



Feasibility and accuracy of pediatric core temperature measurement using an esophageal probe inserted through the gastric lumen of a second-generation supraglottic airway device: a prospective observational study

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Background: Accurate core temperature measurement in children is crucial; however, measuring esophageal temperature (T_E) using a supraglottic airway device (SAD) can be challenging. Second-generation SADs, which have a gastric channel, can measure T_E , and reduce gastric air volume. This study aimed to compare T_E , measured using a probe inserted through the SAD gastric channel, with tympanic membrane (T_{TM}) and forehead (T_{ZHF}) temperatures, measured using a zero-heat-flux cutaneous thermometer, with rectal temperature (T_R).

Methods: Temperature was recorded at 10-min intervals from 10 min after probe insertion until completion of surgery. We performed an equivalence test to evaluate whether the T_E , T_{TM} , and T_{ZHF} were equivalent to T_R , with a margin of 0.3°C . Additionally, intraclass correlation coefficients (ICC) were calculated to assess the reliability of T_E and T_R at each time point.

Results: We included 41 patients in the final analysis. In all patients, the esophageal probe was successfully inserted through the gastric channel of the SAD. When assessing agreement with T_R as a reference, T_E demonstrated equivalent results at all time points ($P < 0.001$ at 0, 10, 20, 30, and 40-min intervals and $P = 0.018$ at the 50-min interval), except at the completion of surgery ($P = 0.697$). T_E also demonstrated good reliability with T_R as a reference throughout the surgery ($\text{ICC} > 0.75$).

Conclusions: In children with SAD insertion, T_E can be accurately and feasibly measured through the SAD's gastric channel, making it suitable for routine application.

Keywords: Anesthesia; Esophagus; Pediatrics; Rectum; Temperature; Tympanic membrane.

INTRODUCTION

Inadvertent perioperative hypothermia is relatively common in patients undergoing general anesthesia and may sig-

nificantly impact patient outcomes adversely [1]. The risk of perioperative hypothermia is higher in pediatric patients than in adult patients, owing to their proportionately larger body surface area and impaired physiological compensatory

mechanisms [2,3]. Adequate core temperature measurement is a prerequisite for detecting and controlling core temperature in pediatric patients during surgery.

Core temperature can be measured at various sites using different techniques. The gold standard for thermoregulation in pediatric patients remains rectal temperature (T_R) measurement [4]. However, this technique can cause complications such as rectal perforation, increased blood pressure, and decreased partial pressure of oxygen [5]. As an alternative, esophageal temperature (T_E), which allows continuous monitoring with minimal adverse effects, is commonly employed in pediatric patients.

The supraglottic airway device (SAD) is widely used in patients undergoing general anesthesia. However, its use makes measuring T_E challenging because it fills the oral cavity. Most second-generation SADs, including AuraGain, i-Gel, Supreme, and ProSeal laryngeal mask airways, which are commonly used nowadays, have a gastric channel that facilitates access to the esophagus and stomach [6]. The gastric channel provides a passage for T_E probe insertion, enabling gastric decompression through removal of air in the stomach resulting from mask ventilation.

In this study, we aimed to assess the feasibility and accuracy of core temperature measurement using a T_E probe inserted through the gastric lumen of a second-generation SAD in pediatric patients. Furthermore, we aimed to examine correlations between T_E and tympanic membrane (T_{TM}) and forehead (T_{ZHF}) cutaneous temperatures in pediatric patients, using T_R as the reference. Additionally, we assessed the gastric decompression effect obtained by performing suction through the T_E probe inserted through the SAD.

MATERIALS AND METHODS

Ethical considerations

This prospective observational study was approved by the Institutional Review Board of Asan Medical Center (Seoul, Korea) (IRB# 2020-1695) in November 2020. Written informed consent was obtained from the legal guardians of each participating patient on the day before surgery. This study was registered at ClinicalTrials.gov (NCT05705206, Principal Investigator: Ha-Jung Kim). This manuscript adheres to the applicable Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement. Our study was conducted in accordance with the Ethical Principles for Medical Research Involving Human Subjects,

as outlined in the Helsinki Declaration.

Patients

Patients aged < 6 years, weighing 10–30 kg, and with an American Society of Anesthesiologists physical status of I–III who were scheduled to undergo general anesthesia using a SAD were enrolled in this study conducted between March 2021 and March 2022. Patients who refused to participate had tumors of the esophagus or esophageal varices, had a monitoring device inserted through the esophagus intraoperatively, had ear inflammation, had a congenital anomaly of the rectum, or were judged ineligible to participate by the medical staff for other reasons, were excluded from the study.

Anesthesia

The patient's preoperative, morphometric, and demographic characteristics were recorded in the ward before consent was obtained. The patients were instructed to fast from midnight the day before surgery. Upon arrival in the operating room, patients were monitored using pulse oximetry, electrocardiography, and noninvasive blood pressure measurements. Preoxygenation was performed, and thiopental (4–5 mg/kg) was administered. When the eyelash reflex subsided, mask ventilation was performed with 5–6% sevoflurane and 100% oxygen for 3 min. Neuromuscular blocking agents were not administered. If the depth of anesthesia was considered sufficient, a second-generation SAD (Ambu® AuraGain™) was placed, and a T_E probe of 9 Fr (standard transverse [ST] probe, S&S MED) was inserted through the gastric channel (Fig. 1). The locations of the SAD and T_E probe were confirmed using sonography [7]. Temperature was measured using a non-invasive zero-heat-flux

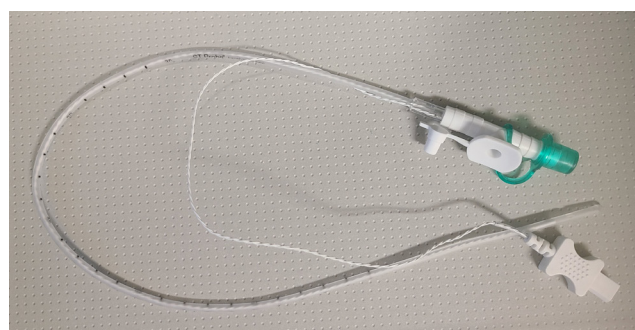


Fig. 1. ST probe with 9Fr used to measure esophageal temperature. ST: standard transverse.

(ZHF) cutaneous thermometer (3MTM Bair HuggerTM Temperature Patient Sensor, Arizant Healthcare Inc.) attached to the patient's lateral forehead and a T_R probe (E-temp, Ewha Biomedics) [8]. The temperature of the operating room was controlled using an air conditioner, and a forced-air warming system (Bair Hugger, Augustine Medical Inc.) was used to maintain normothermic body temperature in each patient.

Outcome assessment

The primary objective was to assess the feasibility and accuracy of body temperature measurement using a T_E probe inserted through the gastric channel of a SAD. As secondary objectives, T_{TM} and T_{ZHF} were compared, with T_R as the reference. Additionally, suction functionality of the T_E probe inserted through the SAD was evaluated.

T_E , T_R , and T_{ZHF} were measured 10 min after probe insertion or attachment to ensure consistency by allowing the external thermistor of the device to reach equilibrium with the ambient temperature. T_{TM} was measured using a Braun ThermoScan 6 (Braun ThermoScan 4020, Braun GmbH) by the same operator for each patient, and two measured values were averaged to enhance the objectivity of the measurement. We measured the temperature at 10-min intervals throughout the surgery. All measurements were performed and recorded by a single anesthesiologist.

Sonography of the gastric antrum was conducted by the attending anesthesiologist using a GE Logiq P9 ultrasound machine with a 12-MHz linear probe (GE Healthcare). The appearance of acoustic shadows or comet-tails after air was injected through the gastric channel was considered to indicate gastric insufflation [9]. Subsequently, negative pressure was applied to the T_E probe to decompress the stomach, and the effects were evaluated via sonography. Once air was removed, the attending anesthesiologist performed sonography to confirm the successful removal and qualitatively assess the absence of air [10,11]. The antrum was considered empty if it appeared flat, with the anterior and posterior walls in close proximity.

RESULTS

A total of 67 pediatric patients, aged < 6 years and weighing 10–30 kg, who were scheduled to undergo general anesthesia, were assessed for eligibility. Among them, one who had a congenital anomaly of the rectum and 24 whose guardians declined participation were excluded. Subsequently, the remaining 42 patients were enrolled. However, one patient was excluded from the final analysis due to an error in the thermometer device. The STROBE flow diagram of patient selection and dropout is presented in Fig. 2. The patients' demographic characteristics and perioperative variables are presented in Table 1. Table 2 shows the range of body temperature data according to the measurement sites during anesthesia.

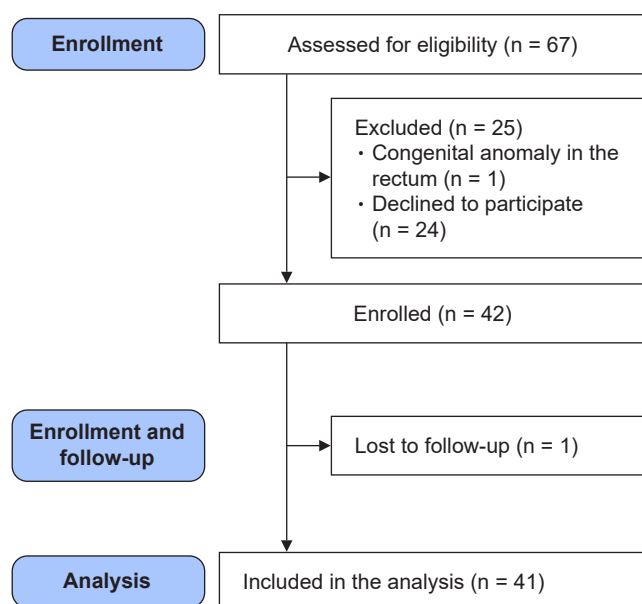


Fig. 2. Flowchart of the study population in accordance with STROBE guidelines. STROBE: Strengthening the Reporting of Observational Studies in Epidemiology.

Table 1. Patient Characteristics and Perioperative Variables

Variables	Patients (n = 41)
Baseline characteristics	
Age (mo)	41.1 ± 22.2
M/F	23/18 (56.1/43.9)
Weight (kg)	18.3 ± 14.1
Height (cm)	98.2 ± 15.4
ASA PS 1/2	21/20 (51.2/48.8)
Intraoperative data	
Anesthetic time (min)	110.3 ± 43.9
Operation time (min)	60.8 ± 37.8
Type of surgery	
Hand surgery	17 (41.5)
Arm surgery	9 (22.0)
Knee surgery	1 (2.4)
Foot surgery	14 (34.1)

Values are presented as mean ± SD, number only, or number (%). ASA PS: American Society of Anesthesiologists physical status.

In all patients, the esophageal probe was successfully inserted through the gastric channel of the SAD. The results of the equivalence test are presented in Table 3, and the Bland-Altman plots illustrating the relationships of T_E , T_{TM} , and T_{ZHF} with T_R are shown in Fig. 3. When considering the initial temperature measurements, the smallest difference was observed with T_E , while the largest difference was noted with T_{TM} , using T_R as a reference. Overall, the minimal difference between temperatures was observed between measurements in the esophagus and rectum during the 0–40-min period, and between the tympanic membrane and rectum from 50–60-min period. When agreement was examined with T_R as a reference, T_E demonstrated equivalent results to

T_R ($P < 0.001$ at 0, 10, 20, 30, and 40-min intervals and $P = 0.018$ at 50-min intervals), except at the 60-min interval ($P = 0.697$). Compared with T_R , T_{TM} was not equivalent until 30 min after surgery ($P > 0.999$ at 0, 10, and 20-min intervals and $P = 0.084$ at the 30-min interval) and then showed equivalent results until the end of the surgery ($P = 0.006$, $P = 0.025$, $P = 0.013$ at the 40, 50, 60-min intervals). When T_{ZHF} was compared with T_R as a reference, there was no difference from 10 min to 40 min after the surgery ($P = 0.216$, $P < 0.001$, $P = 0.003$, $P < 0.001$, $P = 0.048$, $P > 0.999$, $P > 0.999$ at 10-min intervals from 0 to 60 min).

Analysis of the intraclass correlation coefficients (ICCs) at each time point revealed that T_E exhibited good reliability with T_R as the reference throughout the intraoperative period ($ICC > 0.75$, Table 4). Both T_{ZHF} and T_{TM} exhibited reliability exceeding the moderate level intraoperatively; however, T_E exhibited the best reliability among the three measurement methods.

In 33 of the 41 included patients, gastric suction through the T_E probe effectively reduced gastric air volume (80.5%). Gastric decompression was not clearly observed on sonography in the remaining eight patients.

Statistical analysis

Based on our clinical experience and findings from a previous study, we considered a difference of up to 0.3°C with a standard deviation (SD) of 0.5 to be accurate [12]. Sample size calculation revealed that enrolling 32 patients would result in a power of 90% at an α -level of 0.05. A final sample size of 42 was selected to account for potential dropout rates.

The Bland-Altman method, which accounts for the agreement of repeated measurements, was used to analyze the

Table 2. Range of Body Temperature Data according to the Measurement Sites during Anesthesia

Time (min)	T_E	T_R	T_{TM}	T_{ZHF}
0	36.9 ± 0.6	36.9 ± 0.6	36.5 ± 0.5	37.1 ± 0.6
10	36.7 ± 0.5	36.7 ± 0.6	36.3 ± 0.5	36.8 ± 0.5
20	36.5 ± 0.5	36.5 ± 0.6	36.2 ± 0.5	36.6 ± 0.5
30	36.4 ± 0.6	36.4 ± 0.6	36.2 ± 0.5	36.5 ± 0.5
40	36.5 ± 0.6	36.3 ± 0.6	36.3 ± 0.6	36.6 ± 0.6
50	36.5 ± 0.6	36.3 ± 0.7	36.3 ± 0.6	36.6 ± 0.6
60	36.6 ± 0.6	36.3 ± 0.7	36.8 ± 0.6	36.7 ± 0.7
70	36.8 ± 0.6	36.5 ± 0.7	36.5 ± 0.6	36.8 ± 0.6
80	36.9 ± 0.5	36.5 ± 0.7	36.7 ± 0.5	36.8 ± 0.6
90	37.0 ± 0.5	36.6 ± 0.5	36.7 ± 0.3	36.9 ± 0.6
100	37.1 ± 0.5	36.7 ± 0.6	36.8 ± 0.3	36.9 ± 0.7
110	37.1 ± 0.1	36.7 ± 0.2	36.8 ± 0.2	37.1 ± 0.2
120	37.0 ± 0.2	36.7 ± 0.2	36.7 ± 0.3	37.0 ± 0.2

Values are presented as mean \pm SD. T_E : core temperature measured in the esophagus, T_R : core temperature measured in the rectum, T_{TM} : core temperature measured in the tympanic membrane, T_{ZHF} : core temperature measured using a zero-heat flux thermometer on the forehead cutaneous site.

Table 3. The Results of the Equivalent Test with T_R as a Reference

Time (min)	T_E				T_{TM}				T_{ZHF}			
	Mean difference	95% CI	P value		Mean difference	95% CI	P value		Mean difference	95% CI	P value	
0	0.030	-0.055	0.115	$< 0.001^*$	0.433	0.319	0.547	> 0.999	0.215	0.077	0.353	0.219
10	-0.025	-0.117	0.067	$< 0.001^*$	0.482	0.381	0.582	> 0.999	0.085	-0.016	0.186	$< 0.001^*$
20	-0.068	-0.161	0.026	$< 0.001^*$	0.418	0.313	0.522	> 0.999	0.073	-0.072	0.217	0.003*
30	0.010	-0.088	0.108	$< 0.001^*$	0.189	0.061	0.316	0.084	0.125	0.036	0.214	$< 0.001^*$
40	0.108	0.018	0.197	$< 0.001^*$	0.113	-0.017	0.244	0.006*	0.200	0.101	0.299	0.048*
50	0.181	0.084	0.279	0.018*	0.139	0.001	0.278	0.025*	0.305	0.172	0.439	> 0.999
60	0.280	0.176	0.384	0.697	-0.046	-0.242	0.150	0.013*	0.357	0.227	0.486	> 0.999

CI: confidence interval, T_R : core temperature measured in the rectum, T_E : core temperature measured in the esophagus, T_{TM} : core temperature measured in the tympanic membrane, T_{ZHF} : core temperature measured using a zero-heat flux thermometer on the forehead cutaneous site. * $P < 0.05$, it means less than the mean difference ± 0.3 .

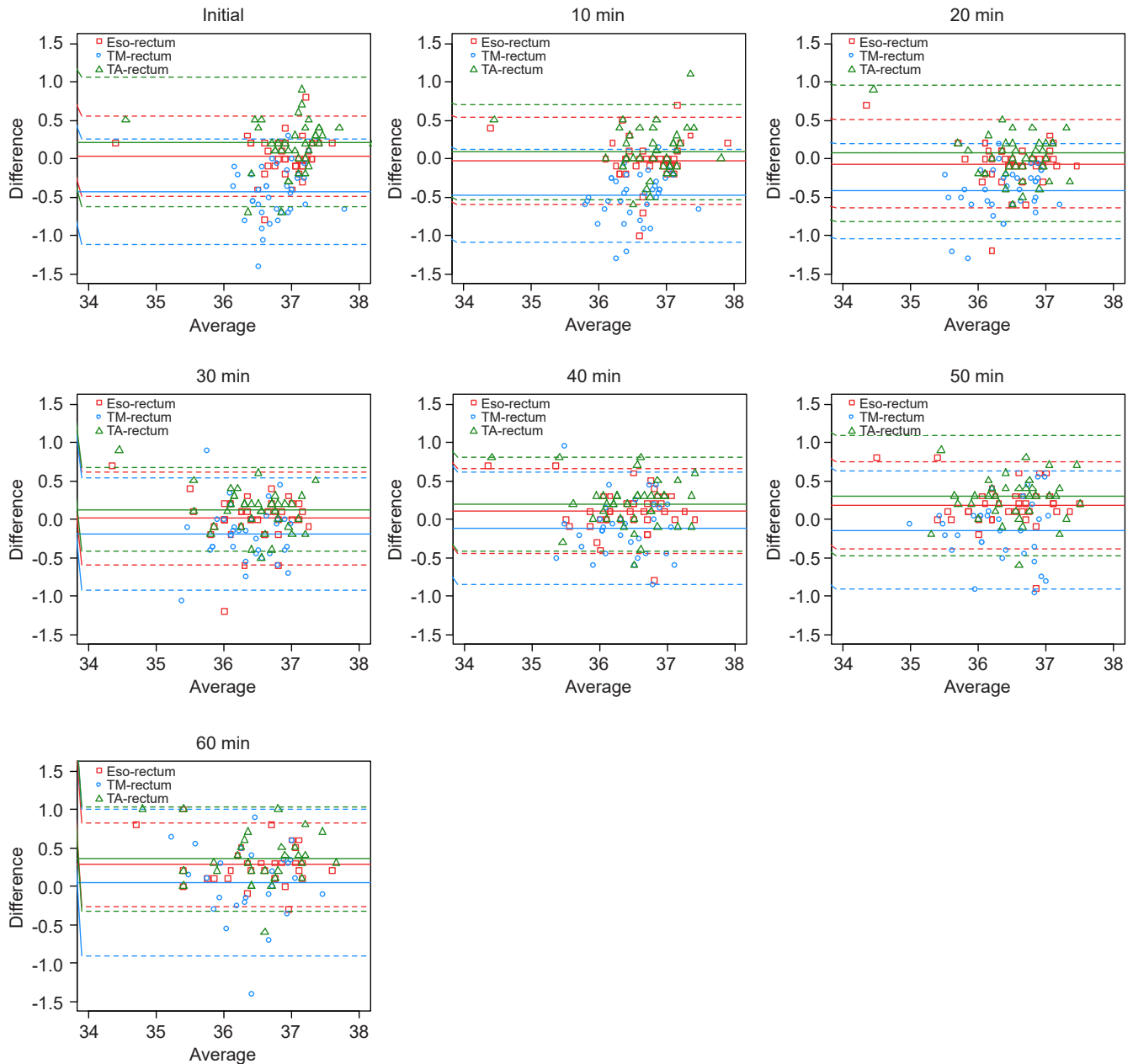


Fig. 3. Results of the Bland-Altman analysis comparing the temperatures recorded in the esophagus, tympanic membrane, and forehead with those recorded in the rectum. The solid line is the mean value of the difference, and the dashed line is the mean \pm 1.96 standard deviation.

accuracy of T_E measurement through the SAD and compare it with that of T_{TM} , T_{ZHP} and T_R [13]. We performed an equivalence test to evaluate whether the T_E , T_{ZHP} and T_{TM} values were equivalent to the T_R value with a margin of 0.3°C . For reliability analysis, we calculated ICCs using a two-way random model [14]. Categorical variables were presented as numbers and percentages. Continuous variables were presented as means \pm SDs with 95% confidence intervals. All analyses were performed using SAS software, version 9.4

(SAS Institute Inc.).

DISCUSSION

We observed T_E measurement using a second-generation SAD to be highly accurate and reliable in pediatric patients undergoing general anesthesia, with T_R as a reference, and it was feasible in all patients. Moreover, effective reduction of gastric air volume was achieved through suction via the gas-

Table 4. Reliability in Temperature

Time (min)	T_E & T_R			T_{TM} & T_R			T_{ZHF} & T_R		
	ICC*	95% CI		ICC*	95% CI		ICC*	95% CI	
0	0.890	0.812	0.937	0.593	-0.028	0.833	0.690	0.453	0.826
10	0.863	0.768	0.920	0.625	-0.080	0.868	0.825	0.706	0.898
20	0.854	0.753	0.915	0.692	-0.017	0.890	0.677	0.490	0.804
30	0.860	0.764	0.919	0.760	0.572	0.865	0.856	0.722	0.923
40	0.879	0.778	0.933	0.793	0.658	0.878	0.826	0.574	0.918
50	0.864	0.664	0.936	0.808	0.677	0.888	0.711	0.302	0.866
60	0.843	0.314	0.944	0.740	0.581	0.845	0.771	0.174	0.915

ICC: intraclass correlation coefficient, CI: confidence interval, T_E : core temperature measured in the esophagus, T_{TM} : core temperature measured in the tympanic membrane, T_{ZHF} : core temperature measured using a zero-heat flux thermometer on the forehead cutaneous site, T_R : core temperature measured in the rectum. *Values of ICC were within 0–1 and were classified as follows: less than 0.5, poor; between 0.5–0.75, moderate; between 0.75–0.9, good; greater than 0.9, excellent.

tric channel of the second-generation SAD.

Accurate intraoperative temperature monitoring is important, especially in children. Several guidelines exist for perioperative temperature monitoring, but none of them specify the best device or site for temperature measurement [15,16]. To ensure patient safety, an ideal temperature monitoring technique should accurately reflect the core temperature while being non-invasive [17]. The device or site used for measuring body temperature is selected based on the type of surgery, accessibility of monitoring sites, and physician's preference. To the best of our knowledge, this is the first study investigating the most appropriate temperature measurement device and site for accurately determining the core temperature with the utilization of SAD in pediatric patients undergoing surgery.

Our study demonstrated that T_E measurements obtained using a SAD exhibited higher agreement and reliability over an extended period than T_{TM} or T_{ZHF} measurements when T_R was used as a reference. This could be attributed to the fact that the distal esophagus receives sufficient blood perfusion from the core, resulting in more accurate and consistent temperature measurements than those at other sites. However, when T_R serves as the reference point in an equivalent test, accuracy of T_E decreases towards the end of the surgery. Conversely, T_{TM} may be more accurate toward the end of surgery, as its accuracy is maintained throughout the later stages. The tympanic membrane, which is located near the hypothalamus, can indeed reflect core temperature [15]. However, accurately inserting the temperature probe can be challenging, particularly in pediatric patients with a small aural canal. Furthermore, concerns exist regarding the feasibility of continuous measurement, reliance on the operator's skill for determining accuracy, and variability of measure-

ments [18]. These limitations prevent precise core temperature measurement using this method [19]. Other monitoring devices, such as zero-heat-flux cutaneous thermometers, have an appealing theoretical basis; however, inconsistent accuracy has been noted, both in our study and in previous studies [19,20].

SADs have gained popularity as advantageous airway management tools in pediatric patients [21]. However, the absence of space for temperature probe insertion in previous SADs necessitated its insertion through the nasopharynx [6]. Consequently, accurate body temperature measurement was challenging due to the cooling effect of anesthetic gases and the potential for procedural trauma during probe insertion into the nasopharynx [22,23]. In a previous study, body temperature measurements in patients with SAD insertion primarily focused on pharyngeal measurements [24]; however, the incorporation of a gastric channel in second-generation SADs for improved esophageal access enables accurate temperature measurement in the distal esophagus and smooth insertion of temperature probes.

In contrast to tracheal intubation, utilization of SADs may lead to increased gastric insufflation in a pressure-dependent manner [25,26]. Moreover, even minor malpositioning of the SAD can result in air leakage from its seal, causing air to flow into the esophagus [27]. Gastric insufflation may increase the risk of pulmonary aspiration of gastric contents and postoperative nausea and vomiting, particularly in high-risk pediatric patients, such as those with an impaired ability to protect their airways [28,29]. The gastric channel of second-generation SADs offers the additional advantage of effectively allowing the suctioning of air that might be introduced into the stomach during mask ventilation [30].

The first limitation of our study pertains to the accuracy of

the T_E probe placement in routine clinical practice. The sensor is intended to be placed in the distal esophagus close to the pulmonary artery, and this is confirmed using sonography [31]. A previous study has demonstrated that the accuracy of T_E measurement increases when the probe is appropriately positioned [32]. However, performing sonography in routine clinical practice is challenging, which might reduce the accuracy compared with that in our study. The second limitation is that our findings are applicable only within a limited range of temperature variations. While events such as tourniquet deflation and cardiopulmonary bypass application could induce rapid and extreme changes in body temperature, such events were not examined in this study.

In conclusion, we demonstrated that T_E measurement through a second-generation SAD is feasible and accurate, making it suitable for routine use in pediatric patients with SAD insertion. Moreover, utilization of suction through the gastric channel of a second-generation SAD effectively reduces gastric air volume.

FUNDING

None.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

DATA AVAILABILITY STATEMENT

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

AUTHOR CONTRIBUTIONS

Writing - original draft: Yeon-Ju Kim, Eundong Lee, Jaedo Lee, Ha-Jung Kim. Writing - review & editing: Hyungtae Kim, Won Uk Koh, Young-Jin Ro, Ha-Jung Kim. Conceptualization: Hyungtae Kim, Won Uk Koh, Young-Jin Ro, Ha-Jung Kim. Data curation: Yeon-Ju Kim, Eundong Lee, Jaedo Lee, Hyungtae Kim, Won Uk Koh, Ha-Jung Kim. Formal analysis: Yeon-Ju Kim, Jaedo Lee, Won Uk Koh, Ha-Jung Kim. Methodology: Ha-Jung Kim. Investigation: Ha-Jung Kim. Resources: Yeon-Ju Kim, Ha-Jung Kim. Supervision: Won Uk Koh, Young-Jin Ro, Ha-Jung Kim.

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