COMPARISON OF CLINICAL PERFORMANCE OF I-GEL WITH CLASSICAL LARYNGEAL MASK AIRWAY IN SPONTANEOUSLY BREATHING CHILDREN UNDERGOING ELECTIVE SURGERY- IN TERMS OF EASE OF INSERTION

Ansal Nelliyullathil[1], Preetha Janardhanan[2], Radhika Kolathu Parambil[3]

[1]Senior Resident, Department of Anaesthesiology, Government Medical College, Kozhikode, Kerala, India.
[2]Additional Professor, Department of Anaesthesiology, Government Medical College, Kozhikode, Kerala, India.
[3]Assistant Professor, Department of Anaesthesiology, Government Medical College, Kozhikode, Kerala, India.

ABSTRACT

BACKGROUND

Supraglottic airways are designed to maintain clear airway which creates a seal around the larynx. I- Gel airway and classical laryngeal mask airway (LMA-Classic) are successfully used in children for elective airway management. Easy placement of airway devices within short time is crucial to prevent airway related complications.

The aim of the study is to compare the clinical performance of novel supraglottic airway- the i-gel airway with LMA-classic in terms of ease of insertion, duration of insertion, and complication.

MATERIALS AND METHODS

This is a prospective randomized single blinded open study. 100 children posted for elective minor surgeries in paediatric operation theatre were enrolled in this study. Children were randomly assigned to size two i-gel group (Group I) and size two LMA group (Group L) of 50 each. All airway devices were inserted by a single junior resident of Anaesthesiology Department who had prior experience of insertion of more than 50 i-gel, and LMA-classic airway. We compared the clinical performance of i-gel airway with LMA- Classic in terms of ease of insertion, duration of insertion and complication.

RESULTS

Demographic data were comparable in both the groups. i-gel size two airway was easier to insert in comparison to LMA- classic. This difference was statistically significant (P = 0.02). The duration of insertion was significantly shorter in i-gel airway compared to LMA-Classic which was statistically significant (p=0.0001). The complications related to both airways were less.

CONCLUSION

i-gel airway is superior to LMA-classic in spontaneously breathing children undergoing elective surgery in terms of ease of insertion and duration of insertion. Both devices were safe and effective in paediatric airway management.

KEYWORDS

Ease of Insertion**,** i-gel Airway, LMA-Classic, Paediatric, Anaesthesia, Supraglottic Airway.

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BACKGROUND

Supraglottic airways are used as an alternative to endotracheal intubation to reduce complications associated with intubation.[1] i-gel a novel supraglottic airway with non-inflatable cuff made of medical grade thermoplastic elastomer.[2] It has a port for gastric tube placement and drainage.[3] i-gel is easy to insert and has good stability.[3] Firmness and natural oropharyngeal curvature allows easy insertion of i-gel airway in to the oropharynx.[3,4,5] Easy and short duration of insertion of airway devices are crucial in paediatric anaesthesia to avoid adverse events. We compared the performance of i-gel and LMA- classic in terms of ease of insertion, duration of insertion and complications.

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Corresponding Author:
Dr. Kolathu Parambil Radhika,
Assistant Professor,
Department of Anaesthesiology,
Government Medical College,
Kozhikode- 673008, Kerala, India.
E-mail: radhikaakp@gmail.com
DOI: 10.18410/jebmh/2018/714

MATERIALS AND METHODS

After approval from Institutional Ethical Committee we enrolled 100 children for this study. Written informed consent was taken from all the parents. Children undergoing elective surgeries less than one hour duration were included in this study. This study was conducted at paediatric surgery operation theatre complex of Govt. Medical College, Kozhikode from June 2016 to June 2017.

American society of physical status I-II, children aged two to ten years, weighing 10-20 kg were included in the study. Children with difficult airway, cervical spine disease, respiratory problems and gastro oesophageal regurgitation were excluded. All the children were fasting as per standard guidelines.

Children were randomly assigned to size two i-gel group (Group-I) and size two LMA-Classic group (Group-L) of 50 each. They were pre-medicated with 0.3mg/kg oral midazolam 30 minutes prior to induction of anaesthesia. Standard monitoring included continuous electrocardiography, noninvasive blood pressure, pulse oximetry and capnography. Intravenous access was established after inhalation induction with 33% oxygen in N_2O and sevoflurane. Once adequate depth of anaesthesia was achieved the supraglottic airway device was inserted by two year experienced single junior resident in Anaesthesiology who had used both the device more than 50 times. Insertion was done as per manufacturer's recommendation. Both the devices were fixed by taping the tube over the chin. The LMA classic cuff was inflated with 10ml air. Analgesia was provided with (1-2µ/kg) Fentanyl citrate. Anaesthesia was maintained with 33% O_2, N_2O and sevoflurane

Heart rate, noninvasive blood pressure, oxygen saturation and end tidal CO_2 were monitored before induction, 1minute and 5 minutes after insertion of the device, then at every 5minutes interval till the end of surgery. Anaesthesia was maintained with 1-2% sevoflurane and 60% N_2O in O_2. Children were breathing spontaneously under General anaesthesia. All LMAs were inserted after lubricating the back of the cuff with water soluble gel, and classic LMA after full deflation.

The independent observer recorded the time needed for device placement (measured from when the device was picked up by the junior resident and till it was connected to the breathing circuit after getting an effective airway. The effective airway or correct placement was defined by visible chest movement, spo2 more than 95%, square wave capnograph trace, and absent leak. In case of failed attempt this was measured to the time the LMA was removed from the mouth. The maximum time allowed for each attempt was 60 seconds. The duration of insertion was the sum of all attempts. If an effective airway could not be achieved the device was removed and reinserted

The ease of insertion was graded on a three point scale

Grade - 1, Very Easy (no resistance, no manipulation required), Grade - 2, Easy (resistance requiring one maneuver like airway rotation, jaw thrust, neck flexion or head rotation.) Grade - 3, Difficult (high resistance, failure at second attempt).

At the end of surgery, anaesthesia was discontinued and the device was removed. Blood staining on device, gastric insufflation, aspiration and sore throat in the immediate postoperative period were noted.

Sample size was calculated based on a previous study by Chauhan et al[10] where a standard deviation (SD) of 4.9 in Group 1, and standard deviation of 17.7 in Group 2, the mean difference ((Group 1Mean) – (Group 2 Mean)) calculated was –9.58 in duration of insertion attempts, and at two sided Type 1 error of 0.05 and power of 95% the sample size calculated was 48 in each group. So we decided to include a total of 100 children with 50 in each group.

Statistical analysis of the data was done using Statistical Package for the Social Sciences software version 18 (SPSS Inc. Chicago, USA). Qualitative data were compared using Chi-square test. Quantitative data were compared using independent t test. P value of less than 0.05 was taken as statistically significant.

RESULTS

Total of 100 children were included in this study with 50 in each group. The age and weight were comparable in both the groups (Table 1). ASA physical status was comparable between two groups (Table 2).

The airway device insertion was very easy in 47 (94%) children in i-gel and 39(78%) children in LMA-Classic group. The insertion was easy in 3 (6%) children in i-gel and 11(22%) children in LMA-Classic group (Figure -1). This difference in ease of insertion was statistically significant (P=0. 02) (Table -3). Duration of insertion of airway device was shorter in i-gel group (15.91±1.63) compared to LMA-Classic group (26.05±5.13) (Table-4). This difference in duration of insertion was statistically significant. (p= 0.0001).

The complications related to airway devices were less in both groups (Table -5).

Parameter	Group I n*=50	Group L n*=50	p-Value
Age (Years) Mean	4.64	4.84	0.61
Weight (kg) Mean	15.54	15.38	0.81
Gender (Male/Female)	23/27	27/23	0.42

Table 1. Demographic Data

Values expressed as mean.
*n= number of cases

ASA* Grade	Group I n †=50	Group L n †=50	P Value
I	50(100%)	48(96%)	0.24
II	0	2 (4%)	

Table 2. ASA Grade

*ASA-American Society of Anesthesiologists
†n=number of cases

Values expressed as number (percentage). n=Number of cases.

	Ease of Insertion		p-Value
Group I	Very Easy	48 (96%)	0.02
	Easy	2 (4%)	
Group L	Very Easy	39 (78%)	
	Easy	11(22%)	

Table 3. Comparison of Clinical Performance in terms of Ease of Insertion

Values expressed as number (percentage). n=Number of cases.

	Duration of Insertion (in Seconds)	p-Value
Group I	15.91±1.63	0.0001
Group L	26.05±5.13	

Table 4. Comparison of Duration of Insertion

Complication	Group I	Group L
Regurgitation	0	0
Aspiration	0	0
Gastric Insufflation	0	3(6%)
Presence of blood on device	0	0
Sore throat	1(2%)	3(6%)

Table 5. Distribution of Complications

Values expressed as number (percentage).

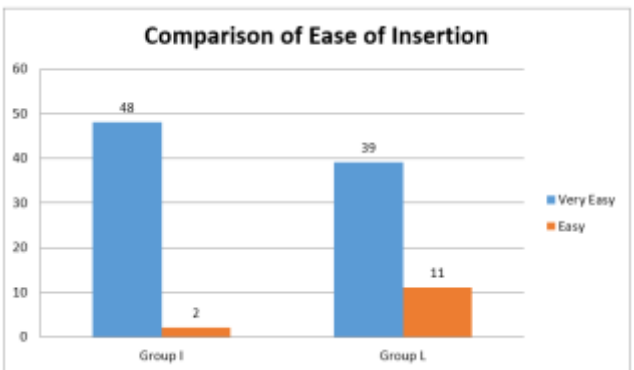

Figure 1. Comparison of Ease of Insertion

The ease of insertion: Grade 1= Very Easy (no resistance while insertion, no manipulation required during insertion) Grade 2= Easy (resistance during insertion which require one manoeuvre like airway rotation, jaw thrust, neck flexion or head rotation.) 3= Difficult (high resistance or failure at second attempt). No patient had Grade 3 insertion.

DISCUSSION

The present study was done to compare the safety and efficacy of i-gel airway with LMA- classic in terms of duration and ease of insertion and complications in 2 year experienced user who had done insertion of i-gel and LMA – Classic more than 50 times. Both airways were effective and safe in spontaneously breathing children undergoing elective surgery. However we found significant differences in clinical performance between these two airway devices in two year experienced user. LMA- classic required longer time for insertion and more adjustment maneuvers to get an effective airway compared to i-gel airway.

In i-gel group insertion was very easy (no resistance on insertion and no airway manipulations were needed) in 94% (47/50,) children compared to 78% (39/50) in LMA- classic group. Insertion was easy (resistance requiring one manoeuvre like airway rotation, jaw thrust, neck flexion or head rotation) in 6% (3/50) children in group i-gel compared to 22% (11/50) in LMA-Classic group. This difference in ease of insertion was statistically significant (P=0. 02). The overall requirements of airway manipulations were less in the i-gel group. These results were in consistence with other studies.[6,7]

Duration of insertion was shorter in i-gel group (15.91 ± 1.63 seconds) compared to LMA classic group (26.05 ± 5.13 seconds). There was a significant difference statistically in duration of insertion between the two groups (p= 0.0001). These results were similar to many other studies by different authors, Helmy et al, Reza Hashemian et al and Chauhan et al.[8,9,10] The time required to achieve an effective airway was shorter with i-gel compared to LMA-Classic, because the i-gel airway could be pushed easily in to oropharynx and it did not require any cuff inflation.[5,11,12] According to Levitan and Kinkle the deflated margin of the inflatable mask may catch the edge of the epiglottis during insertion and leads to downward folding of epiglottis causing obstruction to get an effective placement of the device.[13] This could be another explanation for longer duration of insertion with LMA with inflatable cuff.

We compared the incidence of complications in both the groups. According to Gabbott et al i-gel provided a good airway seal pressure due to the thermoplastic properties of the soft cuff which form an effective seal around the laryngeal inlet.[11] This property reduces gastric insufflations and pulmonary aspiration with i-gel airway. In our study there was no incidence of gastric insufflation with i-gel airway probably this could be due to the effective mask seal around the laryngeal inlet and presence of nasogastric tube through the gastric channel which helped to vent out air and gastric contents. We observed three cases of gastric insufflation with LMA- classic and no gastric insufflations in i-gel airway group. Brimacombe et al. observed one case of gastric insufflation with LMA-ProSeal; the reason was due to the folding of the tip of the LMA-ProSeal, posteriorly causing failure to drain the gastric contents through the gastric channel.[12] This shows that gastric insufflations can occur even in the presence of gastric channel in the airway device and in i-gel the tip is firm which may prevent folding of tip after insertion.

In our study there was no incidence of regurgitation or aspiration with both i-gel and LMA-Classic. All the children posted for surgery were adequately fasting preoperatively. We observed that in i-gel group, one (2%) child complained sore throat immediately in the postoperative period whereas in LMA-Classic group three (6%) children complained of sore throat.

Lesser incidence of sore throat was observed in i-gel airway compared to LMA- Proseal in a study by Solivers et al.[14] Similarly in our study we found lesser incidence of sore throat with i-gel airway compared to LMA-Classic. Studies have reported similar findings in which the incidence of sore throat was lesser with i-gel airway in comparison to other supraglottic airway devices.[5,8,15,16] The lower incidence of sore throat could be due to the soft seal formed by the gel like cuff of i-gel airway. The non-inflatable cuff of i-gel airway has many advantages like easier insertion with shorter duration and less soft tissue compression.[17,18,19] In this present study no incidence of blood staining occurred in

both i-gel and LMA-Classic airway devices. In our study the insertion of both i-gel and LMA-Classic were either easy or very easy to insert without much resistance, and none of the children had difficult insertion, this could be the reason for no blood staining on all the airway devices on removal. Goyal Rakhee et al noted blood staining on few airway devices which was not significant.[20]

There are some limitations to our study. Oropharyngeal sealing pressure was not studied. The airway device position was not confirmed by a fiber optic bronchoscope. We did not compare the clinical performance with the likely competitor of the i-gel airway such as ProSeal LMA.

CONCLUSION

i-gel airway is superior to LMA-classic as a supraglottic airway device in spontaneously breathing children undergoing elective surgery. Size two i-gel airway is easier and faster to insert in paediatric population compared to size two LMA-Classic. Both airway devices were safe and effective in paediatric airway management.

REFERENCES

[1] Richez B, Saltel L, Banchereau F, et al. A new single use supraglottic airway device with a non-inflatable cuff and an esophageal vent: an observational study of the i-gel. Anesth Analg 2008;106(4):1137-1139.

[2] i-gel supraglottic airway device with non-inflatable cuff Org. (Last accessed on 2011 Nov 29). Available from: http://www.i-gel.com/products/the inventor/

[3] i-gel User-guide. (Last accessed on 2011 Nov 29). Available from: http://www.i-gel.com/lib/docs/user guides/i-gel_User_Guide_English.pdf.

[4] i-gel supraglottic airway device with Non inflatable cuff. (Last accessed on 2011 Nov 29). Available from: http://www.i-gel.com/faq/i-gel .

[5] Singh I, Gupta M, Tandon M. Comparison of clinical performance of i-gel with LMA-proseal in elective surgeries. Indian J Anaesth 2009;53(3):302-305.

[6] Singh J, Yadav MK, Marahatta SB, et al. Randomized crossover comparison of the laryngeal mask airway classic with i-gel laryngeal mask airway in the management of difficult airway in post burn neck contracture patients. Indian J Anaesth 2012;56(4):348-352.

[7] Siddiqui AS, Raees US, Siddiqui SZ, et al. Comparison of performance and safety of i-gel with laryngeal mask airway (classic) for general anaesthesia with controlled ventilation. Anaesth Pain Intensive Care 2010;14(1):17-20.

[8] Helmy AM, Atef HM, El-Taher EM, et al. Comparative study between i-gel, a new supraglottic airway device, and classical laryngeal mask airway in anesthetized spontaneously ventilated patients. Saudi J Anaesth 2010;4(3):131-136.

[9] Reza Hashemian SM, Nouraei N, Razavi SS, et al. Comparison of i-gel™ and laryngeal mask airway in anesthetized paralyzed patients. Int J Crit Illn Inj Sci 2014;4(4):288-292.

[10] Chauhan G, Nayar P, Seth A, et al. Comparison of clinical performance of the i-gel with LMA proseal. J Anaesthesiol Clin Pharmacol 2013;29(1):56-60.

[11] Gabbott DA, Beringer R. The i-gel supraglottic airway: a potential role for resuscitation? Resuscitation 2007;73(1):161-162.

[12] Uppal V, Gangaiah S, Fletcher G, et al. Randomized crossover comparison between the i-gel and the LMA-unique in anaesthetized, paralysed adults. Br J Anaesth 2009;103(6):882-885.

[13] Levitan RM, Kinkle WC. Initial anatomic investigations of the i-gel airway: a novel supraglottic airway without inflatable cuff. Anaesthesia 2005;60(10):1022-1026.

[14] Soliveres J, Balaguer J, Richart MT, et al. Airway morbidity after use of the laryngeal mask airway LMA proseal vs. i-gel. Eur J Anaesthesiol 2010;27(47):257-258.

[15] Gatward JJ, Cook TM, Seller C, et al. Evaluation of the size 4 i-gel airway in one hundred non-paralysed patients. Anaesthesia 2008;63(10):1124-1130.

[16] Keijzer C, Buitelaar DR, Efthymiou KM, et al. A comparison of postoperative throat and neck complaints after the use of the i-gel and the La premiere disposable laryngeal mask: a double-blinded, randomized, controlled trial. Anesth Analg 2009;109(4):1092-1095.

[17] Twigg S, Brown JM, Williams R. Swelling and cyanosis of the tongue associated with use of a laryngeal mask airway. Anaesth Intensive Care 2000;28(4):449-450.

[18] Stewart A, Lindsay WA. Bilateral hypoglossal nerve injury following the use of the laryngeal mask airway. Anaesthesia 2002;57(3):264-265.

[19] Lowinger D, Benjamin B, Gadd L. Recurrent laryngeal nerve injury caused by a laryngeal mask airway. Anaesth Intensive Care 1999;27(2):202-205.

[20] Goyal R, Shukla RN, Kumar G. Comparison of size 2 i-gel supraglottic airway with LMA-proseal™ and LMA-classic™ in spontaneously breathing children undergoing elective surgery. Paediatr Anaesth 2012;22(4):355-359.