



ORIGINAL INVESTIGATION

Comparison of Proseal LMA with i-Gel in children under controlled ventilation: a prospective randomised clinical study

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KEYWORDS

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Abstract

Background: Supraglottic airway device is presently the most common modality of airway management in children for short surgical procedures. The i-gel is one such novel supraglottic airway device with a non-inflatable cuff. The objective of the present study was to evaluate the efficiency of i-gel compared to LMA Proseal regarding oropharyngeal leak pressure, insertion time, ease of insertion, and fibreoptic view of larynx.

Methods: After obtaining ethical clearance and parental consent, 70 children aged 2–10 years, weighing 10–30 kg were randomised to receive LMA Proseal or i-gel for airway management. Data with respect to oropharyngeal leak pressure, insertion time, ease of insertion, number of attempts, and fibreoptic score were collected. The primary outcome was the oropharyngeal leak pressure with the two supraglottic airway devices measured by manometric stability.

Results: Demographic data were comparable between the two groups. The oropharyngeal leak pressure (LMA Proseal vs. i-gel, 20.51 ± 4.71 cmH₂O vs. 19.57 ± 5.71 cmH₂O), ease of insertion, number of attempts, and fibreoptic view score was similar between the two groups. The insertion time was faster with i-gel (22.63 ± 5.79 s) compared to LMA Proseal (43.26 ± 7.85 s).

Conclusion: I-gel was similar to LMA Proseal with respect to oropharyngeal leak pressure in children under controlled ventilation.

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Introduction

Supraglottic Airway Device (SAD) is presently the common modality of airway management in children for short surgical procedures under general anesthesia.¹ It not only provides adequate ventilation, oxygenation, and delivery of anesthetic agents, but has lower risk of respiratory adverse

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events, thus replacing the need for conventional tracheal intubation. To overcome the risk of regurgitation and aspiration of gastric contents with the first-generation SAD, several second generation SADs with a gastric drain tube have been introduced.² LMA Proseal and i-gel are two such second-generation SADs. LMA Proseal with its unique design specifications is regarded as a state-of-the-art SAD and is compared with all latest SADs.³

Several studies have established the efficiency of both devices, however i-gel has been studied broadly in adults with limited literature on their use in children.⁴⁻⁶ It was assumed i-gel to be more effective than LMA Proseal with respect to Oropharyngeal Leak Pressure (OLP) in children. The study intended to compare the efficacy of i-gel and LMA Proseal under controlled ventilation in children undergoing elective surgeries. The primary objective was to evaluate the efficiency of i-gel compared to LMA Proseal in terms of oropharyngeal leak pressure under controlled ventilation in children undergoing short elective surgeries.

Methods

The study was conducted after obtaining Institutional Ethical Committee clearance and informed consent from the parents/guardians of the children in a tertiary care hospital (mono center study). The study was also registered in the Clinical Trial Registry (CTRI/2018/03/012287).

Children scheduled for elective short duration surgeries (< 2 h), aged between 2 and 10 years, weighing 10–30 kg and with American Society of Anesthesiologists (ASA) physical status I and II were included. Children with a history of obstructive sleep apnea, laparoscopic surgeries, intraoral surgeries, risk of aspiration of gastric contents, anticipated difficulty in the airway, and children who were to be operated in prone positions were excluded from the study. Eligible patients were randomly assigned to either group LMA Proseal or group i-gel by computer-generated random number table and concealed in a sequentially numbered sealed envelope by an anaesthesiologist not involved in the study. The sealed envelopes were opened to reveal the group allocation just before induction of anaesthesia by another anaesthesiologist, who had the sealed envelopes in his safe keeping. The size of each SAD was selected based on the bodyweight of children (LMA Proseal: 10–20 kg: size 2; 20–30 kg: size 2.5; i-gel: 10–20 kg: size 2; 25–30 kg: size 2.5).

All the children were fasting as per the ASA fasting guidelines and were premedicated with oral Phenergan 0.5 mg.kg⁻¹ on the morning of surgery. An intravenous line was secured in the ward under EMLA cream (lidocaine 2.5% and prilocaine 2.5%) analgesia as per institutional practice. Following minimal mandatory monitoring, anesthesia was induced with fentanyl 2 mcg.kg⁻¹ and propofol 2 mg.kg⁻¹. After ensuring bag-mask ventilation, atracurium 0.5 mg.kg⁻¹ was administered to achieve neuromuscular blockade and after attaining adequate jaw relaxation, an appropriate size SAD was inserted as per the manufacturer's recommendation. The cuff of LMA Proseal was inflated to achieve 60 cmH₂O pressure with a cuff pressure monitor. Later, the SAD was connected to a circle breathing system and appropriate placement was confirmed by movements of chest wall, aus-

cultation of breath sounds, an absence of gastric insufflation (determined by epigastric auscultation), and a square-wave capnograph. The OLP was measured with head in the neutral position, under manual ventilation by closing the expiratory valve of the circle system at a fixed gas flow of 3 L.min⁻¹ and documenting the airway pressure at equilibrium.^{7,8} To avoid barotrauma during measurements, the peak airway pressure was limited to 40 cmH₂O. After the OLP measurement, a flexible fiberoptic scope was guided through the airway tube and the visualization of the glottis was scored⁹ as follows: (1) vocal cords not seen; (2) vocal cords + anterior epiglottis seen; (3) vocal cords + posterior epiglottis seen; (4) only vocal cords are seen.

A lubricated gastric tube was then guided through the drainage channel, and the number of attempts at placement was recorded. Gastric tube placement was checked by auscultation of injected air over the epigastrium. Insertion time was defined as the time between picking up the device and obtaining an effective airway with capnograph trace on the monitor. Failed device placement was defined as being unable to observe a smooth square-wave capnograph, inadequate ventilation, no rise of the chest wall, and significant leakage from the gastric drain tube. Patients with three failed attempts at device insertion were intubated and omitted from the study. While placing the device, the following manoeuvres were done to achieve correct placement: movement of device upwards and downwards, jaw lift-jaw thrust, and head extension neck flexion. Ease of device placement was graded⁵ from 1 to 3 on a scale: 1 – very easy (no maneuver), 2 – easy (one maneuver), 3 – difficult (requiring more than one maneuver). Following the surgery, patients were examined for any perioperative complications such as coughing, bronchospasm, laryngospasm, hiccup, blood on the device after removal, injury to lips, teeth or tongue, and sore throat.

Statistical analysis

The sample size was obtained using R software. In the hypothesis, it was assumed that i-gel is more effective than LMA Proseal in terms of the oropharyngeal leak pressure. With power 80%, 95% confidence level, assuming large effect size as 0.6 and for one-tailed test, minimum sample size required was 34.03 per group. Hence, the minimum sample size required for each group was 35 subjects. SPSS v.15 (SPSS Inc., Chicago, Illinois, USA) was used to analyse the data. Descriptive and inferential statistics were used to analyse the data. Continuous data were presented as mean ± SD and assessed using Student's *t*-test. Categorical data were presented in frequency (%) and assessed using Chi-Square and Fisher Exact tests. Significance was assessed at 5% level of significance.

Results

Among the 85 children who were assessed for eligibility for the study, 15 were excluded (6 did not meet inclusion criteria, 6 declined to participate, and 3 underwent laparoscopic surgery). Of the 70 children who were randomized, all completed the study and were included for analysis (Fig. 1). Demographic characteristics and opera-

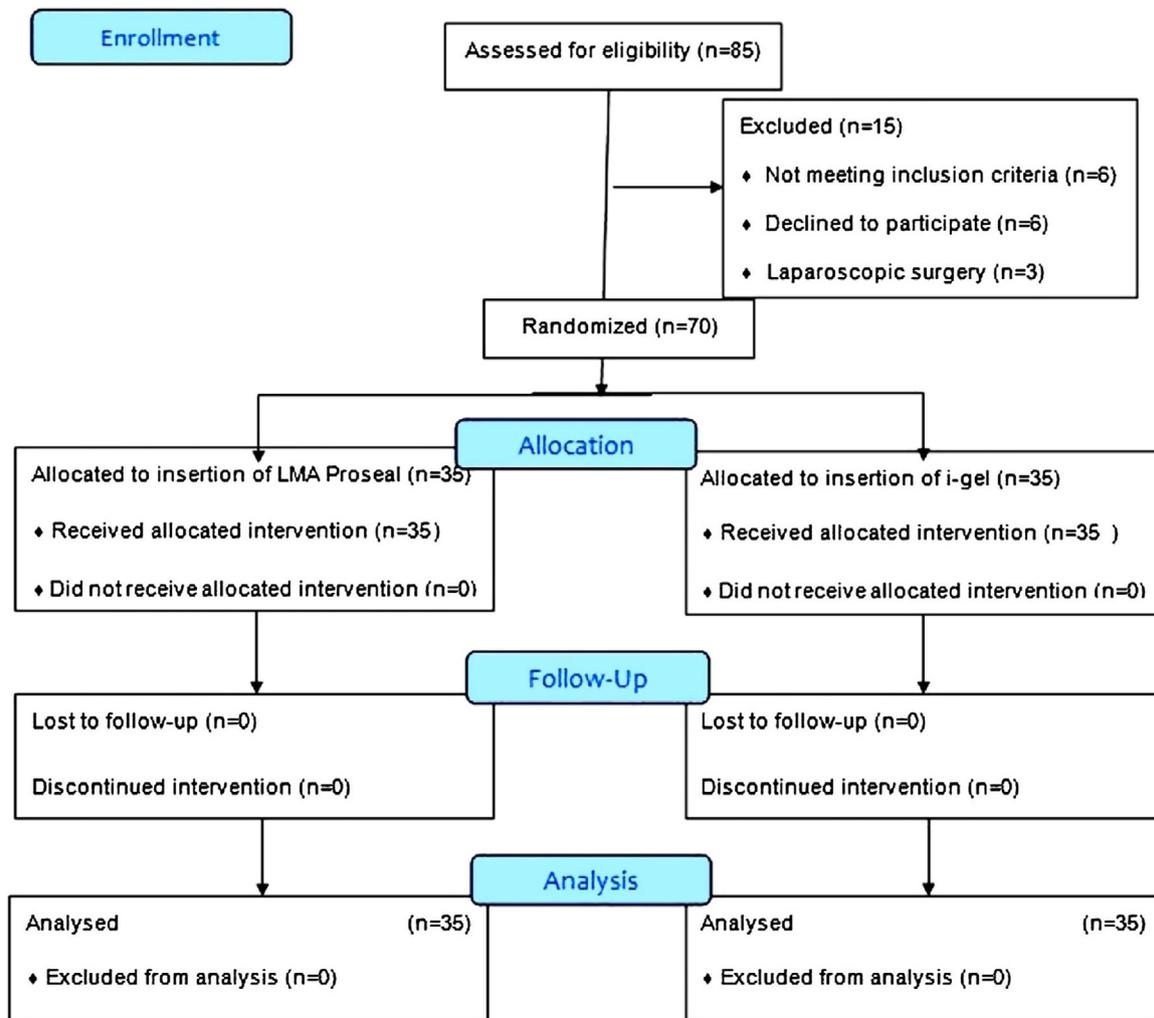


Figure 1 CONSORT 2010 Flow Diagram.

Table 1 Patient baseline characteristics and operative data.

Variables	Group LMA Proseal	Group i-gel	p-value
Age (years) ^{a,b}	4.87 ± 2.89	4.86 ± 3.01	0.984
Gender ^c			
Male	30 (85.7%)	29 (82.8%)	1.000
Female	5 (14.3%)	6 (17.2%)	
Weight (Kg) ^{a,b}	16.09 ± 5.18	16.37 ± 5.53	0.824
BMI (Kg.m ⁻²) ^{a,b}	14.57 ± 2.29	15.13 ± 1.50	0.232
Type of surgery			
Cervical lymph node excision	13 (37.1%)	11 (31.4%)	-
Circumcision	7 (20%)	12 (34.3%)	
Herniotomy	5 (14.3%)	3 (8.6%)	
Hypospadiasis repair	3 (8.6%)	1 (2.9%)	
Miscellaneous	7 (20%)	8 (22.9%)	

^a Data expressed in terms of Mean ± SD.^b Student *t*-test.^c Chi-Square test.

tive data of the patients are summarised in Table 1. Most of the children in this study were aged between 2 and 5 years (Group LMA Proseal: 57.1%; Group i-gel: 60%) with striking

male predominance (Group LMA Proseal: 85.7%; Group i-gel: 82.8%). No significant difference was observed between the groups in terms of age, gender, Body Mass Index (BMI),

Table 2 Comparison of clinical performance of LMA and i-gel.

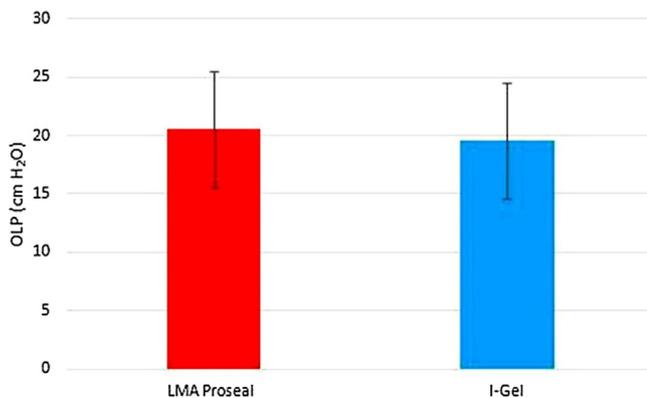
Variables	Group LMA Proseal	Group i-gel	p-value
Size of SAD^a			
2	25 (71.4%)	30 (85.7%)	0.145
2.5	10 (28.6%)	5 (14.3%)	0.145
Insertion time (s)^{b,c}	43.26 ± 7.85	22.63 ± 5.79	0.0001
Ease of insertion^a			
Grade 1	32 (91.4%)	28 (80%)	0.172
Grade 2	3 (8.6%)	6 (17.1%)	0.284
Grade 3	0	1 (2.9%)	1.000
Number of attempts^d			
1	35 (100%)	33(94.3%)	0.493
2	0	2 (5.7%)	
Gastric tube placement^a	35 (100%)	35 (100%)	1.000
Oropharyngeal leak pressure (cmH₂O)^{b,c}	20.51 ± 4.71	19.57 ± 5.71	0.453
Fibreoptic view score^a			
1	5 (14.3%)	9 (25.7%)	0.232
2	11 (31.4%)	15 (42.9%)	0.322
3	0	1 (2.9%)	1.000
4	19 (54.3%)	10 (28.6%)	0.029

^a Chi-Square test.

^b Data expressed in terms of Mean ± SD.

^c Student *t*-test.

^d Fischer Exact test.

**Figure 2** Mean oropharyngeal leak pressure between the two groups.

height, and weight. ASA status was comparable between the groups ($p = 1.00$). Most of the patients in group LMA Proseal underwent cervical node excision (37.14%) whereas group i-gel underwent circumcision (34.28%). The mean duration of surgery in group LMA Proseal was higher as compared to group i-gel; however, statistically insignificant ($p = 0.203$).

Size 2 device was used in most of the children in both groups. In most of the children, LMA Proseal or i-gel insertion was achieved in the first attempt. Ease of insertion was graded as "very easy" in most children of both groups. Size of the device, ease of insertion and number attempts were comparable between the groups. The OLP was similar between the two groups and the difference was not statistically significant (LMA Proseal vs. i-gel, 20.51 ± 4.71 cm H₂O vs. 19.57 ± 5.71 cm H₂O; $p = 0.453$); (Fig. 2). The mean insertion time was faster in group i-gel as compared to group LMA Proseal and the difference was statistically significant

Table 3 Profile of perioperative complications.

Variables	Group LMA Proseal	Group i-gel	p-value
Blood on device	1 (2.9%)	0	1.000
Sore throat	2 (5.7%)	3 (8.6%)	
Post-extubation cough	1 (2.9%)	0	

($p = 0.0001$). The fibreoptic view was comparable in both the groups, where most of the cases in group LMA Proseal (54.3%) had grade 4 view while most cases in group i-gel (42.9%) had grade 2 view. Gastric tube placement was 100% successful in both groups (Table 2). Perioperative complication was comparable between the groups (Table 3). The sore throat was the commonest complication observed in both groups.

Discussion

The study found that the OLP immediately following insertion of i-gel was similar to LMA Proseal and hence the superiority hypothesis cannot be adopted. Similarly, the ease of placement of the device, first insertion attempt success, and the fiberoptic visualization of the glottis was comparable between the two devices. However, the time to successful placement of i-gel was significantly shorter than LMA Proseal.

A higher OLP is required to ensure positive pressure ventilation with SADs. It was speculated that i-gel with its soft, non-inflatable, gel-like cuff designed to mirror the pharyngeal structures may result in a higher OLP than LMA Proseal. Although there was no significant difference in OLP immediately after device insertion, the results of the present

study should be interpreted with caution. The finding with respect to OLP in the present study is similar to studies of Gasteiger et al.¹⁰ and Saran et al.,⁴ who observed that the OLP between the two devices was similar. In contrast, the OLP with i-gel was significantly higher than LMA Proseal in a few studies.^{6,11–14} The comparison of OLP between various studies is complicated by the difference in the methodology adopted, such as under spontaneous ventilation, presentation of results, and the size of the device employed in the study. The studies by Acharya R et al.¹¹ and Goyal R et al.,¹² employed spontaneous ventilation, whereas in the present study children were paralysed, which might explain the difference in the results. OLP is difficult to perform accurately in spontaneously ventilating patient, since a constant airway pressure cannot be obtained, as the seal probably varies throughout the respiratory cycle due to changes in pharyngeal wall tone, as opined by Brimacombe.¹⁵ In the study by Mitra S et al.,¹³ the device size used was only 2.5. In the present study, although the devices of size 2 and 2.5 were used, the predominant size of device used was number 2 in more than 70% of children, which might explain the difference in the results. The sealing pressure of i-gel has been suggested to improve over time as it may conform to the upper airway anatomy better as it approaches body temperature due to the thermoplastic nature of the material.¹⁶ In the present study the OLP was measured in both groups immediately following device insertion, and may be another reason for similarity in the OLP in the two groups.

Fibreoptic visualization of glottis used to assess appropriate placement of SAD was comparable between the two devices and was consistent with previous studies.^{4,6,10,14} The incidence of complications in the present study was low in both groups, however no statistical inference about the same can be drawn as it is not powered to study the same.

The present study had a few limitations that need to be acknowledged. First, unblinded observers collected the data. Blinding was not possible as i-gel appears different from LMA Proseal. Second, the study was performed in children with normal airway and hence the findings cannot be inferred to those with difficult airway or abnormal upper airway anatomy. Third, insertion of devices was performed by a single experienced user and hence the findings may not apply to inexperienced users, such as residents. Finally, the number of children receiving 2.5-size device was relatively small.

Conclusion

The present study showed that the OLP with i-gel was similar to LMA Proseal immediately following insertion of the device under controlled ventilation in children. In addition, the two devices were similar with respect of ease of insertion, number of attempts, and fiberoptic view of glottis. The i-gel demonstrated a shorter time to successful placement compared with LMA Proseal.

Author's contributions

Study conceptualization and designing have been done by Dr. Tejesh CA. Data acquisition, analysis and interpretation of

the data have been performed by Dr. Praveen. The first draft of the manuscript has been prepared by Dr. Praveen. Draft is revised by Dr. Tejesh CA. Both the authors have approved the final manuscript and are the grantor for this study.

Conflicts of interest

The authors declare no conflicts of interest.

Acknowledgments

Both the authors have contributed equally in the development of manuscript.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:<https://doi.org/10.1016/j.bjane.2021.02.042>.

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