

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

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Research article

Keywords: continuous blood pressure monitoring, radial artery tonometry, perioperative measurement, non-invasive arterial blood pressure

Posted Date: January 30th, 2020

DOI: <https://doi.org/10.21203/rs.2.17738/v2>

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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 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 accurately, 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 in 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 is currently only marketed in China. 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, so far, no studies have investigated 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.

Therefore, the primary objective of this study was to investigate whether in clinical situations requiring special attention or action by the treating physician, the AT device is comparable to IBP measurement. As a 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 informed written consent.

Inclusion and exclusion criteria

Inclusion criteria were: age at least 18 years old, ASA II-III, body weight 40-180 kg, height 137-198 cm (weight and height were set according to the instructions for use of the AT device), absence of exclusion criteria, and the need of a radial arterial catheter insertion during the study period between June 2017 and April 2018. Exclusion criteria were anatomical abnormalities or injuries at the AT sensor application site or a brachial cuff pressure difference > 10 mm Hg between the right and left arm. Decision on the need for IBP monitoring was made by the treating anesthesiologist based on his/her preoperative evaluation of the planned surgery and the patient's clinical condition.

AT, IBP and NIBP measurements

Patients eligible for inclusion were randomly assigned to a right-arm AT group or a left-arm AT group. 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's 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 where 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 measured and displayed SBP, DBP, MAP, as well as the blood pressure curve in real time.

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

Automated NIBP measurement was also performed using the hospital's 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 minute intervals according to ASA standard monitoring guidelines. The required cuff was placed on 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 < 90/60 mm Hg or MAP < 70 mm Hg, while hypertension was defined as SBP/DBP > 140/90 mm Hg or MAP > 115mmHg. These criteria were set identical for IBP, AT and NIBP and were chosen according to the standard definition of hyper- and hypotension in medical textbooks.

Management of the patient was based 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 action chosen by the anesthetist was recorded but is not shown here. Further, as not every patient required a clinically-appropriate measure when said blood pressure thresholds were reached, "do nothing" was also an option for the treating anesthetist.

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 or NIBP should call simultaneously when the IBP signal called for action.

When a decision moment occurred based on the signal of IBP, decision-moments were noted as well as the corresponding SBP, DBP, and MAP values of each device.

Data were recorded manually, as the AT device had no interface with automated record-keeping software.

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 in clinical decision-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 during which 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 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 mm Hg, -2.8 mm Hg, and -3.4 mm Hg, 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 mm Hg to +16.2 mm Hg and 7% for SBP, -25.4 mm Hg to +15.8 mm Hg and 15% for DBP, -23.1 mm Hg to +16.3 mm Hg and 10% for MAP. Overall bias of -3.9 mm Hg, -8.4 mm Hg, and -4.3 mm Hg 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 mm Hg to +31.2 mm Hg and 14% for SBP, -30.9 mm Hg to +14.1 mm Hg and 22% for DBP, -30.4 mm Hg to +21.7 mm Hg 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 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 however, 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 is considered a standard method in today's operating rooms regarding its 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 5 min 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 yet non-invasive. Nevertheless, this option needs to be validated before it can replace the other two methods or can fill 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 greater importance than absolute accuracy and precision is the question if clinical decisions would be identical to those based on Gold Standard IBP if only AT or NIBP were available.

In terms of accuracy and precision, before qualifying a new method, expected target criteria need to be defined. According to the US FDA, interchangeability is granted when a non-invasive method meets the AAMI SP10 or subsequent AAMI 80601 criteria for the 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 criteria were not fully met (Table 4) nevertheless, the fact should be considered that we only compared ABP data during hyper- or hypotension situations. It is however worth noting that NIBP failed to meet the AAMI criteria even more pronounced in the overall comparison to the IBP (Table 5), 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 in 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 drastically influence overall accuracy and precision. In addition, in our study we enrolled patients during urologic, neuro, thoracic surgeries, and complex general surgeries 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 in such situations by either manual or automated recalibration. Nevertheless, during such moments there is a potential for artifacts or – in the case of recalibration – a phase of “no valid data” for 1-2 minutes. With the NIBP method on the other hand, even if cuff intervals are reduced from 5 minutes (as chosen in this study) to 1-2 minutes, such “blind spots” occur routinely and more often.

It can be said 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. 15 mm Hg or 30 mm Hg, is of less importance, because too high is too high and too low is too low and requires 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, our results compare very well to those of previous literature.

The most important and innovative part of this study, however, is the question if clinical decision making is impacted by AT? So far, all studies 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 uses 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 require 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 had no statistical difference compared to IBP, NIBP however, it 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 rapid changes of blood pressure. Our study found, that although AT could not achieve complete coincidence with IBP, the discrepancy does not negatively affect the anesthesiologists

ability to make efficient and appropriate clinical decisions. Of course, with approximately 77% of captured IBP decision-making moments (IBP n=513, AT n=394, Table 2), AT may not yet be the perfect alternative to IBP. But compared to only 45% of captured IBP decision-making moments of the cuff (IBP n=513, NIBP n=233, Table 2), AT seems to be a reasonable and clinically acceptable alternative.

During initial evaluation, the absolute number of decision making moments with – on average 2.1 per surgery – seems to be low, this however can be explained by several factors: We decided to exclude intubation and extubation period because during this period in our OR, the draping, undraping, and positioning of the patient is happening in tandem. During this process arm and body positions are constantly changing which would have required frequent repositioning or restarting of the non-invasive devices. As the latter would potentially have falsified the results, we justified that excluding this period was appropriate for a first study of this kind. Moreover, if an event did last for several minutes, we did not count it as a new event, but we only counted the first decision-making moment. If e.g. hypotension was detected as decision-moment, but after the first clinical action the blood pressure did not increase satisfactorily thus requiring a second clinical action, this was not counted as additional decision-making moment.

To our best knowledge, this study is the first one to record the moments of ABP-related clinical decisions as well as the ABP values at these decision-making 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 are not, the latter having missed 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. Considering this, our accuracy comparisons of a potentially 5-minute-old NIBP signal to an actual IBP or AT signal must be interpreted with caution. On the other hand, our approach reflects a 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 the possibility that we

may have missed some data points. Applying the NIBP to the same arm as the IBP however would not have been a solution, as then we would have repeatedly lost the Gold Standard signal thus also resulting in “missing data”.

This last limitation especially calls for another study with a 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 AT or NIBP data only where only their consequent action, based on such information, is recorded. Once such a study has been performed with positive results, a final comparative outcome study would also be warranted.

However, although radial arterial tonometry is an intriguing approach, its susceptibility to 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. The latter method would seem to be the best choice if highest safety for the patient is indicated. 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

Acknowledgements

The authors are grateful to the nurses in the operating room from the department of anesthesiology, West China Hospital, who contributed to this study.

Funding:

This study was funded by Sichuan Science and Technology Department Support Program

(grant number 2018SZ0155); Ministry of Science and Technology - National Key Research and Development Program(grant number 2018YFC2001803-2)

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
Type of Surgery (n, (%))	
General	211 (86.8%)
Neuro	22 (9.1%)
Urology	9 (3.7%)
Thoracic	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

Figure 3: Relationship between number of decision-moments and age, BMI, and length of surgery

		IBP	AT	Concordance rate	P Value	
Age	Total moments	77	62			
	≥65years	Median	1	1	80.5%	
	(n=40)	IQR	0-3	0-2		
	≤18 years	Total moments	436	332		0.402
BMI	≥65 years	Median	2	1	76.1%	
	(n=203)	IQR	0-3	0-3		
	Total moments	180	142			
	≥24	Median	1	1	78.9%	
Length of surgery	(n=91)	IQR	0-3	0-3		
	≤24	Total moments	333	252		0.422
		Median	1	1	75.7%	
	(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		0.226
	≤3 hours	Total moments	373	281		
	Median	1	0	75.3%		
(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 clinical decision-moments

Total	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						
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 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 \pm standard deviation

n: number of decision-moments of each subgroup

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

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
Diastolic blood pressure (mm Hg)	55.7 (15.6)	64.2 (14.5)	-8.4 (11.5)	22%	-30.9 to 14.1
Mean blood pressure (mm Hg)	70.9 (20.7)	75.2 (15.8)	4.3 (13.3)	16%	-30.4 to +217

BP data are expressed as mean ± standard deviation

Figures

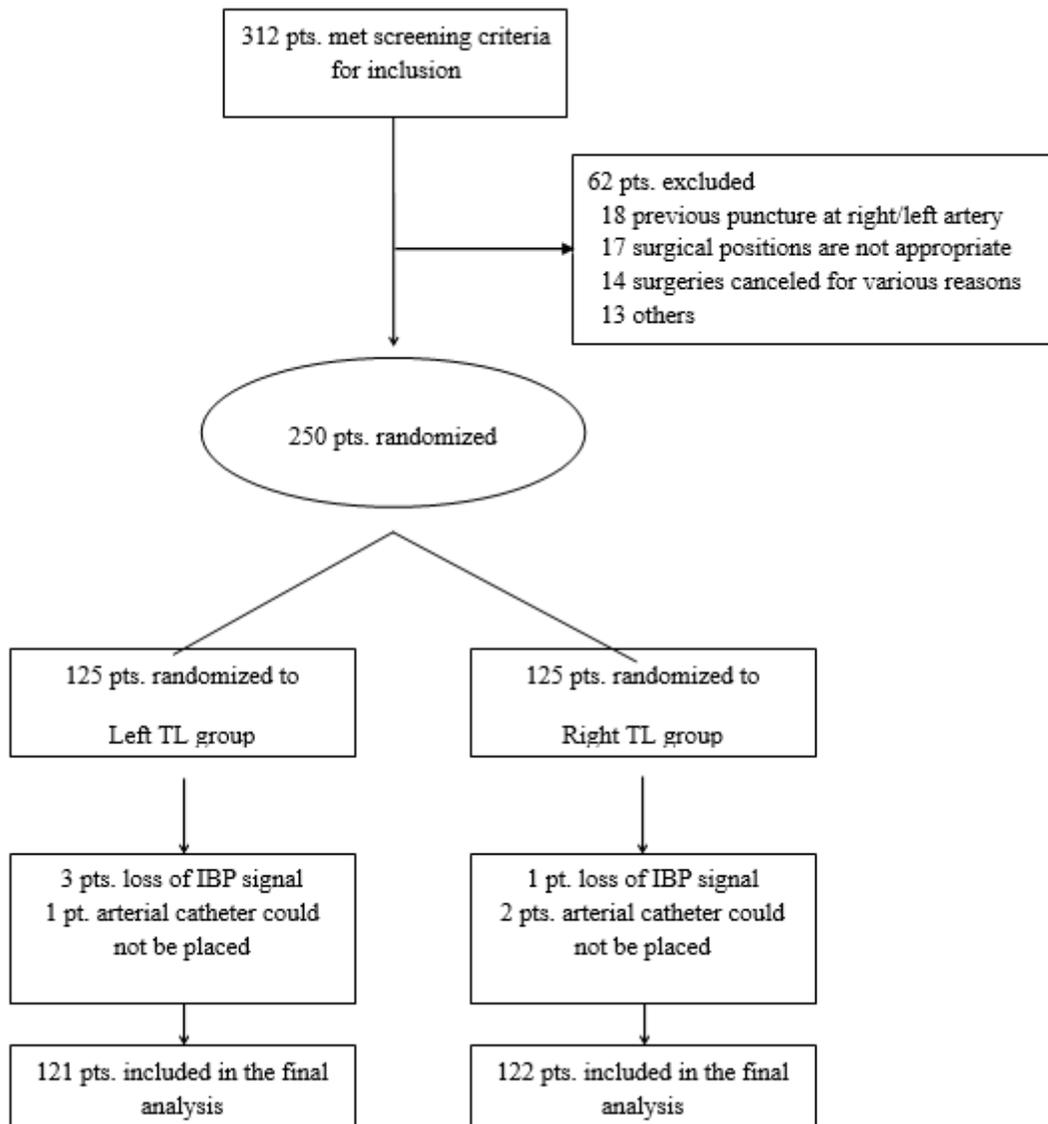
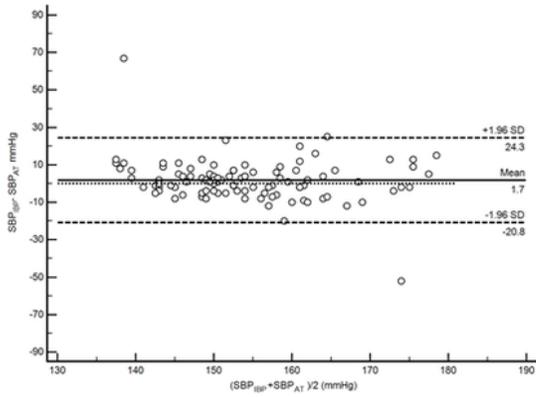


Figure 1

Flow Chart of Randomization

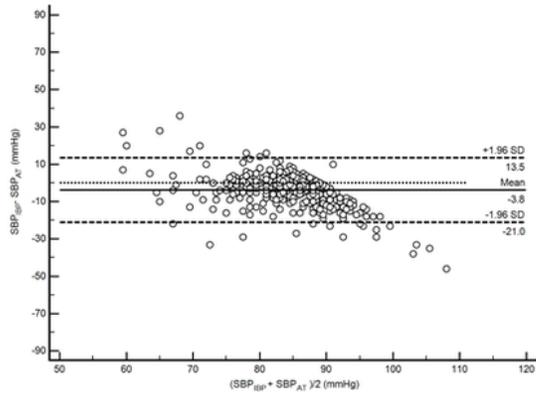
Hypertension (n=101)

A

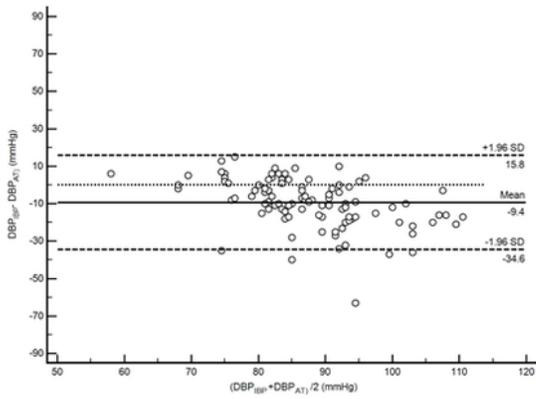


Hypotension (n=412)

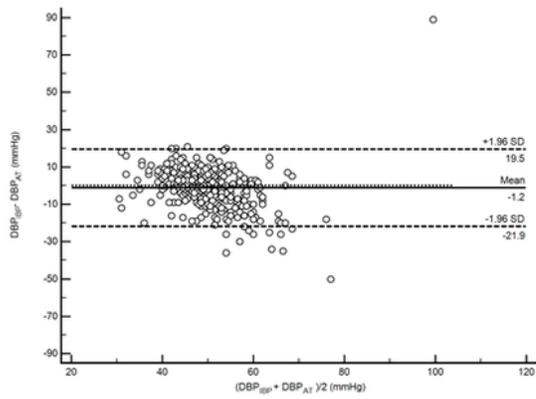
D



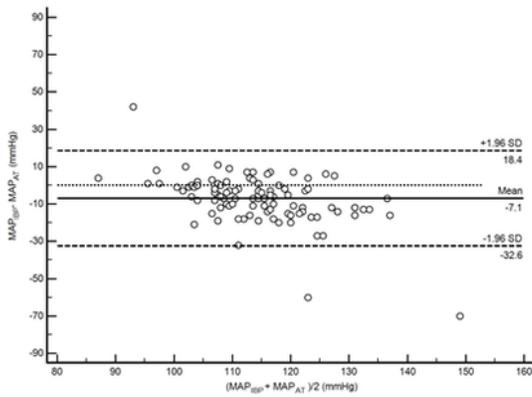
B



E



C



F

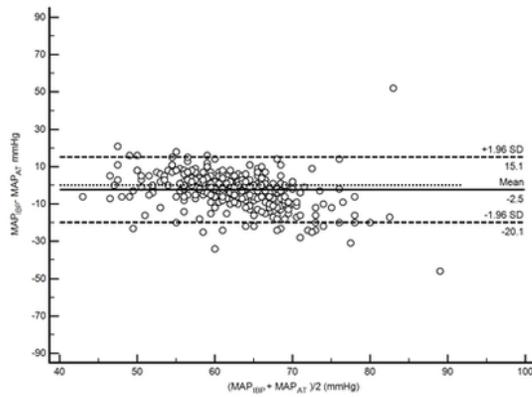


Figure 2

AT vs. IBP Bland-Altman plots during hyper- and hypotension moments Bland-Altman plots for systolic (A, D), diastolic (B, E), and mean (C, F) blood pressure during hypertension (left column) and hypotension (right column). Bias and standard deviations are given at respective lines.

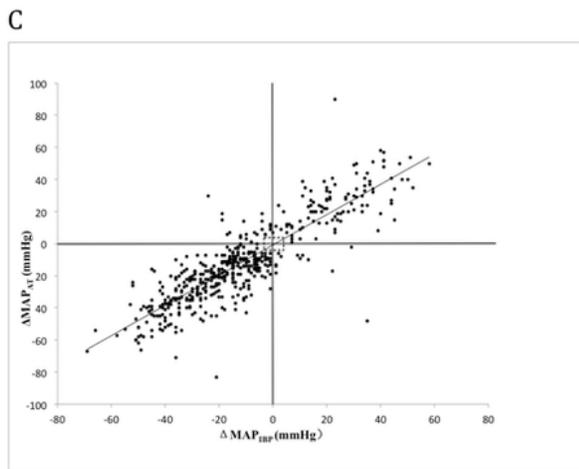
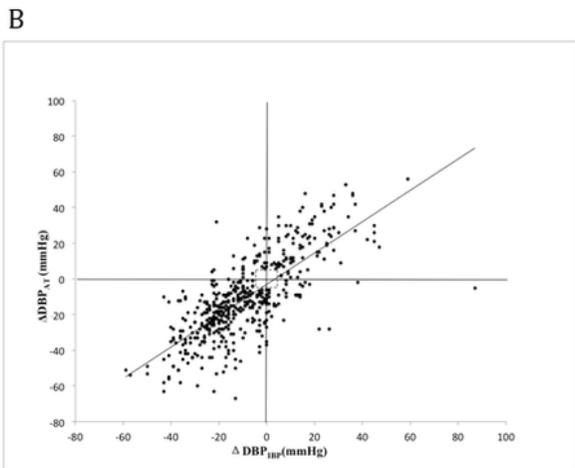
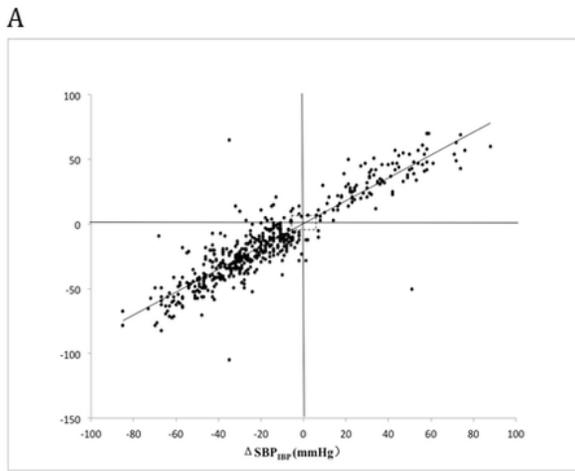


Figure 3

Four-quadrant plots AT vs. IBP 4-quadrant plots for systolic (A), diastolic (B), and mean (C) blood pressure Exclusion zone was 5 mm Hg for each plot and concordance was 0.910 for systolic, 0.752 for diastolic, and 0.871 for mean blood pressure