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Agreement of zero-heat-flux thermometry compared with infrared tympanic temperature monitoring in adults undergoing major surgery

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Abstract

The patient's body temperature significantly fluctuates, affected by factors, including anesthesia. The ideal temperature monitoring method that is suitable for perioperative application is of great significance for identifying hypothermia and malignant hyperthermia early, as well as for guiding intraoperative temperature protection. This study aims to compare the cutaneous zero-heat-flux (ZHF) thermometer application in general anesthesia using the infrared tympanic measurement as a reference. We conducted a prospective observational study and enrolled 130 patients scheduled for major surgery with general anesthesia. A forehead ZHF sensor (T_{zhf}) and an infrared tympanic thermometer (T_{tym}) were used to continuously measure core temperature. We assessed the agreement using Bland–Altman analysis and concordance correlation coefficient, comparing the paired measurement of T_{zhf} and T_{tym}. We further calculated the percentage of difference within 0.5 ℃ between the two devices. Sensitivity, specificity, and predictive values were estimated to interpret the performance of the ZHF thermometer in detecting hypothermia and hyperthermia. The analysis involved 1626 pairs of measurements for the comparison. The mean difference between the ZHF and the tympanic measurements was 0.11 ℃ ± 0.27 ℃, 93.5% of the measurements differences fell within ± 0.5 ℃. T_{zhf} was significantly correlated with T_{tym} ($r = 0.90$). The ZHF thermometry detected the presence of T_{tym} hypothermia with sensitivity and specificity of 0.89 and 0.88, respectively. Temperature monitoring with the ZHF thermometer indicates a good agreement with the infrared tympanic measurement and a high performance for detecting intraoperative hypothermia.

Keywords Core temperature measurement, Hypothermia, General anesthesia

Introduction

Monitoring core body temperature in patients undergoing surgery is as critical as blood pressure, pulse oximetry, and electrocardiogram within perioperative settings. Perioperative hypothermia is the most predominant thermoregulatory dysfunction in patients undergoing surgery aside from a febrile response or malignant hyperthermia [1, 2]. The normal heat balance of patients is disrupted by anesthesia and surgical factors [3], and subsequent hypothermia produces a range of complications [4, 5]. Accurate monitoring is crucial to determine core temperature changes and thermoregulation management perioperatively.

Specific difficulties remain in accurate and reliable core temperature monitoring perioperatively. Core temperature monitor mainly includes four sites: pulmonary artery, tympanic membrane, distal esophagus, and

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nasopharynx [6, 7]. A pulmonary artery catheter remains the gold standard of core temperature measurement [8]; however, it's invasive, and rarely available. The tympanic infrared thermometer and nasopharynx and esophageal thermocouples are mostly used perioperatively [2]. However, the thermocouples meet several constraints for somewhat invasive and infectious concerns. Under appropriate use, the infrared tympanic temperature monitoring can maintain good consistency with the pulmonary artery measurement [9, 10], and it can also provide continuous monitoring for conscious patients. Then, it meets the ideal requirements for perioperative core temperature monitoring to a certain extent. However, repeated operations during surgery increases the workload of anesthesiologists, and its stability may be affected by the operator and equipment.

Fox et al. [11] first proposed a noninvasive core temperature measurement based on the zero-heat-flux (ZHF) principle, upgraded into the Bair Hugger Temperature Monitoring System (3 M, St. Paul MN, USA). The ZHF system consists of an improved forehead sensor and establishes an isothermal tunnel from the skin surface underneath to the external environment. Furthermore, the sensor contains a servo-controlled heater to ensure no heat gradient across the body core to the underlying skin, then maintained equilibrated with core temperature [12]. Several validation studies have identified the consistency between the ZHF system and infrared tympanic thermometer in intensive care and postoperative environments [13, 14]. However, studies investigating the consistency of the two thermometers in surgical environments, where there may be significant changes in core temperature are limited.

This observational study aimed to identify the agreement of the ZHF thermometer compared to the infrared tympanic temperature measurement for patients undergoing elective major surgery. As secondary indicators, we evaluated the acceptable accuracy and precision of the ZHF measurement, as well as its performance in diagnosing hypothermia and hyperthermia, from a clinical perspective.

Materials and methods

The ethics committee of Baoding No.1 Central Hospital approved this study protocol, registered at the Chinese Clinical Trial Registry (ChiCTR2200057548). The participants signed informed consent, and the study conformed to the declaration of Helsinki.

Adults undergoing major surgery with an estimated general anesthesia duration of > 120 min were recruited from January 2022 to January 2023. This study excluded patients with the American Society of Anesthesiology physical status beyond IV and any conflict with the standard operation of these thermometers, such as preexisting ear diseases or external auditory canal deformities. Other exclusion criteria were incidents that may cause inaccuracy in core temperature measurement, including cerebral disease, thermoregulation abnormalities, and a history of hypothyroidism or hyperthyroidism.

The same anesthetists who had standardized training conducted the temperature measurements. Upon arrival in the operation room before induction of anesthesia, all participants were placed with a disposable sensor (SpotOn Temperature Monitoring System, 3 M, St. Paul MN, USA) on the right forehead, following the operation manual. The skin of the forehead should be cleaned before placement while avoiding forehead skin folds. The stable core temperature is obtained after attaching the electrode sheet for 5 min. The Braun Pro 4000 Thermoscan (Braun GmbH, Kronberg, Germany) was used to monitor tympanic membrane temperature (T_{tym}) every 15 min. The ear canal needs to be cleaned with a cotton swab before the first measurement. The medical staff mildly pulled back the pinna to straighten the external auditory canal sufficiently and inserted the probe into the ear canal to form a seal.

All the patients received standard monitoring, including pulse oximetry, electrocardiogram, blood pressure, bispectral index, and ventilatory parameters. General anesthesia, ventilation, and fluid management are based on the discretion of the attending anesthesiologist. All patients were kept warm in active or passive ways. The active warming method utilizes the forced-air patient warming system (WarmTouch 5300A, SOMA TECH INTL, Bloomfield, CT, USA). Passive insulation consisted of cotton blankets and surgical draping. The ambient temperature was adjusted to 20 ℃–24 ℃.

The agreement were the bias and limits of agreement between the reference thermometer and ZHF measurement. Based on most studies [2, 15, 16], we adopt a range of differences (bias and limits of agreement) within ± 0.5 ℃, which is clinically acceptable. This range is close to the rhythmic changes of normal temperature, and there is no randomized study to prove that temperature differences within 0.5 ℃ may lead to direct adverse consequences[17]. We considered that a sample size of 130 would be sufficient based on previous studies due to the deficiency of a unified power calculation standard [16, 18].

Bland–Altman analysis with random effects model was utilized for the primary outcome measure to identify the level of agreement with repeated measurements between the two devices, which display the mean differences as a measure of accuracy and 95% limits of agreement (precision) [19, 20]. In addition, a 95% confidence interval (CI) was estimated. The correlation between T_{zhf} and T_{tym} was evaluated with Lin's concordance correlation coefficient. The modality of ZHF measurement in detecting hypothermia and hyperthermia was calculated, as the second outcome measure, with sensitivity, specificity, and positive (PPV) and negative predictive values (NPV). Hypothermia was defined as T < 36.0 ℃, whereas hyperthermia was T of > 37.5 °C based on previous literature [21]. Statistical significance was assigned at $p < 0.05$.

Statistical Package for the Social Sciences version 26.0 (IBM Corp., Armonk, NY, USA), MedCalc software version 20.111 (MedCalc Software Ltd, Ostend, Belgium), and GraphPad Prism version 9.0 (GraphPad Software, San Diego, California, USA) were used for statistical analyses.

Results

This study enrolled 130 patients aged 18–80 years. Table 1 shows demographic characteristics. The mean age was 58 ± 13 years, and 50% were > 65 years. The observed types of surgeries included thoracic, orthopedic, urological, gynecological, and general surgeries. Furthermore, 34 (26.2%) patients were warmed with forced-air active heating systems.

A total of 1700 measurement points were obtained from the tympanic membrane and 1696 sets of ZHF thermometers. The final analysis included 1626 paired measurements. Temperature measurement for all patients was conducted safely with no side effects or adverse events. Mean ZHF temperatures were slightly lower than tympanic temperatures by 0.11 ℃ (95% CI 0.10–0.13) with a standard deviation (SD) of 0.27. The 95% limit of agreement (LOA) for the ZHF thermometer in comparison with tympanic temperature was relatively narrow. The estimated upper LOA was 0.64 ℃ (95% CI 0.62–0.66), and the lower limit was − 0.41 ℃ (95% CI − 0.43 to − 0.39). Figure 1 illustrates the Bland–Altman plot between T_{zhf} and T_{tym} with no apparent variability with changing temperature. The difference proportion within 0.5 ℃ of T_{tym} was 93.6% (95% CI 92.3–94.7%) for T_{zhf}. The CCC resulted in 0.90 (95% CI 0.89–0.91), indicating a positive relationship (Fig. 2).

Table 2 presents the ZHF thermometer-detected hypothermia and hyperthermia characterized by sensitivity, specificity, PPV, and NPV. 4% of the measurements caused hypothermia misdiagnosis. We received 49 sets of hyperthermia temperatures from 18 patients. Figure 3 displays the mean temperature changes using each device intraoperatively.

Table 1 Patient demographics and anesthesia/surgery data

Variables	Value, proportion (%); or Median
Age, n, mean ± SD (year)	130, 58 ± 13
Age > 65	65 (50%)
Gender	130 (100%)
Male	82 (63.1%)
Female	48 (36.9%)
BMI	130, 24.5 ± 4.9
Type of surgery	
Thoracic Surgery	73 (56.2%)
Orthopedic surgery	33 (25.4%)
Urological surgery	10 (7.7%)
Gynecological surgery	2 (1.5%)
General surgery	12 (9.2%)
Room temperature (°C)	22 ± 1.3
Patient warming	
Intraoperative passive warming	96 (73.8%)
Intraoperative active forced-air warming	34 (26.2%)

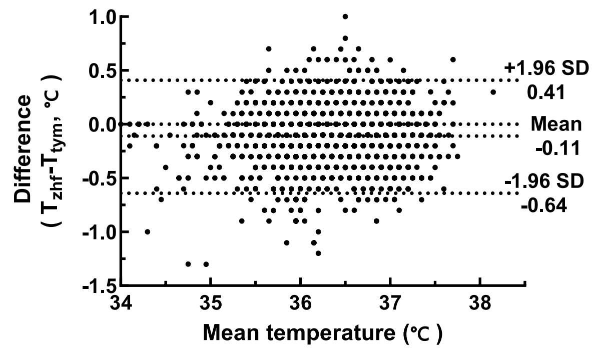

Fig. 1 Bland–Altman plots of the differences between zero-heat-flux forehead temperature and tympanic temperature. T_{zhf} = temperature of zero heat flux thermometer, T_{tym} = temperature of tympanic membrane, SD standard deviation

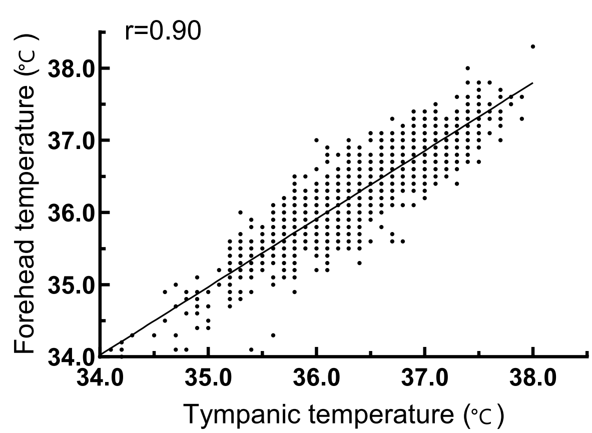

Fig. 2 Correlation estimated between the zero-heat-flux forehead temperature and tympanic membrane temperature

Table 2 Sensitivity, specificity, positive and negative predictive values for the detection of hypothermia and hyperthermia of temperature measured with the zero-heat-flux thermometer

	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
Detection of hypothermia	0.89 (0.85–0.92)	0.88 (0.87–0.91)	0.65 (0.61–0.69)	0.96 (0.96–0.98)
Detection of hyperthermia	0.37 (0.25–0.51)	0.99 (0.99–1)	0.69 (0.50–0.84)	0.98 (0.97–0.99)

PPV positive predictive value, NPV negative predictive value

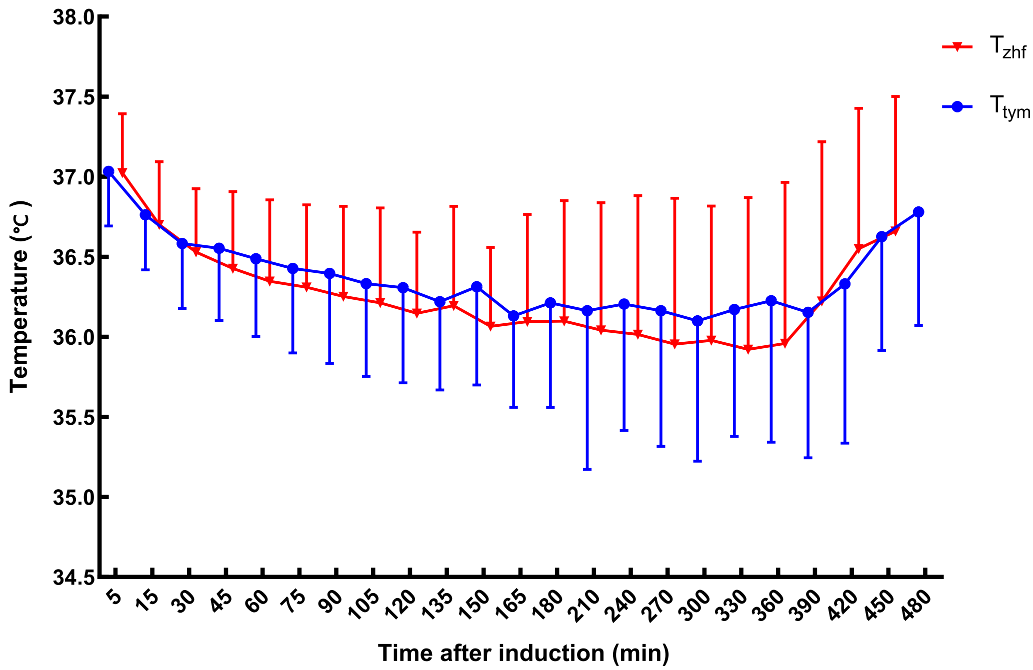

Fig. 3 Mean temperature changes as measured by each method. T_{zhf} = temperature of zero-heat-flux thermometer; T_{tym} = temperature of infrared tympanic membrane

Discussion

The current method-agreement study has revealed additional validation data for the ZHF device used in patients perioperatively. Sessler indicated that a good rule of thumb is that the thermometer inaccuracy should not exceed 0.5 ℃ [1]. We measured a bias of 0.11 with the ZHF sensor compared with the mean core temperature. Bland–Altman analysis 95% LOA was at − 0.41 ℃ to 0.64 ℃, which slightly oversteps the ideal limit. Furthermore, 93.6% of all ZHF temperatures were within ± 0.5 ℃ of the referenced core temperature. The CCC of 0.90 indicates good agreement between the ZHF sensor and the infrared tympanic thermometer. The ZHF thermometry well detected the presence of T_{tym} hypothermia with sensitivity 0.89, specificity 0.88, PPV 0.65, and NPV 0.96. We revealed the ZHF sensor demonstrated a good agreement with the infrared ear temperature regarding accuracy, precision, and correlation, as previous comparative studies of temperature measurement modes reported similar limiting accuracy [17].

Temperature monitoring should start 1 h before anesthesia, with temperature measured at least every 15–30 min and continued until the surgery is completed and the patient leaves the post-anesthesia care unit to prevent hypothermia [6, 22]. The temperature monitoring method throughout the entire process should be as consistent as possible [6]. Infrared ear thermometers detect thermal radiation from the eardrum without direct contact; thus, they are widely applied in different clinical disciplines and practices. Yaw et al. indicated a high consistency between the infrared tympanic thermometer and pulmonary artery temperature, and the errors likely related to the suboptimal operator technique [10]. Recently, several studies have further assessed and recognized the accuracy of the infrared tympanic thermometers [23–25]. We compared the ZHF thermometer with the infrared tympanic thermometers, because both are closer to the ideal perioperative temperature monitoring standard [26]. However, the infrared tympanic thermometers should be operated repeatedly at specific angles which may increase the workload and measurement errors due to personnel's technical level. The ZHF monitor can be placed preoperatively, and the patient's core temperature can be continuously monitored during the entire perioperative period, achieving consistent results [26].

This study revealed that the 95% LOA between the ZHF thermometer and infrared eardrum temperature slightly exceeded 0.5 ℃ but still exhibited a good agreement, which is consistent with previous results [14, 27]. Considering the substantial differences in core temperature between different measurement sites [2], several studies do not simply define 95% LOA of < 0.5 ℃ as the sole criterion for consistency evaluation [17, 28, 29]. The clinical assessment of the ZHF thermometer during cardiac surgery implicated better agreement with the pulmonary artery catheter than other thermometers (nasopharyngeal, rectal, and bladder) [28].

Accurate core temperature monitoring is crucial perioperatively to quantify inadvertent hyperthermia and detect malignant hyperthermia. We further evaluated that the ZHF thermometer demonstrated good sensitivity, specificity, and PPV or NPV in identifying hypothermia (defined as the tympanic temperature of < 36.0 ℃). However, poor sensitivity and higher specificity were demonstrated in determining hyperthermia. This may be because of the low frequency of hyperthermia occurring perioperatively [21] and the small sample size causing a sensitivity underestimation. The recently published comparative study in patients with acute stroke showed 94.1% accuracy of the ZHF thermometer in diagnosing hyperthermia [13]. However, the ZHF temperature records in that study were calculated with an algorithm based on ZHF theory which is different from the device of us.

The accuracy and precision of any core temperature monitoring depend on the equipment and measurement location[16]. A qualified thermometer undoubtedly exhibited a sufficient basic theory for support. However, in the operating environment, the accuracy of some thermometers may be affected. It is necessary to test the accuracy of measurements in clinical settings. Our results revealed acceptable clinical agreement in comparing the ZHF thermometry and the infrared tympanic temperature monitoring which was constant with the previous studies [13, 14, 27, 30]. This indicates that the ZHF thermometry can effectively monitor patients' perioperative core temperature in major surgery.

The study has several limitations. Our results apply to patients undergoing non-cardiac surgery. Cardiac surgery has a more fluctuating range and extent of core temperature than general. Further confirming this in a specific environment is necessary. One preliminary study compared 15 patients undergoing cardiac surgery with cardiopulmonary bypass and revealed that the ZHF system exhibited a good agreement with the pulmonary arterial temperature [29]. Another limitation is the small sample size of our study with hyperthermia, and evidence on the performance of ZHF thermometers for detecting hyperthermia, even fever, was insufficient. The comparison of core temperature monitoring for hyperthermia patients is worth further research. Finally, this study only utilized a single brand of ZHF temperature monitoring equipment, and differences in performance for other similar products may exist. Moreover, the monitoring of the ZHF device requires the use of disposable sensor, which is more expensive compared to the infrared tympanic and nasopharyngeal measurement.

In conclusion, the ZHF thermometer has demonstrated well representing an acceptable clinical core temperature compared to the infrared tympanic measurement in major surgery. Accuracy, precision, feasibility, and performance in detecting hypothermia make the ZHF method beneficial in perioperative circumstances. However, the agreement was questionable in hyperthermia detection and worthy of further study.

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Author contributions
Jingyan Wang conceived the study and wrote the manuscript. Hao Liang conducted the study and wrote the manuscript. Xinfeng Shao contributed to edit the manuscript and data analysis. Guiyuan Rong and Hao Liang contributed to data collection. Cheng Ran and Congzhe Tian contributed to concept and supervision. All authors have read and approved the final manuscript.

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Availability of data and materials
Sequence data that support the findings of this study have been deposited in Mendeley Data (http://doi.org/https://doi.org/10.17632/2vmxwc257w.1).

Declarations

Ethics approval and consent to participate
The study was approved by the ethics committee of Baoding NO.1 Central Hospital. Written informed consent was obtained from the participating patients.

Competing interests
The authors declare no competing interests.

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