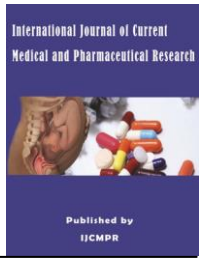
Research Article

INTERNATIONAL JOURNAL OF CURRENT MEDICAL AND PHARMACEUTICAL RESEARCH

ISSN: 2395-6429, Impact Factor: SJIF: 4.656
Available Online at www.journalcmpr.com
Volume 8; Issue 09; September 2022; Page No. 395-403
DOI: http://dx.doi.org/10.24327/23956429.ijcmpr20220090



TO COMPARE SUPRAGLOTTIC AIRWAYS-LMA SUPREME AND I-GEL IN SHORT SURGICAL PROCEDURES WITH THEIR EFFECT ON HEMODYNAMIC PARAMETERS AND COMPLICATIONS-ARANDOMISED SINGLE BLINDED STUDY TRIAL.

Yasha Tiwari

Department of Anaesthesiology, CIMS, Bilaspur.

ARTICLE INFO

Article History:

Received 12th June, 2022
Received in revised form 23rd July, 2022
Accepted 7th August, 2022
Published online 28th September, 2022

Key words:

LMA Supreme, IGel, Supraglottic airway devices.

ABSTRACT

Primary Objective: To compare the ease of insertion of LMA Supreme vs I-Gel in short surgical procedures which will be assessed by Number of attempts taken to insert the Supraglottic airway device (SAD). **Secondary Objectives:** 1) To compare LMA Supreme vs I-Gel the following parameters, 2) Oropharyngeal Leak Pressure, 3) Haemodynamic responses, 4) Adverse effects: Visible blood on device, Lip or dental injury, Laryngospasm, Bronchospasm, Post extubation cough, Gagging, Sore throat, Dysphagia, Dysphonia, Hoarseness of voice, Lip or tongue swelling, Tongue numbness. **Materials and Methods:** Total 60 patients of age between 18 to 60 years with ASA grade I and II were selected who underwent short elective procedures under general anaesthesia with spontaneous ventilation in a tertiary care institute after approval from institutional ethical committee with written informed consent. Patients were randomized to 2 groups (Group I and Group S)to compare LMA Supreme and I-gelInj. Ranitidine 2mg/kg and Ondansetron 0.1 mg/kg were given intravenously. Premedication with Inj. Glycopyrrolate 0.004 mg/kg, Inj. Midazolam 0.03mg/kg and Inj. Fentanyl 2mcg/kg. Patient was induced with titrated dose of Inj. Propofol (2 mg/kg). LMA Supreme or I-Gel-Each device was inserted by the same anaesthesiologist. In both groups, successful airway insertion was assessed. **Number of attempts** to establish adequate ventilation was noted. Patients hemodynamic parameters like Heart rate, systolic and diastolic blood pressure, $EtCO_2$, SpO_2 was noted before induction (baseline), after induction, at insertion and then every minute till 10 mins and then every 5 min till 20 min after insertion of the device and also postoperative complications were assessed till 24 hrs. Difference between the two means was tested using student t test & p value <0.05 was considered significant. **Results:** Chi square test and Independent student t test were used to compare the difference in between two groups. Demographic profile and hemodyamic parameters did not vary significantly in both groups and was comparable.The mean oropharyngeal leak pressure in Group I and Group S was 25.21 ± 2.73 cmH_2O and 22.93 ± 1.96 cmH2O respectively and this difference was statistically significant (P<0.05).Among the Group I, about 93.33% needed single attempt, 6.67% needed double attempts, none needed 3 or more than 3 attempts. Among the Group S, 83.33% needed single attempt, 13.33% needed double attempt, none required 3 attempts and 3.33% needed more than 3 attempts. I-gel has a better first insertion success rate but the difference was statistically not significant. (P>0.05). **Conclusion:** Both the devices are comparable in terms of ease of insertion in anesthetized spontaneously breathing patients in short surgical procedures. I-gel can be preferred over LMA Supreme because of its better oropharyngeal leak pressure and lesser postoperative complications.

INTRODUCTION

The prime responsibility of an anaesthesiologist is to maintain a proper airway and provide adequate ventilation to the patient. Airway management has come a long way starting from the use of facemask to the development of endotracheal tube to the present day usage of sophisticated devices [(1)].

Disadvantages of face mask are requirement of higher gas flows, gastric inflation with positive pressure ventilation with mask and risk of aspiration.

The endotracheal tube remains the gold standard to secure the airway. However, laryngoscopy and endotracheal intubation may be associated with complications like sore throat and hoarseness of voice.

Supraglottic Airway Devices have an upper hand over endotracheal intubation of having ease of insertion, reduced insertion time, maintenance of haemodynamic stability and less postoperative complication. These use both inflatable and non-inflatable cuff that fit into the pharynx and laryngopharynx and gives an oropharyngeal airway seal. However the cuff has the potential to cause tissue distortion by edema, venous congestion and nerve injury. Depending upon the material used to make the cuff, they can absorb anaesthetic gases, which can lead to increased mucosal pressure. In

Yasha Tiwari
Department of Anaesthesiology, CIMS, Bilaspur.

addition, it has potential risk of aspiration as it lack airway protection from gastric contents[2].

The Laryngeal Mask Airway Classic (LMA-C) is the most widely used SAD and since it was introduced, several devices have been incorporated in order to improve the SAD indications, some of them with incorporation of a gastric access. There are six SADs with a drain tube available in the market at present: the Laryngeal Tube Suction (LTS or LTS-D if disposable), LMA Proseal (LMA-P), LMA Supreme (LMA-S), I-gel and recently Baska Mask and Ambu Aura Gain. The LMA-P,LMA-S and I-gel are devices having gastric channel and have a high airway seal pressure making them device of choice for surgeries associated with high peak airway pressure like laparoscopy. Additionally, the drain channel helps to spot the proper tip position after insertion.

Introduced in the late 2007, the LMA Supreme is a new supraglottic device that has features of LMA ProSeal (presence of gastric channel and high airway seal pressure) and the LMA Fastrach (curved, rigid manifold for easy insertion).These factors reduce the risk of gastric insufflation, regurgitation and aspiration. It is considered to be the most advanced supraglottic airway device.

The I-gel [Intersurgical Ltd., Wokingham, UK] is a Supraglottic Airway Device which was introduced into clinical practice in the United Kingdom in January 2007. The second generation newer airway device I-gel is a new,novel disposable single use supraglottic airway device made of athermoplastic elastomer (styrene ethylene butadiene styrene) that is anatomically designed to fit the peri-laryngeal and hypo-pharyngeal structures without the use of an inflatable cuff. With body temperature it configures itself to the supraglottic tissue hence minimizing air leak. The soft non-inflatable cuff fits onto the supraglottic area with its tip at the proximal opening of the oesophagus hence isolating the oropharyngeal opening from the laryngeal opening. The device has a buccal cavity stabilizer housing the airway tube and a separate gastricchannel which facilitates the efflux of gastric fluid and gas allowing the entrance of a nasogastric catheter that decreases the risk of aspiration.[3,4]

There have been various studies reported about LMA Supreme and I-gel due to their acclaimed advantages. However there have been conflicting results regarding the ease of insertion, oropharyngeal leak pressure and postoperative complications. Hence, we proposed to assess these two devices for ease of Insertion, oropharyngeal leak pressure, hemodynamic changes and airway complications.

MATERIALS AND METHODS

The study was initiated after approval of institutional ethical committee & written informed consent obtained from all patients. Study was carried out in department of anaesthesia at our institute from November 2015 to September 2018

Inclusion Criteria

1. Adults aged between 18-60years.
2. ASA status I or II.
3. MPC Grade 1 and 2.
4. BMI upto 25 kg/m2.
5. Patients undergoing elective surgery in supine position under general anaesthesia with spontaneous ventilation.
6. Duration of surgery< 60 minutes.
7. Patients willing to participate in the study.

Exclusion Criteria

1. Anticipated difficult airway.
2. Patients with restricted mouth opening.
3. Recent history of upper respiratory tract infection.
4. Any increased risk of aspiration.
5. Patients having history of GERD.

Withdrawal Criteria

If the insertion of Supraglottic Airway Device requires more than 3 attempts, it will be considered a failure, and an endotracheal tube will be inserted.

Intervention Allocation

The patients were divided into 2 groups

A.Group G (I-Gel) n=30
B.Group S (LMA Supreme) n=30

Preoperative Assessment And Patient Preparation

- Institutional Ethics Committee permission was taken.
- Study included patients of age between 18 to 60 years who underwent short elective surgery under general anaesthesia with spontaneous ventilation.
- Written informed consent was taken from all patients included in study.
- In all cases a detailed record was maintained regarding age,gender,

MPC grade, ASA status, vital parameters, ease of insertion, number of attempts, oropharyngeal leakpressure, post-operative airway complications, monitoring of Heart rate, Systolic Blood Pressure, Diastolic Blood Pressure, End Tidal Carbon dioxide($ETCO_2$),Oxygen saturation(SpO_2).

Perioperative Management

After pre-anaesthetic check-up and Written Informed consent, a. Multichannel monitor was attached to patients for SpO_2, ECG, $ETCO_2$ and NIBP. Intravenous line was secured and Ringer lactate was administered at 10ml/kg. Before induction patient's head was placed on a soft pillow. Patient was preoxygenated for 3 minutes.

Anaesthesia induction was done as follows

Inj. Ranitidine2mg/kg and Ondansetron 0.1 mg/kg were given intravenously. Premedication with Inj.Glycopyrrolate 0.004 mg/kg, Inj. Midazolam 0.03mg/kg and Inj. Fentanyl 2mcg/kg. Patient was induced with titrated dose of Inj. Propofol (2 mg/kg). Using Bain's Circuit patient was manually ventilated with bag and mask, using O_2+N_2O (50%:50%) till there is lack of response to jaw thrust.

LMA Supreme or I-Gel was inserted as per written over the opaque envelope was handed over by senior anaesthesiologist. Each device was inserted by the same anaesthesiologist. Appropriate size device using body weight as the guide was selected.

For (group S) LMA Supreme:

S-LMA cuff to be inflated with air after insertion.
S-LMA No 3 for patients 30 to 50 kg inflate with 30 ml air.
S-LMA No 4 for patients 50 to 70 kg inflate with 45 ml air.

For (group I) I-gel:
No 3 for patient 30 to 60 kg.
No 4 for patient 60 to 90 kg.

Allotted device was lubricated using water-based lubricant - K-Y Jelly. The patient was in supine position with head in the "sniffing the morning air" position prior to insertion with the assistant helping to open the patient's mouth.

Optimum depth of anaesthesia was assessed as absence of eyelash reflex, easy up and down movement of the lower jaw, no reaction to pressure applied to both angles of the mandible. Once optimum depth of anaesthesia was achieved allotted device was inserted.

Patient was maintained on O_2:N_2O: Sevoflurane on spontaneous ventilation. Patient was connected to closed circuit.

In both groups, successful airway insertion was assessed by:

- Adequate bilateral symmetrical chest movements during ventilation.
- Auscultation –air entry bilaterally equal.
- Absence of air leak during ventilation with airway pressure of 20cm of H2O with fresh gas flow of 3litres/min.
- Capnograph showing square wave of $ETCO_2$.
- Stable SPO_2 not less than 95%.

Number of attempts to establish adequate ventilation was noted. If insertion was failed, insertion was re-tried after 1 minute of positive pressure ventilation with face mask with 100% O_2 and after giving titrated dose of Inj. Propofol. If there was resistance during insertion of either device then following airway manoeuvres were allowed – "chin lift" "jaw thrust", "head extension" or "flexion of neck".If three attempts had failed in securing a successful airway, it was termed as failure and airway was maintained using endotracheal tube and the case was excluded from the study.

Oropharyngeal leak pressure was calculated by closing the APL valve of the closed circle system with gas flow of 3L/min, and observing the airway pressure at which equilibrium would reach. At this point, gas leakage was heard at the epigastrium (epigastric auscultation) or coming out of the drainage tube and mouth.

Intraoperative

Heart rate, systolic and diastolic blood pressure, $EtCO_2$, SpO_2 was noted before induction (baseline), after induction, at insertion and then every minute till 10 mins and then every 5 min till 20 min after insertion of the device. Surgery was asked to start after 5 minutes of insertion of device. Once consciousness was regained and protective reflexes such as coughing and swallowing had returned, gentle suction was done.Device was removed after the patient awake by asking the patient to open his/her mouth wide, and was replaced with a medium concentration oxygen mask.

Postoperative

Incidence of airway complications caused by supraglottic devices was assessed. On removal of device, blood on device (indicating trauma to the pharyngo-laryngeal framework), lip or dental injury, post extubation cough, gagging, laryngospasm, bronchospasm were noted. After patient regained full consciousness patient were asked about sore throat (constant pain independent of swallowing), dysphagia (difficulty or pain with swallowing), dysphonia (difficulty or pain while speaking), hoarseness of voice, tongue numbness immediately post operatively and then after 24 hours.

Statistical Analysis

Study Design

Prospective randomized single blinded study.

Study Setting

The study was conducted in Department of Anaesthesia of a tertiary care institute.

Sample Size

A study conducted by **Wang F *et al***[24]inferred that the mean (±SD) of insertion time in LMA supreme group was 4.1 ± 3.2 seconds and in I-Gel group was 8.2 ± 4.1 seconds. Using this, with 95% confidence interval and 95% power the minimum sample size was calculated to be 21 in each group. We considered 30 subjects in each group for our convenience using the following formula:

$$n_2 = \frac{(\kappa * \sigma_1^2 + \sigma_2^2)(z_{1-\alpha/2} + z_{1-\beta})^2}{\Delta^2} \qquad n_1 = \frac{(\sigma_1^2 + \sigma_2^2/\kappa)(z_{1-\alpha/2} + z_{1-\beta})^2}{\Delta^2}$$

Where,
1 n = sample size of Group 1
2 n = sample size of Group 2
σ 1 = standard deviation of Group 1
σ 2 = standard deviation of Group 2
Δ = difference in group means
κ = ratio = n2/n1 Z1-α/2 = two-sided Z value (eg. Z=1.96 for 95% confidence interval).
Z1-β = power

60 patients undergoing elective surgical procedure will be divided into two groups:

C.Group G (I-Gel) n=30
D.Group S (LMA Supreme) n=30

Data Analysis Method

The data was collected, entered and compiled using Microsoft Excel 2013.The data was analysed using Epi info version 7.2.The qualitative variables were expressed in terms of percentages and the difference between two proportions was tested by fisher's exact or chi square test. The quantitative variables were expressed either in terms of mean and standard deviation or categorised and expressed in terms of percentages. The difference between the two means was tested using student t test. All the analysis was 2 tailed and significance level was set at 0.05.

Level of significance:
P = Level of significance
P> 0.05 = Not significant
P< 0.05 = Significant
RANDOMISATION was computer generated

Blinding

It was a single blinded study. Patients were blinded to the device used. Anaesthesiologist performing the procedure was not blinded

RESULT

In 1 of the patients in LMA-Supreme group, insertion of LMA Supreme was unsuccessful after 3 attempts and was considered as failure and was excluded from the study. Airway was maintained using endotracheal tube. Considering

this, results obtained were from 29 patients in LMA Supreme group and 30 patients in I-gel group.

Demographic data of patients like Age, Weight, Height, ASA status were comparable in both groups and the difference was not statistically significant.

Table 1 Distribution of the study subjects based on number of attempts

Number of attempts	Group S		Group I		P value
	No	%	No	%	
1	25	83.33	28	93.33	0.3992
2	4	13.33	2	6.67	
>3	1	3.33	0	0	
Total	30	100	30	100	

Among the Group I, about 93.33% needed single attempt, 6.67% needed double attempts. Among the Group S, 83.33% needed single attempt, 13.33% needed double attempt and 3.33% needed more than 3 attempts. This difference was not statistically significant.(P>0.05)

Figure 1 Bar diagram showing distribution of cases as per number of attempts for insertion in both the groups

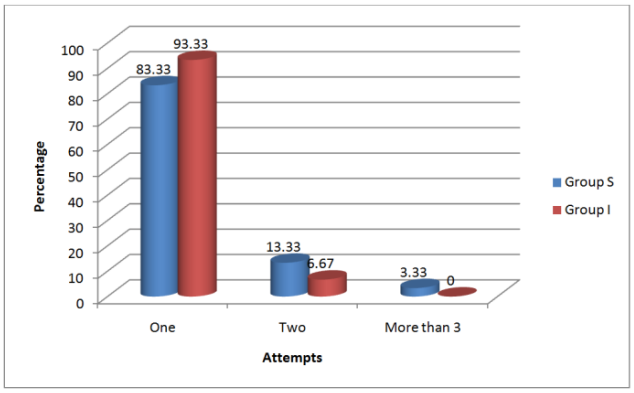


Table 2 Distribution of the study subjects based on ease of insertion

Ease of insertion	Group S		Group I		P value
	No	%	No	%	
Easy	25	83.33	28	93.33	0.3992
Difficult	4	13.33	2	6.67	
Failed	1	3.33	0	0	
Total	30	100	30	100	

In Group I, 93.33% had easy intubation,6.67% had difficult intubation. In the Group S,83.33% had easy intubation, 13.33% had difficult intubation and 3.33% had failed intubation. This difference was not statistically significant. (P>0.05)

Figure 2 Bar diagram showing distribution of the study subjects based on ease of insertion

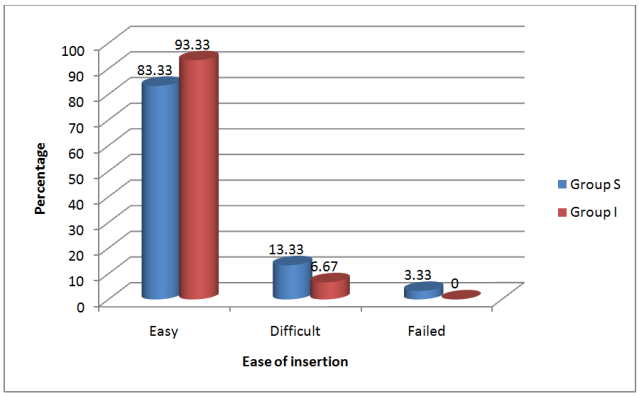


Table 3 Distribution of the study subjects based on oropharyngeal leak pressure

Oropharyngeal leak pressure (cmH_2O)	Group S		Group I		P value
	Mean	SD	Mean	SD	
	22.93	1.96	25.21	2.73	0.0005[b]

b- Independent student t test

The mean oropharyngeal leak pressure in Group I and Group S was 25.21 ± 2.73 cmH_2O and 22.93 ± 1.96 cmH2O respectively and this difference was statistically significant (P<0.05).

Figure 3 Bar diagram showing comparison of mean oropharyngeal leak pressure between both the groups

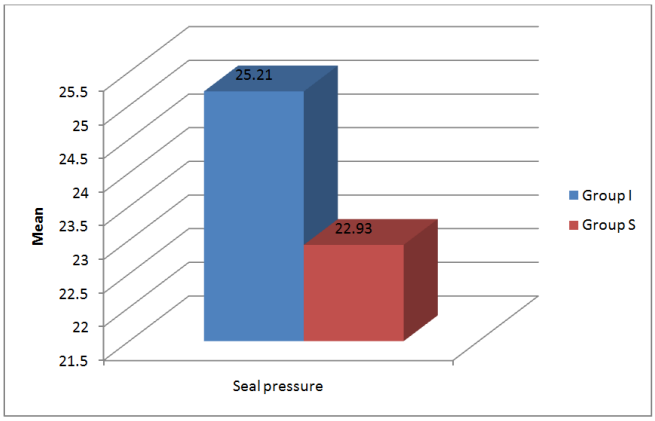


Table 4 Distribution of the study subjects based on complications

Complications	Group S*		Group I		P value
	No[r]	%	No[r]	%	
Immediate	**(n=29)**		**(n=30)**		
Blood on device	4	13.79	1	3.33	0.1492[a]
Laryngospasm	0	0	1	3.33	1.000[a]
1 hour post operative	**(n=29)**		**(n=30)**		
Sore throat	4	13.79	1	3.33	0.1492[a]
Dysphagia	0	0	1	3.33	0.2736[a]
24 hour post operative	0	0	0	0	---

a- Fisher's exact test, *one failed case has been excluded

Immediate complications were one case of blood on device and one case of laryngospasm in Group I and 4 cases of blood on device and no cases of laryngospasm in Group S. This difference was statistically not significant. 1 hour postoperatively, we found one case with sore throat and one case with dysphagia in Group I and 4 cases of sore throat and no cases of dysphagia in Group S. This difference was statistically not significant. There were no complications 24 hours post operatively in both the groups.

Table 5 Distribution of the study subjects based on heart rate changes

Heart rate	Group S		Group I		P value[b]
	Mean	SD	Mean	SD	
Baseline	84.72	10.50	84.13	13.56	0.8526
After induction	84.00	9.39	86.23	13.03	0.4525
At insertion	87.59	12.30	90.43	13.80	0.4068
1 minute	87.52	12.95	89.70	13.45	0.5281
2 minute	86.31	12.59	90.03	15.73	0.3207
3 minute	85.34	13.34	87.00	20.99	0.7201
4 minute	83.66	13.96	87.43	15.70	0.3333
5 minute	83.00	12.36	86.50	14.81	0.3294
6 minute	84.03	11.89	88.03	15.38	0.2697
7 minute	84.28	10.68	88.73	14.86	0.1924
8 minute	85.00	11.64	88.70	15.16	0.2988

9 minute	85.24	10.22	88.00	15.27	0.4197
10 minute	85.86	10.73	88.73	13.73	0.3757
15 minute	86.48	9.73	88.63	11.82	0.4494
20 minute	86.28	10.11	89.43	11.25	0.2621

b- Independent student t test

The baseline heart rate in Group I and Group S was 84.13 ± 13.56/ min and 84.72 ± 10.50/min and this difference was statistically not significant. (p>0.05) The heart rates in both the groups did not differ at any time interval till 20 minutes post insertion.

Chart 1 Distribution of the study subjects based on heart rate changes

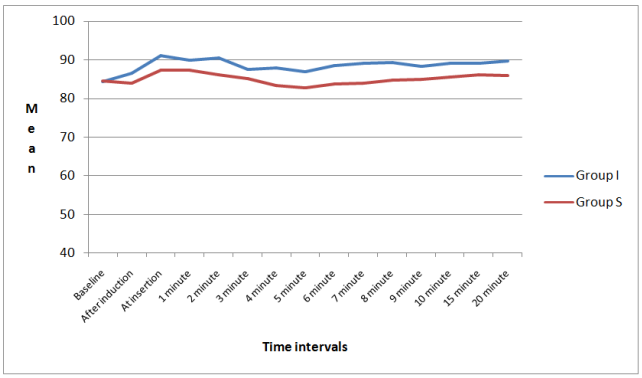


Table 6 Distribution of the study subjects based on systolic blood pressure changes

Systolic blood pressure(mmHg)	Group S		Group I		P value[b]
	Mean	SD	Mean	SD	
Baseline	127.72	14.29	123.97	11.48	0.2674
After induction	118.07	13.37	114.10	13.65	0.2641
At insertion	118.86	14.87	111.17	16.42	0.0645
1 minute	115.00	16.39	112.23	16.47	0.5205
2 minute	113.93	17.30	110.63	15.89	0.4486
3 minute	113.38	15.76	110.40	15.08	0.4611
4 minute	114.38	16.39	110.30	13.81	0.3811
5 minute	110.66	21.54	109.97	13.91	0.8842
6 minute	114.28	11.24	109.34	12.34	0.3849
7 minute	114.76	12.01	111.13	13.58	0.2826
8 minute	114.34	11.89	112.47	11.98	0.5482
9 minute	115.00	12.20	113.53	12.63	0.6519
10 minute	116.03	13.36	113.60	10.92	0.4460
15 minute	117.48	12.68	114.77	10.84	0.3798
20 minute	117.34	12.75	112.47	8.85	0.0923

b- Independent student t test

The baseline systolic blood pressure was 123.97 ± 11.48 mmHg and 127.72 ± 14.29 mmHg in Group I and Group S respectively and this difference was statistically not significant.

Chart 2 Distribution of the study subjects based on systolic blood pressure changes

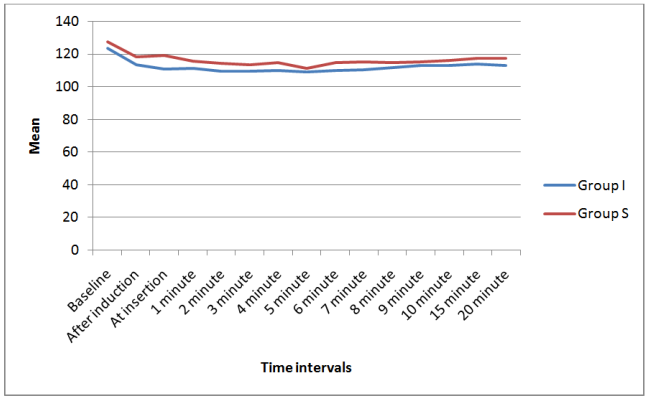


Table 7 Distribution of the study subjects based on diastolic blood pressure changes

Diastolic blood pressure (mmHg)	Group S		Group I		P value[b]
	Mean	SD	Mean	SD	
Baseline	78.69	11.42	77.50	9.43	0.6638
After induction	76.59	12.18	72.00	11.85	0.1481
At insertion	75.66	11.44	68.33	3.38	0.0280
1 minute	71.79	13.38	68.90	13.95	0.4198
2 minute	71.31	13.53	67.03	13.43	0.2279
3 minute	70.28	12.43	66.43	12.39	0.2395
4 minute	71.31	13.12	66.60	10.97	0.1395
5 minute	70.48	9.30	65.97	9.34	0.0679
6 minute	70.48	8.33	67.07	8.37	0.1219
7 minute	71.10	8.07	66.33	8.29	0.0292
8 minute	70.32	8.01	67.70	7.25	0.2235
9 minute	70.48	8.69	68.53	8.97	0.4002
10 minute	71.66	9.64	69.63	8.00	0.3838
15 minute	73.41	9.17	71.17	6.80	0.2885
20 minute	73.17	9.42	71.67	6.73	0.4817

b- Independent student t test

The baseline diastolic blood pressure was 77.50 ± 9.43 mmHg and 78.69 ± 11.42 mmHg in Group I and Group S respectively and this difference was not statistically significant. (P>0.05).At post insertion and 7 minutes post insertion the diastolic blood pressure was significantly lower in Group I when compared with Group S.All other time intervals,there was no significant difference between the diastolic blood pressures.

Chart 3: Distribution of the study subjects based on diastolic blood pressure changes

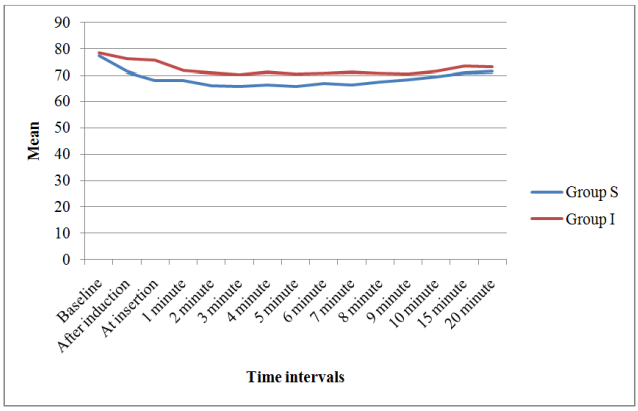


Table 8 Distribution of the study subjects based on $ETCO_2$ changes

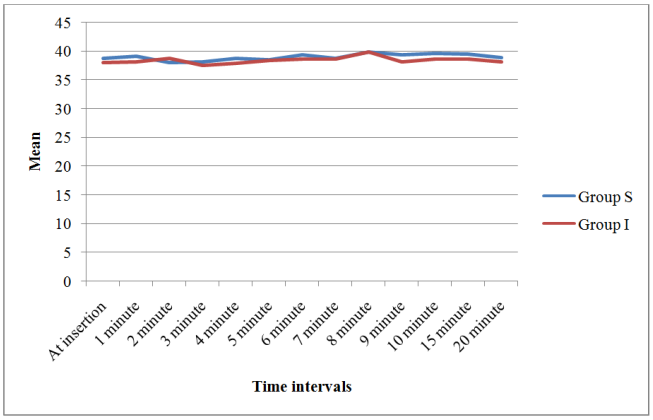
ETCO2	Group S		Group I		P value[b]
	Mean	SD	Mean	SD	
At insertion	38.66	3.38	38.00	3.03	0.4361
1 minute	39.03	2.81	38.13	2.62	0.2078
2 minute	37.93	3.00	38.67	2.59	0.3171
3 minute	38.07	2.23	37.47	3.01	0.3882
4 minute	38.69	2.16	37.80	2.43	0.1426
5 minute	38.40	2.19	38.34	2.00	0.9201
6 minute	39.31	2.63	38.53	2.34	0.2359
7 minute	38.62	2.01	38.53	2.46	0.8820
8 minute	39.79	2.47	39.79	2.47	0.2072
9 minute	39.31	2.22	38.07	2.20	0.0348

10 minute	39.52	2.31	38.60	2.24	0.1267
15 minute	39.38	1.86	38.60	2.88	0.2242
20 minute	38.83	2.54	38.07	2.65	0.2652

b- Independent student t test

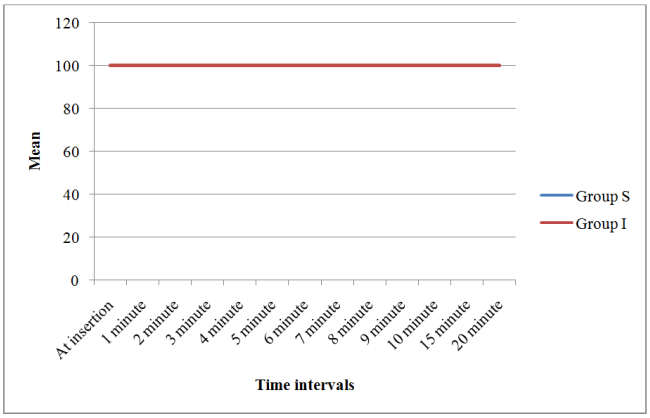
The baseline $EtCO_2$ levels in Group I and Group S were 38.00 ± 3.03 and 38.66 ± 3.38 and this difference was statistically not significant(P>0.05). At 9 minute post insertion, there was a significant difference between the $ETCO_2$ levels and no other time interval showed significant difference.

Chart 4 Distribution of the study subjects based on $ETC0_2$



There was no change in SpO_2 among the two groups at different time intervals.

Chart 5 Distribution of the study subjects based on SpO_2



DISCUSSION

The use of supraglottic airway devices has been in an increasing trend[8] Supraglotticairway devices have been used as an alternative for endotracheal tube.Endotracheal tube produces a stress response that will be deleterious for patients with cardiac disease and hypertensive disorders.In such patients supraglottic airway devices produces an alternate airway technique.Also the plane of anaesthesia needed for inserting endotracheal tube is much deeper and almost always muscle relaxant is required.But for insertion of supraglottic airway device deep plane is not required as it is required for intubation.

LMA Supreme has curved and rigid design (features of LMA Fastrach)has cuff which provides a good airway seal, and has a gastric channel that promotes the drainage of stomach contents (features of LMA ProSeal).

On the other hand the non-inflatable cuff of I-gel™ is made of medical grade thermoplastic elastomer(styrene ethylene butadiene styrene)that fits the supraglottic structures. It also has a gastric channel parallel to airway tube to prevent regurgitation and aspiration[5,7].

Number of attempts

Our study

Among the Group I,about 93.33% needed single attempt,6.67% needed double attempts, none needed 3 or more than 3 attempts. Among the Group S, 83.33% needed single attempt,13.33% needed double attempt, none required 3 attempts and 3.33% needed more than 3 attempts. I-gel has a better first insertion success rate but the difference was statistically not significant(P>0.05).

Studies in concordance with the present study

Table 9 Studies with I-gel having a better first attempt insertion success but statistically not significant

Study	Year	First attempt success rate		Significance	Conclusion
		Lma Supreme	I-Gel		
Fenner LB *et al* [17]	2010	78%	87%	Not significant	-
Teoh WHL *et al* [13]	2010	94%	96%	Not significant	-
Mukadder S *et al* [22]	2015	85.7%	94.3%	Not significant	-
Park S *et al* [19]	2015	45 cases	46 cases	Not significant	-
Liew GHC *et al* [10]	2016	82%	90%	Not significant	I-gel is easier to insert because of its gel-like material, its shape, contour and epiglottis blocker that reduces epiglottis downfolding.

Table 10 Studies with LMA Supreme having a better first attempt insertion but statistically not significant

Study	Year	First attempt success rate		Significance	Conclusion
		Lma supreme	I-gel		
Theiler LG *et al* [11]	2009	95%	93%	Not significant	The success rate was less compared to other studies .
Chew EF *et al*[12]	2010	97.8%	93.3%	Not significant	-
Joly N *et al* [16]	2014	44 cases	43 cases	Not significant	-
Belena JM *et al* [18]	2014	95%	70%	Not significant	The anatomical shape of LMA Supreme is the reason for its higher success rate.
Henlin T *et al* [21]	2015	95.1%	87%	Not significant	-
Radhika KS *et al* [23]	2016	76%	71%	Not significant	The higher rates of failures in I-gel group were attributed to overlap in size selection.

Table 11 Studies not in concordance with the present study

Study	Year	First attempt success rate		Significance	Conclusion
		Lma Supreme	I-Gel		
Ragazzi R *et al* [15]	2012	77%	54%	Significant	The success rate is related to the low repositioning rate.
Kang F *et al* [20]	2015	128 cases	108 cases	Significant	In many cases the mask of the I-gel was obstructed by tongue sliding backwards. Hence I-gel insertion was more difficult & required more assistance.

Ease of insertion

Table 12 Studies in favour with our study

Study	Year	Easy insertion		Significance	Conclusion
		Lma Supreme	I-Gel		
Mukadder S *et al* [22]	2017	77.1%	91.4 %	Not Significant	I-gel is easy to insert because of its shape, contours and noninflatable cuff.

Both the devices have their unique features adding to their advantages

- Number of attempts required for I-gel is less because of its gel-like material, its shape, contour and epiglottis blocker that reduces epiglottis down folding.
- Number of attempts required for LMA Supreme is less because of its anatomical shape (curved, rigid manifold).

Majority of the studies along with our study inferred that the first attempt insertion success rate and the overall success rate among the two groups did not significantly differ.

As per our study I-gel was much easier device to insert because of its shape, contour with non-inflatable cuff. But our study did not attain the level of significance. Knowledge of which device is easier to place is important and helpful in difficult airway and emergency scenarios.

Oropharyngeal leak pressure (OLP)

Table No.13: Studies in accordance with the present study

Study	Year	Oropharyngeal leak pressure (cmh_2o)			Significance	Conclusion
		Time of Measurement	Lma Supreme	I-Gel		
Atef HM *et al* [14]	2012	After insertion	21.2±7.7	25.6±4.9	Significant	I-gel has a better seal as it fits well with the anatomy of supraglottic region.
Joly N *et al*[16]	2014	After insertion	21	23	Not significant	-
Belena JM *et al*[18]	2014	Afteer insertion	27.5	28.2	Not significant	-
Mukadder S *et al*[22]	2015	After insertion	24.9	21	Significant	The improvement of the leak pressure after 30 min was because of the thermoplastic nature of the I-gel cuff which expands due to temperature of body providing better seal.
		30 min after insertion	25	28.3	Significant	
Henlin T *et al* [21]	2015	After insertion	24.8	25.3	Not significant	-
Wang F *et al*[24]	2016	After insertion	25.2	26.1	Not significant	Seal pressure is better in I-gel due its design matching to airway anatomy and physiology and because of its thermoplastic elastomer cuff.
Liew --GHC *et al*[10]	2016	After insertion	23.6±0.7	27.31±0.92	Significant	The cuffless nature of I-gel makes it more prone to air leaks if anatomical fit is insufficient.

Majority of the studies reported that the oropharyngeal leak pressure of I-gel was higher than LMA supreme which was in accordance to our study.

The airway leak pressure is used to evaluate the safety and efficacy of Supraglottic Airway Devices, because high leak pressures indicate that adequate ventilation can be achieved without air leakage during positive pressure ventilation at high inspiratory pressures.

Complications

Our Study

Immediate complications were one case of blood on device and one case of laryngospasm in Group I and 4 cases of blood on device and no cases of laryngospasm in Group S. This difference was statistically not significant. The 1hr post operatively, we found one case with sore throat and one case with dysphagia in Group I and 4 cases of sore throat and no cases of dysphagia in Group S. This difference was statistically not significant. There were no complications 24 hours post operatively in both the groups.

Heart rate and blood pressure changes

Our Study

The heart rates in both the groups did not differ at any time interval till 20 minutes post insertion. The systolic blood pressure remained lower in Group I when compared to Group S but was not statistically significant. At post insertion and 7 minutes post insertion the diastolic blood pressure was significantly lower in Group I when compared with Group S.

Table 14 Studies not in accordance with the present study

Study	Year	Orophryngeal leak pressure(cmh_2o)		Significance	Conclusion
		Lma Supreme	I-Gel		
Teoh WHL *et al*[13]	2010	26.4	25	Not significant	Low leak pressure in I-gel is because of the non-inflatable Cuff of I-gel or wrong size selection causing air leakage
Fenner LB *et al*[17]	2010	25.5	22.5	Not significant	-
Ragazzi R *et al*[15]	2012	28	24	Not significant	-

Table 15 Comparison of complications with LMA Supreme and I-gel in various studies

Study	Year	Sore throat		Dysphagia		Blood on device		Laryngospasm	
		I-Gel	Lma supreme	I-Gel	Lma supreme	I-Gel	Lma supreme	I-Gel	Lma supreme
Fenner LB *et al*[17]	2010	-	-	-	-	5/45	1/45	-	-
Teoh WHL *et al*[13]	2010	1/45	4/45	-	-	1/45	2/45	-	-
Ragazzi R *et al* [15]	2012	20%	44%	-	-	20%	13%	2%	3%
Joly N *et al*[16]	2014	-	18/46	16/46	15/46	-	-	-	-
Park SY *et al* [19]	2015	4 cases	1 case	-	-	3 cases	2 cases	-	-
Mukadder *et al* [22]	2015	17.1%	0%	22.9%	0%	17.1%	0%	0%	0%
Radhika KS *et al* [23]	2016	-	-	-	-	-	1/30	-	-
Liew GHC *et al* [10]	2016	4%	28%	-	14%	-	9/35	-	1/35
Wang F *et al* [24]	2016	1/45	5/45	-	-	1/45	4/45	-	-

Atef HM *et al* [14] (2012)conducted a comparative study between the I-gel and LMA Supreme among the anaesthetized ventilated patients. Both devices were similar in terms of heart rate, blood pressure,SpO_2 and end-tidalCO_2. Radhika KS *et al*[23] (2016 assessed the suitability of I-gel and LMA Supreme for controlled ventilation in anesthetised paralysed patients. There was no significant difference in heart rate between the two groups. There was a significant fall in mean blood pressures (MBPs) after induction compared to baseline in both groups. At 3 min after insertion of the devices, there was a significant rise in MBP in LMA-S group when compared to the I-gel group.

Park SY *et al* [19] (2015)compared the I-gel and LMA Supreme during laparoscopic cholecystectomy. Hemodynamic parameters were comparable between the 2 groups.

Teoh WHL *et al*[13] (2010)compared LMA supreme and I gel among the paralysed patients undergoing gynaecological surgery with controlled ventilation. Systolic blood pressure($p = 0.64$),diastolic blood pressure ($p = 0.70$),mean arterial pressure($p = 0.69$)and heart rate($p = 0.63$)were comparable between groups.

Limitations

There are some limitations to our study.

Single blinded study-The anaesthesiologist carrying out the procedure was not blinded,it will affect the yield of study.

We have included ASA I and II patients, BMI <25kg/m2 who had normal airway anatomy.Hence results may not be applied to obese and patients with difficult airway.

Complications

COMPLICATION	GROUP I	GROUP S
IMMEDIATE	1 case of laryngospasm	4 cases of blood on device
AFTER 1 HOUR	1 case of dysphagia & 1 case of sore throat	nil
AFTER 24 HOURS	Nil	nil

Conclusions

We found that

- Both the devices were comparable in terms of demographic data and patients hemodynamic parameters.
- First attempt success rate was higher in I gel group when compared to LMA supreme but did not yield a statistical significant result.
- Ease of insertion was comparable in both the devices
- The mean oropharyngeal seal pressure among Group I gel was statistically higher when compared with Group LMA supreme.
- Immediate and postoperative complications were also statistically not significant in both the devices.

To conclude, both the devices are comparable in terms of ease of insertion in anesthetized spontaneously breathing patients in short surgical procedures. I-gel can be preferred over LMA Supreme because of its faster insertion time,better oropharyngeal leak pressure and lesser postoperative complications.

Financial support and sponsorship
nil

References

1. Brandt L, Pokar H, Schütte H. 100 years of intubation anesthesia. William Macewen, a pioneer of endotracheal intubation. Der Anaesthesist. 1983 May;32(5):200-4.
2. Bennett JA, Mahadeviah A, Stewart J, Lingaraju N. Desflurane controls the hemodynamic response to surgical stimulation more rapidly than isoflurane. Journal of clinical anesthesia. 1995 Jun 1;7(4):288-91.
3. Millers R, Eriksson L, FleisherL. Airway Management in adults. In:Miller' sanesthesia. 8th ed. 2014.
4. Levitan RM, Kinkle WC, Levin WJ Laryngeal view during laryngoscopy: a randomized trial comparing

cricoid pressure, backward-upward-rightward pressure, and bimanual laryngoscopy. Annals of emergency medicine. 2006 Jun 1;47(6):548-55.

5. Ramachandran SK, Kumar AM. Supraglottic Airway Devices. Respir Care [Internet]. 2014 Jun 1;59(6):920 LP – 932. Available from: http://rc.rcjournal.com/ content/59/6/920.abstract
6. Sorbello M, Petrini F. Supraglottic Airway Devices: the Search for the BestInsertion Technique or the Time to Change Our Point of View? Turkish J Anaesthesiol Reanim [Internet]. 2017/04/01. 2017 Apr;45(2):76–82. Available from: https://www.ncbi.nlm.nih. gov/ pubmed/28439437
7. Cook T, Howes B. Supraglottic airway devices: recent advances. BJA Educ [Internet]. 2010 Dec 29;11(2):56–61.Availablefrom: https://doi.org/ 10.1093/ bjaceaccp/ mkq058
8. Sharma B, Sahai C, Sood J. Extraglottic airway devices: technology update. Med Devices (Auckl) [Internet]. 2017 Aug 17;10:189–205. Available from: https:// www.ncbi.nlm.nih.gov/pubmed/28860875
9. Keller C, Brimacombe J, Bittersohl J, Lirk P. Aspiration and the laryngeal mask airway: three cases and a review of the literature†. BJA Br J Anaesth [Internet]. 2004 Jul 9;93(4):579–82. Available from: https://doi.org/ 10.1093/bja/aeh228.
10. Liew GHC, Yu ED, Shah SS, Kothandan H. Comparison of the clinicalperformance of i-gel, LMA Supreme and LMA ProSeal in elective surgery. Singapore Med J [Internet]. 2016 Aug;57(8):432–7. Available from: https://www.ncbi.nlm.nih.gov/pubmed/27549212
11. Theiler L, Brueggeney M, Kaiser D, Urwyler, *et al*. Crossover Comparison of the Laryngeal Mask Supreme TM and the i-gel TM in Simulated Difficult Airway Scenario in Anesthetized Patients. Anesthesiology. 2009;111:55–62.
12. EF C, NH H, CY W. Randomised comparison of the LMA Supreme with the I-Gel in spontaneously breathing anaesthetised adult patients .Anaesth Intensive Care. 2010;38(6):1–2.
13. Teoh WHL, Lee KM, Suhitharan T, Comparison of the LMA Supreme vs the i-gel TM in paralysed patients undergoing gynaecological laparoscopic surgery with controlled ventilation *. Anaesthesia. 2010;65:1173–9.
14. Hm A, Am H, Em.Comparative study between I-gel, a new supraglottic airway device,and classical laryngeal mask airway in anesthetized spontaneously ventilated patients.Middle East J Anaethesiol. 2012;21(4):583–90.
15. Ragazzi R, Finessi L, Farinelli I, Alvisi R, Volta CA. LMA Supreme Vs. i-gelacomparision of insertionsuccess in novices. Anaesthesia. 2012;67:384–8.
16. Joly N, Poulin L, Tanoubi I. Randomized prospective trial comparing two supraglottic airway devices :i-gel TM and LMA-Supreme TM in paralyzed patients. Can J Anesth. 2014;61:794–800.
17. LB F, Handel J, Srivastava R, Nolan J, Seller C, Tm C. A Randomised Comparison of the Supreme Laryngeal Mask Airway with the i-gel During Anaesthesia. J Anesth Clin Res. 2014;5(9).
18. Belena J, Nunez M, Vidal A, Gasco C, Alcojor A, Lee P, *et al*. Randomized comparison of the i-gel TM with the LMA Supreme TM in anesthetized adult patients. Anaesthesist. 2015;64(4):271–6.
19. Park SY, Rim JC, Kim H, Lee JH. Comparison of i-gel and LMA Supreme during laparoscopic cholecystectomy. Korean J Anesthesiol. 2015;68(5):456–61
20. Kang F, Li J, Chai X, Yu J, Zhang H, Tang C. Comparison of the I-gel Laryngeal Mask Airway With the LMA-Supreme for Airway Management in Patients. J NeurosurgAnesth. 2015;27(1):37–41.
21. Henlin T, Sotak M, Kovaricek P, TyllT,Comparison of Five 2nd-Generation Supraglottic Airway Devices for Airway Management Performed by Novice Military Operators. Biomed Res Int. 2015;2015:1–8.
22. Mukadder S, Zekine B, Erdogan KG, Ulku O, Muharrem U, Saim Y, *et al*. Comparison of the Proseal,Supreme ,and I-Gel SAD in Gynecological Laparoscopic Surgeries. Sci World J. 2015;2015:1–7.
23. Radhika KS, SripriyaR,RavishankarM,Kumar VRH, Jaya V, Parthasarathy S.Assessment of suitability of i-gel and laryngeal mask airway-supreme for controlled ventilation in anesthetized paralyzed patients :A prospective randomized trial. Anesth essays Res. 2016;10(1):88–93.
24. Wang F,Zhang R. Application of the LMA-Supreme and i-gel laryngeal masks during pelvic operations in adults. Asian J Surg. 2016;39:1–5.

****