Accuracy of a New Zero-heat-flux Cutaneous Thermometer (SpotOn⊠) in Pediatric Intensive Care Patients

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Original

Accuracy of a New Zero-heat-flux Cutaneous Thermometer (SpotOn™) in Pediatric Intensive Care Patients

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Background: In pediatric intensive care, temperature management is very important and requires precise monitoring. The new zero-heat-flux cutaneous thermometer (SpotOn™) has been introduced as a measurement tool with good correlation to core body temperature. The aim of this study is to evaluate the accuracy of SpotOn™ in pediatric intensive care unit (ICU) patients.

Methods: Critically ill pediatric patients weighing less than 10 kg were included in this study. After admission to the ICU, core body temperature was measured with both the SpotOn™ system and a rectal thermistor and recorded at one-minute intervals.

Results: From 30 patients, 53,492 pairs of temperature data were collected and analyzed retrospectively. The median age and weight of the patients were 4.5 months and 5.6 kg, respectively. SpotOn™ showed a good correlation with measured rectal temperature, with a Pearson's correlation coefficient of 0.729 ($p<0.001$). However, a Bland-Altman analysis showed that the SpotOn™ bias in comparison to rectal temperature was +0.87℃ (SD: 0.51℃), and the 95% limits of agreement (LOA) were −0.14℃ and 1.83℃.

Conclusions: The SpotOn™ system has a low level of accuracy as a method of monitoring core body temperature in pediatric patients weighing less than 10 kg.

Key Words: core body temperature, pediatric, intensive care unit, SpotOn™, zero-heat-flux

Introduction

Body temperature is an important vital sign in the intensive care unit (ICU)[1] and is continuously monitored in ICU patients to evaluate the severity of patients' conditions and their reactions to the treatments. A strict temperature control may be required because surgery, inflammation from infectious diseases and sepsis, intracranial diseases, and many other pathologies can cause abnormal body temperatures. It has been reported that approximately 44% of ICU patients have a fever of 38.3°C or above, with a fever of 39.5°C or higher associated with an increased mortality risk.[2] For these reasons, body temperature is incorporated into the severity score of

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Figure 1 SpotOn™ system and zero-heat-flux (ZHF) technology.
The thermal insulator and warming circuit are used to eliminate the flow of skin-surface heat to the environment, establishing conditions in which the temperature gradient should be zero between the thermistor on the skin surface of forehead and deep tissue. Core temperature rises the surface through isothermal pathway. Figures are reprinted with permission from 3M.

critically ill patients to predict mortality.[3]

Debate surrounds the effects of active antipyretic treatments on patients with high fevers,[4, 5] targeted temperature management on patients with cerebral hypoxia following cardiac arrest,[6-8] proactive introduction of hypothermia in neonates with hypoxic-ischemic encephalopathy,[9, 10] and other similar treatments. Therefore, accurate measurement of body temperature is extremely important,[11] especially in pediatric patients in whom body temperatures rise rapidly.

According to established guidelines and previous research, the blood, bladder, nasopharyngeal, esophageal, and rectal temperatures reflect the core body temperature with particular accuracy.[1, 11-13] It has also proposed that an ideal body temperature monitor would be noninvasive, continuous, accurate, and easy to use.[12] Although the importance of accurately measuring core body temperature is recognized more in the pediatric ICU, there is no clear optimal measurement method as, unlike in adults, there are restrictions on the measurement sites and devices in pediatric patients.[14, 15]

SpotOn™ (3M, St. Paul, MN, US) is a new system that was designed for easy and continuous measurements of core body temperature using a sensor attached to the forehead[12, 16-23] (**Figure 1**). Recently, reports studying the correlation between temperatures measured with SpotOn™ and blood, esophageal, and rectal temperatures have begun to appear.[16-23] However, only an extremely small number of reports have been focused in pediatric patients.[21] In addition, most of these reports describe the measurement of body temperature during surgery, and few studies have reported the use of SpotOn™ in the ICU.[22, 23] Therefore, we conducted a retrospective study targeting SpotOn™ use with pediatric ICU patients. To our knowledge, no such reports have been published thus far. This study aims to demonstrate the accuracy of SpotOn™ by comparing it with the rectal temperature, which is commonly used to measure core body temperature in pediatric ICU patients.

Materials and Methods

This study is a single-center retrospective study conducted at Yokohama City University Hospital (Yokohama, Japan) under the approval of the ethics committee (approval number: B160401003), and registered in the University Hospital Medical Information Network (UMIN) (UMIN000038112, registration date: September 26, 2019). We targeted critically ill pediatric patients weighing less than 10 kg admitted to the ICU from February 27, 2015 to April 26, 2016. Neonates under 28 days of age and cases in which radiant warmers or forced-air warming systems were used were excluded. Written informed consent was obtained from the patients' guardians. The temperature in the ICU was adjusted to approximately 24°C.

After admission to the ICU, the patients' foreheads were wiped clean, the SpotOn™ sensor was attached, and temperature measurements were initiated. The SpotOn™ sensor was replaced every 24 hours. A thermistor temperature probe model 402J for infants (NIHON KOHDEN, Tokyo, Japan) was used to monitor rec-

tal temperatures. Nurses trained in pediatric intensive care inserted and secured the probe to a depth of 2-4 cm depending on the size of the patients. The rectal temperature probe was temporarily removed for treatments, such as nursing care, defecation, and diaper changes. The probe was then reinserted in the same manner, following the treatment.

Body temperatures measured by both SpotOn ™ (Tspot) and rectal temperature (Trect) were continuously recorded on the bedside monitor BSS-9800® (NIHON KOHDEN, Tokyo, Japan). Both data sets were collected at one-minute intervals and retrospectively analyzed.

Data obtained from the beginning of body temperature monitoring to temperature stabilization were excluded, as were the data for treatment periods and periods when the forehead sensor or the rectal probe was removed.

Categorical data are expressed as the number and percentage, n (%), and quantitative data are reported as median values and interquartile range (IQR). Pearson's correlation analysis was applied to assess the correlation between Tspot and Trect. Bland-Altman plots were used to test differences between Tspot and Trect and the mean bias, standard division (SD), and limits of agreement (LOA) were obtained. $P<0.05$ was considered to be statistically significant. Statistical analysis was performed using JMP™ Pro14 (SAS Institute, Cary, NC, USA).

Table 1 Patients' characteristics.

Patients' characteristics (n = 30)	Median	IQR
Age (month)	4.5	1.3-10.8
Weight (kg)	5.6	4.1-7.8
Sex (male/female)	14 / 16	
Mechanical ventilation (%)	28 (93.3)	
Use of catecolamines (%)	29 (96.7)	
Surgical patient (%)	26 (86.7)	
Cardiac surgery (CPB used)	20	
Cardiac surgery (CPB not used)	5	
Plastic surgery	1	
Non-Surgical patient (%)	4 (13.3)	
Heart failure	4	

Categorical data are expressed as number and percentage n (%), quantitative data are reported as median values and IQR.
CPB, cardiopulmonary bypass; IQR, interquartile range.

Results

Thirty patients who met the inclusion criteria were registered during the study period. Twenty-five patients were admitted to the ICU following cardiac surgery, one patient was admitted following plastic surgery, and four patients were admitted for internal medical treatment for heart failure. The median age and weight of the patients were 4.5 months [IQR: 1.3-10.8 months] and 5.6 kg [IQR: 4.1-7.8 kg], respectively (**Table 1**). A total of 53,492 pairs of temperature data from the 30 patients were subjected to analysis. Tspot showed a good correlation with Trect with a Pearson's correlation coefficient of 0.729 ($p<0.001$) (**Figure 2**). However, a Bland-Altman analysis showed that the Tspot bias in comparison to Trect was +0.87°C (SD: 0.51°C), and the 95% LOA were −0.14°C and 1.83°C (**Figure 3**). Furthermore, the SpotOn ™ sensor resulted in contact dermatitis in one

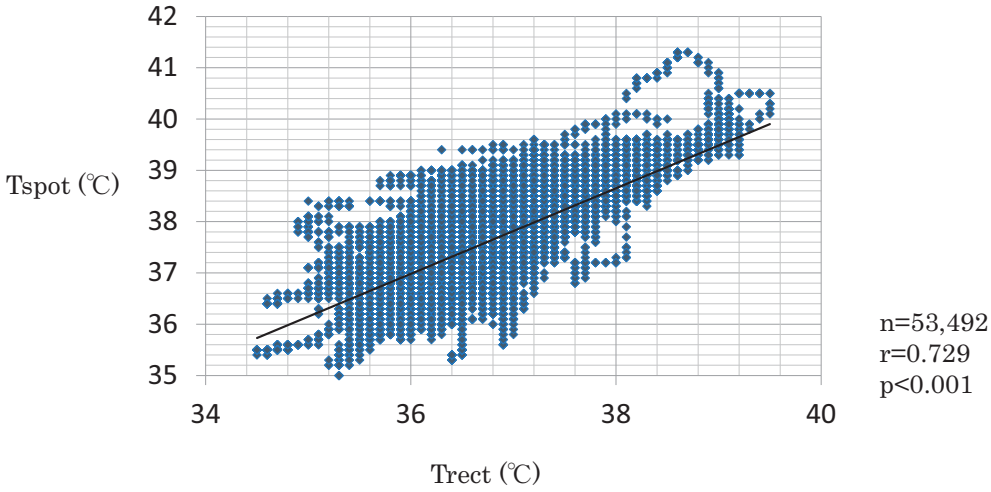

Figure 2 Pearson's correlation between Tspot and Trect.
Tspot, temperature measured by SpotOn; Trect, rectal temperature.

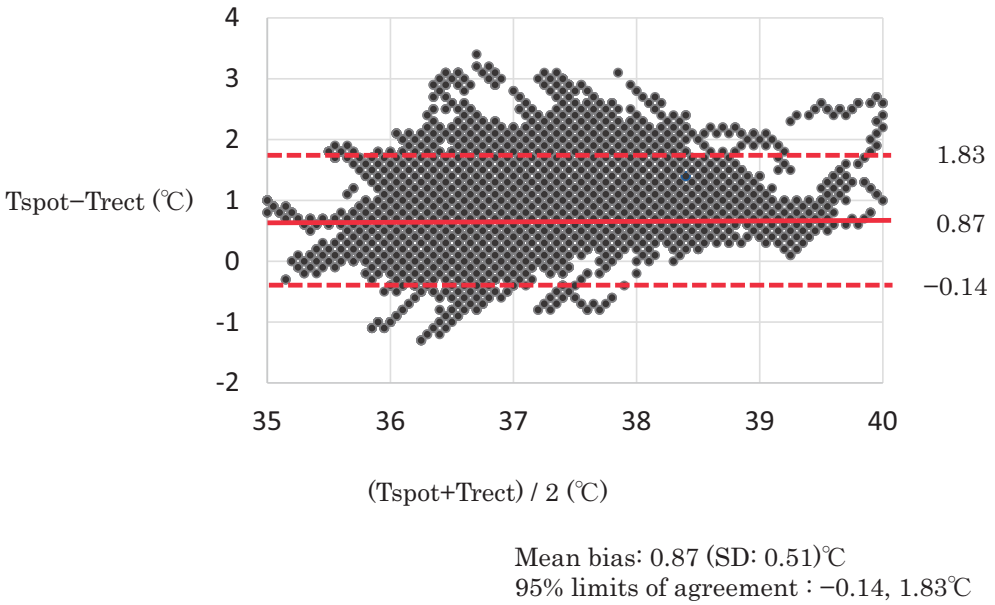

Figure 3 Bland and Altman plot between Tspot and Trect.
Solid line represents the bias between Tspot and Trect, and dotted lines represents the 95% limits of agreement.
Tspot, temperature measured by SpotOn™; Trect, rectal temperature; SD, standard division.

case, but improved after one week of observation.

Discussion

Our study is the first report on the accuracy of the SpotOn™ temperature measurement system for pediatric patients requiring intensive care. Although our analysis showed a good correlation between Tspot and Trect, there was also a difference of 0.87°C between the two, and only 15,385 pairs of temperature data in 53,492 pairs (28.8%) were within the bias range of ± 0.5°C, which is generally recognized as an acceptable error in body temperature monitoring.[12] These results highlight that attention must be paid to the accuracy of the SpotOn™ system in pediatric intensive care.

Several factors are thought to have caused this difference. First, the proportion of head size to body size increases as an infant's age decreases. Furthermore, the volume and blood flow in cerebral white matter and grey matter, as well as blood flow in the frontal lobe, change considerably as children grow.[24] These changes may have affected the temperature taken by SpotOn™, and therefore, resulted in measurement errors. The accumulation of further data on this topic is necessary, as there are currently no reports regarding the clinical use of SpotOn™ in infants weighing 10 kg or lower.

Second, 83.3% of patients in this study were post-cardiac surgery patients, and catecholamine was used in 96.7% of these patients. In cases of insufficient cardiac output, the difference between core body temperature and peripheral temperatures increases, such that the circulation of blood from the cold lower limbs decrease the rectal temperature.[25-27] Third, small infants are fundamentally sensitive to the external temperature, and cold blood flowing from the lower limbs, cooled by the surrounding environment, may have lowered the rectal temperatures. In addition, it is possible that the rectal temperatures may have been measured at lower levels due to the insertion depth of the probe becoming shallower as a result of body movement, which is common in ICU patients.

The SpotOn™ system is a recently available noninvasive and continuous core temperature monitoring system that uses zero-heat-flux (ZHF) technology.[12, 16-23] This system is composed of a control unit, a sensor cable, and a small 4-layer disposable sensor that is affixed to the lateral part of the patient's forehead.[12, 23] The thermal insulator and resistive warming circuit are used to eliminate the flow of skin-surface heat to the environment, establishing conditions in which the temperature gradient should be zero between the thermistor on the skin surface and deep

tissue.[12, 21, 23] SpotOn™ has been designed to monitor core body temperature by measuring the temperature 1-2 cm beneath the skin surface using an isothermal tunnel created under the sensor.[12, 23]

Reports until now regarding the use of SpotOn™ during surgery on adult patients have shown favorable correlations with other methods, such as blood, esophageal, and rectal temperatures that are used to measure core body temperature.[16-19] Differences between SpotOn™ and these methods are considered to be less in adults. Fizelier et al. showed, using 61,298 pairs of data from 52 adult patients in an ICU setting, that temperatures measured by SpotOn™ were only 0.19 ± 0.53°C higher than esophageal temperatures, with 92.6% of the measurements being within 0.5°C, thereby confirming a high level of accuracy.[22] Hildy and colleagues showed, using 748 pairs of data from 38 adult ICU patients, a favorable correlation with rectal and bladder temperatures.[23] These studies demonstrated that SpotOn™ is a new and useful method of continuously monitoring core body temperature in adult ICU patients, which can be used in place of other methods.

However, reports regarding SpotOn™ use in pediatric patients are extremely limited. Carvalho and colleagues compared SpotOn™ temperatures with esophageal temperatures in 54 children under 12 years of age, who were relatively older children in whom surgery was performed under general anesthesia.[21] The results showed a small difference of 0.14°C (95% LOA: −0.39°C to 0.66°C) and a favorable Lin's concordance correlation coefficient of 0.83, and they reported that SpotOn™ was a useful method to measure core body temperature during pediatric surgery.[21] To our knowledge, this is the only report that mentioned the use of SpotOn™ in pediatric patients.

Currently, body temperature measurements are performed at various sites on the body and in various ways. Both esophageal and nasopharyngeal temperatures are considered to correlate well with blood temperature.[1, 15] However, since the probe may interfere with the narrow airway of infants and cause patient discomfort, trauma, and perforations,[15] these methods are not suitable for long-term use in ICU patients and are primarily used for monitoring anesthetized patients in the operating room.[15, 28] Bladder temperature correlates well with blood temperature; however, due to the size limitations of bladder catheters equipped with thermistors, it is difficult to use this method in small infants.[15] Tympanic, axillary, and dermal temperatures are measured using noninvasive methods, but they are not recommended for use in the ICU as they deviate significantly from the core body temperature and have poor reproducibility.[1, 15, 29-31]

Rectal temperature, which we used in this study as a comparison subject, shows few differences from blood temperature. It, therefore, has been recognized as a regular method to measure the core body temperature in pediatric ICU patients and is commonly used instead of blood temperature.[15, 27] However, rectal temperature may sometimes deviate from blood temperature due to some factors. First, for patients in shock, blood flow to the rectum decreases, and the temperature measured can be relatively low.[15, 27] Rectal temperature may also be affected by stools, heat-producing bowel organisms, and cool blood returning from the lower limbs.[15] Furthermore, rectal ulcers, perianal abscess, and hemorrhaging may occur, and the risk of a vagal response and cross contamination cannot be ignored.[30-34] Due to these concerns, the establishment of a new, continuous, noninvasive, and reliable method to monitor core body temperature is extremely important in pediatric intensive care.

There are several limitations to this study. This study was a retrospective study conducted at a single center, and many of the cases studied involved post-cardiac surgery patients. Furthermore, the control in this study was the rectal temperature; the fact that comparisons were not conducted with blood temperature, the gold standard for core body temperature, is also a significant limitation. However, this method is highly invasive, and there were limited indications for the use of intravascular devices, such as pulmonary artery catheters for pediatric patients. These points provide challenges for future research. As mentioned previously, this study is the first to use SpotOn™ to monitor small pediatric patients in the ICU. To overcome the limitations of this study, other body temperature measurement methods, including blood temperature, should be compared to SpotOn™. Also, additional data targeting a variety of pediatric ICU patients, including those from multi-centers, should be analyzed.

Conclusion

Body temperature measured by SpotOn™ showed a relatively significant measurement difference in measurement from rectal temperature in small pediatric ICU patients weighing 10 kg or less. The SpotOn™ bias in comparison to rectal temperature was +0.87℃ (SD: 0.51℃), and the 95% LOA were −0.14℃ and 1.83℃. This indicates that SpotOn™ is not recommended as a method of monitoring core body temperature in pediatric ICU patients, due to its low level of accuracy. Further research is necessary to evaluate the accuracy and utility of this device in pediatric ICU patients.

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Conflicts of Interest: The authors have no conflicts of interest to declare.

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