

Analysis of ease of insertions, its attempts and time taken to insert for i-gel and cLMA in paediatric cases.

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Aim: Analysis of ease of insertions, its attempts and time taken to insert for i-gel and cLMA in paediatric cases. **Methods:** We did a prospective, randomised single-blind study on Eighty patients of either sex belonging to American Society of Anaesthesiologists (ASA) physical status class I or II, between 6 months to 8 years of age, scheduled to undergo elective surgery for less than one and half hour duration under general anaesthesia. In this study we analysed the ease of insertion, attempts and time were taken to insert the supraglottic airway device. **Results:** The ease of insertion observed was easy in 39(97.5%) in the i-gel group and 35(87.5%) in cLMA group in our study. The i-gel was placed successfully in 39 out of 40 (97.5%) patients in the first attempt, and achieved 100% insertion on the second attempt. Correct positioning of cLMA in the first attempt was seen in 35 out of 40 (87.5%) patients. The remaining 5 patients (12.5%) required a second attempt. The average insertion time of cLMA (12.88 ± 1.771 seconds) was longer than the average time of insertion of i-gel (9.48 ± 1.037 seconds), and these differences were highly significant statistically ($p= 0.000$). **Conclusion:** To conclude, i-gel and cLMA is effective and safe devices for use in children. Both are easy to insert and have insignificant morbidity, however, time taken and attempts of insertions for i-gel was lesser than cLMA. Also, the ease of insertion was relatively easy for i-gel than cLMA in pediatric cases.

Keywords: i-gel, cLMA, Pediatric, Insertion

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Introduction

Supraglottic airway devices are now widely used for surgery requiring general anaesthesia and have shown safety and efficacy in children [1]. These provide ventilation and oxygenation to the patients by delivering anaesthetic gases above the level of vocal cords. In this way, these provide an airway intermediate between the face mask and tracheal tube in terms of anatomic position, invasiveness and security in the unconscious patient. The advantages of the use of supraglottic airway devices include: avoidance of laryngoscopy, increased ease of placement, improved haemodynamic stability, less coughing, less sore throat and hands-free airway [2].

A variety of supraglottic airway devices available, among them we studied Classic LMA and i-gel. The cLMA is a well-established device for airway management in children and Paediatric i-gel have been found safe & effective for airway management in children in many studies. Notably many advantages of i-gel over cLMA like it has a non-inflatable cuff an anatomically designed mask made up of a thermoplastic elastomer, styrene-ethylene butadiene styrene (SEBS) with a soft durometer (hardness) and gel-like feel. The tube section is harder and more rigid than the soft bowl of the device. There is a second lumen that runs on the right side of the airway tube along the entire length of the device to the distal tip that can accommodate a gastric tube [3]. This is intended to separate the airway from the gastrointestinal tract resulting in three potential advantages over more traditional supraglottic airway devices; allowing venting of regurgitated gastric content; reducing gastric regurgitation during controlled ventilation; allowing easy insertion of the gastric tube [4]. A small rigid projection from the proximal section of the bowl sits against the base of the tongue and helps in stabilizing the device [3]. Evaluation of the i-gel in adult patients has shown that it is easy to insert and provide an effective airway in the majority of patients [4].

The paediatric size i-gel have been introduced in January 2010. It is available in 5 sizes- 1, 1.5, 2, 2.5 and 3. Like adult i-gel, it has a gastric drain except for size 1.

Studies done on i-gel by various investigators have found that i-gel is an effective device for airway management in children.

Beylacq et al performed an observational study on i-gel in 50 children above 30 kgs undergoing short-duration surgery. In their study it was possible to insert i-gel in the first attempt in all the cases. The authors concluded that the success rate of insertion of i-gel was 100% and was accompanied by very few complications. Also the author reported that i-gel could be an efficient and safe device for paediatric airway management [5].

Beringer et al in 2011 conducted a study to evaluate the paediatric i-gel airway in 120 children (ASA physical status 1-2) weighing between 5-35kg, scheduled for elective surgery under general anaesthesia. They collected the data relating to the performance of the device during insertion, maintenance of anaesthesia, device removal and following recovery. During insertion they recorded the number of insertion attempts, the time taken to establish an effective airway, the number and type of airway manipulations required and complications if any.

They reported that insertion was successful on the first/second/third attempt in 110/8/1 children and failed in one child. The median insertion time was 14seconds. The i-gel was inserted without complications, establishing a clear airway and enabling spontaneous and controlled ventilation, in 113 (94%) children. They concluded that the i-gel is an effective supraglottic airway device for use in children. It is easy to insert and has few complications [3].

Goyal et al did the randomized prospective study on 120 children aged 2-5 years, weighing 10-20 kg, ASA physical status I-II scheduled for routine elective surgeries of <1-h duration using the size 2 i-gel supraglottic airway with LMA-ProSeal™ and LMA-Classic™. They noted the ease of insertion. The success rate for first attempt was 95% for the i-gel group and 90% for the two laryngeal mask airway groups. Insertion was found to be easy in the majority of cases in all groups, The difference between i-gel and both laryngeal mask airway groups was statistically significant ($P < 0.01$).

They detected no clinically important complications in the postoperative period. They devised the conclusion that pediatric size 2 i-gel is easy to insert with same size PLMA and cLMA in spontaneously breathing children undergoing elective surgery. Also, it may be a safe alternative to laryngeal mask airways in daycare surgeries [6].

Objectives

To compare the efficacy of i-gel with Classic LMA in paediatric patients concerning

- Ease of insertion
- Insertion time
- Number of attempts

Material & Methods

We did a prospective, randomised single-blind study in the Department of Anaesthesiology & Critical Care, Pt. B.D. Sharma, PGIMS, Rohtak. Eighty patients of either sex belonging to American Society of Anesthesiologists (ASA) physical status class I or II, between 6 months to 8 years of age, scheduled to undergo elective surgery for less than one and half hour duration under general anaesthesia were included in the study.

Exclusion Criteria: Patients having difficult airway, restricted mouth opening, risk of aspiration, upper respiratory tract infection, congenital heart disease, surgery in a position other than supine, history of upper gastrointestinal surgery, bleeding or clotting abnormalities, and oesophageal trauma was excluded from the study.

Clinical Examination: All the patients were examined during the preoperative visit a day before surgery. Informed written consent was obtained from the parents. Patients were subjected to detailed clinical history, complete general physical and systemic examination. Routine investigations like hemoglobin (Hb), bleeding time (BT), clotting time (CT), urine complete examination and other investigation of need were carried out.

Preparation of Patient: The patients were kept fasting for six hours for solids, four hours for breast milk and two hours for clear fluid before the scheduled time of surgery. They were premedicated with syrup midazolam 0.5 mg kg⁻¹ one hour before surgery. After arrival in the operation theatre routine monitoring e.g. Heart Rate (HR), Electrocardiography (ECG), Pulse oximetry (SpO₂), non-invasive blood pressure (NIBP), end-tidal CO₂ (EtCO₂), Respiratory rate (RR), inhaled and exhaled anaesthetic gases concentration using Phillips IntelliVue MP 50 monitor were set up. Baseline readings of vital parameters were recorded.

Patients were then be randomly allocated to one of the two groups using a computer-generated sequence of random numbers, as follows:

Group-1 – (n=40), LMA Classic was used as an airway conduit.

Group-2 – (n=40), i-gel was used as an airway conduit.

Anaesthetic technique: Induction of anaesthesia was achieved with standardized anaesthesia technique using either intravenous thiopentone 5 mg kg⁻¹ or inhaled sevoflurane 6-8% in 100% oxygen along with intravenous glycopyrrolate 0.005 mg kg⁻¹ and fentanyl 1 microgram kg⁻¹ Inj. atracurium 0.5 mg kg⁻¹ was used to facilitate airway device insertion. All patients were ventilated for two minutes via face mask and anaesthesia breathing system using sevoflurane 2% in 100% O₂. The patient's head was positioned with flexion of the neck and extension of the head using the non-dominant hand. The appropriate size airway device was used as per weight criteria, cLMA cuff was inflated partially before insertion which is a slight modification of the standard technique described by Brain. Water-soluble jelly was applied on the posterior aspect of the cuff of the device to be used. The cLMA and i-gel were held like a pen and inserted while pressing against the hard palate and posterior pharyngeal wall until resistance is felt when the mask tip reached the base of the hypopharynx.

After insertion, cLMA cuff was inflated to 60cmH₂O pressure. The airway device was connected to the anaesthesia breathing system. Positive pressure ventilation was commenced with a tidal volume of 8 ml kg⁻¹, respiratory rate as per age and I: E ratio of 1:2. Correct placement of the device was confirmed by manual ventilation and obtaining a square wave capnograph on the monitor. The presence or absence of oropharyngeal air leaks (detected by listening over the mouth), and gastric leaks (by listening with the stethoscope over the epigastrium) were checked and the airway device was fixed with the help of adhesive tape.

The following data was observed-

Ease of insertion: The ease of insertion was graded on a three-point scale

Easy

Difficult

Failure

An easy insertion was defined as an insertion within the pharynx without resistance in a single manoeuvre.

A difficult insertion was the one in which there is resistance to insertion or where more than one attempt was required to seat the device within the pharynx. In case it was not possible to insert the device in three attempts it was labelled as a failure.

Time of insertion: The time interval between picking up the device and obtaining effective ventilation was recorded.

Number of attempts: In the event of complete or partial airway obstruction or a significant leak the airway device was removed and reinsertion attempted. A maximum of three insertion attempts was allowed before the placement of the device was considered a failure. In case of failure alternative airway device was used to secure the airway.

Statistical analysis: At the end of the study, the data of various parameters were compiled and analyzed statistically by using the Chi-square test, Student t-test (unpaired) and paired t-test.

We based our sample size calculation on our primary outcome variable. Very little data about the performance of the paediatric-sized i-gel were available for a reliable sample size calculation. We estimated a necessary sample size of 40 children in each group. We compared the overall performance of both masks. Success rates and other frequency data were compared with the chi-square test. Insertion times, the attempt of insertion and other continuous data were analysed by Mann-Whitney test if the data were not normally distributed; otherwise the independent two-tailed Student *t*-test and paired *t*-test were used to compare All data were analyzed with SPSS version 15 (SPSS) and are presented as mean with standard deviations or number and percentage. A probability of *P* = 0.05 was considered statistically significant.

Results

Different parameters including ease of insertion, time of insertion, number of attempts were studied.

Demographic Profile: The demographic details of the patients in our study had no significant difference between the groups in terms of age, sex and weight. The two groups were comparable concerning the duration of surgery and ASA physical status.

Time of insertion: The time interval between picking up the device and obtaining effective ventilation was recorded.

The results in table 1, shows lesser time was required to achieve effective ventilation for i-gel cases as compared to cLMA. And the data showed it as highly significant statistically.

Table 1: Time of insertion of two groups studied i.e i-gel and cLMA

	i-gel(n=40)	cLMA(n=40)	P value
Time of insertion (sec.) (mean ± SD)	9.48± 1.037	12.88± 1.771	0.000

Attempts of insertion: In the event of complete or partial airway obstruction or a significant leak the airway device was removed and reinsertion attempted. A maximum of three insertion attempts was allowed before the placement of the device was considered a failure. In case of failure alternative airway device was used to secure the airway.

In our study i-gel was placed in a single attempt in 39 out of 40 cases, and one remaining case achieved proper insertion in the second attempt. On the other hand, cLMA was inserted in a single attempt in 35 out of 40 cases and the remaining cases achieved proper insertion in a second attempt (Table 2).

Table 2: Attempt of insertion of two devices i.e i-gel and cLMA.

Attempts of insertion	i-gel(n=40)	cLMA(n=40)	p-value
First	39 (97.5%)	35 (87.5)	0.090
Second	1 (2.5%)	5 (12.5)	

Thus i-gel needed a smaller number of attempts for insertion than cLMA but this difference was statistically non-significant when two groups were compared.

Ease of insertion: The ease of insertion was graded on a three-point scale, easy, difficult, and failure. An easy insertion was defined as an insertion within the pharynx without resistance in a single manoeuvre. A difficult insertion was the one in which there is resistance to insertion or where more than one attempt was required to seat the device within the pharynx. In case it was not possible to insert the device in three attempts it was labelled as a failure.

In our study i-gel had easy ease of insertion in 97.5%, and difficult in 2.5% of case. However, for cLMA easy ease of insertion was noted in 87.5% of cases and the rest of the cases (12.5%) had difficult ease of insertion (Table 3).

Table 3: Ease of insertion of the two devices i.e. i-gel and cLMA.

Ease of insertion	i-gel(n=40) [number (%)]	cLMA(n=40) [number (%)]	p-value
Easy	39 (97.5%)	35 (87.5)	0.090
Difficult	1 (2.5%)	5 (12.5)	

When compared between two groups ease of insertion was found to be statistically non-significant (p-value= 0.090).

Discussion

The cLMA is an established supraglottic airway device for airway management in paediatric patients. The i-gel of paediatric size is a relatively newer device, having a noninflatable supraglottic airway for use in anaesthesia during spontaneous or intermittent positive pressure ventilation [7]. We undertook this prospective, randomized, single-blind study to compare i-gel and cLMA in the Indian paediatric population.

The two groups were similar demographically in terms of age, gender, weight, height and BMI. They were also similar concerning ASA physical status and duration of surgery. Therefore, we can say that results obtained after the study was purely due to the characteristics attributable to devices rather than any bias associated with the sample selected.

Attempts of insertion: In our study i-gel was placed successfully in 39 out of 40 (97.5%) patients in the first attempt, and achieved 100% insertion on the second attempt. Correct positioning of cLMA in the first attempt was seen in 35 out of 40 (87.5%) patients. The remaining 5 patients (12.5%) required a second attempt. Our results on insertion of i-gel nearly correspond to those of Diemunsch P involving 50 children undergoing surgery under general anaesthesia using i-gel pediatric device. In their study, the success rate for inserting the device was 80% on the first attempt and 100% after two attempts [8].

Also another study performed by Beringer et al on i-gel showed that insertion was successful on the first/second/third attempt in 110/8/1 children and failed in one child [4]. Hughes et al in their study on i-gel on 154 children, achieved 93.5% insertion at the first attempt and the second attempt was taken in 5.8% of cases. They also reported one failure with i-gel which was replaced by cLMA without any further problem. The insertion quality reported by them was very easy or easy [9].

In another randomized controlled study, Lee et al compared i-gel with cLMA in 99 children and found

96% and 100% success on the first and second attempt respectively with i-gel as compared to 92% and 100% success with cLMA on first and second attempts respectively [10]. In our study the lesser number of attempts of i-gel can be explained by its less flexible stem that facilitates its easy insertion. The first attempt failures of cLMA were related to the distal cuff being folded over or inadequate lubrication during insertion. The larger number of attempts for insertions in the cLMA group may also be explained by the relative anatomy of the paediatric oropharynx particularly, a relatively large tongue, a floppy epiglottis, a cephalad and more anterior larynx and the frequent presence of tonsillar hypertrophy which may disturb cLMA insertion in paediatric patients. Thus, our study, similar to the studies mentioned above on i-gel and cLMA showed that i-gel took a lesser number of attempts compared to cLMA.

Ease of insertion: In our study the ease of insertion was graded on a three-point scale, easy, difficult, failure. An easy insertion was defined as an insertion within the pharynx without resistance in a single manoeuvre. A difficult insertion was the one in which there is resistance to insertion or where more than one attempt was required to seat the device within the pharynx. In case it was not possible to insert the device in three attempts it was labelled as a failure. The ease of insertion was easy in 39 (97.5%) cases in i-gel and 35 (87.5%) cases in cLMA group in our study. In none of the patients more than two attempts were required thus there was no failure of the device or switch to alternate airway were needed in our study.

Beylacq et al in their observational study in 50 children using i-gel, graded ease of insertion as very easy, easy, difficult and very difficult based on the airway manipulation done while placing the device. They found the insertion of i-gel as very easy in 45 out of 50 cases suggesting no need for airway manipulation and easy in remaining cases suggesting single manoeuvre like chin lift or jaw thrust were needed to place the device [1]. Lee et al in their randomized trial in 99 children studied ease of insertion comparing i-gel with cLMA and graded ease of insertion using a subjective scale of 1-4 (1-no resistance; 2-mild resistance; 3-moderate resistance; 4-inability to place the device).

They found the ease of insertion of the two devices were similar (i-gel=78% and cLMA=76%) and both devices were placed without any difficulty [10].

Goyal et al in their study on comparison of size 2 i-gel, cLMA and PLMA on 120 children defined ease of insertion as very easy (no airway manipulation), easy (one airway manipulation like jaw thrust, neck flexion, head extension or deep rotation) or difficult (more than one airway manipulation) based on the airway manipulation done while placing the device. The ease of insertion was similarly based on very easy/easy/difficult grades for i-gel (34/4/2), cLMA (35/4/1) and PLMA (32/5/3) [6]. In our study the easy ease of insertion of i-gel can be explained by its less flexible stem that facilitates its easy insertion. The difficult ease of insertion of cLMA (in 12.5% of cases) can be explained by the distal cuff being folded over or inadequate lubrication during insertion. Thus in our study similar to other studies higher number of easy ease of insertion was noted for both devices. However, when compared between two groups i-gel had more easy ease of insertion (97.5%) than cLMA (87.5%), though this difference was statistically non-significant.

Time of insertion: The average insertion time of cLMA (12.88 ± 1.771 seconds) was longer than the average time of insertion of i-gel (9.48 ± 1.037 seconds), and this difference in time was found to be highly significant statistically ($p = 0.000$). Other studies comparing i-gel with cLMA also shows that time taken to insert i-gel was less than cLMA. A study performed by Huges et al showed that the median (IQR) time to insertion with i-gel was 14 (13-16) seconds [9]. Lee et al also found that median (IQR [range]) time to successful device placement was shorter with i-gel [17.0 (13.8-20.0) seconds] compared with the LMA Classic [(21.0 (17.5-25.0) seconds)] [10].

Another comparable study of i-gel with PLMA performed by Tokgoz et al showed that lesser time was required to insert i-gel and achieving effective airway than PLMA (19 ± 4 vs. 28 ± 5 seconds, $P < 0.01$) [11]. The shorter insertion time for i-gel compared with c-LMA was probably because the tube section is firmer in i-gel making insertion easier than cLMA. The firmness of the tube section in i-gel and its natural oropharyngeal curvature allows the device to be smoothly inserted by grasping the proximal end of it which helps to glide the leading edge against the hard palate into the pharynx.

Also, there was no need for cuff inflation in i-gel in contrast to LMA. So the time required to secure the airway and give the first breath is less with i-gel.

The time taken to achieve effective airway for i-gel was higher in other studies than the time taken in our study, which could probably be due to differences in technique of insertion, the experience of the anaesthetist, demographic profile and other variables.

Conclusion

To conclude, both supraglottic airway devices are better and effective regarding attempts, time is taken and ease of insertion. Both are easy to insert and have insignificant morbidity, however the time taken for insertion of i-gel was less. Also, the ease of insertion was easy for i-gel as compared to cLMA. And attempts taken to insert i-gel was relatively lesser than cLMA. Making inference that i-gel a better airway device than cLMA in pediatric cases.

What does this study add to existing knowledge?

Both supraglottic airway devices are better and effective regarding attempts, time is taken and ease of insertion. Making inference that i-gel a better airway device than cLMA in pediatric cases.

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Contributors Details

NJ: conceptualized, manuscript preparation, acquisition, literature research and statistical analysis; NJ, ST: analysis, manuscript editing and review, provided intellectual inputs to the manuscript; KS is the guarantor for this paper.

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