

Comparison of Supraglottic Devices I-gel and LMA Fastrach^R as Conduit for Endotracheal Intubation

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ABSTRACT

Aim and Objectives: Comparative evaluation of clinical performance of I-GEL with LMA fastrach in elective surgeries.

Materials and Methods: The present study was conducted in the Department of Anesthesiology, Teerthanker Mahaveer Medical College & Research Centre, Moradabad during the period 2015-2017, on 80 patients undergoing elective surgery under general anesthesia. The parameters recorded were Time taken for successful placement, Time taken for insertion of Endo-tracheal Tube, Number of insertion attempts, Quality of ventilation during anesthesia, Haemodynamic parameters such as pulse rate, systolic and diastolic blood pressure and SpO₂, Airway trauma and Gastric distension.

Results: There was no significant difference in mean Heart Rate, Systolic and Diastolic blood pressure and mean Arterial pressure at Baseline, 1 minute, 3 minutes and 5 minutes between I-GEL and LMA FOSTRACH groups. The mean Time taken for supra-glottic device was significantly more among LMA FOSTRACH (31.57±3.08) in comparison to I-gel (15.07±1.65). The mean Time taken for Endo-tracheal tube was significantly more among I-gel (24.00±0.31) minutes in comparison to LMA FOSTRACH (19.95±0.37).

Conclusion: Both Fastrach LMA and I-gel are suitable devices to be used as conduit to endotracheal intubation particularly in susceptible patients where hemodynamic disturbances during intubation are not required. But I-gel proved to be better than Fastrach LMA in terms of benefits.

Key words: Elective Surgeries, Endo-Tracheal Tube, General Anesthesia, Hemodynamic Disturbances.

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INTRODUCTION

Secure airway management in anesthesia is critical for appropriate treatment of respiratory complications and successful operation.¹ Successful transition of these devices through anatomical elements and their proper placement is vital.² Intubation is one of the most important procedures related to prognosis in severely ill patients.³ Tracheal intubation is considered the gold standard for protecting the airway.⁴ However, the success rates for intubation are variable depending on airway structure, a patient's clinical status, practitioner's skills, and so forth.^{5,6} The European Resuscitation Council guidelines for cardiopulmonary resuscitation (2010) recommend that intubation be performed by experienced and trained personnel only.⁷ Endotracheal intubation is a definitive way of securing the airway and is routinely done by laryngoscopy and visualization of cords. However, this involves distortion of upper airway to bring glottis into the line of sight⁸ and in some situations such as high larynx, facial trauma, etc., tracheal intubation fails. Sufficient anatomical distortion is not always easy or possible, leading to intubation difficulties in 1–3%⁹ and failure in 0.05–0.2% of cases.^{10,11}

As a result of studies regarding the provision of an airway that is less invasive than intubation but safer than mask to maintain the patency of airway after anaesthesia induction in brief surgical interventions, supraglottic airway devices (SADs) have been introduced into practice. They are inserted into glottic entry via the oral route and can be used in emergency conditions when tracheal intubation and mask anesthesia are challenging.¹²

The laryngeal mask airway and similar supraglottic airway devices use an inflatable cuff to wedge into the upper oesophagus and provide a perilaryngeal seal.¹ The mask shape of these devices resembles a wedge-shaped doughnut in overall design. They have a tapered leading tip, a rounded proximal shape and with inflation these masks have a flat face when viewed from a lateral perspective.

Inflatable masks provide an airway seal but can negatively impact on how these devices are inserted, how they are positioned and how they perform. On insertion the deflated leading edge of the mask can catch the epiglottis edge and cause it to down-fold or impede proper placement beneath the tongue. The best

performance of the laryngeal mask airway occurs with semi-inflation.²⁻⁴ Inflation using the recommended volumes increases mask rigidity, decreases conformity with peri-laryngeal structures and lessens the effective seal pressure.²⁻⁴ Mechanically, inflation can cause movement of the device because the distal wedge shape of the mask is forced out of the upper oesophagus. Inflatable masks also have the potential to cause tissue distortion, venous compression and nerve injury.⁵⁻⁷

SAD has the advantage of easier use without examining the vocal cords in a difficult airway. While tracheal intubation requires effort and time to maintain skills, SADs do not.¹³ However, SADs are limited in their ability to completely maintain and protect the airway. For this reason, blind intubation is required through a SAD after insertion. Many SADs have been developed and many studies have evaluated blind intubation through SADs.¹⁴

Tracheal intubation with Macintosh laryngoscope was considered as the “gold standard” in airway management.¹⁵ Supraglottic airway devices (SADs) are helpful in difficult airways and in emergency life threatening situations. The use of supraglottic devices as a means of rescue in patients who are difficult to intubate or ventilate has increased in the field of anesthesiology and in emergency medicine.

Laryngeal mask airway (LMA) classic (c-LMA)¹⁶ is one such device which is included in Difficult Airway Society guidelines for unanticipated difficult intubation.¹⁷ Laryngeal mask airway classic was designed for maintenance of airway in emergency situations, especially by untrained personnel. Later it was modified into intubating LMA (ILMA) or LMA Fastrach.⁸

I-gel is a relatively new single-use SAD which does not have an inflatable cuff.¹⁸⁻²² It is made from a soft, gel-like and transparent thermoplastic elastomer (styrene ethylene butadiene styrene) which creates a non-inflatable seal which is a mirror impression of the supraglottic anatomy.²³⁻²⁵ The i-gel has several other useful design features including a gastric channel, an epiglottic ridge and a ridged flattened stem to aid insertion and reduce the risk of axial rotation.²⁶ The stem of the i-gel is less flexible than that of the LMA-classic and has an integral bite.²⁷

I-gel results in higher sealing pressures by matching the peripharyngeal anatomy despite the absence of an inflatable cuff.²⁸ In a cadaveric study full glottis view was obtained in 60% of the cases soon after I-Gel insertion while some glottic opening was visible in 95% of the cases.²⁹ The present study was conducted at comparative evaluation of clinical performance of I-GEL with LMA fastrach in elective surgeries.

MATERIALS AND METHODS

The present study was conducted after clearance from Board of Studies, Department of Anesthesiology and Ethical committee in the Department of Anesthesiology, Teerthanker Mahaveer Medical College & Research Centre, Moradabad during the period 2015-2017, on 80 patients undergoing elective surgery under general anesthesia.

Inclusion Criteria

- Patients undergoing general anesthesia for elective surgical procedures lasting more than 30 minutes.
- American society of anesthesiology grades I
- Age group 20 to 50 years of either sex.
- BMI 18-24Kg/m²
- Adequate mouth opening.

Exclusion Criteria

- Patient contraindication to spinal anesthesia.
- Patients with neurological deficits, spinal cord deformities, psychological illness, hypertensive or hypovolemic.
- Emergency lower segment caesarean section.
- Patients with use of oral opioids or non-steroidal anti-inflammatory drugs.

Sample Size

The sample size calculation was based on a 28 seconds (50%) reduction in the intubation time comparing I-gel and LMA fastrach. The sample size was calculated to be 36 patients each of I-gel and LMA fastrach to detect a significant difference between the groups at 5% alpha error and 80% power. Considering a drop-out rate of 10%, the sample size was taken to be 40 patients per group.

Randomization

The patients were divided into two groups: Group I: Anesthesia was delivered using I-gel in 40 patients and Group LF: Anesthesia was delivered using LMA fastrach in 40 patients. Learning curve was achieved by doing 10 intubations using each of the devices on patients, prior to start of study.

Technique of Anesthesia

Insertion of I-gel/LMA fastrach was carried out as per the study protocol. LMA fastrach was chosen according to the weight of the patient. Recommended size of LMA according to weight of patients are as follows:

For I-Gel/Pro-Seal Group			
Size of supraglottic devices		Patients' body weight	ETT size internal diameter (mm)
I-GEL	Size 3	30-50kg	7.0
	Size 4	50-90kg	7.5
ILMA	Size 3	30-50kg	7.0
	Size 4	50-70kg	7.5
	Size 5	>70kg	7.5

Lubrication of the front and back of the SAD and a jaw lift was carried out with head in neutral/extended position to facilitate its insertion. After insertion, the cuff was inflated, and its pressure adjusted to between 60-70 cmH₂O. Proper placement was confirmed by listening for signs of a leak, observing rising of the chest, by auscultation and noting the presence of a normal square wave pattern on capnograph tracing, under manually assisted ventilation. Following successful insertion of the airway devices, breathing circuit was attached and patient was maintained on O₂, Nitrous Oxide, Isoflurane (1%) and Intermittent doses of Inj. Vecuronium (0.02 mg/kg IV). Surgery was allowed to commence only after the collection of the last haemodynamic data at 10 minutes post-insertion interval.

Parameters Recorded

The parameters recorded were Time taken for successful placement, Time taken for insertion of Endo-tracheal Tube, Number of insertion attempts, Quality of ventilation during anesthesia, Haemodynamic parameters such as pulse rate, systolic and diastolic blood pressure and SpO₂, Airway trauma and Gastric distension.

Table 1: Comparison of mean Heart rate between I-gel and LMA FOSTRACH groups at Baseline, 1 minute, at 3 minutes and at 5 minutes

Heart Rate	I-GEL		LMA FOSTRACH		t-test value	p-value ^a
	Mean	Std. Deviation	Mean	Std. Deviation		
Baseline	85.70	4.44	83.70	4.77	1.941	0.056 [#]
1 minute	86.58	4.91	83.33	4.83	2.984	0.074 [#]
3 minutes	95.98	7.46	90.23	4.02	1.748	0.060 [#]
5 minutes	82.53	3.73	78.73	2.77	2.784	0.058 [#]
p-value ^b	< 0.001*		< 0.001*			
Post-hoc comparisons ^c	3>1,2,4		3>1,2,4			

^aMann-whitney U-test; ^bFriedman's test; ^cWilcoxon-sign rank test; * Significant difference; # Non-significant difference

Table 2: Comparison of mean Systolic blood pressure between I-gel and LMA FOSTRACH groups at Baseline, 1 minute, at 3 minutes and at 5 minutes

Systolic blood pressure	I-GEL		LMA FOSTRACH		t-test value	p-value ^a
	Mean	Std. Deviation	Mean	Std. Deviation		
Baseline	121.25	3.67	121.53	3.97	-0.321	0.749 [#]
1 minute	127.93	2.16	129.53	6.85	1.391	0.102 [#]
3 minutes	120.53	2.00	122.83	4.01	2.863	0.091 [#]
5 minutes	117.73	3.58	116.25	3.03	1.989	0.051 [#]
p-value ^b	< 0.001*		< 0.001*			
Post-hoc comparisons ^c	2>1,3,4		2>1,3,4			

^aMann-whitney U-test; ^bFriedman's test; ^cWilcoxon-sign rank test; * Significant difference; # Non-significant difference

Table 3: Comparison of mean Diastolic blood pressure between I-gel and LMA FOSTRACH groups at Baseline, at 1 minute, at 3 minutes and at 5 minutes

Diastolic blood pressure	I-GEL		LMA FOSTRACH		t-test value	p-value ^a
	Mean	Std. Deviation	Mean	Std. Deviation		
Baseline	78.48	4.80	79.33	3.68	-0.889	0.377 [#]
1 minute	81.48	2.66	84.00	2.98	-2.909	0.060 [#]
3 minutes	80.10	4.93	81.50	3.80	-2.454	0.081 [#]
5 minutes	75.35	3.30	76.00	4.16	-1.157	0.102 [#]
p-value ^b	0.102 [#]		< 0.001*			
Post-hoc comparisons ^c	N/A		2>1,4			

^aMann-whitney U-test; ^bFriedman's test; ^cWilcoxon-sign rank test; * Significant difference; # Non-significant difference

Table 4: Comparison of mean Arterial pressure between I-gel and LMA FOSTRACH groups at Baseline, at 1 minute, at 3 minutes and at 5 minutes

Mean Arterial pressure	I-GEL		LMA FOSTRACH		t-test value	p-value ^a
	Mean	Std. Deviation	Mean	Std. Deviation		
Baseline	92.73	3.46	93.39	3.33	-0.867	0.389 [#]
1 minute	99.29	2.09	99.18	2.20	1.327	0.083 [#]
3 minutes	95.58	3.69	95.28	2.07	0.448	0.655 [#]
5 minutes	88.84	3.25	89.42	2.45	-1.981	0.071 [#]
p-value ^b	< 0.001*		< 0.001*			
Post-hoc comparisons ^c	2>1,3,4		2>1,3,4			

^aMann-whitney U-test; ^bFriedman's test; ^cWilcoxon-sign rank test; * Significant difference; # Non-significant difference

RESULTS

The study population consisted of 36 (45.1%) males and 44 (55.0%) females. Among I-gel group, there were 13 (32.5%) males and 27 (67.5%) females. Among LMA FOSTRACH group, there were 23 (57.5%) males and 17 (42.5%) females. The mean age of the study population was 36.04±9.62 years. The mean age of the subjects in the I-gel group was 35.90±10.69 years and LMA Fastrach was 36.18±8.55.

There was no significant difference in mean Heart Rate at Baseline, 1 minute, 3 minutes and 5 minutes between I-GEL and LMA FOSTRACH groups. Among I-GEL group, the mean Heart Rate was significantly more at 3 minutes in comparison to all other time intervals. Among LMA FOSTRACH group, the mean Heart Rate increased significantly from baseline and 1 minute to 3 minutes which increased significantly to 5 minutes. (Table 1)

There was no significant difference in mean Systolic blood pressure at Baseline, 1 minute, 3 minutes and 5 minutes between I-GEL and LMA FASTER groups. Among I-GEL group, the mean Systolic blood pressure increased significantly from baseline to 1 minute and then decreased significantly to 5 minutes. Among LMA FASTER group, the mean Systolic blood pressure increased significantly from baseline to 1 minute and then decreased significantly to 3 and 5 minutes. (Table 2)

There was no significant difference in mean Diastolic blood pressure at Baseline, 1 minute, 3 minutes and 5 minutes between I-GEL and LMA FASTER groups. Among I-GEL group, there were no significant changes in the mean Diastolic blood pressure over the different time intervals. Among LMA FASTER group, the mean Diastolic blood pressure increased significantly from baseline to 1 minute and then decreased significantly to 5 minutes. (Table 3)

There was no significant difference in mean Arterial pressure at Baseline, 1 minute, 3 minutes and 5 minutes between I-gel and

LMA FASTER groups. Among I-GEL group, the mean Arterial Pressure increased significantly from baseline to 1 minute and then decreased significantly to 3 and 5 minutes. Among LMA FASTER group, the mean Arterial Pressure increased significantly from baseline to 1 minute and then decreased significantly to 3 and 5 minutes. (Table 4)

The mean Time taken for supra-glottic device was significantly more among LMA FASTER (31.57±3.08) in comparison to I-gel (15.07±1.65). The mean Time taken for Endo-tracheal Tube was significantly more among I-gel (24.00±0.31) minutes in comparison to LMA FASTER (19.95±0.37). (Table 5)

The distribution of Number of Attempts for insertion of supra-glottic device and Number of Attempts for Endotracheal Intubation was done between I-GEL and LMA FASTER groups using the Mann-whitney U-test. No significant difference was found in the distribution of number of Attempts and Number of Attempts for Endotracheal Intubation for supra-glottic device between I-GEL and LMA FASTER groups. (Table 6)

Table 5: Comparison of mean Time taken for insertion of supra-glottic device between I-gel and LMA FASTER groups

	I-GEL		LMA FASTER		t-test value	p-value
	Mean	SD	Mean	SD		
Time taken for supraglottic device	15.07	1.65	31.57	3.08	-29.856	0.001*
Time taken for Endotracheal Tube	24.00	0.31	19.95	0.37	23.299	0.001*

^aMann whitney U-test; * Significant difference

Table 6: Comparison of frequency distribution of Number of Attempts for supra-glottic device insertion between I-gel and LMA FASTER groups

		Groups		Total	p-value ^c
		I-GEL	LMA FASTER		
Number of Attempts for supra-glottic device	One	40 100.0%	37 92.5%	77 96.3%	0.077#
	Two	0 0.0%	3 7.5%	3 3.8%	
Number of Attempts for Endo tracheal Intubation	One	26 65.0%	32 80.0%	58 72.5%	0.133#
	Two	14 35.0%	8 20.0%	22 27.5%	

^cChi-square test; # Non-significant difference

DISCUSSION

SGA is an integral part of difficult airway algorithm and resuscitation protocols.²² It is also commonly used as a rescue device when a “cannot intubate, cannot ventilate” scenario arises.²³ Recently, the resuscitation outcomes such as survival to hospital discharge, return of spontaneous circulation, and 24-hour survival were shown to be better following endotracheal intubation in comparison to SGA when used for OHCA.^{24,25}

In this study, overall success rate of insertion of supraglottic devices in both the groups was 100% which was similar to various previously conducted studies. In the present study, first attempt success rate for blind tracheal intubation was comparable in both the groups and overall success rate was higher in I group (100.0%) as compared to F group (92.5%) which was similar to the studies by Sahi et al.²⁶ the insertion success rate in group I-gel

was 83.3% for the 1st attempt while in Group LMA Fastrach, it was 65% for the 1st attempt and Bhandari et al.²⁷ in which 95% reported first time and 100% overall success rate with I-gel. This was dissimilar to the results of Halwagi et al.²⁸ and Sastreet al.²⁹ who noticed higher success rate of blind tracheal intubation with ILMA.

Raggazi et al.³⁰ in their study found that LMA supreme has fewer insertion failures as compared to I-Gel but because of its inflatable cuff caused transient pharyngolaryngeal pain. Theiler et al.³¹ in their study concluded that both LMA supreme and I-Gel have a similar insertion success and clinical performance in the simulated difficult airway situation. However, Singh et al.³² found that that I-Gel was easier to insert and required less attempts of insertion when compared with proseal LMA.

The overall intubation success rate using LMA Fastrach was comparable to published studies.³³⁻³⁶ The cases in which blind tracheal intubation failed only two patients needed stylet for intubation with Macintosh laryngoscope in group I-gel and none in group LMA Fastrach. The easier and a quicker insertion of i-gel was probably due to non-inflation of cuff. Time was not wasted in inflating the cuff, and moreover, the rigid structure of LMA Fastrach causes delay in insertion as compared to i-gel.

Michalek et al.²⁰ did blind tracheal intubation in three different airway manikins through the i-gel with a success rate of 51%. Theiler et al.³¹ studied “visualised blind intubation” through the i-gel and the LMA Fastrach. Their results showed a poor success rate (15%) with i-gel as compared with the LMA Fastrach (69%). Sastre et al.²⁹ also showed an inferior intubation rate of 40% through i-gel as compared to 70% with LMA Fastrach.

The mean Time taken for supra-glottic device was significantly more among LMA FASTERACH (31.57±3.08) in comparison to I-gel (15.07±1.65). This was similar to the studies by Moore et al.³⁷ The time required for tracheal intubation were significantly lower in the IG group (30 ± 11 seconds vs 50 ± 21 seconds; P < 0.0001), Chauhan et al.³⁸ have observed significantly lower insertion times with i-gel (11.12 ± 1.814 seconds) when compared with LMA proSeal (15.13 ± 2.91 seconds) and Halwagi et al.,²⁸ showed longer intubation times with ILMA in comparison to I-Gel.

However, in the study by Sahi et al.,³⁹ the time taken for Endotracheal intubation by Fastrach LMA was 18.953±0.925 seconds for one attempt with overall mean of 21.509±5.374 seconds while that of i-gel was 23.00±1.433 seconds for one attempt with overall mean of 26.906±7.517 seconds showing that intubation through Fastrach LMA took lesser time than i-gel, which is found to be statistically highly significant, Fernández et al.⁴⁰ had observed longer insertion time (32.5 seconds) with i-gel compared to LMA-S (27.1 seconds) and lower first attempt placement rates with i-gel (86%) compared to with LMA-S (95.2%) and Theiler et al.³¹ LMA-S needed shorter insertion time (34±12 s vs. 42±23 s, P = 0.024). Theiler et al.³¹ have attributed the longer insertion time for i-gel to the bulky design of the airway device. The mean Time taken for Endo-tracheal Tube was significantly more among I-gel (24.00±0.31) minutes in comparison to LMA FASTERACH (19.95±0.37). This was similar to the study by Kapoor et al.¹⁴ (24.04 ± 9.42 seconds) and Halwagi et al (22 ± 13 seconds).²⁸

The flexible silicon tipped tube is a well-designed, straight, soft, wire-reinforced silicon tube which lacks wire reinforcement in the distal inch and terminates like a conical soft tip for use with ILMA. This combined with the enhanced curved shape of the ILMA leads these flexible tubes towards the plane of the glottis at an angle of 35°. The relatively straight shape of the I-gel stem and the ending of the airway channel deep into the bowl of the cuff may direct the soft tip of FST posteriorly thereby increasing the risk of oesophageal intubation or snaring on the arytenoids. The more rigid PVC tubes have a fixed curvature directed anteriorly thereby better aligning the tube towards laryngeal inlet than FST when advanced through an I-Gel.⁴¹

The incidence of postoperative complications was comparable in both the groups. In the present study, dysphonia was more in I group which was similar to study conducted by Sastre et al.²⁹ While the incidence of sore throat was lesser in I group when compared to F group; this observation is similar to that of Keijzer et al.⁴²

There was no significant difference in mean Heart Rate, systolic blood pressure, diastolic blood pressure and mean Arterial pressure between I-GEL and LMA FASTERACH groups at all time intervals. This was similar to the study by Sahi et al.³⁹ hemodynamic changes were comparable as is shown by insignificant statistical difference during induction, SAD insertion, intubation and throughout the surgery.

In the study by Gupta et al.⁴³ the mean heart rate, systolic, diastolic, mean arterial blood pressure and SpO₂ in LMA-Supreme group and I-gel group did not have significant difference between two groups at different intervals of time. Shin et al.⁴⁴ found no difference in the hemodynamic data immediately after insertion of device. Shin et al.⁴⁴ also concluded that the tongue, lip & dental trauma and blood staining of the device was more with LMA-Supreme than with I-gel but with no statistical significance. These observations are consistent with our results and with Helmy et al.³⁶ study in which they concluded that there was no statistically significant difference found between both I-gel and classical laryngeal mask airway groups with regard to sore throat, hoarseness and dysphonia 24 hours after the surgery.

As such, no post-operative complications were reported in the present study. The similar results were also reported by Goyal et al.⁴⁵ no sore throat and hoarseness was reported though there was blood contamination in all three SADs (i-gel, proSeal, and classical). Similar to our findings, Shin et al.⁴⁴ did not determine any blood contamination or sore throat in the i-gel group who underwent orthopedic surgery in the supine position. Uppal et al.²⁰ compared the i-gel with a tracheal tube, they found 12% blood contamination in relation with the insertion method and ease. Ragazzi et al.³⁰ compared target-controlled anesthesia with the I-gel and supreme and found one blood contamination in the I-gel group and two in the supreme group. The gel-like cuff minimizes trauma of the airway and neurovascular compression. Theiler et al.³¹ reported that Fiberoptic view of the glottis was remarkably good through the i-gel™ compared with the LMA-S™. This finding and the smaller proportion of epiglottic down folding were the only statistically significant differences in favour of the i-gel™. Similar findings have been reported in the earlier fiberoptic findings¹⁹. Neither epiglottic down folding nor fiberoptic view could be correlated to ventilation success and possible tidal volume applied. However, in LMA Fastrach, there was no difference in successful blind tracheal intubation with conventional tracheal tube and silicon wire reinforced tracheal tube in studies conducted by Lu et al.¹¹ and Kundra et al.³⁶ but in case of i-gel further studies are required.

CONCLUSION

It can therefore be inferred that both Fastrach LMA and i-gel are suitable devices to be used as conduit to endotracheal intubation particularly in susceptible patients where hemodynamic disturbances during intubation are not required.

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