Original Research

Accuracy and feasibility of portable blood pressure monitoring in the detection of atrial fibrillation in hemodialysis patients

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Atrial fibrillation (AF) is the most prevalent cardiac arrhythmia in clinical practice and is a common comorbidity in hemodialysis patients. AF contributes to cardiovascular complications; therefore, it is recommended to screen for AF in high-risk patients to prevent serious complications. As we currently lack a handy AF screening tool, the aim of this study was to assess the accuracy of a modified BP monitor (Omron M6), in detecting AF in hemodialysis patients. In a cross-sectional analysis conducted from October 2018 to February 2019, we enrolled all the hemodialysis patients, older than 18 years and maintained on hemodialysis for at least 3 months in four hemodialysis centers in Jordan. Logistic regression was used to predict the accuracy, while the R package (epiR) was used to determine the sensitivity and specificity of the Omron M6 in screening AF. A total of 227 patients participated in the study, with a median age of 57 years (42.8-67.3); among these, 44.5% were female. Of all the participants, 18 were detected with AF, which was confirmed by a 12-lead ECG. The prevalence of AF in our study was 7.9%, while the sensitivity, specificity and accuracy of the Omron M6 in detecting AF were calculated as 83.0% (95% CI, 59.0-96.0), 94.0% (95% CI, 90.0-97.0) and 93.4% (95% CI, 88.0-95.0) respectively. We concluded that Omron M6 has high sensitivity, specificity, and accuracy in screening AF among hemodialysis patients. However, further studies are required to ascertain and firmly establish this preliminary finding.

Keywords

Hemodialysis; Atrial fibrillation; Arrhythmia; ESRD; Blood pressure monitor; Electrocardiogram

1. Introduction

Atrial fibrillation (AF) is the most common cardiac arrhythmia worldwide and is a major health concern. It is linked to an increased risk of death and morbidities such as stroke and heart failure [1, 2]. Additionally, AF has a global prevalence of about 0.5% and significantly affects more males than females. Compared to the year 1990, the prevalence of disability and mortality due to AF has been on the rise [3]. The age-adjusted male prevalence increased from 569.5 to 596.2 per 100,000 people between 1990 and 2014, while that of females also experienced a similar increase from 359 to 373.1 per 100,000 people within the same period [3]. With the increasing risk factors of AF such as hypertension, obesity, diabetes and an aging population, experts expect a parallel worldwide escalation of the AF burden [1].

On the other hand, chronic kidney disease (CKD), also represents a serious global health concern with a prevalence of about 11-13% [4]. The global prevalence of end-stage renal disease (ESRD) is estimated at 0.1% [4]. The incidence of AF among ESRD patients on hemodialysis varies from 6.6-20% and is usually associated with an elevated risk of morbidity and mortality in patients with cardiovascular diseases [5]. Cardiovascular diseases such as sudden cardiac death, cardiac arrhythmias and coronaropathies are responsible for over 40-50% of all-cause mortality in ESRD-hemodialysis patients [6–8]. Chronic volume overload and neurohormonal alterations in ESRD may promote ventricular hypertrophy and dilation along with left atrial enlargement, which can be implicated in the pathophysiology of AF in ESRD [9].

AF has been associated with higher rates of ischemic stroke, myocardial infarction, heart failure and mortality in patients maintained on hemodialysis. There is strong evidence that supports the efficacy and benefit of oral anticoagulants in patients with AF, particularly in patients with high risk of ischemic stroke. This evidence, though, remains indefinable in dialysis patients [10]. The American Heart Association/American Stroke Association recommends active screening for AF among high-risk patients in primary care settings [11, 12]. Early detection may prevent thromboembolic events and the risk of a stroke by means of anticoagulation therapy [2, 5]. Hemodialysis patients are currently not actively screened for AF, because of the added costs and difficulties in technical diagnostic. Clinical tools like $CHADS_2$, CHA_2DS_2-VASc and HAS-BLED have significantly helped in evaluating the risk of stroke and bleeding in the general population. However, they have been of limited use in dialysis patients, where most patients have scores that exceed the

threshold, for both high thromboembolic and bleeding risks [10]. Recently, it has been revealed that upper arm oscillometric blood pressure (BP) measuring devices, which are economical and ubiquitous, are effective in screening for AF. These devices have an embedded AF detection algorithm that can detect AF while measuring BP [13] and were quite effective in detecting AF in the general population, with a high degree of sensitivity and specificity. WatchBP (by Microlife) and Omron M6 (by Omron Healthcare Co. Ltd, Japan) with a 100% sensitivity, were found to be extremely helpful in detecting AF in the elderly primary care population and convenient for use in its screening [14]. However, to the best of our knowledge, the efficacy of this handy tool has not been yet evaluated in detecting AF among hemodialysis patients with ESRD. The novelty of this approach in the high-risk hemodialysis patients stems from the fact that with no additional cost or effort we may screen all the patients routinely three times a week, all through their hemodialysis sessions, indefinitely. Early diagnosis of AF might be crucial to initiate treatment and prevent life-threatening complications. This study sought to determine the accuracy of a portable BP measuring device with an AF sensor, in screening AF during hemodialysis.

2. Methods

2.1 Study design and setting

We conducted a cross-sectional study from October 2018 to February 2019 in four hemodialysis centers in Amman, Jordan-The Jordan University and the Al-Bashir Hospitals which are state-owned tertiary referral and teaching centers, and the private and pedagogic Islamic and Al-Essra Hospitals. Each dialysis center managed by a nephrologist, serves about 50 to 150 maintenance hemodialysis patients.

2.2 Study population and sample

For eligibility, we assessed all the patients with ESRD undergoing maintenance hemodialysis and then invited them to join the study. Consenting participants aged older than 18 years, diagnosed with ESRD and who had received hemodialysis for at least three months prior to the study, were enrolled consecutively. Patients with any psychiatric, psychological, or debilitating disorder that could prevent them from either being interviewed or understanding the questions were excluded.

2.3 Ethical considerations

This study was approved by the ethical review boards (IRB) of the Jordan University, Al-Bashir, the Islamic and Al-Essra hospitals. After they were explained the details of the research, its procedure, potential benefits and harm and their questions satisfactorily answered, all participants signed an informed, written consent form. We conducted this study in accordance with the World Medical Association's Declaration of Helsinki principles involving human subjects.

2.4 Study procedure and data collection

Demographic data (e.g., age and gender), past medical history (e.g., history of hypertension, history of diabetes mellitus and ischemic heart disease) and dialysis-related information (e.g., duration of dialysis, dialysis access and number of sessions per week) were collected by trained final-year medical students using a pre-structured questionnaire. An automated BP monitor with an irregular heartbeat detector (Omron M6, Omron Healthcare Co. Ltd, Japan) was used during the BP recording to detect the presence of irregular heartbeats. The device operates on the oscillometric principle and the Omron IntelliSense technology. It detects pulse, in the range between 40 to 180 beats/min with an accuracy of ± 5% of the displayed reading. The device's irregular heartbeat detection algorithm is independent from the BP measurement and is accomplished by measuring the last ten pulse intervals during cuff deflation, and then calculating the mean and standard deviation of the intervals. An irregularity index is defined as the standard deviation divided by the mean of the time intervals. To reduce the effect of premature beats on the irregularity index, a cut-off value of 25% was chosen, so that each of the ten pulse beat intervals that is 25% greater than or 25% less than the mean time interval was deleted. The remaining time intervals are used to calculate the irregularity index. If the irregularity index surpasses a threshold value of 0.06, the rhythm is considered irregular [15].

At baseline, prior to hemodialysis sessions, all the patients were screened for AF by palpating their pulse and auscultating the heart to check for irregularities, using the automated BP monitor and obtaining a reading using a12-lead ECG. During the dialysis sessions, the patients' BP and pulse were monitored every 30 minutes using the automated BP monitor. If an irregular heartbeat was detected, an irregular heartbeat sign would flash on the device screen. If the sign flashed, the BP was retaken after five minutes to confirm its presence and a pulse palpation and heart auscultation was performed. A second ECG was obtained if the sign persisted. All ECGs were done by trained final-year medical students, and the findings were further interpreted by a consultant cardiologist twice, in two separate sessions.

2.5 Statistical analysis

Microsoft Excel 2010 spreadsheets was used for data entry and curation. The statistical software R (version 3.5.3, The R Foundation for statistical computing, Vienna, Austria 2019) was used for data analysis. Qualitative variables were reported as counts and proportions, while quantitative variables were summarized as means and medians with their corresponding standard deviation (SD) and interquartile range (IQR) respectively. Logistic regression was used to evaluate the accuracy of the Omron M6 device in predicting the presence of AF. The *ROCR* [16] and *epiR* [17] packages were used to visualize and calculate the accuracy of the Omron M6 device in diagnosing AF. We also reported information on the sensitivity and specificity of the device alongside their 95% confidence intervals, respectively.

Table 1. Demographic characteristics, comorbidities, and dialysis factors of the study population

Variables	Frequency	Percentage
Section 1: Sociodemographic data		
Age in years, median (IQR)	57.0 (42.8-67.3)	
Gender, Female (%)	101	44.5
Section 2: Comorbidities		
Hypertension, Yes (%)	171	75.3
Diabetes mellitus, Yes (%)	89	39.2
Dyslipidemia, Yes (%)	69	30.4
Ischemic heart disease, Yes (%)	32	14.1
Heart failure, Yes (%)	33	14.5
Valvulopathy, Yes (%)	4	1.8
Section 3: Dialysis		
Duration of dialysis (in hours)	4 (3-4)	
Number of sessions per week	3 (3-3)	
Dialysis access type		
Arteriovenous fistula	170	74.9
Arteriovenous graft	3	1.3
Central catheter	49	21.6
Pre-dialysis		
Average Systolic BP (in mmHg)	133 (28.4)	
Average Diastolic BP (in mmHg)	78.3 (13.5)	
Post dialysis		
Average SBP (in mmHg)	120.5 (28.6)	
Average DBP (in mmHg)	73.3 (14.1)	
Average weight gain during dialysis (in kg)	3.1 (1.0)	

3. Results

Out of the two-hundred and twenty-seven (227) of the total 231 participants included in the analysis, none had been previously diagnosed with AF. Four participants were excluded because of missing values related to their screening with the Omron M6 and/or the ECG results. The median age of the participants was 57 years (interquartile range = 42.8-67.3) and 44.5% were females. Hypertension, diabetes and dyslipidemia were the most common comorbidities presented in 75.3%, 39.2% and 30.4% of the participants respectively, as shown in Table 1.

The CHA_2DS_2-VASc and HAS-BLED scores were calculated for each patient and the mean scores of our population were 2.6 ± 1.1 and 2.43 ± 0.69 respectively.

3.1 Accuracy of Omron M6 in screening for AF

Of the 227 participants, 27 (11.9%) were diagnosed as suspected cases of AF by the portable BP monitor, whereas only 18 (7.9%) were confirmed by the ECG to have AF. Premature ventricular contractions (PVCs) were mostly responsible for the false positive results of the Omron M6 device, as shown in Table 2.

Using logistic regression analysis, we found the accuracy, sensitivity and specificity of the Omron M6 device in screening for AF was 93.4% (95% CI, 88.0-95.0), 83.0% (95% CI, 59.0-96.0) and 94.0% (95% CI, 90.0-97.0), respectively, as shown in Table 3.

4. Discussion

In the present study, we evaluated the accuracy of a modified BP monitor in screening for AF among patients with ESRD on maintenance hemodialysis. To the best of the authors' knowledge, this is the first study to evaluate the efficacy of this device in relation to this high-risk group of participants. In a sample of 227 participants, with a median age of 57 years and 44.5% females, the Omron M6 was found to be precise, sensitive, and specific in identifying cases of AF among patients with ESRD on maintenance dialysis. The higher rate of AF detection by the BP monitor (11.9%) compared to the rate confirmed by ECG (7.9%) maybe explained by the paroxysmal nature of AF, missed PVCs, or a device artifact. The median age of hemodialysis patients in the region of study is 55 years, which reflects a considerably younger age group compared to other studies worldwide. Prevalence of AF is known to be more common in elderly patients. Although the sensitivity of the Omron M6 in our study was high at 83%, we found it to be lower than the values of 100% reported in the previous literature [14]. This disparity is most likely due to differences in sample size, the number of AF cases and study methodology. Additionally, Marazzi et al. [14] included 503 participants with an AF prevalence of 11.3%, and the ECG readings were evaluated by more than one cardiologist, although the number of cardiologists involved in the interpretation was not stated by the authors. However, the sensitivity of the Omron M6 in screening for AF reported in our study was considerably higher than that reported by Wiesel et al. [18] (sensitivity = 30%), who recruited a lower sample of 183 outpatients. This extremely low sensitivity has not been replicated by further studies and remains unexplained. Conversely, the specificity of the Omron M6 in our study was similar to that of previous studies [14, 18].

These findings suggest that the Omron M6 might be a promising tool to screen for AF among patients with ESRD on maintenance hemodialysis. Although many screening methods may be employed, automated BP monitors with AF sensors may be advantageous in terms of cost-effectiveness and ease of regular use in clinical settings. To reiterate, the BP of hemodialysis patients is routinely measured several times through each hemodialysis session and does not require advanced knowledge of ECG interpretation to detect the presence of AF. This modified BP device has the potential to diagnose paroxysmal AF, as it could be used as a home BP and AF monitor. However, the usability of this tool as a home BP and AF monitor is yet to be validated.

Despite the promising outcomes, our study design did have some limitations. The use of continuous rhythm monitoring during dialysis sessions, rather than the 12-lead ECG to confirm AF was preferable but was refrained from due to technical and financial constraints. The cross-sectional design will not permit further follow-up, to determine the nature and fate of the AF. Our analysis might have been limited by a relatively smaller sample size with a small number of AF cases, even though patients were recruited from four major

Table 2. Confusion matrix of cases of atrial fibrillation (AF) diagnosed with Omron M6

		Diagnosis of atrial fibrillation with ECG		
		Positive	Negative	Total
Diagnosis of atrial fibrillation with Omron 6	Positive	15	12	27
	Negative	3	197	200
	Total	18	209	227

ECG = electrocardiography

Table 3. Diagnostic performance of Omron M6 in diagnosing cases of atrial fibrillation (AF)

	Value	95% confidence interval
Sensitivity	83.0%	59.0-96.0
Specificity	94.0%	90.0-97.0
Positive Likelihood ratio	14.51	8.07-26.10
Negative Likelihood ratio	0.18	0.06-0.50
Positive predictive value	56.0	35.0-75.0
Negative predictive value	98.0	0.98-100.0

hemodialysis centers. This is due to the difficulty of finding a large sample of patients with ESRD who are on maintenance hemodialysis. This, therefore, calls for a national collaboration, with multiple centers and a cohort design to improve the sample size and number of AF cases for future studies, to evaluate the usefulness of this tool in screening for AF in this group of high-risk patients. Also, we did not evaluate the usefulness of the WatchBP device, a tool which has proven to have a sensitivity as high as the Omron M6 [14] in screening for AF among the elderly in primary care and has been recommended by the National Institute for Health and Care Excellence (NICE) for screening of AF in this group [19, 20]. Future studies should, therefore, consider comparing the effectiveness of Omron M6 and WatchBP in screening for AF with reference to 24-hour Holter monitor results among patients with ESRD on maintenance hemodialysis. To the best of our knowledge, this study is the first to evaluate the efficacy of the Omron M6 among patients with ESRD on hemodialysis and, therefore, sets the pace in trying to identify and reduce a potential cause of morbidity and mortality prevalent among this group of patients.

5. Conclusions

Early diagnosis and treatment of cardiac arrhythmias are vital to prevent serious complications and premature death among patients on maintenance hemodialysis; unfortunately, the diagnosis is frequently missed or late. Currently, active screening for AF in hemodialysis patients is not routinely employed; due to continuous technical and financial issues, ECG monitoring during dialysis is not a practicable approach. In this study, we found that a widely available BP monitor (Omron M6) is accurate in detecting previously undiagnosed AF in patients on maintenance hemodialysis. As the BP is routinely measured several times during the dialysis session, we suggest implementing this technique in all hemodialysis

units. We hope this will improve the poor rate prognosis of this high-risk group of patients. However, more studies are needed to confirm our preliminary results and to compare the efficacy of the device to others like the WatchBP monitor and to determine the fate of the discovered AF cases, by using a 24-hour Holter monitor.

Author contributions

IA, AS contributed to the conception and design of the work. IA, AS, AW, SJ, SI, RF contributed to the acquisition of data. SJ recruited and supervised patients from private hospitals. IA, AS, AW and RF contributed to the interpretation of data. IA, AS and AA contributed to the analysis of data of the study. IA, SI, AA and RF drafted the manuscript. IA, AS, SJ, AA, AW and RF critically revised the manuscript. All authors gave final approval and agree to be accountable for all aspects of work ensuring integrity and accuracy.

Ethics approval and consent to participate

This study was approved by the ethical review boards (IRB) of the Jordan University, Al-Bashir, the Islamic and Al-Essra hospitals. The IRB approval number is 190/2018. All subjects signed an informed written consent form after explaining the details of the research, its procedure, potential benefits and harm, and their questions were satisfactorily answered. We conducted this study in accordance with World Medical Association Declaration of Helsinki principles involving human subjects.

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Conflict of interest

The authors have no conflicts of interest to declare.

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