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Trials

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The selection of ventilation devices in children with mild or moderate upper respiratory tract infections: a randomised controlled trial

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Abstract

Purpose Administering anaesthesia to children with upper respiratory tract infections (URTIs) increases the risk of perioperative respiratory adverse events (PRAEs). Several observational studies have suggested that the supraglottic airway (SGA) technique could be a potential alternative for airway management in children. This randomised controlled trial assesses whether using a SGA instead of an endotracheal tube (ETT) in children with mild or moderate URTIs affects the incidence of PRAEs.

Methods A total of 78 paediatric patients with mild or moderate URTIs who received either a SGA or ETT were included. Patients were monitored for adverse events such as cough, laryngospasm, bronchospasm, breath-holding, postoperative stridor or desaturation (< 90%) during the following stages: induction of anaesthesia, tube placement, surgery, tube removal and postanaesthesia care.

Results Throughout the perioperative period, 56.4% (44/78) of children experienced PRAEs. The incidence was 77.5% (31/40) in those receiving ETT and 34.1% (13/38) in those receiving SGA. The relative risk (RR) of PRAEs in children receiving SGA was 0.417 (95% CI: 0.248–0.701) compared with those receiving ETT ($p < 0.001$). Specifically, the incidence of minor PRAEs was significantly lower in the SGA group (28.9%, 11/38) compared with the ETT group (67.5%, 27/40) (RR: 0.429, 95% CI: 0.249–0.738, $p < 0.001$). There were significant differences between the groups in the incidence of perioperative cough ($p = 0.043$) and desaturation ($p = 0.031$).

Conclusion Using a SGA reduced the incidence of coughing, bronchospasm and oxygen desaturation, providing an acceptable alternative to ETT in children with mild or moderate URTIs.

Keywords Airway management, Paediatric anaesthesia, Respiratory adverse events, Upper respiratory tract infection, Postanaesthesia care unit

Introduction

Children often suffer from upper respiratory tract infections (URTIs), and some require anaesthesia for emergency surgeries during this period. Anaesthesia in children with URTIs increases the risk of perioperative respiratory adverse events (PRAEs), such as bronchospasm, breath-holding, cough, laryngospasm and oxygen desaturation, which complicate perioperative management [1, 2]. However, studies suggest that these adverse

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events typically do not result in long-term morbidity [3]. As a result, many clinicians agree that children with mild, uncomplicated URTIs can safely undergo non-airway-instrumentation procedures. Nonetheless, variations in the definitions of URTIs and clinical outcomes have made establishing standardised, evidence-based guidelines challenging.

Currently, the standard anaesthetic approach for managing the airways in children involves using an endotracheal tube (ETT). Although an ETT provides a secure airway, it is associated with certain drawbacks, including the potential for airway trauma and a higher incidence of adverse events such as laryngospasm and increased airway resistance [4, 5]. In contrast, the supraglottic airway (SGA) technique has gained popularity as an alternative due to its ease of insertion and lower incidence of certain adverse events, making it an attractive option in many paediatric patients [4, 5]. Despite the growing use of SGA, no studies have evaluated the comparative effects of SGA and ETT on the incidence of PRAEs in children with URTIs receiving anaesthesia. We hypothesise that SGA may offer superior benefits in reducing the incidence of PRAEs in children with mild or moderate URTIs. Therefore, this study explores the efficacy and safety of a SGA as an alternative to an ETT in this specific patient population.

Methods

Study participants

This study was conducted at Hebei Children's Hospital as a single-centre randomised controlled trial (RCT). It was approved by the ethics committee of our hospital (No. 165) on 15 March 2021 and registered in the China Clinical Trial Registry (ChiCTR1900025530). The study adhered to the principles of the Helsinki Declaration, and data publication followed the CONSORT 2010 checklist for RCTs. Informed consent was obtained from all parents/guardians after a detailed discussion with the patients and their parents/guardians by a qualified physician (JS). A total of 86 children with mild to moderate URTIs were enrolled using convenience sampling. Upper respiratory tract infections were defined as the presence of at least two of the following symptoms: rhinorrhoea, sore or scratchy throat, sneezing, nasal congestion, malaise, cough or fever exceeding 38 °C. All participants had an American Society of Anesthesiologists (ASA) physical status classification of I or II and were scheduled for elective surgery. The surgical procedures included urological, ophthalmological, orthopaedic and general surgeries.

The inclusion criteria were as follows: patients (1) who met the diagnostic criteria for mild to moderate acute URTI in the Clinical Diagnosis and Treatment Guidelines: Paediatric Internal Medicine [6] based on symptoms; (2) aged 11–96 months, with a weight of 9–25 kg; (3) initially diagnosed with mild to moderate acute URTI, which required a clinical diagnosis of URTI severity; (4) with a white blood cell count of $>10\times10^9$/L; and (5) classified as ASA physical status I or II. The exclusion criteria were as follows: patients (1) classified as ASA physical status III or higher; (2) with abnormal airway anatomy; (3) who underwent surgery involving the upper or lower airway; and (4) who suffered from severe URTI, defined as having systemic symptoms, such as high fever (>38.5 °C), significant respiratory distress or requiring systemic medication.

Implementation of randomisation

Patients diagnosed with URTI who were scheduled for surgery were randomly assigned by an anaesthesiologist (WJC) to receive either SGA or ETT through computer-generated variable block randomisation. The allocation was concealed using sequentially numbered, sealed randomisation envelopes. Sequence generation and preparation of randomisation envelopes were carried out by an individual (WJC) independent of the research team, who had no further involvement in the trial. The envelopes were opened immediately before anaesthesia induction by the anaesthetist. Study personnel were informed of the randomisation outcome only after the envelope was opened.

Anaesthesia management [7]

Patients in the ETT group were intubated orally with a high-volume, low-pressure-cuff plain ETT (Tuoren Medical Equipment Co., Ltd., Xinxiang, Henan, China, appropriate size: age/4 + 3.5) using direct laryngoscopy by the attending or resident anaesthetist. The size of the SGA, specifically the laryngeal mask (Ambu AuraFlex, Ambu Inc, Ballerup, Denmark), was selected based on the manufacturer's recommendations (size 2 for patients weighing 10–20 kg and size 2.5 for those weighing 20–30 kg). After lubrication of the posterior surface with water-based jelly, the SGA was inserted using a standard digital technique. The cuff was fully deflated before insertion, and the pressure was < 30 cmH_2O after insertion. The tube was connected to the anaesthesia circuit, and gentle manual ventilation was commenced. If airway management remained unsatisfactory (SaO_2 < 90% for more than 10 s), the anaesthetist replaced the SGA with tracheal intubation.

All children were evaluated preoperatively using a standard protocol, which included an assessment of their respiratory status and a review of their medical history to confirm eligibility. Patients were transferred to the postanaesthesia care unit (PACU) by the

anaesthesiologist after ensuring that they were able to maintain adequate airway patency and followed up by the study team until 1 day after surgery. In the PACU, if patients required supplemental oxygen, it was provided via nasal cannula or oxygen mask.

Data collection and outcomes analysis

Patients were observed for the appearance of any adverse events, such as severe cough (>10 s), laryngospasm, bronchospasm, breath-holding (>15 s), postoperative stridor or desaturation < 90% (>10 s) during the following stages: induction of anaesthesia, tube placement, surgery, tube removal and in the PACU. All observations were recorded by qualified professionals, including physicians and nurses with over 5 years of clinical experience, who were not involved in the study. The incidence of events was documented in the medical record system from the initiation of anaesthesia until discharge from the PACU, and the records were subsequently reviewed by the data collection personnel. On the day after the children's surgery, the incidences of postoperative sore throat, nausea and vomiting were also recorded. The major PRAEs included laryngospasm and bronchospasm. Minor PRAEs included cough, breath-holding, desaturation (SaO_2 < 90% for more than 10 s) and postoperative stridor.

The primary outcome was the comparison of the effect of SGA versus ETT on the incidence of PRAEs. The secondary outcome included the incidence of PRAEs during different periods (intraoperative or PACU), as well as the incidence of various types of PRAEs. All data were collected by an anaesthesiologist and an operating room nurse. The study was conducted between January 2020 and December 2021.

Statistical analysis

All data were recorded using a standardised data collection sheet and analysed using the statistical software, SPSS Statistics 18 (SPSS Inc., Chicago, IL, USA). The sample size was calculated using the following formula: $N = Z^2 \times (P \times [1-P]) \ / \ E^2$. In this formula, $\alpha = 0.05$ represents the significance level, and $\beta = 0.1$ corresponds to the type II error rate; N denotes the required total sample size, with Z representing the standard score for the desired confidence level, P indicating the estimated proportion of the population exhibiting the studied characteristic (such as the expected prevalence or probability of the primary outcome) and E representing the margin of error, which defines the desired precision level for the estimate. According to the prevalence rate (30%) obtained from the literature, the sample size was calculated as 37 children in each group. Due to the possibility of unavailable data or surgery cancellations, a dropout of 5% was foreseen in each group; therefore, it was decided to recruit at least 80 participants.

This study conducted data analysis according to the per-protocol principle. Comparisons between the two groups (SGA group vs ETT group) were performed using the Student's *t*-test for normally distributed continuous variables and the Mann–Whitney U test for non-normally distributed variables. The chi-squared test or Fisher's exact test was used for categorical variables, depending on the expected counts. The primary outcome was the comparison of the effect of SGA versus ETT on the incidence of PRAEs, with multivariate logistic regression analysis conducted to address potential confounders, including variables that were significantly different at baseline or potentially relevant to the outcome. The results were adjusted for these variables to estimate the adjusted odds ratios with 95% CIs. Sensitivity analyses, including a worst-case scenario where all missing data were assumed to have adverse outcomes, were performed to test the robustness of the findings; however, the alpha estimate was not corrected for multiple comparisons. A p-value of < 0.05 was considered statistically significant.

Results

Of the 86 participants, 6 were not included in the analysis: 3 due to cancelled procedures and 3 meeting the exclusion criteria. The complete data were available for 80 children, consisting of 40 patients assigned to the SGA group and 40 assigned to the ETT group (Fig. 1). Two patients in the SGA group needed an ETT due to excessive leak: there were thus 38 patients in the SGA group. Participant demographics and surgical speciality are presented in Table 1, and patient anaesthesia management details are presented in Table 2. There were no significant differences between the two groups in terms of age, ASA physical status, duration of anesthesia and surgery, or the experience level of the anesthesia personnel. Additionally, the distribution of orthopedic, ophthalmologic, and general surgical procedures was comparable between the groups.

Throughout the perioperative period, 56.4% (44/78) of children experienced PRAEs, with an incidence of 77.5% (31/40) in those receiving ETT and 34.1% (13/38) in those receiving SGA (see Table 3 for details). The relative risk (RR) of PRAEs in children receiving SGA was 0.417 (95% CI: 0.248–0.701) compared with those receiving ETT ($p < 0.001$). Specifically, the incidence of minor PRAEs was significantly lower in the SGA group (28.9%, 11/38) compared with the ETT group (67.5%, 27/40) (RR: 0.429, 95% CI: 0.249–0.738, $p < 0.001$), whereas no significant difference was found in major PRAEs. Intraoperatively, the incidence of PRAEs in the SGA group (23.7%, 9/38) was significantly lower than in the ETT group (72.5%,

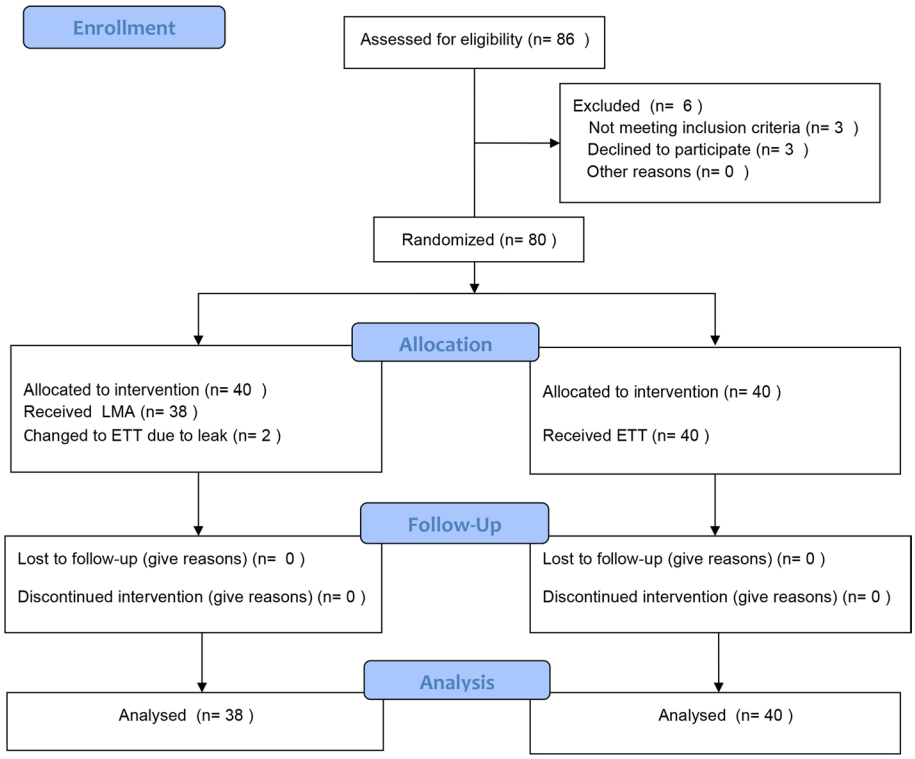

Fig. 1 Trial profile. SGA, laryngeal mask airway; ETT, endotracheal tube

Table 1 Demographics and characteristics

	SGA ($n=38$)	ETT ($n=40$)
Age (months, mean ± SD)	30.4 ± 21.3	26.6 ± 13.4
Sex (male / female), *n*	27 / 11	30 / 10
Weight (kg, mean ± SD)	12.4 ± 2.8	15.6 ± 3.8
URTI (mild / moderate), *n*	28 / 10	32 / 8
Family history of [*n* (%)]		
Smoking	20 (52.7)	18 (45.0)
Asthma	3 (7.9)	1 (2.5)
Surgical service [*n* (%)]		
Urology	19 (50.0)	22 (55.0)
Ophthalmology	5 (13.2)	4 (10.0)
Orthopedic surgery	4 (10.5)	6 (15.0)
General surgery	6 (15.8)	3 (7.5)
Other	4 (10.5)	5 (12.5)

SGA Supraglottic airway, *ETT* Endotracheal tube, *URTI* Upper respiratory tract infections

Table 2 Anesthetic management of participants

	SGA ($n=38$)	ETT ($n=40$)
Induction of anaesthesia [*n* (%)]		
Inhalational	3 (7.9)	2 (5.0)
Intravenous	35 (92.1)	38 (95.0)
Anesthesia maintenance [*n* (%)]		
Propofol + remifentanil	16 (42.1)	15 (37.5)
Propofol + remifentanil + Sevoflurane	18 (47.4)	22 (55.0)
Sevoflurane	4 (10.5)	3 (7.5)
Person responsible for airway management [*n* (%)]		
Resident	6 (15.8)	6 (15)
Consultant	32 (84.2)	34 (85)
Anesthesia duration (min, mean ± SD)	56.2 ± 29.5	63.8 ± 33.6
Surgery duration (min, mean ± SD)	46.8 ± 28.4	55.2 ± 30.8

SGA Supraglottic airway, *ETT* Endotracheal tube

29/40) (RR: 0.402, 95% CI: 0.248–0.701, $p<0.001$), with a statistically significant difference in minor PRAEs and no difference in major PRAEs. During the PACU period, no statistically significant differences were observed in major or minor PRAEs between the two groups.

All individual PRAEs occurred at lower rates in the SGA group during the perioperative period (Fig. 2). There were differences between the groups regarding the incidence of perioperative cough ($p=0.043$) and desaturation ($p=0.031$). One patient (2.5%) in the ETT group experienced one episode of bronchospasm. No episodes of

Table 3 Incidence of perioperative respiratory adverse events

	Total ($n=78$)	SGA ($n=38$)	ETT ($n=40$)	Risk ratio (95% CI)	*p* value
Perioperative [*n* (%)]					
Major	6(7.7)	2(5.3)	4(10.0)	0.667(0.210–2.116)	0.433
Minor	38(48.7)	11(28.9)	27(67.5)	0.429 (0.249–0.738)	0.001
Overall	44(56.4)	13(34.1)	31(77.5)	0.417 (0.248–0.701)	< 0.001
Intraoperative [*n* (%)]					
Major	5(6.4)	1(2.6)	4(10.0)	0.395 (0.067–2.311)	0.148
Minor	33(42.3)	8(21.1)	25(62.5)	0.364 (0.192–0.688)	< 0.001
Overall	38(48.7)	9(23.7)	29(72.5)	0.402 (0.221–0.731)	0.001
PACU [*n* (%)]					
Major	1(1.3)	1(2.6)	0	-	0.979
Minor	18(23.1)	6(15.8)	12(30.0)	0.625 (0.32–1.252)	0.137
Overall	19(24.4)	7(18.4)	12(30.0)	0.655 (0.344–1.247)	0.155

SGA Supraglottic airway, *ETT* Endotracheal tube, *PACU* Postanesthesia care unit. Major adverse events: Events requiring significant medical intervention or prolonged hospital stay; Minor adverse events: Events managed with minimal intervention and no lasting effects

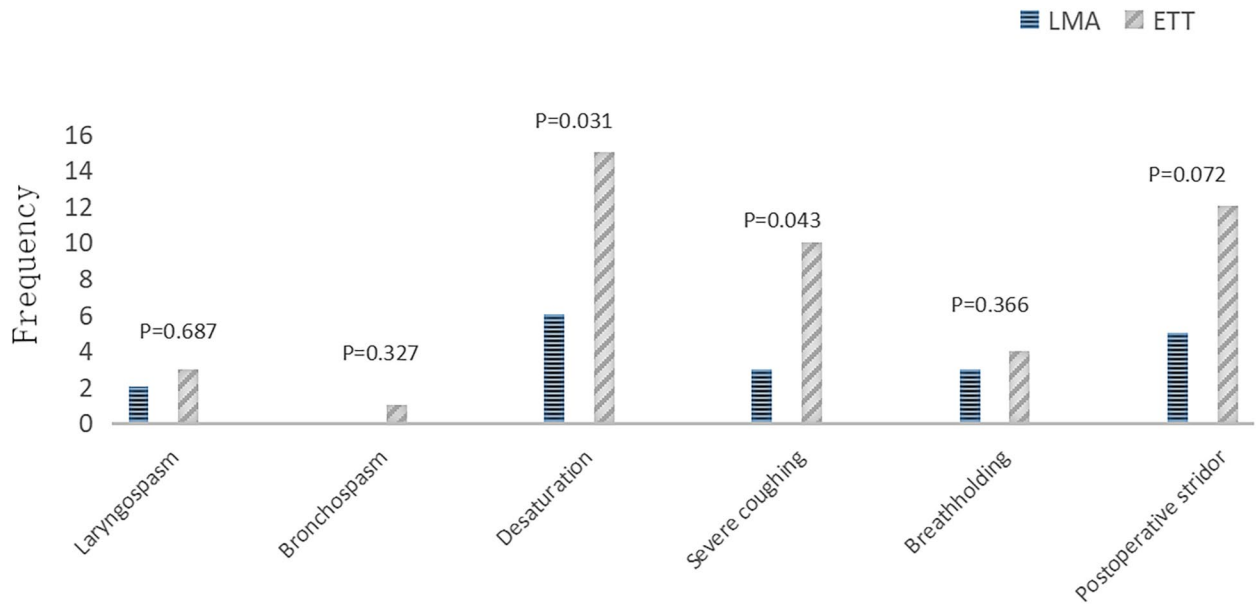

Fig. 2 Frequency of perioperative respiratory adverse events in two groups

bronchospasm were recorded in the SGA group. Laryngospasm problems were reported in 2 (5.3%) children in the SGA group compared with 3 (7.5%) children in the ETT group ($p=0.687$). During the routine postoperative follow-up, 6 (15.8%) children in the SGA group and 18 (45%) in the ETT group reported common problems, such as postoperative sore throat, nausea and vomiting ($p=0.005$).

Discussion

In this trial, we demonstrated that the use of an ETT was associated with a higher incidence of PRAEs compared with the use of the SGA technique in children with URTIs. This RCT significantly contributes to evaluating the effect of an ETT and SGA on PRAEs in children with URTIs undergoing anaesthesia. Our findings suggest that children with URTIs who were treated with ETTs experienced more respiratory adverse events compared with those using a SGA.

Most URTIs are self-limiting, and children who may present with airway hyperreactivity that persists for several weeks after infection experience 6–8 URTIs per year [8]. Minimising secretions and avoiding the stimulation of a potentially sensitive airway are important in managing children with URTIs. The majority of observational

studies and RCTs show that an ETT is associated with the highest risk of PRAE compared with less invasive airways (a SGA or a face mask) [9]. This study supported these findings, revealing that under the specific experimental conditions of muscle relaxation and deep anaesthesia for device removal, the use of an ETT resulted in a higher incidence of adverse respiratory events [10]. Previous research has demonstrated that ETT airway management increases respiratory adverse events [11]. For example, Tait et al. reported that respiratory adverse events were twice as common with tracheal intubation compared with SGA use in children with URTIs [12]. Similarly, Drake-Brockman found that the incidence of PRAEs was significantly higher with tracheal intubation (53%) than with SGA (18%) [13]. These findings underscore the importance of minimal airway stimulation during anaesthesia. The reduced laryngeal stimulation with SGA highlights their potential as a better alternative for managing the airway, particularly since a randomised trial noted the advantages of SGA in spontaneously breathing children, although it did not employ positive pressure ventilation [14–16].

In this study, we found a lower incidence of PRAEs than previously reported for the paediatric population in general [15]. The difference between the results of the two studies could be explained by the choice of different anaesthetics. In our study, most children received propofol for both induction and maintenance and seldom received inhalational agents. Observational data suggested that the induction and maintenance with propofol were over inhalational induction for children with URTIs to reduce the incidence of PRAEs [17, 18]. A higher incidence of respiratory adverse events, notably cough and desaturation, occurred during tube placement or removal compared with the PACU. Coughing is particularly significant as it may lead to laryngospasm. Drake-Brockman [13] found that cough was also less frequent during the removal of the SGA. Additionally, the more severe coughing seen in the ETT group during tube placement or removal likely contributed to the higher levels of oxygen desaturation observed at those times.

Observational data suggested that the deep removal of the SGA or ETT reduced the occurrence of PRAEs [12]. Awake extubation was associated with increased coughing (60%), whereas airway obstructions (26%) were increased following deep extubation [18]. The incidence of respiratory adverse events was not statistically significant between the SGA group and the ETT group in the PACU. In our hospital, ETTs and SGAs were removed from the operating theatre before the children were transferred to the PACU. Even though no direct mechanical stimulation occurred in the children in the two groups, we found a slightly higher incidence of respiratory adverse events in the PACU. In a study by von Ungern-Sternberg et al., adverse respiratory events were significantly higher in children with URTIs than those with no URTI in the PACU [19].

One of the most relevant anaesthesia adverse events in the children was laryngospasm. Lignocaine jelly applied to the surface of the tube and deep extubation may reduce the incidence of laryngospasm [20]. Von et al. [19] found that the incidence of bronchospasm in children increased five-fold when a respiratory tract infection was present. One patient in the ETT group experienced one episode of bronchospasm, and no episodes of bronchospasm were recorded in the SGA group, which suggested an important advantage of SGA over ETT in this population of children.

This study involves several limitations. First, the sample size is small, which may introduce bias in the extrapolation of the results. Specifically, the statistical analysis for secondary outcomes was not based on sample size calculations, which could lead to inaccurate results. Additionally, the alpha estimate was not corrected for multiple comparisons, which could lead to the detection of differences that may not be of practical significance. Therefore, in the future, we will consider multi-centre, large-sample research for further verification. Second, we included all mild or moderate patients with URTI but excluded patients with severe URTI or children who presented with systemic symptoms or significant respiratory distress, with symptoms suggesting lower respiratory tract infection. In the follow-up study, we will strengthen the exploration of patients with severe URTI. Third, our anaesthetic choices, tailored for minimal respiratory impact, may not reflect broader clinical practices, limiting generalisability. This highlights the need for further research under various conditions to validate our findings and enhance their applicability across different healthcare settings. Another important issue that interferes with the results of this study is the lack of evidence for airway intubation device removal under deep anaesthesia and awake anaesthesia. There is no evidence that inhalants and intravenous agents affect PRAEs.

Conclusion

In summary, the use/removal of a SGA seemed to reduce the incidence of cough, bronchospasm and oxygen desaturation and to offer several advantages. Notably, the incidence of bronchospasm was significantly lower in the SGA group, with no events recorded among 38 patients. Laryngeal mask airways provided an acceptable alternative to ETTs in children with mild or moderate URTI.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-025-08815-9.

Supplementary Material 1.

Supplementary Material 2.

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Authors' contributions
(I) Conception and design: Shi J. (II) Administrative support: Shi J and Liu X. (III) Provision of study materials or patients:Chen WJ and BaoWJ. (IV) Collection and assembly of data: Shi J and Chen WJ. (V) Data analysis and interpretation: Liu X, and BaoWJ. (VI) Manuscript writing: All authors. (VII) Final approval of manuscript: All authors.

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Data availability
All data generated or analyzed during this study are included in this published article.

Declarations

Ethics approval and consent to participate
This study was conducted in accordance with the declaration of Helsinki. This study was conducted with approval from the Ethics Committee of Hebei Children's Hospital (No.165).Written informed consent was obtained from all parents/guardians.

Consent for publication
The manuscript is not submitted for publication or consideration elsewhere.

Competing interests
The authors declare that they have no competing interests.

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