Comparison of I-gel Supraglottic Airway with LMA Classic in Children Undergoing Elective Surgeries

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Abstract

Background: A new SADs called I-gel has several advantages such as easy insertion, stability after insertion and minimal risk of tissue compression. Incidence of postoperative complication was not differ among I- gel and c-LMA. Very few reports that have evaluated the paediatric I-gel, especially in small children. Methodology: Total 90 ASA grade I-II patients of 1-12 years age group (45 patients in Group I: I – gel, 45 patients in group L: c-LMA classic) who undergone elective urology surgery from civil hospital, Ahmedabad were included in the study. A supraglottic device was inserted after required depth of anaesthesia achieved. The ease of insertion, insertion time, attempt of insertion and sealing pressure were noted. Vital parameter during surgery and complication in post anaesthesia care unit were recorded. Result: Success rate for first attempt in I-gel group was significantly higher (85.0%) as compared to cLMA (80.0%). The insertion time was shorter with I-gel (14.64 + 16.7 sec) than with c-LMA (20.11 + 28.5 sec). Airway leak pressure of I-gel is higher (26 + 2.63 mmHg) than c-LMA (22 + 2.3 mmHg). On removal, blood stain was present in one patient in I-gel group and 3 patient in c-LMA group. There was no significant change in hemodynamic parameters before and after insertion in both the group. Conclusion: I-gel is superior than c-LMA in terms of significantly easier and more rapid insertion with high leak pressure. The hemodynamic changes after insertion and the postoperative complication are not significantly differ between c-LMA and I-gel patients.

Keywords: I-gel; LMA Classic; Leak pressure; Insertion time.

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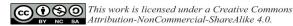
Introduction

Paediatric patient is associated with higher rates of complication of laryngoscopy and intubation. Oxygenation and ventilation without endotracheal intubation are facilitated by supraglottic airway devices [1]. Supraglottic airway devices (SADs) have been increasingly used in recent years in suitable cases. Insertion into hypopharynx is easy to form a seal around the larynx and useful for difficult and failed intubation. Drainage of gastric fluid and visualization the larynx without cervical

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spine neck extension is possible with SADs. These devices have minimal cardiovascular responses than the tracheal tube [2].

A new SADs called I-gel (Intersurgical, Wokingham, UK) was developed by Dr. Mohammad Aslam Nasir and it has soft gel-like thermoplastic elastomer, a non inflatable cuff and a channel for gastric suction catheter placement. The soft non inflatable cuff creates a perfect fit with accurately mirrors the perilaryngeal frame work [2]. It has several advantages such as easy insertion, stability after insertion and minimal risk of tissue compression [3,4].

Recent studies showed that I- gel is better device as compared to LMA Classic (c-LMA) for easier insertion and maintenance of anaesthesia [5,6]. It provided a higher leak pressure [7,8] a shorter insertion time [9] and improved glottis view compared with c-LMA in children [9]. There were no differences in the incidence of postoperative airway complication, hoarse cry or sore throat [10]. Very few reports that have evaluated the paediatric I-gel, especially in small children. Hence, we decided to compare clinical performance of both devices in paediatric patient undergoing elective surgery.

Aims & Objective

a) To compare the clinical performance of both the devices regarding number of attempts, ease of insertion, sealing quality and time to successful device placement. b) to compare hemodynamic effects and complication of both devices.

Methodology

This observational comparative study was conducted in anesthesia department of institute of kidney disease and research center, civil hospital, Ahmedabad after institutional ethics committee approval. Total 90 ASA grade I-II patients of 1-12 years age group who undergone elective urology surgery were included in the study. Patients with upper respiratory tract infection, significant cardiovascular, pulmonary, renal or hepatic diseases, oropharyngeal pathology were excluded. Patients were randomly divided into two groups of 45 each by sealed envelope technique - Group I: I – gel, group L: c -LMA classic.

All patients underwent thorough preoperative assessment. Patient's history and demographic data were noted. Airway assessment including mouth opening, neck movements, teeth,

mallampatti grading and systemic examination and pre operative investigations were carried out. All patients were kept nil per orally. On arrival in the operation theatre, vital parameters were noted and routine monitoring ECG, NIBP and SpO₂ were applied.

All patients were given 0.5 mg/kg of midazolam syrup, injection glycopyrrolate 0.004 mg/kg and fentanyl 2 μg/kg intravenously prior to induction of anaesthesia. Patients were induced with 6% sevoflurane in oxygen. After required depth of anaesthesia achieved, the supraglottic device was inserted in "sniffing" position by an experienced anaesthesiologist as per standard procedure recommended by manufacturer. There was a subjective scale of 1-3 (1= Very easy, 2= Easy, 3= Difficult) for ease of insertion assessment. Ventilation was considered inadequate, if there was no square shaped capnography wave and or inadequate chest movement and second attempt was done. Failure was considered when there was not successful insertion in three attempts. This patient was then excluded from the study and tracheal intubation was planned. Insertion time was calculated from placement from grasping of the device to observing a first square wave capnograph trace. The sealing pressure was measured by an aneroid manometer (Mallinckrodi Medical) placed at the proximal end of the supraglottic device via a connector (maximal allowable was 40 cm H₂O). The air leak was detected by auscultation of anterior neck for all patients.

Heart rate, diastolic, systolic and mean blood pressure, end tidal carbon dioxide tension and oxygen saturation were recorded after induction at one, five minutes after airway device placement, every 5 minutes till half an hour and then after every 10 minutes up to 1 hours, at 90 minutes and 120 minutes. After shifting to post anaesthesia care unit, parents were assessed about hoarse cry, sore throat or any other discomfort. Normal insertion time for the I- gel and c-LMA was 9.25 ± 1.08 seconds and 12.95 ± 1.08 seconds respectively.

Statistically analysis: Continuous variables are expressed as mean ± standard deviation (SD). The comparison of between the groups was performed by Z test. Qualitative data was compared using Fischer's exact test. A value of p less than 0.05 is considered significant.

Results

The present study was conducted among 90 peadiatrict patients belonging to ASA physical

Table 1: Demographic and surgical profile of study participants *.

Variables	Group I (n= 45)	Group L (n= 45)	p value
Age (year)	5.3 ± 3.4	8.2 ± 5.0	0.01
Weight (kg)	16.1 ± 5.4	15.3 ± 5.1	0.74
Duration of surgery (min.)	35.6 ± 21.7	52.8 ± 19.0	0.37
Duration of anaesthesia (min.)	38.5 ± 21.9	55.1 ± 18.9	0.33

^{*}p value was calculated by Z test

Table 2: Airway insertion and maintenance characteristics of study participants

Variable	Group I (n=45)	Group L (n=45)	p value
Insertion success			
Success rate	45 (96.3%) out of 47	45 (97.5%) out of 46	0.005*
First attempt	40 (85.0%)	36 (80.0%)	
Second attempt	5 (11.3%)	8 (17.7%)	
Third attempt	0 (0.0%)	1 (2.0%)	
Ease of insertion			
Very easy	0 (0.0%)	0 (0.0%)	1.0*
Easy	45 (100%)	44 (98%)	
Difficult	0 (0.0%)	1 (2%)	
Insertion time (sec)	14.6 ± 16.7	20.1 ± 28.5	0.001#
Peak inspiratory pressure (mmHg)	12.5 ± 1.5	12.8 ± 1.6	0.80#
Leak pressure (mmHg)	26.0 ± 2.6	22.0 ± 2.3	0.01#

^{*}p value was calculated by fisher test. *p value was calculated by Z test

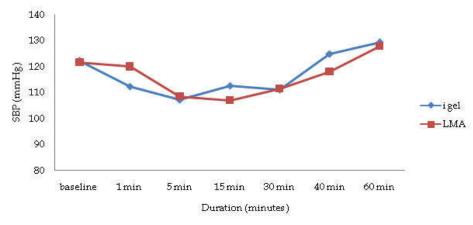


Fig. 1: Intra-operative systolic blood pressure (mmHg) at different time intervals in 2 groups

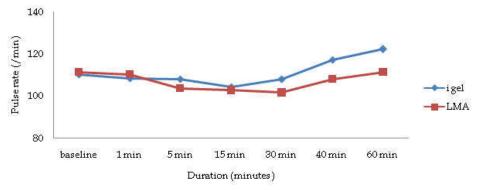


Fig. 2: Intraoperative mean pulse rate (/min) at different time intervals in 2 groups

status I and II. Significant difference was not observed in two groups of patients respect to weight, duration of surgery and duration of anesthesia (Table 1, p>0.05). However, patients in group L (8.19 \pm 5.03 year) were elder as compared to patients in group I (5.35 \pm 3.47 year, p = 0.01). Distribution of urological surgeries and used device size were similar between two groups.

Table 2 shows that overall success rate was similar with I-gel and c-LMA. However, the insertion success rate at first attempt was significantly high with I-gel as compared to c-LMA. Significant difference was not found between I-gel and c-LMA with regard to peak inspiratory pressure and ease of insertion. Insertion time for I-gel device was 14.6 ± 16.7 seconds which was significantly shorter than c-LMA device (20.1 \pm 28.5, p = 0.001). Airway leak pressure for I-gel group (26.0 \pm 2.6 mmHg) was also significantly higher than the c-LMA group (26.0 \pm 2.6 mmHg).

During insertion, one patient of group I (2.2%) had laryngospasm as compared to none in group L. During maintenance, child movement was observed only in one patient with c-LMA (2.2%). Coughing and blood stain on removal were reported higher with c-LMA as compared to I-gel. (2.2% in group I v/s 4.4% in group L for cough and 2.2% in group I v/s 6.6% in group L for blood stain on removal) but statistically not significant. None of the patients had hypoxia, laryngeal stridor, bronchospasm, regurgitation aspiration, loss of airway, wheeze and loss of tooth.

Mean SBP and pulse rate was comparable in both groups. After induction, there was fall in SBP and returned to baseline after 1 hour. There was no statistically significant difference in change in SBP in both groups (Fig. 1). In both groups, rise in pulse rate during induction and insertion was observed; thereafter heart rate decreased, which was statistically not significant (Fig. 2).

Discussion

The I-gel is a single use supraglottic airway device, available in CE marked paediatric sizes and officially launched for use in January 2010. Result of our study showed that the overall insertion success rate was similar with both the devices. However, success rate for first attempt in I-gel group was significantly higher (85.0%) as compared to c-LMA (80.0%). R Goyal *et al.* [11] found that insertion of I gel was successful on first attempt (95.0%) which was high as compared to laryngeal mask airway (90.0%). This is in consonance with various studies [12,13].

In the present study, we observed that the insertion time was shorter with I-gel ($14.64 \pm 16.7 \text{ sec}$) than with c-LMA ($20.11 \pm 28.5 \text{ sec}$). Lee *et al.* [9] also found the shorter insertion time with I-gel as compared with the c-LMA. A report by RM Bringer *et al.* [14] has revealed that the median insertion time for the I-gel in paediatric patients was 14 sec. Ease of insertion of I-gel can be partially explained by less flexible stem and there is no need for cuff inflation. The insertion of c-LMA is difficult due to a large cuff which can impede digital intra oral position and propulsion in the pharynx. The lack of back plate which cause cuff more likely to fold over at the bases of mouth.

In our study, It was found that airway leak pressure of I-gel is higher $(26 \pm 2.63 \text{ mmHg})$ than c-LMA $(22 \pm 2.3 \text{ mmHg})$. Similar results were found by Lee et al. [9]. Theiler *et al.* [15] compared I gel with aura Once and found that average leak pressure was higher with I-gel (22 mmHg v/s 19 mmHg) but difference was not considered clinically significant. We found that laryngospasm in one child during I- gel insertion, one child moved in cLMA group during maintenance in L group and during removal coughing occurred in one child in I-gel group and 2 patient in c-LMA group. The study of R.M. Beringer *et al.* [14] showed similar complication rate in both groups (13, 11%). However, anaesthetic technique is known to affect complication rates.

On removal, blood stain was present in one patient in I-gel group and 3 patient in c-LMA group. R.M. Beringer *et al.* [14] found that blood on 3% of I-gel following removal which was less compared with 3-6% for Clma [16]. Singh *et al.* [17] reported that the incidence of lip, tongue and dental trauma was 16.7% in the L group and 3.3% (1/30) patients in I group. The I-gel-filled cuff is less traumatic to the airway as compared with more traditional air-filled cuffs, as non inflatable cuff inserts less pressure on the perilaryngeal tissue. Postoperative vomiting was significantly higher in L group; it might be due to gastric insufflations.

We did not observed significant changes in hemodynamic parameters like systolic blood pressure and heart rate before and after insertion in both the group. This finding was supported by the finding of Shin *et al.* [18].

Conclusion

I-gel is comparable to the c-LMA with regards to securing airway in children undergoing elective surgery. I-gel is better than c-LMA in terms of significantly easier and more rapid insertion with high leak pressure. The hemodynamic changes after insertion and the postoperative complication are not significantly different between c-LMA and I-gel patients.

Limitation

Only children with normal airway anatomical structure were included. The anaesthetist were more experience in inserting the LMA Classic than the I-gel and this may lead to bias.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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