Rectal and Bladder Temperatures vs Forehead Core Temperatures Measured With SpotOn Monitoring System

By Hildy M. Schell-Chaple, RN, PhD, Kathleen D. Liu, PhD, MD, Michael A. Matthay, MD, and Kathleen A. Puntillo, RN, PhD

Background Methods and frequency of temperature monitoring in intensive care unit patients vary widely. The recently available SpotOn system uses zero-heat-flux technology and offers a noninvasive method for continuous monitoring of core temperature of critical care patients at risk for alterations in body temperature.
Objective To evaluate agreement between and precision of a zero-heat-flux thermometry system (SpotOn) and continuous rectal and urinary bladder thermometry during fever and defervescence in adult patients in intensive care units.
Methods Prospective comparison of SpotOn vs rectal and urinary bladder thermometry in eligible patients enrolled in a randomized clinical trial on the effect of acetaminophen on core body temperature and hemodynamic status.
Results A total of 748 paired temperature measurements from 38 patients who had both SpotOn monitoring and either continuous rectal or continuous bladder thermometry were analyzed. Temperatures during the study were from 36.6°C to 39.9°C. The mean difference for SpotOn compared with bladder thermometry was -0.07°C (SD, 0.24°C; 95% limits of agreement, ±0.47°C [-0.54°C, 0.40°C]). The mean difference for SpotOn compared with rectal thermometry was -0.24°C (SD, 0.29°C; 95% limits of agreement, ±0.57°C [-0.81°C, 0.33°C]). Most differences in temperature between methods were within ±0.5°C in both groups (96% bladder and 85% rectal).
Conclusions The SpotOn thermometry system has excellent agreement and good precision and is a potential alternative for noninvasive continuous monitoring of core temperature in critical care patients, especially when alternative methods are contraindicated or not available.
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This article is followed by an *AJCC* Patient Care Page on page 51.

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Critically ill patients are at risk for alterations in body temperature, which may be related to a patient's clinical diagnosis, therapies administered, or exposure in the intensive care unit (ICU) environment (eg, during bathing and procedures). Frequent monitoring of body temperature facilitates early detection of changes in clinical condition and a patient's responses to therapies. For example, early detection of a fever due to an infection or a drug reaction and/or hypothermia related to continuous renal replacement therapy or a massive blood transfusion can lead to further assessments, interventions, or both. However, temperature monitoring in ICUs is highly variable with regard to the site of measurement, thermometry technology used, and the frequency of measurement.[1-3]

Although 37°C is widely accepted as normal core temperature, various temperatures exist within the body at the same time. The temperatures of the core organs and large vessels (eg, brain, heart, liver, pulmonary artery, jugular vein) are influenced by the metabolic rate of the thermometry site. Core temperature is typically higher than the temperatures at peripheral tissue and skin sites because the last 2 sites are influenced by dynamic alterations in vascular perfusion.[4] A recent meta-analysis[5] indicated that esophageal, urinary bladder, and rectal temperatures are within clinically acceptable limits of agreement (LOA) compared with pulmonary artery blood temperatures and hence are widely accepted as accurate estimates of core temperature. Evidence-based guidelines[6] for temperature monitoring in ICU patients also recommend the use of pulmonary artery, esophageal, bladder, and rectal thermometry.

A continuous, noninvasive, accurate measure of core temperature that is feasible for use and comfortable for patients would be ideal.

The ideal monitoring system would provide a continuous, noninvasive accurate measure of core body temperature and be feasible for use, comfortable for patients, and compatible with care interventions in ICU patients. Unfortunately, the standard thermometry methods used in ICUs for continuous monitoring are invasive and have barriers to use. The pulmonary artery catheter is designed to measure the temperature of blood in the pulmonary artery, and this measurement is considered the gold standard for core body temperature. Yet, pulmonary artery catheters are invasive, associated with potential risks, not broadly used across ICUs, and typically used for only a short time during an ICU stay.[7-10] Although strong agreement exists between temperatures obtained via urinary catheter and pulmonary artery catheter thermometry, urinary catheters are also invasive. Current practice standards include efforts to reduce duration of use of urinary catheters because of the risk for device-related infection of the urinary tract.[11,12] Continuous esophageal probe thermometry also provides accurate measures of core temperature, but maintaining the position of the probe for more than a short time is challenging, and use of this method is typically limited to intubated patients.[13] Continuous rectal thermometry is now used less frequently than before in ICUs for various reasons: a recent focus on prevention of device-related pressure injuries to skin and mucosa, introduction of new fecal management devices, and concerns about patients' dignity and discomfort.[3,14] Temporal artery thermometry is noninvasive, but not continuous, and is not recommended for use because of the limited precision of the method, especially in febrile patients.[6,15] Thus, obtaining continuous data on core temperature in ICU patients remains a challenge.

A recently available continuous, noninvasive temperature monitoring system that uses zero-heat-flux (ZHF) technology to measure core temperature is the SpotOn system (3M Healthcare). This system consists of a control unit, a cable, and a small disposable sensor applied to the lateral part of the patient's forehead. The thermal insulator and resistive warming circuit are used to eliminate flow of skin-surface heat to the environment, establishing conditions in which

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the temperature gradient should be zero between the thermistor on the skin surface and deep tissue. ZHF technology is designed to provide an estimate of core temperature by measuring the temperature from 1 to 2 cm below the skin surface via the isothermal tunnel created under the sensor (Figure 1). A manufacturer-sponsored trial to evaluate clinical accuracy of the device indicated excellent agreement between the forehead core SpotOn system and pulmonary artery blood temperatures, with a mean difference of -0.23°C (SD, 0.42°C) between methods in perioperative cardiac surgery patients.[16] The distinction between temperature measurement via ZHF technology and measurement with skin sensor technology with thermally sensitive resistors is important. Skin temperature sensors are not insulated to ambient air and allow heat radiation from the skin. Forehead skin temperatures can be up to 3°C lower than forehead core temperatures measured at the same time by using the SpotOn system.[17]

Method-comparison study design is widely accepted for evaluation of technology used to measure physiological variables in health care.[18,19] This design is used to determine the degree of accuracy, evaluated on the basis of the mean difference between the measurement obtained with the new method and the true value or gold standard reference measurement. The method-comparison design may also be used when adoption of new technology is considered and new methods of measurement are compared with established methods. The mean of differences between temperatures quantifies the degree of agreement between measurement methods in the sample. The standard deviation of the mean difference represents the degree of imprecision with repeated measurements and is used to calculate the 95% LOA, an estimate of where most differences will fall in similar subjects. The LOA and precision data help inform decisions when use of an alternative measurement method for clinical practice is considered.

Studies designed to evaluate the accuracy of earlier thermometry systems with ZHF technology compared with standard core thermometry methods (pulmonary artery, esophageal, nasopharyngeal, urinary bladder) used in perioperative and ICU settings have indicated that the ZHF technology is a sufficiently accurate measure of core body temperature in surgical patients.[16,17,20] However, method-comparison studies of the recently available SpotOn system in diverse populations of patients across a range of temperatures are needed to determine the usefulness of this thermometry method in ICUs before the method is widely accepted in clinical practice. Thus, the purpose of our study was to evaluate the agreement and precision between the SpotOn temperature monitoring system and established rectal and urinary bladder continuous thermometry methods during fever and defervescence in ICU patients with medical, surgical, and neurological conditions.

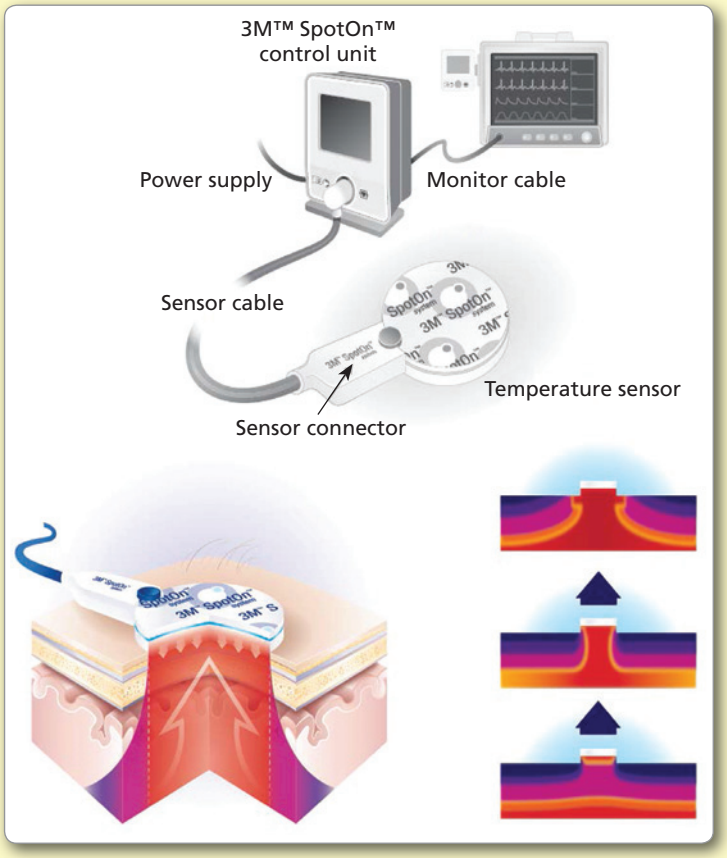

Figure 1 3M SpotOn temperature monitoring system and isothermal tunnel formation with zero-heat-flux technology.

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Methods

Patients enrolled in a randomized clinical trial[21] to test the effects of intravenous acetaminophen on core temperature and hemodynamic responses in febrile critically ill patients were eligible for the study. We used a method-comparison study design to compare simultaneous temperature measurements obtained from the continuous, noninvasive SpotOn system with measurements from continuous rectal or urinary bladder temperature monitoring systems. Rectal and bladder thermometry methods were selected as reference

> The SpotOn system was used to measure core temperature continuously and noninvasively.

sources of temperature; obtaining gold-standard core temperatures was not feasible because of the limited use of pulmonary artery catheters in the ICU. We hypothesized that the noninvasive SpotOn system with ZHF technology is sufficiently comparable to invasive continuous rectal and bladder thermometry methods to within a value of ±0.5°C for agreement and precision.

A total of 41 patients enrolled from the adult medical-surgical and neuroscience ICUs at the University of California, San Francisco Medical Center, during the period September 2013 through August 2015 were randomized to receive the study intervention of either intravenous acetaminophen (1 g) or placebo during a 15-minute period, and data were collected during a 4-hour period. Patients were eligible for enrollment if they were 18 years or older, weighed at least 50 kg (110 lb), had a fever (temperature ≥38.3°C [≥100.9°F]) and did not meet exclusion criteria of malignant hyperthermia or heat stroke, acute liver failure, therapeutic temperature management, or extracorporeal blood circuit therapy. Among the 41 patients, 3 did not have continuous rectal or bladder thermometry and therefore were excluded from this study. Approval was obtained from the appropriate institutional review board, and signed written informed consent was obtained from patients or patients' surrogates before data collection. Patients' characteristics, therapies administered during the study period, and ambient room temperature were recorded. Physical cooling and warming interventions were not permitted during the study period.

Temperatures measured with SpotOn were compared with rectal and bladder temperatures.

Temperature Measurement

Forehead Core Temperatures. Forehead core temperature was measured on all patients by using the noninvasive SpotOn temperature monitoring system during the study period. The SpotOn system is accurate for a temperature range of 25°C to 43°C (SD, 0.2°C). The disposable sensor (SpotOn Temperature Monitoring Sensor, model 36000) was connected to the control unit (SpotOn Temperature Monitoring System Control Unit, model 370). After the skin was cleansed with alcohol, the sensor was placed on the left lateral part of the patient's forehead above the orbital ridge. Time (1-4 minutes) was allotted for system equilibration of temperature from the deeper tissue to the skin surface.

Rectal Temperatures. Rectal temperatures were measured continuously by using temperature probes inserted at least 10 cm (3.9 in) into the rectum and connected to the Solar 8000i Bedside Monitor (GE Healthcare). The temperature probes (Level-1, Smiths Medical ASD Inc) have thermally sensitive resistors that measure temperature in the surrounding environment.

Bladder Temperatures. Bladder temperature-sensing catheters (DeRoyal, DeRoyal Industries, Inc) were used for continuous monitoring and were connected to the Solar 8000i Bedside Monitor. The bladder thermometers also have thermally sensitive resistors that measure the temperature of the urine flow through the catheter.

Calibration. All the thermometer systems used in the study were calibrated in accordance with manufacturers' recommendations. The same investigator (H.S.) applied the thermometry systems and measured temperatures to ensure fidelity to the study protocol. Simultaneous measurements of temperatures from both the SpotOn system and the rectal or bladder thermometry system were recorded at baseline, every 5 minutes for 15 minutes, and then every 15 minutes for the 4-hour study period.

Statistical Analysis

The Bland-Altman method[22] was used to analyze the comparison data to estimate the direction and extent of agreement and the precision among the measurement methods. Graphical plots of the method temperature differences were examined for patterns, and calculated estimates for agreement and precision were analyzed. Agreement is presented as the bias (mean difference) with the 95% CI. Precision is presented as the 95% LOA, either a single value (±[SD × 1.96]) or as upper and lower LOA values surrounding the bias (bias ± [SD × 1.96]). For example, if the bias is 0.25 with a standard deviation of 0.15, then the LOA would be 0.15 × 1.96 = ±0.29 or 0.25 ± 0.29 = -0.04, 0.54). In this article, both single values and upper and lower values for the 95% LOA are presented. A priori, we chose ±0.5°C as a clinically acceptable limit for agreement and precision. Consistent with previous thermometry method-comparison studies[13,16,17,20,23,24] in populations of critically ill patients, this limit was selected because differences beyond these limits are deemed clinically significant.

The proportion of temperature differences within ±0.5°C from SpotOn and corresponding rectal and bladder temperature comparisons were also computed for both groups. Large proportions of temperature

differences beyond ±0.5°C were interpreted as clinically relevant. Analysis of data for the subset of patients with external ventricular drainage devices was also conducted to evaluate for differences in agreement and precision.

A sample size for the method-comparison analysis was not calculated before the study because the sample was based on the number of patients eligible for the clinical trial. Yet, the sample sizes of 180 and 568 paired temperatures in the bladder and rectal comparisons, respectively, provided adequate power to detect a significant difference between the measurement methods. Data were analyzed by using SPSS, version 24, computer software (SPSS, Inc).

Results

A total of 748 paired temperature measurements from 38 patients from the clinical trial who had both SpotOn and either continuous rectal (n = 29) or bladder (n = 9) thermometry were included in this study. A total of 20 temperature pairs were recorded from all patients with the exception of 8 pairs collected from 1 patient who did not complete the primary study protocol. Patients' characteristics for the sample are shown in the Table. A total of 20 patients in the sample (53%) received acetaminophen during the study period. Temperature ranges during the study period were from 36.9°C to 39.7°C (rectal), 36.9°C to 39.9°C (bladder), and 36.6°C to 39.4°C (forehead core SpotOn).

Figures 2 and 3 display the Bland-Altman plots with graphical presentation of agreement and precision for SpotOn compared with bladder temperatures and SpotOn compared with rectal temperatures, respectively. Inspection of the data plots revealed no patterns of temperature differences between SpotOn and either rectal or bladder thermometry methods across the range of temperature values. The mean difference for SpotOn measurements compared with bladder measurements was -0.07°C (SD, 0.24°C; 95% CI, -0.04°C to -0.11°C) with 95% LOA of ±0.47°C (-0.54°C, 0.40°C). The mean difference for SpotOn measurements compared with rectal measurements was -0.24°C (SD, 0.29°C; 95% CI, -0.21°C to -0.26°C) with 95% LOA of ±0.57°C (-0.81°C, 0.33°C).

Most differences in temperature between the methods of measurement used were within ±0.5°C in both groups. The proportion of differences within ±0.5°C was high at 96% (95% CI, 93%-99%) in the bladder comparison group and 85% (95% CI, 82%-88%) in the rectal comparison group.

Table
Characteristics of 38 patients and the environment

Characteristic	Value
Age, mean (SD), range, y	57 (15), 20-78
Sex, male/female, No. (%)	20/18 (53/47)
Ethnicity, No. (%)	
Asian/Pacific Islander	10 (26)
Black	2 (5)
White	17 (45)
Hispanic	9 (24)
Admitting diagnosis type,[a] No. (%)	
Medical	9 (24)
Neurological	23 (61)
Surgical	6 (16)
APACHE II score, mean (SD), range	24 (6), 14-43
Body mass index,[b] mean (SD), range	29.8 (6.6), 18.1-48.2
Mechanical ventilation, No. (%)	26 (68)
Cause of fever, No. (%)	
Infectious	28 (74)
Neurological	10 (26)
Ambient ICU room temperature, mean (SD), °C	21.4 (1.2)
Temperature, mean (SD), range, °C	
Bladder comparison (n = 180)	
Urinary bladder	38.2 (0.61), 36.9-39.9
SpotOn forehead core	38.2 (0.71), 36.7-39.9
Rectal comparison (n = 568)	
Rectal	38.4 (0.53), 36.9-39.7
SpotOn forehead core	38.2 (0.59), 36.6-39.4

Abbreviations: APACHE, Acute Physiology and Chronic Health Evaluation; ICU, intensive care unit.
[a] Because of rounding, percentages may not total 100.
[b] Calculated as weight in kilograms divided by height in meters squared.

The subset of 10 patients who had neurological injury and an external ventricular drainage device had intracranial pressure monitoring as well as rectal thermometry. The results of the subgroup analysis of 200 paired SpotOn temperatures with rectal temperatures in this subset were similar to the results of the larger sample: subset mean difference -0.29°C (SD, 0.33°C) with 95% LOA of ±0.65°C (-0.95°C, 0.36°C).

No indications of skin irritation under the sensor were noted when the sensor was removed after 4.5 hours, and discomfort was not mentioned by patients who could self-report. Despite sweating in some patients during febrile periods and defervescence, the forehead ZHF sensors maintained their seal during the study period. Severe diaphoresis related to autonomic dysfunction in 1 neurologically injured patient did not disrupt the SpotOn thermometry system, and the ZHF sensor maintained its seal. Also, the mean difference between this patient's 20 paired rectal measurements and SpotOn temperatures was 0.24°C (SD, 0.11°C).

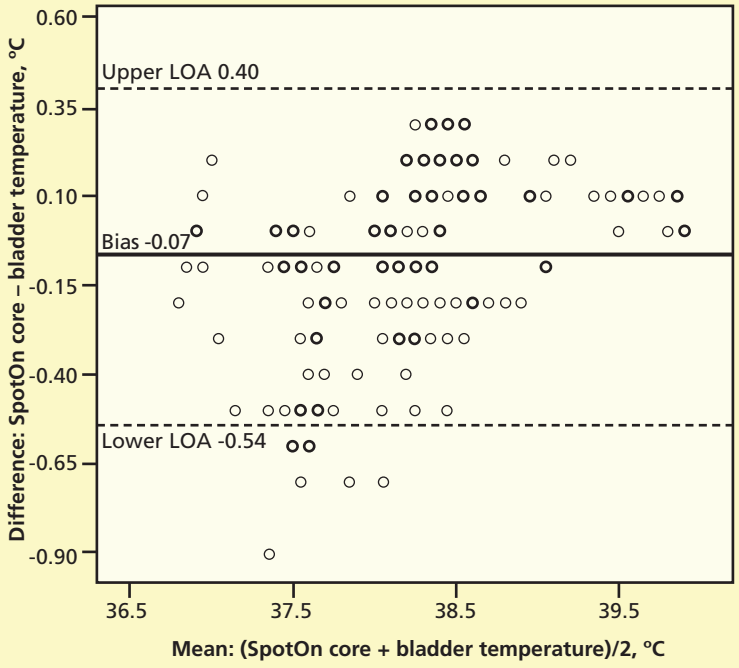

Figure 2 Bland-Altman plot of SpotOn forehead core temperatures and urinary bladder temperatures (n=180 paired measurements). Bias, -0.07˚C (SD, 0.24˚C); 95% limits of agreement (LOA), -0.54ºC, 0.40ºC. Bolded outline of plot points indicates multiple difference measures.

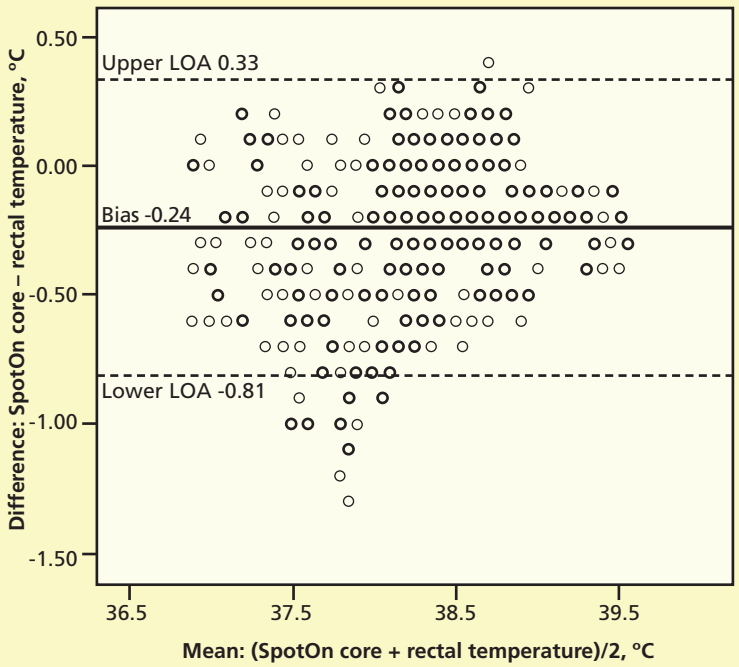

Figure 3 Bland-Altman plot of SpotOn forehead core temperatures and rectal temperatures (n = 568 paired measurements). Bias, -0.24˚C (SD, 0.29˚C); 95% limits of agreement (LOA), -0.81ºC, 0.33ºC. Bolded outline of plot points indicates multiple difference measures.

Discussion

This study is the first one in which the SpotOn system was compared with 2 established thermometry methods used to monitor core temperature in ICU patients. Our results indicate that the SpotOn system has excellent agreement with the established clinical thermometry systems. Both comparison groups were within the a priori defined accuracy limits (difference of means) for both bladder and rectal groups and revealed slight underestimates of temperature by the SpotOn system compared with both rectal and bladder temperatures. The SpotOn system also had good precision in both comparison groups even though the 95% LOA for the rectal group slightly exceeded the a priori defined clinically acceptable LOA of ±0.5°C for precision (95% LOA: bladder, ±0.47°C; rectal, ±0.57°C).

Eshraghi et al[16] evaluated the accuracy of the prototype SpotOn system by comparing the forehead core (SpotOn Prototype) with pulmonary artery temperatures in 105 cardiac surgical patients during intraoperative and postoperative ICU periods. The level of agreement and precision were sufficiently accurate for use in intraoperative and postoperative clinical practice: mean overall difference, -0.23°C (SD, 0.42°C) with 95% LOA of ±0.82°C (-1.06°C, 0.60°C). The levels of agreement and precision for the temperature comparisons in the postoperative ICU subset were similar to the combined intraoperative and postoperative estimates: mean difference, -0.32°C (SD, 0.38°C) with 95% LOA of ±0.74°C (-1.06°C, 0.42°C). Although Eshraghi et al compared SpotOn temperatures with pulmonary artery blood temperatures, the percentage of differences (84%) within 0.5°C in the ICU subset was similar to our findings.

In studies[16,17,20,25] of other thermometry systems with ZHF technology, mostly prototypes, temperatures obtained with the ZHF systems were compared with temperatures from pulmonary artery, esophageal, and bladder sources. In a method-comparison study[25] of esophageal and forehead core temperatures in which a ZHF thermometry prototype was used in patients during targeted hypothermia therapy and rewarming after cardiac arrest, the results indicated a good level of agreement, with a mean difference of -0.12°C, and good precision with a 95% LOA of ±0.48°C (-0.59°C, 0.36°C). Yet, Makinen et al[17] found poor agreement between SpotOn and nasopharyngeal temperatures in cardiac surgery patients during induced hypothermia. A limitation of our study was the lack of hypothermic patients in our sample; that condition warrants continuous

thermometry, especially during targeted temperature management in critically ill patients.

Makinen et al also compared the SpotOn system with esophageal thermometry in patients undergoing cardiac and vascular surgery and reported excellent agreement and precision: mean difference, 0.08 °C (SD, 0.16 °C) and a 95% LOA of ± 0.32 °C (-0.25 °C, 0.40 °C). Iden et al[26] compared nasopharyngeal temperatures with forehead core temperatures obtained by using the SpotOn system during elective surgical procedures and also found excellent agreement and precision: mean difference, 0.07 °C (SD, 0.21 °C) and a 95% LOA of ± 0.41 °C (-0.34 °C, 0.48 °C). The agreement and precision findings in both of these studies are similar to our findings for bladder thermometry. Esophageal and nasopharyngeal sources are considered accurate and reliable estimates of core temperature.

The 4-hour time frame of the study period is a limitation of our study. Further evaluation of sensor securement to maintain ZHF insulation and the related reliability over longer periods is warranted. Evaluation of the SpotOn system with cooling via fans and other physical interventions used in the ICU is also indicated because we did not permit physical cooling, including use of fans, during the study period. Another limitation of our study is that the SpotOn system was not evaluated in patients with spontaneous or induced mild hypothermia, a condition that warrants continuous thermometry.

Conclusion

The findings of our method-comparison study indicate that the SpotOn system is a suitable noninvasive alternative to established invasive methods for continuous thermometry in medical, surgical, and neurologically injured ICU patients. The SpotOn system is an appealing alternative for continuous measurement of core temperatures because of its unique noninvasive design. Further research to evaluate agreement and precision of the SpotOn system during longer periods and during targeted temperature therapies in ICU patients is warranted.

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