Original article:

Study of Comparison of I-gel with Classic Laryngeal Mask Airway Regarding the Ease of Use and Clinical Performance

Shafeek[1] , Mundwadkar[2] , Ramanan[3]

[1]Post Graduate, [2] Professor, [3]Assistant Professor

Department of Anaesthesiology and Critical Care, Sri Venkateshwaraa Medical College Hospital and Research Centre, Puducherry

Corresponding author*

ABSTRACT

Background: Supraglottic airway devices have been widely used as an alternative to tracheal intubation during general anaesthesia.Laryngeal mask airway is a supraglottic airway device with an inflatable cuff forming a low-pressure seal around the laryngeal inlet and permitting ventilation. The i-gel is a novel supraglottic airway device made of thermoplastic elastomer, which is soft, gel-like and transparent. Unlike the conventional LMA it does not have an inflatable cuff. The present study was undertaken to compare the performance of two-supraglottic airway devices classic laryngeal mask airway and i-gel in anaesthetized, adult patients posted for elective surgeries under general anesthesia.

Methodology: Eighty patients, scheduled for various elective surgical procedures under general anesthesia belonging to ASA class I and II were included in the study and were randomly divided into two groups with 40 patients in each group. In Group 1 (n=40), classic laryngeal mask airway supraglottic airway device was used and in Group 2 (n=40) i-gel was used. Both the devices were compared in relation to the ease of insertion, duration of insertion and attempt of insertion between i-gel during general anaesthesia

Results: There was no statistically significant difference between the devices with respect to ease of insertion, number of attempts of insertion,hemodynamic changes and postoperative complications. The mean time of insertion for i-gel was 7.9±0.96 secs which was significantly shorter compared to c-LMA with a mean insertion time of 15.08±2.33 secs (p=0.0001).

Conclusion: Both i-gel and c-LMA are easy to insert and provide an effective airway during positive pressure ventilation

Keywords: Laryngeal mask airway; i-gel; supraglottic airway device

INTRODUCTION

The supraglottic airway device is a novel device that fills the gap in airway management between tracheal intubation and use of face mask, jaw holding for prolonged periods. Dr Archie Brain, a British anaesthesiologist, for the first time introduced the laryngeal mask airway in 1983.A new single-use supraglottic airway device was introduced into clinical practice in 2007 by Dr Muhammed Aslam Nasir, The i-gel^{TM} (Intersurgical LTD, Wokingham, Berkshire, UK) which is made up of a soft gel-like thermoplastic elastomer [styrene ethylene butadiene styrene (SEBS)].

METHODOLOGY

80 patients belonging to ASA I or II, with age between 18 and 65 years were recruited for randomized study. Hospital ethics committee approval and written informed from all patients were taken. The study

population was randomly divided into two groups with 40 patients in each group.Any pathology of the neck and upper respiratory tract or alimentary tract ,Mouth opening ≤ 2 cm,Pregnancy,Upper respiratory tract infections,Risk of aspiration,BMI >25 kg/m^2 ,Cervical spine disease,Head and neck surgical procedures,History of obstructive sleep apnea ,History of allergy to one or more drugs and latex,Duration of surgery >3 hrs,LMA classic or i -gel placements had failed after three attempts.,Laparoscopic surgeriesare excluded from study. Detailed history, general physical examination and routine investigations were done prior to the day of surgery.

All patients included in the study were pre-medicated with tablet alprazolam 0.5 mg, tablet ranitidine 150 mg and tab metoclopramide 10mg orally at bed time the previous night before surgery. They were kept nil orally for solids 11.30 pm onwards on the previous night.

On arrival of the patient in the pre-anaesthetic room, an 18-gauge intravenous cannula was inserted under local anaesthetic infiltration and inj. Metoclopramide 10 mg. i.v. 60 min before expected time of induction.Then the patient shifted to operating room, an infusion of ringer's lactate was started. The patient's head was placed on a soft pillow of 10 cms before induction of anaesthesia with the neck flexed and head extended. The patient was connected to multiparameter monitor (L AND T), which records heart rate, non-invasive measurements of SBP, DBP, MAP, $EtCO_2$.SpO2 and continuous ECG monitoring and oxygen saturation. The baseline mean arterial pressure, $EtCO_2$, SpO_2 and heart rate were recorded. The i-gel supraglottic airway was used in Group 2 patients. The size of the device was decided by anaesthetist based on patient's body weight and manufacturer's recommendation.

After recording the baseline reading, the patient was premedicated with Inj.glycopyrrolate 0.2mg.iv, inj. Midazolam 1.5mg.iv and inj. Fentanyl 2mcg/kg.iv. Then the patient was preoxygenated with 100% oxygen for 3 minutes via a face mask. Intravenous lignocaine (2%) 2 ml was given to prevent pain on injection of propofol. Anaesthesia was induced with propofol 2.5 mg/ kg body weight and inj. Atracurium 0.5mg/kg intravenously. Induction of anaesthesia was confirmed by loss of verbal communication with the patient and loss of eyelash reflex. Once an adequate depth of anaesthesia was achieved, the allotted device was inserted according to the manufacturer's instructions. The patient's head was placed in 'sniffing the morning air' position. Insertion of all the devices was done by the same anaesthesiologist.

The broad aim of the study were to assess the ease of use of the device, the quality of airway achieved and any associated complications.

Successful ventilation was defined as visible chest movement, square wave capnogram, stable arterial oxygen saturation above 95% and if it was not possible to ventilate the lungs, the same adjustments as for insertion were allowed. If ventilation was still not possible, further attempts at insertion of the device were allowed to a maximum of three attempts.The lubricated c-LMA was inserted by 180^0 technique [18,19] .An effective airway was confirmed by bilateral symmetrical chest movement, square waveform on capnograph, normal end tidal CO_2 and stable SpO_2 (>95%). The device was secured with adhesive tape. Bite block was kept in case of c-LMA and secured along with it with adhesive tape.Anaesthesia was maintained using 66% nitrous oxide and 33% of oxygen with 0.8-1% Isoflurane & inj. Atracurium 0.1mg/kg.

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At the end of the operation, patient remained in the supine position and anesthetic agents will be discontinued, allowing smooth recovery of consciousness. Patient was reversed with inj. neostigmine 0.05mg/kg and Inj. glycopyrrolate 0.01mg/kg. The device will be removed after the patient regains consciousness spontaneously and responds to verbal command to open the eyes. The patient was inspected for any injury of the lips, teeth or tongue and interviewed for any post-operative device related complications like dysphagia, dysphonia, nausea, vomiting, trauma to mouth, tooth or pharynx and sore throat will be recorded and after 24 hours.

STATISTICAL METHODS

The data thus obtained was compiled and analyzed using Statistical Package for Social services. (SPSS version 20). Quantitative data was analyzed by using student't' test. Qualitative data was analyzed using Chi – Square test. A p value of less than 0.05 was considered as statistically significant

RESULTS

Table 1 Comparison of ease of insertion between Groups

	LMA	IGEL	Total	p
Easy	33	36	69	0.49
Satisfactory	5	2	7	
Difficult	2	2	4	
Total	40	40	80	

There is no significant difference in ease of insertion between LMA and IGEL (p=0.49)

Table 2 Comparison of Duration of insertion between Groups

	LMA	IGEL	P value
DI	15.08 ± 2.33	7.9 ± 0.96	**0.0001**

There was significant difference in Duration of Insertion; there mean values ranged 15.08± 2.33 and 7.9 ± 0.96 for LMA and IGEL group respectively (p = 0.0001)

Table 3 Comparison of number of insertion attempt between Groups

IA	LMA	IGEL	Total	p
First Attempt	37	38	75	0.6
Second Attempt	3	2	5	
Total	40	40	80	

There is no significant difference in no of attempts of insertion of devices between LMA and IGEL (p=0.6)

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Table 4: Comparison of Base line Measurements in both groups

Variable	LMA	IGEL	P Value
HR	84.12 ± 2.99	91.15 ± 4.42	**0.0001**
MAP	85.15 ± 3.87	87.45 ± 1.32	**0.001**
SpO_2	99.8 ± 0.4	99.98 ± 0.16	0.13
$EtCO_2$	36.62 ± 1.06	36.2 ± 1.54	0.15

Table 4 describe the comparison of baseline vitals between LMA and IGEL group, there was significant difference in Heart Rate, the mean values ranged 84.12 ± 2.99 and 91.15 ± 4.42 for LMA and IGEL group respectively (p = 0.0001). Same way there was significant difference in MAP; the mean values ranged 85.15 ± 3.87 and 87.45 ± 1.32 for LMA and IGEL group (p=0.001). There were no difference between SpO_2 and $EtCO_2$ (p>0.05).

Table 5: Comparison of Post Induction in both groups

Variable	LMA	IGEL	P Value
HR	90.45 ± 3.06	84.22 ± 4.49	**0.0001**
MAP	80.92 ± 3.36	82.62 ± 1.33	**0.004**
SpO_2	100	99.98 ± 0.16	0.32
$EtCO_2$	32.7 ± 0.94	32.68 ± 1.23	0.9

Table 5 explain the comparison of Post Induction values between LMA and IGEL group, there was significant difference in Heart Rate, the mean values ranged 90.45 ± 3.06 and 84.22 ± 4.49 for LMA and IGEL group respectively (p = 0.0001). Same way there was significant difference in MAP; the mean values ranged 80.92 ± 3.36 and 82.62 ± 1.33 for LMA and IGEL group (p=0.004). There were no significant difference between SpO_2 and $EtCO_2$ (p>0.05).

Table 6: Comparison After Removal of Device in both groups

Variable	LMA	IGEL	P Value
HR	101. 88 ± 2.68	84.28 ± 9.22	**0.001**
MAP	98.2 ± 1.52	85.18 ± 0.9	**0.001**
SpO_2	100	100	
$EtCO_2$	36.62 ± 1.06	36.2 ± 1.47	0.14

Table 6 shows the comparison of After Removal of Device values between LMA and IGEL group, there was significant difference in Heart Rate, the mean values ranged 101. 88 ± 2.68 and 84.28 ± 9.22 for LMA and IGEL group respectively (p = 0.001). Same way there was significant difference in MAP; the mean values ranged 98.2 ± 1.52 and 85.18 ± 0.9 for LMA and IGEL group (p=0.001). There were no significant difference between SpO_2 and $EtCO_2$ (p>0.05).

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Table 07: Comparison of Heart Rate (mins) in both groups over the time

Heart Rate	LMA	IGEL	P Value
1 Min	92 ± 2.58	81.58 ± 4.09	**0.0001**
5 Mins	92.82 ± 0.83	80.85 ± 1.01	**0.0001**
10 Mins	93.42 ± 2.28	80.28 ± 3.59	**0.0001**
15 Mins	93.42 ± 2.28	80.1 ± 3.85	**0.0001**
20 Mins	94.52 ± 2.67	80.2 ± 4.14	**0.0001**
25 Mins	94.74 ± 2.75	80.42 ± 3.73	**0.0001**
30 Mins	95.35 ± 2.56	81.13 ± 3.75	**0.0001**
45 Mins	94.09 ± 2.38	78.61 ± 10.54	**0.0001**
60 Mins	93.83 ± 2.32	79.22 ± 12.33	**0.009**

Table 8: Comparison of MAP in both groups over the time

MAP	LMA	IGEL	P Value
1 Min	86.3 ± 2.32	82.85 ± 0.92	**0.0001**
5 Mins	87.4 ± 2.44	82.98 ± 4.05	**0.0001**
10 Mins	88.35 ± 2.35	83.2 ± 1.02	**0.0001**
15 Mins	88.35 ± 2.35	83.48 ± 0.9	**0.0001**
20 Mins	90.62 ± 2.5	83.65 ± 1.14	**0.0001**
25 Mins	91.53 ± 2.36	84.12 ± 0.74	**0.0001**
30 Mins	92.38 ± 2.73	84.1 ± 0.66	**0.0001**
45 Mins	92.91 ± 2.21	84.13 ± 0.55	**0.0001**
60 Mins	93.83 ± 2.23	84.17 ± 0.62	**0.0001**

Table 9 : Comparison of SpO_2 in both groups over the time

SpO_2	LMA	IGEL	P Value
1 Min	100	100	
5 Mins	100	100	
10 Mins	100	100	
15 Mins	100	100	
20 Mins	100	100	
25 Mins	100	97.94 ± 1.84	0.31
30 Mins	100	99.47 ± 2.92	0.36
45 Mins	100	99.3 ± 3.34	0.5
60 Mins	100	99.11 ± 3.77	0.58
90 Mins	100	100	

Table 9 shows there were no significant difference in SpO_2 values over the time period between the two groups ($p > 0.05$).

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Table 10: Comparison of $EtCO_2$ in both groups over the time

ET	LMA	IGEL	P Value
1 Min	32.98 ± 0.83	32.72 ± 1.01	0.23
5 Mins	32.62 ± 2.56	32.98 ± 1.03	0.42
10 Mins	33.32 ± 0.66	33.12 ± 1.07	0.32
15 Mins	33.32 ± 0.66	33.48 ± 1.04	0.44
20 Mins	33.95 ± 0.59	33.65 ± 0.92	0.08
25 Mins	34.03 ± 0.58	35.88 ± 11.54	0.35
30 Mins	34.27 ± 0.6	35.87 ± 12.29	0.51
45 Mins	34.45 ± 0.69	36.96 ± 13.78	0.55
60 Mins	34 ± 0.63	38.11 ± 15.47	0.52

DISCUSSION

The major responsibility of the anesthesiologist is to provide adequate ventilation to patient. The most vital element in providing respiration is maintenance of a patent airway. The tracheal intubation is the gold standard method for maintaining a patent airway during anaesthesia.[3] Many studies have been done to compare i-gel and classic–LMA. The study population consisted of 80 patients divided into two groups randomly using simple closed envelope method with 40 patients in each group. Group 1 consisted of 40 patients in whom classic- LMA supraglottic airway device was used and group 2 consisted of 40 patients in whom I GEL was used.

The current study was based on statistical analysis of mean insertion time, first attempt success, ease of insertion, hemodynamic responses and pharyngolaryngeal morbidities. The parameters have been taken from previous studies comparing the classic laryngeal mask airway with i-gel. The results of the present clinical trial have shown many advantages of I-gel. These include high success rate at shorter time insertion and less hemodynamic changes compared to classic-LMA.

Ease of insertion

One of the primary objectives was to compare the ease of insertion between the two devices. The grading of insertion was done similar to the study conducted by G. Srinivas Rao et al, [37]. In present study ease of insertion in i-gel was easy in 36 (90%) patients, satisfactory in 2(5%) patient and difficult insertion was noticed in 2(5%) patient whereas insertion of c-LMA was easy in 33(82.5%) patients, satisfactory in 5(12.5%) patients and difficult in 2(5%) patients. The ease of insertion was statistically not significant between the two groups ($p<0.05$). The ease of insertion of the devices in the Present study was comparable with study conducted by Gatward JJ et al[22], Francksen et al[23], Ansar Ali et al [26], Haq Dad et al [30], Shwetha K.M et al [34], G.Srinivas Rao et al [37], who also found statistically no significant difference.

Number of Attempt of insertion

In this study, insertion of i-gel was successful in first attempt in 38(98%) patients as compared to 37(92%) first time insertion with c-LMA. Airway manipulation like jaw thrust was required during second attempt insertion in twopatient of i-gel insertion and 3 patients with c-LMA insertions. The attempt of insertion was not statistically significant between the two groups ($p>0.05$).

Very similar results were found in studies conducted by Francksen H et al [23], Ansar Ali et al[26], Haq Had Durrani et al [30], Seyed Mohammed et al [33], Shwetha K.M et al [34] Dilek Erdogan Ari et al [36], G.Srinivas Rao et al [37].

Duration of insertion

The time for insertion was considered according to the study conducted by Seyed Mohammed et al[33], from picking up the device to confirmation of effective ventilation by bilateral chest movement, square wave pattern capnography, normal range end tidal CO_2 and stable arterial SpO_2 (>95%).In current study, the duration of insertion of i-gel (7.9 ± 0.96s) was shorter compared to c-LMA (15.08 ± 2.33s) which was statistically significant.

Consistent with our results, Helmy AM et al[5], Jeevan Singh et al [29], Priyamvada Gupta et al [32], Seyad Mohammed et al [33], Shwetha K.M et al [34], Dilek Erdogan Ari et al [36], G.Srinivas Rao et al [37], Smita R Engineer et al [38], N.Pratheeba et al [39] also had significant difference in the insertion times.

Hemodynamic Responses

Heart rate [HR] ,Mean arterial pressure [MAP] in mm of Hg,$EtCO_2$, SpO_2 , were monitored in the following time interval - Basal before premedication, at the time of insertion, 1 minute after insertion, every 5 minutes after insertion till 30 min, every 15 mins till 2hours and at the time of removal.[15]The results of present study were similar to the studies done by Jindal P et al[46] who in their studies found significant difference between i-gel and c-LMA with regard to heart rate, mean blood pressure.

Post-operative device related complication

In present study, the patients were inspected for any injury of the lips, teeth or tongue and the device for bloodstain after its removal at the end of the surgery and other complication after 24 hours. The presence of blood on device, Post Extubation Cough were noted in 3 each patients and one patient had Dysphonia in group (c-LMA) out of 40 and none in 4 in group (I-gel). However the incidence was not statistically significant when compared between both the groups. One case in c-LMA had Odynophagia.However the incidence was not statistically significant when compared between both the groups. 4 patients each had developed sore throat post operatively in both groups. The incidence was not statistically different when compared between the groups. The sorethroat in all the 8 cases were mild & no treatment were required. None of the patients in both the groups developed Laryngospasm, Trauma to Lips/teeth/Pharynx, Arrhythmia, Ear Pain/Blocked Ears and Numbness of Tongue. The present study was comparable with Gatward et al [22], Francksen et al[23], Helmy et al[5], Ashish Kannaujia et al [24], Haq Had Durrani et al [30], Seyed Mohammed et al [33] Shwetha et al [34],Venkkateshwasrlu et al [35],where none of the post-operative complications were statistically significant when compared between the groups.

CONCLUSION

Classic-LMA and i-gel can be used safely and effectively during general anaesthesia with positive pressure ventilation in selected patients. Both devices are easy to insert. The post-operative complications were not significant among LMA and I-gel patients.

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