APPARATUS

An evaluation of the T-Line® Tensymeter continuous noninvasive blood pressure device during induced hypotension*

P. Szmuk,1,6 E. Pivalizza,2 R. D. Warters,3,4 T. Ezri5,7 and R. Gebhard6

1 Associate Professor, Department of Anaesthesiology, University of Texas South-western Medical Center and Children’s Medical Center, Dallas, TX, USA
2 Associate Professor, 3 Professor, Department of Anaesthesiology, University of Texas Health Science Center, Houston, TX, USA
4 Professor, Department of Anaesthesiology, Medical University of South Carolina, Charleston, SC, USA
5 Chairman, Department of Anaesthesia, The Edith Wolfson Medical Center, Holon, Israel
6 Associate Professor, Department of Anaesthesiology, University of Miami – Miller School of Medicine, Miami, FL, USA
7 Member, Outcome Research Group

Summary

A new continuous noninvasive blood pressure measurement device, the T-Line® Tensymeter TL100 (Tensys Medical Inc., San Diego, CA, USA) which enables avoidance of arterial cannulation has been developed. We compared the values obtained using the T-Line values to simultaneous arterial line measurements in patients undergoing general anaesthesia with induced hypotension. Twenty-five patients, aged 18–70 years, were studied. The T-Line and arterial line were positioned on the contralateral wrists. Intra-operative, real-time, blood pressure data were electronically captured and stored on a computer. Bland–Altman plots and 95% limits of agreement show that the majority of T-Line data points were within 5 mmHg of the arterial line measurements (67%) and agreement was within 15 mmHg in 94.6% or more of all measurements. There was virtually no distinguishable error over the course of surgery using the device. In conclusion, the T-Line measurements correlate with arterial measurements during anaesthesia in which there were periods of both normotensive and hypotensive anaesthesia. The T-Line Tensymeter represents a noninvasive alternative to an arterial line in cases when arterial blood sampling is not required.

Correspondence to: P. Szmuk
E-mail: pszmuk@gmail.com
Accepted: 2 October 2007

Systemic arterial blood pressure provides valuable information about cardiac output, cardiac pressures and haemodynamic stability [1]. Intra-operative blood pressure is monitored either intermittently with a blood pressure cuff or continuously via an arterial line. Although widely used, percutaneous arterial cannulation requires skill and time, is invasive and is associated with several rare, but serious complications. Intermittent, noninvasive blood pressure (NIBP) monitoring has a number shortcomings: there may be nerve [2] and skin damage in the arm [3, 4] with prolonged use; readings are not continuous (the Association for the Advancement of Medical Instrumentation (AAMI) standard is once every 3–5 min [5]), potentially resulting in missed haemodynamic events; and at low pressures cuff readings are inaccurate. The development of a continuous (beat-to-beat) noninvasive blood pressure monitor is warranted and its availability may lead to widespread application in high-risk surgical populations, in cases where maintenance of normotension is critical, and in any case in which haemodynamic instability is anticipated.
The T-Line extracts pressure signals from which systolic, diastolic and mean blood pressure are derived through the use of a disposable sensor on the wrist. The device consists of three separate subsystems: the disposable sensor assembly, the wrist appliance and the monitor electronics. The wrist appliance (Fig. 1) includes the sensor actuator and a brace. The actuator is designed to move the sensor over the radial artery. The movement of the sensor is achieved by two small motors within the actuator which can create lateral and ‘applanation’ displacement. Applanation refers to motion which compresses or decompresses the radial artery by increasing or decreasing pressure against the skin, both the average pressure and pulse pressure measured by the transducer are the largest. Once the transducer lateral positioning is complete, the T-Line compresses the tissue and underlying radial artery. With increasing compression of the transducer against the skin, both the average pressure and pulse pressure measured by the transducer increase and the externally sensed pressure waveform closely resembles the intra-arterial pressure waveform. When the transducer compresses the tissue with sufficient force such that the maximum pulse pressure is reached, the average pressure measured by the sensor is approximately the mean arterial pressure of the patient. Correlation between the sensing of maximum pulse pressure and mean arterial pressure is analogous to oscillometric blood pressure measurement when the patient’s mean pressure is associated with the maximum pulse pressure measured by an occlusive cuff during the deflation cycle. Further compression eventually over-compresses the radial artery and the measured pulse pressure decreases rapidly. As the pulse pressure diminishes, the system decompresses the transducer to the position where the maximum pulses were obtained and maintains, through its proprietary algorithms, that operating position throughout the monitoring period, thereby constantly maintaining mean pressure.

Not all of the pulse pressure is transferred to the transducer as some is lost to the surrounding tissues. This loss is variable and is partially attributed to system compliance, but is also a function of the characteristics of the tissue surrounding the radial artery. Body mass index and other patient-specific parameters are used to characterise these tissue losses and a scaling factor is derived to compensate and appropriately scale the pulsatile component of the sensed pressure waveform.

Induced hypotension is used to reduce intra-operative blood loss and to facilitate surgical exposure during spinal surgery [7]. The primary aim of this study was to compare real-time T-Line blood pressure measurements with simultaneous arterial line measurements in patients undergoing spinal surgery under general anaesthesia using induced controlled hypotension. Additionally, we monitored the possible adverse effects related to the device from continuous pressure application to the skin (local skin breakdown, ischaemia or necrosis).

Methods

With Institutional Review Board approval and informed patient consent we studied 25 patients, aged 18–70 years, ASA 1–3, scheduled to undergo general anaesthesia for multilevel spine surgery. Exclusion criteria were as follows: weight < 40 kg or > 180 kg, no palpable radial artery pulses, history of, or current, arterio-venous shunt, propensity to hand ischaemia in the presence of radial

Figure 1 The T-Line Tensymeter TL100 wrist appliance.
arterial obstruction as evidenced by a positive Allen’s test (defined as lack of return of colour within 7 s after release of the ulnar artery compression), and a pre-operative mean blood pressure difference > 10 mmHg between the upper limbs as determined by an oscillometric method.

In addition to applying standard monitors (ECG, pulse oximetry, temperature, end-tidal carbon dioxide and end-tidal anaesthetic agent), a central venous line was inserted and invasive and noninvasive continuous blood pressure from an arterial line and the T-Line TL100 were commenced. The T-Line was positioned on the wrist of the opposite arm in which the radial artery line was placed, with initial measurements done in the supine position. The T-Line was disconnected during prone positioning and reconnected immediately thereafter. Subsequent blood pressure measurements were continuous throughout surgery and during emergence. Anaesthesia was induced with fentanyl and propofol and neuromuscular blockade achieved with rocuronium. Anaesthesia was maintained by a combination of an inhaled anaesthetic (isoflurane, sevoflurane or desflurane), intermittent boluses of fentanyl and rocuronium. The choice of agents used for the provision of induced hypotension was left to the discretion of the attending anaesthesiologist. The targeted mean blood pressure of 55–60 mmHg was achieved primarily with one of the following techniques: increased concentration of volatile anaesthetic, sodium nitroprusside, nitroglycerine alone or combined with esmolol, metoprolol or labetalol.

Peri-operative, real-time, beat-to-beat blood pressure data were electronically captured from both the T-Line and the arterial line. The effects of hydrostatic head height were minimised by placing the arterial line transducer at the same height as the T-Line transducer, or by electronically levelling the T-Line to the arterial line transducer by entering into the instrument keypad the vertical height above or below the reference level at which the transducer was located at the time of measurement. Data recording was interrupted during prone positioning and the return to the supine position at the end of the procedure. The data logging computer operated continuously during surgery, and all data were retained from every subject studied. The arterial line signal was electronically ‘split’ so the pressures could be displayed on the patient monitor simultaneously with being recorded on the computer along with the T-Line pressure signal. The original pressure signals from both modalities were sampled at 160 Hz and processed so that simultaneous systolic, mean and diastolic pressure comparisons could be made. After logging all subject data, individual beat-to-beat measurements of systolic, diastolic and mean blood pressure for both the arterial line and T-Line were passed through a seven-beat median filter to reject noise spikes occurring during data collection. Subsequently, paired differences of systolic, diastolic and mean values were calculated for each measurement of the T-Line and the arterial line pressures. The simultaneously recorded mean, systolic and diastolic pressures were plotted for each subject and visually reviewed to ensure that periods of noise due to external disturbances, such as leaning, bumping or other significant motions which could cause the T-Line to re-acquire the pulse pressure signal, were eliminated.

For each patient, 250 randomised sample data sets were extracted for analysis. These sample times were generated by a random function algorithm which created a uniform distribution of samples over the entire surgical period. At each sampled time, a 10-beat average difference (T-Line minus arterial line) for the systolic, diastolic and mean pressures was computed. The sampling methodology resulted in a uniform amount of data for each patient (approximately 40 min), thereby eliminating potential bias due to the impact of longer cases.

Data recorded during arterial line flushes and external movement due to surgical manipulation which may have caused the system to go ‘off-line’ were excluded. The mean and standard deviation of the systolic, mean and diastolic 10-beat epoch average differences for the entire population were computed. In addition, computations were made for the percentage of the 10-beat averages that lay within 5 mmHg, 10 mmHg and 15 mmHg. Bland–Altman plots were constructed.

The sample size of 25 patients was chosen based on recognised standards from the Food and Drug Administration and the American National Standards Institute for evaluation of noninvasive blood pressure monitors [8]. The AAMI SP10 specifies that a minimum of 15 subjects and 10 readings per subject should be reported if a contralateral arterial line is used as the reference. With 15 subjects, the maximum allowable 95% confidence interval is 4 mmHg (SD 8 mmHg). With 25 subjects, the maximum allowable 95% confidence interval is 3.1 mmHg. The substantially larger number of beat-to-beat measurements enhances the precision of the measurements beyond these AAMI recommendations (150 readings).

**Results**

Data were collected from 25 subjects for a total recording time of 60 h. Only data from 22 patients were used in data analysis. Three patients were eliminated due to data collection problems: one patient due to failed radial arterial cannulation in both arms, a second due to excessive ‘knocking’ of the T-Line device by the surgical team as they leaned over the patient, and the third due to
excessive damping of the arterial line. Patient morpho-
metric and demographic data are presented in Table 1.

Surgical procedures included lumbar laminectomy (4),
microdiscotomy (2), multiple level lumbar decompression
(3), fusion (11) and thoracic anterior–posterior decom-
pression with fusion (5). Duration of blood pressure
recording ranged from 73 to 330 min (mean 161, SD 16),
with a total of 5450 10-beat epochs analysed from the
60 h of data. Epochs recorded during arterial line flushing
or external physical movement of the T-Line which
could have caused it to go into its ‘motion recovery’
sequence were eliminated, although such episodes were
infrequent.

The ranges of blood pressure measurements were
42–192 mmHg for systolic blood pressure, 25–106 mmHg
for diastolic blood pressure, 32–135 mmHg for mean
blood pressure. Bland–Altman plots and 95% limits
of agreement for the 5425 10-beat epoch differences
between the T-Line and arterial line measurements are
shown in Fig. 2. The means (SD) of all paired differences
and of all paired absolute differences were calculated over
the entire data set to further define the magnitude of the
average differences between the T-Line and the arterial line
(Table 2). The number of T-Line measurements within
15 mmHg of corresponding arterial line measurement in
the contralateral arm, represented 90.6%, 96.8% and 97.2%
for systolic, diastolic and mean pressures, respectively. The
differences between the T-Line and arterial line values for
each of the 22 subjects are presented in Fig. 3.

There were no adverse events associated with use of the
T-Line system, and no patients had signs of skin pressure
at the T-Line application site 2 h postoperatively.

**Discussion**

The results of our study demonstrate that blood pressure
measured with the T-Line Tensymeter correlates with
that measured by an arterial line in the contralateral wrist
during both normotensive and induced hypotensive
periods. Our results are in concordance with recently
published data from Janelle and colleagues [6], in which
the blood pressure from the T-Line agreed with

**Figure 2** Bland Altman plots for systolic (a), diastolic (b) and
mean (c) blood pressure

simultaneous contralateral blood pressures measured from
arterial catheters over a systolic blood pressure range from
41 to 189 mmHg.

The sample size of 25 patients for this study was
relatively small, although both the sample size and the
number of data points included in the comparison exceed

---

**Table 1** Patient morphometric and demographic data. Data are
number or mean (SD).

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age; years</td>
<td>48.6 (12.4)</td>
</tr>
<tr>
<td>Gender; M/F</td>
<td>10/15</td>
</tr>
<tr>
<td>Height; m</td>
<td>1.7 (0.1)</td>
</tr>
<tr>
<td>Weight; kg</td>
<td>88.9 (18.3)</td>
</tr>
<tr>
<td>Body mass index</td>
<td>30.7 (5.6)</td>
</tr>
<tr>
<td>ASA physical status classification</td>
<td>1 2 3</td>
</tr>
</tbody>
</table>
the minimum figure recommended by the AAMI SP10 standard [5]. Data were included from epochs throughout the anaesthetic. The different surgical procedures led to variable monitoring periods and the possibility of bias from the potential for subjects with better correlation between the two techniques to have longer periods of monitoring or, conversely, for patients with poorer correlation to have longer monitoring periods. It was felt that rather than introduce investigator bias by arbitrarily choosing equal monitoring periods from each procedure, all periods would be included in the data analysis. Signal processing and a 7-beat median filter were used to exclude data from comparison when both monitors were not functioning. This occurred during arterial sampling and following periods of excessive device movement necessitating off-line recalibration. Although fewer than 3% of all epochs were eliminated because of noise or arterial line flushing, it is conceivable that these epochs contained periods of time during which the T-Line yielded poor results compared with arterial line data.

Currently there are three blood pressure monitoring devices available that offer noninvasive alternatives to arterial cannulation for frequent blood pressure determinations. The Finapres (TNO Biomedical Instrumentation, Amsterdam, the Netherlands) measures the capillary bed pressure of fingers based on the Penaz volume-clamp method [9, 10]. It has been shown to correlate inconsistently with arterial blood pressure [11] and has been associated with distal tissue hypoxia [12]. Although this device is no longer marketed, Finapres Medical Systems currently offers the Finometer and Portapres devices based on similar technology (Finapres Medical Systems BV, Arnhem, the Netherlands). The Colin N-CAT tonometer (Colin Corporation, Komaki, Japan) requires a cuff to calibrate the device and is therefore susceptible to inaccuracies from calibration, including errors associated with rhythm disturbances such as atrial fibrillation [13]. This device has been reported to be less accurate than the Finapres, particularly at lower mean blood pressure [14]. The Colin tonometer was compared with the Finapres in healthy voluntaries [15] and the recovery time after measurement was found to be slower with the Finapres due to possible distortion secondary to peripheral

### Table 2

<table>
<thead>
<tr>
<th></th>
<th>Arterial line</th>
<th>T-Line</th>
<th>Paired differences</th>
<th>Paired absolute differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic</td>
<td>98.3 (18.2)</td>
<td>98.3 (16.9)</td>
<td>0.0 (7.9)</td>
<td>6.2 (4.9)</td>
</tr>
<tr>
<td>Mean</td>
<td>71.2 (13.3)</td>
<td>72.8 (12.3)</td>
<td>1.6 (5.3)</td>
<td>3.8 (4.1)</td>
</tr>
<tr>
<td>Diastolic</td>
<td>57.1 (10.7)</td>
<td>58.6 (10.0)</td>
<td>1.6 (5.6)</td>
<td>4.2 (4.1)</td>
</tr>
</tbody>
</table>

**Figure 3** Differences between the T-Line and arterial line values for systolic (a), diastolic (b) and mean (c) blood pressure for each individual subject. The mean (black dot) and median (horizontal line) values are shown within the box. The vertical height of the box describes the standard deviation and the 5–95% range is indicated by the horizontal ‘whiskers’. 

© 2008 The Authors

Journal compilation © 2008 The Association of Anaesthetists of Great Britain and Ireland
vasoconstriction. The Medwave Vasotrac (Medwave, Arden Hills, MN, USA) provides near-continuous, noninvasive arterial blood pressure monitoring averaging 12–15 beats. The readings are updated every time the device cycles, like a conventional NIBP cuff system. Therefore, it provides intermittent, but not truly continuous, blood pressure measurements. Belani and colleagues [16] compared direct radial artery measurements with the Vasotrac in more than 17 000 measurements in 80 patients and found close agreement between the two techniques. More recently, Cua and colleagues [17] found that arterial blood pressure measurements obtained from the Vasotrac agreed with arterial line monitoring in paediatric patients.

The T-Line is well suited for use in the operating suite where rapidly changing individual blood pressure readings are important and where intermittent automatic oscillometric monitors may not be able to deliver a high degree of accuracy [18]. Thus, the T-Line could be useful in cases in which continuous blood pressure measurements are required without the need for arterial cannulation. The T-Line does have a number of limitations: it does not allow arterial blood sampling, making it less useful for situations in which arterial blood gas sampling is necessary; the device has limited use in situations in which the arms have to be ‘tucked’; and use may be problematic in cases in which there is significant patient motion or surgical manipulation of the limbs. The more recent model (TL-150) is more user-friendly. It is easier to apply the sensor and it uses a simpler and more informative user interface, resulting in a faster set-up and initialisation time, and improved motion handling (reduced off-line time and faster recovery).

In conclusion, we found that T-Line measurements correlate with arterial line measurements during anaesthesia in which there were both normotensive periods and induced hypotensive periods. The T-Line represents a noninvasive alternative to the arterial line in cases in which arterial blood sampling is not a requirement.

Acknowledgements

This study was supported by a grant (031703) from Tensys Medical, Inc. The authors thank Stuart Gallant, Anthony T. Butler, Cory J. Cortese and Joel M. Saulsberry, RN, from Tensys Medical Inc., for their enthusiasm and help with this project.

References


