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Original Article

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

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Abstract

Background: I-gel, the novel Supraglottic airway device, 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 the paediatric population.

Methods: A randomised parallel group study was done in Department of Anesthesiology, Kanti Children Hospital, Kathmandu for a 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 a better leak pressure seal (16.40±3.42 vs. 23.11± 6.17 cm of H_2O, 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

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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]

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] However, airway cuff

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has to be inflated to get a good peri-laryngeal seal. There is also the risk of nerve injury, venous compression and tissue distortion.[3,4] I-gel is effective, safe for paediatric airway management.[5] I- gel is easier to insert, less tissue compression and more stable after insertion.[6] With the introduction of newer supraglottic devices and their modification, the study aims to compare the efficacy of I-gel with classic LMA in the paediatric population.

Methods

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

A parallel group study was conducted in Department of Anesthesiology, Kanti Children Hospital, Kathmandu for a period of three months. Patients recruited in the study were randomised into two groups by lottery method. The sample was picked up by a blinded care provider from an envelope containing an equal number of I-gel and cLMA slip of similar sizes. The sample size was calculated with reference to Bikramjit et al study[14] with primary outcome variable as airway leak pressure of the I−gel group (27.1±2.6 cm H_2O) and the classic LMA group (23.63±2.3 cm H_2O). 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 a 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 kilogramme were included in the study. A patient who refused to participate in the study and had anticipated difficult airway with known allergy with the use of devices and possible risk of aspiration were excluded from the study.

Intervention Details

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 patient's 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 fully deflated prior to insertion. Premedication was not administered.

The patient was kept on the soft pillow with neck flexed and head extended before induction of anaesthesia. Standard monitors were connected. Anaesthesia 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 anaesthesia. 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 H_2O after connecting the breathing system. The 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 the 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 cmH_2O, the cuff was deflated to allow the cuff pressure to fall below 40 cm H_2O. 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. An anesthesiologist with a personal experience of > 50 classic LMA and 10 I-gel supra-glottic airway insertions 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 the number of insertions were kept.

Anaesthesia 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 a deep plane of anaesthesia followed by suctioning of airway if required and transferred to the recovery room.

Data was entered into and analysed 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 comparison of time of insertion.

Results

The flow of the participants in the randomized trial is

shown in the Consort 2010 flowchart (Figure 1).

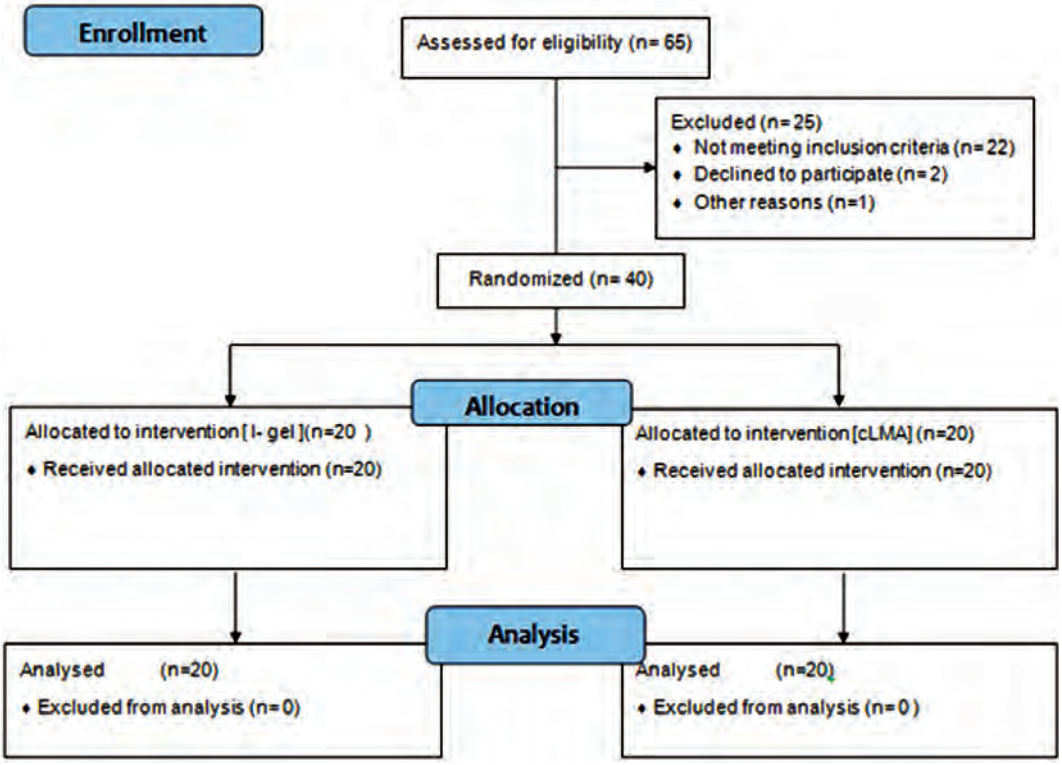

Table 1. Comparison of age and weight of children between the two groups

Parameters	cLMA	I-gel	p-value
Age in years (Mean±SD)	7.40±3.500	6.80±1.704	0.495
Weight in Kgs (Mean±SD)	20.30±5.886	19.45±2.350	0.552

Table 2. Comparison of leak pressure and time taken for inserting the devices

Variables	cLMA	I-gel	p-value
Leak airway pressure (cm of H_20) (Mean±SD)	16.40±3.42	23.11±6.17	0.027
Time of insertion (seconds) (Mean±SD)	29.84±7.70	19.42±4.40	0.02

Higher leak pressures were possible in the I-gel group.

Table 3. Ease of insertion of the devices

Device	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 the patients had severe resistance during insertion of the devices, still all the devices were inserted successfully.

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] 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] 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.[8]

Dr Bain's cLMA was introduced into clinical practice in 1988 and it has ample evidence to prove its safety profile and effectiveness.[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 H_2O, rarely 30 cm H_2O, 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.[9] I-gel has been specifically designed to address this shortcoming as a newer generation supraglottic airway devices.[2]

The airway pressure at which air leaks around the device is higher for I-gel as compared to cLMA. Similar significant finding is also found in Janakiraman's study where the time of leak airway pressure in I-gel group is 20 [14-24] cm of H_2O as compared to cLMA group.[10] 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.[9] Bikramjit Das also suggests an I-gel leak airway pressure (27.11±6.17 cm of H_2O) significantly better than cLMA (16.49± 3.42 cm of H_2O).[7] 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 was inserted significantly faster than cLMA. 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].[9] The possible reason is the absence of inflatable cuff which require more time for completing insertion as was defined in our details.

The ease of insertion is not significantly different between the groups. 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 is less easy to insert in 40 (80%) of subject as compared to cLMA 45 (90%).[10] He pointed out the reason of size recommendation of I-gel by the manufacturer was not justified. Bikramdas also suggested no difference in ease of insertion.[7] The difference in perilaryngeal framework in different population can be another possible reason.

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, though, a power analysis was done for sample size calculation. A large multi-institutional study could give a more accurate picture and the findings may be generalized as more and more experts start using I-gel more than cLMA.

In Conclusion, I-gel compared to classic LMA provides better sealing effect, faster time of insertion with comparable ease of insertion in pediatric populations.

Informed consent: Informed consent was obtained from parents of all the participants included in the study.

Conflicts of interest: Authors declare no competing interests.

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