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ORIGINAL ARTICLE

Intraoperative temperature monitoring with zero heat flux technology (3M SpotOn sensor) in comparison with sublingual and nasopharyngeal temperature

An observational study

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BACKGROUND Perioperative hypothermia is common in patients undergoing general anaesthesia and is associated with important adverse events. The 'gold standard' for monitoring body core temperature – the pulmonary artery catheter – is invasive and unsuitable for most patients. For routine clinical practice, other sites and methods of temperature monitoring are commonly used.

OBJECTIVE The aim of this study was to evaluate a new temperature sensor (3M SpotOn) using the 'zero heat flux' method attached to the forehead, and compare it to sublingual and nasopharyngeal sensors in terms of correlation, accuracy and precision.

DESIGN An observational study.

SETTING University Medical Center Schleswig Holstein, Campus Kiel, Germany from October 2013 to January 2014.

PATIENTS One hundred and twenty patients scheduled for elective gynaecological or trauma surgery undergoing general anaesthesia were enrolled into this study. Data of 83 patients were finally analysed. Patients with unexpected blood loss, haemodynamic instability determined by the need for continuous norepinephrine infusion and/or need for postoperative ventilation were excluded from this study.

INTERVENTION Temperature monitoring was established after induction of anaesthesia with sublingual and nasopharyngeal probes, and the SpotOn sensor.

MAIN OUTCOME MEASURES Body temperature was measured 15, 45 and 75 min after induction of anaesthesia from sublingual and nasopharyngeal probes and the 3M SpotOn sensor at precisely the same moment.

RESULTS Analysis of 83 data sets revealed that 3M SpotOn temperatures were almost identical with nasopharyngeal temperatures (mean difference 0.07°C; $P = 0.1424$) and slightly lower than sublingual temperatures by 0.35°C ($P < 0.0001$). Coefficients of determination (r) for both methods were between 0.87 (SpotOn vs. nasopharyngeal measurement) and 0.77 (SpotOn vs. sublingual measurement). Bland–Altman analysis revealed a bias (SD) between 0.07°C (0.21) (SpotOn vs. nasopharyngeal) and −0.35°C (0.29) (SpotOn vs. sublingual measurement).

CONCLUSION With respect to correlation, accuracy and precision, the 3M SpotOn sensor provides a good measurement of body temperature in comparison to the nasopharyngeal probe and an acceptable measurement in comparison with sublingual thermometry. It is adequate for clinical use.

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Introduction

Inadvertent perioperative hypothermia is associated with complications such as impaired coagulation and increased blood loss,[1] increased cardiac morbidity[2] and higher incidence of wound infections.[3] Negative aspects such

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as patient discomfort have also been demonstrated.[4] Prevention of perioperative hypothermia has become a major topic of care for anaesthesiologists, surgeons and nurses. Publication of a new German guideline for prevention of perioperative hypothermia,[5] together with the British National Institute for Clinical Excellence guideline[6] have given it further emphasis.

Adequate measurement of the body core temperature is a prerequisite in detecting and preventing perioperative hypothermia. The best site for temperature monitoring is still under debate.

Pulmonary artery catheters (PACs) are still considered as the 'gold standard' in body core temperature monitoring;[7] however, they are invasive, dangerous, expensive and inappropriate for most routine surgery. Nasopharyngeal measurement has been shown to be a reliable method for core temperature monitoring, but it is not applicable in awake or head-injured patients.[8] Sublingual temperature has been demonstrated as a good 'near to core' measurement both in awake and anaesthetised patients.[9]

Another comfortable and noninvasive method for core temperature assessment follows the 'zero heat flux' (ZHF) principle, which was first described in the early 1970s.[10] The new 3M SpotOn sensor works by insulating the site of measurement, the forehead, against surrounding influences. It allows the skin underneath to heat up to body core temperature by creating an isothermic tunnel. At the point of 'zero heat flux', when the transfer of heat from the core to the forehead skin is complete, the temperature under the adhesive sensor reflects body core temperature.[11]

The aim of this study was to compare the 3M SpotOn ZHF sensor with the sublingual and nasopharyngeal probes with respect to accuracy, precision and correlation in patients undergoing elective surgery. We hypothesised that the ZHF sensor was adequate for temperature monitoring in the clinical setting to within a value of 0.5°C for accuracy and precision.

Materials and methods

This study was approved by the Institutional Review Board on 23 July 2013 (D 477/13) and registered with ClinicalTrials.gov (NCT02031159).

Men and women undergoing elective trauma or gynaecology surgery under general anaesthesia gave written consent and were enrolled in the study between October 2013 and January 2014. Patients with unexpected blood loss, haemodynamic instability determined by the need of continuous norepinephrine infusion or needing postoperative ventilation were excluded from this study.

All patients received a premedication of oral midazolam (0.07 to 0.1 mg kg^{-1}, maximum 7.5 mg) 30 min before induction of anaesthesia. Standard monitoring including ECG, pulse oximetry, noninvasive blood pressure (3 to 5 min intervals) and neuromuscular monitoring was established. General anaesthesia was induced with sufentanil and propofol, and maintained by sevoflurane (0.7 to 1 MAC). An endotracheal tube or laryngeal mask airway was inserted according to applied standard operating procedures of the department of anaesthesiology. Patients were actively warmed during surgery using a forced air warming blanket device (3M Bair Hugger Therapy, St. Paul, Minnesota, USA), which was set to a working temperature of 43°C.

Body core temperature was measured at 15, 45 and 75 min after induction of anaesthesia from the nasopharyngeal probe (Adult temperature probe, D-OS4; Exacon Scientific A/S, Roskilde, Denmark) and sublingual probe (SureTemp Plus; WelchAllyn Inc. Corporate Headquarters, Skaneateles Falls, New York, USA) and also, at the same time, from single-use sensors (3M SpotOn, St. Paul, Minnesota, USA) attached to the forehead using the ZHF method.[11] Sublingual temperature was monitored in the posterior sublingual pocket by lifting the tongue. For nasopharyngeal temperature, the sensor was carefully inserted through a nostril just posterior to the soft palate.

To estimate the sample size needed to detect a significant difference in mean temperatures (paired Student's *t*-test corrected for multiple testing), we used data from our previous temperature study.[9] The analysis was performed with G*Power 3.1.9.2 using the following values: mean difference = 0.15°C, SD = 0.333, power (β) = 95% and α (two-sided) = 5%, giving 77 patients. Due to the evaluation of a new thermometer device with an unknown reliability and dropout rate, we decided to include 120 patients.

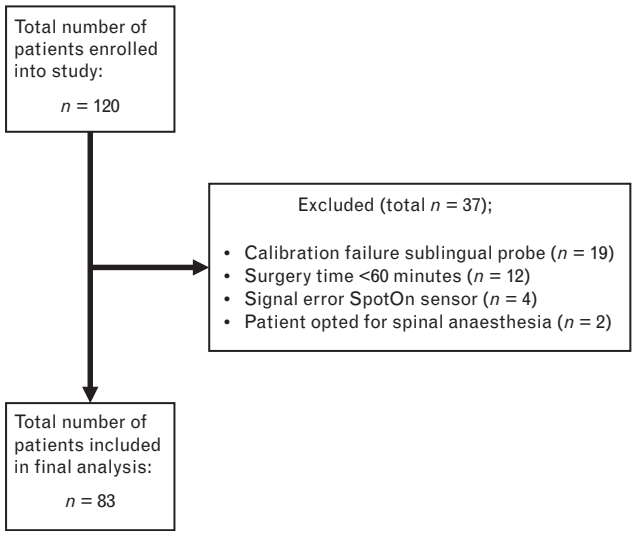
Statistical analysis was performed using GraphPad Prism 5.0 software (GraphPad Software, San Diego, California, USA). Correlation between sublingual and ZHF, and nasopharyngeal and ZHF was evaluated by Spearman's rank correlation analysis.

Bland–Altman statistics were used for interpretation of accuracy (mean difference between methods = bias), precision [standard deviation (SD) of difference] and limits of agreement (1.96 SD). From previous studies, we determined that a value of 0.5°C for accuracy and precision is considered as clinically sufficient.[8] A *P* value of less than 0.05 was considered statistically significant.

Results

Of 120 patients recruited, 37 patients were excluded for different reasons (Fig. 1). For 19 patients, sublingual temperature could not be obtained at 45 min of surgery time because of calibration failure of the sublingual probe. For another 12 patients, surgery time was less than 60 min, for four there were signal errors with the SpotOn sensor and two patients opted for spinal

Fig. 1



Patient enrolment flow diagram.

anaesthesia shortly before surgery, leaving 83 for analysis. Patient characteristics are presented in Table 1.

ZHF, sublingual and nasopharyngeal temperature measurement was performed without any noticeable side effects. Data sets were analysed separately to ensure independent data. ZHF temperatures measured by the 3M SpotOn sensor were minimally higher than nasopharyngeal temperatures (mean difference 0.07°C) ($P = 0.1424$) and slightly lower than sublingual temperatures by 0.35°C ($P < 0.0001$).

Analysis of Spearman rank correlation between ZHF and nasopharyngeal pairs gave a correlation coefficient (r) of 0.85 [95% confidence interval (95% CI) 0.78 to 0.90] at 15 min, 0.88 (95% CI 0.81 to 0.92) at 45 min and 0.89 (95% CI 0.83 to 0.93) at 75 min after induction of anaesthesia (Fig. 2).

At the same times, ZHF and sublingual pairs showed r-values of 0.69 (95% CI 0.55 to 0.79), 0.76 (95% CI 0.64 to 0.84) and 0.84 (95% CI 0.75 to 0.90), respectively (Fig. 3).

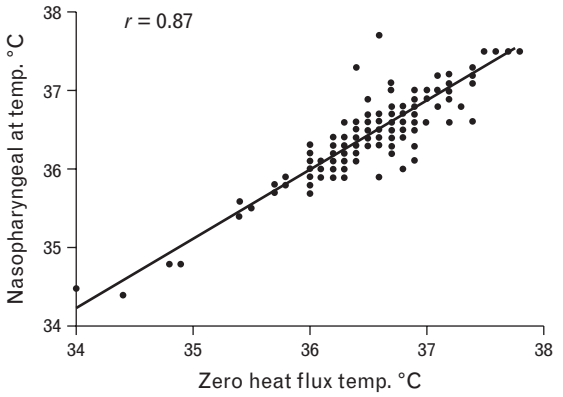
For ZHF vs. nasopharyngeal group, Bland–Altman analysis revealed a bias (SD) [95% limits of agreement] of 0.07°C (0.22) [−0.38 to 0.51] at 15 min, a bias of 0.05°C

Table 1

Patient characteristics	$n = 83$
Sex (female:male)	55:28
Age, female (years)	47.7 (14.1)
Age, male (years)	55.0 (16.8)
BMI, female (kg m^{-2})	26.1 (5.6)
BMI, male (kg m^{-2})	25.8 (4.8)

Data are presented as mean (SD) or absolute numbers.

Fig. 2



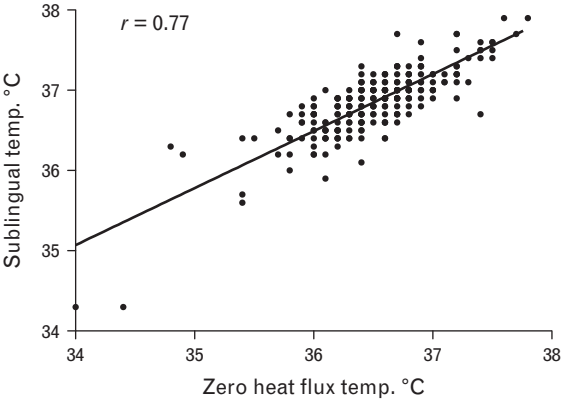
Scatter plot for nasopharyngeal (vertical axis) and zero heat flux (horizontal axis) temperatures measured 15, 45 and 75 min postanaesthesia induction. r, Spearman's rank correlation coefficient; temp., temperature.

(0.22) [−0.39 to 0.48] at 45 min and a bias of 0.10°C (0.18) [−0.25 to 0.46] at 75 min after induction of anaesthesia (Fig. 4). The ZHF vs. sublingual group showed a bias of −0.37°C (0.30) [−0.95 to 0.22], −0.36°C (0.30) [−0.95 to 0.23] and −0.33°C (0.27) [−0.84 to 0.19] (Fig. 5).

Discussion

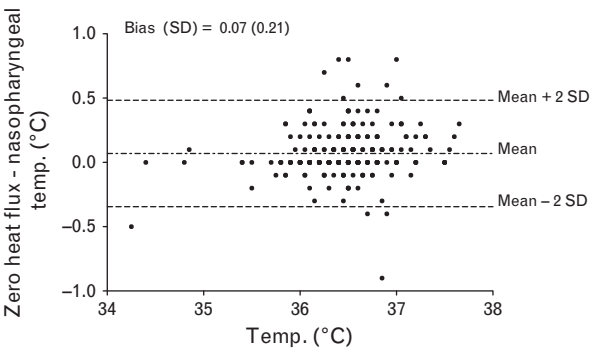
Our main findings in this study can be summarised as follows: In comparison with the nasopharyngeal probe, the 3M SpotOn sensor shows a bias of no more than 0.1°C, which can be interpreted as negligible.[8] With sublingual, we measured a bias of up to −0.37°C. The SpotOn sensor correlates well with the nasopharyngeal (sublingual) probe, with a coefficient of up to 0.89 (0.84). Compared with the nasopharyngeal probe, the ZHF sensor almost perfectly represents body temperature, but shows slightly lower values than sublingual

Fig. 3



Scatter plot for sublingual (vertical axis) and zero heat flux (horizontal axis) temperatures measured 15, 45 and 75 min postanaesthesia induction.

Fig. 4

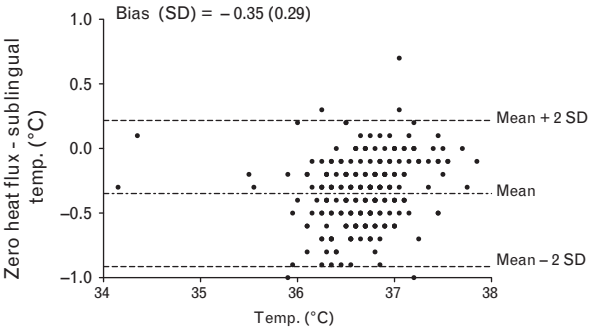


Bland–Altman analysis for zero heat flux vs. nasopharyngeal temperature monitoring 15, 45 and 75 min postanaesthesia induction.

measurement ($P < 0.0001$). In comparison with the sublingual and nasopharyngeal probes, we found the SpotOn sensor adequate for clinical pracice in terms of correlation, accuracy and precision, in haemodynamically stable patients without unexpected blood loss.

Obtaining accurate measurement of core body temperature during an entire perioperative period is still a challenge, and it remains the basis for the prevention and detection of perioperative hypothermia. Ideally, the recommendation of the new German S3 guideline should be followed and a single method and site of measurement should be used throughout the entire perioperative period to avoid a comparison of different techniques. In the absence of a PAC, sublingual temperature monitoring is accepted as a reliable alternative and can be regarded as a 'near to gold' standard.[12] Interestingly, this applies to both awake and intubated patients.[13] Nasopharyngeal temperature monitoring is also well accepted and, according to the German guideline, is a valid technique,[5] but adverse events have been reported including severe nasal bleeding.[14]

Fig. 5



Bland–Altman analysis for zero heat flux vs. sublingual temperature monitoring 15, 45 and 75 min postanaesthesia induction.

Nasopharyngeal temperature probes are unsuitable in the awake patient. Sublingual devices can be used but seem bulky in the perioperative setting with a cover that has to be replaced for hygiene reasons every time a probe is taken out of the mouth. The patient must also be able to breath through the nose, and temperature differences of up to 0.9°C have been found with probes placed incorrectly, for instance behind the front teeth.[15]

Infrared thermometers are commonly used but have failed to show sufficient agreement with established methods such as rectal thermometry,[16] and therefore, should not be used for temperature assessment.[5]

There are no hygienic concerns with the ZHF forehead sensor used in this study. It allows continous temperature monitoring with the same device throughout the perioperative period and therefore does not impair data interpretation.

In our study, were measured a negligible difference of 0.07°C in mean temperature between ZHF and nasopharyngeal probes and a slight but significant difference of 0.35°C between ZHF and sublingual temperatures. However, the clinical relevance of these differences is questionable. The tolerable accuracy and precision of temperature measurement is still in discussion. In 2008, Sessler[8] regarded an inacurracy in body core temperature of up to 0.5°C as tolerable for clinical routine because adverse effects were not observed for less than 0.5°C. But modern temperature monitoring equipment should be able to measure more exactly, and within a range of ±0.1 to 0.2°C. Therefore, a mean deviation of 0.35°C, as found in our study, should represent the maximum tolerable difference. However, in the absence of a real gold standard in our study, we are unable to define the true core temperature.

Our study may be criticised for the high number of patients who failed to reach the final analysis. Technical problems with the sublingual probe calibration were responsible for 19 of these. Nevertheless, we decided to follow a strict regimen regarding data analysis, which resulted in 3 x 83 data sets. There may have been a possible bias arising from the fact that sublingual and nasopharyngeal temperature monitoring devices are widely used in our hospital, although the SpotOn sensor is a new and unfamiliar device. To keep this to a minimum, only one person, familiar with the relatively easy SpotOn sensor technique, was responsible for all measurements in the operating theatre, so bias was little or absent altogether.

We chose to exclude urgent and unstable patients from our study and concentrate on those scheduled for elective surgery. Elective patients were preferred because they reflected daily clinical routine and provided better standardisation. Thermoregulation is subject to greater disturbance in noneuvolaemic patients, and there may be

a need for vasoactive agents, making data incomparable. More studies are needed to elucidate this.

In one recently published report, a prototype SpotOn sensor was tested against the PAC in patients undergoing elective cardiac surgery under cardiopulmonary bypass.[17] This provided good evidence that the new device will work well in haemodynamically unstable patients, with an overall temperature difference of −0.23°C. Intraoperatively, Eshraghi *et al.*[17] found an average temperature difference of −0.08°C, which is comparable to our bias of 0.07°C (SpotOn vs. nasopharyngeal). The authors conclude that core temperature can be measured noninvasively via the prototype SpotOn sensor even though precision was slightly worse than the designated 0.5°C limits compared with PAC measurements.

The SpotOn sensor had a high failure rate in comparison to the nasopharyngeal sensor in our study, but it performed better than the sublingual probe. We found a SpotOn failure rate of 3.3%, while Eshraghi *et al.*[17] found a rate of 1.9%, which seems comparable. Future software enhancements may be able to eradicate this problem.

In summary, we found the 3M SpotOn sensor using the ZHF method to be an adequate, noninvasive, single-use device for temperature monitoring during the perioperative period in haemodynamicly stable, noncritically ill patients. Correlation, accuracy and precision were on a high level in comparison to nasopharyngeal measurement and indicated acceptability for clinical use in comparison with sublingual measurement.

Acknowledgements relating to this article

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Conflicts of interest: none.

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