Non-invasive continuous arterial pressure measurement based on radial artery tonometry in the intensive care unit: a method comparison study using the T-Line TL-200pro device

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Editor’s key points

• Several devices have been developed recently for continuous, non-invasive arterial pressure measurement.
• This study in 34 patients compared the TL-200pro device at the radial artery with values from a femoral arterial catheter.
• Mean bias was low for mean arterial pressure, with limits of agreement of +/− 10 mm Hg.
• Limits of agreement were higher still for systolic and diastolic pressures.

Background. The T-Line TL-200pro (TL-200pro) device (Tensys Medical, Inc., San Diego, CA, USA), based on radial artery tonometry, provides an arterial pressure (AP) waveform and beat-to-beat values of systolic arterial pressure (SAP), mean arterial pressure (MAP), and diastolic arterial pressure (DAP). The aim of the study was to evaluate this non-invasive technique for continuous AP monitoring in medical intensive care unit (ICU) patients.

Methods. Arterial pressure measurements obtained using the TL-200pro technology were compared using Bland–Altman analysis with values measured directly from a femoral arterial catheter in 34 ICU patients.

Results. Arterial pressure values were analysed and compared in 4502 averaged 10-beat epochs. A bias of +0.72 mm Hg (95% limits of agreement −9.37 to +10.82 mm Hg) was observed for MAP. For SAP and DAP, there was a mean difference of −1.39 mm Hg (95% limits of agreement −18.74 to +15.96 mm Hg) and +4.36 mm Hg (95% limits of agreement −8.66 to +17.38 mm Hg), respectively. The percentage error for MAP, SAP, and DAP was 12%, 14%, and 21%, respectively.

Conclusions. Arterial pressure measurement based on radial artery tonometry using the TL-200pro technology is feasible in medical ICU patients. The TL-200pro system is capable of providing MAP values with high accuracy (low mean difference) and precision (narrow limits of agreement) compared with MAP measured invasively using a femoral arterial catheter. The TL-200pro technology is promising for the measurement of SAP and DAP but further development is necessary to improve accuracy and precision.

Keywords: arterial pressure, measurement; measurement techniques, arterial pressure; monitoring, intensive care

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The T-Line® system (Tensys Medical, Inc., San Diego, CA, USA) is a non-invasive arterial pressure (AP) monitoring technology based on radial artery tonometry providing continuous measurements of systolic arterial pressure (SAP), mean arterial pressure (MAP), and diastolic arterial pressure (DAP).1–4 The most recent version of this technology is the T-Line® TL-200pro (TL-200pro) device.

Studies using previous versions of this device have demonstrated that the T-Line® technology allows determination of AP with a satisfactory agreement with values from a radial arterial catheter in surgical patients.1–3

In addition, our group recently demonstrated that AP monitoring using the predecessor T-Line® system (T-Line® TL-200) is feasible in medical intensive care unit (ICU) patients with T-Line® MAP measurements showing a low mean difference when compared with MAP measurements obtained using a femoral arterial catheter.4

Using radial arterial tonometry, the latest T-Line® version, the TL-200pro, computes AP values by processing pressure signals that are recorded by a worked-over sensor (Supplementary Fig. S1a) that is placed over the patient’s radial artery using a disposable locator with a lubricated film
(Supplementary Fig. S1a). The sensor is affixed using a brace-let placed on the ulnar side of the wrist of the patient’s arm (Supplementary Fig. S1c). To obtain the optimal pressure signal, the sensor moves over the radial artery driven by an electromechanical system integrated in the bracelet. Once the sensor found the maximum of the arterial pulse, the T-Line™ monitor displays a continuous AP waveform and values of SAP, MAP, and DAP (Supplementary Fig. S1a).

So far, there are no clinical data on the applicability and accuracy of the TL-200pro technology. Therefore, it was the purpose of this study, to compare the TL-200pro device with invasive AP determination using a femoral arterial line in medical ICU patients.

Methods

Study design and patients

This method comparison study using the CE-marked TL-200pro device was appraised and approved by the institutional review board of our hospital. All patients enrolled in the analysis or their legal representatives gave written informed consent. Patients aged 18 yr or older with a body weight between 40 and 180 kg and height between 137 and 198 cm, in whom AP monitoring was performed using a femoral arterial line (Pulsiocath; Pulsion Medical Systems, Munich, Germany), because it was clinically indicated were eligible for study enrolment. Patients with arteriovenous shunts on the study limb, anatomical abnormalities of the wrist, or a brachial cuff pressure difference >10 mm Hg between the right and the left arm were not included.

Measurement procedure and data extraction

After a patient’s enrolment in the study, the TL-200pro device was set up. In order to check the damping coefficient of the arterial line system, we performed a fast flush test of the invasive femoral AP measurement. Arterial pressure was measured for a total of 15 min (3 × 5 min intervals within 60 min). The corresponding values assessed using the arterial catheter and the TL-200pro device were recorded simultaneously. Measurements using the TL-200pro system were performed as described before and according to the instructions of Tensys Medical, Inc. Both AP waveforms and numeric values for SAP, MAP, and DAP were displayed on the T-Line™ monitor using an electronic splitter for the arterial catheter-derived signal as described previously. Simultaneously recorded AP values were extracted from the TL-200pro monitor to a computer with analysing software resulting in a ‘beat-to-beat’ report of AP values providing SAP, MAP, and DAP for every heart beat recorded during the measurement procedure. Arterial pressure data were analysed in 4502 averaged 10-beat epochs.

Episodes of data recording with an externally disturbed arterial line signal (e.g. line flushing) were excluded from the analysis.

The patients’ clinical characteristics were recorded from their medical records.

Statistical analysis

We used SPSS Statistics 20 (SPSS, Inc., Chicago, IL, USA) and the statistical software package R 2.14.1 (The R Foundation for Statistical Computing, Vienna, Austria) for statistical analyses. Patients’ characteristics and AP values are described by median and inter-quartile range (25–75% percentile) and mean (so), respectively. Categorical data are described by absolute and relative frequencies. For the comparison of data obtained using the TL-200pro device and the arterial catheter, data were analysed in 10-beat epochs. We computed the mean difference (bias) and so separately for each individual patient. In addition, we computed Bland–Altman plots accounting for repeated measurements including all patients and calculated the mean difference (bias), so, and 95% limits of agreement. Moreover, we calculated the percentage error as follows: 2 × so/mean of measurements. Possible non-uniform relations between mean differences and mean values of AP were investigated by mixed models. In order to analyse the ability of the TL-200pro device to track trends of AP changes in comparison with the invasively assessed values, we performed concordance analysis using 4-quadrant plots with an exclusion zone of 3 mm Hg. We defined concordance as the percentage of measurement pairs (10-beat epochs) that agreed regarding the direction of AP changes.

Results

Patients and patients’ characteristics

Thirty-seven patients were included in the study (Table 1). Three patients were excluded from the final statistical analysis because recordings had to be stopped because of excessive movement of the patients’ upper extremities. Therefore, data from 34 patients were available for analysis.

Non-invasive (TL-200pro) vs invasive AP measurements

In the 34 patients included in the data analysis, simultaneously assessed measurements of SAP, MAP, and DAP were recorded and analysed in 4502 averaged 10-beat epochs (with a mean of 132 10-beat epochs per patient; minimum 87 10-beat epochs, maximum 172 10-beat epochs).

For each individual patient included in this study, individual basic characteristics and the individual mean difference (bias) between AP measurements using the TL-200pro device and the arterial catheter are given in Supplementary Table S1.

In Table 2, mean values of AP variables obtained using both methods and the mean difference (bias) between the AP measurements with corresponding 95% limits of agreement are presented.

For the totality of patients, Bland–Altman analysis revealed a bias of +0.72 mm Hg and 95% limits of agreement of −9.37 to +10.82 mm Hg for MAP (Table 2, Fig. 1a). For SAP, a bias of −1.39 mm Hg with 95% limits of agreement of −18.74 to +15.96 mm Hg was observed (Fig. 1b).
For DAP, the analysis resulted in a bias of +4.36 mm Hg with 95% limits of agreement of −8.66 to +17.38 mm Hg (Fig. 1c).

The analysis of potential trends demonstrated that for MAP, SAP, and DAP the TL-200pro device overestimated higher AP values and underestimated lower AP values. The percentage error was 12% for MAP, 14% for SAP, and 21% for DAP.

Concordance analysis with 4-quadrant plots revealed a concordance of 0.881 for MAP (0.745 for SAP and 0.834 for DAP) (Fig. 2A–C).

### Discussion

Accurate, continuous AP monitoring is considered mandatory in critically ill patients to allow changes in AP to be detected rapidly and to guide vasoactive therapy; an arterial catheter sited in the radial, or femoral artery is commonly used.

A recent consensus statement on haemodynamic monitoring declared that an ideal haemodynamic monitoring technique—among other things—provides accurate and reproducible measurements, is easy to use, is readily available, causes no harm, and should provide information that is able to guide therapy. In addition, continuous measurement of all haemodynamic parameters is recommended.

An accurate, non-invasive AP monitoring system providing a ‘beat-to-beat’ arterial waveform could fulfill these requirements without the risks of arterial cannulation. Different technologies for continuous non-invasive AP monitoring are available including technologies based on photoplethysmography using a finger-cuff (e.g. the Nexfin™ device (BMEYE, Amsterdam, The Netherlands) or the CNAP® system (CNSystems Medizintechnik AG, Graz, Austria)) or on radial artery tonometry (T-Line® technology). In this study, we found that the most recent T-Line® device, the TL-200pro, determined MAP with a high accuracy (low bias: +0.72 mm Hg) and high precision (narrow 95% limits of agreement: −9.37 to +10.82 mm Hg) compared with invasive assessment of MAP using a femoral arterial catheter (percentage error 12%). For SAP and DAP we observed a bias of −1.39 mm Hg and of +4.36 mm Hg, respectively, with a percentage error of 14% and 21%, respectively. We also found that the TL-200pro device tends to overestimate higher values and underestimate lower values of AP.

In a previous study, we evaluated the T-Line® TL-200 system—the predecessor version of the TL-200pro device—in medical ICU patients. For MAP, we obtained a comparably low mean difference with lower SD in the

### Table 1 Basic patient characteristics. Data are presented as absolute and relative frequencies or as median and inter-quartile ranges (25–75% percentile)

<table>
<thead>
<tr>
<th>Basic patient characteristics</th>
<th>63 (51–74)</th>
<th>23 (68%)</th>
<th>1.73 (1.67–1.80)</th>
<th>80 (63–85)</th>
<th>25.6 (22.5–27.2)</th>
<th>22 (16–28)</th>
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<tbody>
<tr>
<td>Age (yr)</td>
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<td>Sex, male [n (%)]</td>
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<td>Height (m)</td>
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<td>Weight (kg)</td>
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<td>Body mass index (kg m⁻²)</td>
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<td>Arterial pressure, femoral</td>
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<td>Arterial pressure, TL-200pro</td>
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<td>Bias [mean (SD) of the difference]</td>
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<td>95% limits of agreement</td>
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### Table 2 Arterial pressure (AP) measurements using the TL-200pro device and the femoral arterial catheter (n=4502 averaged 10-beat epochs in 34 patients). Mean (σ) of AP variables is presented. Bias [mean (σ) of the difference] and 95% limits of agreement calculated using the Bland and Altman analysis accounting for repeated measurements are shown for AP values simultaneously assessed using the TL-200pro device and the femoral arterial catheter

<table>
<thead>
<tr>
<th>Arterial pressure, n=4502 averaged 10-beat epochs</th>
<th>Femoral arterial catheter</th>
<th>TL-200pro device</th>
<th>Bias [mean (σ) of the difference]</th>
<th>95% limits of agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean arterial pressure (mm Hg)</td>
<td>82.3 (11.3)</td>
<td>83.0 (11.4)</td>
<td>+0.72 (5.15)</td>
<td>−9.37 to +10.82</td>
</tr>
<tr>
<td>Systolic arterial pressure (mm Hg)</td>
<td>123.6 (17.8)</td>
<td>122.2 (16.6)</td>
<td>−1.39 (8.85)</td>
<td>−18.74 to +15.96</td>
</tr>
<tr>
<td>Diastolic arterial pressure (mm Hg)</td>
<td>60.1 (8.8)</td>
<td>64.5 (9.6)</td>
<td>+4.36 (6.64)</td>
<td>−8.66 to +17.38</td>
</tr>
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</table>
present study using the most recent TL-200pro technology compared to this previous version of the T-Line® device. The trend to overestimate high BP values and to underestimate low values was observed in both the previous and the present study for MAP, SAP, and DAP. However, compared with the previous version, the TL-200pro provided SAP and DAP values with markedly lower bias and limits of agreement.4

We, therefore, conclude that the latest TL-200pro device using a new, modified, disposable locator used for placement of the system’s sensor over the patient’s radial artery allows markedly improved AP recording compared with former versions of the device. This new locator is covered with a lubricated film placed between the patient’s skin and the sensor that facilitates the sensor’s movement towards the maximum of the radial arterial pulse and, therefore, probably allows more accurate AP signal transduction.

Former versions of the T-Line® system have been evaluated in surgical patients equipped with a radial arterial catheter.1–3 Compared with these previous studies, we revealed a lower bias and SD for MAP in our study.1–3 For DAP, we observed a slightly higher bias with comparable 95% limits of agreement in our study in medical ICU patients.1–3 For SAP, the 95% limits of agreement were slightly wider (with comparable bias) in our study compared with these previous trials.1–3 Because there are data demonstrating that SAP values are not interchangeable between the femoral and radial artery,15–17 this finding might be explainable by our study protocol including only patients with arterial catheter placed in the femoral artery. This study design was chosen, because we aimed to evaluate the TL-200pro system in the most critically ill patients in need for advanced haemodynamic monitoring. In these patients, therapy is guided based on transpulmonary thermodilution using a femoral thermistor-tipped arterial catheter in our ICU.

Apart from the fact that the radial TL-200pro AP values were compared with AP values assessed using a femoral arterial line, our study has further limitations. We report a single centre experience evaluating the TL-200pro technology in a limited number of critically ill patients treated in a medical ICU under routine clinical conditions. In this context, it has to be mentioned that external factors may have disturbed single AP measurements during data collection, because the T-Line® system is motion sensitive and therefore prone to artifacts caused by movement of the patient’s arm or the bracelet affixing the sensor.

In conclusion, we found that AP measurement based on radial artery tonometry using the TL-200pro technology is feasible in medical ICU patients. The TL-200pro system provided MAP values with high accuracy (low mean difference) and high precision (narrow limits of agreement) compared with values measured using a femoral arterial catheter. For SAP and DAP, the TL-200pro technology is promising but further development is necessary to improve accuracy and precision. Moreover, studies in medical ICU patients are needed to compare the device with invasive measurements from a radial artery catheter.
**Supplementary material**

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

**Acknowledgements**

Tensys Medical, Inc. (San Diego, CA, USA) provided the monitoring equipment for this study and a computer for data recording. The photographs of the TL-200pro device (Supplementary Fig. S1) were provided by Tensys Medical, Inc.

**Declaration of interest**

W.H. is member of the Medical Advisory Board of Pulsion Medical Systems (Munich, Germany).

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**References**


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**Fig 2** Four-quadrant plots. Four-quadrant plots with an exclusion zone of 3 mm Hg are shown for MAP (concordance 0.881) (a), SAP (concordance 0.745) (b), and DAP (concordance 0.834) (c).


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