy (15.3±3.01 mmHg). The drug combinations used in dual and triple therapy in this group of patients are listed in Table 2. Figure 6 compares BPV in patients with diabetes treated with dual and triple antihypertensive therapies. Similarly, Figure 7 analyses BPV in patients with hypertension using one antihypertensive drug compared to those on combination therapies.

DISCUSSION

According to Lawes et al the theoretical minimum SBP was estimated at a mean of 115 mmHg with a SD of 6 mmHg across all age, sex and subregional groups.[12] This SD represents the expected variability in SBP within populations and highlights the range within which most individuals' SBP would fall. The estimate is based on epidemiological data, which suggests that cardiovascular disease risk declines down to this level, beyond which further reductions provide no additional benefit.[12] Our study included all the patients with SD 24-h SBP greater than 6 mmHg. Hence, we compared the SD of 24-h SBP across various patient subgroups to gain insights into BPV.

Patients with hypertension exhibited greater blood pressure variability (BPV), indicated by a higher standard deviation (SD) of 24-hour SBP, consistent with their increased cardiovascular risk. Interestingly, the SD of 24-hour DBP was slightly higher in normotensive patients than in hypertensive patients. Exact SD values for 24-hour SBP are presented in Table 1 (Supplementary Information). A study by Keehn et al showed that ABPM measurements have notable within-individual variability for both normotensive and hypertensive individuals.[13] Systolic BP variability was around 5-7% and diastolic BP variability about 6-8%, with no significant difference between groups. Carotid-femoral pulse wave velocity (PWV) showed even greater variability and was not independently linked to BP variability. These findings align with the observation that 24-hour SBP variability is higher in hypertension, but DBP can vary slightly more in normotension due to measurement noise. Overall, a single ABPM may misclassify BP status; repeated monitoring can improve accuracy and treatment decisions. A study evaluated and compared non-invasive blood pressure measurements obtained from two different monitoring devices.[14]

Shaphe et al analysed blood pressure variability and dipping patterns in 58 normotensive patients with type 2 diabetes using 24-hour ABPM. Over 77% of participants exhibited a non-dipping pattern, which is associated with higher cardiovascular risk despite normal routine BP checks.[15] Interestingly, patients with a dipping pattern had higher 24-hour average systolic BP but better postprandial glucose control. Consistent with these findings, Figure 3 shows that diabetic patients classified as hypertensive by ABPM had greater SBP variability than those labelled normotensive. Together, these results underscore the value of ABPM in uncovering hidden BP abnormalities in diabetes, supporting more precise risk assessment and tailored management.

Figure4 highlights the elevated BPV in patients with diabetes, compared to patients with hypertension. This elevated BPV in diabetic populations is consistent with prior research, which links higher BPV to endothelial dysfunction and poor glycaemic control.[2] Elevated BPV is known to increase the risk of cardiovascular events and mortality in diabetes.[7] Findings from a study by Ozawa et al reinforces that patients with diabetes have greater blood pressure variability than non-diabetic hypertensives, despite having similar average 24-hour BP values.[16] The findings show that diabetic hypertensives exhibit significantly higher short-term systolic and diastolic BP variability compared to their non-diabetic counterparts. Notably, fasting blood glucose emerged as an independent predictor of both systolic and diastolic BP variability, suggesting that elevated glucose levels may directly contribute to increased BP fluctuations and instability. Patients with other comorbidities such as anxiety, hypoglycaemia, dyslipidaemia, obesity, gastroesophageal reflux disease and gout were found to have the least BPV.

It is to be noted that patients with both diabetes and hypertension and those with only hypertension had closely related BPV. These patients were prescribed one or more than one antihypertensive drug. Interestingly, in this group of patients, males exhibited a lower SD 24-h SBP compared to females in both the hypertension and the combined diabetes and hypertension groups (Figure 5). Previous studies indicate that hormonal and autonomic differences may contribute to this sex disparity.[6-8] Additionally, factors such as body composition and insulin sensitivity may influence BP regulation differently in men and women.[6-8] The lack of correlation between age and SD 24-h SBP ($R^2 = 0.006$) in our study suggests that BPV in diabetes may be influenced more by disease duration and treatment patterns rather than age alone, as supported by Parati et al in their study.[5]

We found that 90% of patients were using Glimepiride and Metformin. Metformin is well-known for improving endothelial function and reducing arterial stiffness.[10,17] Moreover, 45% of patients were on Rosuvastatin, which has been shown to reduce BPV and improve vascular stability.[18] However, despite antihypertensive and statin therapies, BPV often remains elevated in diabetes, highlighting the need for individualised treatment approaches.[9] A post hoc study compared the effects of liraglutide versus a combination of glimepiride and

metformin on 24-hour blood pressure (BP) in patients with type 2 diabetes.[19] Participants randomized to the glimepiride plus metformin group (4 mg glimepiride once daily and 1 g metformin twice daily) showed no significant changes in 24-hour systolic or diastolic BP over the 18-week study period. Despite metformin's known vascular benefits and glimepiride's glucose-lowering action, this combination did not reduce BP or influence BP variability. These findings suggest that while glimepiride and metformin are effective for glycemic control, they may have limited impact on ambulatory BP patterns in the short term. BPV has been associated with microvascular and macrovascular complications in diabetes. Increased BPV can contribute to target organ damage, including nephropathy and retinopathy.[20,21] Therefore, consistent BP control is critical in reducing these risks. Future research should explore how specific antihypertensive regimens and glycaemic control strategies influence BPV and cardiovascular outcomes in real-world diabetic populations.

Higher SD SBP in patients on triple therapy in Figure 6 shows greater difficulty achieving BP control, potentially indicating difficult-to-control hypertension. Similarly, data in Figure 7 may highlight the fact that multiple drugs are associated with higher BPV, reflecting the complexity of managing more severe hypertension

The findings are consistent with research suggesting that more intensive antihypertensive regimens may indicate greater difficulty in achieving BP control, associated with higher BPV. Higher BPV in patients with triple therapy may reflect difficult-to-control hypertension, often linked to poor glycaemic control and vascular dysfunction.[10] Previous studies highlighted that adding diuretics to antihypertensive combinations can reduce BPV more effectively than other drug classes alone.[4] The persistence of elevated BPV despite triple therapy underscores the need for personalised interventions and closer monitoring in these patients.[9] The ONTARGET study evaluated whether clinic BP reductions observed with telmisartan (T), ramipril (R), or their combination (T+R) reflected changes in 24-hour ambulatory BP, a better predictor of cardiovascular risk.[22] Among 422 patients, 24-hour systolic BP reductions were similar with T (−2.1 mmHg) and R (−2.0 mmHg), but significantly greater with the T+R combination (−5.3 mmHg). Despite better 24-hour BP control, the combination therapy did not provide additional cardiovascular or renal protection compared to monotherapy. These findings confirm that the lack of added benefit with T+R was not due to inadequate ambulatory BP control and underscore that tighter clinic BP control can align closely with 24-hour BP values, especially when systolic clinic BP falls below 120 mmHg.

Another study assessed 24-hour ambulatory blood pressure control in 1,920 Chinese outpatients aged ≥60 years, treated with either monotherapy or dual combination therapy from among the five major antihypertensive drug classes.[23] Calcium channel blockers (CCBs) were the most commonly used monotherapy, while renin–angiotensin system (RAS) blockers combined with CCBs were the most frequent dual therapy. Beta-blocker monotherapy was most effective for daytime BP control, whereas diuretics were associated with better nighttime BP control and higher likelihood of a normal nocturnal dipping pattern. Patients receiving RAS/diuretic combinations had superior nighttime BP control compared to RAS/CCB users. These findings suggest that optimal 24-hour BP control in older adults may require individualized therapy targeting both daytime and nighttime BP patterns. This finding aligns with studies that associate increased BPV with difficult-to-control hypertension and suggests that patients requiring multiple drugs may have more severe underlying vascular dysfunction.[3] Future studies should explore whether specific combinations of antihypertensive agents can stabilise BPV.

This study included a relatively small sample size (n=58), which may limit the generalizability of the findings. The observational design cannot establish causal relationships between variables. Additionally, the use of a single 24-hour ABPM session may not fully capture long-term blood pressure variability patterns.

CONCLUSION

This study highlights the prevalence of elevated BPV in patients with diabetes, which was effectively identified using ABPM. Significant gender differences in BPV were observed, with males exhibiting higher SD 24-h SBP than females. Elevated BPV in diabetes, despite antihypertensive and statin therapy, underscores the complexity of managing BP in this population. The findings reinforce the need for individualised treatment approaches to reduce cardiovascular risks associated with BPV. Poor glycaemic control and endothelial dysfunction likely contribute to these outcomes. Effective BP control strategies should consider comorbidities and sex-specific factors. Future research should explore tailored interventions to mitigate BPV and improve cardiovascular outcomes in patients with diabetes.

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