Accuracy and precision of a novel non-invasive core thermometer

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Background. Accurate measurement of core temperature is a standard component of perioperative and intensive care patient management. However, core temperature measurements are difficult to obtain in awake patients. A new non-invasive thermometer has been developed, combining two sensors separated by a known thermal resistance ('double-sensor' thermometer). We thus evaluated the accuracy of the double-sensor thermometer compared with a distal oesophageal thermometer to determine if the double-sensor thermometer is a suitable substitute.

Methods. In perioperative and intensive care patient populations (n=68 total), double-sensor measurements were compared with measurements from a distal oesophageal thermometer using Bland–Altman analysis and Lin’s concordance correlation coefficient (CCC).

Results. Overall, 1287 measurement pairs were obtained at 5 min intervals. Ninety-eight per cent of all double-sensor values were within +0.5°C of oesophageal temperature. The mean bias between the methods was −0.08°C; the limits of agreement were −0.66°C to 0.50°C. Sensitivity and specificity for detection of fever were 0.86 and 0.97, respectively. Sensitivity and specificity for detection of hypothermia were 0.77 and 0.93, respectively. Lin’s CCC was 0.93.

Conclusions. The new double-sensor thermometer is sufficiently accurate to be considered an alternative to distal oesophageal core temperature measurement, and may be particularly useful in patients undergoing regional anaesthesia.

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Skin and the other facing the environment) in a plastic shell which can be affixed to a patient’s forehead. The new thermometer has already been tested in firefighters in a simulated work environment to determine heat strain and provided adequately accurate measurements.21

We compared the new non-invasive double-sensor thermometer in a perioperative and intensive care patient population with an established invasive core temperature measurement method (distal oesophageal temperature) to determine the accuracy and sensitivity/specificity of the new method for the detection of hypothermia and fever. We hypothesized that the new double-sensor thermometer was an adequate clinical substitute for the invasive distal oesophageal thermometer. For reference, we also evaluated the accuracy of a simple forehead skin temperature, adjusted upwards by 2°C.

Methods

Our study was approved by the Ethics Committee of the Medical University of Vienna and written informed consent was obtained from all participants. All patients were 18–80 yr old and were studied perioperatively (36 patients) during non-cardiac or non-neurosurgical surgery or in general intensive care units (ICU, 32 patients). All patients were anaesthetized and undergoing mechanical ventilation. Patients studied during surgery were not restudied, if admitted to an ICU. Patients were excluded, if attachment of the double-sensor to the forehead via the headband was not possible due to surgical incision, injury, or small head circumference. Patients were also excluded, if the oesophageal sensor could not be properly positioned because of surgery or coexisting disease.

Protocol

Thermal management in the operating theatre was standardized and comprised forced-air warming (Bair Hugger, Arizant, MN, USA). Depending on the location of surgery, an upper- or lower-body forced-air blanket was used (model #522 or model #525) with a model #750 warming unit. The plastic flap of the upper body cover was positioned to cover the face and neck, but left the double sensor exposed to the ambient environment. ICU patients were warmed with a whole-body forced-air cover (model #300) if hypothermic (<36°C) or cooled with forced air (Polar Air, Arizant, MN, USA). The double sensor was not specifically shielded against warm or cold air.

Measurements

Patient characteristics were recorded. Anaesthetic management was at the discretion of the attending anaesthetist. Double-sensor thermometer measurements were conducted by an experienced researcher who was trained to use the device. The reusable sensor was held adjacent to the patients’ foreheads with an elastic headband, and a small amount of contact gel was applied between sensor and skin. At least 10 min was allowed for thermal equilibration, after the sensor was applied.

Calculation of core temperature

Core temperature (Tcore) is estimated from the double-sensor system from Th1 (skin temperature under the insulator), Tg (temperature above the insulator), the heat conduction coefficient (Kg) of the insulator (calibrated at Draeger AG for each double sensor), and an empirically estimated heat transfer coefficient of human tissue (Kg=45 W m⁻² K⁻¹). The formula for calculating core temperature with the empiric human tissue heat transfer coefficient using the double sensor is thus:

$$T_{\text{core}} = T_{h1} + \frac{K_s}{K_g} (T_{h1} - T_{h2})$$

Forehead skin temperature was also recorded from Th1. As in previous studies,22 23 a 2°C offset was added to approximate core temperature to account for skin temperature being less than core temperature. We included the analysis of the forehead temperature +2°C in the present study primarily to show that the double-sensor thermometer markedly outperforms a simple forehead thermometer with a fixed correction like, for example, a liquid crystal thermometer. A distal-oesophageal, single-use thermometer (Smiths Medical, London, UK) was introduced under direct laryngoscopic vision and was used as the reference core temperature. Oesophageal temperature is considered one of the four reliable core temperature monitoring sites, the others being pulmonary artery, tympanic membrane (measured with a thermocouple), and nasopharynx.24
All temperatures were measured at 5 min intervals with a Datalogger (Eltek 400 Series Squirrel Model 401/451, Eltek Limited, Haslingfield, Cambridge, UK). Double-sensor-derived core temperature was calculated from temperatures $T_{h1}$ and $T_{h2}$ after the experiment offline using R software (R Project for Statistical Computing) and the formula above.

**Statistical analysis**

Our primary outcome was the agreement between the oesophageal and the double-sensor thermometers. One secondary outcome was the new thermometer’s sensitivity and specificity for fever ($>37.8$°C) and hypothermia ($<36.0$°C). Another secondary outcome was the agreement between the oesophageal and the forehead skin temperature with its $2$°C adjustment. We *a priori* defined limits of agreement to be $\pm0.5$°C. These limits have been used in previous studies\cite{19,20,24} and correspond to the usual magnitude of the human circadian temperature variation.\cite{25,26} Furthermore, no perioperative temperature-related outcomes have been demonstrated at temperature differences $<0.5$°C. Analysis of agreement between the methods was performed as suggested by Bland and Altman.\cite{27}

Bias (oesophageal temperature minus double sensor) was calculated for each outcome at each time point, along with the mean bias across all pairs of measurements. A Bland–Altman plot of bias vs the average of each pair of measurements was created to allow visual observation of agreement with standard core temperature measurements as a function of the range of temperatures. Statistically, mixed effects modelling and the Pearson correlation [with 95% confidence interval (CI) adjusted for within-subject correlation] were used to assess the change in bias as a function of increasing temperature (average of double sensor and standard core thermometers). Bland–Altman’s limits of agreement were used to estimate where ~95% of future differences from the standard core temperature methods were expected to be located. To compare the accuracy of the forehead sensor bias with the double-sensor, an F-test was performed.

A single-number agreement summary between double-sensor vs standard core thermometer was obtained using Lin’s concordance correlation coefficient (CCC).\cite{28} The CCC takes into account the correlation between measurements and the bias from the 45° line of agreement, in contrast to the Pearson correlation. $P<0.05$ was considered statistically significant; results presented as means (SDs) or means (95% CIs). R 2.4.1 (R Project for Statistical Computing) was used for all analyses.

**Results**

Patient characteristics and incidence of treatment with a warming or cooling device are shown in Table 1. Overall, 1287 measurement pairs were obtained over ~120 h ($n=36$ patients in the operating theatre, $n=32$ patients in the ICU).

<table>
<thead>
<tr>
<th></th>
<th>Perioperative patients ($n=36$)</th>
<th>ICU patients ($n=32$)</th>
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<tbody>
<tr>
<td>Age (yr)</td>
<td>62 (19–80)</td>
<td>59 (44–77)</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>169 (8)</td>
<td>167 (11)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>78 (19)</td>
<td>82 (22)</td>
</tr>
<tr>
<td>Gender (female/male)</td>
<td>23/13</td>
<td>20/12</td>
</tr>
<tr>
<td>Ambient temperature (°C)</td>
<td>19.3 (1.1)</td>
<td>24.4 (3.2)</td>
</tr>
<tr>
<td>Fever* ($T_{core} &gt; 37.8$°C)</td>
<td>0 (0%)</td>
<td>6 (19%)</td>
</tr>
<tr>
<td>Hypothermia* ($T_{core} &lt; 36$°C)</td>
<td>27 (75%)</td>
<td>3 (9%)</td>
</tr>
<tr>
<td>Use of forced-air warming*</td>
<td>36 (100%)</td>
<td>2 (6%)</td>
</tr>
<tr>
<td>Use of forced-air cooling*</td>
<td>0 (0%)</td>
<td>4 (13%)</td>
</tr>
<tr>
<td>Duration of surgery (h)</td>
<td>3.1 (2.4)</td>
<td>N/A</td>
</tr>
<tr>
<td>Type of surgery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Orthopaedic</td>
<td>15 (41%)</td>
<td>N/A</td>
</tr>
<tr>
<td>Gynaecological</td>
<td>17 (47%)</td>
<td></td>
</tr>
<tr>
<td>Urological</td>
<td>2 (6%)</td>
<td></td>
</tr>
<tr>
<td>General</td>
<td>2 (6%)</td>
<td></td>
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</tbody>
</table>

Oesophageal core temperature ranged from 34.4°C to 38.6°C, double-sensor temperature ranged from 34.3°C to 38.8°°C. Bias of measurements did not appear to change systematically with the mean core temperature ($r= -0.18, P=0.33$; for Pearson’s correlation). The mean bias between the oesophageal thermometer and the double-sensor thermometer was $-0.08$°C; limits of agreement were $-0.66$°C to $+0.50$°C (Fig. 2). Ninety-eight per cent of all double-sensor values were within $\pm0.5$°C of oesophageal temperature. Bias and limits of agreement of normothermic, hypothermic, and hyperthermic measurements are displayed in Table 2. Bland–Altman’s analysis of the forehead skin-derived core temperature (i.e. measured value +2°C; Fig. 3) resulted in a bias of $-0.58$°C, limits of agreement ranging from $-2.1$°C to $+0.98$°C, which significantly exceeded bias of the double-sensor thermometer ($P<0.01$, F-test).

The double-sensor detected fever with a sensitivity of 0.86 (95% CIs 0.69–1.00) and a specificity of 0.97 (0.92–1.00). Sensitivity and specificity for hypothermia were 0.77 (0.54–0.99) and 0.93 (0.70–0.99), respectively. Lin’s CCC was excellent for correlation of the double-sensor measurements with oesophageal temperature (CCC=0.93); in contrast, CCC for the forehead skin-derived core temperature was only 0.49.

The only adverse effects associated with double-sensor use were moderate skin pressure marks; the resulting round marks on the patients’ foreheads lasted <3 h and resolved without treatment. The oesophageal thermometer caused transient nose bleeding in two patients in whom the thermometer was inserted through a nostril.

**Discussion**

In a mixed population of surgical and ICU patients, a new non-invasive sensor combining a skin thermometer and
a heat flux measurement measured core temperature is sufficiently accurate to be considered an alternative to distal oesophageal measurements. The technology thus allows accurate, continuous core temperature measurements in patients having regional anaesthesia or sedation—whose core temperature is currently often unmeasured. Furthermore, the double sensor was significantly more accurate than adjusted forehead skin-surface temperatures. As adverse effects, only moderate skin pressure marks were visible after extended double-sensor use.

Even though the calculated limits of agreement were slightly higher than the a priori defined limits, 98% of all measurement points were within the limits of ±0.5°C. In accordance with previous studies, we chose limits of ±0.5°C, as this range is within the normal circadian body temperature fluctuation. Since 98% of the double-sensor values were within ±0.5°C of the reference oesophageal temperature, we consider the double sensor to be sufficiently accurate for routine clinical use and consider it an acceptable substitute for oesophageal thermometry.

According to the manufacturer, the thermometer needs to equilibrate at least 10 min before providing accurate temperatures. This equilibration requirement precludes using the double-sensor system for fever screening. Furthermore, the double sensor may prove difficult to use during cranial or facial surgery as the sensor constrains surgical access.

Zero-heat-flux thermometers are also able to accurately measure core temperature via a forehead or sternum skin temperature probe. Although this technique shares some similarities with the presented double sensor, there is a profound difference: the zero-heat-flux sensor incorporates a warming element and thus requires a dedicated power supply to heat the sensor. According to the manufacturer, the sensor takes about 5 min longer than the double sensor to measure core temperature. The zero-heat-flux sensor has to be cleaned and reused, in contrast to the double-sensor system which will be a single-use device. Our results indicate that the double-sensor thermometer is sufficiently accurate to replace an oesophageal thermometer. Because nasopharyngeal and tympanic membrane temperatures are nearly identical to oesophageal temperature, we can assume that the double sensor can substitute for them as well.

A limitation of our study is that we did not evaluate a wide range of temperatures with relatively few patients developing marked hypothermia or fever. The statistical analyses we used assume that each pair of values is independent. That was not the case in our study, since repeated measurements were made in each patient. Nonetheless, previous evaluations of thermometer systems have used

Table 2 Difference between distal oesophageal thermometer and double-sensor thermometer. *No occurrence of fever was detected in the operating theatre. Pairs are the number of double-sensor and oesophageal measurements. Data presented as mean (SD)

<table>
<thead>
<tr>
<th></th>
<th>Difference (°C)</th>
<th>Limits of agreement (°C)</th>
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<tbody>
<tr>
<td>Normothermic (688 pairs)</td>
<td>0.00 (0.31)</td>
<td>-0.62 to 0.61</td>
</tr>
<tr>
<td>Operating theatre (326 pairs)</td>
<td>+0.03 (0.33)</td>
<td>-0.63 to 0.69</td>
</tr>
<tr>
<td>ICU (362 pairs)</td>
<td>-0.02 (0.17)</td>
<td>-0.36 to 0.32</td>
</tr>
<tr>
<td>Fever, Tcore &gt;37.8°C (100 pairs)</td>
<td>-0.15 (0.37)</td>
<td>-0.99 to 0.49</td>
</tr>
<tr>
<td>Hypothermia, Tcore &lt;36.0°C (499 pairs)</td>
<td>-0.07 (0.26)</td>
<td>-0.59 to 0.45</td>
</tr>
<tr>
<td>Operating theatre (237 pairs)</td>
<td>-0.09 (0.24)</td>
<td>-0.57 to 0.39</td>
</tr>
<tr>
<td>ICU (262 pairs)</td>
<td>-0.06 (0.28)</td>
<td>-0.62 to 0.50</td>
</tr>
</tbody>
</table>

Fig 2 Bland–Altman plot comparing the distal oesophageal and double-sensor temperature measurements (n=1287). The x-axis is the average of the two measurements. The y-axis is the bias that is the difference of the two measurements (oesophageal–double-sensor). Bias: −0.08°C; limits of agreement: ±0.58°C.
In conclusion, the novel double-sensor core thermometer we tested was sufficiently accurate to be considered an alternative to distal oesophageal core temperature measurements in perioperative and critical care patients. This non-invasive sensor, which is easy to use, can thus facilitate temperature measurements in sedated patients or patients having regional anaesthesia.

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**Fig 3** Bland–Altman plot comparing the forehead and double-sensor temperature measurements (n=1287). The x-axis is the average of the two measurements. The y-axis is the bias that is the difference of the two measurements (oesophageal–double-sensor). Bias: −0.56°C; limits of agreement: ±1.54°C.

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a similar approach. Furthermore, the percentage of double-sensor values that were within 0.5°C of the reference distal oesophageal core temperature requires no assumption of independence. An impressive 98% of all measurements were within our a priori set limits. Finally, all patients studied were anaesthetized and thus vasodilated. However, we have previously shown that thermoregulatory vasomotion has little influence on forehead skin temperature. It thus remains possible, but unlikely that values would differ in awake subjects.

In conclusion, the novel double-sensor core thermometer we tested was sufficiently accurate to be considered an alternative to distal oesophageal core temperature measurements in perioperative and critical care patients. This non-invasive sensor, which is easy to use, can thus facilitate temperature measurements in sedated patients or patients having regional anaesthesia.
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