Comparison of I-Gel and classic Laryngeal Mask Airway in pediatric population: a parallel group study

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**Abstract**

**Background:** I-gel is easier to insert, has improved stability after insertion with reduced tissue compression.The study aims to compare the efficacy of I-gel with classic Laryngeal Mask Airway in pediatric population.

**Methods:** A randomized parallel group study was done in Department of Anesthesiology, Kanti Children Hospital, Kathmandu for period of three months. I gel and classic LMA was compared based on leak airway pressure, time of insertion and ease of insertion.

**Results:** Age and weight are comparable among groups. Compared to cLMA, I-gel provides better leak airway pressure seal (16.40±3.42 vs. 23.11± 6.17 cm of H2O, p 0.027), faster time of insertion (19.42±4.40 vs. 29.84±7.70 seconds, p-0.02) and similar ease of insertion (p-0.571).

**Conclusions:** I-gel compared to classic Laryngeal Mask Airway provides better resistance to leak airway pressure, faster time of insertion with comparable ease of insertion.

**Keywords:** airway, I -gel, laryngeal mask airway, supraglottic devices

# Introduction

Use of supraglottic airway devices has been a common practice. Nowadays various modifications have been done to make it easier to use with improvements in the safety profiles. I-gel is a newer second generation supraglottic airway device with promising results.[1](#_ENREF_1)

The cLMA (classic laryngeal mask airway) is the earliest of supraglottic device discovered in 1983 by Archie Bains. It is recommended as a conduit in difficult airway guidelines and also used routinely for elective surgery and cardiopulmonary resuscitation.[2](#_ENREF_2)However, airway cuff has to be inflated to get good perilaryngeal seal. There is also risk of nerve injury, venous compression and tissue distortion.[3](#_ENREF_3), [4](#_ENREF_4) I-gel is effective, safe for pediatric airway management.[5](#_ENREF_5) I- gel is easier to insert, less tissue compression and more stable after insertion.[6](#_ENREF_6) With the introduction of newer suproglottic devices and their modification, the study aims to compare the efficacy of I-gel with classic LMA in pediatric population.

# Materials and Methods

A parallel group study was done in Department of Anesthesiology, Kanti Children Hospital, Kathmandu for period of three months. Patients recruited in the study were randomized into two groups by lottery method. The sample was picked up by a blinded care provider from envelope containing equal number of I-gel and cLMA slip of similar sizes. The sample size was calculated with reference to Bikramjit et al study[7](#_ENREF_7) with primary outcome variable as airway leak pressure of the I‑gel group (27.1±2.6 cm H2O) and the classic LMA group (23.63±2.3 cm H2O). Z-alpha at 95% confidence interval as 1.96 and Z-beta at 95% power as 1.6 was considered for the study. The sample calculated was 13 in each group and taking the drop out consideration of forty percentages in each group sample calculated was total 40 with 20 in each group. The secondary outcome variables were time of insertion and ease of insertion. All cases belonging to American Society of Anesthesiology Physical Status Grade I under elective surgical list with estimated weight of 10 to 30 kilogram were included in the study. Patient who refused to participate in the study and had anticipated difficult airway with known allergy with use of devices and possible risk of aspiration were excluded from the study.

## Intervention Details

Preoperative:

Pre-operative fasting was done according to hospital guidelines. The size of I-gel (Intersurgical) or LMA Classic (Intavent) selected for insertion was based on the patients weight and according to the manufacturer’s recommendations (i-gel: size 1.5, 10-12 kg; size 2, 12–25 kg; size 2.5, 25–30 kg. LMA Classic: size 2, 10–20 kg; size 2.5, 20–30 kg.).The standard pre-use tests for both devices were performed. Both devices were lubricated using on the tip and posterior surface as recommended by the manufacturers and the cLMA was full deflated prior to insertion. Premedication was not administered.

Intraoperative:

Patient was kept on soft pillow with neck flexed and head extended before induction of anesthesia. Standard monitors were connected. Anesthesia was induced intravenously using a Propofol 2.5mg/kg or Halothane. Loss of verbal communication with the patient with lost eyelash reflex, central and constricted pupil and relaxed jaw was taken as a confirmed sign of induction of anesthesia. Adequate depth of anaesthesia was adjusted with additional propofol infusion in case the patient had coughing, gagging or any body movements. Increments of 5 ml air were introduced into the cuff until a good seal was achieved. This was checked by squeezing the breathing bag gently with the adjustable pressure limiting valve set to 10 cm H2O after connecting the breathing system. Presence of a square wave pattern on capnography and absence of any audible leak was used to indicate a good seal and adequate ventilation. Total time of insertion was from the moment of removal of facemask to first upstroke on capnograph monitor. Manipulations were allowed in the following sequence: gentle pushing or pulling of the device; changing head position by extension or flexion; and jaw thrust. The pressure inside the cuff of the laryngeal mask was then measured by closing the expiratory valve, keeping fresh gas flow at 4 liters/min and allowing the pressure to rise gradually until the audible leak was heard. If the cuff pressure was > 40 cmH2O, the cuff was deflated to allow the cuff pressure to fall below 40 cm H2O. If the airway had to be taken out of the mouth because of an audible leak or the absence of a square wave on capnography, it was considered unsuccessful and the same device was re-inserted. Two insertion attempts were allowed for each device before declaring failure. A larger sized device was used if there was an unacceptable leak even at low pressures following successful insertion. The anesthesiologist with a personal experience of > 50 classic LMA and 10 I-gel supra-glottic airway insertions before commencing the study inserted all devices. The ease of insertion was graded as no resistance, mild resistance, moderate resistance or inability to place the device. Records of any complications including airway obstruction and number of insertions were made. Anesthesia was maintained using halothane, oxygen and spontaneous ventilation. At the end of the procedure the patients remained in the supine position and device was removed in deep level of anesthesia followed by suctioning of airway if required and transferred to recovery room. Data was entered into and analyzed using Microsoft Excel 2007 and SPSS (Statistical package for social sciences). Chi-square test was used for ease of insertion, gender (categorical variables). An unpaired t-test was used for time of insertion.

Written consent was taken prior to surgery with the patient party after explaining all the details of the study. Approval was taken from the institutional review board (IRB) of Kanti children hospital prior to start of the study.

# CONSORT FLOW DIAGRAM

## Allocation

Excluded (n= 25)

  Not meeting inclusion criteria (n= 22)

  Declined to participate (n= 2)

  Other reasons (n=1)

Assessed for eligibility (n= 65 )

## Enrollment

Randomized (n= 40 )

Allocated to intervention [ cLMA ] (n=20 )

 Received allocated intervention (n=20 )

Allocated to intervention [ I- gel ](n=20 )

 Received allocated intervention (n=20 )

Analysed (n=0)
 Excluded from analysis (n= 0 )

Analysed (n=20)
 Excluded from analysis (n= 0 )

## Analysis

# Results:

## Table 1. Age and weight among two groups (Mean**±Standard Deviation)**

|  |  |  |  |
| --- | --- | --- | --- |
|  | cLMA | I-gel | **p-value** |
| Age | 7.40±3.500 | 6.80±1.704 | 0.495 |
| Weight | 20.30±5.886 | 19.45±2.350 | 0.552 |

Age and weight are comparable among groups with both the I-gel and cLMA. There is no much difference in the demographic status as they are not statistically significant.

## Table 2. Variables among two groups (Mean**±Standard Deviation)**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **cLMA** | **I-gel** | **p-value** |
| **Leak airway pressure (cm of H20)** | 16.40±3.42 | 23.11±6.17 | 0.027 |
| **Time of insertion ( seconds)** | 29.84±7.70 | 19.42±4.40 | 0.02 |

Leak pressure is better with I-gel group then cLMA and is statistically significant (p- 0.027). Compared to cLMA leak airway pressure for I-gel is 23.11± 6.17 cm of H20.

## Table 3. Ease of insertion

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | No | Mild | Moderate | p-value |
| cLMA  | 6 | 3 | 11 | 0.571 |
| I-gel | 7 | 1 | 12 |  |

There is no much difference in ease of insertion between the groups. Majority of groups fall in moderate resistance category.

# Discussions

I-gel is a latex single use device. This device is based on anatomy and physiology of perilaryngeal framework. The shape, softness and contours accurately mirror the perilaryngeal anatomy to create the perfect fit. The perfect fitting ensures that no cuff inflation is required. The device gets its name from the soft gel-like material from which it is made. It is made of a thermoplastic elastomer (SEBS, styrene ethylene butadiene styrene) which ensures that no cuff is required.[2](#_ENREF_2)The device can be used for routine and emergency surgical procedures, spontaneous and intermittent positive pressure ventilation, resuscitation and also as recommended conduit for difficult airway.[2](#_ENREF_2) The I-gel is a novel SAD designed by UK anaesthetist, Muhammed Nasir. Pediatric I- gels were introduced in 2009: preliminary evaluation are positive.[2](#_ENREF_2) In pediatric population it is available in four pediatric sizes and its use in this group has been equally justified as in adult population.The I-gel also incorporates a gastric channel which allows the nasogastric tube to empty stomach contents and facilitates venting. The integral bite block reduces the possibility of airway channel occlusion. The buccal cavity stabilizer aids insertion and eliminates the potential for rotation. The epiglottic rest reduces the possibility of epiglottic ‘down folding’ and airway obstruction.[8](#_ENREF_8) A better hemodynamic profile with proper positioning has also been demonstrated feature of I-gel.[9](#_ENREF_9)

Dr Bain’s cLMA was introduced into clinical practice in 1988 and it has

ample evidence to prove its safety profile and effectiveness.[2](#_ENREF_2)However,

there is always a risk of pulmonary aspiration of regurgitated material and lesser possibility of controlled ventilation due to moderate degree of pharyngeal seal. The low pressure pharyngeal seal given by cLMA (median 20 cm H2O, rarely 30 cm H2O, there is always risk of hypoventilation, environmental pollution and wastage of drug. Additionally there is higher risk of regurgitation and subsequent aspiration as the larger proportion of the gas leaks and enters the esophagus and stomach. I-gel has been specifically designed to address this shortcoming as a newer generation supraglottic airway devices.[2](#_ENREF_2)

Leak airway pressure in our study is significant (p-0.027) in cLMA group (16.40±3.42 cm of H2O) as compared to I-gel (23.11±6.17 cm of H2O). Similar significant (p-0.023) finding is also found in Janakiraman‘s study[10](#_ENREF_10) where the time of leak airway pressure in I-gel group is 20 [14-24] cm of H2O as compared to cLMA group. The fiberoptic view is also better with I-gel than cLMA (p-0.003). However, Lee[11](#_ENREF_11) suggests a contrast finding in his study where there is no significant difference but a better fiberoptic view. Bikramjit das[7](#_ENREF_7) also suggests an I-gel leak airway pressure (27.11±6.17 cm of H2O) significantly better than cLMA ((16.49± 3.42 cm of H2O). Other studies involving leak pressure also suggested similar leak pressure in his finding.[12](#_ENREF_12), [13](#_ENREF_13) The reason behind is possibly due to thermoplastic elastomer with soft durometer materials designed to fit automatically in perilaryngeal and hypopharyngeal structures without the use of inflatable cuff, a feature unique to i.gel.

I-gel in our study (19.42±4.40 seconds) has significantly (p-0.02) better time of insertion than cLMA (29.84±7.70 seconds). A similar finding was also shown by Lee[11](#_ENREF_11) [cLMA - 21 (17.5-25) seconds, I-gel: 17 (13.8-20.00) seconds, p-0.002]. Straoumpoulis also suggested better insertion time [13.32± 4.99 seconds].[14](#_ENREF_14) The possible reason is the absence of inflatable cuff which require more time for completing insertion as was defined in our details. Other reason could be ease of insertion that accounted for the decrease.

The ease of insertion is not significant among the groups and almost comparable. It is thought that I-gel has had a broader shaft which would prevent rotation and make the resistance less. Similar observation is also made by Janakiraman[10](#_ENREF_10) where I- gel is less easy to insert in 40 (80%) of subject as compared to cLMA 45 (90%). He pointed out the reason of size recommendation of I-gel by the manufacturer was not justified. Bikramdas[7](#_ENREF_7) also suggested no difference in ease of insertion. The difference in perilaryngeal framework in different population can be another possible reason. Majority of patients falling under moderate resistance category may be due to the fact that most of the working anesthesiologist were initial users of i-gel and classic LMA.

The study highlights that I- gel provide better option in terms of safety and effectiveness in our pediatric populations. Even though the study suggested a difference in finding among the groups, the chances of interpersonal variability in the skill couldn’t be neglected. The sample size could be very less to come to strong conclusion even though the statistical analysis suggest. A large group multiinstituional study could give a more accurate picture and the findings may improve as the people are used to using I-gel more than cLMA.

# Conclusions:

I-gel compared to classic LMA provides better resistance to leak airway pressure, faster time of insertion with comparable ease of insertion in pediatric populations.

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