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Comparison of i-gel™ Airway with Laryngeal Mask Airway Supreme™ in children undergoing elective cataract surgeries

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Summary : *Background* : i-gel™ Airway (i-gel™) and Laryngeal Mask Airway Supreme™ (LMA supreme™) are two second generation supraglottic airway devices (SAD) with inbuilt drain tube which were designed to provide better laryngeal seal. Objective of our study was to compare i-gel™ with LMA supreme™ in children for routine airway management and also to compare the intra ocular pressure (IOP) changes with insertion of both the devices.

Methods : 104 patients of either sex with ASA I-II status, in the age group of 1.5 - 8 years, weighing 10 to 20 kg who underwent elective cataract surgery were randomly divided into two groups of 52 each, in group I LMA supreme™ while in group II i-gel™ was inserted. The primary outcome was effectiveness of both the devices which was measured in terms of oropharyngeal leak pressure (OLP). We also measured IOP changes, ease of insertion, time taken for placement, number of attempts, any intraoperative or postoperative complications as our secondary outcome.

Results : The OLP for i-gel™ was higher than LMA supreme™ which was statistically significant (p= 0.003). IOP with LMA supreme™ was raised after insertion (p value = 0.001). IOP with i-gel™ was decreased after insertion but the difference was not statistically significant. (p value = 0.65). No difference was observed in any other parameter.

Conclusion : We conclude that i-gel™ airway is better than LMA supreme™ in terms of demonstrating higher leak pressure and better stability of intraocular pressure on insertion in children with normal airway.

Key words : Oropharyngeal leak pressure ; intra ocular pressure ; i-gel™ ; LMA supreme™.

Introduction

i-gel™ Airway (i-gel™) and Laryngeal Mask Airway Supreme™ (LMA supreme™) are two recent second generation supraglottic airway devices (SAD) with inbuilt drain tube which were designed to provide better laryngeal seal. Effectiveness of a SAD is usually assessed with oropharyngeal leak pressure (OLP) (1). Various previous studies done in children differed on their results about OLP, some suggesting higher OLP for i-gel™ while some suggesting higher OLP for LMA supreme™ (2-4). Previous studies had reported that i-gel™ insertion was not associated with increase in intra ocular pressure (IOP) but similar study was not available for LMA supreme™ (5-6). So, objective of our study was to compare i-gel™ with LMA supreme™ in children undergoing cataract surgeries for routine airway management and to compare the IOP changes with insertion of both the devices.

Methods

This prospective randomized study got approval by the Ethics committee of PGIMER Chandigarh (NK/MD/1003/13462-63) and was registered with Clinical Trial Registry of India (CTRI) (CTRI/2014/06/004682). Written informed consent was obtained from the parents of the children. One hundred fifteen children were assessed for eligibility, one hundred ten met inclusion criteria out of which six were excluded because of parent's consent refusal (Fig. 1). One hundred and four patients of either sex with American Society of Anaesthesiologists (ASA) I-II status, in the age group of 1.5-8 years, weighing 10 to 20 kg who underwent elective cataract surgery were included in the study. Children were randomly divided into two groups using a computer generated block of six

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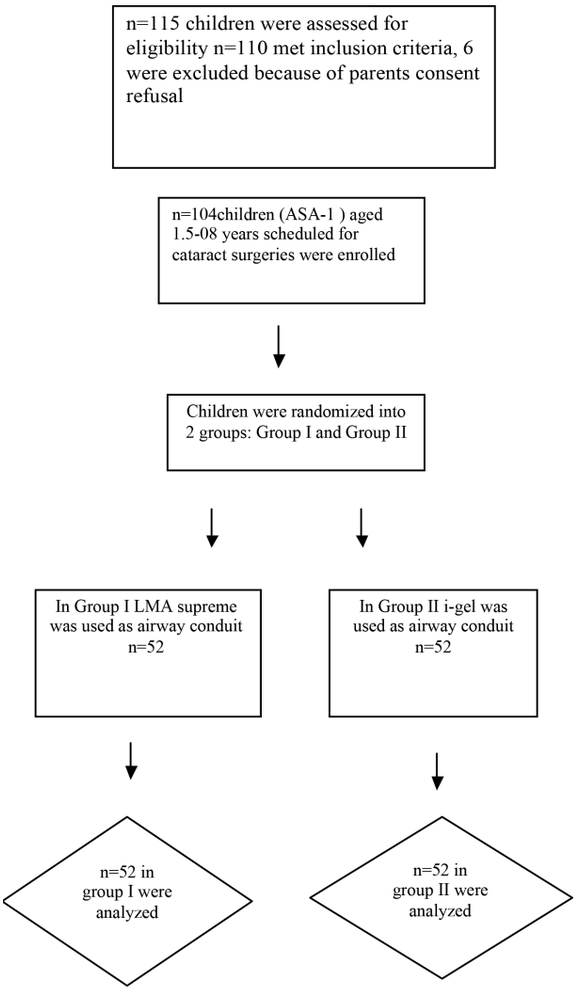

Fig. 1. — Consort diagram of participants

randomization table. In group I, LMA supreme™ was inserted while in group II, i-gel ™ was inserted. Children were excluded from the study if parents refused consent, had upper respiratory tract infection prior to surgery, anatomical abnormality in upper respiratory tract, anticipated difficult airway, and children with increased risk of aspiration. Prior to surgery, patients were evaluated, fasting status was confirmed and the parents were explained about the anaesthetic procedure. No premedication was given. For children who were apprehensive were induced in the presence of parents after fully explaining the steps to the parents. Monitoring consisted of standard ASA recommended monitors like pulse oximetry, non invasive arterial blood pressure, electrocardiograhy and capnography (Aestiva 5™ 7900, Datex Ohmeda, USA). The standardized anaesthetic technique consisted of induction with 50% O_2 and N_2O with sevoflurane (6-8%) followed by intravenous access. Patients were spontaneously ventilated till the child was induced. Adequate depth of anesthesia was considered when there was no response to the jaw thrust. Just after the induction intra ocular pressure (IOP) was measured using Schiotz tonometer (Riester GmbH, Bruckstr, 31 Jungingen Germany) by an independent investigator to determine the baseline values. When the depth of anesthesia was adequate, the lubricated supraglottic device was inserted and fixed by tapping as per the manufacturer's recommendation (7-8). In LMA supreme™ group the cuff was inflated to 60 cm H_2O using an aneroid cuff pressure gauge as per the manufacture's recommendation for size 2 LMA supreme™ (7). Post insertion IOP was measured after 2 min by the same investigator to look for any IOP changes with insertion. After recording the IOP, fentanyl 2μ/kg was administered. SAD was inserted by one investigator and another investigator recorded the OLP and assessed for gastric insufflations. The numbers of attempts were recorded. Proper placement of the device was defined as bilateral chest movements on gentle manual ventilation and absence of any significant leak. Any adverse events during placement of device were noted and the maneuvers to correct it were also noted. If there was significant airway obstruction or a significant air leak, the device was removed and reinsertion attempted. Maximum three reinsertion attempts were taken and unsuccessful placements were termed as device failure. In cases of device failure the trachea was intubated with endotracheal tube for airway management. The total time taken from picking up the supraglottic device above the incisors and obtaining an effective airway was recorded. The ease of insertion was assessed based on a subjective scale (1 = easy, 2 = moderate 3 = difficult, 4 = impossible). The ease of placement of gastric tube through gastric port was assessed based on a subjective scale (1 = easy, 2 = difficult 3 = unable to pass). To measure the leak pressure, the fresh gas flow was kept at 3 L/min until equilibrium was reached and then released completely (not allowed to exceed 40 cm H_2O) (1). The leak pressure was measured with head in neutral position. The patients were spontaneously ventilated with 50% nitrous and oxygen with flow rate of 3L/min and we maintained End tidal carbon dioxide ($EtCO_2$) of 35-45 mmHg. If required (when $EtCO_2$>45 mmHg), ventilation was assisted to maintain $EtCO_2$ between 35-45 mmHg. At the completion of procedure the devices were removed under a deeper plane of anesthesia to prevent any complication like coughing and laryngospasm. Any incidence of coughing, laryngospasm, or

bronchospasm), desaturation (SPO2 < 90%), and blood staining on the device after removal, were also noted. Coughing was recorded in immediate postoperative period (0 h), at discharge (4 h) and after 24 h.

Statistical Analysis

Sample size was estimated based on mean difference of airway leak pressure as 3 5.18 cm H_2O between 2 groups as reported in a study by Jagannathan et al. (2). Our sample size came out to be 47 subjects per group at a power of 80% and confidence interval of 95%. For possible dropouts, it was decided to include 52 patients per group. All observations were recorded in a standardized data collection sheet and analyzed statistically. The statistical analysis was carried out using Statistical Package for Social Sciences (SPSS Inc., Chicago, IL, version 17.0 for Windows). Mean were calculated for all quantitative variables and for measures of dispersion standard deviation or standard error were calculated. Qualitative or categorical variables were described as frequencies and proportions. Continuous variables were compared with independent sample *t*-test when data are normally distributed, otherwise Mann-Whitney U test was used. Qualitative data was compared using Chi-square test and $p < 0.05$ was considered as significant.

Results

One hundred and four children were randomized to either LMA supreme™ group (n=52) or i-gel™ group (n=52). Data from all patients have been included in this study. A CONSORT flow diagram has been provided in figure 1.

In both the groups the demographic data such as age, sex and weight were comparable (Table 1).

Table 1

Demographic data of patients.

	LMA supreme TM group	i-gelTM group	p value
Age (yrs)	4.91 ± 1.49	4.47 ± 1.64	0.15*
Gender			
Female n (%)	16 (31)	22 (42)	0.22#
Male n (%)	36 (69)	30 (58)	
Weight (kgs)	15.40 ± 2.89	14.99 ± 3.12	0.49*

Data expressed as mean ± SD or proportions, as applicable
* Independent (unpaired) sample t-test
# Chi-square test

We found that mean OLP for i-gel™ was higher than LMA supreme™ which was statistically significant (25.51 ± 4.08 vs 22.73 ± 5.05 cm H_2O, p= 0.003) (Table 2).

In LMA supreme™ group 50 (96%) children had successful LMA supreme™ insertion in 1st attempt and 1 (2%) in 2nd attempt. In 1 (2%) child it was not possible to insert the device after 3 attempts so it was regarded as device failure and intubation was done to maintain the airway. In i-gel™ group 49 (94%) children had successful i-gel™ placement in 1st attempt and 3 (6%) in 2nd attempt. Overall success rate of insertion in LMA supreme™ group was 98% while in i-gel™ group it was 100% (Table 2).

Time taken for successful placement of LMA supreme™ (8.26 ± 2.01 seconds) and i-gel™ (6.68 ± 1.60 seconds) was comparable (p value =0.39) (Table 2).

In LMA supreme™ group ease of insertion of orogastric tube (OGT) was moderate in 2 (4%) and was easy in rest of the patients. In i-gel™ group ease of insertion of OGT was easy in all the patients. Overall success rate was 100% in both the groups (Table 2).

There was no difference in number of manipulations required for any malposition during placement of device (2 for LMA supreme™ *vs* 3 for i-gel™). There was no difference in the incidence of intraoperative displacement of devices between both the groups (2 in LMA supreme™ group and 1 in i-gel™ group). In both the groups the displaced device was advanced further and fixed again (Table 2).

In LMA supreme™ group there was single incidence of laryngospasm during removal of device and presence of blood stain on device in 2 children. In i-gel™ group there was no incidence of any adverse events during removal of device (Table 2).

Mean IOP for LMA supreme™ and i-gel™ before insertion was 10.55 ± 3.24 mm Hg and 11.43 ± 2.65 mmHg respectively. IOP with LMA supreme™ was increased after insertion (10.55 ± 3.32 *vs* 11.68 ± 3.09 mm Hg) and the difference was statistically significant (p value = 0.001). IOP with i-gel™ was decreased after insertion (11.43 ± 2.65 *vs* 11.29 ± 3.04 mm Hg) but the difference was not statistically significant (p value = 0.65) (Table 3).

Incidence of postoperative cough was similar in both the groups. There was 1 incidence of failure of device in LMA supreme™ group due to inability to place the device in 3 attempts while there was no incidence of failure of device in i-gel™ group (Table 4).

Table 2

Data on LMA supremeTM and i-gelTM insertion

	LMA supremeTM group	i-gelTM group	p value
Oropharyngeal leak pressure (cm H2O)	22.73 ± 5.05	25.51 ± 4.08	0.003*
Success rate of insertion			
1st attempt n (%)	50 (96)	49 (94)	0.66#
2nd attempt n (%)	1 (2)	3 (6)	
3rdattempt n (%)	1 (2)	0	
Time taken for LMA supreme/i-gel insertion(sec)	8.26 ± 2.01	6.68 ± 1.60	0.39*
Ease of insertion			
Easy n (%)	45 (86)	42 (81)	0.42#
Moderate n (%)	6 (11)	10 (19)	
Impossible n (%)	1 (2)	0	
Ease of orogastric tube (OGT) insertion			
Easy n (%)	49 (96)	52 (100)	0.47#
Moderate n (%)	2 (4)	0	
Reaction during placement			
Laryngospasm/bronchospasm/obstruction n (%)	0	0	
Malposition n (%)	2 (4)	3 (6)	0.66#
Intra operative adverse events and manipulation of device			
Displacement n (%)	2 (4)	1 (2)	0.54#
Device Failure n (%)	1 (2)	0	0.31#

Data expressed as mean ± SD or proportions, as applicable

* Independent (unpaired) sample t-test

Chi-square test

Discussion

Principal finding of our study shows that oropharyngeal leak pressure of i-gel™ airway is significantly higher than that of LMA supreme ™ and the IOP with LMA supreme ™ when compared to i-gel™ has increased significantly after insertion.

Our results were in agreement to the results of various studies who also reported higher OLP for i-gel™ than LMA supreme™ (2, 3, 9-13). Jagannathan et al. reported the OLP for i-gel™ to be 20 cmH_2O and that of LMA supreme™ to be 17 cmH_2O, revealing a significant difference. (3). Overall leak pressures in both the groups were lower in their study as compared to ours. This might be due to the fact that they had used different sizes of devices from size 1.5 to 3 for different age groups and then they reported common OLP for all the sizes. In our study we had used only size 2 i-gel™ and LMA supreme™ and measured the OLP with head in neutral position while they had not commented on the position of head during the measurement which might be the cause of difference. Our results were in contrast to those of Kus et al. who reported higher OLP for LMA supreme™ than i-gel™ (20.9 ± 3.2 cm H_2O vs 18.9 ± 3.2 cm H_2O) (4). This difference might be due to the fact they had done the study in children with simulated difficult airway by applying the neck collar to limit the movement of neck while our study was on children with normal airway.

In our study we found that i-gel™ insertion was associated with slight fall in IOP 2 minutes post insertion This might be due to the soft gel like consistency of i-gel™ with no inflatable cuff that might had prevented stress response while placement. Our results were similar to the results reported by Sahin et al. who had reported significant fall in IOP from 10.57 ± 3.00 mm Hg to 7.90 ± 2.96 mm Hg 2 minutes after insertion of i-gel™ (6). This might be due to the fact that they had used propofol and fentanyl during induction. We in our study induced the children with sevoflurane and we gave fentanyl after the measurement of IOP.

In our study we found small but statistically significant increase in IOP, 2 minutes post insertion with LMA supreme™ which might be due to the stress response caused by inflation of cuff for a proper seal.

We could not find any study reporting the IOP changes with insertion of LMA supreme™.

Time taken for LMA supreme™ placement was slightly more in our study which might be due to the fact that it required cuff to be inflated for proper placement and the time required to inflate the cuff could increase the total time required for the device placement. Overall our insertion time was less with both the devices than the previous studies in children (3-4) which might be due to the fact that they had calculated the time from removal of the facemask including the time taken to pick up the device till bilateral chest rise was observed. We had reported the time taken from handling the device above the teeth to the obtaining of $EtCO_2$ trace. Our insertion time represented the actual time taken for successful insertion.

In our study success rate of OGT insertion was 100 % in both the groups and were similar to the results reported by Jagannathan et al. (3).

Our results for malposition during placement for i-gel™ were also similar to the results reported by other studies (3, 11, 14).

Our results regarding displacement of device intraoperatively was comparable in both the groups and these displaced devices were advanced further and refixed again. The results of our study were comparable with most of the studies (3, 11, 15) but were in contrast to the results reported by Hughes et al.who reported higher incidence of intraoperative displacement with i-gel™ requiring manipulation (16). This might be due to the fact that they had not used bimaxillary fixation as recommended by the manufactures to maintain it in proper place but in our study we have used bimaxillary fixation.

In the present study none of the patients in either group had any adverse events like laryngospasm, bronchospasm, desaturation and tongue, lip or dental trauma while placement of device. There was only 1(2%) incidence of laryngospasm during removal in LMA supreme™ group which promptly resolved with continuous positive airway pressure via facemask. Our reported findings were similar to results reported by other studies (3, 11-12). Absence of the above complications might be due to the fact that strict selection criteria were followed before enrolling the children for study. An adequate depth of anaesthesia was ensured before attempting insertion thereby limiting the number of attempts used and following standardized techniques for insertion of devices.

In our study blood on device was in agreement to other studies of the same cohort (3, 11-12).

The incidence of postoperative cough, dysphagia or hoarseness in both the groups were similar to the results of other published data (3, 11). In both

Table 3

Data on intraocular pressure.

	Mean IOP before insertion (mm Hg)	Mean IOP after insertion (mm Hg)	Difference in IOP before and after insertion (mm Hg)	p value
LMA supremeTM group	10.55 ± 3.24	11.68 ± 3.09	1.13 ± 2.33	0.001*
i-gelTM group	11.43 ± 2.65	11.29 ± 3.04	0.14 ± 2.35	0.65*

Data expressed as mean ± SD

* Independent (unpaired) sample t-test

Table 4

Post operative data.

Ease of removal of device	LMA supremeTM group	i-gelTM group	p value
Easy n (%)	50 (98)	52 (100)	0.3#
Moderate n (%)	1 (2)	0	
Response during removal of device			
Laryngospasm n (%)	1 (2)	0	0.31#
Blood on device n (%)	2 (4)	0	0.14#
Post operative cough			
0 hr n (%)	10 (20)	4 (8)	0.07#
4 hr n (%)	0	0	
24 hr n (%)	0	0	

Data expressed as proportions.

Chi-square test

the groups cough was detected only in immediate postoperative period. Although i-gel™ inserts less pressure on the perilaryngeal tissue because of non-inflatable cuff, the incidence of cough was comparable in both the groups. The slightly higher incidence of cough in our study might be due to use of sevoflurane anaesthesia. These patients didn't complain of cough when enquired about it subsequently at discharge and after 24 hours.

Limitations

The patient population included in this study consists of patients with normal airways. Our current findings might not be applicable to patients with difficult airways. However our current findings warrant future similar studies on patient with difficult airways. Lack of visualization of the position of the devices in relation to the laryngeal structures was other possible limitation of the present study. In addition a good mask larynx relationship was ascertained clinically rather than from fibreoptic view. The IOP in our study was measured only twice due to time constraint, and in children in whom there was no risk factors for raised IOP. The other limitation was lack of blinding which reflects that it was impossible to conceal the airway device during insertion which was a possible source of bias.

Conclusion

So, we conclude that i-gel™ airway is better than LMA supreme™ in terms of demonstrating higher leak pressure and better stability of intraocular pressure on insertion in children with normal airway.

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