Usefulness of a radial applanation tonometry device in blood pressure related clinical decision making by anesthesiologists

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Abstract

Purpose: Radial artery tonometry (AT) can continuously measure arterial blood pressure (ABP) noninvasively. This study aimed to evaluate AT for continuous ABP monitoring during anesthesia and compared AT to invasive (IBP) and non-invasive (NIBP) ABP measurements at clinical decision-making moments.

Methods: 243 patients undergoing elective surgery were prospectively included in the study and AT was applied on the right or left arm while IBP and NIBP were recorded simultaneously. At moments when the IBP signal required a clinical decision by the anesthesiologist for situations of hyper- or hypotension, comparison was made whether AT and NIBP signals would require a clinical decision as well. Agreement/discrepancy of clinical decision-making was analyzed, additionally bias, precision, and percentage error of AT was compared to IBP at these moments.

Results: 513 clinical decision moments were recorded. Decision moments based on AT signal did not differ significantly from decision moments based on IBP (1 vs. 1; IQR, 1 – 2 vs. 0 – 3, $P = 0.06$), while NIBP based decision moments showed significant differences (0 vs. 1; IQR, 0 – 2 vs. 0 – 3, $P = 0.001$). Subgroup analysis of patients divided by age, BMI and surgery time also showed no significant differences between IBP and AT.

Conclusions: ABP measurement using AT is feasible and safe. AT provides relevant and efficient information to anesthesiologists; at moments when IBP called for action, AT called for action as well, but not NIBP. AT also showed clinically satisfactory agreement with IBP at moments of hypo- and hypertension.

Introduction

Arterial blood pressure (ABP) monitoring is of critical importance during the perioperative course of surgical patients. The most widely used method is intermittent non-invasive oscillometric monitoring by automated blood pressure cuffs (NIBP) inflating every 3 or 5 minutes. This method, however, has serious drawbacks because hypotensive or hypertensive episodes can remain undetected or detection be delayed, which can potentially increase morbidity and mortality in high risk surgical patients. Invasive arterial blood pressure (IBP) measurement by radial catheters acquires blood pressure timely and most accurate, but risks and clinical complications like thrombosis, bleeding and hematoma formation [1–4] must not be neglected.

Various noninvasive continuous blood measurements devices have been developed recently which can narrow the gap between IBP and NIBP, offering continuous but still non-invasive ABP monitoring. Besides photoplethysmography technologies [5–8], devices using applanation tonometry at the radial artery (AT) have demonstrated clinical usefulness in general-anaesthetized patients undergoing surgery and at the ICU [9, 10]. The latest development and commercially available AT system is the TL-400 system by Tensys Medical Inc. (San Diego, CA, USA). The TL-400 is a more modern and more user friendly system

than its predecessors TL–200 and TL–200pro which have been investigated with predominantly good results already [10–12]. While the latter were marketed in the United States and China, the TL–400 currently is marketed in China only. AT measures systolic (SBP), diastolic (DBP), and mean (MAP) arterial blood pressure after processing pressure signals obtained by a sensor compressing the radial artery against the head of the radius bone [13, 14].

There have been several studies published comparing the values obtained by AT and IBP measurements, demonstrating a sufficient accuracy of AT [10, 12, 14]. However, no studies exist so far investigating whether AT has an impact on clinical decision-making and if it provides reliable information to help anesthesiologists for proper intraoperative blood pressure management. Any non-invasive method, intermittent or continuous, should only then be used as a replacement for gold standard IBP monitoring, if data delivered by such devices are comparable in information delivery and lead to the same clinical decisions.

It therefore was the primary objective of this study to investigate whether in clinical situations requiring special attention or action by the treating physician, the AT device is comparable to IBP measurement. As secondary objective we investigated accuracy and precision of the AT device in these specific situations.

Methods

Study design and setting

This study was performed in patients who underwent major surgeries and needed arterial cannulation in West China hospital, Sichuan University. It was approved by the local Ethical Committee of the West China Hospital (No. 2016–192) and all patients (or their legal representatives) gave written informed consent.

Inclusion and exclusion criteria

Patients with age higher than 18 years, ASA II-III, body weight 40–180 kg, height 137–198 cm, and the need of a radial arterial catheter insertion between XXXXX and XXXXX (please enter date) were enrolled in this study. Decision on the need for IBP monitoring was made by the treating anesthesiologist based on his/her preoperative evaluation of planned surgery and the patients' clinical condition. Patients with anatomical abnormalities or injuries at the AT sensor application site or a brachial cuff pressure difference > 10 mm Hg between right and left arm were not eligible for study enrollment.

AT, IBP and NIBP measurements

Patients eligible for inclusion were randomly assigned to a right-arm AT group or a left-arm AT group by random number table. AT by TL-devices (Tensys Medical Inc., San Diego CA, USA) has already been described elsewhere [11], in short, it is an AT device which measures radial arterial pressure by an

automated sensor placed on the patient wrist. The sensor automatically locates its optimum position over the radial artery and is self-calibrating.

Once the sensor has found its position (which usually takes 1–2 minutes after application of the bracelet in which the sensor is mechanically located) and patient gender, age, height, and weight are entered into the system, the TL–400 device used in this study continuously and real-time measures and displays SBP, DBP, MAP, and the blood pressure curve.

IBP measurement was applied at the contralateral arm using the hospitals standard cannulation (SCW MEDICATH LTD, Shenzhen, China) and monitoring equipment (Philips Intellivue MX 600, Philips Company, Holland). Before any data collection IBP and AT devices were zeroed according to hospitals standard procedure and the manufacturer's instructions respectively.

Automated NIBP measurement was also performed using the hospitals standard cuffs (adjusted for patient size) and equipment (Shenzhen Mindray Bio-Medical Electronics Co Ltd, Shenzhen, China and Philips multifunctional vital signs monitor, Philips Intellivue MX 600, Philips Company, Holland) and set to 5 min intervals. The required cuff was placed at the same arm as the AT device.

Measurement procedure and data collection

To compare equivalence of information delivery, clinical conditions requiring action by the attending anesthetist (decision moment) have been defined in the study protocol as follows: hypotension was defined as SBP/DBP < 90/60mmHg or MAP < 70mmHg, while hypertension was defined as SBP/DBP > 140/90mmHg or MAP > 115mmHg. These criteria were set identical for IBP, AT and NIBP.

Management of the patient was performed solely on the data delivered by IBP and the anesthetist was blinded to the values of AT and NIBP. Because the study protocol did not require a specific predetermined action (give drugs, deepen sedation/anesthesia, etc.) in our predefined decision moments, the activity finally chosen by the anesthetist was recorded but is not shown here.

If the IBP signal called for action based on the predefined hypo- or hypertension thresholds, and AT or NIBP did call for action as well, it was noted as a decision moment for each device. If IBP signal called for action, but none of the other devices did, it was noted as a decision moment for IBP only. Ideally, at exactly the same moments when the IBP signal called for action, AT or NIBP should call as well.

When a decision moment occurred based on the signal of IBP, not only decision-moments itself were noted, but also the corresponding SBP, DBP, and MAP values of each device.

Statistical analysis

We used SPSS Statistics 21 (SPSS, Inc., Chicago, IL, USA) and Medcalc Software for statistical analyses. Patients' characteristics are described by median and inter-quartile range (25–75% percentile). Moments

of BP-related decisions are also described by median and inter-quartile range (25–75% percentile), and the differences of clinical decisions making moments among three groups were tested by Tamhane's T2 test. In addition, we used the Chi-squared test to analyze whether age, length of surgery, or BMI would affect the accuracy of AT compared to IBP.

For the comparison of ABP values obtained at the decision moments by AT and IBP, the bias for paired BP values was evaluated using Bland-Altman plots for repeated measurements and based on this analysis, the mean bias with standard deviation and corresponding 95% limits of agreement and confidence intervals are presented. Additionally, 4 quadrant plots were performed for ABP pairs to show concordance of signal delta.

Results

Patient characteristics

A total of 342 patients were recruited into this study and 250 were randomized, while 62 patients were excluded due to reasons shown in Figure 1. Of the 250 patients, 121 [49.8%] were randomized into left arm AT application (Left-AT group) and 122 [50.2%] into right arm AT application (Right-AT group). Drop out reasons after randomization are also displayed in Figure 1. Demographic data and clinical characteristics of the 243 patients finally enrolled in the study are shown in Table 1.

Comparison of decision moments

The average surgery time while clinical decision moments for the treating physicians would occur was 204 minutes (Table 1). During that time a total of 513 decision moments were documented based on IBP signal and the aforementioned criteria for hypo- or hypertension, while 394 and 233 were documented for the AT and NIBP signal, respectively. Statistical comparison of frequency of decision moments is shown in Table 2, decision moment frequency based on IBP signals did not differ significantly from AT (1 vs. 1, $P = 0.06$), while decision moment frequency did differ significantly for NIBP signal (0 vs. 1, $P < 0.001$). In addition, decision moment frequency of NIBP did differ significantly from AT (0 vs. 1, $P < 0.05$).

Influence of age, BMI, length of surgery on precision of AT

As depicted in Table 3, patient age ≥ 65 years (total moments, 77 vs. 62) compared to 18–65 years (total moments, 436 vs. 332), in total did not affect the decision moments frequency between IBP and AT

The BMI of patients did also not significantly affect the decision moments frequency between IBP and AT, nor did age, length of surgery, longer or shorter than 3 hours (Table 3).

Comparison of AT, IBP, and NIBP during hypo- and hypertension

Overall results of the Bland-Altman analyses are summarized in Table 4. An overall bias of -2.7 mmHg, -2.8 mmHg, and -3.4 mmHg, was detected between IBP and AT values of SBP, DBP and MAP, respectively, with 95% limits of agreement and a percentage error of -21.6 mmHg to $+16.2$ mmHg and 7% for SBP, -25.4 mmHg to $+15.8$ mmHg and 15% for DBP, -23.1 mmHg to $+16.3$ mmHg and 10% for MAP. Overall bias of -3.9 mmHg, -8.4 mmHg, and -4.3 mmHg was shown between IBP and NIBP values of SBP, DBP and MAP, respectively with 95% limits of agreement and a percentage error of -38.9 mmHg to $+31.2$ mmHg and 14% for SBP, -30.9 mmHg to $+14.1$ mmHg and 22% for DBP, -30.4 mmHg to $+21.7$ mmHg and 16% for MAP (not shown in table). As ABP values were recorded only at decision moments at hypo- or hypertension, we plotted Bland-Altman analyses separately for SBP, DBP and MAP for hypo- or hypertension in Figure 2 respectively. Table 4 shows the Limits of Agreement and Percentage Error of the respective subgroups.

Comparison by 4-quadrant plots of alike ABP changes during decision making moments of IBP and AT values show favorable results with concordance of 0.910, 0.752, and 0.871 for SBP, DBP and MAP, respectively (Figure 3).

Discussion

In this study, ABP was monitored in patients undergoing elective surgery using 3 different methods. ABP monitoring with IBP is considered the Gold Standard with regards to accuracy and reliability although this method is associated with potential complications related to intravascular catheter placement such as bleeding, limb ischemia, and catheter-related bloodstream infections [15, 16].

NIBP may be considered as a standard method in today's operating rooms regarding practicability, quick and easy employment and appropriateness for the needs of a majority of physicians and patients not requiring blood gas analyses. Most anesthetists believe to be able to cope with the drawbacks of NIBP like wrong cuff size and the ABP blind window of 5min or longer, although there exists evidence that both can have a negative impact on accuracy or outcome [17–20]. The third method, radial applanation tonometry using AT, is an alternative that combines the best of both worlds, being continuous but being still non-invasive. Nevertheless, this offer needs to be validated before it either can be a replacement of

the other two methods or can be filling the gap in between. One part of such validation is comparing accuracy and precision of absolute values of ABP signals by AT with the Gold Standard IBP, which has been done already in the past and was part of this study as well. However, of much higher importance than absolute accuracy and precision is the question if clinical decisions would be identical to that based on Gold Standard IBP if only AT or NIBP would be available.

In terms of accuracy and precision, before qualifying a new method, expected target criteria need to be defined. According to US FDA, interchangeability is given when a non-invasive method meets the AAMI SP10 criteria for non-invasive ABP monitoring 21]. With regards to bias between IBP and AT this is the case for our results in the mean, although—and this is very important—we only compared ABP values in hyper- or hypotensive situations.

Looking at hyper- or hypotensive data alone, AAMI SP10 bias criteria are not fully met (Table 4). Regarding limits of agreement, AT data of our study do not completely meet AAMI SP10 criteria (Table 4), because bias is required to be lower than 5mmHg and $SD \leq 8\text{mmHg}$, which translated into $\leq 16\text{mmHg}$ for $2 \times SD$ in Bland-Altman plots. Here again, the fact must be considered that we only compared ABP data during situations of hyper- or hypotension.

It is however remarkable that NIBP failed to meet the AAMI SP10 criteria even more pronounced in the overall comparison (Table 5) to the IBP, showing that NIBP is clearly not only inferior to IBP but also to AT.

Comparing our results to previous literature, where accuracy and precision of AT was evaluated in the OR or at the ICU 10–12, 14, 22, 23], we also found a comparable bias but higher limits of agreement in our study, which underlines the already mentioned reasoning that only looking at hyper- and hypotonic situations where ABP fluctuates more remarkably can have drastic influence on overall accuracy and precision. In addition, in our study we enrolled patients during urologic, thoracic surgery, and complex general surgery where occasional signal loss due to repositioning or external pressure from surgeons on the AT bracelet may occur more often than in quiet ICU situations. Generally, the AT device can compensate such situations by either manual or automated recalibration, nevertheless during such moments there is a potential for artifacts or—in case of recalibration—a phase of no valid data for 1–2 minutes.

One may say that, especially in the more extreme ABP situations accuracy and precision is of higher importance as during normal conditions, on the other hand, one could argue that whether ABP is too high or too low by e.g. 15mmHg or 30mmHg, is of less importance, because too high is too high or too low is too low and requests for action anyway.

This is why not only absolute accuracy and precision is important but also trending capabilities. Looking into trending capabilities, the results of our 4-quadrant plots (Figure 3) show that with concordance rates of 0.75 to 0.91 AT shows good results and can be considered as a replacement to IBP from this perspective. Here our results compare very good to that of previous literature.

The most important question and most innovative part of this study, however, is the question if clinical decision making is impacted by AT. All studies so far have only compared measured ABP values, but not investigated if AT could really replace IBP with regards to clinical decision making. A Gold Standard method to evaluate this, would be an outcome study where in one group only IBP and in the other group only AT would be available for the anesthetists. For ethical and safety reasons we preferred to go a different route by defining ABP criteria based on IBP data which would evoke action by the treating physician and then evaluating if those criteria are met at the same statistically significant frequency by AT and NIBP.

We found that the frequency of ABP decision moments based on AT has no statistical difference compared to IBP, NIBP however clearly showed significantly lower frequency (Table 2). As NIBP does not allow beat-to-beat monitoring, it may be blind to rapid ABP changes or short episodes of hemodynamic instability. Thus, NIBP is not applicable in patients undergoing surgeries with risk of massive hemorrhage or fast changes of blood pressure. Our study found, that although AT could not achieve complete coincidence with IBP, the small discrepancy does not negatively affect the anesthesiologists to make efficient and right clinical decisions.

To our best knowledge, this study is the first one to record the moments of ABP related clinical decisions and the ABP values at these decision moments. As such, for the first time we could show that IBP and AT are clinically equivalent for decision making but not IBP and NIBP, the latter missing several moments of hypotension or hypertension (1, IQR 0–2). Given also the inherent risks on patient outcome associated with blind moments of the NIBP technology [17, 19, 20] AT is clearly superior to NIBP.

In addition, we found that neither age, BMI, nor length of surgery affects the comparison of decision moments, making AT the device of choice for surgeries with no absolute necessity of IBP. A timelier monitoring of ABP compared to use of NIBP may have positive impact on patients' prognosis and outcome.

Our study has some limitations. Firstly, as we collected ABP data only during hyper- or hypotensive periods, we were not able to compare ABP data of the investigated methods over the full spectrum of ABP. This however was not the primary scope of this study anyway, as it was not the primary intention to compare NIBP to AT, which would have required that NIBP is triggered exactly when a decision moment had occurred. Under this aspect, our accuracy comparisons of a potentially almost 5 minute old NIBP signal to a actual IBP or AT signal must be interpreted with caution. On the other hand, our approach reflects a realistic real world scenario. Secondly, our patient setting of applying AT on the same arm as NIBP may have reduced the frequency of simultaneous AT vs. IBP measurements and thus could have led to some "AT missing data" in the statistical review. NIBP inflates in regular intervals, causing a short "black out" of any downstream-applied blood pressure measurement device. However, as the AT device has an automated compensation mechanism for such short moments of NIBP inflation, we consider the number of potentially missed AT decision moments as low, but we cannot completely rule out that we may have missed some data points. Applying the NIBP at the same arm as the IBP however would not

have been a solution, as then we would have lost the Gold Standard signal repeatedly and also have “missing data”.

Especially the last limitation calls for another study with larger sample size, in which not only frequency of decision moments is investigated, but—same as in this study- at predefined clinical situations based on Gold Standard IBP—physicians are confronted with only AT or NIBP data only and their consequent action based on such data alone is recorded. Once such study has been performed with positive results, as a final consequence a comparative outcome study is warranted.

However, although radial arterial tonometry is an intriguing approach, its susceptibility to the external interference preclude the use of the device as a single source of BP information in unstable patients or surgeries with high risk. In such situations either IBP is needed or the blind spots of NIBP should be “closed” by shorter NIBP intervals or by continuous AT monitoring. Especially the latter seems to be the method of choice if highest security for the patient is aimed for. In types of surgery where frequent blood-gas analyses are needed, IBP should still be the method of choice.

In conclusion, we found that ABP measurement based on AT technology is feasible in anesthetized patients and in contrast to NIBP does not show statistically significant difference regarding timely information delivery for clinical decision making compared to IBP.

Declarations

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Conflict of Interest:

The authors declare that they have no conflict of interest.

Authors' contributions

XZ analyzed and interpreted the patient data, drafted the manuscript. HL drafted the manuscript and assisted with data analysis. XL collected the experimental data. BL and JL conceived the study. GC designed the study and conceived the study. All authors read and approved the final manuscript.

Ethics approval and consent to participate

This study was approved by the Ethical Committee of the West China Hospital from Sichuan University. Personal written informed consent were obtained before entering the study.

Consent for publication

Not applicable

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Tables

Table 1: Demographic and clinical characteristics of study patients	
Age (yr)	51.6 ± 12.9 (18-83)
Sex, male (n (%))	154 (63%)
Height (cm)	163.4 ± 7.7
Weight (kg)	62.0 ± 9.8
Body mass index (kg m ⁻²)	22.6 ± 2.9
Length of surgery (min)	203.9 ± 89.9
Surgery Department	
General Surgery (n (%))	211 (86.8%)
Neurosurgery (n (%))	22 (9.1%)
Urology Surgery (n (%))	9 (3.7%)
Thoracic Surgery (n (%))	1 (0.4%)

Table 2: Moments of BP-related clinical decisions

	Total moments	Median	IQR	Concordance rate ^a
IBP	513	1*	0-3	100%
NIBP	233	0 [#]	0-2	45.4%
AT	394	1△	1-2	76.8%

IQR: interquartile range

* IBP compared with NIBP, P < 0.05;

[#] NIBP compared with AT, P<0.05;

△ AT compared with IBP, P>0.05

a: All concordance rates compared to IBP

Table 3: Relationship between Times of BP-related clinical decisions and age, BMI, length of surgery

		IBP	AT	Concordance rate	P Value
Age	Total moments	77	62		
	≥65years	1	1	80.5%	
	(n=40)	IQR	0-3	0-2	
	≤18 years	Total moments	436	332	0.402
	≥65 years	Median	2	1	
	(n=203)	IQR	0-3	0-3	
BMI	Total moments	180	142		
	≥24	Median	1	1	78.9%
	(n=91)	IQR	0-3	0-3	
	≤24	Total moments	333	252	0.422
		Median	1	1	
	(n=152)	IQR	0-3	0-2	
Length of surgery	Total moments	138	111		
	≥3 hours	Median	2	1	80.4%
	(n=138)	IQR	0-5	0-4	
	≤3 hours	Total moments	373	281	0.226
		Median	1	0	
	(n=105)	IQR	0-2	0-1.5	

BMI: body mass index

IQR: interquartile range

n: number of patients in each subgroup

Table 4: BP measurements by AT and IBP at decision moments.

Total	BP, n=513	IBP	AT	Bias [mean (SD) of the difference]	Percentage error	95% limits of agreement
Systolic blood pressure (mm Hg)		97.0(29.6)	99.7(28.4)	-2.7(9.6)	7%	-21.6 to +16.2
Diastolic blood pressure (mm Hg)		55.7(15.6)	58.6(19.8)	-2.8(9.5)	15%	-25.4 to +15.8
Mean arterial pressure (mm Hg)		70.9(20.7)	74.3(23.8)	-3.4(10.1)	10%	-23.1 to +16.3

Hypertension

BP, n=101

Systolic blood pressure (mm Hg)		155.0(10.5)	153.3(12.5)	1.7(11.5)	4.6%	-20.8 to +24.3
Diastolic blood pressure (mm Hg)		82.8(8.7)	92.2(13.8)	-9.4(12.9)	15%	-34.6 to +15.8
Mean arterial pressure (mm Hg)		110.4±8.7	117.5(14.4)	-7.1(13.0)	9%	-32.6 to +18.4

Hypotension BP, n=412

Systolic blood pressure (mm Hg)		97.0(29.6)	99.7(28.4)	-3.8(8.8)	8.1%	-21.0 to +13.5
Diastolic blood pressure (mm Hg)		55.8(15.6)	58.6(19.8)	-1.2(10.6)	14.9%	-21.8 to +19.5
Mean arterial pressure (mm Hg)		70.9(20.7)	74.3(23.8)	-2.5(9.0)	10.8%	-20.0 to +15.1

Data are expressed as mean ± SD

n: number of decision moments of each subgroup

Table 5: BP measurements by NIBP and IBP at decision moments.

Total	BP, n=513	IBP	NIBP	Bias [mean (SD) of the difference]	Percentage error	95% limits of agreement
Systolic blood pressure (mm Hg)		97.0 (29.6)	100.9 (22.8)	-3.8 (17.9)	14%	-38.9 to +31.2

Figures

Figure 1

Flow Chart of Randomization

Hypertension (n=101)

A

Hypotension (n=412)

D

B

E

C

F

Figure 2

AT vs. IBP Bland-Altman plots during hyper- and hypotension moments

Figure 3

Four-quadrant plots AT vs IBP Plots with an exclusion zone of 5 mm Hg are shown for SBP (concordance 0.910) (A), DBP (concordance 0.752) (B), and MAP (concordance 0.871) (C).