Anesth Pain Med 2023;18:51-56
https://doi.org/10.17085/apm.22209
pISSN 1975-5171 • eISSN 2383-7977

Clinical Research

Comparison of oropharyngeal leak pressure of I-gel™ and Blockbuster™ laryngeal mask airway in anaesthetized pediatric patients

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Received July 7, 2022
Revised August 22, 2022
Accepted September 9, 2022

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Background: Supraglottic airways (SGA) are increasingly used in pediatric anesthesia. Among SGA, I-gel™ is a commonly used device in pediatric patients. The Blockbuster™ laryngeal mask airway (LMA) is latest addition in pediatric airway armamentarium. This study was conducted to compare the clinical performance of I-gel™ and Blockbuster™ LMA in pediatric patients.

Methods: A total of 140 children aged 1–5 years, who were undergoing elective surgery, were randomized into two groups either I-gel™ (Group I) or Blockbuster™ LMA (Group B). Airway was secured with appropriate-sized LMA according to group allocation under general anesthesia. The primary objective of study was oropharyngeal leak pressures (OPLP), and secondary objectives were number of attempts of device insertion, success rate, ease of LMA insertion, hemodynamic parameters, and postoperative pharyngolaryngeal morbidities.

Results: The mean OPLP was significantly higher for I-gel™ compared to Blockbuster™ LMA (27.97 ± 1.65 vs. 26.04 ± 2.12; P < 0.001). The devices were successfully inserted on the first attempt in 97.14% and 90% of the Group I and Group B respectively. The insertion time, ease of insertion, hemodynamic parameters and postoperative complications were comparable between groups.

Conclusions: The I-gel™ was more efficacious device in term of OPLP than Blockbuster™ LMA for positive pressure ventilation in pediatric patients undergoing short surgical procedures under general anesthesia.

Keywords: Blockbuster LMA; I-gel; Pediatric anesthesia; Supraglottic airways.

INTRODUCTION

Airway management is a challenging task in children and a variety of devices have been developed precisely for this purpose. A safer alternative to endotracheal intubation was brought to the fore by Archie Brain, namely a supraglottic airway (SGA) [1]. The advent of SGAs has reduced perioperative airway-related side effects and they have become a more popular device for securing the airway, as reported by the National Audit Project-4 (NAP-4) [2].

Pediatric-size SGAs are limited, and these devices have been innovated and modified from their adult counterparts,

although their efficacy and safety in this subset of the population are limited [3]. A network meta-analysis on the use and evaluation of different SGAs in pediatric patients concluded that I-gel™ (Intersurgical Ltd., UK) is one of the most studied SGAs in children with a high oropharyngeal leak pressure (OPLP) and the lowest risk of blood staining among 16 SGAs studied [4]. Another second-generation laryngeal mask airway (LMA) is Blockbuster™ LMA (Touren Medical Instrument Co., Ltd., China), invented in 2012 by Professor Ming Tian, made of silicone with an inflatable cuff [5]. Till now no study was available in literature that compared efficacy and safety of these devices in pediatric population.

Therefore, we designed this study to compare the clinical performance of Blockbuster™ LMA with that of I-gel™ in pediatric patients with the hypothesis that LMA-Blockbuster would have comparable efficacy to I-gel when used in pediatric patients.

METHODS

This study was conducted in tertiary care centre after approval from Institutional Ethics Committee (no. SNMC/IEC/2020/Plan/313) and registration in the Clinical Trial Registry of India (no. CTRI/2020/09/028079). Informed written consent was taken from the parents of all patients. Children of age 1–5 years, weighing between 5 and 25 kg, belonging to the American Society of Anesthesiologists- physical status I or II, scheduled for elective surgery under general anesthesia were included in this study. The syndromic babies, upper respiratory tract infections, silicone allergy, emergency surgery, abnormal anatomy of pharynx and larynx, those at increased risk of aspiration and patients who have received oxygen support or mechanical ventilation in the past one month were excluded from the study.

Children were randomized to either group- the I-gel™ group (Group I) or the Blockbuster™ LMA group (Group B) using a computer-generated random number table. To ensure the confidentiality of the assignment, random numbers were placed in a sealed opaque envelope which was opened upon the child's arrival in the operating room.

Patients were kept nil per oral as per standard fasting guidelines. Monitoring consisted of electrocardiography, non-invasive blood pressure (NIBP), and pulse oximetry, and baseline vital parameters were recorded. Children were premedicated with midazolam 0.05 mg/kg intravenously (IV), and anesthesia was induced with fentanyl 2 μg/kg and and propofol 2–3 mg/kg IV. Intravenous atracurium 0.5 mg/kg was administered after confirmation of satisfactory mask ventilation. The airway was secured with one of the airway devices as per group allocation. The airway device size was chosen according to body weight and manufacturer recommendations. The lubricated device was inserted in a neutral head position. Both these devices were inserted along the hard palate with the airway device shafts held approximately parallel to the patient's chest until resistance was felt. The Blockbuster™ LMA cuff was inflated with the appropriate amount of air according to the manufacturer's instructions. The ventilator was attached to the device and effective placement was assessed by bilateral equal chest movements, square wave capnograph, absence of gastric insufflations epigastrium auscultation and delivery of adequate tidal volume. The insertion time was calculated as the time from picking up the device to the appearance of the first capnographic waveform on the monitor. The number of insertion attempts was also calculated. Insertion failure was marked if the airway could not be secured in three attempts and the patient was intubated via direct laryngoscopy with an appropriate size endotracheal tube. The primary outcome of the study was the comparison of the OPLP and secondary outcomes were insertion parameters such as ease of insertion, time of insertion and number of attempts, as well as hemodynamic changes and incidence of postoperative complications.

The OPLP was determined one minute after securing the airway by closing the circle system's expiratory valve at a fixed gas flow of 3 L/min. The airway pressure at which equilibrium was reached and a gas leak occurs as determined by an audible leak or by detection of an audible noise with a stethoscope placed directly lateral to the thyroid cartilage was the OPLP [6].

Ease of insertion was assessed by an objective rating depending on the number of airway manipulations required to introduce the LMA with no manipulation, only one manipulation and more than one manoeuver rated as very easy, easy and difficult respectively. Hemodynamic parameters including heart rate, NIBP and peripheral oxygen saturation (SpO_2) were recorded at baseline, immediately after device insertion and every 5 min until surgery was completed. Anesthesia was maintained with sevoflurane in an O_2-air mixture with a targeted FiO_2 of 40%. Anesthetics were discontinued at the end of the operation; 0.05 mg/kg neostigmine was administered together with 0.01 mg/kg glycopyrrolate to reverse the effect of the neuromuscular blocking agent. Upon return of adequate spontaneous breathing and muscle

strength, the device was removed as soon as the child was awake. The device was examined for blood stains and the child was evaluated for other postoperative complications.

All patients' SGAs were inserted by anesthesiologists, who had at least 3 years of SGAs insertion experience or had at least 50 SGAs insertions before the start of the study. The OPLP, SGA insertion time, hemodynamic parameters, and postoperative complications were noted and recorded by an independent observer who was unaware of the inserted device.

The sample size was calculated on previous study by Kim et al. [7] The oropharyngeal leak pressure for I-gel™ was mean ± SD; 27.1 ± 6.1 cmH_2O. Assuming a minimum difference of 3 cmH_2O to be clinically significant, the minimum sample size calculated to be 66 in each group at type I error of 0.05 and power of 80%. To account for potential dropouts, we enrolled 70 patients in each group.

The Kolmogorov–Smirnov test was used to determine the distribution of all continuous variables. An independent *t*-test was used for the normally distributed variables. Fisher's exact test and chi-square test were used for comparison of qualitative data. The continuous variables were described in mean ± SD, while categorical variables were described in numbers and percentages. Differences were considered significant at $P < 0.05$.

RESULTS

A total of 149 patients were evaluated for eligibility, of which 5 patients were excluded due to symptoms of upper respiratory tract infection on the day of surgery and the parents of 4 children refused to participate, so the remaining 140 patients were included in the final analysis. Selected children were randomly assigned to Group I and Group B (Fig. 1). Children included in both groups had comparable demographic variables (Table 1).

The mean OPLP was significantly higher for I-gel™ (27.97 ± 1.65) than for Blockbuster™ LMA (26.04 ± 2.12) ($P < 0.001$) (Fig. 2). Total insertion time was comparable between I-gel™ and Blockbuster™ LMA at 15.51 ± 1.62 and 15.92 ±

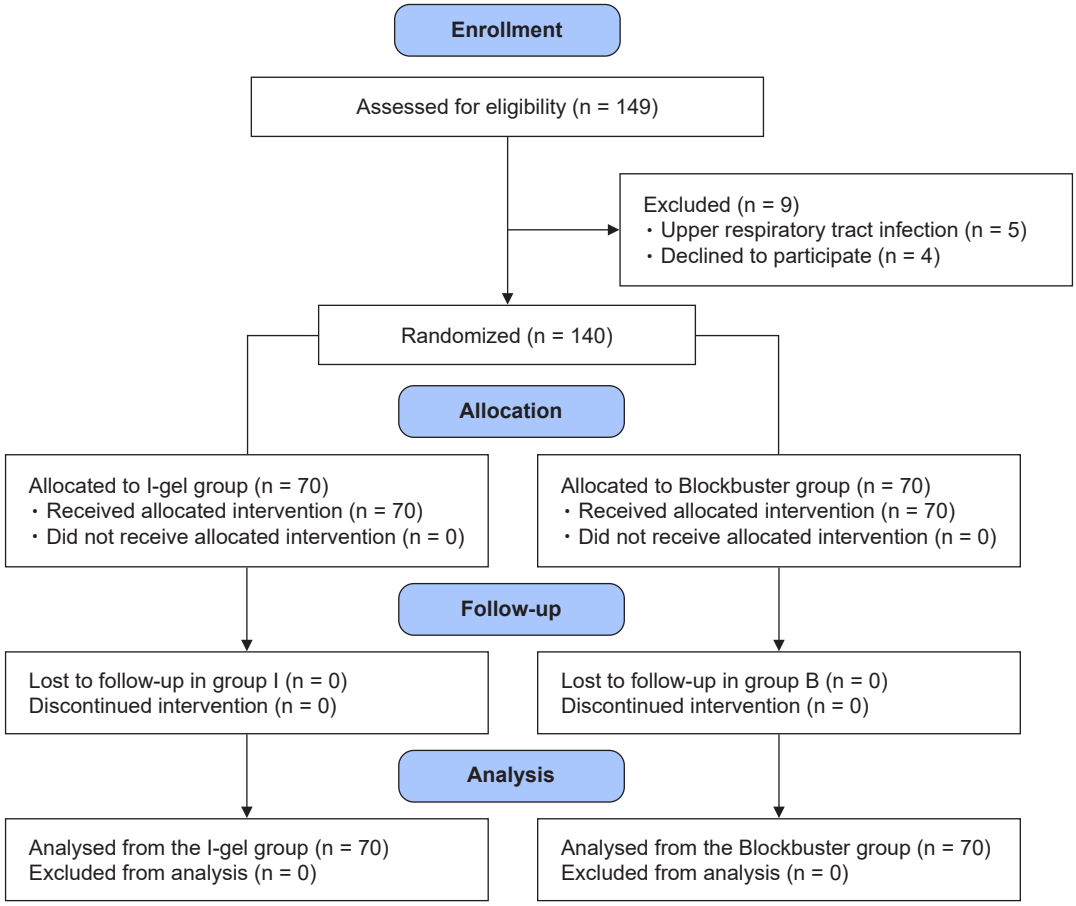

Fig. 1. CONSORT flow diagram. CONSORT: consolidated standards of reporting trials.

Table 1. Demographic Variables

S. No.	Parameter	Group I (n = 70)	Group B (n = 70)	P value
1	Age (yr)	3.40 ± 1.36	3.16 ± 1.44	0.320
2	Sex (M/F)	59/11	61/9	0.629
3	Weight (kg)	12.81 ± 3.82	12.54 ± 3.66	0.673
4	ASA-PS (I/II)	70/0	70/0	1.000
5	Duration of surgery (min)	31.49	32.09	0.190

Values are presented as mean ± SD or number. n: number, M: male, F: female, ASA-PS: American Society of Anesthesiologists-physical status. Independent t-test or chi-square test used.

Table 2. Comparison of Oropharyngeal Leak Pressure, Ease of insertion, Number of Attempts and Time for Insertion

S. No	Parameter	Group I (n = 70)	Group B (n = 70)	P value
1	Oropharyngeal leak pressure (cmH_2O)	27.97 ± 1.65	26.04 ± 2.12	< 0.001*
2	Ease of insertion (easy/very easy/difficult)	68/2/0	63/7/0	0.066
3	Number of attempts for insertion (1/2/3)	68/2/0	63/7/0	0.066
4	Time for insertion (s)	15.51 ± 1.62	15.92 ± 3.02	0.314

Values are presented as mean ± SD or number. Independent t-test or chi-square test used. *P < 0.05.

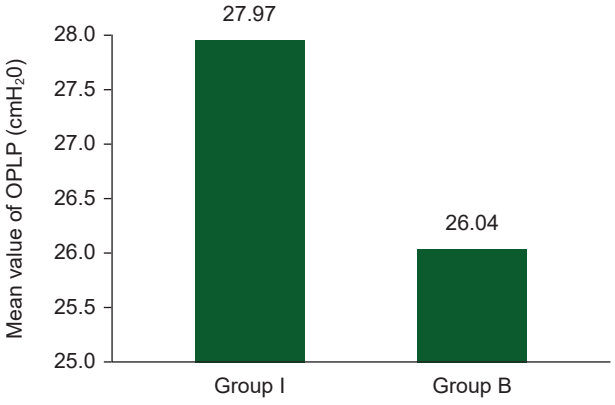

Fig. 2. Comparison of oropharyngeal leak pressure. OPLP: oropharyngeal leak pressure.

3.02 s respectively. Both groups were found to be comparable in terms of ease of SGA insertion. The devices were successfully inserted on the first attempt in 97.14% and 90% of the I-gel™ group and Blockbuster™ LMA groups respectively (Table 2). All hemodynamic parameters and cases of postoperative complications were comparable between both groups.

DISCUSSION

The main results of the study show that both I-gel™ and Blockbuster™ LMA provide adequate sealing pressure around the laryngeal inlet. However, the I-gel™ provides a comparatively better airway seal than the Blockbuster™ LMA.

Effective and adequate sealing around the glottis becomes important when SGAs are used during surgery to prevent loss of tidal volume, avoidance of operative room air contamination, repeated airway switching and reduce the risk of regurgitation. To ensure adequate ventilation, an ideal SGA should have an OPLP higher than ventilation airway pressure or greater than 20 cmH_2O [8]. In the literature pediatric counterparts of various first-generation SGA such as classic LMA, flexible LMA, LMA unique, etc. have reported OPLP of 16 to 20 cmH_2O [9]. Second-generation devices such as the LMA Proseal, Air-Q, I-gel™, and LMA Supreme are also available in pediatric sizes and have better seal pressure compared to first-generation devices [7,9–11].

In our study, the OPLP of Blockbuster™ LMA has been reported to be lower than I-gel™ (26.04 ± 2.12 mmHg and 27.97 ± 1.65 mmHg respectively), although both these devices provide adequate seal pressure when used for positive pressure ventilation. I-gel™ has a non-inflatable thermoplastic polymer cuff that is known to conform itself to the glottis to provide an effective seal around the glottis. The cuff is said to respond to body temperature to create an adequate seal around the glottis to resist leakage during positive pressure ventilation [11,12]. With the Blockbuster™ LMA, the 95-degree angled breathing tube and the cuff shape of the BlockbusterTM LMA can be responsible for the high sealing pressure [5]. In most studies, the OPLP of I-gel™ was reported to be greater than 20 cmH_2O in pediatric patients [13–15]. While studies using Blockbuster™ LMA in pediatric patients are limited. Endigeri et al. [16] reported an OPLP of Block-

buster™ LMA of 33.7 ± 1.8 cmH_2O in adult patients, which is higher than observed in our study. Though a higher OPLP doesn't always guarantee an appropriate placement, it is commonly used objective test to guide correct placement. A higher OPLP suggests proper placement of device around perilaryngeal structure and ability of the device to sustain leak during positive pressure ventilation. Though in our study a statistically significant difference was observed between two devices, with I-gel™ reported to have higher seal pressure, but clinically this difference was not very significant as if SGA is achieving an OPLP more than 20 cmH_2O, it can sustain leak during spontaneous or controlled ventilation in pediatric patients. There are plenty of studies in I-gel™ in pediatric patients and I-gel™ is considered to be a prototype second generation LMA but Blockbuster™ LMA is newly introduced with limited studies available on its use in children. So, our study finding support the use of Blockbuster™ LMA for pediatric airway management, however further randomized controlled trial are required to confirm and support our study findings. We inflated the Blockbuster™ LMA as per manufacturer specification but further study of inflation pressures and positioning may help optimize the Blockbuster™ LMA.

There was no case of failed insertion of the LMA in either group, with airways secured in 97% and 90% of the first attempts in the I-gel™ and Blockbuster™ LMA groups respectively. Studies have reported a greater than 95% first-attempt success rate for I-gel™ [17]. Ease of insertion was comparable for both I-gel™ and Blockbuster™ LMA with 100% of both groups having “easy” and “very easy” insertion. Total insertion time was comparable between I-gel™ and Blockbuster™ LMA at 15.51 ± 1.62 and 15.92 ± 3.02 s respectively. All insertions were performed in < 30 s which is acceptable given the time required to secure an airway. Both I-gel™ and the Blockbuster™ LMA had a sleek and streamlined design that could be deployed quickly, even considering the anatomical challenges presented by pediatric airways. Previous studies have found that I-gel™ took a longer time to insert and this was attributed to I-gel™ straight shape which showed frequent displacements. It has also been shown that the I-gel™ requires consistent downward mechanical pressure to stay in place with close contact with the glottis. We had no such difficulties in our study and were able to promptly fix I-gel™ in place. The Blockbuster™ LMA with its inflatable cuff and the angled tube, did not cause any difficulties worth mentioning during insertion.

All hemodynamic variables were comparable in both groups with no significant change in parameters at different intervals in the study. Similarly, the incidence of postoperative complications was zero in I-gel™ and one incidence of blood stains in Blockbuster™ LMA. All insertions were performed by trained individuals and therefore the optimal safety seen with both SGA devices was to be expected.

Limitations of our study include enrolling subjects with normal airways with no prior anatomical pathology. Second, we did not evaluate the additional features of both LMAs such as gastric channels and the ability to be used as a channel for intubation. Third, we have not confirmed the fiberoptic position of any of the LMA after insertion and we have not evaluated the inflation cuff pressure in the Blockbuster™ LMA.

To conclude, the I-gel™ delivered significantly higher OPLP than Blockbuster™ LMA, otherwise, both LMAs are comparable in terms of performance. Both I-gel™ and Blockbuster™ LMA are appropriate devices for positive pressure ventilation in pediatric patients undergoing short surgical procedures under general anesthesia with minimal pharyngolaryngeal morbidity.

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

Conceptualization: Caren Candace Selvin, Geeta Singariya, Manoj Kamal. Data curation: Manoj Kamal. Formal analysis: Caren Candace Selvin, Manoj Kamal. Methodology: Caren Candace Selvin, Geeta Singariya, Pooja Bihani, Naveen Paliwal. Project administration: Caren Candace Selvin, Geeta Singariya. Writing - original draft: Caren Candace Selvin, Geeta Singariya, Pooja Bihani. Writing - review & editing: Caren Candace Selvin, Geeta Singariya, Pooja Bihani,

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