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Original Article

Physiology Section

Prognostic Significance of ABPM in Comparison to Clinical Blood Pressure Monitoring and their Association with Various Risk Factors Involved in CKD Predisposition in North Indian Patients

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ABSTRACT

Introduction: Ambulatory Blood Pressure Monitoring (ABPM) has been found to be a more reliable method for diagnosing Hypertension (HTN) and stratifying cardiovascular risk than Continuous Blood Pressure (CBP) monitoring.

Aim: To evaluate prognostic significance of ABPM in comparison to clinical Blood Pressure (BP) Monitoring and their association with various risk factors involved in Chronic Kidney Disease (CKD) patients.

Materials and Methods: This was a prospective study done in Era's Lucknow Medical College and Hospital, Lucknow, Uttar Pradesh, India. Routine laboratory tests were conducted for all patients. Casual Blood Pressure (BP) was obtained by a trained staff through a digital BP monitor (CITIZEN-CH-432) and Meditech ABPM-05 device was used for ABPM. Pearson's correlation method was used to analyse the relationship between the two continuous variables.

Results: Present study included 400 patients of which 225 (56.25%) were male subjects, and mean age was 62 (Range-21-76) years. Of the study population, 90 (22.5%) were CKD G1-2, 79 (19.75%) were CKD G3a, 96 (24%) were CKD G3b, and 135 (33.75%) were CKD G4. Among all the patients included in the study, the most common was normal BP (33.75%), sustained HTN (26.25%), White Coat Hypertension (WCH) (6.5%), and masked HTN (33.5%). When multiple logistic regression analyses were done, estimated Glomerular Filtration Rate (eGFR), and BP data, night-time Systolic Blood Pressure (SBP) (OR, 1.043; 95% CI, 1.025-1.067; p<0.001), and night-time Diastolic Blood Pressure (DBP) was found (OR, 1.050; 95% CI, 1.013-1.075) to have an independent association with non/reverse-dippers.

Conclusion: The ABPM has more prognostic significance when compared to office BP measurements in all kind of normotensive, hypertensive and CKD patients at all stages. ABPM measurements are often abnormal in CKD, with CKD patients frequently showing an altered circadian rhythm with an increased rate of non dipping and reverse dipping.

Keywords: Ambulatory blood pressure monitoring, Blood pressure, Chronic kidney disease, Hypertension

INTRODUCTION

The HTN is prevalent among people with CKD and is a momentous risk factor for Cardiovascular Disease (CVD) [1,2]. In India, it has been depicted that diabetes and HTN today accounted for 40-60% cases of CKD [3]. Prevalence of diabetes according to recent data of Indian Council of Medical Research (ICMR), Indian adult population has hiked to 7.1%, ranging from Jharkhand (5.8%) to Chandigarh (13.5%) and in urban population age above 40 years, the occurrence is as high as 28% [4,5]. Similarly, the HTN prevalence in the adult population today is 17% (14.8% from rural and 21.4% from urban belt). Panesar S et al., found alike prevalence of 17.4% (in the age group of 20-59 years) from slum-resettlement colony of Delhi, India [6,7]. With increasing frequency of these diseases in India, pervasiveness of CKD is estimated to rise, and it is seen as the key target population to be addressed.

The ABPM has been found to be a more reliable method for diagnosing HTN and stratifying cardiovascular risk than CBP monitoring particularly in patients with CKD stage 3 [8,9]. ABPM has been demonstrated to be preferable to CBP in adults with CKD for diagnosing HTN and monitoring therapy adequacy [10-12]. ABPM uses a wearable, oscillometric BP monitor that monitors and records BP at predetermined intervals (every 20 minutes when awake and every 30 minutes to 1 hour while sleeping) during a 24-hour period [13]. This enables for the evaluation of a patient's overall exposure to high BP load as well as variations in the typical circadian BP pattern. Furthermore, when BP is monitored over a prolonged duration in the patient's own surroundings, ABPM reduces the effect of anxiety-induced BP abnormalities known as WCH [14,15]. Masked HTN is a condition in which the CBP in an office setting is normal, but the BP is discovered to be high at other times of the day [15]. Masked HTN is a serious situation that has been demonstrated to predict end-organ damage, necessitating its diagnosis and treatment [16]. Although several researches have looked into the role of ABPM in people with CKD, there is currently a lack of data in this population in India [17-19].

The aim of this research was to examine BP control status and patterns and dipping patterns in Indian diabetic hypertensive patients with different stages of CKD.

MATERIALS AND METHODS

This was a prospective study done at Era's Lucknow Medical College and Hospital, Lucknow, Uttar Pradesh, India after obtaining permission from Institutional Ethical Committee (IEC) (ECR/717/Inst/UP/2015/RR-21). The study was conducted for 24 months (September 2018-Sepetember 2020).

Sample size calculation: Sample size was calculated according to the formula given by basic methods of medical research.

$N= \{Z\alpha+Z\beta\}^2/\{\ln(1-e)\}^2\ (1-p_1/p_1+1-p_2/p_2)$

The sample size came out to be 400 for each group.

Inclusion criteria: Diabetic hypertensive patients with CKD stages G1-G4 were enrolled in this study. All adults (age of 20-70 years), BP ≥140/90 mmHg and were considered for the inclusion in the study.

Exclusion criteria: Patients with acute kidney injury, hospitalisation, renal replacement therapy, previous kidney transplantation, uncontrolled arrhythmia, asthma, chronic obstructive pulmonary disease, and primary endocrine disorders except diabetes mellitus were excluded. Pregnant women were also excluded.

The study was conducted over 450 patients who gave their consent and underwent ABPM examination although 50 patients were exempted from the study as their ABPM measurements were not adequate. Finally, 400 CKD patients were enrolled in this study. Consecutive sampling of all the patients giving informed consent was included. GFR categories in CKD are illustrated in [Table/Fig-1] [20].

Category	GFR mL/min/1.73 m^2	Terms
G1	≥90	Normal or high
G2	60-89	Mildly decreased*
G3a	45-59	Mildly to moderately decreased
G3b	30-44	Moderately to severely decreased
G4	15-29	Severely decreased

[Table/Fig-1]: GFR categories in CKD [20].
CKD: Chronic kidney disease; GFR: Glomerular filtration rate; *Relative to young adult level

Data Collection

Baseline demographics and clinical characteristics were recorded from all the subjects. Routine laboratory tests consisted of complete blood count, serum biochemistry including assessment of vitamin D level, haemoglobin (Hb), albumin, Creatinine (cr), calcium (Ca), phosphorus (P), total cholesterol (Total-C), High-Density Lipoprotein Cholesterol (HDL-C), Low-Density Lipoprotein Cholesterol (LDL-C), triglycerides (TG), uric acid, albumin, calcium and were obtained at the baseline study visit.

Casual Blood Pressure (CBP)

Casual BP was obtained by a trained staff through a digital BP monitor (CITIZEN-CH-432) in the office setting. Appropriate size BP cuffs were used to record BP after five minutes of rest. Sphygmomanometer was used for measuring the casual BP. Several consecutive recordings were taken if the BP was found to be elevated and the mean value of three consecutive readings during the clinic visit was taken.

Ambulatory Blood Pressure Monitoring (ABPM)

Meditech ABPM-05 device was used for ABPM monitoring. This instrument was validated according to the prescribed standard guidelines. A 24 hour period monitoring was done through ABPM which provides a vision into BP variability throughout the day. Typical working weekday is advised for 24-h ABPM to the patient to record the log of activities throughout the day which includes wake and sleep times, medications timing, meals, and any symptoms. Pulse regularity check is the first step. ABPM should not be used in the cases in which irregular pulse is detected, as it may not give the accurate BP reading. The cuff is placed on the non dominant arm of the patient for 24 hours, continuing his or her normal daily activities. A total of 21 readings in the daytime and 7 at night are recommended. The cuff is removed after 24 hours and a report is generated by the ABPM device.

Certain steps were followed regarding the measurement of ABPM:

- WCH identification
- Masked HTN identification
- Abnormal 24-hour BP patterns identification
- Nocturnal HTN
- Dipping status
- Morning BP surge
- Treatment assessment
- BP variability assessment
- 24-hour BP control assessment

STATISTICAL ANALYSIS

All the variables were presented as mean±Standard Deviation (SD) for normally distributed variables. Non parametric variables are expressed as median (range) using Analysis of Variance (ANOVA) and categorical variables were expressed as numbers with proportions using or the Kruskal-Wallis or Mann-Whitney rank sum tests. Categorical variables were compared through Chi-square tests. Dipping patterns and BP control patterns were subjected to multiple logistic regression analysis with adjusted for factors with $p<0.05$. Pearson's correlation method was used to analyse the relationship between the two continuous variables. Statistical analysis was performed using International Business Machines (IBM) Statistical Package for the Social Sciences (SPSS) Statistics 20.0 (SPSS Inc., Chicago, IL, USA). A p-value <0.05 was considered statistically significant.

RESULTS

Of the 400 patients, 225 (56.25%) were male subjects, and the median age ranged from was 62 (21-76) years. Of all patients, it was observed that 90 (22.5%) were CKD G1-2, 79 (19.75%) were CKD G3a, 96 (24.0%) were CKD G3b, and 135 (33.75%) were CKD G4 [Table/Fig-2].

BP control patterns: Among all the patients included in the study, the most common was normal BP (33.75%), sustained HTN (26.25%), WCH (6.5%), and masked HTN (33.5%). It was also observed that in case of sustained HTN the median 24-hour SBP, daytime SBP and night-time SBP ($p<0.001$) were found to be the highest in comparison to normal BP, masked HTN, and WCH. It was also revealed that normal BP showed lower median Cr ($p<0.001$) and higher median HDL-C and eGFR whereas, lower proportion of CKD

Variables	Total (n=400)	CKD G1-2 (n=90)	CKD G3a (n=79)	CKD G3b (n=96)	CKD G4 (n=135)	p-value
Male (n (%))	225 (56.25)	62 (68.8)	48 (60.75)	55 (57.29)	60 (44.44)	0.367
Age, years (range)	62 (21-76)	64 (25-75)	66 (21-75)	68 (24-76)	63 (28-77)	0.013
BMI, kg/m^2 (M±SD)	25.2±3.7	24.8±3.8	25.1±2.8	24.6±4.1	25.4±3.9	0.196
Diabetes mellitus	145 (36.25)	30 (33.33)	18 (22.7)	32 (33.3)	65 (48.1)	<0.001
Current smoker (n (%))	56 (14.0)	16 (17.7)	23 (29.11)	10 (10.41)	7 (5.1)	0.385
Alcohol (n (%))	102 (25.5)	32 (35.55)	20 (25.31)	26 (27.0)	24 (17.7)	0.215
Cr, mg/dL (range)	1.59 (0.52-4.39)	0.98 (0.52-1.40)	1.37 (0.94-1.94)	1.84 (1.25-2.58)	3.11(1.59-4.39)	<0.001
eGFR, mL/min/1.73 m^2 (range)	42.1 (16.0-137.2)	73.7 (60.0-133.8)	51.4 (46.2-60.5)	37.4 (31.3-46.6)	23.1 (15.0-28.9)	<0.001
Total-C, mg/dL (M±SD)	167±45	172±43	175± 40	175±43	162±52	0.105
LDL-C, mg/dL (M±SD)	93±34	99±32	94±36	95± 33	90±41	0.743
HDL-C, mg/dL (range)	47 (23-216)	49 (31-98)	47 (31-116)	46 (20-215)	44 (24-145)	0.011
TG, mg/dL (range)	135 (35-1135)	126 (50-701)	120 (48-337)	165 (49-1185)	142 (30-439)	0.225

Hb, g/dL (M±SD)	13.1±2.4	14.9±1.9	14.5±2.40	12.8±1.8	10.5±1.6	<0.001
Albumin, g/dL (range)	4.1 (2.4-5.5)	4.3 (2.9-4.7)	4.2 (3.6-6.1)	4.1 (2.6-4.9)	4.4 (2.9-4.1)	<0.001
No. of drugs (range)	2 (0-7)	2 (0-4)	2 (0-4)	2 (0-5)	2 (0-7)	0.007

[Table/Fig-2]: Demographic and clinical characteristics according to CKD stages.
Values for categorical variables are given as a number (%); Values for continuous variables are given as mean±standard deviation or median (range); p-value was calculated using Chi- square test; p-value <0.05 is significant; BMI: Body mass index; Cr: Creatinine; eGFR: Estimated glomerular filtration rate; Hb: Haemoglobin; HDL-C: High-density lipoprotein cholesterol; LDL-C: Low-density lipoprotein cholesterol; TG: Triglyceride; Total-C: Total cholesterol

G3b/G4 and DM. Sustained HTN in comparison to masked HTN however, showed a greater proportion of DM and lesser proportion of CKD G3b/G4. Sustained HTN and masked HTN also showed lower median albumin (p=0.003) as compared to normal BP and WCH [Table/Fig-3].

Multiple logistic regression analyses showed that age ≥60 years, Cr, and HDL-C independently associated with normal BP. DM and LDL-C independently associated with sustained HT. Age ≥61 years independently correlated with white-coat HT. CKD G3b/G4 independently correlated with masked HT [Table/Fig-4].

Dipping patterns: The ABPM findings viz. Clinic (SBP and DBP), 24-hr (SBP and DBP) Daytime (SBP and DBP Nighttime (SBP and DBP) were recorded of all patients at the time of admission and is summarised in [Table/Fig-5].

Multiple logistic regression data showed that the albumin was associated independently with the non/reverse-dippers (BP data not included). When multiple logistic regression analyses were done, eGFR, and BP data, nighttime SBP, and nighttime DBP was found to have an independent association with non/reverse-dippers [Table/Fig-6].

Variables	Normal BP (n=135)	Sustained HT (n=105)	White-coat HT (n=26)	Masked HT (n=134)	p-value
Male (n (%))	67 (49.6)	75 (71.4)	24 (92.3)	77 (57.4)	0.182
Age, yr (range)	60 (24-77)	65 (32-78)	68 (25-79)	64 (24-76)	0.033
BMI, kg/m^2 (M±SD)	25.3±4.2	23.9±3.6	25.6±4.1	25.8±3.6	0.803
Diabetes mellitus (n (%))	32 (23.7)	57 (54.2)	17 (65.3)	41 (30.5)	<0.001
Current smoker (n (%))	21 (15.5)	14 (13.3)	3 (11.5)	17 (12.6)	0.784
Alcohol (n (%))	45 (33.3)	32 (30.4)	8 (30.7)	42 (31.3)	0.117
Cr, mg/dL (range)	1.28 (0.61-3.52)	1.66 (0.64-4.41)	1.82 (0.71-4.17)	1.92 (0.71-3.89)	<0.001
eGFR, mL/min/1.73 m^2 (range)	54.1 (16.0-134.5)	38.8 (16.0-92.1)	34.8 (16.8-94.5)	36.7 (16.0-90.6)	<0.001
CKD G3b/4 (n (%))	44 (32.5)	72 (68.5)	24 (92.3)	78 (58.2)	<0.001
Total-C, mg/dL (M±SD)	169±42	174±51	163± 34	165±49	0.174
HDL-C, mg/dL (range)	52 (25-143)	49 (23-101)	52 (28-78)	45 (26-217)	0.008
LDL-C, mg/dL (M±SD)	94±32	101±42	85± 32	96±37	0.063
TG, mg/dL (range)	127 (48-443)	143 (62-1182)	154 (52-320)	137 (35-815)	0.316
Hb, g/dL (M±SD)	12.7±1.9	13.1±2.5	13.1±2.6	13.1±2.6	0.028
Albumin, g/dL (range)	4.5 (2.6-5.1)	4.2 (2.9-6.0)	4.5 (3.7-5.2)	4.8 (3.2-5.8)	0.003
No. of drugs (range)	2 (0-6)	2 (0-6)	2 (0-5)	2 (0-7)	0.163
Clinic SBP (range)	126 (91.0-145.3)	148 (116.0-209.0)	145 (113.0-183.0)	132 (102.0-138.7)	<0.001
Clinic DBP (range)	76 (55-91.2)	88 (32-117)	84 (57-101)	76 (54-92)	<0.001
24-hr SBP (range)	120 (95.0-130.1)	144 (114.0-210.0)	122 (106.0-132.0)	137 (113.0-181.0)	<0.001
24-hr DBP (M±SD)	73.6±7.1	84.4±11.2	69.1±6.9	84.2±9.2	<0.001
Daytime SBP (range)	124 (10-143)	146 (109-215)	126 (109-137)	135 (113-180)	<0.001
Daytime DBP (M±SD)	77.6±7.6	86.0±12.5	72.8±7.6	84.9±9.8	<0.001
Nighttime SBP (range)	113 (88-135)	134 (96-197)	114 (96-133)	127 (103-175)	<0.001
Nighttime DBP (M±SD)	69.7±7.1	78.3±12.1	65.2±8.2	78.9±9.2	<0.001

[Table/Fig-3]: Demographic, clinical, and BP characteristics according to BP control pattern.
p-value was calculated using Chi- square test; p-value <0.05 is significant

Factors	Multivariate OR	95% CI	p-value
Normal BP			
Age ≥60, yr	0.602	0.376-0.947	0.032
Cr (per 1 mg/dL)	0.351	0.241-0.553	<0.001
HDL-C	1.017	1.003-1.029	0.021
Sustained HT			
Diabetes mellitus	1.926	1.171-3.144	0.010
LDL-C (per 1 mg/dL)	1.009	1.000-1.017	0.038
White-coat HT			
Age ≥60, yr	2.118	1.041-4.344	0.050
Masked HT			
CKD G3b/G4	2.881	1.696-4.554	<0.001

[Table/Fig-4]: Factors related to BP control patterns.

DISCUSSION

The BP control is seen as an important step for CKD management and its progression and thus is associated with cardiovascular complications. The study was conducted on 400 patients who gave their consent and underwent ABPM examination. In the present study results revealed that out of 400 patients (56.25%) were male subjects, and the median age ranged from was 62 (21-76) years. Present study results were in concordance with the study done by Salagre SB et al., whose results revealed that among all patients of CKD males (57.3%) were more susceptible than females (42.7%) [21]. Kumar SS et al., also observed concomitant results that out of 50 patients, 38 (76%) were males and 12 (24%) were females [22]. Among all the patients included in the study, the most common was normal BP (33.75%), sustained HTN (26.25%), WCH (6.5%), and masked HTN (33.5%). African American Study of Kidney Disease

Variables	Normal BP (n=135)	Sustained HT (n=105)	White-coat HT (n=26)	Masked HT (n=134)	p-value
Clinic SBP	127 (91.0-142.5)	152 (119.0-210.0)	148 (114.0-184.0)	135 (105.0-14.5)	<0.001
Clinic DBP	76 (55-91.2)	88 (32-118)	82 (62-101)	72 (56-92)	<0.001
24-hr SBP	126 (95.0-132.5)	156 (115.0-210.0)	127 (123.0-123.0)	145 (124.0-178.0)	<0.001
24-hr DBP	74.3±6.7	84.2±11.2	71.5± 8.0	89.0±9.4	<0.001
Daytime SBP	124 (8-143)	152 (112-217)	126 (118-142)	143 (116-182)	<0.001
Daytime DBP	77.2±8.1	89.0±11.3	72.8±8.17.4	86.0±10.1	<0.001
Nighttime SBP	113 (85-136)	143 (102-198)	115 (98-146)	132 (103-182)	<0.001
Nighttime DBP	68.7±8.4	76.4±13.0	65.1±8.9	77.4±10.4	<0.001

[Table/Fig-5]: Demographic, clinical, and BP characteristics according to dipping pattern.
p-value was calculated using Chi-square test; p-value <0.05 is significant

Factors	Model 1			Model 2		
	Multivariate OR	95% CI	p-value	Multivariate OR	95% CI	p-value
Albumin (per 1 g/dL)	0.364	0.176-0.768	0.008	-	-	-
Nighttime SBP (per 1 mmHg)	-	-	-	1.043	1.025-1.067	<0.001
Nighttime DBP (per 1 mmHg)	-	-	-	1.050	1.013-1.075	0.009

[Table/Fig-6]: Factors related to non /reverse-dippers.

Cohort study also revealed similar pattern (2.2% and 42.9%, respectively) [23].

Present study results also revealed that of all patients, it was observed that 90 (22.5%) were CKD G1-2, 79 (19.75%) were CKD G3a, 96 (24.0%) were CKD G3b, and 135 (33.75%) were CKD G4. Age ≥ 61 years (OR, 2.118; 95% CI, 1.041-4.344; p=0.050) independently correlated WCH. CKD G3b/G4 (OR, 2.881; 95% CI, 1.696-4.554; p<0.001) independently correlated with masked HTN. Gorostidi M et al., observed similar pattern through his study in which they showed that BP control trends from non CKD stage to CKD stage 5 progressively increased for BP maintenance at the <130/80 mmHg threshold and also reported that ABPM did not change from non CKD to CKD stage 5 [24]. Contrasting results were obtained by Wu Z et al., who stated that in CKD stages 4-5 it was found that SBPs and DPBs (24-hour, daytime, and night-time) were found higher than CKD stages 1-3. They also found that clinic SBP was higher in CKD G4 in comparison to other groups. In the case of ABPM, CKD G3b/G4 showed higher 24-hour, daytime, and night-time SBPs than CKD G1-2/G3a [25]. Kidney Disease Improving Global Outcome (KDIGO) study also demonstrated that results and risk profiles and BP control patterns, differed between CKD G1-2/G3a and CKD G3b/G4. Thus, these results recommend that proper BP monitoring and treatment are vital from the initial CKD stage up to CKD G3b [26].

Limitation(s)

To acquire more clear data, a bigger scale study to determine the target BP and interventional trials on ABPM-based BP control are necessary.

CONCLUSION(S)

The ABPM has more prognostic significance when compared to office BP measurements in all kind of normotensive, hypertensive and CKD patients at all stages. ABPM measurements are often abnormal in CKD. CKD patients frequently show an altered circadian rhythm with an increased rate of non dipping and reverse dipping. One of the reasons for considering clinical BP inadequate to monitor HT and overall BP control since it does not associate well with ABPM, which includes white-coat or masked HT. CKD is associated with white-coat or masked HT along with abnormal dipping pattern. Abnormal ABPM patterns are also considered to be linked with CVD and CKD progression. Thus, this study helps to examine BP control status and dipping patterns in CKD patients.

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