# Comparing I-Gel to Proseal Laryngeal Mask Airways in Infants: A Prospective Randomised Clinical Study

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## Abstract

**Objective:** Laryngeal mask airways and the I-gel have become increasingly popular for children undergoing minor surgery. The goal of our study is to compare I-gel and ProSeal laryngeal mask airways (LMA) in infants by analysing different parameters, such as insertion success, ventilation, haemodynamic changes and postoperative complications.

**Methods:** For this prospective, randomised study, we selected 123 infants with an American Society of Anaesthesiologists (ASA) status I, who were undergoing minor elective lower abdominal surgery. After obtaining verbal and written informed consent from the parents, the infants were divided into two groups: the I-gel group (n=60) and the ProSeal LMA group (n=63). The times and ease of insertion, percentages of tidal volume leakage, and means and leakage pressures of these two supraglottic airways were noted. The complications and side-effects of each method were also recorded.

**Results:** The insertion time of the ProSeal group was statistically shorter than that of the I-gel group. The peak and mean pressures and the leakage percentage of the ProSeal group were statistically lower than those of the I-gel group. The leakage pressure of the ProSeal group was statistically higher than the I-gel group.

**Conclusion:** In comparison with I-gel, the use of ProSeal LMA in infants' anaesthesia presents many advantages, such as the ease of its insertion, better oropharyngeal leakage pressure and less mucosal hyperaemia.

**Keywords:** I-gel, infant, proseal laryngeal mask

## Introduction

In modern anaesthetic practice, supraglottic airway devices (SADs) have become increasingly preferred for children undergoing minor surgery. Various laryngeal mask airways (LMAs) and I-gel been compared in many studies. In the previous literature, studies involving infants (i.e., children aged less than 12 months) are very rare (1-10).

Authors of previous studies have reported that in children, I-gel provides an effective airway and is easy to place (11, 12). Due to of its non-inflatable cuff, the insertion of I-gel is time-saving and can be easily placed even by inexperienced users.

Several randomised studies have compared the I-gel with the ProSeal LMA in infants, however, the results of these studies remained inconsistent (2, 13-15).

In this study, we investigated different parameters of the two methods of intubation, such as insertion success, insertion time, airway leak pressure, induced haemodynamic changes, oxygen saturation ($SpO_2$) values, end tidal $CO_2$ ($EtCO_2$) values, and postoperative complications to emphasise the advantages of utilising one method over the other.

## Methods

After obtaining the approval of an institutional review board (SEEAH/23.01.2018/1871), informed consent was obtained from the parents of all the infants who were included in this prospective randomised study.

In this study, we included infants having an American Society of Anaesthesiologists (ASA) status I, who were under 12 months of age, and were undergoing minor (<1 hour in duration) elective surgery. These surgeries included unilateral orchidopexy and unilateral herniorrhaphy. Patients with pulmonary disease, upper respiratory tract infections, a history of prematurity, probable airway difficulties and diseases predisposing them to aspiration were excluded from the study.

We selected 123 infants (Table 1) and divided them as follows: 60 infants in the I-gel group (Group I) (İntersurgical, Sankt Augustin, Germany) and 63 infants in the ProSeal LMA group (Group P) (North America Inc. San Diego, California). A nurse who was not involved in the patients' anaesthetic or postanaesthetic care performed the randomisation. The infants were not premedicated. In the operating room, monitoring (Drager Infinity Delta XL Lübeck, Germany) was instituted through electrocardiography, pulse oximetry, non-invasive blood pressure measuring, capnography, and the bispectral index (BIS) (Covidien, Colorado,USA). The demographic data contained each patient's age, sex, type of operation and duration of anaesthesia and surgery. For both groups, the anaesthesia technique applied was the same.

For each patient's anaesthesia induction, 6% sevoflurane was administered and an intravenous cannula was inserted. To obtain BIS index values of less than 60, 1% propofol and 1 µg kg$^{-1}$ fentanyl was injected. The sizes of the SADs were selected according to each infant's weight and as recommended by the manufacturer. For patients who weighed less than 5 kg, a size 1 SAD was used, whereas for patients who weighed between 5 kg and 10 kg, a SAD of size 1.5 was used. A Mallinckrodt monitor was used to obtain an LMA cuff pressure of 30-40 mmHg. The same anaesthesiologist who had performed this procedure more than 50 times inserted all the devices. Symmetrical movement of the chest wall and a square waveform on the capnognaph indicated a as a successful insertion. A maximum of three attempts were made to insert the SADs in each patient. The insertion time was defined as the time between the moment of the SAD selection and the first waveform appearance on the capnograph. A scoring system from 1 to 3 was used to grade the simplicity of the insertion (1=easy; 2=difficult; 3=impossible) (11, 16). An unsuccessful insertion after three attempts was defined as a failed insertion.

In order to attain a BIS index between 50 and 60, we used a 50% oxygen-air mixture containing 6% sevoflurane. A Draeger anaesthesia machine (Primus) was adjusted to provide each infant with a respiratory frequency of 18-24, a tidal volume of 6-8 mL kg$^{-1}$, and an EtCO$_2$ value of less than 50. No neuromuscular blockers were used.

The percentage of the tidal volume leakage and the peak, mean, and leakage pressures were noted at three time points: immediately after the insertion of the SAD, 10 minutes after insertion and the just before extubating. The difference in the inspiratory and expiratory tidal volume divided by the inspiratory tidal volume was accepted as the leakage percentage. The leakage pressure was calculated by closing the expiratory valve of the circle system at a fixed gas flow of 3 L minute$^{-1}$ and recording the airway pressure when the equilibrium was reached. While performing manual positive pressure ventilation, the maximum peak pressure that caused air leakage from the mouth (and was audible) was accepted as the leakage pressure (7, 16).

After the ProSeal LMA or I-gel insertion and before and after extubating, the HR, SpO$_2$, and EtCO$_2$ values for each patient were recorded.

After the surgery, when each patient regained consciousness, their ProSeal LMA or I-gel was removed. Upon removal, each device was observed for any evidence of blood and any mucosal hyperaemia or mucosal damage was recorded.

### Statistical analyses

Assuming at least a 30% possible difference between the two groups, we calculated the sample size to be 40 patients per group. We designed the groups such that we could obtain an alpha error in the range of 5% with an 80% statistical power, taking into account the unpredictable loss of some data. Statistical analyses were done with Statistical Package for the Social Sciences (SPSS Inc.; Chicago, IL, USA) version 15.0 for Windows software. Mean, standard deviation and median were calculated as numbers, while the number and percentage were calculated as categorical variables for descriptive statistics.

The Student's t-test was used for normal distributions and the Mann-Whitney U test was used for non-parametric data. The ratio of categorical variables between the two groups was calculated using the Chi-square method. A p-value of less than 0.05 was accepted as significant.

## Results

In the I-gel group, 60 patients completed the study. Due to excessive secretions at the induction of anaesthesia, three cases were excluded.

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The demographic and surgical data of the two groups were similar (Tables 1 and 2). The insertion time of the ProSeal group was statistically significantly shorter (8.1±2.8 minutes) than that of the I-gel group (11.2±2.7 minutes; p<0.001). The I-gel was successfully inserted in 43 patients (71.1%) after a single attempt versus 53 patients (84.1%) in the ProSeal LMA group. In 13 patients (21.7%) in the I-gel group and 10 patients (15.9%) in the ProSeal LMA group, insertion of the device was successful in the second attempt. Four failed insertions were observed in the I-gel group. The ease of insertion for both SADs was comparable (Table 3). HR values at pre- and post-extubation were also similar in both groups (p=0.824 and p=0.472, respectively). In the two groups, the

SpO$_2$ and EtCO$_2$ values were not statistically different (Table 4). The peak and mean pressures and the leakage percentage of the ProSeal LMA group were statistically significantly lower as compared to the I-gel group. The leakage pressure of the ProSeal group was statistically significantly higher as compared to the I-gel group (Table 5). Postoperative complications, such as blood on the surface of the SAD, mucosal damage, bronchospasms, coughing and bloating, were similar between the two groups, however, mucosal hyperaemia was observed more frequently in the I-gel group (15 patients; 25.0%) than in the ProSeal group (4 patients; 6.3%) (p=0.004) (Table 6).

## Discussion

The use of SADs has gained popularity in paediatric anaesthesia, although tracheal intubation is still the gold standard method for airway safety and ventilation.

In the previous literature, studies concerning the use of I-gel in infants are very rare (11, 15). Studies conducted on older children and adults generally concluded that I-gel is comparable to LMA.

In this study, the I-gel and ProSeal LMA were compared in infants. Due to the proven safety of the ProSeal LMA in infants and the results of our previous study that showed that ProSeal LMA is safer than Supreme LMA in infants, we preferred to compare I-gel with ProSeal LMA in this study (4, 15).

The insertion time of the ProSeal LMA was shorter than that of the I-gel, the peak and mean pressures and the leakage percentage of the ProSeal LMA were lower, and the oropharyngeal leakage pressure was higher in the ProSeal LMA than in the I-gel. The leakage percentage is a rapid indicator of the tidal volume loss and is even more important in our study

### Table 1. Patient demographics

|  | Group I (n=60) | Group P (n=63) |
|---|---|---|
| Age (months) mean±SD | 5.3±3.3 | 5.4±2.9 |
| Gender (F/M) (%) | 14 (23.3)/46 (76.7) | 14 (22.2)/49 (77.8) |
| Weight (kg) mean±SD | 6.6±2.2 | 6.9±1.6 |
| LMA Size 1 (n) (%) | 22 (36.6) | 24 (38.0) |
| LMA Size 1.5 (n) (%) | 38 (63.3) | 39 (61.9) |

LMA: Laryngeal Mask Airway: F: female; M: male; SD: standard deviation

### Table 2. Surgical characteristics

|  | Group I (n=56) Mean±SD | Group P (n=63) Mean±SD | p |
|---|---|---|---|
| Anaesthesia time (minutes) | 45.8±13.9 | 45.2±18.4 | 0.384 |
| Surgical time (minutes) | 34.8±13.0 | 35.4±14.0 | 0.964 |
| SAD duration (minutes) | 39.8±14.0 | 40.8±17.6 | 0.970 |
| Recovery time (minutes) | 7.1±2.4 | 7.3±2.1 | 0.496 |

p<0.05 is statistically significant. SAD: supraglottic airway device

### Table 3. Laryngeal Mask Airway insertion characteristics

|  |  | Group I (n=60) Mean±SD | | Group P (n=63) Mean±SD | | p |
|---|---|---|---|---|---|---|
| SAD Insertion Time (seconds) | | 11.2±2.7 | | 8.1±2.8 | | <0.001 |
|  |  | n | % | n | % | p |
| Ease of SAD Insertion | 1 | 43 | 71.7 | 53 | 84.1 | 0.064 |
|  | 2 | 13 | 21.7 | 10 | 15.9 |  |
|  | 3 | 4 | 6.7 | 0 | 0.0 |  |
| Number of Manipulations Required | 1 | 43 | 71.7 | 53 | 84.1 | 0.155 |
| To Insert SAD | 2 | 16 | 26.7 | 10 | 15.9 |  |
|  | 3 | 1 | 1.7 | 0 | 0.0 |  |

p<0.05 is statistically significant. Ease of SAD insertion was graded as 1: no resistance (easy), 2: moderate resistance (difficult), or 3: inability (impossible) to place the SAD
SAD: supraglottic airway device; SD: standard deviation

because the tidal volumes of infants are very small. I-gel is a second-generation, disposable SAD with a non-inflatable cuff made of thermoplastic elastomers, and it differs from other laryngeal masks (2). In sizes other than size no. 1, the I-gel has a gastric drain port. The second-generation LMA ProSeal is reusable. None of the paediatric sizes have a dorsal cuff, and the ProSeal LMA has a gastric drain port in all sizes.

| Table 4. Hemodynamic variables | | | |
|---|---|---|---|
| | Group I (n=56) Mean±SD | Group P (n=63) Mean±SD | p |
| HR Beginning | 136.1±12.9 | 137.2±8.4 | 0.545 |
| HR after SAD insertion | 134.0±10.6 | 135.1±12.9 | 0.958 |
| HR before extubating | 129.5±9.6 | 129.2±9.0 | 0.824 |
| HR after extubating | 133.2±11.5 | 133.7±9.1 | 0.472 |
| $SpO_2$ beginning | 99.9±0.3 | 99.9±0.2 | 0.925 |
| $SpO_2$ after SAD insertion | 99.7±0.7 | 99.6±1.0 | 0.899 |
| $SpO_2$ before extubating | 99.8±0.5 | 99.7±0.7 | 0.162 |
| $SpO_2$ after extubating | 99.8±0.5 | 99.7±0.7 | 0.279 |
| Et $CO_2$ beginning | 32.5±3.5 | 32.1±1.9 | 0.717 |
| Et $CO_2$ before extubating | 32.4±3.5 | 32.1±1.8 | 0.672 |

p<0.05 is statistically significant. HR: heart rate; SAD: supraglottic airway device; $SpO_2$: oxygen saturation; $EtCO_2$: end tidal carbon dioxide value

| Table 5. Mean ventilation parameters[a] | | | |
|---|---|---|---|
| | Group I (n=56) Mean±SD | Group P (n=63) Mean±SD | p |
| Peak pressure (cm $H_2O$) | 21.5±2.4 | 18.2±3.2 | <0.001 |
| Mean pressure (cm $H_2O$) | 8.6±1.0 | 7.1±1.3 | <0.001 |
| Leakage percentage (%) | 7.5±1.0 | 6.1±1.3 | <0.001 |
| Leakage pressure (cm $H_2O$) | 31.1±2.0 | 33.2±2.0 | <0.001 |

[a]the parameters were measured thrice: first, after LMA insertion; second, 10 minutes after SAD insertion; and third, before extubating. The mean±SD were statistically analysed. P<0.05 is statistically significant. SD: standard deviation

| Table 6. Mucosal damage and complications | | | | | |
|---|---|---|---|---|---|
| | Group I (n=56) | | Group P (n=63) | | |
| | n | % | n | % | p |
| Mucosal damage | 5 | 8.3 | 3 | 4.8 | 0.484 |
| Mucosal hyperaemia | 15 | 25.0 | 4 | 6.3 | 0.004 |
| Blood on SAD | 7 | 11.7 | 3 | 4.8 | 0.198 |
| Complications | 4 | 6.7 | 3 | 4.8 | 0.713 |
| Bronchospasm | 1 | 1.7 | 0 | 0.0 | |
| Bloating | 1 | 1.7 | 1 | 1.6 | |
| Cough | 2 | 3.3 | 2 | 3.2 | |

p<0.05 is statistically significant. SAD: supraglottic airway device

Previous studies have demonstrated that the I-gel provides an effective airway and that its placement is easy (11, 12). As it is unnecessary to inflate its cuff, the I-gel is time-saving and can be easily placed even by inexperienced users (17, 18). However, the insertion of SADs, especially in small infants, may be more challenging because of their small dimension laryngeal and oropharyngeal anatomy, anteriorly and highly situated larynx, floppy epiglottises and larger tongues.

Only a few clinical studies on SADs have been conducted on small infants. Though several randomised trials have compared the ProSeal LMA with the I-gel in infants, their conclusions were shown to vary widely (11-15).

In a study conducted by Sanket et al. (13), the I-gel and ProSeal LMAs were found to be similar in their use in children, including infants. The insertion time of the I-gel in their study was significantly shorter as compared to the insertion time of the ProSeal LMA. The researchers also reported that, regarding the paediatric sizes of the ProSeal LMA, an absent dorsal cuff may have reduced the overall bulk of the cuff, improving the ease of insertion. They also added that a study with a larger sample size, particularly for size no. 1 ProSeal and I-gel LMAs, should be undertaken to establish their safety in neonates.

In another previous study on infants, I-gel was compared with the Classic LMA. The I-gel was found to be easier to insert than the Classic LMA. A limitation of this study was that the number of infants receiving a size no. 1 LMA was small (11).

Kayhan et al. (2) reported that the I-gel is advantageous for paediatric patients over 5 kg due to the ease of its insertion, ease of gastric tube insertion, and sufficient ventilation. On the other hand, based on their clinical observations, the researchers agreed that paediatric-sized I-gels are likely to dislodge and should be taped well. They warned that the absence of a gastric drainage tube in a size 1 I-gel may increase

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the risk of gastric regurgitation or aspiration (2). Likewise, in four of our cases, I-gel devices dislodged and surgical intervention continued after these patients' intubations. In three cases in the I-gel group, after two manipulations for insertion, the $SpO_2$ decreased to less than 90 and we could, therefore, not attempt the third manipulation.

Hughes et al. (12) evaluated the I-gel in child anaesthesia and concluded that a paediatric I-gel size between 1.5 and 2.5 provided a satisfactory airway. On the other hand, the I-gel tended to displace upward out of the mouth, which could be reversed by extending the proximal tube toward the forehead and flexing it toward the feet. In our study, we encountered the same problem when using the I-gel, i.e., in infants, the I-gel tended to displace upward out of the mouth. Compared to other studies, the number of infants of low weight in our study was larger, therefore, we inserted a size 1 I-gel in 22 infants and a ProSeal in 24 infants. An explanation for this may be that the paediatric-sized I-gels are simply scaled-down versions of the adult sizes. Consequently, in comparison with the ProSeal LMAs, the insertion time of the I-gel LMAs was longer because two manipulations were required in 16 infants and three manipulations in one infant. All four patients, who were intubated, belonged to the I-gel size 1 group. The operations selected for our study were minor lower abdominal surgeries that ensured the easy correction of any respiratory complications.

In adult I-gel sizes, there is a horizontal line on the integral bite block that indicates proper positioning. This line is not present in paediatric sizes, which is another issue. As the oropharyngeal-laryngeal arch is variable in children, it is recommended that the paediatric I-gel be inserted until resistance is felt. Abukawa et al. (1) investigated the relationship between the insertion length of I-gel sizes 1.5, 2 and 2.5, along with the patients' heights and weights. The size 1 I-gel was not assessed in the study, as the patient cohort did not require that size. Appropriate I-gel sizes were determined according to each patient's weight. The results revealed that I-gel insertion length was related to patient height for paediatric sizes 1.5 and 2.0, but not for size 2.5. Considering our own results, which demonstrated the superiority of the ProSeal LMA over the I-gel in infants, we believe that it is necessary for further studies to investigate the use of the I-gel in infants under the same method used by Abukawa et al. (1).

In their study, Pant et al. (6) reported that the oropharyngeal seal pressure of the I-gel was higher compared to classic laryngeal masks, thus, they recommended the use of the I-gel in infants. However, their study was limited by its small sample size.

Our study has several limitations. One of them is that the same experienced paediatric anaesthetist inserted all the

SADs and it may be assumed that this affected the results related to insertion. Another limitation is that all the infants were ASA I and had normal airways. Finally, the positioning of the SADs was not controlled through fibreoptic laryngoscopy.

## Conclusion

Our study showed that in comparison with the I-gel, the use of ProSeal LMA in infant anaesthesia presents many advantages, such as the ease of its insertion, better oropharyngeal leakage pressure and less mucosal hyperaemia.

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