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Blood pressure monitoring during arrhythmia: agreement between automated brachial cuff and intra-arterial measurements

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Abstract

Background: Since arrhythmia induces irregular pulse waves, it is widely considered to cause flawed oscillometric brachial cuff measurements of blood pressure (BP). However, strong data are lacking. We assessed whether the agreement of oscillometric measurements with intra-arterial measurements is worse during arrhythmia than during regular rhythm.

Methods: Among patients of three intensive care units (ICUs), a prospective comparison of three pairs of intra-arterial and oscillometric BP readings was performed among patients with arrhythmia and an arterial line already present. After each inclusion in the arrhythmia group, one patient with regular rhythm was included as a control. International Organization for Standardization (ISO) standard validation required a mean bias <5 (SD 8) mm Hg.

Results: In 135 patients with arrhythmia, the agreement between oscillometric and intra-arterial measurements of systolic, diastolic and mean BP was similar to that observed in 136 patients with regular rhythm: for mean BP, similar mean bias [−0.1 (SD 5.2) and 1.9 (SD 5.9) mm Hg]. In both groups, the ISO standard was satisfied for mean and diastolic BP, but not for systolic BP (SD >10 mm Hg) in our ICU population. The ability of oscillometry to detect hypotension (systolic BP <90 mm Hg or mean BP <65 mm Hg), response to therapy (>10% increase in mean BP after cardiovascular intervention) and hypertension (systolic BP >140 mm Hg) was good and similar during arrhythmia and regular rhythm (respective areas under the receiver operating characteristic curves ranging from 0.89 to 0.96, arrhythmia *vs* regular rhythm between-group comparisons all associated with $P>0.3$).

Conclusions: Contrary to widespread belief, arrhythmia did not cause flawed automated brachial cuff measurements.

Key words: atrial fibrillation (MeSH); blood pressure determination (MeSH); intensive care units (MeSH); oscillometry; sphygmomanometer

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Editor's key points

- During anaesthesia, oscillometric techniques are most commonly used for automated non-invasive blood pressure measurement.
- Arrhythmias cause irregular pulse waves that may jeopardise the accuracy of oscillometric methods.
- The authors compared oscillometric readings with invasive arterial pressure measurements in ICU patients with arrhythmias.
- The accuracy of automated oscillometric readings was acceptable.

Introduction

Non-invasive blood pressure (NIBP) monitoring with an oscillometric automated brachial cuff is often the cornerstone of decision making.[1] Since established protocols for the validation of NIBP devices exclude patients with arrhythmia,[2 3] the vast majority of studies assessing the accuracy of NIBP involve patients with regular cardiac rhythm.[4] During arrhythmia, the BP fluctuations due to beat-to-beat variability of stroke volume are considered to cause flawed NIBP measurements, as these are based on the detection of beat-to-beat oscillations of the arterial wall.[5] Current official guidelines underline the lack of reliability of NIBP monitoring in patients with arrhythmia,[5–7] leaving physicians with no alternative to invasive monitoring despite the lack of strong data supporting this statement. Indeed, only a few studies have addressed the important issue of the accuracy of NIBP devices during arrhythmia and have yielded conflicting results.[4 8] Importantly, all but one[9] of these studies suffer from an important weakness: they used the manual auscultatory technique as a gold standard even though it can also be flawed by arrhythmia since beat-to-beat changes in Korotkoff sounds greatly increase user bias.[5 6 8 10] One study used intra-arterial readings as a reference,[9] but its results have been questioned.[11] Thus an important gap of knowledge remains given the wide use of NIBP in the critically ill and during the perioperative period (not to mention other settings, including the outpatient)[1 5] and the growing incidence of arrhythmia.[12 13] Recent guidelines stress the urgent need for studies addressing the accuracy of NIBP during arrhythmia.[7]

The primary objective of our study was to assess the agreement of NIBP measurements with a robust intra-arterial reference in a large, multicentre sample of patients with arrhythmia. The acceptability of NIBP was defined by the fulfilment of current recommendations for the validation of BP measuring devices before their commercialization [International Organization for Standardization (ISO) standard 81060-2:2013].[3 14] To strengthen our investigation, patients with regular rhythm were also analysed as a control group. In addition, we assessed the performance of NIBP for simple decision-making processes: detection of hypotension, response to urgent therapy, and hypertension.

Methods

Setting

Patients were included from three ICUs in three tertiary teaching hospitals in France: one surgical ICU (university hospital Laënnec, Nantes) over a 21-month period (from June 2012 to February 2014) and two medical ICUs (university hospital of Tours and regional hospital of Orléans) over a 12-month period (from July 2012 to July 2013).

Patients

Adult patients with arrhythmia were consecutively included in this prospective study if they were carrying an arterial line, if their BP was stable [no change in vasoactive drugs dosage and no significant (>10%) variation of mean BP over 10 min], and if they exhibited sustained (>15 min) arrhythmia. As a control group, one patient with regular rhythm was included after each patient in the arrhythmia group, based on the same criteria.

Patients were not included if they had contraindication for brachial cuff placement or for supine position or a difference in mean NIBP between the upper limbs >5 mm Hg (anatomically induced bias). In case of a cuff inflation–induced increase in heart rate (>5 beats min^{-1}) or in mean BP (>5 mm Hg), indicating potential measurement-induced pain, cuff inflation was interrupted and the patient was excluded.

Arrhythmia was defined as atrial fibrillation, atrial flutter or frequent extrasystoles (≥1 of 6 heart beats). Acute circulatory failure was defined by the presence of at least one of the following criteria: hypotension (invasive systolic BP <90 mm Hg and/or mean BP <65 mm Hg), oliguria (<0.5 ml kg h^{-1}) considered to be related to circulatory failure, arterial lactate >2.5 mmol $litre^{-1}$, skin mottling, or vasopressive and/or inotropic drug infusion.

The ethics board of Orléans Hospital approved the study design and waived the need for prior and written consent since the study procedures fulfilled the criteria of a non-interventional study as defined by French law.[15] Patients' next of kin and the patients themselves (if they regained capacity) were informed of their participation and of their right to refuse the use of the data.

Material

A brachial cuff was chosen according to mid-arm circumference.[5] The lower edge of the cuff was placed 2 cm above the antecubital fossa. The cuff was placed on the arm opposite to the radial artery catheter, if any, and was connected to an oscillometric device (Intellivue MP70 monitor, Philips Medical Systems, Best, The Netherlands).

For invasive BP monitoring, a pressure transducer (T100209A, Edwards Lifesciences, Irvine, CA, USA) was zeroed (atmospheric pressure) at the level of the mid-axillary line and was connected to the Intellivue MP70 monitor. The correct shape of the BP waveform was ascertained via a fast flush test.[16]

Measurements

In the supine position, three pairs of contemporaneous intra-arterial and non-invasive measurements of BP were prospectively collected. A new inflation of the brachial cuff was manually started approximately 60 s after the previous NIBP measurement was displayed.[3] Pairs of intra-arterial and NIBP measurements were manually collected, in real time, from the trend database of the monitor displaying data sampled every 12 s (Supplementary data 1).

We carefully checked that the cardiac rhythm during measurements corresponded to the group in which patients were assigned (arrhythmia or regular rhythm group).

Only in patients with circulatory failure and only if decided by the attending physician was cardiovascular intervention initiated after the first set of measurements. To better reflect real-life practice, this cardiovascular intervention was not standardized for the study purpose: volume expansion, passive leg raising, initiation/change in dosage of vasopressive or inotropic medications, or a combination of these interventions. Thereafter, a second set of BP measurements was collected. This second set was only used for the analysis of changes of BP, i.e. it was not included in our main analysis.

Statistical analysis

Study size

The ISO standard 81060-2:2013 requires the collection of three pairs of BP measurements in 35 patients for special populations such as patients with arrhythmia,[14] which we rounded to 40 to account for the risk of NIBP failure. Each arrhythmia and regular rhythm group was split into subgroups according to the circulatory status: circulatory failure or not.

Patients with arrhythmia were consecutively enrolled until we reached 40 patients with arrhythmia and circulatory failure and 40 other patients with arrhythmia without circulatory failure. Until this minimum of 40 patients in each subgroup was reached, we continued enrolling patients, even in a subgroup already exceeding 40 patients.

Statistical tests

Main analysis. The error (bias) of NIBP measurements was calculated (bias=non-invasive–intra-arterial measurement). Owing to pathophysiological variations of our reference intra-arterial measurements during NIBP measurement, the ISO standard included the zero-zone approach.[17] An NIBP measurement falling into the zero zone is associated with a 0 mm Hg error, as compared with intra-arterial readings. The zero zone is defined as the range of 1 SD around the mean value of three intra-arterial measurements in each patient.[3] If the value obtained from each NIBP measurement was outside the zero zone, the value of the NIBP measurement was subtracted from the adjacent limit of the zero zone. To comply with the ISO standard, the mean bias between the two techniques over the study population must be ≤5 (SD ≤8) mm Hg.[3]

Secondary objectives. Correlation and agreement between triplicates of intra-arterial and non-invasive readings of BP were assessed by linear regression, calculation of the concordance correlation coefficient,[18] and Bland–Altman analysis.[19]

The ability of NIBP to detect (1) hypotension (defined as intra-arterial mean BP <65 mm Hg or systolic BP <90 mm Hg),[20 21] (2) response to an urgent cardiovascular intervention (>10% increase in intra-arterial mean BP), and (3) hypertension (defined as intra-arterial systolic BP >140 mm Hg or diastolic BP >90 mm Hg)[22] was assessed through area under the receiver operating characteristic curve (AUC_{ROC}) analysis.

Categorical data were expressed as percentages and continuous variables with Gaussian/non-Gaussian distribution (as assessed graphically) were expressed as mean (SD) and median [interquartile range (IQR)], respectively. Between-group comparisons relied on chi-squared, Student's *t*, and Mann–Whitney tests and comparison of the AUC^{23}_{ROC}. A *P*-value <0.05 was considered significant. Analysis was performed with MedCalc 13.1.0.0 (MedCalc Software, Ostend, Belgium). No data imputation was deemed necessary. This article is in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology STROBE statement for the reporting of observational studies.[24]

Results

Among 181 consecutive patients with arrhythmia fulfilling the inclusion criteria, 135 were analysed (Fig. 1). The regular rhythm group comprised 136 other patients. Patients were included from Nantes [*n*=185 (68%)], Orléans [*n*=44 (16%)], and Tours [*n*=42 (16%)].

Patients with arrhythmia mostly exhibited atrial fibrillation [*n*=119 (88%)], and less frequently extrasystoles [*n*=11 (8%)] or atrial flutter [*n*=5 (4%)]. As expected,[13] when compared with regular rhythm patients, patients with arrhythmia had a higher heart rate, were older, were more often male, and were more often in acute circulatory failure. In addition, they had a higher body mass index and brachial circumference (Table 1).

The NIBP monitor never failed to display a BP value.

Primary objective: agreement between intra-arterial and NIBP measurements and ISO standard validation

Mean BP

In patients with arrhythmia, mean bias, limits of agreement, and concordance correlation coefficients between intra-arterial and

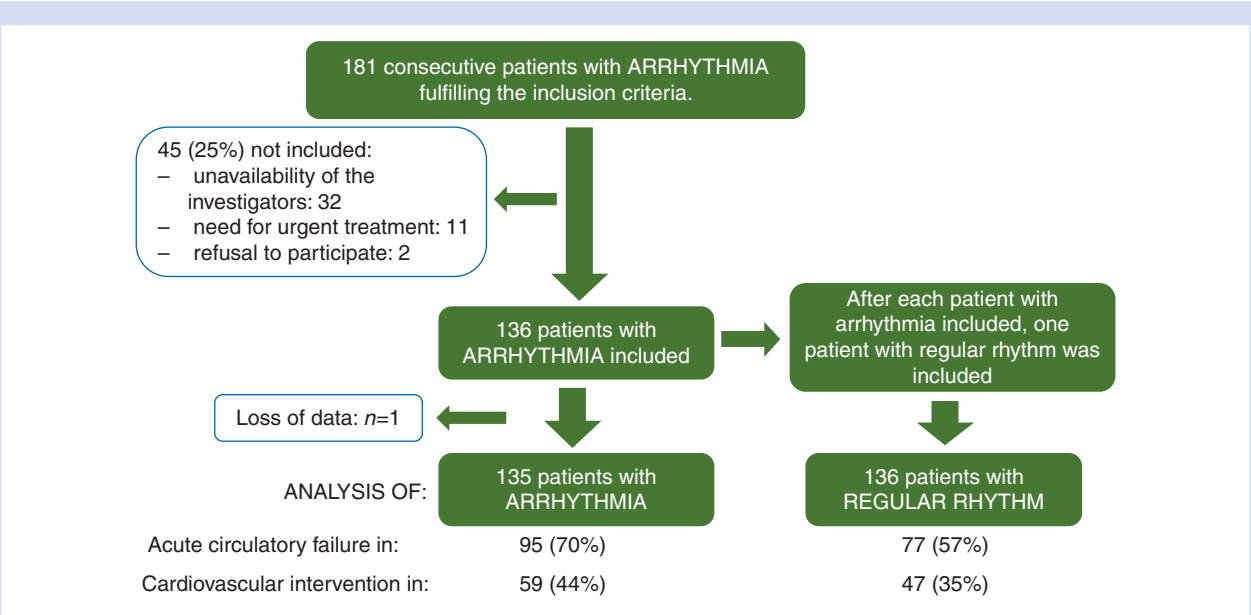

Fig 1 Study flow chart.

Table 1 Patients' characteristics. IQR, interquartile range; ICU, intensive care unit; BP, blood pressure. [a]By the means of a dedicated radiologic procedure. These data were collected in the medical file. Thus the mentioned prevalence is likely to underestimate the actual prevalence of these artery diseases in our population, as some patients did not undergo exploration. [b]Intra-arterial measurement. [c]Ramsay Sedation Scale ranges from 1 (anxious and/or agitated and/or restless) to 6 (unresponsive).[25] [d]Including patients with brain injury and inadequate brain perfusion because of deep sedation

	Regular rhythm group (*n*=136)	Arrhythmia group (*n*=135)	P-value
Whole population			
Age, mean (SD), years	60 (14)	69 (11)	P<0.0001
Female, *n* (%)	41 (30)	22 (16)	P=0.01
Simplified acute physiology score II, mean (SD)	42 (20)	45 (19)	P=0.3
Body mass index, mean (SD), weight (kg)/height (m^2])	25 (6)	28 (6)	P=0.0001
Brachial circumference, mean (SD), cm	29 (4)	31 (18)	P=0.01
Vascular disease (established diagnosis[a] of), *n* (%)			
Atherosclerosis of the lower limbs	24 (18)	21 (16)	P=0.5
Carotid stenosis	19 (14)	24 (18)	P=0.6
Coronary artery disease	34 (25)	51 (38)	P=0.1
Aortic calcifications	12 (9)	11 (8)	P=0.6
Main diagnosis at admission, *n* (%)			
Shock	39 (29)	59 (44)	P=0.03
Coma	34 (25)	13 (10)	
Post-operative care	29 (21)	31 (23)	
Respiratory failure	23 (17)	23 (17)	
Trauma	3 (2)	2 (1)	
Multiple organ failure	2 (1)	3 (2)	
Renal failure	1 (<1)	2 (1)	
Other	5 (4)	2 (1)	
Heart rate at baseline, mean (SD), beats min^{-1}	90 (21)	105 (25)	P<0.0001
Systolic BP at baseline,[b] mean (SD), mm Hg	121 (25)	113 (21)	P=0.004
Diastolic BP at baseline,[b] mean (SD), mm Hg	58 (11)	57 (10)	P=0.6
Mean BP at baseline,[b] mean (SD), mm Hg	76 (14)	74 (16)	P=0.2
Mechanical ventilation, *n* (%)	113 (83)	108 (80)	P=0.6
Ramsay sedation scale, *n* (%)			
>4	88 (65)	75 (56)	P=0.1
4	21 (15)	18 (13)	
≤3	27 (20)	42 (31)	
Delay between ICU admission and measurements, median (IQR), days	3.1 (0.8–5.9)	4.9 (1.2–8.7)	P=0.01
Delay between intra-arterial catheter insertion and measurements, median (IQR), days	2.8 (0.7–5.8)	3.7 (1.0–7.8)	P=0.05
Site of the intra-arterial catheter, *n* (%)			
Radial artery	117 (86)	120 (89)	P=0.7
Femoral artery	19 (14)	15 (11)	
Duration of oscillometric measurement of BP, median (IQR), sec	42 (38–50)	48 (40–58)	P=0.0006
Patients with circulatory failure, *n* (%)	77 (57)	95 (70)	P=0.03
Type of circulatory failure, *n* (%)			P=0.2
Septic shock and severe sepsis	32 (42)	51 (54)	
Cardiogenic shock	19 (25)	24 (25)	
Effects of mechanical ventilation and sedation[d]	12 (16)	9 (9)	
Haemorrhagic shock	2 (3)	4 (4)	
Other (trauma, hypovolaemia, combination)	12 (16)	7 (7)	
Mean BP at baseline,[b] mean (SD), mm Hg	79 (14)	74 (14)	P=0.04
Catecholamines, median (IQR), µg kg^{-1} min^{-1})			
Norepinephrine	0.3 (0.1–0.5) *n*=54 (70%)	0.3 (0.1–0.7) *n*=37 (39%)	P=0.9
Dobutamine	5.1 (3.6–9.2) *n*=17 (22%)	5.6 (3.5–9.5) *n*=23 (24%)]	
Others	NA *n*=5 (6%)	NA *n*=7 (7%)	
Delay between onset of circulatory failure and measurements, *n* (%)			
<6 h	19 (25)	21 (22)	P=0.8
<24 h	38 (49)	42 (44)	

Continued

Table 1 *Continued*

	Regular rhythm group (*n*=136)	Arrhythmia group (*n*=135)	*P*-value
Cardiovascular intervention, *n* (%)	47 (35)	59 (44)	*P*=0.9
Volume expansion, *n* (%)	22 (47)	22 (37)	*P*=0.4
Initiation/increase (>10%) of catecholamine, *n* (%)	17 (36)	21 (36)	
Passive leg raising, *n* (%)	6 (13)	11 (19)	
Combination of two or more interventions, *n* (%)	1 (2)	5 (8)	

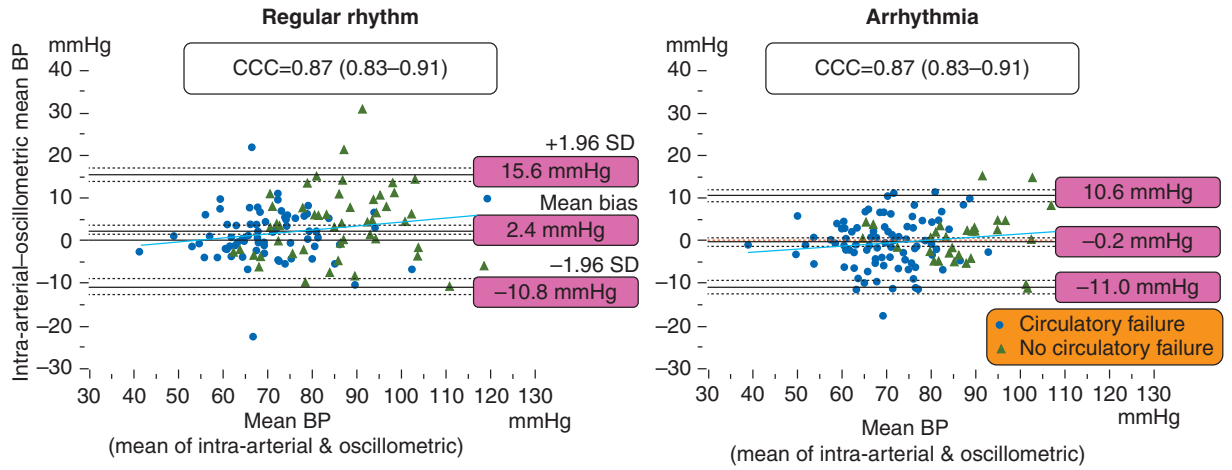

Fig 2 Agreement between intra-arterial and oscillometric measurements of mean blood pressure (Bland–Altman analysis). Bland–Altman analysis for each study group (patients with arrhythmia and with regular rhythm) of the agreement between intra-arterial and oscillometric measurements of mean BP in patients with (circles) and without (triangle) circulatory failure. In each patient, three pairs of intra-arterial and oscillometric measurements were collected. The three thick horizontal lines represent the mean bias and the upper and lower limits of agreement. The dotted lines represent their 95% confidence intervals. The oblique line represents the regression line linking the bias and mean BP. The Bland–Altman graphic presentation[19] enables the plotting of bias of a new technique compared with a reference method in order to depict if clinically relevant differences are observed. In the present case, no clinically significant differences were observed between the plots of patients in regular rhythm compared with patients with arrhythmia. This Bland–Altman analysis differs slightly from the calculation of bias (SD) proposed by the ISO standard (detailed in the 'statistical analysis' section of the article). CCC: concordance correlation coefficient.

NIBP readings of mean BP were similar to those observed in patients with regular rhythm (Fig. 2). The ISO standard was satisfied in both groups (Table 2). When excluding other causes of arrhythmia, patients with atrial fibrillation also passed the ISO standard for mean BP (*n*=119; Table 3).

Considering the mean of triplicates, NIBP was not associated with better accuracy than isolated NIBP measurements (Supplementary data 2).

Systolic and diastolic BP

For systolic and diastolic BP, mean bias, limits of agreement, and concordance correlation coefficients between the two techniques were similar in cases of arrhythmia and regular rhythm (Table 2). In our ICU population, the ISO criteria were achieved for diastolic but not for systolic BP in patients with either arrhythmia or regular rhythm.

Detection of hypotension, therapy-induced changes in BP, and hypertension

The ability of NIBP to detect a mean BP <65 mm Hg or an intra-arterial systolic BP >140 or <90 mm Hg was similar in patients with arrhythmia and patients with regular rhythm (Fig. 3). Fifty-nine (44%) patients with arrhythmia and 47 (35%) patients with regular rhythm underwent a cardiovascular intervention. For the detection of responders to therapy (>10% increase in intra-arterial mean BP), the AUC_{ROC} was similar between patients with arrhythmia (30 responders) and patients with regular rhythm (21 responders) (Fig. 2).

Impact of clinical parameters on measurements of mean BP

Site of the intra-arterial catheter

The ISO standard was satisfied in patients with a radial intra-arterial catheter as well as in patients with a femoral intra-arterial catheter (Table 4).

Categorical variables that differ between the arrhythmia and the regular rhythm groups

In patients with arrhythmia, the mean bias (calculated according to Bland–Altman) was statistically different between males and females [–0.7 (SD 6.3) *vs* 2.8 (6.1) mm Hg, *P*<0.0001] and also between patients with and without circulatory failure [0.1 (SD 6.3) *vs* 2.9 (7.5) mm Hg, *P*<0.0001]. However, the ISO standard was satisfied in each subgroup when splitting the arrhythmia group with respect to gender and to the presence of circulatory failure (Table 4).

Table 2 Relationship between intra-arterial and oscillometric measurements of blood pressure (BP) in patients with arrhythmia (n=135) and with regular rhythm (n=136). r^2: Pearson coefficient; mean bias: mean of the difference (intra-arterial – oscillometric BP) between the two techniques. Mean bias is expressed as mean (SD). Limits of agreement: mean bias (1.96SD). ISO standard[3] method for calculation of the bias and SD (mean $bias_{ISO}$), differs slightly from that of Bland–Altman (see the 'statistical analysis' section for details)

		Number of measurements	r^2	Lin concordance correlation coefficient[17]	Bland–Altman analysis		ISO standard	
					Mean bias (SD) (mm Hg)	Limits of agreement (mm Hg)	Mean $bias_{ISO}$ (SD) (mm Hg)	Validation of the ISO standard
Mean BP	Arrhythmia	405	0.81 (P<0.001)	0.87 (0.83–0.91)	−0.2 (5.5)	−11.0, 10.6	−0.1 (5.2)	Yes
	Regular rhythm	408	0.79 (P<0.001)	0.87 (0.83–0.91)	2.4 (6.8)	−10.8, 15.6	1.9 (5.9)	Yes
Systolic BP	Arrhythmia	405	0.71 (P<0.001)	0.83 (0.77–0.88)	2.0 (11.1)	−19.8, 23.8	1.5 (10.3)	No
	Regular rhythm	408	0.72 (P<0.001)	0.83 (0.77–0.87)	4.8 (13.0)	−20.7, 30.2	3.7 (11.7)	No
Diastolic BP	Arrhythmia	405	0.77 (P<0.001)	0.77 (0.71–0.82)	−5.6 (5.3)	−16.1, 4.8	−4.7 (5.9)	Yes
	Regular rhythm	408	0.76 (P<0.001)	0.80 (0.74–0.85)	−4.7 (6.0)	7.1, 16.4	−3.6 (5.7)	Yes

Table 3 Relationship between intra-arterial and oscillometric measurements of blood pressure (BP) in 119 patients with atrial fibrillation (i.e. excluding other causes of arrhythmia). r^2: Pearson coefficient; mean bias: mean of the difference (intra-arterial – oscillometric BP) between the two techniques. Mean bias is expressed as mean (SD). [a]ISO standard[3] method for calculation of the bias and SD (see the 'statistical analysis' section for more details)

	r^2	Lin concordance correlation coefficient[17]	Mean bias (SD)[a] (mm Hg)	Validation of the ISO standard
Mean BP	0.81 (P<0.001)	0.87 (0.83–0.91)	−0.2 (5.3)	Yes
Systolic BP	0.71 (P<0.001)	0.83 (0.77–0.88)	1.6 (10.4)	No
Diastolic BP	0.77 (P<0.001)	0.77 (0.71–0.82)	−4.9 (6.0)	Yes

Continuous variables

There was a significant correlation between baseline heart rate and the mean bias (i.e. the error of non-invasive measurements; r=−0.2, P<0.0001). However, in patients with arrhythmia, the ISO standard was satisfied for each quartile of heart rate. Similar results were found with other continuous variables differing between the two groups: baseline BP (r=0.4, P<0.0001), body mass index (r=−0.1, P<0.05), brachial circumference (r=−0.1, P=0.01). Age was not correlated with the mean bias.

Discussion

The main finding of this study challenges current guidelines:[5–7] arrhythmia did not significantly impact the agreement of NIBP measurements with intra-arterial measurements. Indeed, the ISO criteria were fulfilled in patients with arrhythmia for mean and diastolic BP, the main determinants of organ perfusion during critical illness or major surgery. In addition, the accuracy and precision of NIBP readings were not worse in patients with arrhythmia than in patients with regular rhythm. Last, the ability to detect hypotension, response to therapy, and hypertension were also similar in the two groups.

Our study size was larger than the requirements of two established protocols, the ISO standard and the European Hypertension Society International Protocol (33 patients), for NIBP device validation.[2]

Current knowledge about the accuracy of NIBP measurements during arrhythmia

During arrhythmia, the pulse wave is often irregular, due to beat-to-beat variability of the stroke volume. This is commonly considered to cause flawed NIBP measurements, as these are based on the detection of beat-to-beat oscillations of the arterial wall.[5] Of note, the available NIBP devices were validated exclusively among patients in sinus rhythm[2] and current recommendations underline the lack of reliability of NIBP monitoring in patients with arrhythmia.[2 5–7] This is a real issue in several common clinical settings in which BP monitoring relies on NIBP only: during initial resuscitation of the critically ill before the insertion of an intra-arterial line, during anaesthesia for short surgery where the insertion of an arterial line is of questionable benefit, and in the outpatient setting, the auscultatory method being impracticable for home self-measurement.[4] Of note, arrhythmia is frequent in these populations.[12 13]

Studies addressing the reliability of NIBP during arrhythmia are scarce and their conclusions are conflicting.[4 8] Beyond limited size and/or methodological weaknesses,[8 26] these studies lack a robust reference method: they used the auscultatory method as the gold standard. However, auscultatory measurements can also produce errors: interobserver error as well as intra-observer error related to beat-to-beat variability of pulse pressure and thus of Korotkoff sounds.[5 27]

Only one study investigated the accuracy of NIBP during arrhythmia using intra-arterial readings as a reference and found that, during arrhythmia or regular rhythm, NIBP was associated with similar agreement with intra-arterial measurements.[9] However, these findings have been questioned,[11] mainly because they lacked the use of established validation criteria (such as the ISO standard) and because of insufficient power (50 patients with atrial fibrillation and 52 patients with sinus rhythm). Furthermore, this previous study evaluated only stable ICU patients at discharge. However, in the anaesthesia and ICU settings, BP monitoring is also of importance in the acute hypotensive phase of management. Last, no data about mean BP were provided in this single-centre study.[9] Since mean BP is the most robust NIBP measurement[28] and is the organ perfusion pressure mainly

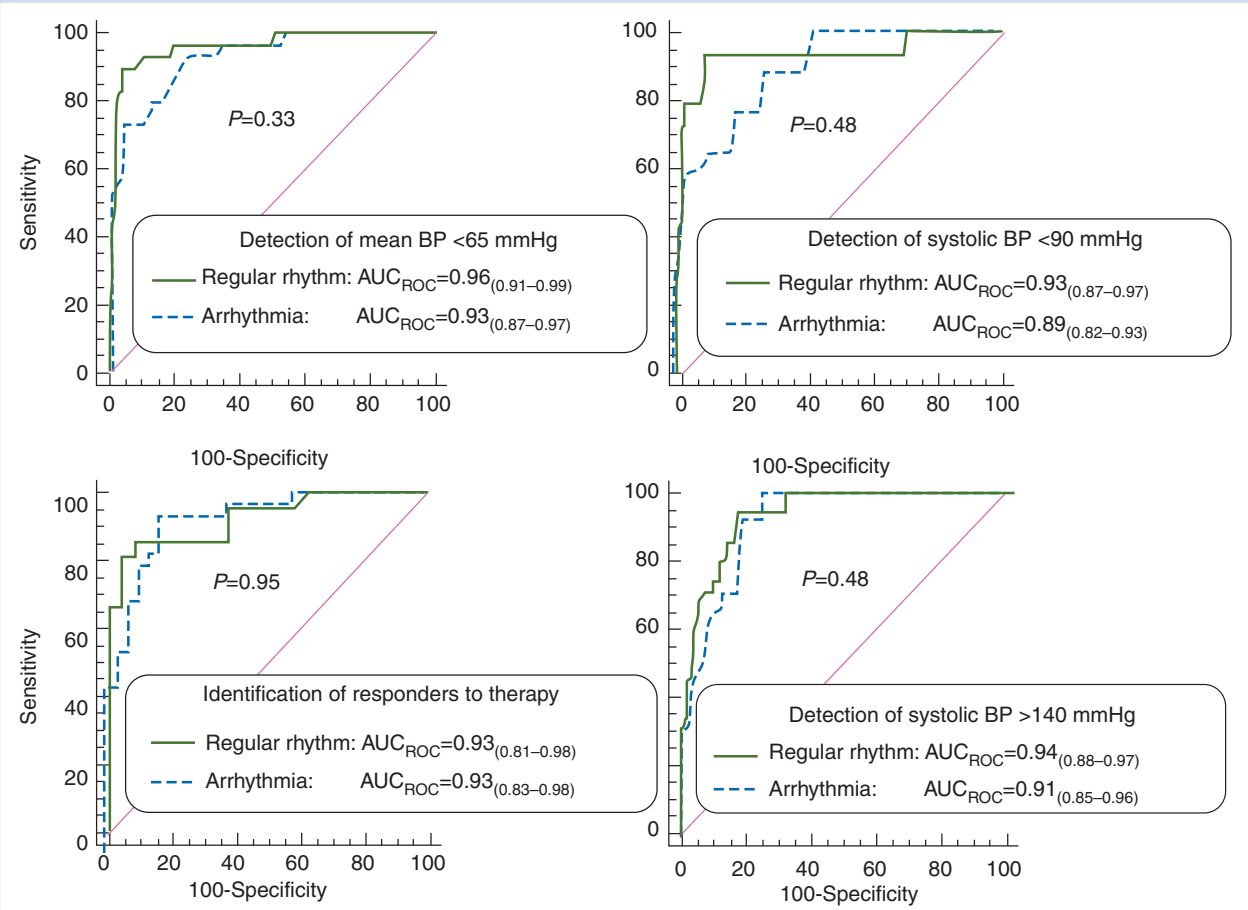

Fig 3 Oscillometric detection of hypertension, hypotension, and response to urgent therapy. Response to therapy was defined by a >10% increase in intra-arterial mean BP after a cardiovascular intervention. The analysis was based on the mean of three consecutive measurements with each technique (intra-arterial and oscillometric). Data are presented as receiver operating characteristic (ROC) curves. AUC_{ROC}: area under the ROC curve (95% confidence interval).

monitored during shock resuscitation and surgery, our study focusing on mean BP, performed in the first days of intensive care and including 172 patients with overt circulatory failure, is complementary to those previous findings of systolic and diastolic BP measured in stable patients at ICU discharge. In addition, our large multicentre study overcomes all the above-mentioned limitations and shows that mean, systolic, and diastolic NIBP are not significantly impacted by arrhythmia. Mean and diastolic BP measurements even satisfied the ISO standard in our critically ill population with arrhythmia. This underscores the overall good performance of the device used.

Clinical implications

Our study validates the common use of NIBP during arrhythmia:[1 4] the agreement of NIBP with intra-arterial readings was not worse than during regular rhythm and NIBP validated the ISO criteria for mean and diastolic BP, the relevant pressures in the critically ill. Furthermore, in arrhythmia and regular rhythm, we reported a similar ability of NIBP to answer some common questions such as 'Is my patient hypotensive?', 'Did he/she respond to urgent therapy?', and 'Is he/she hypertensive?' (Fig. 3).

Systolic BP measurements did not pass the ISO standard testing in our ICU population. This may be related to the fact that, in most patients, intra-arterial measurements were performed at the radial level whereas NIBP measured the brachial artery BP (Table 1). Hence the well-known BP discrepancies along the arterial tree[29] that mostly affect systolic BP could have contributed to the non-validation of the ISO standard for systolic BP. One may hypothesize that, with invasive readings in the brachial artery, the agreement between intra-arterial and NIBP readings of systolic BP could have been stronger. In addition, systolic BP calculation is based on device-specific algorithms developed in the outpatient setting (as opposed to mean BP, which is directly measured by oscillometric devices).[28] Therefore, for systolic BP, the non-fulfilment of the ISO criteria in our ICU population may not apply in other settings. Again, mean BP, the organ perfusion pressure, the key component of BP when caring for the critically ill,[20] passed the ISO standard.

Study limitations

First, even if the ISO standard was fulfilled for mean and diastolic BP in our arrhythmia and regular rhythm groups, the agreement between intra-arterial and NIBP readings could be seen as imperfect in a critically ill population. Of note, one cannot guarantee that intra-arterial readings reflect the actual BP, despite our efforts to obtain reliable intra-arterial BP measurements (see

Table 4 Impact of clinical parameters on the agreement between intra-arterial and non-invasive measurements. Mean $bias_{ISO}$ (SD): ISO standard method for the calculation of the bias and SD (see the 'statistical analysis' section for details). *n*: number of patients, but for each calculation of the bias (SD), three pairs of measurements were analysed, i.e. bias (SD) was calculated as *n*×3 pairs of intra-arterial and non-invasive measurements. In the arrhythmia group, the first quartile of heart rate ranged between 41 and 85 beats min^{-1}, the second and third quartiles ranged from 86 to 121 beats min^{-1}, and the fourth quartile ranged from 122 to 178 beats min^{-1}

Variable	Mean $bias_{ISO}$ (SD) (mm Hg)		
	All patients (*n*=271)	Arrhythmia group (*n*=136)	Regular rhythm group (*n*=135)
Heart rate			
First quartile	2.5 (5.8)	2.0 (4.7)	2.2 (6.9)
Second and third quartiles	0.8 (4.7)	0.0 (4.5)	1.4 (5.2)
Fourth quartile	−0.2 (6.9)	−2.3 (6.1)	3.0 (6.1)
Mean blood pressure			
First quartile	−1.5 (4.8)	−1.7 (5.0)	−1.2 (4.5)
Second and third quartiles	0.8 (4.7)	−0.2 (4.7)	1.7 (4.8)
Fourth quartile	3.4 (7.3)	1.4 (6.0)	5.2 (7.5)
Body mass index			
First quartile	1.4 (4.3)	0.2 (4.6)	1.2 (4.0)
Second and third quartiles	1.2 (6.4)	−0.4 (5.7)	2.9 (6.8)
Fourth quartile	−0.2 (5.2)	0.0 (4.7)	0.3 (4.1)
Brachial circumference			
First quartile	1.6 (5.4)	−0.1 (4.7)	3.2 (5.6)
Second and third quartiles	0.8 (4.8)	0.0 (4.9)	1.6 (4.5)
Fourth quartile	0.4 (6.9)	−0.6 (6.3)	1.2 (8.5)
Circulatory failure			
Circulatory failure	0.1 (5.2) (*n*=172)	−0.5 (5.3) (*n*=95)	0.8 (5.1) (*n*=77)
No circulatory failure	2.2 (6.2) (*n*=99)	0.7 (5.0) (*n*=41)	3.2 (6.6) (*n*=58)
Gender			
Females	3.5 (5.2) (*n*=63)	2.4 (5.3) (*n*=22)	4.1 (5.0) (*n*=41)
Males	0.1 (5.6) (*n*=208)	−0.6 (5.1) (*n*=113)	0.9 (6.0) (*n*=95)
Site of the catheter			
Radial artery	0.7 (5.5) (*n*=237)	−0.5 (5.1) (*n*=120)	1.8 (5.6) (*n*=117)
Femoral artery	2.5 (6.6) (*n*=34)	2.9 (5.2) (*n*=15)	2.5 (7.5) (*n*=19)

'Methods' section). However, for BP measurement, intra-arterial readings are the most robust method readily available in a large population of patients. Furthermore, because of a lack of consensus to define the acceptability of NIBP in the critically ill,[30] we chose to apply the ISO criteria even if they were not fully designed for this specific population.

Second, our findings may be extrapolated only cautiously to non-ICU patients. We included ICU patients only to take advantage of the presence of an arterial line. However, it appears unlikely to observe in non-ICU patients, an impact of arrhythmia on the accuracy of NIBP not observed in the particularly challenging ICU population. Therefore we believe that our findings may potentially step outside the frame of the ICU. As intra-arterial measurements may raise ethical issues outside of the population of critically ill patients, robust confirmation studies in non-ICU patients may still lack in the future.

Third, since we only tested one NIBP device, we cannot come to any conclusions about the accuracy of other commercial BP devices in case of arrhythmia.

Fourth, there were some discrepancies between the characteristics of the arrhythmia and regular rhythm groups (Table 1). These expected discrepancies[13] were either unlikely to impact the reliability of oscillometry (male sex) or were likely to favour the regular rhythm group, given that acute circulatory failure, high body mass index, and brachial circumference may have hampered oscillometry in the arrhythmia group.[31 32] Therefore we strongly believe that these discrepancies did not favour the performance of NIBP in the arrhythmia group. Furthermore, in our arrhythmia group there was no impact of these discrepant variables on fulfilment of the ISO standard (Table 4).

Fifth, heart rate may impact the accuracy of NIBP. In our population, the ISO standard was fulfilled for the mean BP in each quartile of heart rate. However, even if our patients with arrhythmia exhibited a wide range of heart rates (first and fourth quartiles, 41–85 and 122–178 beats min^{-1}, respectively), a definite conclusion during extreme heart rates cannot be drawn.

Sixth, in order to prevent cuff inflation–induced distortion of the intra-arterial waveform, intra-arterial and NIBP measurements were not performed on the same limb. This could have exposed our investigation to an anatomically induced bias. To limit this, patients whose mean BP differed by >5 mm Hg between the upper limbs were not included. Of note, this did not alter our finding that NIBP was in agreement with intra-arterial readings in patients with arrhythmia and in those with regular rhythm.

Last, most of our patients had a radial intra-arterial catheter and the cuff was placed at the brachial level. Again, this could have contributed to increase the bias between NIBP and intra-arterial readings, as BP discrepancies along the arterial tree (pulse wave amplification phenomenon) are well known, in particular in vasoconstrictive states (disease or vasopressive drug related). However, this phenomenon mostly alters systolic BP, and only to a lesser extent diastolic and mean BP.[29] Therefore neither physicians nor official guidelines consider the site of the arterial catheter when setting clinical endpoints for mean BP.[20 21]

Importantly, these physiological considerations could not be seen as a limitation of this study since they did not alter our finding, i.e. the agreement of NIBP with intra-arterial measurements was not worse in case of arrhythmia than during regular rhythm.

Conclusion

By using a robust technique as a reference for BP measurement and a modern NIBP device, our study demonstrates that arrhythmia does not cause flawed NIBP measurements in critically ill patients.

Authors' contributions

Conception and design: K.L., T.B., and S.E. Acquisition of data: K. L., T.B., S.E., M.M., S.F., F.R., and R.C. Statistical analysis: K. L. Drafting and revision of the manuscript: K.L., T.B., S.E., B.R., K.A., Y.B., and X.C.

Supplementary material

Supplementary material is available at *British Journal of Anaesthesia* online.

Declaration of interests

The authors declare that they have no competing interests. The automated brachial cuffs and monitor used is the present study were those used for routine care.

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