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Comparative Study of LMA Supreme versus I-gel in Patients Undergoing Laparoscopic Surgeries with Positive Pressure Ventilation

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Abstract

Backround: The main objective of this study is to compare the efficacy of two newer supraglottic airway devices LMA Supreme and I GEL in patients undergoing laparoscopic surgeries with positive pressure ventilation. *Materials and methods:* A total of 50 patients with 25 in each group ('LMA Supreme' or 'I GEL) undergoing laparoscopic surgery at SMVMCH from October 2014 to May 2016 were included in the study. Based on the score given by the inserting anaesthetist, parameters like ease of insertion, number of insertion attempts, ease of insertion of Ryles tube, airway seal by the device before and after creating pneumoperitoneum and any complications arising after removing the device were assessed. *Results:* LMA Supreme and I GEL have an equally high successful rate in terms of ease of insertion and both devices have a similar number of attempts for insertion. In terms of ease of insertion of ryles tube, all patients in LMA supreme group were successfully inserted with a ryles tube (Insertion score 1), where as there was some difficulty encountered in inserting the ryles tube in I GEL group. There was no audible leak throughout the period before creating pneumoperitoneum and after creating pneumoperitoneum showing that both devices are equally effective in providing an adequate airway seal with positive pressure ventilation. Both the devices were equally effective in providing airway seal with a minimal increased requirement of tidal volume in I GEL group. Thus inferring both the devices are equally effective in working performance as an effective airway device in laparoscopic surgeries with positive pressure ventilation. *Conclusion:* Both LMA Supreme and I GEL are equally effective in maintaining adequate airway seal in laparoscopic surgeries with positive pressure ventilation. LMA Supreme is superior over I GEL in terms of ease of insertion of Ryles tube and increased tidal volume requirement in I GEL group for maintaining the ventilation when compared to LMA supreme.

Keywords: LMA; Supreme; I-gel; Laparoscopic surgeries; Positive pressure ventilation.

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Introduction

Anaesthesiologists have a major responsibility to secure airway and provide adequate ventilation to anaesthetized patient. Maintaining patent airway is the most vital element in providing respiration. Endotracheal intubation is the gold standard method for maintaining a patent airway during anaesthesia. Laryngoscopy and endotracheal intubation produce reflex sympatho-adrenal stimulation and are associated with raised levels of plasma catecholamines, hypertension, tachycardia [1].

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Airway devices available can be classified as intraglottic and extraglottic airway devices, which are employed to protect the airway both in elective as well as emergency situations [2]. The supraglottic airway device is a novel device that fills the gap in airway management between tracheal intubation and use of face mask. Dr. Archie Brain, a British anaesthesiologist, for the first time introduced the laryngeal mask airway designed to be positioned around the laryngeal inlet that could overcome the complications associated with endotracheal intubation and the insertion was simple and atraumatic [3]. Careful observations and clinical experience have led to several refinements of Brain's original prototype leading to development of newer supraglottic airway devices with better features for airway maintenance [4].

I-Gel (Intersurgical Ltd, Wokingham, UK) is a new, supraglottic airway device, with a non inflatable cuff, composed of soft gel like, transparent thermoplastic elastomer. It is designed to achieve a mirror impression of pharyngeal and laryngeal structures and to provide a perilaryngeal seal without cuff inflation. The I GEL has several other useful design features including a gastric channel (which allows early recognition of regurgitation of gastric contents and passage of a drainage tube) [5].

The LMA Supreme (SLMA, Intavent Orthofix, Maidenhead, UK) is a new supraglottic airway device, made of medical grade PVC and is latex-free. It has an anatomically shaped airway tube into which a separate drain tube has been incorporated and a modified inflatable cuff, designed to offer higher airway seal pressures around the laryngeal opening. This also incorporates an integral bite block and a tab for adhesive tape fixation of the device and for sizing purposes. The firm, elliptical and anatomically shaped airway tube facilitates easy insertion, without placing fingers in the patient's mouth or requiring an introducer tool for insertion, includes patented 'fins' designed to prevent occlusion of the airway by the epiglottis [6].

There has been a lot of interest in these two devices due to their acclaimed advantages, and there have been a number of studies in response to concerns regarding their effectiveness and safety during positive pressure ventilation in laparoscopic surgeries [6]. But still controversies exist whether and which supraglottic airway devices can be used in Laparoscopic surgeries with positive pressure ventilation [7].

The main aim of this study is to compare the LMA Supreme with the I-Gel LMA in patients undergoing Laparascopic surgeries in terms of the success of insertion of the device, haemodynamic changes before and after insertion, airway seal, and peak airway pressure before and after creating pneumoperitoneum and post operative device related complications like sore throat, bleeding, etc.

Materials and Methods

After obtaining approval from institutional ethical committee and after getting written, informed valid consent, patients were enrolled in our study. Using 2 tailed t test from mean differences between two independent mean values, with an alpha error of 0.05 and power of 0.95 the total sample was calculated to be 44, in which 22 in each group. For statistical purposes the sample size was made to be 25 in each group and a total of 50 patients scheduled for elective abdominal laparoscopic surgeries in SMVMCH from October 2014 to May 2016 were included in this study.

Patients with anticipated difficult airway, ASA physical status 3 & 4, cervical spine disease, obese with body mass index > 30 kg/m 2 and patients with thyromental distance < 65 mm, having history of regurgitation were excluded from the study.

Patients were randomly allocated into two groups. 'Group S' for patients inserted with LMA Supreme and 'Group I' for patients inserted with I GEL, using a computer-generated random codes. Participants were blinded to their group allocations.

Procedure

All patients underwent a pre operative assessment in pre anaesthetic clinic. Patients were pre medicated with Inj.Glycopyrrolate 5 mics/kg i.v, Inj.Midazolam 0.05 mg/kg i.v, Inj. Ondensetron 4 mg i.v. Patients were positioned supine on the operating table, with the head resting on a pillow. Standard monitoring was ensured before induction of anaesthesia, i.e. pulse oximetry, electrocardiograph and non-invasive blood pressure. Patients were pre-oxygenated for 3 min with 100% oxygen. Induction of anaesthesia was done with intravenous fentanyl (2 mic/kg), propofol (2 mg/kg) and atracurium (0.5 mg/kg) was administered for neuromuscular blockade after confirmation of successful manual bag-mask ventilation.

Three minutes after the administration of the neuromuscular blocking drug, the airway device was inserted when the jaw was sufficiently slack.

The cuff of the LMA Supreme was inflated as per manufacturer recommendations. The appearance

of the first square end tidal carbon dioxide trace denoted successful establishment of effective ventilation. If end tidal CO_2 could not be recorded then the device was removed and repeated for another insertion attempt. Each 'attempt' was defined as re-insertion of the airway device into the mouth. 'Insertion failure' of the device was defined as > 3 unsuccessful attempts or if the entire process of insertion exceeded 120 sec. This includes the time the airway device was removed from the mouth and any bag-mask ventilation done in between.

The number of insertion attempts and the time to establish effective ventilation (interval from when the LMA Supreme or I GEL entered the mouth to first CO_2 trace), the ease of insertion of the airway, subjectively assessed on a 5-point scale (1 = easy, 2 = not so easy, 3 = difficult, 4 = very difficult, 5 = impossible). In case of failure of both devices, the airway was secured according to the decision of the attending Anaesthetist. Once the airway device was in place, the SGA device was fixed by taping over the patient's cheek. For both the airway devices, a ryles tube was inserted through the gastric drain outlet (size 14 FG for the LMA Supreme and 10 FG for the I-gel).

These Ryles tube were prelubricated with a water-soluble lubricant. Ease of insertion of Ryles tube was graded on a three point scale (1 = easy, 2 = difficult, 3 = impossible).

Confirmation of correct placement of the ryles tube was detected by injecting air and by auscultation of the epigastrium and aspiration of gastric contents. Gastric decompression was performed.

Blood pressure and heart rate was recorded as baseline, 0 mins, 10 mins, 20 mins, 30 mins, 60 mins, 90 mins and 120 mins. Maintenance of anaesthesia was achieved with oxygen: N_2O mixture with 1–2 MAC sevoflurane.

Initial ventilator tidal volumes was set at 8 ml/Kg. Volume controlled, positive pressure ventilation to maintain O2 saturation > 95% and end-tidal CO2 35-45 mmHg through tidal volumes of 8–10 ml/kg and respiratory rate of 10–16 per minute.

All patients were positioned in Trendelenburg position (Head down) after the surgeon inserting the laparoscopic ports and creating a pneumoperitoneum using carbon dioxide insufflation.

Peak airway pressures (before and after creation of pneumoperitoneum), Tidal volume requirement before and after creating pneumoperitoneum were noted. At the end of surgery, the effects of neuromuscular blocking drug were reversed with neostigmine 0.04 mg/kg and Glycopyrrolate 10 mic/kg.

The following parameters were measured.

1. Heart rate, NIBP, Oxygen saturation (SpO_2) at baseline and after insertion of device.
2. Number of insertion attempt of the SGA device.
3. Time taken for insertion of the device.
4. Ease of insertion was described according to subjectiveness of single user as 1 = easy, 2 = not so easy, 3 = difficult, 4 = very difficult, 5 = impossible.
5. Ease of insertion of passing a Ryles tube. Ease of insertion was graded 1–3 (1 = easy, 2 = difficult, 3 = impossible).
6. Peak airway pressure before and after creating pneumoperitoneum.
7. Tidal volume required for maintaining ventilation before and after creating pneumoperitoneum.
8. Incidence of intra and post operative complications caused by using the SGA devices was assessed.

The airway device was removed upon return of spontaneous breathing and eye opening of the patient. Forty-five minutes later, patients will be assessed by a blinded independent observer for postoperative sore throat, dysphonia or dysphagia.

Results

The following observations were made during the course of the study. The demographic and anthropometric profile was comparable among both groups. The ASA grade and Mallampati grade between the two groups were comparable and there is no significant difference between the two groups (Table 1).

In both the groups, Mean Heart Rate (Figure 1), Mean SBP and Mean DBP were comparable. In terms of ease of insertion, only 5 patients in I GEL group and 3 patients in LMA supreme group was given a score of 2. There were no statistically significant difference between the groups in inserting the device, both groups have a similar number of attempts for insertion. All patients in LMA supreme group were successfully inserted with a ryles tube (Insertion score 1), where as 20 patients only given insertion score 1 and remaining 5 patients given insertion score 2 in I GEL group. Also there is no significant difference in mean time taken for inserting the device between the groups (Table 2).

As there was no audible leak throughout the period before creating pneumoperitoneum and after creating pneumoperitoneum, showing both the devices provide an adequate airway seal with positive pressure ventilation (Fig. 2 & 3). There was a statistically significant increase in tidal volume requirement to maintain ventilation in I GEL group when compared to LMA supreme group (Table 3). Post operative complaints like sore throat, dysphagia, blood stain on removal were seen with LMA supreme group when compared to IGEL (Table 4).

Table 1: Patient Demographic and Anthropometric Data

	Group S (n=25)	Group I (n=25)
Age	37.72 ± 11.9460	37.04 ± 15.1672
Sex (M/F)	5/20	6/19
Height (Cms)	161.080 ± 5.0902	163.480 ± 4.4918
Weight(Kg)	53.720 ± 5.6827	57.360 ± 6.3893
Thyromental Distance (Cms)	6.732 ± 0.3716	6.820 ± 0.4153
Sternomental Distance(Cms)	12.688 ± 0.3972	13.036 ± 0.2970
Asa Grade (1/2)	20/5	18/7
Mallampati Grade (1/2/3)	9/9/7	10/10/5

The above tables show the values of Age, Sex, Height, Weight, Thyromental and Sternomental distance, ASA grade and Mallampati grade as Mean ± Standard deviation (Table 1).

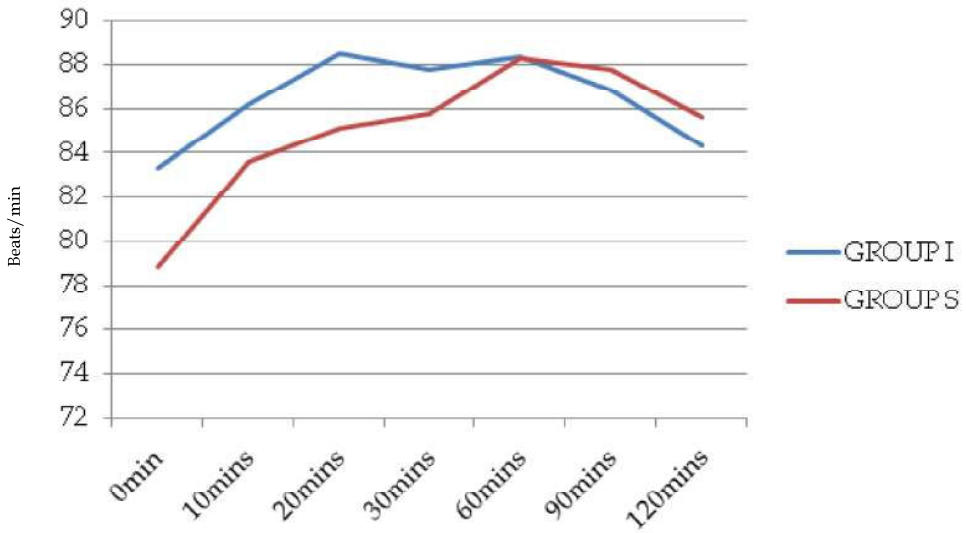

Fig. 1: Comparison of Mean Heart Rate

Table 2: Comparative data for Supreme and I-gel

Score	Group S (n=25)	Group I (n=25)
Ease of insertion (1/2/3)	21/3/1	20/5/0
No. of insertion attempts (1/2/3)	21/4/0	20/5/0
Ease of insertion of ryles tube (1/2/3)	25/0/0	20/5/0
Time taken for inserting the device (Sec)	14 ± 5.016	12.52 ± 4.726

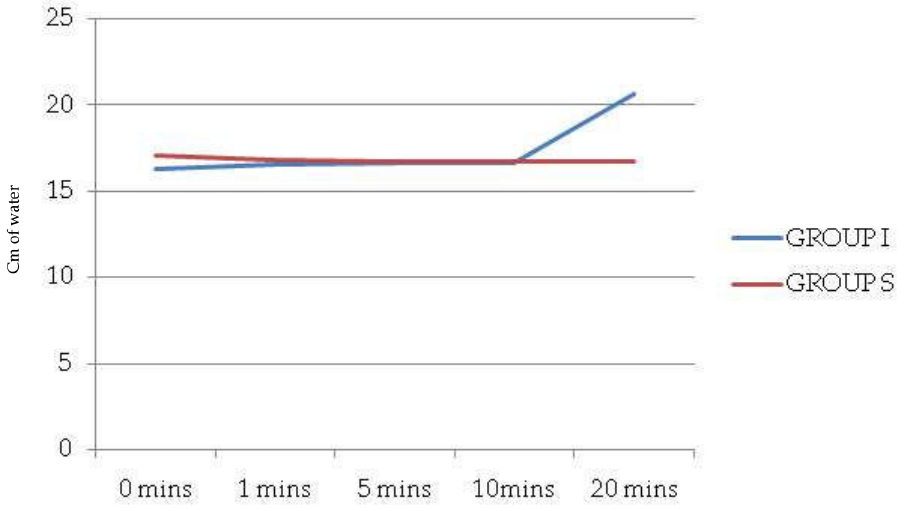

Fig. 2: Comparison of mean peak airway pressure before creating pneumoperitoneum

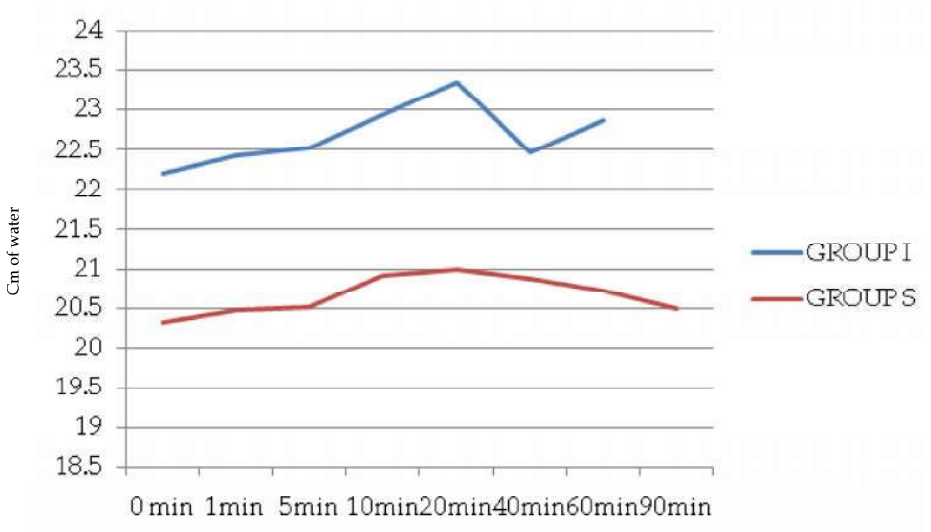

Fig. 3: Comparison of mean peak airway pressure after creating Pneumoperitoneum

Table 3: Comparison of Tidal Volume before creating Pneumoperitoneum

		Group S		Group I	
		Mean	**Standard deviation**	**Mean**	**Standard deviation**
Before creating pneumoperitoneum	0 mins	423.600	44.1475	440.400	46.3213
	5 mins	423.600	44.1475	440.300	47.1699
	10 mins	423.600	44.1475	440.000	47.1699
After creating pneumoperitoneum	0 mins	432.400	37.6696	464.000	39.2641
	5 mins	432.400	37.6636	465.200	38.3101
	10 mins	432.400	37.6696	465.200	38.3101
	30 mins	432.400	37.6696	467.083	37.9335
	60 mins	432.400	37.6696	468.216	35.4256

The above table shows mean tidal volume before and after creating pneumoperitoneum between both the groups (Table 3).

Table 4: Post removal complications between the groups

Symptom	Group S (n=25)	Group I (n=25)
Sore throat	7 (28%)	3 (12%)
Dysphagia	4 (16%)	2 (8%)
Nausea	3 (12%)	2 (8%)
Blood staining	3 (12%)	0
Post extubation cough	5 (20%)	3 (12%)

Discussion

From the time of introduction of supraglotic airway devices various modifications have been made to meet out the needs as similar to that of endotracheal tubes. These modifications now enable us to incorporate these devices in various places as an alternative to endotracheal tubes. Various models of supraglottic airway devices have been manufactured to overcome the needs of other. We have used two newer supraglottic devices LMA supreme and IGEL to compare their efficacy in airway seal during laparoscopic surgeries with positive pressure ventilation. Also we have compared both the devices in terms of ease of insertion, time taken for insertion, number of attempts required for insertion, peak airway pressure before and after creating pneumoperitoneum, haemodynamic variations and complications of their use. Various authors have assessed these devices individually as observational studies and some authors also compared the SGA devices to assess the superiority of one over the other.

In our study, both LMA supreme and I GEL group were comparable in terms of demographic data and anthropometric values.

Varghese et al. observed that the ease of insertion of LMA supreme and LMA proseal on 36 patients were identical and there were no failures in inserting the device in both the groups [6]. Similarly in our study, only 5 patients in IGEL group and 3 patients in LMA supreme group was given a score of 2 in ease of insertion, thereby inferring that both the devices are equally effective in terms of ease of insertion.

Hosten T et al. demonstrated that the number of attempts of insertion were identical in both LMA Proseal and LMA Supreme devices among 60 adult patients [8]. Similarly, Majority of the patients were inserted in the first attempt itself, whereas 4 patients in LMA supreme group and 5 patients in IGEL group had a need for second attempt for inserting the devices successfully. So both the devices were identical in terms of number of insertion attempts.

All patients in LMA supreme group were successfully inserted with a ryles tube (Insertion score 1); whereas there was some difficulty encountered in inserting the ryles tube in I GEL group. 5 patients were given score 2 which means that it was not very easy to insert ryles tube in these patients. There was a statistically significant difference between both the groups showing that LMA supreme is superior to IGEL in terms of ease of insertion of ryles tube.

Sang Yoong Park et al. compared the I-gel and LMA Supreme airway devices during laparoscopic cholecystectomy regarding sealing pressure and respiratory parameters before, during, and after pneumoperitoneum. The gastric tube insertion time was longer in the I-gel group than in the SLMA group [9].

Our study also showed the similar result. The peak airway pressures between the groups before creating pneumoperitoneum, there was no audible leak throughout the period before creating pneumoperitoneum. Even though there was a statistically significant difference at 20th minute depicting a rise in peak airway pressure due to manipulations done to create pneumoperitneum at that point of time, both the devices were not having any audible leak at any point before creating pneumoperitoneum. This shows that both devices are equally effective in providing an adequate airway seal with positive pressure ventilation before creating pneumoperitoneum.

Peak airway pressure after creating pneumoperitoneum was also noted to compare the efficacy of airway seal among both the devices during rise in intrabdominal pressure. Even though there was a rise in peak airway pressure in I GEL group making a statistically significant difference in airway pressure after creating pneumoperitoneum which makes the parameter not comparable. There was no clinically audible leak in any of the devices after creating pneumoperitoneum. Both the devices were equally effective in sustaining the raise in peak airway pressures without leak during pneumoperitoneum and trendlenberg position. The

intrabdominal pressure was maintained between 14-15 cm of water in both the groups. In both the devices, peak airway pressure did not rise above 22 cm of water. Comparing the devices in higher peak airway pressures above 25 cm of water is not possible in this study.

The tidal volume which was set based on patients weight before creating pneumoperitoneum was not statistically significant. Whereas there was a statistically significant increase in tidal volume requirement to maintain ventilation and Etco 2 in I GEL group when compared to LMA supreme group. This increase in tidal volume requirements may be due to rise in peak airway pressures after creating pneumoperitoneum in IGEL group. Though there was a moderate increase in tidal volume requirement for maintaining ventilation, both the devices were equally effective in providing airway seal with a minimal increased requirement of tidal volume in I GEL group. Thus inferring that both devices are equally effective in working performance also.

In terms of post removal complications of the device, LMA supreme was associated with increased incidence of sore throat (28%), post removal cough (20%), dysphagia (16%)and nausea (12%) when compared to IGEL. The probable cause may be due to inflatable cuff of LMA supreme would have produced an increased pressure over the laryngeal mucosa causing these post removal complications.

W.H.L. Teoh et al. compared the efficacy of the inflatable cuff of the LMA Supreme against the non-inflatable I GEL in providing an adequate seal for laparoscopic surgery in the Trendelenburg position in 100 female patients [10]. Many parameters like ease of insertion, number of insertion attempts, ease of ryles tube insertion, peak airway pressures were compared between both the devices. They concluded that both the devices were identical in terms of ease of insertion, number of insertion attempts. They also found that gastric tube insertion was easier and achieved faster with LMA supreme when compared to IGEL. They also found that there was blood on removal of two LMA Supreme patients and one I-gel patient. Four patients in the LMA Supreme group and one patient in the I-gel group experienced mild postoperative sore throat [11]. Our study was also consistent with the above study in terms of ease of insertion, number of attempts of inserting the device, ease of ryles tube insertion and post removal complications. In our study also there was a moderate increase in tidal volume requirement in I GEL group for maintaining ventilation.

Conclusion

In conclusion, both LMA Supreme and IGEL are equally effective in maintaining adequate airway seal in laparoscopic surgeries with positive pressure ventilation in trendlenberg position. Both the devices were similar in terms of ease of insertion, number of insertion attempts, time taken for insertion. LMA supreme is superior over I GEL in terms of ease of insertion of Ryles tube. Increased requirement of inspiratory tidal volume in I GEL group when compared to LMA supreme group for maintaining the ventilation. Post removal complications like sore throat, dysphagia, and blood stain on removal are seen more in LMA supreme group when compared to I GEL group.

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