Atrial fibrillation (AF) is a significant risk factor for stroke and early detection of AF may help to identify patients in need of treatment. Automated blood pressure (BP) monitors with implemented AF or arrhythmia detection systems may be a useful tool for early diagnosis of AF. A systematic review (Medline/PubMed, Embase, Cochrane) of studies was performed to assess the accuracy of modified BP monitors (for diagnosing AF). A total of five studies (four tests in the physician’s office and one at home) were selected. For the most accurate AF detection, three sequential BP measurements should be performed. Direct comparison against a 12-lead ECG showed that the highest sensitivity, 97% (95% CI: 94–100%), for detecting AF was obtained when three readings were assessed with two or three AF-positive readings. The highest specificity (97%) was obtained when performing three measurements, of which all three must be AF positive. The modified BP monitor (Microlife Corporation, Taipei, Taiwan) has high potential in improving AF screening.
As all except one of the papers that were selected dealt with the AF detection system of Microlife corporation (Taipei, Taiwan) only, no statistical comparison was performed. For calculating averages of specificity and sensitivity, we weighted with inverse variances (direct pooling) \cite{8} using aggregate-level data (‘metareg’) in Stata version 9.2 Texas.

Results

Altogether, five studies were found, of which four were tested in the physician’s office \cite{9–12}. In one study, the feasibility of the modified sphygmomanometer for home use was assessed \cite{13}. We analyzed the accuracy of the AF detector of Microlife only, as this is the only system that has been investigated in more than one study. The one paper that provided the results of the arrhythmia detection system of the Omron device was discussed separately.

Working of the AF detection system of the Microlife BP monitors

The automated BP monitor measures the last ten pulse intervals during the cuff deflation phase of a regular BP measurement and calculates the mean and SD of the time intervals. In order to reduce the influence of premature beats on the results, a cutoff value of 25% was chosen so that each interval greater or less than 25% of the mean time interval is deleted. Then an irregularity index, which is defined as the SD divided by the mean of the time intervals, is calculated from the remaining data. If the irregularity index exceeds a threshold value of 0.06 the rhythm is considered irregular \cite{10–12}.

Performance of the modified blood pressure monitor in the office

The four studies that investigated the modified sphygmomanometer in the physician’s office for accuracy in diagnosing AF involved 1430 subjects in whom all were recruited from outpatient hypertension clinics or a cardiology practice. The average age of the participants was (mean ± SD) 70 ± 2.4 years with 55 ± 4% males. The prevalence of AF averaged 20 ± 7% and the prevalence of non-AF arrhythmias was 10 ± 11%. All studies indicated that the measurements were performed at only one clinic visit. A 12-lead ECG measurement that was either taken simultaneously \cite{10,12} or within 2 \cite{11} or 5 \cite{9} min from the measurements with the modified sphygmomanometer (two \cite{9} or three \cite{10–12} measurements) served as gold standard. All 12-lead ECG’s were evaluated by an experienced cardiovascular consultant.

Table 1 provides an overview of the studies and shows that sensitivity and specificity values differed slightly between and within studies, and were mainly dependent upon the number of measurements (readings) and the algorithm, that is, the number of AF-positive readings used for classifying a patient as AF positive.

There were three studies \cite{9–11} that investigated the 1 out of 1 algorithm that led to an average sensitivity of 97% (95% CI: 94–100%) and specificity 84% (95% CI: 83–86%). There were two studies \cite{10,11} that investigated the ≥2 out of 3 algorithm and showed an
average sensitivity of 97% (95% CI: 94–100%) and a specificity of 89% (95% CI: 86–92%). The algorithm 1 out of 2 and 2 out of 2, investigated in different studies, both obtained 100% sensitivity with specificity levels of 76 and 92%, respectively [9,10]. The highest sensitivity (97%) was obtained from three measurements, of which all three must be AF positive for classifying a patient as being AF positive (Figure 1). As a reference, two commonly used methods for diagnosing AF in the GP’s practice have been added to (Figure 1): 12-lead ECG diagnosed by a GP and pulse palpation.

Performance of the modified blood pressure monitor at home

Wiesel et al. investigated the feasibility of the AF detection system for detecting recurrent AF at home [13]. A total of 19 cardiac outpatients (average age: 74 years; 59% men) who were in sinus rhythm but had at least one documented episode of AF during a previous office visit or during the index hospitalization were studied. Patients were first measured in the office with the modified sphygmomanometer in order to exclude the presence of AF at that moment. The patient then had to measure his or her BP on a once-daily basis. If, at any time, the patient found an irregularity, a second measurement was required; if this was also positive then the patient needed to perform a third measurement 1 h later. If patients had found irregularities, they were asked to go to the hospital for a 12-lead ECG to document the rhythm before its duration exceeded 24 h. Results showed that with the modified sphygmomanometer seven patients could be detected who had recurrent AF. Three patients had false-positive readings that were the result of sinus arrhythmia or ectopy, and nine patients had no irregular measurements during the study period.

Conclusion

Overall, the AF detector of the modified Microlife BP monitor shows high accuracy for detecting AF compared with the 12-lead ECG diagnosed by a cardiovascular consultant. Sensitivity and specificity values are dependent upon the number of readings and the algorithm used. The highest sensitivity is obtained with two readings, of which at least one must be AF positive or with three measurements with at least two AF-positive readings. The highest specificity is obtained when taking three readings all three of which must be AF positive.

The most important question with regard to the modified oscillometric BP monitor is what would be the best algorithm to serve its purpose. Although the present review indicates that high sensitivity and specificity levels can be obtained with two measurements, the performance of one extra measurement in combination with the right algorithm should improve the screening accuracy. For this reason, three measurements should be preferred over two. Comparing the studies from both Stergiou et al. [10] and Wiesel et al. [11] with the study of Marazzi et al. [12] shows that changing the ≥2 out of 3 algorithm to a ≥3 out of 3 algorithm decreases sensitivity and increases specificity.

Since clinical measurements are usually performed at one occasion (clinical visit) at a certain time point, a higher sensitivity would be more useful than a higher specificity in order to increase the chance of diagnosing AF-positive patients. Generally, when people measure their BP at home or when they would be asked to screen for AF at home they should measure themselves on multiple occasions [14]. Therefore, a relatively low specificity would lead to many false-positive results. This may cause anxiety to the patients and may lead to unnecessary visits to the doctor. Lower sensitivity, on the other hand, increases the chance of false-negative readings. However, owing to the frequent number of measurements, the chance of missing (paroxysmal) AF, when present, becomes very small. Based on the above-described arguments, Microlife corporation has chosen to use different algorithms for evaluation at home (3 out of 3) and at the office (≥2 out of 3).

Marazzi et al. assessed two automated BP devices for their accuracy in detecting AF: the Omron M6 with implemented irregular heartbeat detector and the Microlife BPA 200 plus for detecting AF [12]. The authors compared three measurements of the Microlife device against one measurement of the Omron device among 503 patients who were referred to a hypertension clinic. They found that the Omron device had higher sensitivity than the Microlife device (100 vs 92%) but lower specificity (94 vs 97%, respectively), and concluded that the Omron device was more accurate. However, the paper contains some serious flaws, indicating that the author’s conclusion is not supported by the data as presented in their paper. First, the conclusion that the Omron device is more accurate is not supported by statistical evidence. Second, accuracy should not be based on sensitivity only as the specificity becomes at least as important when considering a population that has a relatively low AF prevalence. In practice, this would mean that at a regular screening session with approximately 2% of all patients having AF, the Omron device

Figure 1. Sensitivity and specificity values for diagnosing atrial fibrillation. (1) The remaining results are obtained with the modified oscillometric blood pressure monitors. 1/1 means one measurement is performed and one atrial fibrillation (AF)-positive reading is required for classifying a patient as having AF; 2/1, two measurements are performed, of which at least one AF-positive is required, and so on. All values are the result of comparison with a 12-lead ECG as diagnosed by a cardiovascular consultant (2). ECG: Indicates 12-lead ECG as diagnosed by a GP; PP: Pulse palpation. The results from both ECG and PP are obtained from the SAFE trial [15].
Pulse palpation versus modified sphygmomanometer
According to amount others, the NICE Guidelines for Hypertension [102], AF should be screened for by means of pulse palpation before routine BP measurement. A systematic review (three studies, 2385 patients) on the accuracy of pulse palpation to detect AF showed a pooled sensitivity of 94% (95% CI: 84–97%) and a pooled specificity of 72% (95% CI: 69–75%) [96]. In addition, Hobbs et al. found in the SAFE trial among 4933 GP patients of 65 years and older a sensitivity of 87% (95% CI: 82–91%) and a specificity of 81% (80–83%) [15]. Although studies that directly compared the AF detection capability of the modified BP monitor with pulse palpation have not yet been performed, it seems that the modified BP monitor is more accurate. In addition, pulse palpation is liable to observer bias and adherence to guidelines among healthcare workers can be poor [16,17].

Strengths & limitations
The strong part of the studies on accuracy of the AF detection system of the modified oscillometric BP monitor in the physician’s office is that a 12-lead ECG diagnosed by a cardiovascular consultant (gold standard) was used as a comparator. In addition, all selected studies were performed with a sufficient number of patients and all studies compared more than one measurement. A weakness might be that the population studied had a relatively high AF prevalence (±20%). Since the modified oscillometric BP monitor is mentioned for screening, the performance and diagnostic ability should be verified in the environment in which it will be used. Therefore, it deserves recommendation to perform a study among a regular GP population with an AF prevalence of approximately 2.5%. A weakness of the device could be that, since the device works according to the principle of calculating the pulse interval times, subjects with some other arrhythmia may have a higher chance of having false-positive measurements than subjects in sinus rhythm. However, the algorithm adjusts for premature beats and showed that it is still accurate when 10% of all patients to be measured have non-AF arrhythmias.

Expert commentary
The modified BP monitor of Microlife can help to improve AF screening in regular clinical practice, without any extra efforts. Although a direct comparison is lacking, it seems that the device is more accurate and less liable to observer bias than pulse palpation. For the most accurate AF detection, three sequential BP measurements, should be performed. For office measurements, two or three measurements should be AF positive for classifying a patient as AF positive. For using the device at home, all readings need to detect AF before a patient is diagnosed with AF. When patients use the device at home for self-measurement of BP it may lead to increased detection of AF, mainly among those who have no symptoms. The device may be promising for the detection of paroxysmal AF for patients at home, although a study performed among a general GP population is desired. Using the device in a regular GP’s practice might lead to more AF patients being diagnosed and to a lower number of subjects erroneously suspected of having AF, and thus to a decrease in unnecessary ECGs for confirmation.

Five-year view
It is expected that the number of patients with AF will increase over the coming 5 years by approximately 0.11–0.16% [18]. This increase, mainly due to demographic aging and a Western lifestyle, indicates that AF will have a bigger impact on overall healthcare expenditure in future. If the modified oscillometric blood pressure monitor is used during routine blood pressure measurement at the GP’s practice, more patients with (asymptotic) AF may be detected and at an early stage. This means that treatment could start early, which would significantly diminish the number...
of AF-related strokes. As a side effect, routine use of the modified oscillometric device may create more awareness about AF for both physicians and patients with positive effects (e.g., improved treatment strategies, high adherence to treatment and lifestyle improvement). If patients start to use the device at home, it may lead to improved detection of paroxysmal AF and may provide an insight into the prevalence of paroxysmal AF.

Key issues

- Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia, occurring in 1–2% of the general population. Its prevalence increases with age to 5% in subjects over 65 years of age.
- AF is often without symptoms and, therefore, remains undetected, whereas when detected at an early stage followed by adequate treatment, the risk of stroke can be reduced by approximately two-thirds.
- One in five of all strokes is attributed to AF.
- Hypertension is a risk factor for AF.
- Currently, it is advised to screen for AF by means of pulse palpation before routine blood pressure measurement in the GP’s practice.
- Pulse palpation generally, shows moderate accuracy and is dependent on observer bias. In addition, currently the detection of AF often depends on the clinicians willingness and awareness to perform pulse palpation.
- With the modified oscillometric blood pressure monitor, AF can be screened during routine BP measurement with high accuracy and without extra effort.
- Routine use of the modified oscillometric blood pressure monitor may lead to more patients being diagnosed with AF at an earlier stage.

References


**Websites**
