Indian Journal of Clinical Anaesthesia 2022;9(3):348–352

Content available at: https://www.ipinnovative.com/open-access-journals

Indian Journal of Clinical Anaesthesia

Journal homepage: www.ijca.in

Original Research Article

# Comparison of i-gel with cuffed endotracheal tube for low flow anaesthesia in paediatric age group for controlled ventilation

**Sumalatha R Shetty[1], Chandana Balaram[2,*], Nagaraj Kandagal[3]**

[1]*Dept. of Anaesthesiology and Critical Care, K S Hegde Medical Academy, Mangalore, Karnataka, India*
[2]*Dept. of Anaesthesiology and Critical Care, M S Ramaiah Medical College and Hospital, Bangalore, Karnataka, India*
[3]*KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre, Belgaum, Karnataka, India*

ARTICLE INFO

*Article history:*
Received 04-07-2022
Accepted 08-07-2022
Available online 13-08-2022

*Keywords:*
Low flow anaesthesia
Paediatric anaesthesia
i-gel ®

ABSTRACT

Low Flow Anaesthesia (LFA) is an environment friendly technique whose use in paediatric population is not popular. LFA with supraglottic airway device is a rare combination in most centres. This prospective randomized controlled study was formulated to analyse the efficacy of i-gel® for LFA as compared with cuffed endotracheal tube (OCETT) in paediatric age group. Children aged between 6 and 12 years requiring general anaesthesia were randomized by closed envelop method into Group I and Group E with 50 in each group. The two groups were compared in terms of air leak, haemodynamic response, end tidal carbon dioxide and inhaled tidal volume (TV), exhaled TV. Incidence of sore throat between the two groups was studied. Position and successful insertion of i-gel® was noted. Air leak observed was significantly higher in Group I but was comparable after 40 min of surgery. Incidence of sore throat was higher in Group E and the difference between the two groups were statistically significant at 0 hours ($p = 0.001$), 12 hours ($p < 0.001$), 24 hours ($p = 0.007$) and 48 hours ($p = 0.004$). LFA can be conducted in paediatric patients using i-gel® and it functions as efficaciously as endotracheal tube.



## 1. Background

Modern anaesthesia practice aims at reducing the wastage and pollution using Low Flow Anaesthesia (LFA).[1] Minimal fresh gas flow (FGF) is used to compensate for the oxygen ($O_2$) and volatile anaesthetics taken up in the lung.[2,3] White and Baum defined LFA as an inhalation anaesthetic technique via a rebreathing system in which the rebreathing fraction amounts to at least 50%.[3–5]

Some of the concerns posed in use of low flow in children are the effect of leaks in the breathing system, unpredictable inspired anaesthetic and oxygen concentration and accumulation of the degradation products, limiting its use in them.[1,6] Supraglottic airway devices (SGAD) are less invasive, better tolerated, and lead to lesser haemodynamic disturbances.[7] The i-gel® launched in 2007, provides non-inflatable anatomical seal of the pharynx, larynx and peri-laryngeal structures, with avoidance of compression trauma, makes it a good choice to use during LFA.[8] The mask sits in the hypopharynx and covers the supraglottic structures providing a good seal.[9]

## 2. Materials and Methods

A prospective randomised study including paediatric patients between 6 to 12 years of American Society of Anaesthesiologists Physical Status (ASA PS) I and II, scheduled for surgery requiring general anaesthesia and controlled ventilation. The aim of this study was to evaluate and compare the efficacy of i-gel® versus endotracheal tube

* *Corresponding author.*
*E-mail address*: drchandana1991@gmail.com (C. Balaram).

https://doi.org/10.18231/j.ijca.2022.069

for LFA in paediatric age group. The primary objective of the study was to determine i-gel® efficacy in terms of inspired and expired tidal volume, amount of air leak during ventilation, occurrence of rebreathing, intra-operative hemodynamic stability and post-operative sore throat and cough. Our secondary objectives were to assess effect of change in position with terms of displacement of the airway device and desaturation, if any.

Children for whom parental/ guardian consent could not be obtained, who had known allergy to any of the drugs that were being used, acute or chronic respiratory disease, increased risk of aspiration, anticipated difficult airway and those who were undergoing airway related surgeries were excluded. Patients were randomized by closed envelope method, Group I and Group E for i-gel® or endotracheal tube respectively with 50 in each group. Student t test was used to compare the difference between the means of inhaled tidal volume (TV), exhaled TV, air leak volumes, end-tidal $CO_2$ ($EtCO_2$) and haemodynamic parameters. Chi square test was used to the association of sore throat.

After Institutional Ethical Committee clearance, patients underwent a thorough pre-anaesthetic evaluation. All the patients were kept nil per oral as per standard guidelines and orally premedicated as per the institutional protocol.

On the day of the surgery, the GE healthcare Datex-Ohmeda machine, monitor and circuits were checked as per the manufacturer's guidelines. Any leak present was noted and added to the fresh gas flow FGF (1L + leak volume).

After shifting the patient to the OT, standard ASA monitors- electrocardiogram (ECG), pulse-oximeter, non-invasive blood pressure (NIBP) were attached and baseline vitals noted. Patients were pre oxygenated with 100% $O_2$ at 10 L/min with an appropriately sized facemask for 3 min using the circle system.

Patient were induced with inj. propofol at 2 mg/kg dose. Analgesia was obtained with 2 mcg/kg of inj. fentanly and paralyzed with inj. atracurium 0.5mg/kg. According to the group allotted, the patient had either an age appropriate OCETT or weight appropriate i-gel® inserted by the consultant anaesthesiologist. Satisfactory positioning of i-gel® and endotracheal tube was confirmed with 5-point auscultation and square waveform capnography. Along with these methods, i-gel® position was confirmed using a fiberoptic scope to visualize laryngeal view and graded according to Cook and Cranshaw [10,11] (Figure 1).

Patients were ventilated with pressure-controlled mode, set to deliver a tidal volume of 8-10 ml/kg, (peak pressure less than 20 cm $H_2O$) at a rate appropriate for age with inspiratory-to-expiratory ratio 1:2, sevoflurane or isoflurane (1 MAC) in $O_2$ and $N_2O$/air (1:1) at FGF of 4 L/min for ten minutes. FGF was then reduced to flow of 1 L/min with $FiO_2$ of 0.5.[3] All patients were monitored for inspiratory inspired and expired TV, occurrence of rebreathing ($FiCO_2$)

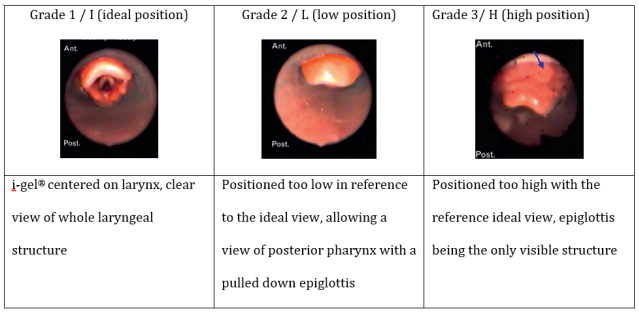



**Fig. 1:** Cook and Cranshaw, fiberoptic laryngeal view and grading [10,11]

every 10 minutes and saturation throughout the procedure. The difference between the inspiratory and expiratory TV was taken as the air leak (AL) in the device.[8] The occurrence of rebreathing was defined as inspired $CO_2 > 5$ mmHg.[12] FGF were increased to 4 L/min, 5 min before the end of surgery. After the procedure, patients were reversed with inj. neostigmine 0.05mg/kg and inj. glycopyrrolate 0.01mg/kg, extubated after complete clinical recovery from neuromuscular blockade and were administered 100% $O_2$ and shifted to post-operative ward.

All patients were evaluated for sore throat immediately after removal of the device and at 12, 24 and 48 hours post-operatively. Sore throat was evaluated using a four-point grading scale as suggested by Harding and McVey.[11,12]

**Table 1:** Post-operative sore throat (POST) 4-point grading scale by Harding and McVey [11,12]

| Score | Symptoms after extubation |
|---|---|
| 0 | No sore throat any time since the operation |
| 1 | Minimal sore throat, less severe than cold |
| 2 | Moderate sore throat, similar to that noted with cold |
| 3 | Severe sore throat, more severe than that noted with cold |

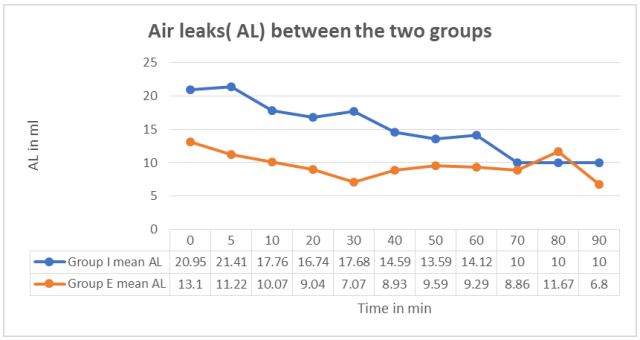
## 3. Results

Mean age of patients undergoing surgery was 8.8 years (±3.44) in group I and 8.2 years (±4.17) in group E. The duration of LFA was considered from the start of low flow (FGF = 1 L/m) till the initiation of high flows at the end of surgery. Mean duration of LFA was noted to be 48.48 min (±12.93) and 57.3 min (±23.128) respectively for Group I and Group E.

Tidal volume delivered and exhaled were comparable between the two groups and the difference was not statistically significant.

Air leak (AL) immediately after insertion of the device at time 0 min was more in i-gel® group with a significant p value of 0.023. Air leak at 5, 10, 20, 30, 40 min was higher in Group I but not statistically significant with the p

value of <0.001, 0.001, 0.001, <0.001 and 0.04 respectively. After the $40^{th}$ minute the difference between the two group was not significant. The Air leak calculated by subtracting exhaled TV from inspired TV though higher in Group I did not impair ventilation or lead to any untoward events.




| | 0 | 5 | 10 | 20 | 30 | 40 | 50 | 60 | 70 | 80 | 90 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Group I mean AL | 20.95 | 21.41 | 17.76 | 16.74 | 17.68 | 14.59 | 13.59 | 14.12 | 10 | 10 | 10 |
| Group E mean AL | 13.1 | 11.22 | 10.07 | 9.04 | 7.07 | 8.93 | 9.59 | 9.29 | 8.86 | 11.67 | 6.8 |

**Fig. 2:** Comparison of air leak between the two groups

The heart rate was compared during insertion and removal of the two airway devices. Both were higher in Group E with the p value of 0.11 (during insertion) and 0.26 (during removal). The blood pressure (SBP and DBP) between the two groups were comparable at baseline and induction. The blood pressure measured during insertion and removal was higher in Group E. The rise in SBP at removal in the endotracheal group was considered statistically significant p value of 0.04. There was no event of desaturation or untoward bradycardia throughout the period of LFA in both the groups.

Fiberoptic laryngeal view and grading described by Cook and Cranshaw (10) showed that 40 cases that is 80% of i-gel® had fiberoptic grade 1 (Ideal position) at first attempt of insertion. In the remaining10 patients of group I Grade 2 (Low position) was seen in 4 patients while the other 6 had grade 3 (High position). All 50 patients had i-gel® inserted in the first attempt with adequate ventilation. In 62 patients, caudal anaesthesia was administered along with general anaesthesia of which 28 patients belonged to Group I. There was no change in the delivered tidal volume, AL and saturation during the procedure or after re-positioning the patient for surgery, suggesting that there was no displacement of the device. The fiberoptic scope inspection of i-gel® position performed after re-positioning the patient for surgery, showed all the 28 patients had grade 1 position. The airway devices did not have to be repositioned for adequate ventilation with change of position of the patient.

The incidence and severity of POST was compared between the two groups showed the incidence of grade 1 sore throat was 52% at 0 hours, 42% at 12 hours and 16% at 24 hours post extubation in Group E, while its incidence was much lesser in Group I (18% and 4% at 0 hours and 12 hours respectively). None of the patients in our study groups had grade 3 POST. The symptoms were much lesser at 48 hours, 18% grade 1 and 4% grade 2 in endotracheal group with no symptoms in the i-gel® group. On comparison, the difference between the two groups were statistically significant at 0, 12, 24 and 48 hours with a p value of 0.001, <0.001, 0.007 and 0.004.

We observed a more comfortable and corporative child in the post-operative period in whom i-gel was used. The incidence of nausea and few episodes of vomiting were noted in group E which was not included for statistical analysis. No regurgitation, aspiration or gastric insufflation was noticed in either of the groups.

## 4. Discussion

In a review by Baxter A D,[13] it was noted that 25% of the expenditure in anaesthesia was due to the volatile agent usage. In another study by Frohlich D[14] and team it was concluded that this method limited the environmental pollution and maintained the temperature and humidification in children which was an enormous advantage.[13,14] The volatile agent consumption could not be measured as the provision to do the same was not available in our anaesthesia machine and hence economic benefits could not be quantified.

Frohlich D, Shwali B, Funk W and Hobbhahn J managed the airway of children aged 2 to 6 years with LMA during the conduct of LFA and found that the ventilatory frequencies, TV and peak pressures were comparable in both groups.[14] A normal capnograph and comparable $ETCO_2$ were noted in both LMA and uncuffed tracheal tube groups during LFA.[7,14] In our institution i-gel® is one of the most used SGAD; it is regularly used with spontaneous ventilation and high FGF but not for LFA. We planned this study to evaluate whether i-gel® could be used for LFA with controlled ventilation.

Uppal V et al (2009) in their study measured the gas leak seen with i-gel® when used for PCV and compared it with endotracheal tube.[15] The leak volume was calculated by taking the difference between inhaled and exhaled TV. The leak pressure of i-gel® was comparable with that of PLMA in a study conducted on children between the age 3 months to 15 years and there was no difference noted between the two devices.[8] A study by Theiler et al. showed that the leak pressure of the i-gel® was significantly higher than that of the Ambu AuraOnce and the device was suitable for use in infants and children during positive pressure ventilation.[16] Aya Fukuhara compared the performance of i-gel® and PLMA in paediatric patients and found that there was no difference in the leak pressure between i-gel® and Proseal LMA (8). Sebastian G Russo et al in their study defined "failure of device" as failure to successfully ventilate the patient to maintain a stable $ETCO_2$ and inability to maintain

a TV of 7ml/kg.[17] We targeted a tidal volume of 8-10 ml/kg and with continuous $ETCO_2$ monitoring we did not have any difficulties in ventilating our patients using i-gel.

Uppal V found that none of the patients undergoing laparoscopic surgery with i-gel® had gastric insufflations,[15] aspiration or regurgitation[16] which was also observed in our study. In all patients in group I, i-gel® were inserted at the first attempt in a study conducted by Uppal V and only four of the 25 needed minor manipulations after insertion.[15]

Russo S G et al[17] and Najeeb R[18] found that the success rate for first attempt insertion was highest with i-gel being 95% and 92.5% respectively in their studies when compared to the other SGAD. The fiberoptic view used to confirm the position of SGAD was found to be better in the i-gel® group than in the PLMA group with all sizes (p value <0.001 and 0.003, respectively).

Even with high or low positioned i-gel® tidal volume delivered was adequate.[8] Though 4 patients had grade 2 (low) and other 6 had grade 3 (high), adequate ventilation and normal $ETCO_2$ was recorded we readjusted the i-gel to obtain proper position. We did not come across any failed insertions. There was no trauma associated with insertion of i-gel® which was supported by other studies where they did not find any trauma associated with SGAD.[19–21]

In this study, there was no re-breathing, desaturation or gastric distention in any patients with LMA. The $ETCO_2$ was within normal ranges in both the groups. There was no obligation to increase the concentration of inhalational anaesthetic above the pre-determined range to compensate for any leakage.[19] In contrast to this, we observed that there was certain amount of rebreathing seen in the i-gel® group (10 patients). The concentration of $FiCO_2$ never increased to >3 mmHg and had no adverse effects on the patient haemodynamics. We noticed that rebreathing occurred only with the use of old i-gel® which probably failed to provide adequate seal. To check and overcome this hurdle we introduced new i-gel® which were exclusively used for this study. There was no rebreathing noted when new set of i-gel® was used. There was no requirement to increase the concentration of the volatile agents to maintain depth of anaesthesia or increase the FGF to compensate for the leak similar to this study.

In a study comparing the haemodynamic trends during insertion and removal of i-gel®, Proseal LMA and endotracheal tube, there was significant increase in heart rate and the mean blood pressure immediately after insertion in the endotracheal group which persisted for 3 minutes after intubation which supports findings in our study.[18]

Luce V (2014) and colleagues conducted a meta-analysis of 19 randomized control trials in paediatric patients, to study complications associated with airway management using LMA (732 patients) and OCETT (766 patients). They concluded that the perioperative respiratory complications such as desaturation, laryngospasm, bronchospasm, cough, and breath holding in paediatric patients were reduced.[20,21] Complications such as desaturations, laryngospasm or bronchospasm were not observed with either of the devices in our study. Incidence of cough and sore throat was more in the endotracheal group.

## 5. Conclusion

We compared the efficacy of i-gel® against endotracheal tube during the use of LFA and found that inhaled tidal volume, exhaled tidal volume, and end tidal carbon dioxide were similar in the two groups. The air leak noted with i-gel®, though higher than endotracheal tube group, provided adequate tidal volume with no deficiencies. The stress response with the insertion and extubation of endotracheal tube is significantly more as in many other similar studies similar. There were no incidence of desaturation or gastric insufflation, bronchospasm, aspiration, etc noted with i-gel® making its use safe even with LFA. The incidence of post-operative sore throat was significantly lesser in i-gel® group keeping the patient more comfortable in the post operative period when compared to endotracheal tube group.

The result of this study is in accordance with the hypothesis that I-gel® can be used effectively for the conduct of low flow anaesthesia with better haemodynamic stability.

In conclusion, we propose the use i-gel® safely in paediatric patients with low flow anaesthesia with lesser complications to the patient and the environment. LFA with i-gel® is an effective and safe alternate technique compared to endotracheal tube.

Global warming and environmental pollution is a major concern. Our anaesthetic gases though in a small quantity contribute to depleting the ozone layer. Low flow anaesthesia has been used comfortably in adults, but it's use in paediatric patients is sparse. We advocate the use of LFA with i-gel® in paediatric population to deliver anaesthesia, economically, safely and effectively.

## 6. Abbreviation

LFA – Low flow anaesthesia; OCETT – Oral cuffed endotracheal tube; TV – Tidal volume; ASA PS – Amaerican society of anaesthesiologist physical status; ETCO2- end tidal cardon – dioxide; FGF – Fresh gas flow; ECG – Electrocardiography; NIBP – Non invasive blood pressure; MAC – Minimum alveolar concentration.

## 7. Source of Funding

No grants or funds taken from any institute or organisation.

## 8. Conflict of Interest

None.

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## Author biography


**Sumalatha R Shetty,** Professor

**Chandana Balaram,** Senior Resident https://orcid.org/0000-0002-9443-9780

**Nagaraj Kandagal,** Senior Resident


**Cite this article:** Shetty SR, Balaram C, Kandagal N. Comparison of i-gel with cuffed endotracheal tube for low flow anaesthesia in paediatric age group for controlled ventilation. *Indian J Clin Anaesth* 2022;9(3):348-352.