Comparison of I-Gel and classic LMA in pediatric population

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**Abstract**

**Background:** I-gel offers the potential for easier insertion, reduced tissue compression and increased stability after insertion.The study aims to compare the efficacy of i-gel with classic LMA in pediatric population.

**Methods:** A randomized, single blinded, 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 peak airway pressure, time of insertion, ease of insertion.

**Results:** Age and weight are comparable among groups with both the i-gel and cLMA. Compared to cLMA, I-gel provides better peak 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 LMA provides better resistance to peak 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 modification has 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

The cLMA(classic laryngeal mask airway) is the earliest of supraglottic device discovered in 1983 by Archie Bains. It has been widely used as a routine airway for elective surgery and during cardiopulmonary resuscitation and also included as a conduit for difficult airway guidelines.2 However, airway cuff has to be inflated to get good perilaryngeal seal. This has the potential to cause tissue distortion, venous compression and nerve injury.3 Depending upon the material from which the cuff is made, they can absorb anaesthetic gases, which can lead to increased mucosal pressure.4

I-gel has a very good insertion success rate and very few complications. It seems to be an efficient and safe device for pediatric airway management.5 This offers the potential for easier insertion, reduced tissue compression and increased stability after insertion.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 randomized, single blinded, study was done in Department of Anesthesiology, Kanti Children Hospital, Kathmandu for period of three months. Patients recruited in the study was randomized into two groups by lottery method. The sample size was calculated with reference to Bikramjit et al study14 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 fort percentage in easch group sample calculated was total 40 with 20 in each group. All cases belonging to American Society of Anesthesiology Physical Status Grade I under elective surgical list with estimated weight of 10 to 25 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

Following Ethical Committee approval and written informed consent, ASA physical status I patients undergoing general anesthesia in which an LMA was considered appropriate were enrolled into the study.

Preoperative:

All patients underwent pre-operative fasting 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 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. Patients were assigned to treatment groups to receive either the i-gel or cLMA supra-glottic airway as the initial airway using a lottery method. No premedication was administered.

Intraoperative:

Once the patient was on the operation table, head was placed on a soft pillow before induction of anesthesia with the patients’ neck flexed and head extended. Standard monitors were connected. Anesthesia was induced intravenously using a Propofol 2.5mg/kg or halothane. Induction of anaesthesia was confirmed by loss of verbal communication with the patient, loss of eyelash reflex and relaxation of the jaw, pupils central and constricted. If coughing, gagging, or body movement occurred during insertion, propofol infusion was adjusted according to adequate depth of anaesthesia. Once an adequate depth of anaesthesia was achieved, the first device was inserted according to the manufacturer’s instructions. Following insertion of the cLMA, 5-ml increments of air was 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. Absence of any audible leak and presence of a square wave pattern on capnography 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 litres/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. An attempt at insertion was considered unsuccessful 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 and re-inserted. Two insertion attempts were allowed for each device. If the insertion failed after two attempts, the insertion was considered as a failure. If there was an unacceptable leak even at low pressures following successful insertion a larger sized device was used. 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). And unpaired t-test was used for time of insertion, number of attempts and degree of airway seal.

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.

# Results:

## Table 1. Age and weight among two groups

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Group**  | **Mean**±Standard Deviation | **p-value** |
| Age | cLMA | 7.40±3.500 | 0.495 |
|  | i-gel | 6.80±1.704 |  |
| Weight | cLMA | 20.30±5.886 | 0.552 |
|  | i-gel | 19.45±2.350 |  |

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

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Group**  | **Mean**±Standard Deviation | **p-value** |
| **Peak airway pressure** | cLMA | 16.40±3.42 | 0.027 |
|  | i-gel | 23.11±6.17 |  |
| **Time of insertion** | cLMA | 29.84±7.70 | 0.02 |
|  | i-gel | 19.42±4.40 |  |

Peak pressure is better with i-gel group then cLMA and are statistically significant (p- 0.027). Compared to cLMA peak airway pressure for i-gel is 23.11± 6.17 cm of H20.

## Table 3. Ease of insertion

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Mild  | Moderate | Severe  | 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 severe resistance catergory and lesser with moderate category.

# Discussions

The I-gel is a truly unique single use, latex and PVC free airway device. Everything about the i-gel has been designed to work in perfect unison with the anatomy; the i-gel design was inspired by the physiology of the perilaryngeal framework itself. The shape, softness and contours accurately mirror the perilaryngeal anatomy to create the perfect fit. This innovative concept means that no cuff inflation is required. I-gel 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).2 It is the innovative application of this material that has enabled the development of a unique non-inflatable cuff.In, adult i-gel is indicated for securing and maintaining a patient airway in routine and emergency anaesthetics for fasted patients, during spontaneous or intermittent positive pressure ventilation (IPPV), during resuscitation of the unconscious patient, and as a conduit for intubation under fibreoptic guidance in a known difficult or unexpectedly difficult intubation, by personnel who are suitably trained and experienced in the use of airway management techniques and devices.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 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.7

Dr Bain’s cLMA was introduced into clinical practice in 1988 and has an enormous body of evidence to support its use: both in terms of efficacy and safety.2 The limitations of the cLMA are largely that controlled ventilation is not always possible due to the moderate pharyngeal seal and there is a risk of pulmonary aspiration of regurgitant matter. Owing to the low-pressure seal afforded between the cLMA and the pharynx (median 20 cm H2O, rarely 30 cm H2O), when the airway pressure increases above the pharyngeal seal (during controlled ventilation), ventilating gas is lost, leading to a risk of hypoventilation, environmental pollution, and drug wastage. Equally important, as airway pressure increases, a larger proportion of gas leaks and a larger proportion of this leaking gas enters the oesophagus and stomach, likely increasing the risk of regurgitation and aspiration. This led to the discovery of its modification in newer generation supraglottic devices. of which I-gel is the one.2

Peak airway pressure in our study is significant (p-0.027) in i-gel group (16.40±3.42 cm of H2O) as compared to cLMA (23.11±6.17 cm of H2O). Similar significant (p-0.023) finding is also found in Janakiraman ‘s study where the time of peak 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 suggests a contrast finding in his study where there is no significant difference but a better fiberoptic view. Bikramjit das also suggests a i-gel peak airway pressure (27.11±6.17 cm of H2O) significantly better than cLMA ((16.49± 3.42 cm of H2O). 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 [cLMA - 21 (17.5-25) seconds, i-gel: 17 (13.8-20.00) seconds, p-0.002]. 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 where i- gel isless 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. Bikram das also suggested no difference in ease of insertion.

Even though the study suggested a difference in finding among the groups, the chances of interpersonal variability in the skill couldnot 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 peak airway pressure, faster time of insertion with comparable ease of insertion in pediatric populations.

**References**

 1. Ramesh S, Jayanthi R. Supraglottic airway devices in children. Indian J Anaesth. 2011 Sep-Oct; 55(5): 476–2.

2. Cook T, Howes B. Supraglottic airway devices: recent advances. Continuing Education in Anaesthesia Critical Care & Pain. 2011:11;2.

3. Twigg S, Brown JM, Williams R. Swelling and cyanosis of the tongue associated with use of a laryngeal mask airway. Anaesthesia and intensive care. 2000; 28: 449–50.

4. Ouellette RG. The effect of nitrous oxide on laryngeal mask cuff pressure. American association of nurse anaesthetists journal. 2000; 68: 411–4.

5. Beylacq L, Bordes M, Semjen F, Cros AM. The i-gel, a single-use supraglottic airway device with a non-inflatable cuff and an esophageal vent: An observational study in children. Acta Anaesthesiol Scand. 2009;53:376–9.

6. Jolliffe L, Jackson I. Airway management in outpatient setting: New techniques and devices. Curr Opin Anaesthesiol. 2008;21:719–22.

7. I-gel.com

8. Lee JR, Kim MS, Kim JT, Byon HJ, Paek YH, Kim HS et al. A randomised trial comparing the i-gel with the LMA Classic in children. Anaesthesia. 2012:67;606–11.

9. Janakiraman C, Chethan DB, Wilkes AR, Stacey MR, Goodwin N. A randomised crossover trial comparing the i-gel supraglottic airway and classic laryngeal mask airway. Anaesthesia. 2009:64;674–8.

10. Gatward JJ, Cook TM, Seller C, Handel J, Simpson T, Vanek V, Kelly F. Evaluation of the size 4 i-gel airway in one hundred non-paralysed patients. Anaesthesia. 2008:63;1124–30.

11. Theiler L, Gutzmann M, Kleine-Brueggeney M, Urwyler N, Kaempfen B, Greif R. i-gel™ supraglottic airway in clinical practice: a prospective observational multicentre study. Br J Anaesth. 2012 Dec;109(6):990-5.

12. Stroumpoulis K1, Isaia C, Bassiakou E, Pantazopoulos I, Troupis G, Mazarakis A, Demestiha T, Xanthos T. A comparison of the i-gel and classic LMA insertion in manikins by experienced and novice physicians. Eur J Emerg Med. 2012 Feb;19(1):24-7.

13. Jindal P, Rizvi A, Sharma JP. Is I-gel a new revolution among supraglottic airway devices?-a comparative evaluation. Middle East J Anesthesiol. 2009;Feb;20(1):53-8.

14. Das B1, Mitra S, Jamil SN, Varshney RK. Comparison of three supraglottic devices in anesthetised paralyzed children undergoing elective surgery. Saudi J Anaesth. 2012 Jul;6(3):224-8.