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Evaluation of the Efficiency of Indirect Blood Pressure Measurement Methods in Comparison to Intra-Arterial Reading among Iranian Individuals

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ABSTRACT

Background: Detecting the suitable non-invasive Blood Pressure (BP) measurement method is a quandary in clinical settings for accurate diagnosis of Hypertension (HTN) status.

Objectives: This study aimed to evaluate the efficiency of indirect BP measurement methods in comparison to the gold standard among Iranian patients admitted for Coronary Angiography (CAG).

Methods: This observational study was conducted on 150 CAG candidates randomly selected using the computerized random numbers from March 2019 to September 2019. The participants' BPs were measured via three different non-invasive methods, including brachial and wrist oscillometric cuffs plus brachial sphygmomanometer, and the results were compared to simultaneous intra-arterial reading as the gold standard. The associations between different non-invasive BP measurements and direct arterial BP reading were assessed using different statistical analyses, including correlation coefficient, chi-square, independent and paired t-test, and Analysis of Variance (ANOVA), as appropriated.

Results: The mean age of the participants was 60.56 ± 11.16 years. Both Systolic BP (SBP) and Diastolic BP (DBP) were positively correlated to the gold standard reading in all measurement methods ($P < 0.001$). After adjustment for potential confounders, the findings revealed no significant difference between the pre-defined BP measurement methods, including brachial sphygmomanometer, brachial oscillometric, and wrist oscillometric, and intra-arterial BP reading regarding the means of SBP and DBP ($P > 0.05$).

Conclusions: The present study findings showed that the selected solution was appropriate in terms of clinical aspects for the patients undergoing CABG surgery with long surgical duration or low Ejection Fraction (EF) and reduced the costs to half. Considering the significant difference in the CK-MB level and the lower troponin level in the combined group (not statistically significant), further studies are required to confirm the clinical priority of the combined solution.

1. Background

Hypertension (HTN) is the condition of persistent elevation of systemic Blood Pressure (BP) indices defined as resting Systolic BP (SBP) and Diastolic BP (DBP) of at least 140 mmHg and/or 90 mmHg, respectively (1). This disorder has been reported to affect more than a billion individuals and has been considered to be a major risk factor for several debilitating diseases, including stroke, myocardial infarction, and renal diseases (2). This major cause of cardiovascular diseases has a prevalence of 17.3% (3), and inevitably induces economic burdens and decreases

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the quality of life (4, 5). Studies have revealed the financial burden of HTN to be about 51.2$ billion per year (6).

Diagnosis and management of HTN depend primarily on precise BP measurements through either indirect methods or arterial catheterization as the gold standard. However, the latter is invasive and cannot be practiced in clinical settings (7). On the other hand, non-invasive methods, including upper arm cuff or digital BP manometer, have their specific practical advantages despite decreased reliability at high and low BP values (8). Some studies have reported no significant differences among the measured BPs by different methods. For instance, Epstein S. et al. disclosed that the calibrated wrist cuff BP measurement tool had the same accuracy as the ascending aorta pressure reading and could be used as a reliable method for assessment of HTN status among patients (9). On the other hand, another study revealed a weak association between direct arterial BP reading and all types of non-invasive methods, and the direct method was recommended to be used when accurate BP status was required (10).

Due to the importance of accuracy in terms of BP reading, the clinical term "treatment gap" has been introduced recently, which refers to improperly undiagnosed hypertensive patients who have been left untreated due to underestimated BP readings (11). Therefore, using accurate devices with the least variability in readings from the gold standard BP measurement method seems to be essential (12).

2. Objectives

The present study aims to assess the precision of indirect BP measurement with brachial and wrist oscillometric cuffs plus brachial sphygmomanometer compared to simultaneous intra-arterial BP readings among Iranian individuals undergoing Coronary Angiography (CAG).

3. Patients and Methods

3.1. Study Participants

This cross-sectional study was performed in one of the governmental tertiary heart centers located in Isfahan, Iran (Chamran hospital) from March 2019 to September 2019. The total number of CAG candidates on each day was gathered, and the participants were selected via computerized random numbers. Any randomly selected patient aged at least 20 years was eligible for recruitment in this study. Presence of chronic kidney diseases requiring hemodialysis or peritoneal dialysis, any gross defect or possible risk of arterial obstruction in the right arm, any differences in terms of regularity or intensity in the pulses of the right and left arms, and carotid arteries were defined as the exclusion criteria. Moreover, any differences of at least 10 mmHg in BP levels between the right and left arms before the initiation of angiography, which was measured by a brachial sphygmomanometer, caused the individuals to be excluded from the study. After executing all inclusion and exclusion criteria, a total of 150 patients (males: 96 (64%) and females: 54 (36%)) were selected. All participants were fully informed by the principal investigator about the aims of the study and were utterly free to accept or decline participation in the research. Furthermore, all participants had enough time to ask any probable questions. After all, the participants were requested to sign informed consent forms. This study was approved by the Ethics Committee of Isfahan University of Medical Sciences (IUMS) (IR. MUI.REC.1396.4.108).

3.2. Blood Pressure Assessment

During the angiography procedure, intra-arterial BP measurement was performed via a direct catheter placed in the aorta, and this reading was defined as the gold standard measurement. Simultaneously with continuous direct BP monitoring, right arm brachial oscillometric (ALPK2, M2, Japan), sphygmomanometer (ALPK2 300V, Japan), and right wrist oscillometric cuff (ALPK2 WS910, Japan) were used for indirect measurement of BP. All abovementioned non-invasive methods were done three times with one-minute intervals, and the means of the second and third readings were considered as the patients' BPs in each measurement method.

3.3. Assessment of Other Variables

Data about age, gender (male/female), smoking status, weight, and height were collected using a questionnaire. Body Mass Index (BMI) was calculated by dividing weight (in kilograms) by height (in meters squared). The participants were categorized according to age (< 65 and ≥ 65 years) and BMI (< 25 and ≥ 25 kg/m2). The patients consuming anti-hypertensive, anti-diabetic, and anti-hyperlipidemic agents were classified as having HTN, Diabetes Mellitus (DM), and dyslipidemia, respectively.

3.4. Statistical Analysis

Categorical and continuous variables were reported as frequency (percentage) and mean ± Standard Deviation (SD), respectively. The correlation coefficient was utilized to compare each indirect BP measurement method to intra-aortic reading in terms of SBP and DBP. In addition to the comparison of categorical variables via chi-square test, numerical ones were compared using independent t-test, Analysis of Variance (ANOVA), and paired t-test, as appropriated. All analyses were done using Statistical Package for Social Sciences (SPSS), version 19 (IBM Corp., Armonk, NY, USA), and p-values less than 0.05 were considered to be statistically significant.

4. Results

The mean age of the participants was 60.56 ± 11.16 years, with no significant difference between the two genders. General characteristics and demographic features of the patients have been presented in Table 1. Accordingly, females were more hypertensive and mostly suffered from dyslipidemia, but had lower percentages of cigarette smoking in comparison to males.

Information about the correlation between the measured SBP and DBP using the three pre-defined methods compared to intra-aortic reading has been presented in Table 2. The findings revealed a significant positive correlation between all indirect BP readings and the gold standard method regarding both SBP and DBP ($P < 0.001$).

The results of comparison of SBP based on the pre-defined

Table 1. General Characteristics of the Study Population

Variables		Females	Males	Total	P
Age (years)		62.22 ± 11.60	59.63 ± 10.86	60.56 ± 11.16	0.14
Age groups (%)	< 65 years old	26 (48.1)	62 (64.6)	88 (58.7)	0.04
	≥ 65 years old	28 (51.9)	34 (35.4)	62 (41.3)	
BMI (Kg/m²)		27.24 ± 6.07	26.81 ± 3.83	26.96 ± 4.74	0.98
BMI categories (%)	< 25	21 (38.9)	34 (35.4)	55 (36.7)	0.67
	≥ 25	33 (61.1)	62 (64.6)	95 (63.3)	
HTN (%)	Yes	40 (74.1)	35 (36.5)	75 (50)	< 0.001
	No	14 (25.9)	61 (63.5)	75 (50)	
DM (%)	Yes	20 (37)	27 (28.1)	47 (31.3)	0.26
	No	34 (63)	69 (71.9)	103 (68.7)	
Dyslipidemia (%)	Yes	25 (46.3)	27 (28.1)	52 (34.7)	0.02
	No	29 (53.7)	69 (71.9)	98 (65.3)	
Smoking (%)	Yes	3 (5.6)	41 (42.7)	44 (29.3)	< 0.001
	No	51 (94.4)	55 (57.3)	106 (70.7)	

Abbreviations: BMI, body mass index; HTN, hypertension; DM, diabetes mellitus

Table 2. The Correlations between Brachial Sphygmomanometer, Brachial Oscillometric, and Wrist Oscillometric Blood Pressure Devices and the Intra-Arterial Method

	Systolic Blood Pressure				Diastolic Blood Pressure			
	r	P	Intra-class correlation	P	r	P	Intra-class correlation	P
Brachial sphygmomanometer Intra-arterial	0.86	< 0.001	0.84	< 0.001	0.45	< 0.001	0.48	< 0.001
Brachial oscillometric Intra-arterial	0.83	< 0.001	0.83	< 0.001	0.48	< 0.001	0.51	< 0.001
Wrist oscillometric Intra-arterial	0.81	< 0.001	0.80	< 0.001	0.45	< 0.001	0.48	< 0.001

variables have been presented in Table 3. As the table depicts, SBP readings with a brachial sphygmomanometer and an oscillometric cuff were significantly lower in comparison to the gold standard method among females (152.96 ± 24.95 mmHg vs. 158.63 ± 26.26 mmHg, P = 0.002 and 152.69 ± 23.36 mmHg vs. 157.81 ± 25.25 mmHg, P = 0.01, respectively). On the other hand, males had higher means of SBP by the wrist oscillometric cuff (147.05 ± 20.05 mmHg vs. 143.61 ± 23.23 mmHg, P = 0.01). In patients suffering from HTN and DM, both SBP levels were remarkably lower using the brachial sphygmomanometer compared to intra-arterial readings (155.72 ± 23.13 mmHg vs. 159.95 ± 25.48 mmHg, P = 0.02 and 150.12 ± 23.34 mmHg vs. 155.5 ± 26.55, P = 0.04, respectively). SBP was also lower by the arm oscillometric cuff among the individuals with dyslipidemia (150.23 ± 21.96 mmHg vs. 155.44 ± 26.29 mmHg, P = 0.04). Moreover, smokers had higher means of SBP when the measurement was done using the oscillometric wrist device in comparison to the intra-aortic method (146.91 ± 22.39 mmHg vs. 140.34 ± 24.41 mmHg, P = 0.001). This relation was inverse among the nonsmokers whose SBP levels were measured by the brachial sphygmomanometer and brachial oscillometric cuff (148.75 ± 22.16 mmHg vs. 152.37 ± 25.20 mmHg, P = 0.03 and 148.55 ± 21.84 mmHg vs. 151.79 ± 24.47 mmHg, P = 0.03, respectively). After adjustment for all potential confounders, no significant relationships were found between the SBP means measured by the indirect methods and the intra-arterial method (intra-arterial vs. brachial sphygmomanometer: 148.78 ± 25.59mmHg vs. 146.19 ± 22.45mmHg, P = 0.79; intra-arterial vs. brachial oscillometer: 148.43 ± 24.99 mmHg vs. 145.99 ± 21.89mmHg, P = 0.78; intra-arterial vs. wrist oscillometer: 148.83 ± 24.91 mmHg vs. 149.85 ± 21.81 mmHg, P = 0.57).

In terms of DBP, as depicted in Table 4, the brachial sphygmomanometer had lower means among males in comparison to inter-arterial reading (75 ± 7.89 mmHg vs. 77.17 ± 9.21 mmHg, P = 0.03). In comparison to the direct BP measurement method, DBP levels measured by the brachial sphygmomanometer were lower among the participants with HTN, DM, and dyslipidemia and nonsmokers (78.05 ± 8.75 mmHg vs. 81.08 ± 11.15 mmHg, P = 0.01; 77.81 ± 9.40 mmHg vs. 81.87 ± 10.29 mmHg, P = 0.009; 77.69 ± 8.89 mmHg vs. 81.29 ± 11.99 mmHg, P = 0.04; and 76.7 ± 8.21 mmHg vs. 78.75 ± 10.92 mmHg, P = 0.04, respectively). The results showed no statistically significant association between the indirect and direct measurements of DBP after adjustment for the potential confounding variables (intra-arterial vs. brachial sphygmomanometer: 78.07 ± 10.15 mmHg vs. 76.06 ± 8.25 mmHg, P = 0.98; intra-arterial vs. brachial oscillometer: 78.09 ± 10.53 mmHg vs. 77.87 ± 9.75 mmHg, P = 0.33; intra-arterial vs. wrist oscillometer: 78.32 ± 10.51 mmHg vs. 79.12 ± 9.56 mmHg, P = 0.33).

5. Discussion

This study aimed to investigate a precise method of indirect BP measurement compared to the gold standard method to find an accurate non-invasive way for assessment of HTN status. This disease has been proven to play a pivotal role in the pathogenesis of cardiovascular diseases (13, 14) and affects the quality of life of most patients (15). Despite major developments in BP measurement tools, this procedure is time-consuming, requires difficult and

Table 3. Comparison of Systolic Blood Pressure across Different Categories of Measurement Methods

Readings		Systolic Blood Pressure								
		Brachial sphygmomanometer	Intra-arterial	P	Brachial oscillometric	Intra-arterial	P	Wrist oscillometric	Intra-arterial	P
Sex	**Female**	152.96 ± 24.95	158.63 ± 26.26	0.002	152.69 ± 23.36	157.81 ± 25.25	0.01	154.83 ± 24.03	158.09 ± 25.29	0.18
	Male	142.39 ± 20.06	143.24 ± 23.59	0.87	142.22 ± 20.17	143.16 ± 23.35	0.60	147.05 ± 20.05	143.61 ± 23.23	0.01
Age groups	**< 65 years old**	141.63 ± 21.28	143.03 ± 24.26	0.42	141.25 ± 20.47	142.91 ± 24.07	0.34	146.52 ± 21.08	142.83 ± 23.76	0.01
	≥ 65 years	152.68 ± 22.63	156.94 ± 25.40	0.02	152.71 ± 22.23	156.27 ± 24.34	0.08	154.58 ± 22.12	157.34 ± 24.19	0.38
HTN	**Yes**	155.72 ± 23.13	159.95 ± 25.48	0.02	155.4 ± 21.63	159.36 ± 24.5	0.09	158.51 ± 22.73	159.69 ± 24.27	0.89
	No	136.67 ± 17.19	137.61 ± 20.42	0.62	136.57 ± 17.79	137.51 ± 20.37	0.46	141.2 ± 17.00	137.96 ± 20.51	0.06
DM	**Yes**	151.68 ± 20.79	156.91 ± 24.04	0.06	151.85 ± 19.06	156.81 ± 23.67	0.05	155.47 ± 19.53	156.7 ± 23.78	0.65
	No	143.69 ± 22.82	145.07 ± 25.53	0.29	143.31 ± 22.64	144.61 ± 24.74	0.38	147.29 ± 22.39	145.23 ± 24.69	0.08
Dyslipidemia	**Yes**	150.12±23.34	155.5±26.55	0.04	150.23±21.96	155.44 ± 26.29	0.04	153.62 ± 21.94	155.35 ± 26.31	0.66
	No	144.11 ± 21.79	145.21 ± 24.47	0.39	143.73 ± 21.62	144.71 ± 23.56	0.42	147.86 ± 21.58	145.37 ± 23.54	0.05
Smoking	**Yes**	140.02 ± 22.18	140.14 ± 24.71	0.84	139.82 ± 20.98	140.34 ± 24.62	0.92	146.91 ± 22.39	140.34 ± 24.41	0.001
	No	148.75 ± 22.16	152.37 ± 25.20	0.03	148.55 ± 21.84	151.79 ± 24.47	0.03	151.08 ± 21.55	152.35 ± 24.37	0.61
BMI Categories	**< 25**	142.75 ± 24.57	144.29 ± 26.69	0.28	143.44 ± 24.15	144.15 ± 26.40	0.33	146.13 ± 22.69	145.22 ± 26.35	0.49
	≥ 25	148.19 ± 20.99	151.38 ± 24.70	0.09	147.46 ± 20.45	150.92 ± 23.92	0.09	152.01 ± 21.10	150.92 ± 23.93	0.31
All patients		146.19 ± 22.45	148.78 ± 25.59 0.45[a] 0.79[b]	0.05	145.99 ± 21.89	148.43 ± 24.99 0.93[a] 0.78[b]	0.07	149.85 ± 21.81	148.83 ± 24.91 0.67[a] 0.57[b]	0.21

Abbreviations: HTN, hypertension; DM, diabetes mellitus; BMI, body mass index
a, adjusted by sex and age. b, adjusted by sex, age, BMI, DM, HTN, dyslipidemia, and smoking.

almost expensive training courses, and is accompanied with some side effects including trauma, bleeding, infection, thrombosis, embolism, distal ischemia, and formation of pseudoaneurysm (16). The present study findings revealed that all pre-defined indirect BP reading methods could measure HTN status as accurately as the direct one. These results were in agreement with those obtained in several studies. For instance, a study was done by Gratz et al. on 24 patients and the results indicated that blood pressure measured by non-invasive methods correlated well to the arterial catheter measurement (16). Another study comparing arterial blood pressure and a finger cuff method also declared that this indirect method acceptably measured BP similar to the direct reading (17). Likewise, Ameloot et al. conducted a study on 110 patients admitted in an Intensive Care Unit (ICU) and demonstrated that the Mean Arterial Pressures (MAPs) measured by either invasive or non-invasive methods differed insignificantly from each other (18). On the other hand, some studies have shown controversial findings in terms of comparison of direct and indirect methods of BP measurement. For instance, wrist cuffs were reported to measure BP means higher than the gold standard method (19). Irving et al. implemented a cross-sectional study to evaluate the diagnostic accuracy of non-invasive methods of BP reading in comparison to the gold standard method; i.e., arterial BP measurement. Although they found that the correctly fitted arm cuff was sufficient and sensitive enough to diagnose HTN compared to arterial BP, their findings should be interpreted with caution due to the presence of obesity as one of their limiting factors (20). Another study analyzed inva¬sive and non-invasive BP levels in a large and diverse population of ICU individuals. The findings revealed discrepancies between invasive and non-invasive oscillometric methods in measurement of SBP. In that study, 65 patients underwent simultaneous radial intra-arterial catheterization as well as indirect BP reading of the same arm using a mercury sphygmomanometer and a standard-sized arm cuff. Their outcomes showed the inadequacy of non-invasive BP measurement in comparison to arterial catheterization (21). Hemodynamic instability of patients should be considered while interpreting the results (22). Furthermore, calibration of BP measurement equipment should be individually considered (23).

This study was one of the first ones in the literature assessing simultaneous BP levels using three indirect measurement methods compared to concurrent intra-aortic reading. BP measurement methods under proved guidelines and with calibrated equipment could be considered as another advantage of the study. Furthermore, measuring BP via both sphygmomanometer and oscillometric tools could

Table 4. Comparison of Diastolic Blood Pressure across Different Categories of Measurement Methods

Reading		Diastolic Blood Pressure								
		Brachial sphygmomanometer	Intra-arterial	P	Brachial oscillometric	Intra-arterial	P	Wrist oscillometric	Intra-arterial	P
sex	Female	77.94 ± 8.61	79.67 ± 11.54	0.197	79.54 ± 10.21	80.07 ± 12.14	0.51	79.69 ± 10.70	80.07 ± 11.83	0.43
	Male	75 ± 7.894	77.17 ± 9.219	0.033	76.94 ± 9.403	76.97 ± 9.396	0.55	78.8 ± 8.9	77.33 ± 9.624	0.14
Age groups	< 65 years old	75.07 ± 7.52	76.73 ± 8.92	0.11	77.16 ± 9.75	76.72 ± 9.56	0.97	79.17 ± 9.82	76.88 ± 9.39	0.09
	≥ 65 years old	77.47 ± 9.07	79.97 ± 11.48	0.058	78.89 ± 9.74	80.03 ± 11.58	0.21	79.05 ± 9.26	80.37 ± 11.71	0.46
HTN	Yes	78.05 ± 8.75	81.08 ± 11.15	0.013	80.17 ± 10.81	81.37 ± 11.55	0.11	81.19 ± 10.1	81.67 ± 11.61	0.81
	No	74.07 ± 7.25	75.05 ± 8.05	0.28	75.57 ± 7.99	74.8 ± 8.25	0.74	77.05 ± 8.57	74.97 ± 8.07	0.15
DM	Yes	77.81 ± 9.40	81.87 ± 10.29	0.009	79.13 ± 9.33	82.09 ± 10.72	0.058	81.23 ± 9.17	82.19 ± 10.63	0.69
	No	75.26 ± 7.59	76.33 ± 9.64	0.23	77.3 ± 9.93	76.26 ± 9.98	0.73	78.16 ± 9.63	76.55 ± 10.03	0.21
Dyslipidemia	Yes	77.69 ± 8.89	81.29 ± 11.99	0.03	80.13 ± 9.74	81.6 ± 12.36	0.24	80.63 ± 9.70	81.6 ± 12.36	0.48
	No	75.19 ± 7.81	76.36 ± 8.61	0.14	76.67 ± 9.59	76.22 ± 8.95	0.85	78.32 ± 9.45	76.58 ± 8.99	0.12
Smoking	Yes	74.52 ± 8.26	76.43 ± 7.86	0.15	77.07 ± 9.34	76.52 ± 8.29	0.85	78.32 ± 8.8	76.5 ± 8.14	0.29
	No	76.7 ± 8.21	78.75 ± 10.92	0.042	78.21 ± 9.94	78.74 ± 11.31	0.27	79.45 ± 9.88	79.08 ± 11.31	0.82
BMI Categories	< 25	73.85 ± 7.23	75.82 ± 9.51	0.12	77.07 ± 10.62	75.84 ± 9.67	0.61	76.56 ± 9.08	76.11 ± 10.14	0.84
	≥ 25	77.34 ± 8.57	79.37 ± 10.33	0.049	78.34 ± 9.24	79.39 ± 10.84	0.12	80.6 ± 9.57	79.6 ± 10.57	0.34
All patients		76.06 ± 8.25	78.07 ± 10.15	0.01	77.87 ± 9.75	78.09 ± 10.53	0.39	79.12 ± 9.56	78.32 ± 10.51	0.41
				0.29[a]			0.20[a]			0.07[a]
				0.98[b]			0.33[b]			0.33[b]

Abbreviations: HTN, hypertension; DM, diabetes mellitus; BMI, body mass index
a, adjusted by sex and age. b, adjusted by sex, age, BMI, DM, HTN, dyslipidemia, and smoking.

extend the generalizability of the outcomes. Nonetheless, the research was not free from limitations. The quite small sample size could be considered as one of the limitations of the current study. Additionally, other chronic disorders were not assessed, which might have affected the outcomes. Moreover, further analysis based on each subgroup of anti-hypertensive agents was not performed.

In conclusion, the results suggested that indirect BP measurement methods, including brachial sphygmomanometer and brachial and wrist cuff devices, could efficiently measure BP levels as accurately as the intra-arterial method. Yet, further studies are necessary in this field in order to clarify the present study findings and to assess the accuracy of each measurement tool across different BP levels.

5.1. Ethical Approval

All procedures were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards (IR. MUI.REC.1396.4.108).

5.2. Informed Consent

Consent forms were obtained from all participants.

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Authors' Contribution

1. Study concept and design: M. E., D. S., A. K, and M. E. 2. Acquisition of data: M. E and D. S. 3. Analysis and interpretation of data: M. E. and M. V. 4. Drafting of the manuscript: E. A. and M. V. 5. Critical revision of the manuscript for valuable intellectual content: M. V., D. S., E. A., and A. K. 6. Statistical analysis: M. E. 7. Administrative, technical, and material support: M. E., D. S., and A. K. 8. Supervision: D. S., M. E., and A. K.

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The authors have no financial interests related to the material in the manuscript.

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