Comparison of clinical performance of laryngeal mask airway supreme™ and I-gel™ in patients undergoing elective non-laparoscopic surgeries

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Abstract

Supraglottic airway devices have a special niche for themselves with regards to airway management in modern anaesthesia practice. They have become a very good alternative to mask ventilation and tracheal intubation in elective surgeries and have an important place in the emergency settings. The single-use supraglottic airway devices I-gel™ and LMA-Supreme™ have been developed with the aim to overcome the limitations and improve the efficacy of currently available supraglottic airway devices like there airway sealing pressure, ease of placement but with discordant results with regards to airway sealing pressure, ease and success of placement and airway morbidity. The aim of this prospective, randomized trial was to evaluate these two airway devices in routine clinical practice.

Materials and Methods: 80 patients (ASA grade1-2) were randomly allocated to two groups; Group I (I-gel™; n=40) and Group S (LMA-Supreme™; n=40). A size 3 or 4 (I-gel™ and LMA-Supreme™) was used in patients and inserted by experienced anaesthesiologists who had 3 years' experience and had performed 20 successful insertions with each device. First attempt success rate, time for insertion and airway sealing pressure of each device was measured. Airway sealing pressure with LMA-Supreme™ was measured at an intracuff pressure of 60cmH_2O. Patients were enquired after surgery for the presence of any dysphagia, sore-throat or hoarseness of voice. Data were analyzed statistically using unpaired 't' test and Chi-square test. A p value of < 0.05 was considered to be statistically significant.

Results: The first attempt success rate for I-gel™ was 92.5% and for LMA-Supreme™ was 87.5%. Ventilation was established in 19.7 seconds (range 14-24 seconds) in the I-gel™ group and in 24.2 seconds (range 19-29seconds) in LMA-Supreme™ group ($p<0.001$). There was no failure in either of the groups. Mean airway sealing pressure was comparable between both the devices (I-gel™ 23.2 cmH_2O; LMA-Supreme™ 22.4 cmH_2O; $p>0.001$).

Conclusion: Both I-gel™ and LMA Supreme™ are disposable, latex-free devices which do not need any digital or introducer tool for insertion. They have good airway sealing pressures, ease of insertion and low airway morbidity especially with I-gel, so they can be a good choice in patients undergoing elective surgeries.

Keywords: I-gel, LMA supreme, Airway sealing pressure.

Introduction

The advent of supraglottic airway devices (SGA) has revolutionized the management of airway for anaesthesiologists and they are being increasingly used for routine practice by them. The newer second generation SGA have an extra channel for passage of a gastric catheter which helps in draining the gastric contents.[1] The latest devices like *LMA Supreme™* and *I-gel™* have been developed to overcome the limitations of previously available supraglottic airway devices like high cost, need for gentle handling to prevent any damage to the cuff, difficulty in placement of the device and concern over the efficacy of cleaning reusable devices.

The *Laryngeal Mask Airway Supreme™* (LMA-S™; Laryngeal Mask Company, Henley-on-Thames, United Kingdom) is a single-use airway device featuring elements of both the ILMA Fastrach™ with its preformed shape and the LMA ProSeal™ with its oesophageal drainage tube to suction gastric contents[2]. *LMA Supreme* is easy to insert and does not need any digital or introducer tool for its placement. It has a preformed shape with an elliptically shaped airway tube that ends distally at the laryngeal mask. It has a built-in bite block that decreases the chances of tube damage and obstruction by patient biting. It is made of medical grade PVC and is latex free.[3]

The *I-gel™* (Intersurgical Ltd, Wokingham, Berkshire, United Kingdom), is a disposable single-use supraglottic airway device that also has an extra tube for passage of a gastric suction catheter.[2] *I-gel™* has a unique design. It has a non-inflatable cuff made from a gel-like thermoplastic elastomer.[4] The special features are the absence of a cuff, obviating the need for cuff inflation with a widened, flattened stem to act as a stabilizer within the buccal cavity and decreases the chances of device malposition.

The supposed benefits of both devices include easier and quicker placement, increased efficacy in terms of more effective ventilation, better airway protection and minimal compression of the oropharyngeal structures.[5-7]

Aims

Our study compared LMA Supreme™ and I-gel™ in anesthetized patients undergoing non-laparoscopic

surgeries; in terms of ease of placement, airway sealing pressure, the number of attempts for proper placement, ease of positioning of the gastric catheter, airway trauma and bronchospasm / laryngospasm.

Materials and Methods

The study was conducted after obtaining ethical committee clearance. The clinical trial registration number for this study is CTRI/2017/04/008357. A total of eighty ASA grade I-II patients whose age ranged between 18 to 60 years, and were scheduled to undergo non-laparoscopic elective surgery participated in this study. Patients having a high risk of aspiration (gastroesophageal disease, hiatus hernia), morbid obesity (BMI > 35 kg/m2), cervical spine disease or difficult airway were excluded from the study. Patients selected for surgery were randomly allocated to one of the two groups based on computer-generated codes.

-Group I (n=40) for I gel™

-Group S (n=40) for LMA Supreme™ (LMA-S™)

Written informed consent was taken from the patients prior to enrollment into the study.

Tab alprazolam 0.5 mg and tab ondansetron 8 mg were given 1 hour prior to surgery to all patients as premedication. On arrival in the operating room, a multiparameter monitor was connected to the patient to monitor heart rate, blood pressure, oxygen saturation (SpO_2) and end-tidal carbon dioxide concentration ($EtCO_2$). Injection Glycopyrrolate 0.2 mg was given intravenously. The airway devices were checked prior to use as per manufacturers recommendations.[3,8] Preoxygenation with 100% oxygen was done for 3 minutes. The patients were given intravenous Fentanyl 2 $\mu g.kg^{-1}$ and then induced with Propofol $2mg.kg^{-1}$. After the loss of eyelash reflex, all the patients were ventilated with bag and mask with 40% O_2, 60% N_2O and Isoflurane 1 MAC. Vecuronium bromide 0.1mg. kg^{-1} intravenous was used to attain neuromuscular blockade.

After three minutes of giving vecuronium bromide, the device chosen (I-gel™ or LMA Supreme™) was inserted. Device insertion was carried out strictly in accordance with the manufacturer's instructions as written in the instruction manual by an experienced anesthetist. The size of the devices was selected as per the manufacturer's recommendations (*LMA-S™*: size 3 in 30-50 kg patients, size 4 in 50 -70kg patients and size 5 in 70 -100kg patients; *I-gel™*: size 3 in 30-50 kg patients, size 4 in 50- 90kg patients and size 5 in patients over 90 kg).

An effective airway was judged by a square wave capnographic waveform, normal thoracoabdominal movement, and absence of a leak. In case of failure to achieve an effective airway, the device was removed and a second attempt was taken. If an effective airway was not attained after a second attempt, failure of placement was recorded.

In case of failure of insertion of the device, the trachea was intubated with an appropriate size cuffed endotracheal tube. Following parameters were recorded after the insertion of devices-

1. The number of insertion attempts.
2. The ease of insertion of the device. It was defined as no resistance to insertion in a single manoeuvre. Ease of insertion of device was recorded as "no or minimal resistance" as grade 0, "significant resistance" as grade 1 and "impossible to pass without excessive force" as grade 2. In a grade 1 insertion, there was resistance to insertion or more than one manoeuvre was required for inserting the device like neck extension or flexion, chin lift and gentle push or pulling of the device.
3. Device placement time. It was noted from the point of picking up of the device to the appearance of a square wave capnographic waveform.
4. The ease of placement of the gastric tube. Its proper placement was judged by epigastric auscultation on injection of air through the tube or aspiration of gastric contents.
5. The airway sealing pressure. It was measured by closing the expiratory valve of the circle system at a fixed oxygen flow of 3 L/min and observing the pressure at which the aneroid manometer dial connected to the airway device reached stability. The airway sealing pressure can also be assessed by observing for end-tidal carbon dioxide in the oral cavity, detection of an audible leak by listening over the mouth and neck auscultation just lateral to the thyroid cartilage for an audible noise. Cuff inflator/pressure gauge from Portex Germany was used to determine the airway sealing pressure. For LMA Supreme™ airway sealing pressure was noted at an intracuff pressure of 60cm H_2O.

Anaesthesia was maintained with 40% O_2 + 60% N_2O + Isoflurane and intermittent doses of intravenous vecuronium and fentanyl. Hemodynamic parameters, oxygen saturation, and end-tidal carbon dioxide were recorded just before induction, at 1 and 5 minutes after placement of the device and then at every 5 minutes till the surgery lasted.

After the surgery anaesthesia was discontinued, neuromuscular blockade reversed and the device was removed. Adverse events like hypoxemia, laryngospasm or bronchospasm, blood staining of the device, tongue/lip/dental trauma were recorded. Regurgitation of gastric contents with a pH strip was also assessed. Airway morbidity was assessed as sore throat or hoarseness of voice in the post anaesthesia care unit by an independent observer who was blinded to the group assignment.

Statistical Analysis

To estimate the required sample size, we used the published data on airway sealing pressures. Assuming a mean airway sealing pressure of 24 cm H_2O for I-

gel[TM6,9] and 26 cm H_2O for LMA Supreme[TM5,7] and a standard deviation of 5 cm H_2O for both the devices, a sample size of 37 per group was required to detect differences with 80% power and a significance level of 0.05. So, a sample size of 40 per group was chosen. Statistical techniques included quantitative and qualitative analysis. Unpaired t-tests were used for comparison of continuous variables between the two groups. Chi-square or Fisher's exact test was used to assess the difference between groups for categorical variables. P value of <0.05 was taken as significant.

Results

The flow of participants in this randomized trial is shown in the Consort flowchart (Fig. 1). A total of 92 patients were assessed for eligibility. Out of these 2 patients refused to give consent and 10 patients did not meet the eligibility criteria. Rest 80 patients were randomized and allocated in two groups of 40 each.

The two groups were comparable in respect to demographic data, surgical details (Table 1) and the number of predictors of a difficult airway. (Table 2)

The mean airway sealing pressure for I-gel[TM] was 23.2 cm H_2O and for LMA Supreme[TM] was 22.4 cm H_2O. The difference was statistically not significant. (p>0.05) (Table 3). The success rate at first attempt of insertion were 37/40 (92.5%) for I-gel[TM] and 35/40 (87.5%) for LMA Supreme[TM] which was statistically not significant**.** (p>0.05) (Table 3). In all patients, a maximum of two attempts were required for successful placement of the supraglottic device, I-gel[TM] or LMA–Supreme[TM]. Manoeuvres to properly place the devices in the form of neck extension or flexion, chin lift, jaw thrust and gentle pushing or pulling of the device were needed in four patients in I-gel[TM] group and six patients in LMA Supreme[TM] group.

The ease of insertion of I-gel [TM] 36/40 (90%) was slightly more as compared to LMA Supreme[TM] 35/40 (87.5%), although the difference was statistically not significant. (p>0.05) (Table 3). The mean time taken for device insertion in our study was 19.7 sec with I-gel[TM] as compared to 24.2 sec with LMA Supreme[TM] which is a statistically significant difference. (p<0.05) (Table 3).

Gastric tube placement was easy with both the devices. (p>0.05) (Table 4). The incidence of perioperative airway morbidity was significantly higher in the LMA Supreme[TM] group as compared to the I-gel[TM] group (Table 4). Sore throat was recorded in six patients in the LMA Supreme group but in none of the patients in the I-gel[TM] group. Trauma and blood staining of the device was seen in one patient in the LMA Supreme[TM] group.

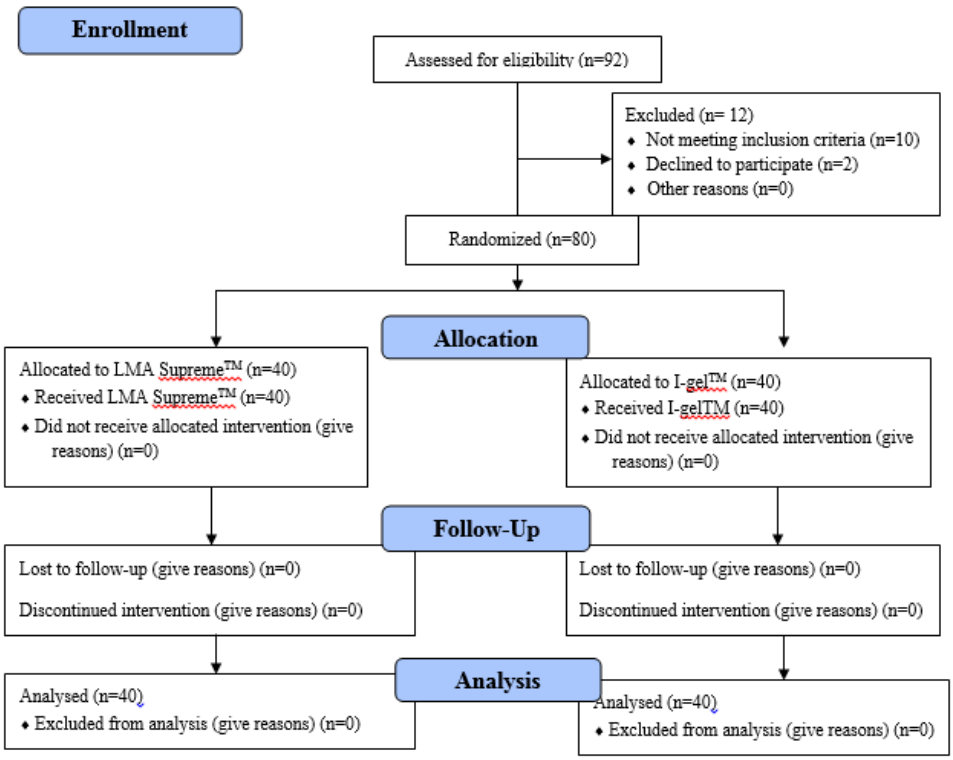

Fig. 1: Consort flow diagram for the study patients

Table 1: Demographic data (Mean±SD or n)

Particulars	I-gel	LMA – Supreme
Age (yrs)	39.05±12.07	39.38±12.61
BMI (kg/m^2)	24.09±3.82	25.49±4.83
Gender		
Male (n1)	18	12
Female (n2)	22	28
N = n1 + n2	40	40
Type of surgery		
Humerus and radius plating	5	3
Skin grafting	8	5
Total abdominal hysterectomy	17	22
Open cholecystectomy	8	9
Appendicectomy	2	1

Table 2: Predictors of difficult airway

Particulars	I-gel	LMA-Supreme
Modified Mallampati (MMP) Classification I/II/III	20/18/2	21/16/3
Inter incisor gap (cm)	4.95±0.36	5.11±0.42
Thyromental distance (cm)	7.5	7.3

Table 3 Comparison of airway sealing pressure, ease of insertion, insertion attempts and time taken for insertion

Parameters	I-gel	LMA Supreme	p value
Airway sealing pressure (cm H2O) Average (SD)	23.20±6.24	22.40±3.67	>0.05
Ease of insertion (n)			
Easy	36	35	>0.05
Difficult	4	5	
Insertion attempts(n)			
1	37	35	>0.05
2	3	5	
Failed	0	0	
Time taken for insertion (seconds) Mean (SD)	19.73±5.24	24.25±5.53	<0.05

Table 4 Comparison of other parameters

Parameters	I-gel	LMA Supreme	p value
Ease of gastric tube insertion			
Easy	39	39	>0.05
Difficult	1	1	
Failed	0	0	
Blood staining of device			
Yes	0	1	>0.05
No	40	39	
Tongue–lip dental trauma			
Yes	0	1	>0.05
No	40	39	
Bronchospasm/ laryngospasm	0	0	>0.05
Hoarseness	0	0	>0.05
Regurgitation	0	0	>0.05
Sore Throat	0	6	<0.05
Coughing	0	0	>0.05

Discussion

The ease of placement and efficacy of a new airway device is of paramount importance especially in emergency difficult airway scenarios as an easy to use device may substantially increase patient's outcome and decrease airway morbidity and mortality. For people not having enough experience, insertion of a supraglottic airway device may be a complex act and may prove to be a significant disadvantage, especially in emergency situations.[4,10,11]

From the results of our present clinical trial both devices appear to be simple and safe alternatives to

secure the airway. The first attempt success rate of insertion of I-gel™ was greater (92.5%) as compared to LMA Supreme™ (87.5%), although the difference was statistically not significant. Two attempts were needed for device placement in three patients in the I-gel™ group and in five patients in the LMA Supreme™ group. Our overall insertion success rate was 100% with no failure of device placement in any of the patients. Other studies have also reported similar findings.[5,12] Gatward et al[6] have reported a first attempt success rate of 86% with I-gel™ but their lower success rate could be due to the fact that the patients in their study were not paralyzed. Similar results with a lower first attempt success rate in non-paralyzed patients have also been reported by Franken et al[13] (2010). They have reported a first attempt success rate of I-gel ™ 80% and LMA-Supreme ™ 86%. Theiler et al[2] (2009) conducted a crossover, randomized controlled trial comparing the performance of I-gel™ and LMA Supreme™ in sixty anesthetized patients and reported a first attempt success rate of 85% with I-gel™ and 93% with LMA Supreme™. But their study was conducted in simulated difficult airway scenario.

In our study, we observed that the ease of insertion with both the devices was almost the same (I-gel ™ - 90%, LMA Supreme™ -87.5%). Airway maneuvers (neck extension or flexion, chin lift, jaw thrust and gentle pushing or pulling of the device) were carried out in four out of forty patients in the I-gel™ group and in five out of forty patients in the LMA Supreme™ group. The mean time taken for device insertion in our study was 19.7 sec with I-gel™ as compared to 24.2 sec with LMA Supreme™ which is a statistically significant difference. Due to its shape, firm body, bite guard and buccal stabilizer I-gel™ is easy to place.[14] In addition, this difference can be accounted for by the fact that I-gel™ does not have an inflatable cuff. Francksen et al[12] (2010) have reported similar results in their study (10sec for I-gel™ and 18sec for LMA Supreme™) although the time taken for insertion of both the devices in their study is significantly less than in our study (19.7sec for I-gel™ and 24sec for LMA Supreme™). But they have not specified the endpoint taken for measuring the time of device insertion. Mukkadder et al[12] have also reported similar results. Bamgbade et al[15] had a first attempt insertion time of less than 5 seconds in 290 patients.

Airway sealing pressure is measured with supraglottic devices to quantify the efficacy of the seal of the airway.[16] It is of great value as it serves as an indicator of the effectiveness of positive pressure ventilation and the level of airway protection offered by the device. In the present study, the mean airway sealing pressure for I-gel™ was 23.2 cm H_2O and for LMA Supreme™ was 22.4 cm H_2O. The difference was statistically not significant. The airway sealing pressure of both the devices was comparable. Keller C, et al[17] and Lopez - Gil et al[18] compared four tests for measurement of airway sealing pressure (detection of an audible noise, detection of end-tidal carbon dioxide in the oral cavity, observation of the aneroid manometer dial to note the airway pressure at which the dial reached stability and detection of an audible noise by neck auscultation) and their results showed that all four tests were excellent. They also recommended that the manometric stability test might be more suitable for researchers comparing airway sealing pressures which we have used in our study. The airway sealing pressure determined for I-gel™ and LMA Supreme™ are similar to those reported by other studies.[2,5,6,19] Chen et al[20] reported a meta-analysis which included ten studies comparing I-gel™ and LMA Supreme™. They concluded that both the devices had comparable airway sealing pressures.

In our study, we had difficulty in placement of the gastric tube in the first attempt in one patient each in the I-gel™ group and in the LMA Supreme™ group. This may have occurred due to suboptimal placement of the device. But our overall success rate of placement of gastric tube was 100%. This is also very similar to the success rates reported in other studies.[2,21-23]

Airway morbidity following anesthesia is an important consideration in the current scenario where patient's satisfaction needs to be balanced with cost containment. The airway morbidity following anesthesia using supraglottic airway devices is dependent on a lot of factors like the depth of anesthesia, the method of insertion, the number of insertion attempts,[24] the mode of ventilation used, the time of anaesthesia[24] and on the type of postoperative analgesia provided.[25] In this study, we tried to control some of these factors by restricting the attempts of insertion to two and limiting the intracuff pressure for the LMA-Supreme™ to 60cm H_2O. Trauma and blood staining of the device was seen in one case in the LMA Supreme™ group but in none of the cases in the I-gel™ group. None of the patients had regurgitation or aspiration intraoperatively. A sore throat was recorded in six patients in the LMA Supreme™ group but in none of the patients in the I-gel™ group which could be attributed to the absence of cuff in I-gel™. Various studies have reported similar results with minimal incidence of a sore throat with the use of I-gel™ as compared to other supraglottic devices.[6,12,20,26-29] Leak pressure of an SGA is dependent upon a firm seal formed by the cuff with the circumferential tissues.[30] If the pressure exerted by the cuff on the mucosa is more than the mucosal perfusion pressure it will lead to tissue ischemia, which contributes to airway morbidity. The gel-like cuff decreases airway injury and pressure on the neurovascular structures.[15]

Conclusion

I-gel™ and LMA Supreme™ have comparable airway sealing pressures. Their relative ease and rapidity of insertion and good airway sealing pressures

make them useful airway rescue devices in cases of difficult mask ventilation. However, in comparison to I-gel™, LMA Supreme™ takes more time to insert (because of need to inflate the cuff) and is associated with a higher incidence of airway morbidity.

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