

Comparison of I-GEL and LMA - Supreme in Patients Undergoing Elective Surgeries under General Anaesthesia: A Prospective Randomised Study

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Abstract:

Background: In this study, we wanted to compare I-GEL and laryngeal mask airway LMA - Supreme in patients undergoing elective surgeries under general anaesthesia.

Methods: This was a hospital based randomized, prospective controlled study conducted among 60 patients undergoing elective surgical procedures in the Department of Anaesthesia, after obtaining clearance from Institutional Ethics Committee and written informed consent from the study participants.

Results: Ease of insertion of supraglottic airway device (SGA) device was significantly better with IGEL (96.7 %) as compared to LMA - SUPREME (80 %). The difference was statistically significant ($p < 0.05$). Mean oropharyngeal leak pressure was significantly higher in I-GEL cases as compared to LMA - SUPREME cases (28.65 vs 24.13 mm Hg; $p < 0.05$). Mean insertion was observed to be significantly faster in I-GEL cases as compared to LMA - SUPREME cases (23.32 vs 29.58 sec; $p < 0.05$).

Conclusion: I-GEL was easier and faster to insert and required less attempts of insertion when compared with LMA-Supreme. I-GEL's non inflatable thermoplastic elastomer cuff fitted snugly creating a good anatomical seal. The I-GEL also showed less peri- and post-operative complications i.e., blood on removal, hoarseness of voice, sore throat, and dysphagia – as its noninflatable cuff probably decreased the risk of airway tissue compression and hence tissue ischemia. Both I-GEL and LMA-SUPREME showed no incidence of severe airway trauma, such as laryngeal stridor, laryngospasm, bronchospasm, hypoxia, or aspiration. We thus conclude that I-GEL is a better in view of ease of insertion, placement was rapid and also less

traumatic to airways than LMA-SUPREME. So, I-GEL is a cheap and effective SAD alternative to LMA-SUPREME.

Keywords: I-GEL, LMA - SUPREME, Elective Surgeries, General Anaesthesia.

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Introduction

Administration of general anaesthesia causes suppression of respiration and airway reflexes. Therefore, one of the important roles of an anaesthesiologist is to intervene and maintain a definitive airway and adequate breathing in patients under general anaesthesia.[1] Endotracheal intubation is the placement of a tube into the trachea (windpipe) in order to maintain an open airway in patients who are unconscious or unable to breathe on their own. Endotracheal tube (ETT) is thus, the gold standard for securing a definitive airway and for preventing aspiration in an anesthetized patient who has lost his/her airway reflexes. [1] But, the endotracheal tube has its own drawbacks. The first being, a high level of skill required to be able to master the technique of intubation. Intubation involves laryngoscopy, which is an extremely stressful manoeuvre and stimulates the sympathetic system reflex and may provoke hemodynamic response and airway response like laryngospasm and bronchospasm in a person having a reactive airway. Endotracheal intubation is more time consuming; in addition, trauma to the lips, teeth, gums, tonsils, etc., increased requirements of anaesthetic agents and muscle relaxants, delayed emergence and recovery are some of the other complications associated with the endotracheal tube. [2] An alternative device was needed for managing airway smoothly without much sympathetic stimulation and airway handling and without complications. Supraglottic airway devices were introduced in 1981 and came into routine use from September 1990. [3,4] The classic laryngeal mask airway (LMA) was introduced by Archie Brain in 1988. [5] The skills required to be developed for

successful insertion of a LMA are much lesser. Some of the advantages of a LMA over an endotracheal tube are that the stress response is way less for an LMA, [6] it is less traumatic, with much less anaesthetic requirements, [7] and faster emergence and recovery from anaesthesia. [8] Since the introduction of the classic laryngeal mask airway, the field of supra glottis airway devices has experienced a remarkable evolution and SGA are now routinely used in clinical anaesthesia. The limitations associated with the classic LMA are relative contraindications of controlled ventilation (due to its moderate oropharyngeal seal) and its unsuitability for patients at risk of aspiration. Second-generation supraglottic airway devices (SADs) like I-GEL®, LMAProSeal™ and LMA - Supreme™ were designed to address these issues. Newer SADs have an inbuilt drainage channel to facilitate the efflux of gastric fluid, gas and allow the insertion of a gastric tube. Many SGA are available in single-use versions. [9,10] The I-GEL™ and LMA-Supreme™ (LMA - SUPREME) are disposable SGA with inbuilt drainage channel. The I-GEL™ has a non-inflatable, gel-filled cuff [11] while the LMA - SUPREME is a disposable, pre-curved modification of the older LMA-ProSeal™. [12] I-GEL is a new supraglottic airway device and comes under uncuffed perilaryngeal sealer group of airway devices as per Miller's classification. The gel like cuff avoids trauma that can occur with other inflatable supraglottic device. [13] I-GEL supraglottic device and LMA - Supreme both attain a good seal over pharyngeal and laryngeal structures and both have a gastric channel for drainage of gastric contents. These two SGA have

previously been evaluated alone or in pairwise comparisons, but differing study designs make it difficult to compare the results. [10-16] We therefore compared the two SGA in a randomized, prospective controlled study with a detailed evaluation of their performance.

Aims and Objectives

To compare I-GEL and LMA - Supreme in patients undergoing elective surgeries under general anaesthesia.

To compare I-GEL and LMA - SUPREME in terms of time taken for proper placement of device.

To compare I-GEL and LMA - SUPREME in terms of:

- Ease of insertion
- Number of attempts needed for insertion Oropharyngeal seal pressure.
- Ease of insertion of gastric tube
- Adverse effects during usage of both devices.

Materials & Methods

This was a hospital based randomized, prospective controlled study conducted among 60 patients undergoing elective surgical procedures in the Department of Anaesthesia, after obtaining clearance from Institutional Ethics Committee and written informed consent from the study participants.

Inclusion Criteria

1. ASA I and II.

2. Age 18 - 60 years.
3. Both sexes.
4. MPC I and II.
5. Elective surgeries with duration less than two hours.

Exclusion Criteria

1. BMI > 30 kg/m²
2. Patients with difficult airway and risk of aspiration.
3. Presence of acute or chronic airway disease.
4. Patients with co-morbid illness like uncontrolled diabetes mellitus, uncontrolled hypertension, cardiac or pulmonary, GERD disease, and obstructive sleep apnoea disease.
5. Patients with history of allergic reactions to drugs used in the study.
6. Patients undergoing head neck face procedures.

Statistical Methods

The quantitative data was represented as their mean \pm SD. Categorical and nominal data was expressed in percentage. The t-test was used for analysing quantitative data, or else non parametric data was analysed by Mann Whitney test and categorical data was analysed by using chi-square test. The significance threshold of p-value was set at < 0.05. All analysis was carried out by using Statistical Package for Social Sciences (SPSS) software version 21.

Results

Table 1: Demographic Distribution

Variables	Group	N	Mean	SD	p- Value
Age (Years)	LMA -SUPREME	30	35.87	10.76	0.57
	I-GEL	30	37.27	7.96	
Weight (Kg)	LMA -SUPREME	30	59.90	5.75	0.13
	I-GEL	30	61.97	4.60	
Height (cm)	LMA -SUPREME	30	164.23	4.13	0.41
	I-GEL	30	165.07	3.55	
Mean Comparison of Age Distribution and Anthropometric Parameters					
Gender	Group		Total		
	I-GEL	LMA - SUPREME			
Female	23	20	43		
	76.7 %	66.7 %	71.7 %		

Male	7	10	17
	23.3 %	23.3 %	23.3 %
Total	30	30	60
	100.0 %	100.0 %	100.0 %
p- value - 0.57			
Sex Distribution			

Mean age of the study group was 36.57 years with no difference between I-GEL and LMA - SUPREME group with respect to age and anthropometric distribution ($p > 0.05$).

Overall female predominance was seen in the study group with 71.7 % females to 28.3 % males. No difference was observed between I-GEL and LMA - SUPREME group with respect to gender distribution ($p - 0.57$).

Table 2: Comparison of Study Groups as Ease of Insertion

	96.7%	80.0%	88.3%
Total	30	30	60
	100.0 %	100.0 %	100.0 %
p- Value < 0.05			

Ease of Insertion	Group		Total
	I-GEL	LMA - SUPREME	
Difficult	1	6	7
	3.3 %	20.0 %	11.7 %
Easy	29	24	53

Ease of insertion of SGA device was significantly better with I-GEL (96.7 %) as compared to LMA - SUPREME (80 %). The difference was statistically significant ($p < 0.05$).

Table 3: Comparison of Study Groups as per Mean Oropharyngeal Leak Pressure

Variables	Group	N	Mean	SD	p- Value
Oropharyngeal Leak Pressure	LMA -SUPREME	30	24.13	0.42	< 0.05
	I-GEL	30	28.65	0.22	

Mean oropharyngeal leak pressure was significantly higher in I-GEL cases as compared to LMA - SUPREME cases (28.65 vs 24.13 mm Hg; $p < 0.05$).

Table 4: Comparison of Study Groups as per Mean Insertion Time

Variables	Group	N	Mean	SD	p- Value
Insertion Time (sec)	LMA -SUPREME	30	29.58	6.40	< 0.05
	I-GEL	30	23.32	3.16	

Mean insertion was observed to be significantly faster in I-GEL cases as compared to LMA - SUPREME cases (23.32 vs 29.58 sec; $p < 0.05$).

Table 5: Comparison of Study Groups as per Long Term Complications

Long Term Complications	Group		Total	p- Value
	I-GEL	LMA -SUPREME		
Hoarseness of voice	2	5	7	0.15
	6.7 %	16.7 %	11.7 %	

Sore throat	2	2	4	1.00
	6.7 %	6.7 %	6.7 %	
Dysphagia	0	4	4	0.11
	0.0 %	13.3 %	6.7 %	
Dysphonia	0	1	1	1.00
	0.0 %	3.3 %	1.7 %	
Numbness of tongue	0	3	3	0.23
	0.0 %	10.0 %	5.0 %	

Overall complication rate was more in cases of LMA - SUPREME as compared to I-GEL group (66.7 % vs 13.3 %; $p < 0.05$). Hoarseness of voice and dysphagia was seen in 16.7 % and 13.3 % cases of LMA - SUPREME group as compared to 6.7 % and 0 % in I-GEL group. Sore throat was seen in 6.7 % cases in each group while dysphonia (3.3 %) and numbness of tongue (10 %) was only associated with LMA - SUPREME group.

Discussion

Ease of Insertion & Number of Attempts

In this study, ease of insertion of SGA device was significantly better with I-GEL (96.7 %) as compared to LMA - SUPREME (80 %). The difference was statistically significant ($p < 0.05$). Insertion in first attempt was observed to be more in cases of I-GEL (96.7 %) as compared to cases of LMA - SUPREME (86.7 %). The difference was however, statistically non-significant due to limited power of the study. Success rate was 100 % in both groups. Mean insertion time in present study was observed to be significantly less in I-GEL cases as compared to LMA - SUPREME cases (23.32 vs. 29.58 sec; $p < 0.05$).

Based on our findings, we postulated that I-GEL SAD should be easier to insert due to its unique gel-like material, shape and contour, buccal stabiliser, and epiglottis blocker that minimises epiglottis downfolding. The faster effective airway

time of I-GEL SAD can be explained by the cuff-less nature of the device, which obviates the necessity to inflate the cuff during insertion.

Liew GH et al. [17] in their study observed that I-GEL was easier to successfully insert at the first attempt. It was also associated with shorter effective airway time than the ProSeal and Supreme SADs. Joly et al. [18] in their study observed that insertion time was shorter with I-GEL (19s) than with LMA S (17s) ($p = 0.003$). Abdullah et al. [19] and Polet et al. [20] in their studies also reported that insertion time was significantly shorter with I-gel. However, Samel S et al. [21] and Govardhane BT et al. [22] observed no difference between the two groups with regards to success rate and mean insertion time. A meta-analysis comparing the I-GEL and supreme SADs also concluded that there was no statistical difference in device placement time and first attempt insertion success rates. [23]

Oropharyngeal Leak Pressure

Mean oropharyngeal leak pressure in present study was significantly higher in I-GEL cases as compared to LMA - SUPREME cases (28.65 vs 24.13 mm Hg; $p < 0.05$).

In general, it is thought that higher oropharyngeal leak pressures in SADs allow the use of safer controlled ventilation at higher airway pressures if required [18]. Our results are in accordance with the study by Liew GH et al. [10] where the mean

oropharyngeal leak pressure following induction was higher in the I-GEL group (27.31 cmH₂O) than the SUPREME (23.60 cmH₂O) group. Shi YB et al. [5] in a similar study observed that airway sealing pressure was significantly higher in group I-GEL as compared with group LMA-SUPREME (30 vs 25 mm Hg; $p < 0.05$). However, the studies by Van Zundert et al., [24] Joly N et al. Katika S et al. [25] and Sarika et al. observed no statistically significant difference between two groups in regards to oropharyngeal leak pressure.

A possible reason for the I-GEL's higher leak pressure in our study, as compared with previous studies, is the modification applied to its weight-based size selection criteria to account for the 10-kg overlap between sizes 3 and 4.

Ease of Insertion of Gastric Tube

We observed ease of gastric tube insertion in 90 % cases of I-GEL and 96.7 % cases of LMA-SUPREME, the difference was statistically non-significant ($p = 0.67$). Success rate was 100 % in both groups. The insertion of gastric tubes in the I-GEL group was slightly more difficult than in the supreme group despite the use of a smaller 12 FG tube, due to the narrower gastric port.

Liew GH et al. in their study observed that gastric tubes were inserted successfully at the first attempt in all patients in the supreme group, and with a 94 % success rate in I-GEL group. Mukadder et al. [26] showed in their study that gastric tube insertion had a similar success rate for the I-GEL and supreme groups, but was more difficult with the ProSeal group. Teoh et al. [27] demonstrated no difference in the success rate of gastric tube insertion for the supreme and I-GEL groups. Shi YB et al. [28] in their study observed success rate of 100 % in both groups with no difference regarding ease of insertion.

Adverse Effects

During the procedure, blood staining of the airway device, which could be indicative of airway mucosal trauma, was seen in 3 cases of (10 %) LMA - SUPREME when compared to none in I-GEL group. No cases in any group suffered supra-glottic tear. Overall postprocedural complication rate was more in cases of LMA - SUPREME as compared to I-GEL group (66.7 % vs 13.3 %; $p < 0.05$). Hoarseness of voice and dysphagia was seen in 66.7 % and 13.3 % cases of LMA - SUPREME group as compared to 6.7 % and 0 % in I-GEL group. Sore throat was seen in 6.7 % cases in each group while dysphonia (3.3 %) and numbness of tongue (10 %) was only associated with LMA - SUPREME group.

Liew GH et al. in their study observed less airway morbidity and fewer complications in the I-GEL group as compared with LMA - SUPREME. Blood staining of the SAD was seen in supreme group, but not in the I-GEL group. Furthermore, post-operative complaints of sore throat, voice hoarseness and dysphagia were either less evident or not observed in the latter group. Samel S et al. observed that sore throat post operatively at 1 hr and 24 hrs was 17.5 % and 0 % with LMA - SUPREME and 2.5 % and 0 % with I-GEL. Dysphagia and dysphonia at 1 hr. and 24 hr. was (20 %, 0 %) and (2.5 %, 0 %) with LMA - SUPREME respectively whereas with I-GEL it was (2.5 %, 0 %) and (2.5 %, 0 %). Similar to our findings, the I-GEL group in Mukadder et al.'s study had fewer reports of blood staining and other post-operative complications. Abdulla S et al. in their study also reported that sore throat was lower with I-GEL compared with LMA - SUPREME.

These findings have been demonstrated by other studies as well. [29]

The I-GEL SAD has a non-inflatable cuff that was designed to provide an anatomical fit over the perilaryngeal structures, minimising the risk of compression of

neurovascular structures in these tissues and thereby reducing the incidence of airway complications. [30,31]

Our study had several limitations. Firstly, it was unblinded, as the investigators could not be blinded during airway management, hence presenting the possibility of researcher bias. Secondly, the oropharyngeal leak pressure was only measured once, at the start of the procedure, although the leak pressure may change over time. The reason for not measuring leak pressure repeatedly was that the unparalysed patients would only be ventilated for a short period of time before resuming spontaneous breathing, hence only the initial leak pressure was deemed important.

To summarize, our study demonstrated that both supreme and I-GEL SADs can provide a safe airway. We also showed that although these devices were comparable in terms of number of attempts, the I-GEL SAD takes shorter time and produced superior results in initial oropharyngeal leak pressure and airway morbidity when compared with the supreme SADs.

Conclusion

I-GEL was easier and faster to insert and required less attempts of insertion when compared with LMA-Supreme. I-GEL's non inflatable thermoplastic elastomer cuff fitted snugly creating a good anatomical seal. The I-GEL also showed less peri- and post-operative complications i.e., blood on removal, hoarseness of voice, sore throat, and dysphagia – as its noninflatable cuff probably decreased the risk of airway tissue compression and hence tissue ischemia. Both I-GEL and LMA-SUPREME showed no incidence of severe airway trauma, such as laryngeal stridor, laryngospasm, bronchospasm, hypoxia, or aspiration. We thus, conclude that I-GEL is a better in view of ease of insertion, placement was rapid and also less traumatic to airways than LMA-SUPREME. So, I-GEL is a cheap and

effective SAD alternative to LMA-SUPREME.

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