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Clinical Comparison of I-gel and Laryngeal Mask Airway-Supreme Airway Devices During General Anaesthesia in the Paediatric Population

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Abstract

Objectives: Both the Supreme™ Laryngeal Mask Airway (SLMA) and the I-gel™ (I-gel) are supraglottic airway devices (SADs) commonly used for airway management in paediatric patients. This study aims to compare the efficacy in terms of insertion and ventilation profiles of size 2 SLMA and the I-gel in anaesthetised paediatric patients.

Methods: 100 children were prospectively allocated to two groups depending upon the device inserted as SLMA (n = 50) and I-gel (n = 50). The primary outcomes were studied in terms of ease of insertion, haemodynamic changes, ventilation parameters, leak pressure and incidences of complications during general anaesthesia.

Results: There were no failed attempts in the insertion of the airways in either group. The SLMA was more easily inserted in the majority of cases compared to the I-gel group. The number of attempts for insertion and the time taken for insertion were comparable in the I-gel and the SLMA group (13.84 ± 2.38 vs. 14.02 ± 1.7) ($P \leq .57$, $\leq .66$). Securing an effective airway took <30 seconds in both the groups with an overall median duration of 15 seconds. There was no difficulty in passing the gastric tube in either group ($P < .30$). There was a statistical difference between the oropharyngeal seal pressure (OSP), which was 25.18 ± 1.59 and 22.10 ± 1.36 cmH_2O for SLMA and I-gel, respectively ($P < .001$). Haemodynamic parameters after the insertion of the device were comparable, and there were no clinically important complications in the post-operative period.

Conclusions: Both the devices appeared to be simple and suitable for airway management during elective surgery in paediatric patients. However, the SLMA was easily inserted with less insertion time in the majority of patients. Also, it provides higher OSP during anaesthesia and is better tolerated during emergence, with minimal risk of injury to the oropharynx.

Keywords: Laryngeal masks airway-supreme, I-gel, paediatric patients, oropharyngeal seal pressure

Introduction

After the introduction of the first supraglottic airway device (SAD) by Dr. Archie Brain in 1983, various SADs now have an established place in anaesthesia. The Supreme Laryngeal Mask Airway (SLMA) (LMA Supreme™) and I-gel™ (I-gel) are the latest and increasingly used for better safety and efficacy during mechanical ventilation.[1,2] The SLMA is an polyvinyl chloride made anatomically shaped, disposable SAD composed of polyvinyl chloride with an inbuilt gastric drainage port.[3] The I-gel is a uniquely designed cuffless disposable SAD, which is made from soft gel-like thermoplastic elastomer (styrene-butadiene ethylene-styrene).[4] The stem of I-gel a has built-in bite block along with a gastric drainage port, which runs from a proximal connector to the mask tip for suctioning. Both devices are second-generation SADs and have separate gastric drain ports. A recent report described the use of SLMA as a rescue airway management device in difficult airway situations in children aged 2 months to 6 months. Extensive research of literature studies has yielded only a few studies evaluating the use of SLMA in paediatric patients during anaesthesia.[5] Due to its inherent superiority, I-gel has gained rampant acclaim amongst

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paediatric anaesthetists. There are plentiful literature studies comparing the SLMA and I-gel.[6,7] However, the studies in the paediatric age group are lacking. In this study, the primary objective was to compare the efficacy of SLMA with the I-gel in paediatric patients undergoing elective surgery under general anaesthesia. The secondary objectives were to compare the ease of insertion, haemodynamic changes, airway seal quality, oxygenation, ventilation parameters and incidences of complications between two devices.

Methods

This prospective study was carried out in a tertiary care hospital, after obtaining approval from the ethics committee of R & R Hospital institutional ethical committee, and a written informed consent was obtained from the parents of patients. A total of 100 paediatric patients aged 2-5 years, undergoing short surgeries (less than 90 minutes) such as herniotomy, orchidopexy and urethroplasty and in American Society of Anesthesiology (ASA) physical status I and II, were enrolled in this study. Patients with increased risk of aspiration, mouth opening of $\leq$2 cm, weight less than 10 kg or greater than 20 kg, and the presence of any disease or surgery of the neck, upper respiratory tract or upper gastrointestinal tract were excluded from the study.

A standard anaesthetic technique was followed in all cases. All children had an intravenous line placed in the ward on the morning of surgery. On arrival in the operation theatre, the child was premedicated intravenously with 0.1 mg kg^{-1} of midazolam for calm parental separation. Anaesthesia was induced with fentanyl (1-2 µg kg^{-1}) and propofol (2.5 mg kg^{-1}). Subsequently, anaesthesia was maintained with oxygen, nitrous oxide, and sevoflurane in appropriate concentrations. During the study period using consecutive sampling, airway management was done with a size of 2 SLMA (group SLMA) for initial 50 patients fulfilling the study protocol, and the next 50 patients with a size of 2 I-gel (group I gel). The device was inserted in the manner recommended by the manufacturer. If the insertion was difficult and required manipulations, the same was also recorded, and the device's replacement with the endotracheal tube was considered. An appropriate-sized lubricated gastric catheter was inserted with ease of insertion or otherwise was recorded after insertion and confirmation of adequate ventilation. The same anaesthesiologist who inserted the device also graded the ease of insertion as per insertion score (1 = very easy, 2 = easy and 3 = difficult). The cuff was inflated in the SLMA group using a cuff pressure monitor to achieve a pressure of 60 cmH_2O, which was maintained throughout the surgery by continuous cuff pressure monitoring. Oropharyngeal seal pressure (OSP) measured in both the groups by the following method: fresh gas flow was fixed at 3 L min^{-1}, with adjustable pressure limiting valve closed, allowing airway pressures to rise. The sealing pressure (also termed the leak pressure point) was measured by a ventilator of the anaesthesia workstation (Spacelabs) at the point of air leakage detected by auscultation of the anterior neck. Further recordings were made for the insertion attempts, ease of insertion, insertion time until first tidal volume and expiratory tidal volume (Exp. TV), oxygen saturation, end-tidal carbon dioxide ($EtCO_2$) and peak airway pressure. Incidences of unsatisfactory ventilation, hypoxemia, gastric insufflation, cough, breath-holding, laryngospasm, or stridor were also recorded. Systolic blood pressure (SBP), heart rate (HR) and SpO_2 were recorded just before, 1, and 5 minutes after insertion. A 20% increase or decrease in SBP and HR from before and after the insertion was considered clinically significant.

Main Points:

- Supreme LMA was more easily inserted in a more significant number of cases (two "difficult" insertions) compared to the I-gel group (four "difficult" insertions).
- Securing an effective airway took <30 seconds in both the groups with an overall median duration of 15 seconds.
- There was no difficulty in passing the gastric tube in either group.
- Oropharyngeal seal pressure (OSP) was significantly higher in Supreme LMA patients.
- Haemodynamic parameters, ventilator parameters, and complications are comparable in both the groups.

Statistical Analysis

Statistical analysis was done using the Statistical Package for the Social Sciences (SPSS) version 17 (IBM SPSS Corp.; Armonk, NY, USA). The sample size was based on a crossover pilot study of 10 patients and was selected to detect a projected difference of 30% between the groups for airway sealing pressure, for a type 1 error 0.05 and a power of 0.8. The demographic data (age, weight and height) and complications were analyzed using the Chi-square test. The OSP and haemodynamic data were compared using the unpaired t-test. Unless otherwise stated, data are presented as mean ± SD. A "*P* value" of <.05 was considered statistically significant.

Results

The ease of SAD insertion was studied in 100 patients from July 2015 to January 2017. Out of a total of 885 patients listed for surgery during the study period, 679 patients did not meet inclusion criteria, and 106 patients were not included due to refusal or unavailability of the investigator (Figure 1). Demographic parameters and clinical characteristics were comparable between the groups (Table 1). Both the SLMA and I-gel groups had 50 patients each. No patient had a history of difficult intubation. Sixty percent of the participants were males, and most of them belonged to ASA physical status I (91%).

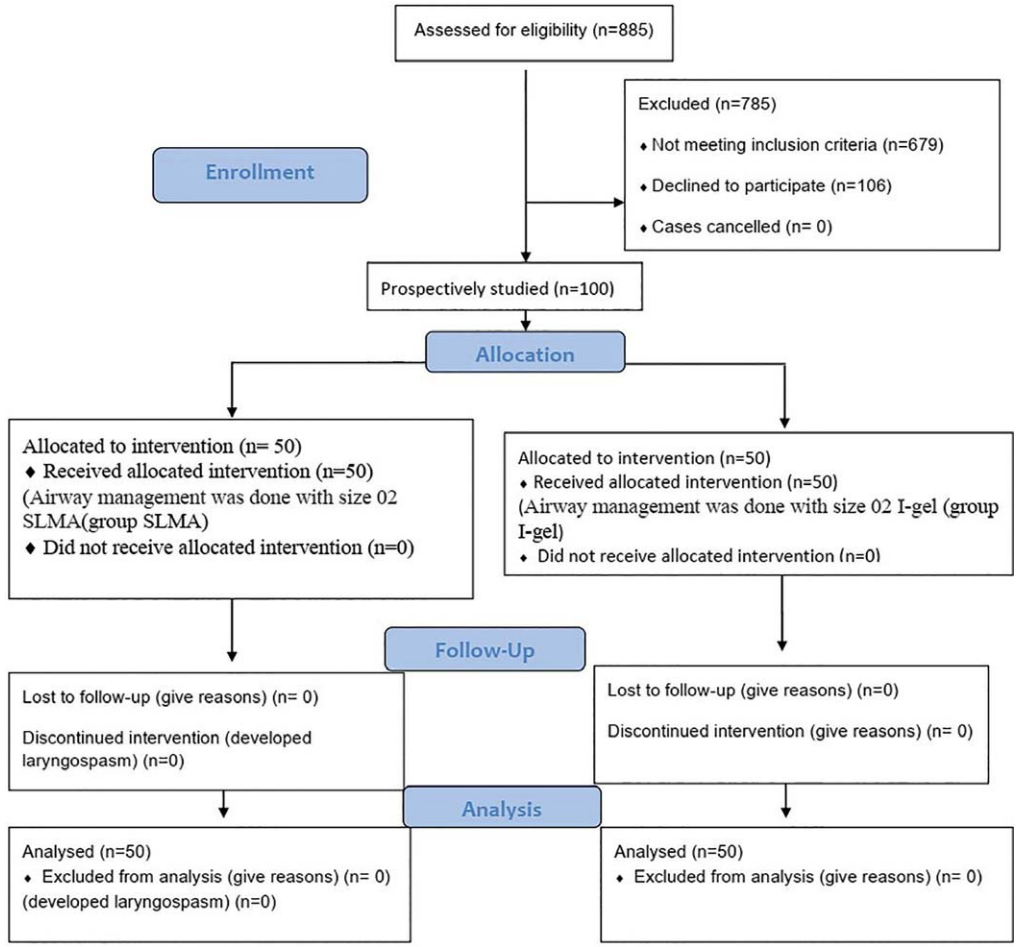

Figure 1. CONSORT 2020 Flow Diagram

There were no failed attempts in the insertion of the airways in either group. The number of attempts for an insertion was comparable ($P < .57$). The SLMA was easily inserted in a more significant number of cases (two "difficult" insertions) compared to the I-gel group (four "difficult" insertions). However, this was not statistically significant (Table 2). Similarly, the insertion time was also comparable in both groups ($P < .66$). Securing an adequate airway took <30 seconds in both the groups with an overall median duration of 15 seconds. There was no difficulty in passing the gastric tube in either group ($P < .30$) (Table 2). The OSP was considerably higher in SLMA when compared with I-gel

Table 1. Demographic Profile and Baseline Clinical Characteristics of Patients in Both the Group

Parameter		Group SLMA (n = 50)	Group I-gel (n = 50)	*P*
Age in years		2.97±0.71	3.09±0.81	.43
Male/female		29/21	31/19	.68
Weight (kg)		14.14±1.68	14.66±1.85	.14
ASA status (I/II)		46/4	45/05	
Surgeries	Inguinal surgery	18	22	
	Lower abdominal surgery	19	18	
	Orthopaedic surgery	13	11	

Abbreviations: SLMA, supreme laryngeal mask airway; ASA, American Society of Anaesthesiology.

Table 2. Comparative Data for the I-gel and the LMA Supreme

Parameters		Group SLMA (n = 50)	Group I-gel (n = 50)	*P*
Insertion attempts	1	45	45	.57
	2	4	5	
	3	1	0	
Ease of insertion: very easy/easy/difficult	Very easy	44	40	.53
	Easy	4	6	
	Difficult	2	4	
Insertion time (second)		13.84±2.38	14.02±1.7	.66
Gastric tube insertion attempts	1	47	49	.30
	2	3	1	
	3	0	0	
OSP (cm H_2O)		25.18±1.59	22.10±1.36	.001
Blood staining on the removal of the device	Yes	2	4	
	No	48	46	

Abbreviations: SLMA, supreme laryngeal mask airway; OSP, oropharyngeal seal pressure.

($P \leq .001$) (Table 2). Similarly, haemodynamic parameters after the insertion of the device were comparable in both groups (Table 3). There was no desaturation or any other significant change in SBP or HR before and after the airway's insertion in any of the cases.

Blood staining of the tip of the device after its removal was recorded in both groups, and it was found that four (8%) cases in the I-gel group had evidence of blood staining as against two (4%) cases in the SLMA group (Table 2). There were no episodes of bucking, breath holding, stridor, coughing, laryngospasm, sore throat or hoarse cry in both the groups.

Discussion

In this study, it was found that the insertion of the SLMA was successful on the first attempt in 90% patients and was equal to the I-gel group with no failures in either group. These rates can be taken as acceptable. However, no comparison can be drawn in view of the dearth of literature on SLMA in children. The success rates for SLMA were found to be similar in studies done in adult patients. Chew et al.[8] reported the first attempt, and the overall insertion success rate for SLMA was 97.8 and 97.8%, whilst for I-gel were 93.3% and 100%, whereas the success rate of insertion for SLMA reported by Theiler et al.[9] is 95% compared to 93%

Table 3. Haemodynamics Parameter at Different Time Intervals in Both Groups

Parameter	Group SLMA (n = 50)	Group I-gel (n = 50)	*P*
HR (before insertion of the device)	106.2±9.4	109.48±9.6	.09
HR (1 minute after the insertion of the device)	107.42±9.4	111.04±9.8	.06
SBP (before insertion of the device)	94.42±5.06	94.56±4.7	.88
SBP (1 minute after the insertion of the device)	96.02±4.5	96.2±4.7	.84
$EtCO_2$ (1 minute after the insertion of the device)	36.02±1.5	36.78±1.5	.40
$EtCO_2$ (5 minutes after the insertion of the device)	34.74±0.9	34.78±0.9	.83
$EtCO_2$ (10 minutes after the insertion of the device)	35.62±1.2	35.24±0.9	.79
Exp. TV (1 minute after the insertion of the device)	127.2±15.05	131.94±16.6	.13
Exp. TV (10 minutes after the insertion of the device)	121.04±13.7	124.38±15.78	.25
Peak airways pressure (1 minute after the insertion of the device)	17	17	–
Peak airways pressure (10 minutes after the insertion of the device)	17.26±0.66	17.36±0.85	.51

Abbreviations: HR, heart rate; SBP, systolic blood pressure; $EtCO_2$, end-tidal carbon dioxide; Exp. TV, expiratory tidal volume.

in the case of I-gel in simulated difficult airway scenario. Similarly, in children, Jagannathan et al.[10] observed no difference in insertion success rate between SLMA and I-gel. Whilst comparing size 2 SLMA with I-gel in children with 2-5 years of age, the first attempt insertion success rate for SLMA reported by Kus et al.[11] is 100% compared to 90% of I-gel, in simulated difficult airway scenario made more difficult by using a cervical collar to limit mouth opening and neck movement.

The ease of insertion was graded as 'easy' or 'very easy' in 96% cases in the SLMA group and 92% in the I-gel groups. The SLMA was easy to insert and required minimal mouth opening. This higher number of difficult insertions in the I-gel group may be explained by the relative anatomy of the paediatric oro-hypopharynx and the bowl and bulky shape of the I-gel in comparison to the deflated cuff of the SLMA. The inbuilt bowl makes I-gel difficult to insert in the patient as it sometimes folds over. The atypical airway anatomy in paediatric patients, including floppy epiglottis, comparatively large tongue, anterior, and cephalad position of larynx and tonsillar hypertrophy, may be the cause in the difficulty of I-gel insertion.[12] Hughes et al.[13] have described several malpositions of the I-gel in the paediatric I-gel size of 1.5-2.5 during the fixation of the device in the mouth. Necessary vigilance is required to avoid the adverse effects of flexion of proximal tubings.

Securing an adequate airway took <30 seconds in both the groups with an overall median duration of 15 seconds. This was noted to be similar to the findings, as obtained in the study by Jagannathan et al.,[10] whilst Kus et al.[11] reported shorter insertion time for SLMA as 11.2 seconds compared to 13.5 seconds with the I-gel.

In the present study, it was found that the passage of the gastric tube through SLMA was 94% in the first attempt and 100% after two attempts compared to 98% on the first attempt and 100% after two attempts whilst passing through I-gel. Similarly, Chen et al.[14] were successfully able to pass the gastric tube through SLMA in all patients with 95% at the first attempt, whilst Kus et al.[11] successfully passed the gastric tube in all patients with 100% success at the first attempt.

We reported that the OSP of the SLMA was significantly higher than that of I-gel, and this result was similar to that in the study by Kus et al.,[11] which reported OSP of SLMA as 20.9 ± 3.2 cmH_2O compared to 18.9 ± 3.2 cmH_2O with I-gel, whilst Jagannathan et al.[10] reported slightly higher OSP with I-gel compared to the SLMA.

The incidence of complications (airway trauma and sore throat) has been very low in all cases. Other studies have also reported a similar incidence.[6,14] Furthermore, the incidence of post-operative dysphagia and sore throat after 24 hours of surgery was not significantly different between the two groups. During the entire study, no adverse events were recorded. It is pertinent to mention that these results obtained when the cuff pressure was consistently maintained at 60 cm H_2O in SLMA to prevent gas leakage. Indeed, Zhang et al.[15] have shown that with an intracuff pressure of 80 cmH_2O, SLMA has higher OSP compared with the intracuff pressure of 60 cmH_2O or 40 cmH_2O without a greater incidence of post-operative adverse effects.

The haemodynamic parameters were comparable for both devices during the perioperative period. Any changes noted during surgery were within an acceptable range of physiological changes and comparable with the previous study.[16]

Limitations of the present study include restriction of the sample population to 2-5 years of age and study of only one size of both the devices. Second, only low-risk patients with normal airways were included in the study. Third, this study did not examined the performance of the SLMA in non-fasting patients or those with a full stomach. Finally, this study is relatively small, and it shows that the SLMA appears to be fairly efficacious and data from a considerably larger cohort in routine practice required for its safe use.

In conclusion, both the devices appeared to be simple and suitable for ventilating the patients' lungs during elective surgery in the paediatric patient. However, the SLMA was easily inserted with less insertion time in the majority of patients. Also, it provides higher OSP during anaesthesia and was well tolerated during emergence without injury to the oropharynx.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of R & R Hospital, Delhi Cantt, India (No: 2014; Date: September 23, 2014).

Informed Consent: A written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Data Collection and/or Processing - M.A.; Supervision - R.Y.; Writing - S.S.; Analysis and/or Interpretation - D.B.; Critical Review - R.Y.

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