Radial artery applanation tonometry for continuous non-invasive arterial pressure monitoring in intensive care unit patients: comparison with invasively assessed radial arterial pressure

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Continuous arterial pressure (AP) monitoring is fundamental to adequately guide fluid therapy and administration of vaso-active agents in critically ill patients. Since the placement of an arterial catheter is associated with potential negative short- and long-term side-effects, non-invasive technologies for continuous AP monitoring have been introduced. Besides photoplethysmography technologies, radial artery applanation tonometry has been demonstrated to be a promising technology for non-invasive beat-to-beat AP monitoring in anaesthetized patients during surgery compared with invasive AP measurements using a radial arterial catheter.

The company Tensys Medical Inc. (San Diego, CA, USA) provides a radial artery applanation tonometry device (T-Line system). When using this uncalibrated applanation tonometry system for continuous non-invasive AP measurement, a raw AP signal (waveform) is obtained using the system’s sensor that is placed over the radial artery. The radial artery site is an ideal choice for applanation tonometry, since it meets the requirements of a superficial artery and a bony structure acting as a counter bearing. The term ‘applanation’ illustrates that a prerequisite for this method is that the sensor compresses the artery for the AP measurement by applying pressure. In the optimal ‘applanation position’, the artery is compressed (but not occluded) by the sensor to an extent that the vascular transmural pressure is minimized and the intraluminal AP (waveform with maximized pulse

Editor’s key points

- Radial applanation tonometry can be used for non-invasive arterial pressure (AP) measurement.
- In 24 intensive care unit patients, the authors simultaneously recorded AP with a tonometry device and an arterial cannula.
- Bias for non-invasive measurements was low.
- Precision was satisfactory for mean and diastolic pressures, but less satisfactory for systolic pressure.

Background. Radial artery applanation tonometry technology can be used for continuous non-invasive measurement of arterial pressure (AP). The purpose of this study was to evaluate this AP monitoring technology in intensive care unit (ICU) patients in comparison with invasive AP monitoring using a radial arterial catheter.

Methods. In 24 ICU patients (German university hospital), AP values were simultaneously recorded on a beat-to-beat basis using radial artery applanation tonometry (T-Line system; Tensys Medical, San Diego, CA, USA) and a radial arterial catheter (contralateral arm). The primary endpoint of the study was to investigate the accuracy and precision of the non-invasively assessed AP measurements with the Bland–Altman method based on averaged 10 beat AP epochs (n=2993 10 beat epochs).

Results. For mean AP (MAP), systolic AP (SAP), and diastolic AP (DAP), we observed a bias (± standard deviation of the bias; 95% limits of agreement; percentage error) of +2 mm Hg (± 6; −11 to +15 mm Hg; 15%), −3 mm Hg (± 15; −33 to +27 mm Hg; 23%), and +5 mm Hg (± 7; −9 to +19 mm Hg; 22%), respectively.

Conclusions. In ICU patients, MAP and DAP measurements obtained using radial artery applanation tonometry show clinically acceptable agreement with invasive AP determination with a radial arterial catheter. While the radial artery applanation tonometry technology also allows SAP measurements with high accuracy, its precision for SAP measurements needs to be further improved.

Keywords: arterial pressure, measurement; measurement techniques, arterial pressure; monitoring, intensive care; T-Line

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pressure) can be transduced to the pressure sensor placed on
the skin. In this position, mean AP (MAP) can then be deter-
mined from the raw AP waveform. The raw AP signal is then
scaled using a proprietary ‘gain function’ resulting in the final
AP waveform allowing the derivation of systolic AP (SAP) and
diastolic AP (DAP). In intensive care unit (ICU) patients,
radial artery tonometry has been previously compared with in-
vasive central aortic AP readings. However, there is a need
for confirmation that AP measurements with radial artery
applanation tonometry technology are reliable compared
with an arterial catheter placed in the radial artery in an ICU
setting. Therefore, in this study we compared radial artery
applanation tonometry AP with invasive radial AP.

Methods

Study design and setting
This study comparing non-invasive (radial artery applanation
tonometry) with invasive (radial arterial catheter) AP moni-
toring was performed in ICU patients treated in a German univer-
sity hospital. It was approved by the appropriate ethics
committee (Ethikkommission der Fakultät für Medizin der
Technischen Universität München) and all patients (or their
legal representatives) gave written informed consent.

Inclusion and exclusion criteria
Inclusion criteria included age 18 yr or older, body weight
40–180 kg, height 1.37–1.98 m, and the presence of an arterial
catheter previously placed in the radial artery for routine clinical
reasons. Patients in whom an arteriovenous shunt was present
were not eligible for study enrolment, as were patients with
anatomical abnormalities or injuries of the wrist. A history of
peripheral vascular disease or cardiovascular disease was not
an exclusion criterion for study enrolment.

Non-invasive and invasive AP measurements
The T-Line system (TL-200 or TL-200pro; Tensys Medical Inc.)
was used for continuous non-invasive assessment of AP, as
described previously. Simultaneously, AP values were measured
using an arterial catheter placed in the radial
artery of the patient’s contralateral arm. In each patient,
three 5 min intervals of AP measurements (resulting in a
total of 15 min) were recorded.

Data extraction, data processing, and statistical
analysis
After simultaneous recording of invasive and non-invasive AP
data, a beat-to-beat report containing numeric AP values
was extracted from the raw data sets using computer software
as previously described. All recorded AP data were included
in the statistical analysis.

For statistical analyses, we used IBM SPSS Statistics 20 (SPSS
Inc., Chicago, IL, USA) and the statistical software package R
When describing patients’ characteristics, the median and
25–75% percentile range (i.e. interquartile range) was used
for continuous data and absolute frequencies with percen-
tages were computed for qualitative measures. Non-invasively
and invasively assessed AP values are described by mean
[standard deviation (SD)]. AP measurements obtained continu-
ously on a beat-to-beat basis were averaged (10 beat epochs)
for comparative statistical analyses.

For each individual patient, radial artery applanation
tonometry-derived AP measurements (SAP, MAP, and DAP)
were plotted against invasively assessed AP measurements
as a scatter plot.

For the comparison of AP measurements using the two
methods, we performed a Bland–Altman analysis [mean dif-
fERENCE (bias), SD, and 95% limits of agreement] for multiple
measurements in one individual as described by Bland and
Altman in 2007 (section 3). To assess potential non-uniform
relations between the bias and mean AP measurements, we
additionally performed mixed models analysis as described
before. The percentage error ($2 SD of the differences/mean of measurements) was also calculated. In addition, modified
Bland–Altman plots showing individual mean AP measure-
ments, the intra-individual AP variability, the individual mean
difference, and the intra-individual mean difference variability
were computed.

Based on the averaged 10 beat epochs, four-quadrant plot
analysis was performed to investigate the concordance of
the AP measurements obtained with radial artery applanation
tonometry and the radial arterial catheter-derived AP mea-
surements regarding the direction of AP changes. For this AP
concordance analysis, we computed four-quadrant plots with
an exclusion zone of 3 mm Hg and calculated concordance
between the two AP measurement methods as described
previously.

Results

Patients
Twenty-eight patients were eligible for study inclusion. Four
patients could not be included in the study because they (or
their legal representatives) refused to give written informed
consent. Therefore, 24 patients (15 males, nine females)
were enrolled in the study. These patients had a median age
of 67 (54–77) yr, a median body weight of 82 (73–93) kg,
and a median height of 1.74 (1.67–1.85) m. On the day of
study inclusion, 11 patients were on mechanical ventilation
and six patients were receiving norepinephrine. Six patients
had atrial fibrillation during study recordings. Patients were
treated in the ICU for the following reasons: pneumonia/ respiratory insufficiency (nine patients), admission after
major surgery (five patients), central nervous system affec-
tion (four patients), gastrointestinal bleeding (three patients), or
other (three patients).

AP measurements
A total of 2993 averaged 10 beat AP epochs were recorded in 24
patients. Using invasive AP measurements (radial arterial cath-
eter), we observed a mean ($\mu$) (minimum, maximum) for MAP,
SAP, and DAP of 86 (15) (62, 137), 133 (20) (82, 192), and 63 (13)
(41, 109) mm Hg, respectively. Radial artery applanation tonometry measurements resulted in a mean (SD) (minimum, maximum) for MAP, SAP, and DAP of 88 (13) (67, 126), 130 (18) (88, 184), and 68 (11) (49, 103) mm Hg, respectively.

For each patient, individual scatter plots with radial artery applanation tonometry-derived MAP, SAP, and DAP plotted against invasively assessed MAP, SAP, and DAP are presented in Figure 1.

The Bland–Altman analyses were performed for MAP, SAP, and DAP. The mean difference (bias) between the radial artery applanation tonometry-derived AP measurements and the AP measurements obtained using the arterial catheter placed in the contralateral radial artery and the corresponding so, 95% limits of agreement, and the percentage error are presented in Table 1 and Figure 2. For MAP, SAP, and DAP, we observed a mean difference (so) of +2 (6), −3 (15), and +5 (7) mm Hg, respectively. This resulted in 95% limits of agreement and a percentage error of −11 to +15 mm Hg and 15% for MAP, −33 to +27 mm Hg and 23% for SAP, and −9 to +19 mm Hg and 22% for DAP. The modified Bland–Altman plots showing individual mean AP measurements, the intra-individual AP variability, the individual mean difference, and the intra-individual mean difference variability are presented in Figure 3.

Fig 1 Scatter plots with non-invasive AP measurements plotted against invasive AP measurements. For each individual patient we computed an individual scatter plot with radial artery applanation tonometry-derived AP measurements (non-invasive, y-axis) plotted against invasively assessed AP measurements (invasive, x-axis). One plot provides information on MAP, SAP, and DAP. In each figure, the diagonal represents perfect concordance.
Table 1  Radial artery applanation tonometry-derived and invasively assessed AP recordings. AP values [mean (SD)] recorded with radial artery applanation tonometry and a radial arterial catheter and comparison of the two methods with the Bland–Altman method (bias, SD of the difference, 95% limits of agreement) and the percentage error. Analyses are based on 2993 averaged 10 beat epochs in the 24 patients included in the study.

<table>
<thead>
<tr>
<th></th>
<th>Radial artery applanation tonometry</th>
<th>Radial arterial catheter</th>
<th>Bias (SD) of the difference</th>
<th>95% limits of agreement</th>
<th>Percentage error (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean arterial pressure</td>
<td>88 (13) mm Hg</td>
<td>86 (15) mm Hg</td>
<td>+2 (6) mm Hg</td>
<td>-11 to +15 mm Hg</td>
<td>15</td>
</tr>
<tr>
<td>Systolic arterial pressure</td>
<td>130 (18) mm Hg</td>
<td>133 (20) mm Hg</td>
<td>-3 (15) mm Hg</td>
<td>-33 to +27 mm Hg</td>
<td>23</td>
</tr>
<tr>
<td>Diastolic arterial pressure</td>
<td>68 (11) mm Hg</td>
<td>63 (13) mm Hg</td>
<td>-5 (7) mm Hg</td>
<td>-9 to +19 mm Hg</td>
<td>22</td>
</tr>
</tbody>
</table>

Figure 4 (four-quadrant plots) illustrates the concordance regarding AP changes between the two AP measurement techniques. This analysis revealed a concordance of 0.882 for MAP, 0.763 for SAP, and 0.824 for DAP.

Discussion

To the best of our knowledge, this is the first evaluation of the radial artery applanation tonometry technology with the T-Line system in comparison with invasive AP measurements obtained using an arterial catheter in the radial artery in ICU patients. According to our findings, MAP and DAP measurements obtained using radial artery applanation tonometry showed clinically acceptable agreement with invasive AP determination. Furthermore, the radial artery applanation tonometry technology provided accurate SAP measurements. However, the precision for SAP measurements using this non-invasive approach needs to be further improved.

Previous studies have reported data on the AP measurement performance of radial artery applanation tonometry using the T-Line system in comparison with radial artery catheter-derived measurements in the operating theatre in surgical patients.7–9 While the bias for SAP, MAP, and DAP and also the 95% limits of agreement for MAP and DAP determinations were comparably low in the ICU patients enrolled in our study and the surgical patients evaluated in these previous studies, the studies of Janelle and Gravenstein,7 Szmuk and colleagues,8 and Dueck and colleagues9 resulted in closer 95% limits of agreement for SAP measurements compared with our results. However, differences in the study settings between these studies and our study in ICU patients need to be emphasized. Considering that radial artery applanation tonometry systems are sensitive to motion of the studied limb, one important difference is that our ICU patients—in contrast to the patients reported in these studies—were not anaesthetized. Only five patients included in the present study were sedated during study measurements. In addition, in our study, all recorded AP data were included in the final analysis without deleting any recording episodes.

When evaluating continuous non-invasive AP monitoring systems in clinical studies, one fundamental problem is that definitions for inter-changeability or for clinically acceptable agreement are not available.3 15 Therefore, some authors suggest defining clinically acceptable agreement between a non-invasive AP monitoring device and arterial catheter-derived AP values according to American National Standards Institute/AAMI standards.2–4 7 When using these ANSI/AAMI standards for the evaluation of a test device with an arterial catheter as the reference method (criterion standard), clinically acceptable agreement is defined as a mean difference (bias) of less than or equal to ± 5 mm Hg with a SD of ≤ 8 mm Hg.16 Considering these ANSI/AAMI performance requirements, in our study, non-invasively and invasively assessed MAP and DAP values were interchangeable. While the bias for SAP also fulfilled the strict ANSI/AAMI standards for clinical acceptability, we observed a SD of > 8 mm Hg for SAP. Nevertheless, it has to be emphasized that the ANSI/AAMI guidelines only cover non-automated, automated, or electronic sphygmomanometers ‘that are used with an occluding cuff for the indirect determination of arterial blood pressure’.16 Measurement requirements for the use of devices obtaining continuous non-invasive AP based on either radial artery applanation tonometry or finger plethysmography are therefore not covered in the ANSI/AAMI guidelines. In addition, the ANSI/AAMI standard explicitly discourages placing the arterial catheter in the radial artery when invasive AP measurements are used as a reference in method comparison studies evaluating non-invasive technologies for continuous AP monitoring.3 16

Considering the increasing number of available devices using different technologies for continuous non-invasive AP monitoring and the increasing number of validation studies evaluating these technologies,2–4 6–10 15 standards defining clinically acceptable agreement/inter-changeability between the non-invasive AP measurements and AP assessment with an arterial catheter (criterion standard) are therefore eagerly awaited. Despite the fact that there are no standards defining acceptable agreement, the low bias observed for AP determination in our study contributes to the increasing body of evidence that radial artery applanation tonometry is capable of providing AP data with good agreement. Therefore, this technology might contribute to an improvement in patient safety in various clinical scenarios. Patients treated in the emergency department or a neurological stroke unit and also patients in...
need for haemodynamic monitoring in the operating theatre or in the ICU in whom arterial line placement is difficult or impossible might therefore benefit from continuous non-invasive AP monitoring.

In our study we performed concordance analysis based on the computation of four-quadrant plots in order to investigate the ability of radial artery applanation tonometry to adequately follow AP changes. Considering the paramount importance of MAP determination in critical care, a concordance of 88% for MAP also indicates that radial artery applanation tonometry is able to provide real-time MAP data for guidance of haemodynamic treatment in good agreement with the reference method. However, it has to be mentioned that there are no generally accepted cut-off values defining good agreement for the interpretation of four-quadrant plots in the evaluation of continuous non-invasive AP monitoring technologies. In addition, the optimal value to use as an exclusion zone in this kind of concordance analyses is also not yet defined.

Some methodological limitations of our study need to be pointed out. The major limitation of our study is the relatively...
small sample size. Our results were obtained in critically ill patients with in part markedly altered haemodynamic state. These limitations might therefore influence the generalizability of our results to other patient collectives like surgical patients or patients treated in the emergency department. The relatively short time of AP recordings in our study limits the possibility of drawing definite conclusions about the measurement performance and trending abilities of the evaluated technology. Therefore, further studies in clinical scenarios where continuous AP monitoring is needed for a longer period of time (e.g. emergency department, operating theatre, ICU) are needed.

Conclusions
In ICU patients, MAP and DAP measurements obtained using radial artery applanation tonometry show clinically acceptable agreement with invasive AP determination with a radial arterial catheter. While the radial artery applanation tonometry technology allows SAP measurements with high accuracy, its precision for SAP measurements needs to be further improved.

Authors’ contributions
A.S.M.: study design and conception, patient recruitment, data collection, analysis and interpretation of data, drafting of the article. W.H.: study design and conception, revising the article for important intellectual content. J.N.M.: patient recruitment, data collection, revising the article for important intellectual content. M.S.: analysis and interpretation of data, revising the article for important intellectual content. A.H.: study design and conception, analysis and interpretation of data, drafting of the article. N.L.: analysis and interpretation of data, revising the article for important intellectual content.
the article for important intellectual content. J.Y.W.: analysis and interpretation of data, revising the article for important intellectual content. F.E.: analysis and interpretation of data, revising the article for important intellectual content. R.M.S.: study design and conception, revising the article for important intellectual content. B.S.: study design and conception, patient recruitment, data collection, analysis and interpretation of data, drafting of the article. All authors approved the version of the manuscript for publication.

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Tensys Medical Inc. (San Diego, CA, USA) provided the technical equipment for recording and extraction of arterial pressure measurements.

Declaration of interest

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Fig 4 Four-quadrant plots illustrating the ability of radial artery applanation tonometry to follow AP changes. We computed four-quadrant plots to evaluate the ability of radial artery applanation tonometry to follow changes in MAP (A), SAP (B), and DAP (C). An exclusion zone of 3 mm Hg was used. MAP-ni, non-invasively assessed mean arterial pressure; MAP-i, invasively assessed mean arterial pressure; SAP-ni, non-invasively assessed systolic arterial pressure; SAP-i, invasively assessed systolic arterial pressure; DAP-ni, non-invasively assessed diastolic arterial pressure; DAP-i, invasively assessed diastolic arterial pressure.
References


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