Title: Accuracy of automated blood pressure measurements in the presence of atrial fibrillation: systematic review and meta-analysis

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Abstract

Atrial fibrillation (AF) affects ~3% of the general population and is twice as common with hypertension. Validation protocols for automated sphygmomanometers exclude people with AF, raising concerns over accuracy of hypertension diagnosis or management, using out-of-office blood pressure (BP) monitoring, in the presence of AF. Some devices include algorithms to detect AF; a feature open to misinterpretation as offering accurate BP measurement with AF. We undertook this review to explore accuracy of automated devices, with or without AF detection, for measuring BP.

We searched Medline and Embase to October 2018 for studies comparing automated BP measurement devices to a standard mercury sphygmomanometer contemporaneously. Data were extracted by two reviewers. Mean BP differences between devices and mercury were calculated, where not reported and compared; meta-analyses were undertaken where possible.

We included 13 studies reporting 14 devices. Mean systolic and diastolic BP differences from mercury ranged from -3.1 to +6.1/-4.6 to +9.0 mmHg. Considerable heterogeneity existed between devices (I^2 80% to 94%). Devices with AF detection algorithms appeared no more accurate for BP measurement with AF than other devices.

A previous review concluded that oscillometric devices are accurate for systolic but not diastolic BP measurement in AF. The present findings do not support that conclusion. Due to heterogeneity between devices, they should be evaluated on individual performance. We found no evidence that devices with AF detection measure BP more accurately in AF than other devices. More home or ambulatory automated BP monitors require validation in populations with AF.

246 words

Summary Table

What is known about the topic

- Hypertension and atrial fibrillation commonly co-exist, so accurate blood pressure measurement is important to facilitate diagnosis and treatment.
- Guidelines recommend manual measurement of blood pressure with atrial fibrillation, but also place emphasis on out of office measurement for diagnosis and management of hypertension.
- Previous evidence suggests that automated blood pressure monitors are accurate for systolic but not diastolic blood pressure measurement in the presence of atrial fibrillation.

What this study adds

- Whilst individual monitors have been shown to be accurate with atrial fibrillation, there is considerable heterogeneity between devices, particularly for diastolic blood pressure measurement, when compared to a mercury standard. Therefore accuracy for other devices in atrial fibrillation cannot be assumed.
- There are relatively few studies of accuracy in atrial fibrillation, in comparison to the number of different devices in current clinical use.
- Most published studies are of limited size, and all were conducted on populations who may not represent the wider population with atrial fibrillation.

Introduction

Raised blood pressure (BP, hypertension) is the main risk factor globally for premature morbidity and mortality.[1] Control of hypertension is fundamental for the prevention of cardiovascular disease, yet international data show that the prevalence of hypertensive heart disease is not declining.[1, 2] Atrial fibrillation (AF) affects 2-3% of adults in Europe and the USA, and over 10% of those aged 80 years or older;[3, 4] prevalence is expected to double in the next 50 years as the population ages.[5] Hypertension is a risk factor for, and approximately doubles the risk of, AF due to development of left ventricular hypertrophy and electrical remodelling where BP control is suboptimal.[6, 7] Hypertension is found in half of those with AF, thus obtaining accurate BP readings is an important component of their diagnosis and managment.[8] Current guidelines advise that BP should be measured manually when the pulse is irregular.[9, 10] International protocols for the validation of BP monitors all exclude subjects with an irregular pulse, identifying those with AF as a special poulation.[11, 12] In the absence of agreed guidelines for BP measurement in AF it is not, therefore, possible to claim validation for accuracy of BP readings for any monitor in the presence of AF.[12, 13] However, studies have undertaken comparisons of various automated BP measurement devices with mercury sphygmomanometers, which themselves are disappearing from clinical use on environmental grounds. In fact, a previous review suggested that automated monitors might be accurate in measuring systolic but not diastolic BP where AF is present.[14] Automated devices are easy to operate and eliminate observer bias, and are now preferred in some hypertension guidelines.[15] There are suggestions that office BP may be reasonably measured oscillometrically in some AF patients. This is a matter of debate,[16, 17] but out of office BP measurement, by definition, relies on the use of automated devices.[13] More recently, automated BP devices are incorporating algorithms for the detection of AF; [18-23] one (Microlife WatchBP Home A device) being the subject of a positive National Institute for Health and Care Excellence (NICE) Technology Appraisal. [19, 24] We therefore carried out a systematic review of the literature to a) update the evidence base and to inform a position statement on recommendations on BP measurement in the presence of AF (INSERT REFERENCE TO POSITION STATEMENT), and b) to

understand the accuracy of newer devices with AF detection in measuring BP, in comparison to other devices.

Methods

We searched Medline and Embase from inception to 26th October 2018 using a broad search strategy (Box 1). Searches were augmented by checking reference lists in review and commentary articles retrieved. We also reviewed relevant journal collections, conference abstracts, relevant guidelines and personal archives for additional citations. We included studies that compared brachial BP measurements using oscillometric or other automated devices with auscultatory mercury sphygmomanometer measurement (as our non-invasive gold standard). Comparison could be by either a simultaneous or contemporaneous sequential method. We sought studies of home, office or ambulatory BP monitoring devices with, or without, automated AF detection functions. It is important to note that we did not undertake assessment of the accuracy of AF detection of such devices.

We excluded studies that split comparisons over different assessment sessions, retrospective analyses, case reports, device studies not comparing BP measurements as primary outcome and those using intra-arterial BP measurement as gold standard. We assessed conference abstracts as eligible where sufficient data and detail could be extracted. Searches were confined to English language papers. Selections were made by one reviewer and checked by a second, with discussion and resolution of disagreements.

Data on study details and populations were extracted by two reviewers. We included mean and variance of BP readings for automated devices and mercury comparisons and, where reported, the proportions of systolic and diastolic BP readings reaching agreement within 5, 10 or 15 mmHg, for comparison with the relevant standards of the European Society for Hypertension (ESH) 2010 International Protocol for validation of BP measuring devices.[11] Mean differences were expressed as

device minus mercury values. Where not reported, differences between devices and mercury were calculated from the reported BP values using a matched pairs approach, with adjustment for intra-class correlation coefficients for systolic and diastolic BP reported in a previous review.[14, 25] Meta-analyses of pooled data were undertaken using random effects models in Stata v14.0. Two reviewers undertook independent quality assessment of included studies with the QUADAS-2 tool.[26]

Medline

1. Exp blood pressure determination
2. Exp atrial fibrillation
3. 1 AND 2

Embase:

1. Blood pressure measurement
2. Atrial fibrillation
3. 1 AND 2

Box 1. Search strategy

Results

Searches up to 26th October 2018 retrieved a total of 746 unique citations. Fifty nine full texts were assessed for eligibility and 13 studies covering 14 devices met inclusion criteria (Figure 1). There were no disagreements on data extraction between reviewers. There were eight studies of automated BP monitors designed for home and/or office use,[27-34] and six studies of four ambulatory BP devices;[27, 35-39] one of these only reported mean 24 hour ambulatory BP, as opposed to contemporaneous measurement with mercury comparison, so was not included in meta-analyses.[35] Three studies used a simultaneous method to compare BP measurements,[30, 34, 39] the remainder used varied sequential protocols. Studies were all undertaken in hospital settings, recruiting either

inpatients, outpatients or both, and the mean ages of participants ranged from 68 to 83 years (Table 1). Six studies reported achievement of some, or all, of the standards for the 2010 International Protocol, although none adopted the precise protocol itself.[27, 29, 30, 32, 34, 39] Four of the devices studied included AF or arrhythmia detection features.[31, 32, 34-36]

Mean BP differences between mercury and automated devices were reported, or calculated from data, for nine studies: For six home or office devices, the pooled systolic difference from mercury standard was 1.0 mmHg (-1.1 to 3.1; I^2 = 81%; Figure 2); heterogeneity was accounted for by exclusion of one outlying study on the Microlife BP A6 (Microlife, Heerbrugg, Switzerland),[31] pooled difference from mercury on exclusion was -0.2 mmHg (-1.1 to 0.8; I^2 = 24%). Pooled diastolic difference was 1.5 mmHg (-1.4 to 4.5; I^2 = 94%; Figure 3), heterogeneity could not be accounted for by any one study.

For two ambulatory devices (three studies), pooled systolic difference from mercury was 0.5 mmHg (-0.9 to 1.9; I^2 = 0%; Figure 2) and pooled diastolic difference was 2.0 mmHg (2.8 to 6.8; I^2 = 92%; Figure 3). Diastolic heterogeneity was accounted for by between device differences: A&D-TM-2430 (A&D Company, Tokyo, Japan) difference form mercury -2.4 mmHg (-4.1 to -0.7; I^2 = 0%) and Spacelabs 90207 (Spacelabs Healthcare, WA, USA) 6.4 mmHg (2.1 to 10.6; I^2 = 68%).

QUADAS-2 quality assessments identified some concern over risk of bias, usually due to unclear reporting of recruitment strategies, for all but two studies.[35, 39] Inspection of funnel plots quantified with Egger's tests did not suggest evidence of small study publication bias (systolic and diastolic BP; P = 0.15).[40] Levels of agreement varied between and within device manufacturers.

Six studies of nine devices reported proportions of readings differing from mercury standard for one or more of the thresholds set by the 2010 International Protocol (Table 2).[11] Reporting of all thresholds was only complete in four studies.[30, 39, 41, 42] In single studies, only one home device, the Tensoval duo control (Hartmann-Rico AG, Heidenheim, Germany), and one ambulatory device, the Spacelabs 90207, met all standards for BP accuracy; one other study of Spacelabs 90207 only

reported against the 5 mmHg thresholds, which were not met.[27] The Microlife Watch BPA100Plus (Microlife, Heerbrugg, Switzerland) met the systolic but not the diastolic BP standards.

Four devices studied feature AF or arrhythmia detection indicators: the Tensoval duo control, Microlife BP A6, Microlife Watch BPA100Plus and the A&D-TM-2430.[31, 32, 34-36] Of these, all except the Microlife BP A6 agreed well for systolic BPs. Only the Tensoval device was also accurate for diastolic BP, although the Microlife BPA6 also showed reasonable diastolic agreement.

Discussion

This systematic review and meta-analysis examined the available evidence for accuracy of automated BP measurements compared to a mercury standard. We only found data assessing 14 devices, a number of which are no longer in production. This represents only a small proportion of the monitors currently available on the market. We found considerable heterogeneity of BP differences according to individual device and type of device, which limited our ability to draw general conclusions.

For systolic BP measurement, ambulatory measurements with either the A&D-TM-2430 device or the Spacelabs 90207 appeared comparable to mercury readings, whilst, for clinical or home settings, reports showed good agreement for the Philips Sure Signs VSi (Philips Medical Systems, Andover, Massachusetts, USA), Welch Allyn Vital Sign 300 (Welch Allyn, Beaverton, Oregon, USA), Microlife Watch BPA100Plus and the Tensoval duo control. The latter was the only monitor that met the International Protocol limits of agreement for both systolic and diastolic BP.

The Microlife Watch BPA100Plus met the systolic International Protocol standards but also underestimated systolic BP by 3mmHg. Two other devices, the Omron HEM-750CP (Omron Healthcare Co. Ltd, Kyoto, Japan) and the Microlife BPA6, overestimated systolic BP by 5 to 6mmHg.

For diastolic BP measurements, the A&D-TM-2430 ambulatory BP monitor underestimated BP by 2 mmHg whilst the Spacelabs 90207 overestimated it by 6 mmHg. Among home and office devices accurate for systolic readings, only the Tensoval device performed accurately for diastolic BP as well.

Our review included four monitors with AF detection technology. Accuracy was not consistently better for these devices with considerable inter-device variation between the two Microlife devices, and no evidence of better overall performance compared to devices without AF detection features was noted.

Strengths and weaknesses

Pooled analysis of findings was limited by a lack of data, and relatively small sample sizes in most studies. The mean age of participants was high (~70 years), with little evidence to support any judgement on accuracy of monitors in participants of a younger age. Since AF is an age related condition this may not be important.[4] We undertook comprehensive searches and sought unpublished data from colleagues actively researching in the field, however, there may be manufacturer's data that we were not able to access. The key limitation in this review is the restricted number of devices that appear to have any published assessment of their BP measuring performance in AF. Although we present pooled mean differences from our analyses, the large variation between device types and within the home and office monitor group, precludes any assumption that the apparently small pooled mean differences can be generalised to other monitors. We retrieved, but did not include, a small number of studies reporting device comparison with intra-arterial BPs, since our interest was in the clinical interpretation of reported BP readings.[43-46] Quality assessment using the QADAS-2 tool did not effectively discriminate between studies, mainly due to unclear reporting of recruitment methods, so no subgroup analyses by study quality were feasible.

Relevance to existing literature

This review updates the 2012 review of Stergiou et al.[14] They reviewed eight studies of 11 devices, and observed that overall study methodology was variable and sample sizes were usually lower than those dictated for validation studies.[11, 47] Their pooled data from six studies showed systolic BP to be overestimated, on average, by 0.5mmHg (-1.0 to 1.9; I^2 =39%) and diastolic BP by 2.5mmHg (-0.6 to 5.7; I^2 =93%). Preliminary findings from their current update confirm a similar systolic difference and unchanged correlation coefficient (0.5mmHg (-1.0 to 1.9); correlation coefficient 0.87), but a smaller pooled diastolic over-estimation of 1.5mmHg (-0.6 to 3.6); these overall updated pooled figures remain subject to significant heterogeneity between studies (I^2 =77% for systolic and 94% for diastolic) emphasising the difficulty in generalising across different devices.[48] One other recent large observational study pooling findings across N specialist centres reported correlation coefficients consistent with previous reviews, and an overall over-estimation of BP of 1.1/0.6mmHg. There was, however, no standardisation of choice of machine and no analysis by type of device, although this does represent real clinic observational data.[49] For this review, we identified five additional studies published since the 2012 review,[14] covering three new devices.[31, 35-37, 39] The Tensoval device study was the highest weighted single study in the previous review (44%), but inclusion of only full study, rather than subgroup data, masks a rate dependency for accuracy.[41] Nevertheless, it still performed well against other newer home BP monitors. Overall, we found substantial heterogeneity of accuracy between devices according to setting and device. Whilst we identified evidence for accuracy of two ambulatory devices for systolic BP readings, there was greater variation between home or office monitors. Diastolic BP accuracy varied to a much greater degree in all settings.

Although no study followed the International Protocol for validation of BP devices, a number reported against its standards.[11] Nine studies noted some absolute differences between automated and auscultatory BP measurements, permitting a partial assessment against this criterion of the International Protocol.[11] Several devices met one standard for systolic BP differences but only the

Spacelabs 90207 and the Tensoval Duo Control met these International Protocol criteria in full. The Microlife Watch BPA100Plus met the standards for systolic BP but not diastolic readings.

In AF, beat to beat variations in stroke volume and ventricular filling lead to marked intra-person and inter-observer variation in measured, particularly diastolic, BP.[50] Consequently, automated oscillometric BP measurement is regarded as inaccurate in the presence of AF. Neither the 2014 NICE guidelines, nor the 2012 European Society for Cardiology guidelines, on management of AF discuss BP measurement.[51, 52] Therefore, current NICE guidance remains that of the 2011 hypertension guideline that BP should be measured manually in the presence of pulse irregularity, following pulse palpation,[9] and this is consistent with European guidelines (ESH 2013).[10] It should, however, be noted that intra and inter observer variability using mercury measurement of BP are also greater in AF compared with sinus rhythm.[53, 54] The systolic and diastolic BP differences may be a consistent feature of the oscillometric method, which detects systolic and mean BP directly but derives diastolic BP from an algorithm, leaving it more susceptible to error with pulse irregularity.[16] Revised algorithms may be able to improve precision in AF,[55] and accuracy can be improved by repetition of BP measurements.[56] We endorse advice to measure BP manually, exercising caution with oscillometric devices, and recommend at least three BP measurements be undertaken with the mean systolic BP value adopted, for maximal accuracy.

Clinical implications

Stergiou et al. concluded that monitors already validated in sinus rhythm against international protocols are accurate in measuring systolic but not diastolic BP in the presence of sustained AF.[14] The heterogeneity between devices in this review, in some cases including different models from the same manufacturer derived from the same base model, suggests that no assumptions can be made about the accuracy of other monitors in the presence of AF. We also found that inclusion of AF detection functions does not indicate a greater likelihood of accuracy in BP measurement and care should be taken not to assume this in practice. On the available evidence, the Tensoval device

appears to be a good choice for home BP monitoring in the presence of arrhythmia. This device is, however, unusual in possessing both oscillometric and auscultatory modes of action. It is able to detect arrhythmia and selects auscultatory mode in this setting, only using oscillometric mode if unable to detect Korotkoff sounds. This technology may account for its superior performance compared to other devices in this review. Importantly, we found no studies of accuracy based outside of hospital settings where most BP measurement arises, and the available evidence is based on a range of older populations.

There does, however, seem to be evidence to support accuracy in interpreting systolic ambulatory BP measurements. Guideline recommendations of adoption of ambulatory BP monitoring for diagnosis in sinus rhythm are based on robust evidence, associating measurements with outcomes.[57] The same cannot yet be said of ambulatory BP measurement in AF however,[58] yet given this caveat, guidelines do not exclude AF patients from ambulatory monitoring.[59] The ambulatory devices covered by this review appear accurate for systolic BP and should be preferred, compared to unevaluated ambulatory devices.

Given the lack of available evidence for accuracy of most commonly used BP monitors in the presence of AF, the British and Irish Hypertension Society (BIHS) stresses the importance of a patient bringing their home BP monitor to appointments, and recommends occasional validation of home monitors against clinical devices at individual clinic appointments (https://bihsoc.org/wp-content/uploads/2017/11/BP-Measurement-Poster-Automated-2017.pdf). The BIHS also maintains the only publicly available independent peer reviewed list of BP monitors (https://bihsoc.org/bp-monitors/).

Further research

The guideline development group for the 2011 NICE guidelines on hypertension remarked on concerns about the accuracy of automated devices for measuring BP in people with AF and

considered this an important area for technology development to see if such problems can be resolved.[9] The findings of this review emphasise that caution. There is currently a lack of evidence regarding the accuracy of most commonly used BP monitors in the presence of AF, and validity of a device in sinus rhythm cannot be assumed to imply similar accuracy with arrhythmia. Proposals for a new universal standard for validation of BP monitors recognise this problem, and suggest that subgroup validation studies in AF should follow successful validation of devices.[60]

Further work is required to determine which automated BP monitors are suitable for people with hypertension and AF, to explore whether existing algorithms should be modified or replaced to improve accuracy of BP measurement in AF compared to mercury standard, and to confirm the validity of ambulatory BP measurements in predicting cardiovascular outcomes in the presence of AF.

Conclusions

The limited data available support the accuracy of some monitors for ambulatory, home or clinical use to measure and monitor BP in the presence of AF. For most widely used devices, no evidence has been found. Devices intended for use with AF should be chosen according to existing evidence of accuracy and have this confirmed by comparison against validated clinical devices for individuals being assessed. Further validation studies are needed, particularly for devices equipped to detect AF, before any general conclusions can be drawn regarding accuracy of BP measurement in the presence of AF.

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Authors' contributions

This study was conceived by CEC and RMcM. CEC undertook the searches, selected studies, extracted and analysed the data. SMcD reviewed the search results, checked and agreed study selections and extracted data. CEC drafted the manuscript which was revised by SMcD and RMcM. All authors have read and reviewed the final manuscript.

Conflict of interest statement

CEC sits on, and RMcM chairs the British and Irish Hypertension Society Blood Pressure Measurement Working Party. We both regularly review validation studies of blood pressure monitors against objective criteria set out in international protocols as part of our work with this registered charity. No manufacturer funding is received. CEC, has, in the past been loaned bilateral blood pressure monitors by Microlife and Jawon Medical for unrestricted evaluation. No company had any involvement in the design or conduct of this study.

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Table and Figure legends

Study ID	Subjects	Mean age (years)	Setting	Device description	Device type	AF or arrhytmia detection	BP measurement method	QUADAS-2 summary judgement - At risk of bias?
Anastas 2008	Male and female patients with AF aged 18 years or more, arm circumference 27 to 34 cm, and able to co-operate with protocol	79	Medical telemetry unit of a community hospital, Pacific Northwest	Welch Allyn Vital Sign 300 (Welch-Allyn, Beaverton, Oregon) with standard BP cuff (5082-206-2, Welch-Allyn, Tycos Instruments Inc, Skanetateles Falls, New York)	Office	No	Single sequential same arm BP measurements were undertaken in randomised order using a calibrated mercury sphygmomanometer and a Welch Allyn Vital Sign 300 monitor	Yes
Farsky 2011	Male and female patients aged 18 years or more with permanent AF and peripheral frequency of up to 100 b·min^{-1}, independent of the disease aetiology	68	Two clinics (Faculty Hospital of Purkyne˘ University in Brno and Regional Hospital in Novy´ Jic˘ı´n) in Czech Republic and three clinics (Faculty Hospital of Nursing in Pres˘ov and Nitra and Dom srdca, Martin) in Slovakia	Tensoval duo control (TDC; Hartmann-Rico AG, Heidenheim, Germany)	Home	Yes	Simultaneous arm BP measurements were undertaken using both a calibrated mercury sphygmomanometer and a TDC digital device (which offers auscultatory and oscillometric BP monitoring methods)	Yes
Giantin 2013	Male and female inpatients, aged 65 years or more, with permanent, stable AF (heart rate; 60–100 b·min^{-1})	83	Geriatric hospital unit, Padua University Hospital	A&D-TM-2430 (Kitamoto Shi, Saitama, Japan)	ABPM	Yes	Using the dominant arm, three BP measurements using the ABPM device were calibrated against a standard Hawksley random zero mercury sphygmomanometer to confirm that the values did not differ by > 5 mmHg. The ABPM device recorded BP at 15 min intervals during the day (0701–2200 hours) and at 20 min intervals during the evening and night (2201–0700 hours)	No
Jani 2006	Medically stable male and female patients with rate controlled AF (heart rate; 75 b·min^{-1})	70	Cardiology clinic	Omron HEM-750CP (Omron Healthcare Co. Ltd, Kyoto, Japan)	Home	No	Four supine BP readings were undertaken in the right arm at 2 min intervals, after a rest period of 15 min	Yes
Lamb 2010 (Omron)	Male and female hospital outpatients or inpatients aged 18 years or more with AF and stable heart rate and BP for 24 hours	74	Royal University Hospital, Canada	Omron HEM 711 AC (Omron Healthcare Co. Ltd, Kyoto, Japan)	Home	No	Supine BP readings were recorded in each arm simultaneously using one test monitor and the mercury sphygmomanometer. The second test monitor then replaced the first and readings were repeated. The mean of two mercury readings for each arm was compared with each single device reading for each arm	Yes
Lamb 2010 (Welch-Allyn)	Male and female hospital outpatients or inpatients aged 18 years or more with AF and stable heart rate and BP for 24 hours	74	Royal University Hospital, Canada	Welch-Allyn 52000 series NIBP/oximeter (Welch-Allyn, Beaverton, Oregon, USA)	Office	No	Same as Lamb 2010 (Omron)	Yes
Lip 1996	Male and female normotensive and hyertensive outpatients with chronic AF	72	Medical outpatient clinic, City Hospital, Birmingham, England	Spacelabs 90207 (Spacelabs Healthcare, WA, USA)	ABPM	No	The ABPM device was calibrated using the mean of two readings from a Hawksley random zero mercury sphygmomanometer, taken before and after the first ABPM measurement. The ABPM recorded BP every 30 min over a 24 hour period (day: 0700-2300, night: 2300-0700 hours) and data were condensed into 1 hour averages	Yes
Maselli 2015	Male and female patients with persistent AF attending a cardiology deparment for cardioversion who remained stable with or wihout drugs to control hear rate (60-100 b·min^{-1})	68	Department of Cardiology (Centro Gallucci – Padua), Padua University Hospital	A&D TM-2430 (A&D Company, Tokyo, Japan)	ABPM	Yes	Using the higher reading arm, and after 5 min of supine rest, three sphymomanometric (using a mercury Erkameter 300 device) and three oscillometric (using the ABPM device) BP measurements were obtained	Yes
Miszkowska-Nagórna 2017	Male and female patients with stable AF attending a clinic for cardioversion	63	Department of Hypertension and Diabetology, and the Department of Cardiology and Cardiac Electrotherapy of the Teaching Hospital of Medical University of Gdańsk, Poland	Spacelabs 90207 (Spacelabs Healthcare, WA, USA)	ABPM	No	After several min of rest, BP was obtained simultaneously using a mercury sphygmomanometer and an ABPM oscillometric device (triggered every two min). Measurements were repeated 10 times and the average of successfully obtained pairs was used for analysis	No

Olson 2002	Male and female AF patients attending a clinic for cardioversion	71	Department of Heart Disease, Haukeland Hospital, Bergen, Norway	Accutraccer II (Suntech Medical Instruments, Raleigh, North Carolina, USA, or Diasys Integra, Novacor, Ruell, France)	ABPM	No	BP was measured by the standard auscultatory technique by using an aneroid sphygmomanometer. Three measurements were performed during seated rest, with 1 min intervals. The mean of the last two measurements was noted as the patient's office BP. Thereafter a 24 hour ABPM monitor was fitted	Yes
Selmyte-Besuspare 2017	Male and female patients with AF and arterial hypertension, aged 18 years or more	68	Department of Cardiology, Vilnius University Hospital, Santariskiu Klinikos, Lithuanua	Microlife BP A6 PC with AF detection system (Microlife, Heerbrugg, Switzerland)	Home	Yes	After 5 min of rest, four auscultatory BP measurements were performed on the non–dominant arm and used as the reference tecnique. Four oscillometric BP measurements were then obtained, using the Microlife device, according to the manufacturer's instructions, using the same arm	Yes
Stergiou 2011	Subjects with AF	74	Hypertension Centre, Third University Department of Medicine, Sotiria Hospital, Athens-Greece	Microlife Watch BPA100Plus (Microlife, Heerbrugg, Switzerland)	Home	Yes	Two sets of three BP measurements were obtained using the test device or a mercury sphygmomanometer and each set of measurements were averaged to give a single systolic and diastolic value	Yes
Stewart 1995 (Takeda UA-751)	Male and female inpatients and outpatients, with normotension and hypertension and confirmed AF	72	Medical wards and outpatient department, Western General Hospital, Edinburgh, Scotland	Takeda UA-751 (A&D Company, Tokyo, Japan)	Office	No	BP was measured twice with each device and a Hawksley random-zero sphygmomanometer during seated rest. Hawksley BP readings were taken immediately before and after each device test using a sequential arm technique. Each patient also had three sequential measurements with the Hawksley sphygmomanometer	Yes
Stewart 1995 (Copal UA-251)	Male and female inpatients and outpatients, with normotension and hypertension and confirmed AF	72	Medical wards and outpatient department, Western General Hospital, Edinburgh, Scotland	Copal UA-251 (A&D Company, Tokyo, Japan)	Office	No	Same as Stewart 1995 (Takeda UA-751)	Yes
Stewart 1995 (Accutracker 1)	Male and female inpatients and outpatients, with normotension and hypertension and confirmed AF	72	Medical wards and outpatient department, Western General Hospital, Edinburgh, Scotland	Accutracker 1 (Suntech Medical Instruments, Raleigh, North Carolina, USA)	ABPM	No	Same as Stewart 1995 (Takeda UA-751)	Yes
Stewart 1995 (Spacelabs 90207)	Male and female inpatients and outpatients, with normotension and hypertension and confirmed AF	72	Medical wards and outpatient department, Western General Hospital, Edinburgh, Scotland	Spacelabs 90207 (Spacelabs Healthcare, WA, USA)	ABPM	No	Same as Stewart 1995 (Takeda UA-751)	Yes
Vazquez-Rodriguez 2010	Inpatients with AF, aged 24-96 years	74	Short-Stay Medical Unit of the Complexo Hospitalario Universitario A Coruña, Spain	Philips Sure Signs VSi (Philips Medical Systems, Andover, MA)	Office	No	Using the higher reading arm, four automatic and four manual measurements were made alternately, with 5 min intervals of rest in between each measurement	Yes

Device (study)	Device type	Systolic agreement			Diastolic agree	
		≤5mmHg	≤10mmHg	≤15mmHg	≤5mmHg	≤10mmHg
International protocol standards	**All of:**	**65**	**81**	**93**	**65**	**81**
	Two of:	**73**	**87**	**96**	**73**	**87**
ABPM devices						
Accutracker 1 (Stewart 1995)		50			36	
Spacelabs 90207 (Miszkowska-Nagórna 2017)**		60	91	96	72	96
Spacelabs 90207 (Stewart 1995)		50			29	
Home and office devices						
Copal UA-251 (Stewart 1995)		68			75	
Microlife Watch BPA100Plus (Stergiou 2011)*		69	85	93	47	76
Omron HEM 711 AC (Lamb 2010)		49	72	84	47	77
Takeda UA-751 (Stewart 1995)		65			54	

Tensoval duo control (Farsky [32]2011)**	80	93.6	97.7	81.6	93.7
Welch Allyn Vital Sign 300 (Anastas 2008)		51	85		85
Welch-Allyn 52000 (Lamb 2010)	46	72	81	57	86

*meets International Protocol standards for systolic blood pressure accuracy

** meets International Protocol standards for systolic and diastolic blood pressure accuracy

ABPM: ambulatory blood pressure monitoring

ement

≤15mmHg

93

96

98

88

92

97.3

92

96

Identification

Records identified through database searching
(n = 884)

Additional records identified through other sources
(n = 2)

Records after duplicates removed
(n = 746)

Screening

Records screened
(n = 746)

Records excluded
(n = 687)

Eligibility

Full-text articles assessed for eligibility
(n = 59)

Full-text articles excluded, with reasons
(n = 46)

11 No direct comparison with mercury reference

11 Study of AF detection not BP measurement

9 Commentary or review

6 Not in English

4 Correspondence on retrieved paper

2 Conference abstract only - insufficient data

1 Conference abstract of retrieved full paper

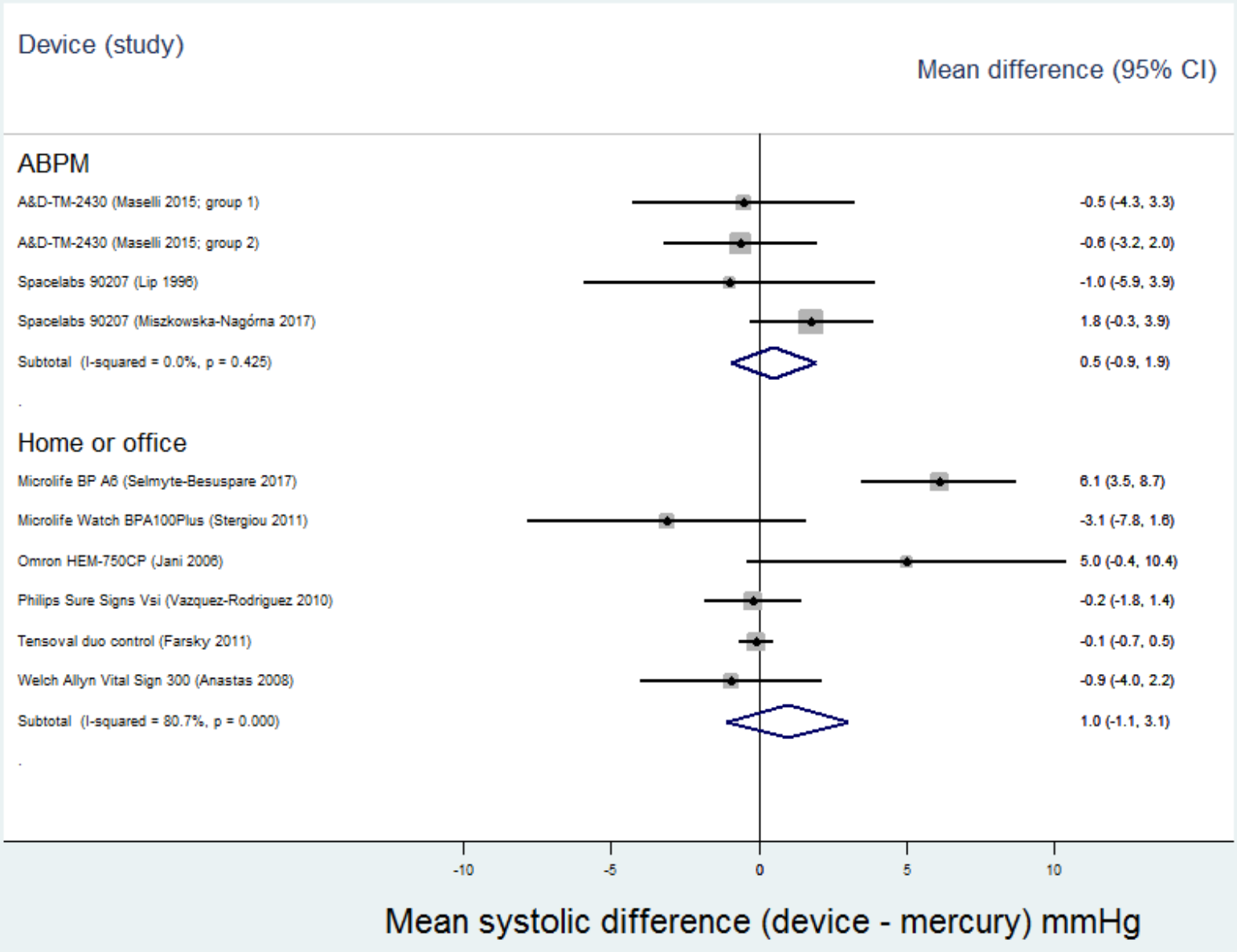
1 Specialist care setting

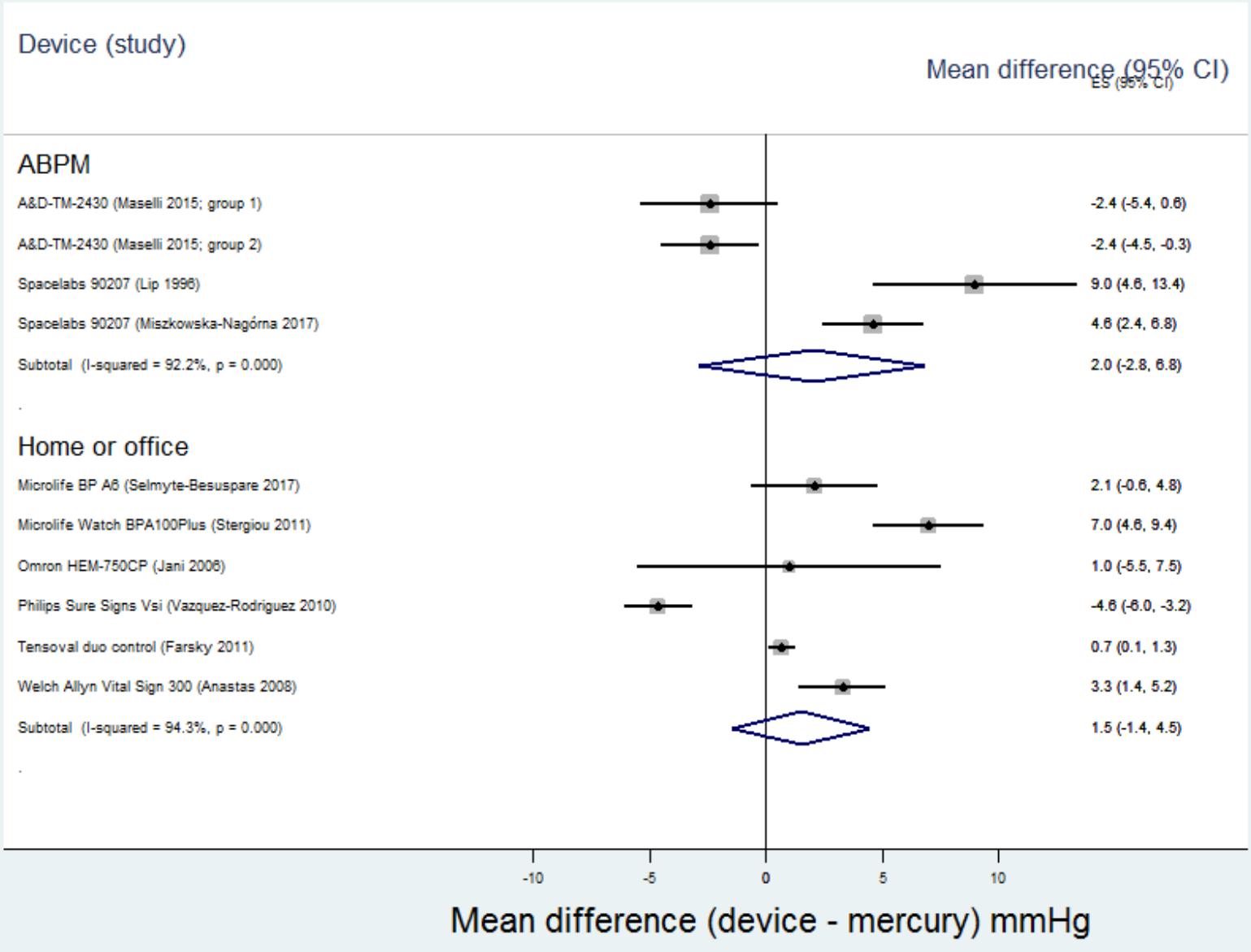
1 Duplicate of included study

Included

Studies included in qualitative synthesis
(n = 13)

Studies included in quantitative synthesis
(meta-analyses)
(n = 12)


Device (study)
Mean difference (95% CI)
ABPM
A&D-TM-2430 (Maselli 2015; group 1)
-0.5 (-4.3, 3.3)
A&D-TM-2430 (Maselli 2015; group 2)
-0.6 (-3.2, 2.0)
Spacelabs 90207 (Lip 1996)
-1.0 (-5.9, 3.9)
Spacelabs 90207 (Miszkowska-Nagórna 2017)
1.8 (-0.3, 3.9)
Subtotal (I-squared = 0.0%, p = 0.425)
0.5 (-0.9, 1.9)
Home or office
Microlife BP A6 (Selmyte-Besuspare 2017)
6.1 (3.5, 8.7)
Microlife Watch BPA100Plus (Stergiou 2011)
-3.1 (-7.8, 1.6)
Omron HEM-750CP (Jani 2006)
5.0 (-0.4, 10.4)
Philips Sure Signs Vsi (Vazquez-Rodriguez 2010)
-0.2 (-1.8, 1.4)
Tensoval duo control (Farsky 2011)
-0.1 (-0.7, 0.5)
Welch Allyn Vital Sign 300 (Anastas 2008)
-0.9 (-4.0, 2.2)
Subtotal (I-squared = 80.7%, p = 0.000)
1.0 (-1.1, 3.1)
-10
-5
0
5
10
Mean systolic difference (device - mercury) mmHg


Device (study)
Mean difference (95% CI)
ES (95% CI)
ABPM
A&D-TM-2430 (Maselli 2015; group 1)
-2.4 (-5.4, 0.6)
A&D-TM-2430 (Maselli 2015; group 2)
-2.4 (-4.5, -0.3)
Spacelabs 90207 (Lip 1996)
9.0 (4.6, 13.4)
Spacelabs 90207 (Miszkowska-Nagórna 2017)
4.6 (2.4, 6.8)
Subtotal (I-squared = 92.2%, p = 0.000)
2.0 (-2.8, 6.8)
Home or office
Microlife BP A6 (Selmyte-Besuspare 2017)
2.1 (-0.6, 4.8)
Microlife Watch BPA100Plus (Stergiou 2011)
7.0 (4.6, 9.4)
Omron HEM-750CP (Jani 2006)
1.0 (-5.5, 7.5)
Philips Sure Signs Vsi (Vazquez-Rodriguez 2010)
-4.6 (-6.0, -3.2)
Tensoval duo control (Farsky 2011)
0.7 (0.1, 1.3)
Welch Allyn Vital Sign 300 (Anastas 2008)
3.3 (1.4, 5.2)
Subtotal (I-squared = 94.3%, p = 0.000)
1.5 (-1.4, 4.5)
-10
-5
0
5
10
Mean difference (device - mercury) mmHg