Journal of Anesthesia (2025) 39:292–298
https://doi.org/10.1007/s00540-025-03462-5

ORIGINAL ARTICLE

Performance of inflationary oscillometric blood pressure measurement in the presence of atrial fibrillation: comparison to sinus rhythm

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Received: 15 June 2024 / Accepted: 2 February 2025 / Published online: 18 February 2025

Abstract

Purpose The purpose of this study was to compare the success rate, measurement duration and the accuracy of inflationary non-invasive blood pressure (iNIBP, Nihon Koden Corp, Tokyo, Japan) during general anesthesia between the subjects with sinus rhythm (SR) and atrial fibrillation (AF) against invasive arterial pressure (IAP).

Methods iNIBP was determined every 5 min and IAP was continuously monitored in 30 subjects with sinus rhythm and 30 subjects with atrial fibrillation. The outcomes of this study were the success rate, the measurement duration of iNIBP and the accuracy of iNIBP in reference to IAP and 5 pair of data from each subject. The accuracy was assessed with concordance correlation coefficient and Bland–Altman method.

Results The success rate of iNIBP was 45% and 59% ($p < 0.01$) with AF and SR, respectively. Measurement duration of iNIBP was not different between AF and SR group. The Lin concordance correlation coefficient of mean blood pressure of iNIBP against IAP of SR group and AF group was 0.83 and 0.77, respectively. The mean bias (SD) of mean blood pressure of iNIBP against IAP of SR group and AF group was 5.8 (8.9) mmHg and 7.1 (11.5) mmHg, respectively. The precision was significantly wider in AF group.

Conclusion Presence of AF decreased the incidence of successful determination of blood pressure during cuff inflation. The accuracy of mean blood pressure determination was not considerably affected except for the wider limits of agreement.

Keywords Inflationary noninvasive blood pressure · Deflationary noninvasive blood pressure · Atrial fibrillation · Sinus rhythm

Introduction

Non-invasive blood pressure (NIBP) measurement with oscillometric method is one of the most basic monitoring modalities for surgical and critically ill patients. Furthermore, recent studies strongly suggest that even brief period of intraoperative hypotension is associated with postoperative morbidities [1, 2]. In that sense, accurate measurement is crucial for providing safe anesthesia care. Traditionally, NIBP is determined during deflation of the cuff and each manufacturer develops proprietary algorithm during deflation phase for obtaining stable oscillometric signal. These features inevitably increase peak cuff pressure and measurement period. To overcome these shortcomings, NIBP determination during inflation (iNIBP, Nihon Kohden Corp, Tokyo, Japan) has been developed and became clinically available [3–7]. These reports unanimously demonstrated that iNIBP algorithm enables quicker determination of NIBP without negatively affecting the accuracy. However, these studies excluded the subjects with clinically relevant arrythmia and whether iNIBP can reliably determine blood pressure in such patients remains to be clarified.

Increasing number of patients with atrial fibrillation (AF) undergo surgery due to the aging society. For example, 1, 077 subjects were in AF rhythm at the time of surgery among the subset of VISION study ($n = 36{,}918$) [8]. Blood pressure determination is frequently difficult due to the large variability of stroke volume in patients with AF. To address this challenge, each manufacturer of patient monitor has

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incorporated proprietary algorithm to modify the cuff pressure and determine reasonable systolic, mean and diastolic pressure. Hence, the accuracy may be somewhat dependent on the systems used [9–15]. On the contrary, inflation pressure of iNIBP is monotonous and is not modifiable during arrythmia including AF rhythm. From this standpoint, iNIBP may be less accurate in measuring blood pressure in patients with AF than in patients with sinus rhythm (SR) but the impact of arrhythmia has not yet been reported.

Due to this lack of information, the purpose of this observational study was to compare the performance of iNIBP between patients with SR and AF throughout the anesthesia care using invasive arterial pressure (IAP) as a reference.

Methods

This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of Toho University Ohashi Medical Center (Feb 10, 2014/ Ohashi 14–14 and Apr 25, 2022/ H22004). This study was registered at UMIN trial registry at https://www.umin.ac.jp/ctr/ (UMIN000018991) on Sept. 14, 2015. This manuscript adheres to the applicable STROBE guidelines. Each participant gave written informed consent during preoperative visit.

Patients undergoing non-cardiac surgery under general anesthesia with the indication of IAP monitoring enrolled in this study. Patients with pacemaker or cardioverter/defibrillator, patients in whom arterial catheter could not be placed on the contralateral side of the oscillometric blood pressure cuff, patients diagnosed and treated as peripheral artery diseases, were excluded from this study.

A specialized patient monitor equipped with iNIBP algorithm was provided by Nihon Kohden Corp (Tokyo, Japan) and used in this study. The basic operation of iNIBP is summarized elsewhere [3, 4, 6, 7]. Briefly, the blood pressure cuff is monotonously pressurized at a rate of 10 mmHg/second and the oscillometric signal was obtained and systolic, mean and diastolic pressure were determined. If the quality of oscillometric signal during inflation was suboptimal, the cuff pressure was gradually decreased and systolic, mean and diastolic pressure were determined with the oscillometric signal obtained during cuff deflation similar to the conventional deflationary NIBP (dNIBP). Proprietary algorithm is applied during deflation to maximize the signal quality. The device used in this study was equipped with modified algorithm compared to the commercially available machine where NIBP was determined during deflation even iNIBP successfully determined NIBP and has the capability to record and download such data as non-invasive and invasive blood pressure, cuff pressure, inflation and deflation time, oscillometric signal for further analysis.

Anesthesia management was at the discretion of the attending anesthesiologists and NIBP was measured every 5 min during anesthetic management. After anesthetic induction, radial artery was cannulated with 22-gage Teflon catheter (Introcan Safety, BBraun, Melsungen, Germany) and IAP was measured with either TruWave transducer or FloTrac sensor (Edwards Lifesciences, Irvine, CA, USA). During the preparation, air bubbles are meticulously removed from the circuit and the transducer was zero-referenced at the mid axillary line during the measurement. In this study, the IAP values were averaged in every 1 min and recorded.

The primary outcome of this study was the incidence when blood pressure was successfully determined during the inflationary phase. The secondary outcome was the duration of total measurement when inflationary measurement was unsuccessful and deflationary measurement was necessary. For this purpose, the duration was defined as the interval between the start of inflation and end of deflationary determination of NIBP. Tertiary outcome was the accuracy of inflationary and deflationary NIBP when IAP was used as reference. Five pairs of measurements from each subject were used to determine the agreement in order to even the weight of data from each subject [16]. In this selection process, we aimed to validate the accuracy of in the wide range of blood pressure. We selected highest, lowest and three equally distributed mean arterial pressure obtained by invasive measurements during the study period according to the aforementioned publication [16]. We calculated the differences between inflationary and deflationary oscillometric measurements and the corresponding IAP values of the five data pairs of each subject (total 300 data points). The correlation between the two measurements of NIBP and IAP was assessed with Pearson's correlation coefficient, Lin concordance correlation coefficient [17] and the accuracy was assessed with Bland–Altman analysis [18–20]. The bias and the precision of mean NIBP are compared between the patients with SR and the patients with AF by t test and F-test, respectively [11]. All the data were statistically analyzed by Stata/SE (ver. 16, Stata Corp, College Station, TX, USA) and R (ver. 4.0.2, R Core Team, Vienna, Austria). These data were expressed as mean (SD) unless otherwise stated. $p < 0.05$ was used as the threshold of statistical significance.

Results

Twenty-six hundred and seventy-three measurements from 30 subjects with SR and eighteen hundred and five measurements from 30 subjects with sustained AF were analyzed (Fig. 1). The demographic and surgical data are summarized in the Table 1.

In SR group, iNIBP successfully determined blood pressure in 59% of measurements while iNIBP could

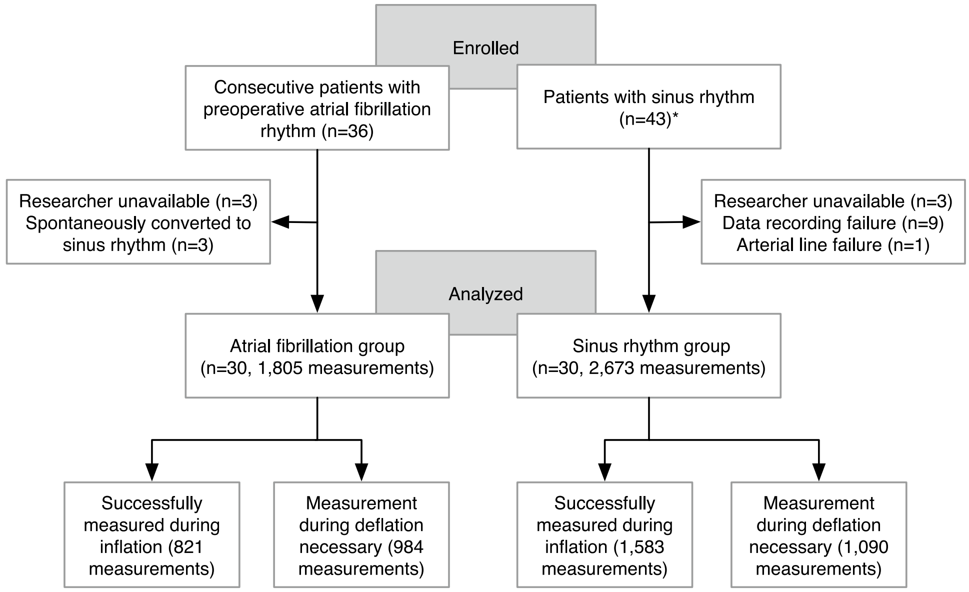

Fig. 1 Patient and data flow. *After each patient in the atrial fibrillation group enrolled, one patient with normal sinus rhythm was included

Table 1 Demographic and surgical data of the subjects

	Sinus rhythm ($n=30$)	Atrial fibrillation ($n=30$)
Age	72 (9)	77 (10)
Gender (male/female)	24/6	17/13
Height (cm)	159 (10)	158 (12)
Weight (kg)	55 (12)	57 (12)
ASA PS (1/2/3/4)	2/18/8/2	0/9/18/3
Surgical procedure (intraperitoneal /bone and joints / thoracic/retroperitoneal/neuro)	21/3/2/4/0	21/3/3/2/1
Duration of anesthesia (min)	556 (163)	410 (179)

Data are expressed as mean (SD) or numbers

successfully determine blood pressure in 45% of measurements in AF group. Consequently, the success rate for iNIBP in the AF patients was significantly lower than in the SR patients ($p<0.01$). At the individual level, median (IQR) of success rate of iNIBP was 62 (35–77) % and 47(32–58) % in SR group and AF group, respectively. In the SR group, the interval needed to determine iNIBP was 14 ± 2 s while the total measurement time was 54 ± 18 s when deflationary mode was necessary. In the AF group, the interval needed to determine iNIBP was 14 ± 4 s while the interval was 55 ± 19 s when deflationary mode was necessary. These intervals were not statistically different between SR group and AF group.

Pearson's correlation coefficient, Lin concordance correlation coefficient, the results of Bland–Altman analysis of systolic, mean and diastolic pressure of iNIBP in SR and AF group are summarized in Table 2. Bland–Altman plot summarizing the difference of mean pressure between iNIBP and IAP (iNIBP-IAP) in SR group and AF group is shown in Fig. 2. Basically, iNIBP, dNIBP and IAP are similarly correlated irrespective of the presence of AF. However, both iNIBP and dNIBP are less closely correlated against IAP in diastolic pressure than systolic and mean pressure. The bias and precision are mostly similar between SR and AF irrespective of the mode used. The bias of mean pressure between iNIBP and IAP was not different between SR and AF group ($p=0.26$ by unpaired t test). However, the variance of mean pressure between iNIBP and IAP was statistically different SR and AF group ($p=0.0027$ by F-test). The same parameters of dNIBP are summarized in Table 3 and the results are similar to the findings of iNIBP.

Discussion

The current study demonstrated that the success rate of iNIBP was significantly lower in patients with AF rhythm compared to SR. However, total duration of measurement

Table 2 Correlation and Bland–Altman analysis of the inflationary phase of oscillometric blood pressure and arterial blood pressure between the patients with sinus rhythm and atrial fibrillation

		R^2	Lin concordance correlation coefficient	Mean bias (NIBP-IAP) (SD) (mmHg)	Limits of agreement in reference to IAP (mmHg)
Systolic BP	SR	0.79	0.91 (0.88–0.94)	− 4.5 (9.6)	− 23.3, 14.3
	AF	0.82	0.89 (0.85–0.92)	− 1.3 (11.3)	− 23.4, 20.1
Mean BP	SR	0.78	0.84 (0.78–0.88)	5.8 (8.9)	− 11.7, 23.3
	AF	0.81	0.77 (0.71–0.83)	7.1 (11.5)	− 15.3, 29.6
Diastolic BP	SR	0.78	0.61 (0.53–0.67)	11.3 (7.0)	− 2.4, 25.0
	AF	0.76	0.59 (0.50–0.68)	11.7 (11.8)	− 11.3, 35.0

Data are expressed as numbers, numbers (95% confidential interval) or mean (SD)

Invasive arterial pressure is used as a reference method for Bland–Altman analysis

NIBP noninvasive blood pressure, *IAP* invasive arterial pressure, *BP* blood pressure, *SR* sinus rhythm, *AF* atrial fibrillation

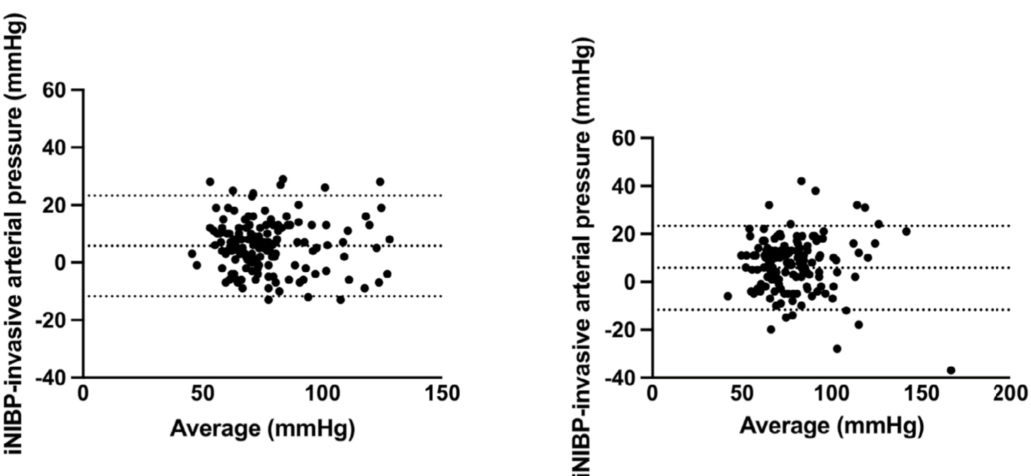

Fig. 2 Bland–Altman plot of mean blood pressure between inflationary noninvasive blood pressure and invasive arterial pressure in sinus rhythm group (left) and atrial fibrillation group (right). The three dotted lines represent the mean bias, the upper and the lower limits of agreement. Invasive arterial pressure is used as a reference method for Bland–Altman analysis. *iNIBP* inflationary noninvasive blood pressure

Table 3 Correlation and Bland–Altman analysis of the deflationary phase of oscillometric blood pressure and arterial blood pressure between the patients with sinus rhythm and atrial fibrillation

		R^2	Lin concordance correlation coefficient	Mean bias (NIBP-IAP) (SD) (mmHg)	Limits of agreement in reference to IAP (mmHg)
Systolic BP	SR	0.83	0.91 (0.88–0.94)	− 4.4 (9.8)	− 23.5, 14.8
	AF	0.81	0.88 (0.85–0.92)	− 3.6 (10.9)	− 25.0, 17.8
Mean BP	SR	0.76	0.85 (0.81–0.89)	1.1 (9.4)	− 17.2, 19.4
	AF	0.69	0.79 (0.73–0.84)	− 0.3 (11.7)	− 23.3, 22.7
Diastolic BP	SR	0.77	0.70 (0.63–0.77)	8.0 (6.8)	− 5.3, 21.3
	AF	0.68	0.68 (0.60–0.76)	7.0 (10.9)	− 14.4, 28.4

Data are expressed as numbers, numbers (95% confidential interval) or mean (SD). Invasive arterial pressure is used as a reference method for Bland–Altman analysis

NIBP noninvasive blood pressure. *IAP* invasive arterial pressure. *BP* blood pressure, *SR* sinus rhythm, *AF* atrial fibrillation was similar in patients with AF and in patients with SR. The accuracy of iNIBP was mostly similar in patients with SR and AF rhythm.

It is predicted that success rate was significantly low in patients with AF compared to SR and the current study confirmed such prediction. This notion is based on the fact that there is no adjustment during inflationary phase while proprietary algorithm was used to adjust the irregularity of oscillometric signal during deflationary phase. Several studies reported higher success rate of iNIBP in patients without arrhythmia. Sasaki et al. and Kikuchi et al. reported 69% and 91% success rate, respectively [4, 7]. The underlying cause of the lower success rate found in this study remains unknown. However, iNIBP helps to determine appropriate peak cuff pressure and reduce the risk of repeated measurements due to inappropriately low peak pressure before deflation. From this standpoint, iNIBP may be advantageous even if the success rate was low.

It is also clear that duration of measurement of inflationary NIBP was basically the same between the patients with SR and with AF since the control of cuff pressure is identical irrespective of the presence/absence of arrhythmia. In this regard, the duration of measurement when inflationary NIBP was unsuccessful is rather critical from the clinical standpoint. We found non-significant 1 s difference between the SR group and AF group. We believe that such quick determination of NIBP in the presence of arrythmia may be clinically relevant for the hemodynamic management of patients with AF. Furthermore, immediate activation of dNIBP after failed iNIBP is reasonable strategy to compensate the reduced success rate of iNIBP in the presence of AF.

ISO standard or European Society of Hypertension protocol are the typical methods to validate the accuracy of NIBP [21, 22]. However, these protocols may not be appropriate for the acute care situations such as perioperative period and intensive care setting. Alternatively, Bland–Altman plot against invasive blood pressure is typically used [3, 16].

The accuracy of NIBP against invasive blood pressure may deteriorate in the presence of arrhythmia including AF. It may be dependent on the system used since each manufacturer incorporate proprietary algorithm to correctly determine NIBP. Lakhal and the colleagues separately compared the accuracy of Philips MP 70 and Draeger Infinity with and without arrhythmia in the ICU patients [10, 11]. They found good correlation between mean NIBP measured with Philips MP 70 and invasive blood pressure and modest bias and precision irrespective of the presence of arrhythmia. Additionally, they found mean and diastolic pressure of NIBP with and without arrhythmia fulfilled the ISO criteria while systolic NIBP did not [10]. The same authors demonstrated similar bias and precision between Draeger Infinity NIBP and invasive blood pressure irrespective of the presence of arrhythmia. Contrary to the Philips MP 70, accuracy of systolic, mean and diastolic pressure measured with Draeger Infinity failed to fulfill ISO criteria [11]. Nevertheless, these studies assessed the accuracy by measuring NIBP three times with 1 min interval. Thus, the results of these studies do not provide information about the accuracy of NIBP during the entire course of general anesthesia. To our knowledge, the current study is the first to longitudinally compare the accuracy of NIBP against invasive blood pressure between the subjects with SR and AF.

This study demonstrated that comparable correlation coefficient, concordance correlation coefficient between the subjects with SR and the subjects with AF both in inflationary and deflationary mode. This result agrees with the results of previous study in which correlation coefficients between conventional NIBP and IAP are comparable between the subjects with regular rhythm and arrhythmia. Although the variance of difference, which is basically the same as precision, of mean blood pressure are significantly wider in AF group than SR group, the bias between iNIBP and invasive arterial blood pressure is not different between SR group and AF group. These data suggest that the accuracy of iNIBP compared to IAP does not considerably deteriorate even when AF is present.

Some differences can be pointed out between the previous study using the monitor manufactured by Philips and the current system. In the previous study, the largest measurement error occurred at the determination of systolic blood pressure and systolic NIBP failed to fulfill the ISO standard [10]. On the contrary, largest inaccuracies are found in the diastolic pressure both in SR and AF patients in this study. We believe that the algorithm to determine systolic, mean and diastolic pressure is different between each manufacturer and such differences may affect the differences found between these studies.

This study has several limitations. First, the current study does not clearly demonstrate whether the iNIBP satisfies the ISO standard. ISO standard requires three consecutive NIBP measurement and such procedure is only clinically relevant under non-operative setting. On the contrary, NIBP is usually measured at certain interval and typical patient monitor does not have averaging function when it has encountered atypical signal such as AF. In this regard, the results based on ISO recommended procedure may not properly reflect the clinical situation. Several studies also found the bias and precision exceed the limits of ISO standard when data during entire anesthetic management was used [23, 24]. Second, since the difficulties of NIBP measurement in AF patients is supposedly based on the irregularity of blood pressure during NIBP measurement. Unfortunately, we are unable to record every systolic and diastolic value of arterial waveform during NIBP measurement and we alternatively used the averaged value during 1 min nearest to the NIBP measurement. This issue warrants further investigation. Third, blood pressure waveforms are dependent on the stroke volume and characteristics of arterial blood vessel and brachial arterial pressure measured by NIBP and radial arterial pressure measured by IAP may be inherently different. However, existing literature did not address this issue irrespective of the presence of arrhythmia. This issue also warrants further attention.

In conclusion, the number of successful measurements with iNIBP decreased in patients with AF rhythm. When successfully measured, iNIBP provides comparable accuracy in patients with SR and AF rhythm.

Acknowledgements We would like to thank Mr. Takashi Usuda and Mr. Yoshiharu Kikuchi of Nihon Kohden Corp. for providing technical assistance to collect iNIBP data from the monitor. We also would like to thank Editage (www.editage.com) for English language editing.

Funding This work was supported by departmental funding. Author Y. Kotake received research support from Nihon Koden Corporation (Tokyo, Japan).

Data availability Data are available upon reasonable request.

Declarations

Conflict of interest Y. Kotake received a speaker's fee from Edwards Lifesciences, Ohtsuka Pharmaceutical Laboratory, MSD, Nihon Koden Corp, GE Healthcare Japan, NXERA Pharma Japan, Covidien Japan. Y Kotake received an unrestricted research fund from Nihon Koden Corp. The other authors have no relevant financial or non-financial interests to disclose.

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