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ORIGINAL ARTICLE

Usefulness of an automatic cuff pressure controller (SmartCuff) in inhibiting gasleakage around the cuff after tracheal intubation: a randomized controlled study

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Abstract

Purpose Gas leakage around the cuff of a tracheal tube may frequently occur after tracheal intubation and inflation of the cuff. We assessed if the SmartCuff (Smiths Medical Japan, Tokyo, Japan), an automatic cuff pressure controller, would effectively prevent gas leakage.

Methods Seventy adult patients were allocated randomly to one of two groups. After induction of general anesthesia and tracheal intubation, in one group (Syringe group), a syringe was used to inflate the cuff, until there was no audible gas leakage, at the airway pressure at 20 cmH_2O. In the other group (SmartCuff group), the SmartCuff was used to maintain the cuff pressure to be 20 cmH_2O. The mechanical ventilation (tidal volume of 8 $ml.kg^{-1}$ and 12 breaths per min) was started. The incidence and percentage of gas leakage, and the proportion of adequate seal (defined as gas leakage of < 10%) between the groups were compared.

Results The incidence of audible gas leakage was significantly higher in the Syringe group (10 of 35 patients (28%)) than in the SmartCuff group (none of 35 patients (0%)) (P = 0.00046, 95%CI for difference: 15–43%), and the proportion of adequate seal was significantly lower in the Syringe group (19 of 35 patients (54%)) than in the Smart cuff group (33 of 35 patients (94%)) (P = 0.0001, 95% CI for difference: 20–58%).

Conclusion Gas leakage may frequently occur after tracheal intubation, and the use of the SmartCuff can effectively maintain the sealing effect of the cuff.

Keywords Airway management · Tracheal intubation · Intracuff pressure · Cuff pressure monitor

Introduction

When tracheal intubation is indicated in adults, inflation of the cuff of a tracheal tube is usually required, to prevent gas leakage around the cuff during positive-pressure ventilation, and to minimize pulmonary aspiration of gastric contents. One major problem with the use of a cuffed tracheal tube is that, when the cuff in overinflated, the pressure exerted by the cuff to the surrounding tissues becomes too high [1], increasing the risk of respiratory complications, such as postoperative sore throat, hoarseness or tissue necrosis [2, 3]. In contrast, if the cuff pressure becomes too low, the incidence of gas leakage around the cuff and of pulmonary aspiration is increased, leading to insufficient ventilation and ventilator-associated pneumonia [4, 5]. Therefore, the cuff of the tracheal tube should be inflated with an adequate volume of air, to achieve an adequate seal around the cuff, and to prevent an excessive pressure exserted by the cuff on the tracheal mucosa.

One adequate inflation method is to inflate the cuff using a syringe with the minimum volume of air, so that there is no gas leakage around the cuff, while the peak airway pressure is maintained to the normal range (usually 20 cmH_2O) (just-seal cuff inflation method) [6–8]. One possible problem with this inflation method is that, when no nitrous oxide is used during anesthesia, the intracuff pressure would frequently be decreased. Nevertheless, there have been no formal studies which assessed the incidence of gas leakage around the cuff when the cuff is inflated with the just-seal inflation method.

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The SmartCuff (Smiths Medical Japan, Tokyo, Japan), a handy automatic cuff pressure controller, has been shown to be able to inflate the cuff with a set intracuff pressure, and to minimize the changes in the cuff pressure during anesthesia [9]. There have been no studies which assessed if the SmartCuff can effectively prevent gas leakage.

The main aim of the study was to assess if the SmartCuff would effectively prevent gas leakage around the cuff, after tracheal intubation.

Methods

The institutional research ethics committee of Dokkyo Medical University Saitama Medica Center approved the study (approved number: 21001; approved date: 17th May, 2021), and written informed consent was obtained from all the participants. We have registered this study with JRCT (Japan Registry of Clinical Trials: jRCT10322110192, principal investigator: Yasuhisa Okuda, on 9th July, 2021), before recruitment of the first subject. This manuscript adheres to the applicable Consolidated Standards of Reporting Trials (CONSORT) guidelines.

In a randomized controlled design, we studied (from 12 July, 2021 to 18 November, 2022) 70 adult patients, aged 20 years or older, American Society of Anesthesiologists (ASA) physical status 1or 2, who were scheduled for elective surgeries in the supine position under general anesthesia in an operating room, in whom tracheal intubation was required. We excluded patients who were pregnant, morbidly obese (body mass index > 35 $kg.m^{-2}$), at increased risk of pulmonary aspiration of gastric contents, having any pathology of the neck or the upper respiratory tract, or unable to consent. We also excluded patients, in whom ventilation through a facemask or tracheal intubation was predicted to be difficult (*e.g.* Mallampati [10] class III or class IV of the modification by Samsoon and Young [11], mouth opening < 3 cm, restricted neck movement, the thyromental distance < 6 cm), or those who would require high airway pressures during intermittent positive pressure ventilation.

Patients were allocated randomly to one of two groups. In one group (Syringe group), a syringe was used to inflate the cuff of a tracheal tube, whereas in the other group (SmartCuff group), the SmartCuff was used to inflate the cuff, after tracheal intubation. Random allocation was made using a block randomization (in block of 10), and each allocation was indicated in a card placed into a sealed opaque envelope.

No premedication was given. In the operating room, the patient was placed supine on an operating table, with the patient's head on a pillow (6 to 7 cm in height). Routine monitors, such as a non-invasive blood pressure cuff, an electrocardiogram, and a pulse oximeter, were applied, and an intravenous cannula (20 or 22 gauge) was inserted either at the back of the hand or the wrist. Shortly before induction of anesthesia, each anesthesiologist opened an envelope, and confirmed the allocation.

After preoxygenation of the patient with 100% oxygen (with the fresh gas flow at 6 $L.min^{-1}$) through a facemask for more than 3 min, general anesthesia was induced with intravenous propofol 2 $mg.kg^{-1}$ and fentanyl 2–4 $\mu g.kg^{-1}$, and neuromuscular blockade was produced with rocuronium 0.6–0.8 $mg.kg^{-1}$. The method of maintaining anesthesia was at the discretion of the anesthesiologist in charge, but the use of nitrous oxide was not allowed.

A tracheal tube with a taper-guard cuff (Covidien, Tokyo, Japan), with the internal diameter of 8.0-mm was used in a male patient, or of 7.0-mm was used in a female patient. Water-soluble lubricant was applied to the cuff of a tracheal tube shortly before tracheal intubation. The patient's mouth was opened, a McGrath® Mac (Covidien, Tokyo, Japan) videolaryngoscope was inserted to confirm the glottis, and a tube was inserted into the trachea, so that the glottis was located between two depth marker lines on the tracheal tube. With this positioning, the depth mark of the tube would be approximately 21–23 cm at the gap between the upper and lower teeth, and the cuff of the tracheal tube would be located at the lower segment of the cervical trachea, 3 to 4 cm beyond the glottis [9, 12]. If tracheal intubation failed twice, the patient was withdrawn from the study, the airway was managed appropriately by the anesthesiologist in charge (*e.g.* another attempts at tracheal intubation using another videolaryngoscope or a fiberoptic bronchoscope, or insertion of a supraglottic airway).

In the Syringe group, anesthesiologist maintained the airway pressure of 20 cmH_2O by manually squeezing an anesthesia reservoir bag. An assistant attached a 10-ml syringe to the pilot balloon valve of the tracheal tube, infused air until there was no audible gas leakage around the cuff (just-seal cuff inflation method), and then detached the syringe from the valve. When a high-volume, low-pressure cuff of a tracheal tube is inflated with the just-seal cuff inflation method, the intracuff pressure should be the same as the pressure exerted by the cuff to the inner surface of the trachea, and thus should be the same as the peak airway pressure (20 cm H_2O) during positive-pressure ventilation [6, 7]. In the SmartCuff group, the SmartCuff was connected to the pilot balloon valve of the tracheal tube, and the cuff pressure was adjusted to be 20 cmH_2O; the SmartCuff was kept attached to the pilot valve of the tube to maintained the intracuff pressure to be 20 cmH_2O.

In both groups, correct tracheal intubation was confirmed by the presence of end-tidal carbon dioxide waveforms, and by auscultation of the chest. If the tube was found to be inadvertently inserted to the esophagus, the tube was taken out, and tracheal intubation was achieved. The patient was withdrawn from the study. The

volume-controlled intermittent positive-pressure ventilation was started, with the ventilator setting of an approximate tidal inspiratory volume of 8 $ml.kg^{-1}$ of the body weight of the patient, and 12 breaths per min, without the positive end-expiratory pressure (PEEP). The inspiratory volumes were provided by a ventilator bellows of the Dräger Fabius Plus (Dräger Medical Japan, Tokyo, Japan), which does not automatically adjust the inspiratory volumes based on the measured expiratory volumes. Oxygen concentration of fresh gas could be adjusted by the anesthesiologist, but the fresh gas flow was kept constant at 6 $L.min^{-1}$ (*e.g.* 4 $L.min^{-1}$ of air and 2 $L.min^{-1}$ of oxygen), during the study period. If the peak airway pressure exceeded 20 cmH_2O with this ventilator setting, the patient was withdrawn from the study.

Using a spirometer (Haloscale® Wright Respirometer, Standard type, nSpire Health Ltd, London, UK), which had been placed between the expiratory side of the breathing tube and the anesthesia machine, the volume of gas returned to the ventilator of the anesthesia machine during 10 respirations was measured, starting at 1 min, 5 min, and 10 min after confirmation of correct tracheal intubation. The mean expired tidal volume was calculated, by diving the measured volume by 10.

If audible gas leakage occurred, the study was terminated, and the cuff of the tracheal tube was inflated using the VBM Cuff Control Inflator (Smiths Medical, Tokyo, Japan). If arterial hemoglobin oxygen saturation (SpO_2) decreased to less than 95%, the study was abandoned immediately, and appropriate treatment was performed. The patient was withdrawn from the study.

The percentage of gas leakage around the cuff was calculated using the following formula.

$$\text{Percentage of gas leakage} = \frac{\text{set inspiratory volume} - \text{measured expiratory tidal volume}}{\text{set inspiratory volume}} \times 100$$

In a preliminary observation, we found that the expiratory tidal volume measured by the spirometer was up to 10% larger or smaller than the set inspiratory volume, when there was no gas leakage. Therefore, we judged that the sealing effect of the tracheal tube cuff was adequate when the calculated percentage of gas leakage was less than 10%.

We also recorded the presence or absence of gas leakage during general anesthesia. When audible gas leakage occurred, the ventilator bellows frequently failed to deliver the set tidal volume, necessitating inflation of the cuff of the tracheal tube. The study was terminated when this occurred. These measurements and the presence and absence of gas leakage were assessed by one of anesthesiologists who was not blind to allocation of patients.

Statistical analysis

The primary outcome measure was the incidence of audible gas leakage around the cuff. Fisher's exact test was used to compare the incidences of gas leakage around the cuff between the two groups. The secondary outcome measures included the proportion of the patients in whom the sealing effect of the tracheal tube cuff was adequate. Fisher's exact test was used to compare the proportions of the patients with adequate sealing effect. The 95% confidence intervals (CI) for the difference in the incidence between the groups were also calculated.

For baseline comparisons, we calculated standardized differences [13], using Cohen's *d* (for continuous data) and Cohen's *h* (for proportions). For the primary outcome measure, we judged that there was a significant difference between the groups, if $P < 0.05$. For the secondary outcome measures, we regarded hypothesis tests as subsidiary, but if $P < 0.001$, we judged that there was a significant difference between the groups.

From our preliminary observation, the incidence of gas leakage in the control group (with the use of a syringe) was about 30%. We expected that the use of the SmartCuff would prevent gas leakage and its incidence would be up to 3–4%. Manual calculations using Altman's nomogram [14] as well as G*Power 3 [15] have indicated that 35 patients per each group would be required to detect this difference, with a power of 0.8, and $P = 0.05$.

Results

We studied 70 patients without withdrawals during the study period (Fig. 1). Patients' characteristics and a set tidal volume after tracheal intubation were similar between the two groups (Table 1).

Within 10 min after tracheal intubation and after inflation of its cuff, audible gas leakage around the cuff occurred in 10 of 35 patients (28%) in the Syringe group, whereas it occurred in none of 35 patients (0%) in the SmartCuff group. The incidence was significantly lower with the SmartCuff group than the Syringe group ($P = 0.00046$, 95% CI for difference: 15–43%).

In the patients in whom no audible gas leakage occurred, the percentages of gas leakage ranged from 0.4 to 47% in the Syringe group, and 0 to 12% in the SmartCuff group (Fig. 2). The sealing effect of the tracheal tube cuff remained adequate during the initial 10 min of tracheal intubation, in 19 of 35 patients (54%) in the Syringe group, and in 33 of 35 patients (94%) in the Smart cuff group; there was a significant difference between the two groups ($P = 0.0001$, 95% CI for difference: 20–58%).

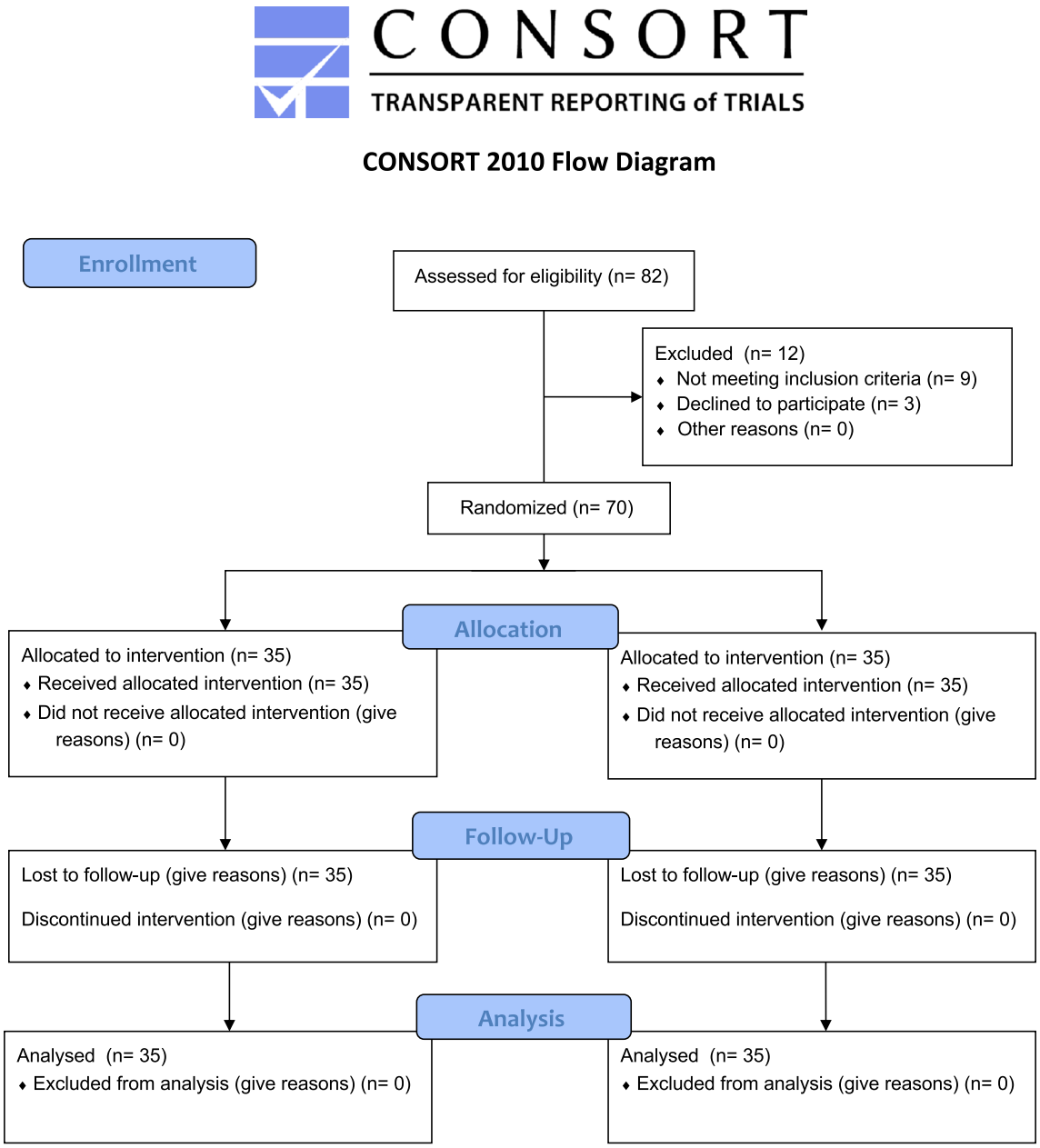

Fig. 1 CONSORT flowchart for the clinical study

Table 1 Patients' characteristics and a set tidal volume after tracheal intubation (Mean (standard deviation) [range] or number)

	Syringe group	SmartCuff group	Standardized difference*
Sex (males/females)	17/18	15/20	0.13
Age (yr)	61 (14.9) [25–79]	62 (13.8) [27–80]	0.12
Height (cm)	160 (7.7) [144–177]	159 (9.5) [142–181]	0.076
Weight (kg)	61 (9.5) [42–80]	60 (11.2) [38–96]	0.082
Body mass index (kg/m^2)	24 (3.1) [17–32]	24 (3.9) [15–34]	0.032
Set tidal volume (ml)	482 (59) [340–640]	479 (63) [350–630]	0.047

*Standardized differences were calculated using Cohen's *d* (for continuous data) and Cohen's *h* (for proportions).

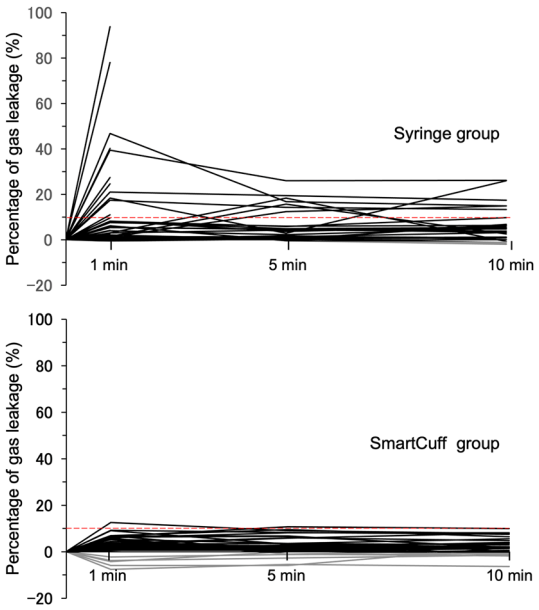

Fig. 2 Individual time-series plots for the percentage of gas leakage around the cuff of a tracheal tube (1 min, 5 min, and 10 min after tracheal intubation and inflation of the cuff) when the cuff was inflated with the minimum volume of air (using a syringe) to prevent gas leakage around the cuff at the airway pressure of 20 cmH_2O (the Syringe group: upper figure), and when cuff pressure was inflated with the SmartCuff with the pressure setting of 20 cmH_2O (the SmartCuff group: lower figure). The percentages of "gas leakage" are indicated in black, whereas the minus percentages of "gas leakage" in grey. The sealing effect of the cuff is judged adequate when the percentage of gas leakage is less than 10% (red dotted line)

In no patient in either group, was there any complication which required termination of the study, nor was there any gas leakage during anesthesia (after 10 min of tracheal intubation).

Discussion

We have shown that, when the cuff of a tracheal tube is inflated with the minimum volume of air to prevent gas leakage around the cuff, gas leakage frequently occurs shortly after inflation of the cuff, and that the use of the SmartCuff can effectively maintain the minimum sealing effect of the cuff.

The intracuff pressure of a tracheal tube may be increased by several different circumstances, such as the use of nitrous oxide during anesthesia, pressure to the neck, pneumoperitoneum during laparoscopic surgery, and the head-down position of the patient [9]. Numerous reports have shown that nitrous oxide markedly increases the intracuff pressure, because nitrous oxide easily diffuses into the cuff [16, 17]. In contrast, there have been no studies which assessed possible changes in the intracuff pressure during anesthesia, when no nitrous oxide is used, and when the cuff is initially inflated with the minimum volume of air just to prevent gas leakage around the cuff.

In our study, when the cuff of a tracheal tube was inflated with the minimum volume of air, and no nitrous oxide was being used during anesthesia, gas leakage frequently occurred shortly after cuff inflation. The reason for gas leakage is not clear, but one possibility is as follows. The diameter of a low-pressure, high-volume cuff of a tracheal tube is designed to be longer than the estimated internal diameter of the tracheal lumen, so that the cuff can seal the gap between the tracheal tube and tracheal lumen, before the cuff is inflated maximally. Therefore, when the cuff is inflated with the minimum volume of air to prevent air leakage around the cuff, the cuff would not be inflated evenly, producing wrinkling of the cuff. The air would distribute over time more evenly in the cuff, so that the area of the cuff attaching to the tracheal lumen would decrease, leading to the decrease in the cuff pressure [9], and gas leakage.

In addition, the sealing effect might have been obtained by a lubricant (which was applied to the tracheal tube cuff) filling the gap between the cuff and the tracheal lumen, even if cuff inflation was not sufficient enough to prevent gas leakage. Positive-pressure ventilation might have blown off the lubricant from the gap, leading to gas leakage.

In our previous study [9], we have shown that the SmartCuff can effectively prevent the increase in the cuff pressure of a tracheal tube in patients undergoing laparoscopic surgeries. In the current study, we have confirmed that the SmartCuff minimizes the changes in the cuff pressure, and would effectively prevent gas leakage around the cuff.

Limitations of the study include that we used only one type of a tracheal tube, made by a manufacturer, and thus the results of the incidence and percentage of gas leakage may not be applicable to other tracheal tubes. We assessed the percentage of gas leakage up to 10 min after tracheal intubation, so that we might have failed to detect gas leakage which occurred after 10 min. Nevertheless, as the Fig. 2 indicates, gas leakage, if any, always occurred within 10 min, and we did not notice any audible gas leakage after 10 min. The presence or the absence of gas leakage around the cuff was judged subjectively by an anesthesiologist who was not blind to patients' allocation, and thus there is a possibility of bias toward the SmartCuff group. The influence of this possibility can be regarded as low, as there was a high incidence of failed ventilation in the Syringe group.

We used the just-seal cuff inflation method with the peak airway pressure of 20 cmH_2O, and this pressure might have been too low. Nevertheless, this pressure is urually used in a daily clinical practice setting [7, 8]. In addition, in the SmartCuff group, in which the intracuff pressure was maintained at 20 cmH_2O, no audible gas leakage occurred in any patient. Therefore, the peak airway pressure (20 cmH_2O)

in the Syringe group would not have been too low. We did not measure the cuff volume and the intracuff pressure (by a conventional intracuff pressure monitor), so that the intracuff pressure in the Syringe group could have been lower (or higher) than in the SmartCuff group. Nevertheless, this is unlikely because of the following reasons. When a tracheal tube with a high-volume, low-pressure cuff is used, the intracuff pressure is theoretically the same as the pressure exerted by the cuff to the inner tracheal wall, and the pressure is also theoretically the same as the peak airway pressure, when the just-seal inflation method is used. Previous studies [6, 7] have shown that these theoretical relationships are true. In addition, in our preliminary observations, we have confirmed that the intracuff pressure was similar to the peak airway pressure (20 cmH_20), when the just-seal inflation method was used.

In conclusion, gas leakage may frequently occur shortly after tracheal intubation and inflation of its cuff, increasing the risk of insufficient ventilation and pulmonary aspiration. The use of the SmartCuff can effectively maintain the sealing effect of the cuff.

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Author contributions KU: This author helped in the study conception and design, proposal writing, data collection and management, as well as writing the initial draft and approving the final version of the manuscript. TA: This author made the study conception and design, proposal writing, data management, analysis and interpretation, as well as drafting and approving the final version of the manuscript. YO: This author helped in the study design, proposal writing, as well as revising and approving the final version of the manuscript.

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Data availability The data that support the findings of this study are available from the corresponding author upon reasonable request.

Declarations

Conflict of interests HA and TS, YO have no conflict of interest; TA is an Associate Editor-in-Chief of the *Journal of Anesthesia*.

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