Comparison of the Microlife Blood Pressure Monitor With the Omron Blood Pressure Monitor for Detecting Atrial Fibrillation

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Screening for atrial fibrillation (AF) by assessing the pulse is recommended in high-risk patients. Some clinical trials demonstrated that the Microlife blood pressure monitor (BPM) with AF detection is more accurate than pulse palpation. This led to a change in practice guidelines in the United Kingdom where AF screening with the Microlife device is recommended instead of pulse palpation. Many BPMs have irregular heart beat detection, but they have not been shown to detect AF reliably. Recently, one study, in a highly select population, suggested that the Omron BPM with irregular heart beat detection has a higher sensitivity for AF than the Microlife BPM. We compared the Microlife and Omron BPMs to electrocardiographic readings for AF detection in general cardiology patients. Inclusion criteria were age ≥50 years without a pacemaker or defibrillator. A total of 199 subjects were enrolled, 30 with AF. Each subject had a 12-lead electrocardiography, 1 Omron BPM reading, and 3 Microlife BPM readings as per device instructions. The Omron device had a sensitivity of 30% (95% confidence interval [CI] 15.4% to 49.1%) with the sensitivity for the first Microlife reading of 97% (95% CI 81.4% to 100%) and the Microlife readings using the majority rule (AF positive if at least 2 of 3 individual readings were positive for AF) of 100% (95% CI 85.9% to 100%). Specificity for the Omron device was 97% (95% CI 92.5% to 99.2%) and for the first Microlife reading of 90% (95% CI 83.8% to 94.2%) and for the majority rule Microlife device of 92% (95% CI 86.2% to 95.7%; p <0.0001). The specificity of both devices is acceptable, but only the Microlife BPM has a sensitivity value that is high enough to be used for AF screening in clinical practice. **(Am J Cardiol 2014;114:1046−1048)**

Active screening for atrial fibrillation (AF) in the primary care setting of high-risk patients, including all patients aged ≥65 years, is now recommended by practice guidelines.[1,2] Microlife Corp (Taipei, Taiwan) developed a blood pressure monitor (BPM) with an algorithm that can detect AF so that patients can be automatically screened for AF whenever their blood pressure is measured. When used in primary care clinics in Great Britain, the Microlife BPM was able to detect twice as many patients with new AF as pulse palpation.[3] As a result of this and other studies, the British National Institute for Health and Care Excellence has recommended the use of the Microlife WatchBP Home A BPM to screen for AF in primary care clinics throughout Great Britain.[4] Omron Corporation (Kyoto, Japan) manufactures BPMs that include a feature designed to detect irregular heart rhythms. A trial by Marazzi et al, comparing the Microlife device with an Omron device, found that the Omron device had a sensitivity of 100% with the Microlife device having a sensitivity of 92% for detecting AF.[5] However, that trial included a highly selected population of patients who were referred to a hypertension clinic. These patients were younger than the typical patient with AF. Despite this, some physicians may still consider using the Omron device to screen for AF although its sensitivity for AF in the target population has not been assessed. The present study was designed to compare the Microlife monitor with the Omron monitor for detecting AF in an older population that is more typical of the patients at risk for asymptomatic AF.

Methods

The study population included all patients aged ≥50 years in 2 outpatient cardiology clinics, who agreed to be enrolled in the trial. Patients with pacemakers or defibrillators were excluded from the study. The tested BPMs were the Omron M6 Comfort (HEM-7223-E; Omron Healthcare Co., Ltd., Kyoto, Japan) and the Microlife BP A 200 (Microlife Corp., Taipei, Taiwan).

A technician obtained a 12-lead electrocardiogram and then took the blood pressure and AF readings using both the Omron and Microlife devices for each patient. The Microlife device recommends 3 sequential readings to diagnose AF. The Omron device does not make any claim for detecting AF. In the study by Marazzi et al, the Omron device showed

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See page 1048 for disclosure information.

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Table 1
Baseline characteristics

Variable	All Patients (N = 183)
Age (range)	74 (50−100)
Male	108 (59%)
Race	
White	130 (71%)
Black	29 (16%)
Asian	7 (4%)
Hispanic	17 (9%)
Medical history	
Hypertension	168 (92%)
Diabetes mellitus	45 (25%)
Congestive heart failure	32 (17%)
Stroke	11 (6%)
Coronary artery disease*	76 (41%)
History atrial fibrillation	50 (27%)
Medications	
Angiotensin converting enzyme inhibitor	60 (33%)
Angiotensin receptor blocker	32 (17%)
Diuretics	47 (26%)
β-blocker	113 (62%)
Calcium blocker	60 (33%)
Digoxin	13 (9%)
Anticoagulant	43 (23%)
Anti-arrhythmic	5 (3%)

* History of disease as per the cardiologist.

Table 2
Omron and Microlife results

	Sensitivity	Specificity	Accuracy
Omron	30 (15.4−49.1)	97 (92.5−99.2)	86 (79.9−90.6)
Microlife 1st measurement	97 (81.4−100)	90 (83.8−94.2)	91 (85.6−94.7)
Microlife 2nd	93 (76.1−100)	88 (82.7−93.4)	89 (84.5−93.9)
Microlife 3rd	90 (72.3−98.6)	89 (83.8−94.2)	89 (84.5−93.9)
Microlife (majority rule)	100 (85.9−100)	92 (86.2−95.7)	93 (88.8−96.2)

Numbers shown are % (95% confidence intervals). The majority rule indicates that the final reading is considered positive for AF if at least 2 of 3 individual readings are positive for AF.

100% sensitivity with only 1 reading.[5] Therefore, the present study used the same protocol as in the study by Marazzi et al of 1 reading for the Omron device and 3 sequential readings for the Microlife device. The demographic information, blood pressure, pulse, and AF readings were recorded by the technicians for each subject on a designated study sheet. The electrocardiogram was read by a board-certified cardiologist who was blinded to the results of the BPM readings.

All subjects in the trial were enrolled and studied by 2 independent cardiologists (BA and DS) with no conflicts of interest. In addition, Parallax Clinical Research, LLC, an independent clinical trial consulting firm was retained to review the original study sheets, electrocardiographic readings and trial results for accuracy. The study was approved by Fox Commercial Institutional Review Board. Written informed consent was obtained from all patients before participation in the study. The sponsor, Microlife, suggested this comparative trial, provided funding for the trial, and was given access to the results of the trial. The final decision on the design of the study and the contents of the publication were determined by the investigators.

Sensitivity, specificity, and accuracy for detecting AF were calculated for the single Omron device readings and for the individual Microlife AF readings compared with the electrocardiographic readings. The 3 Microlife readings for each subject are combined to give a single reading based on the majority rule in which the final reading is considered positive for AF if at least 2 of 3 individual readings are positive for AF. Confidence intervals were calculated based on the efficient score method described by Robert Newcombe based on the procedure of E.B. Wilson.[6,7] The sensitivity and specificity of the Omron device were compared with those of the Microlife device using the McNemar test with the Yates correction for continuity to assess the significance of the difference between 2 correlated proportions.[8,9]

Results

There were 199 subjects enrolled in the study, of which 183 fulfilled all the inclusion criteria. The 16 subjects who did not meet the enrollment criteria were aged <50 years. AF readings for 99.5% of the subjects were recorded for both the Omron and Microlife devices. Demographic and medical history for the subjects who met the enrollment criteria are listed in Table 1. The age of the subjects is typical for those with AF. Subjects with a history of AF did not necessarily have AF on the electrocardiogram done at the time of the study.

There were 30 patients with AF documented on electrocardiogram at the time of the study. The results of the Omron reading and the individual Microlife readings for subjects enrolled per protocol are listed in Table 2. The Microlife and Omron results were significantly different with $p < 0.0001$. The average sensitivity for the individual Microlife readings was 93%. For the 146 patients aged ≥65 years, the Omron device had a sensitivity of 30%, with a specificity of 97% and accuracy of 84%, whereas the Microlife device, using the majority rule, had a sensitivity of 100% with a specificity of 91% and an accuracy of 92%. The average heart rate for the subjects with AF was 79 beats/min.

The results for all the enrolled subjects were not much different than for those who met all the enrollment criteria. The Omron device had a sensitivity of 30% (15.4% to 49.1%) and a specificity of 98% (94.2% to 99.7%), and the Microlife majority rule results showed a sensitivity of 100% (85.9% to 100%) and a specificity of 91% (85.4% to 94.8%) in all the enrolled subjects.

Discussion

The Omron M6 BPM with irregular heart beat detection had a very low sensitivity for detecting AF. The results for the Microlife monitor confirm the results of previous studies performed in medical clinics that demonstrated a sensitivity of 93% to 100% and a specificity of 86% to 93% for

detecting AF.[10−12] This high sensitivity makes the Microlife device a good choice for screening for AF in the clinic setting. Screening and early treatment of AF is likely to reduce the risk of stroke, although this has not yet been proved in clinical trials. Because of the increasing use of automated BPMs in medical clinics, the opportunity to detect AF by auscultation or palpation is reduced. Therefore, there is an increased need for an automatic BPM that has been validated to detect AF.

The Microlife monitor has good sensitivity and specificity when 3 readings are combined. Although blood pressure and AF detection accuracies may be better with multiple readings, this may be a burden in a busy clinic. Taking only 1 Microlife BP reading reduces both the sensitivity and specificity for AF, although not statistically significantly. The results of using 1 Microlife BP reading may be acceptable because the vast majority of patients with AF will still be detected. The Microlife devices that are commercially available provide 3 sequential readings, which report a positive result only if all 3 readings are positive. This latter function is designed for home use because it reduces the false-positive rate.

The results of this study differ markedly from those of the study by Marazzi et al. This may be due to the unique population that Marazzi et al studied. All the subjects in the Marazzi study were referred to a hypertension clinic presumably due to poor blood pressure control. In that study, 20% of the subjects had AF, which is an exceptionally large percentage of patients with AF in an unselected relatively young population. The percentage of patients found to have undiagnosed AF that was detected by 1 electrocardiographic reading was 9%, which is almost 10 times the percentage found in AF screening studies that used 1 electrocardiographic reading in older community-based populations.[10,13] The subjects in the study by Marazzi et al were much younger, average age of 67 years, than the typical patient with AF. In addition, all the patients with AF in the study by Marazzi et al had a heart rate >100 beats/min, which is unusual for the asymptomatic older patients that have AF detected during routine screening. This was confirmed by a recent study that invited all 75-year-old residents of a municipality in Sweden to be screened for asymptomatic AF. That study found a mean heart rate of 83 beats/min in those with newly diagnosed AF.[13]

Based on the unusual population studied by Marazzi et al and the results of the present trial, the Microlife BPM is significantly better than the Omron monitor for AF screening in the general population. The Omron monitor should not be used to screen for AF.

Disclosures

Dr. Wiesel has a patent for the atrial fibrillation algorithm, which is licensed to Microlife Corp. There are no other potential conflicts of interest relevant to this study.

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