Comparison of I-gelTM and LMA-SupremeTM With Respect To Ease Of Insertion, Sealing Airway Pressure And Postoperative Throat Complaints

M Z Abdullah, A Izaham, N A Manap, R A Rahman, J M Zain, A Dan

Citation

M Z Abdullah, A Izaham, N A Manap, R A Rahman, J M Zain, A Dan. *Comparison of I-gelTM and LMA-SupremeTM With Respect To Ease Of Insertion, Sealing Airway Pressure And Postoperative Throat Complaints*. The Internet Journal of Anesthesiology. 2015 Volume 34 Number 1.

DOI: 10.5580/IJA.25993

Abstract

Background: Many types of supraglottic airway devices are now available for clinical use. To ensure patient safety, it is important that their advantages and limitations are studied.

Objectives: This study compared the ease of insertion, sealing airway pressure and incidence of postoperative throat complaints between the single-use supraglottic airway devices I-gelTM and laryngeal mask airway (LMA)-SupremeTM.

Patients and Methods: This was a prospective randomised double-blinded study comparing I-gelTM and (LMA)-SupremeTM. One hundred and twenty ASA I or II non-paralysed patients were randomly allocated to receive either device and assessed for ease of insertion, the sealing airway pressure and the incidence of postoperative throat complaints.

Results: The success rate using I-gelTM and LMA-SupremeTM were comparable but the insertion time was significantly shorter with I-gelTM (14 seconds vs 16 seconds, p = 0.001). The sealing airway pressure was better with LMA-SupremeTM (35 cmH2O vs 30 cmH2O, p = 0.001). The incidence of sore throat and throat dryness was significantly lower in the I-gelTM group as compared with the LMA-SupremeTM group at one hour, 12 hours and 24 hours following anaesthesia. There was no significant difference in the incidence of hoarseness and cough between the two groups at all time intervals.

Conclusion: The I-gelTM and the LMA-SupremeTM were comparable in their successful rates of insertion. The I-gelTM had a significantly shorter insertion time and fewer throat complaints, but the LMA-SupremeTM maintained a better sealing airway pressure.

INTRODUCTION

Supraglottic airway devices are frequently used for routine anaesthesia and have gained acceptance in emergency airway management. Currently, a wide range of supraglottic airway devices are available for airway management and these include the LMA-ClassicTM, LMA-SupremeTM, LMA-ProsealTM, Cobra perilaryngeal (CobraPLA®), Streamlined Liner of the Pharynx Airway (SLIPATM) and LMA-FastrachTM(1).

The LMAs and similar supraglottic airway devices have a mask shape that resembles a wedge-shape doughnut in overall design. They use an inflatable cuff to wedge into the upper oesophagus and provide a perilaryngeal seal (1). Most of the supraglottic airway devices required an inflatable mask in order to provide a good seal but this can press the surrounding tissues which may lead to postoperative sore throat (2).

The laryngeal mask airway LMA-SupremeTM (Laryngeal Mask Company, Henley-on-Thames, United Kingdom) is a single-use supraglottic airway device with an inflatable cuff and an oesophageal drainage tube to suction gastric content (3). Verghese & Ramaswamy published a crossover trial that showed equal performance of the LMA-SupremeTM and the LMA-ProsealTM (4).

The I-gelTM (Intersurgical Ltd, Wokingham, Berkshire, United Kingdom) is a novel supraglottic device made up of a thermoplastic elastomer with a soft durometer and gel-like

feel (5). It is a single-use, non-inflatable supraglottic airway for use in anaesthesia during spontaneous or intermittent positive pressure ventilation (5-8). I-gelTM design was inspired by the physiology of the perilaryngeal framework itself.5 The shape, softness and contours accurately mirror the perilaryngeal anatomy to create the perfect fit with no cuff inflation required (5,7,8). This device has several potential advantages including easier insertion, minimal risk of tissue compression and stability after insertion (5,9). Although its cuff is non-inflatable, I-gelTM provides a good seal during anaesthesia for spontaneously breathing patients and for controlled ventilation (10). An integrated gastric channel is provided for passage of nasogastric tube to empty the stomach (5,8,9,11). Theoretically, I-gelTM is able to reduce the incidence of postoperative throat complaints in view of the absence of an inflatable cuff. Shin et al found that the incidence of postoperative sore throat with I-gelTM was lower than LMA-ClassicTM and LMA-ProsealTM (7).

This study aimed to compare the ease of insertion, sealing airway pressure and the incidence of postoperative throat complaints between the supraglottic airway devices, I-gelTM and laryngeal mask airway (LMA)-SupremeTM.

MATERIALS AND METHODS

This was a prospective, double-blinded and randomized trial by a single operator who had an experience of more than twenty successful first attempt insertions for both devices prior to this study. This study was carried out in Universiti Kebangsaan Malaysia Medical Centre (UKMMC) following institutional research and ethics approval. Informed consent was obtained from every patient.

American Society of Anesthesiologists (ASA) physical status I or II in-patients scheduled for any surgery under general anaesthesia where the use of I-gelTM (Intersurgical Ltd, Wokingham, Berkshire, United Kingdom) and LMA-SupremeTM (Laryngeal Mask Company, Henley-on-Thames, United Kingdom) were regarded as an acceptable alternative for airway management were included in this study. The exclusion criteria were neck, throat or oropharyngeal airway surgery, anticipated difficult airway, presence of preoperative sore throat or respiratory infection, risk of gastric aspiration, known allergy or contraindication to medications used in this study and body mass index (BMI) of more than 35 kg/m2.

One hundred and twenty patients, aged between 18 to 65 years, were enrolled and randomly allocated into I-gelTM or LMA-SupremeTM groups. Randomization was done using 'random numbers table' from the website www.randomization.com which generated a number for every patient. Patients with odd numbers were placed into the I-gelTM group and those with even numbers into the LMA-SupremeTM group. Patients were fasted for at least 6 hours before the surgery and oral midazolam 7.5 mg was given as premedication.

All the supraglottic airway devices were lubricated with K-Y jelly over the back of the cuff. The size of devices was chosen according to patients' body weight as recommended by the manufacturers. Both devices were introduced blindly as described by the manufacturer's user booklet. The cuff of the LMA-Supreme™ was fully deflated prior to insertion. Once in place, the cuff of the LMA-Supreme™ was inflated and adjusted to 60 cm H2O using a cuff pressure manometer.

Continuous monitoring of electrocardiogram, non-invasive blood pressure monitor and pulse oximetry were established before induction of anaesthesia. Anaesthesia was induced with intravenous (IV) fentanyl 1.5 µg/kg and IV propofol 2.5 mg/kg. After full jaw relaxation was established, supraglottic airway device was inserted. The placement of the device was confirmed by chest auscultation and capnograph as well as visualization of normal thoraco abdominal movements. Anaesthesia was maintained with 40% oxygen in air with sevoflurane to achieve minimum alveolar concentration (MAC) of 1.0 – 1.2.

All patients were allowed a maximum of three insertion attempts. Patients with failure of insertion after three attempts were paralysed with suxamethonium 1.5 mg/kg and intubated with an appropriate size endotracheal tube. The number of attempts and insertion time were recorded. Insertion time was measured from the time of removal of facemask until successful ventilation of the patient after the airway device was in situ. Successful ventilation is defined as the ability to attain two consecutive tidal volume of at least 6 ml/kg ideal body weight with an anaesthesia machine.11

Gastric tube (size 12 F to 14 F) was inserted through the drain tubes of the devices in all patients. The correct placement of the gastric tube was confirmed by 'gurgling' sounds at epigastric auscultation during insufflation with air.

The airway sealing pressure was determined by closing the adjustable pressure limiting (APL) valve of the circle system

at a fixed gas flow of 3 L/minute. The airway pressure was recorded (maximum allowed 40 cmH2O) when equilibrium was achieved or when there was no audible gas leak. Audible gas leak was determined by listening at the mouth and/or lateral thyroid cartilage using a stethoscope for audible noise.

Patients were initially ventilated with a tidal volume of 6 ml/kg ideal body weight and a respiratory rate of 12 per min with an inspiratory:expiratory ratio of 1:2. The tidal volume and/or respiratory rate were later adjusted to obtain an end-tidal carbon dioxide (ETCO2) between 35-40 mmHg.

At the end of the surgery, sevoflurane was turned off and oxygen was increased to 100%. The supraglottic airway device was removed when the patient had adequate spontaneous ventilation and consciousness, with eye opening to verbal command. The duration of anaesthesia were recorded.

All patients were interviewed by trained personnel who were unaware of the study groups at the recovery area and in the ward at one hour, 12 hours and 24 hours following anaesthesia. Assessment of sore throat, throat dryness, hoarseness of voice and cough were done by direct questioning. The severity of sore throat was assessed using the visual analog score of 1 - 10. If the pain score was more than 5 at 24 hours following anaesthesia, the patient was prescribed with oral paracetamol 1g 6 hourly and thymol gargle 15 ml 8 hourly for 3 days.

Statistics

Sample size was calculated using the formula n = 2 × standard deviation2 × (power + significant level)2 ÷ difference2. Sample size was calculated based on the study by Theiler et al (2009), in which the power of study was 95% and level of significance level was 0.05(3). The calculated sample size including dropout rate of 20 %, was 60 patients in each arm.

All the comparative parameters were analysed using a chi-square test and Student's t-test except for insertion time and sealing airway pressure where Mann-Whitney U test were used because the data were not normally distributed. A p value of less than 0.05 was considered as statistically significant. All statistical analyses were performed using IBM SPSS version 20.

RESULTS

One hundred and twenty patients were recruited into this study with 60 in each group and there were no dropouts. Table I shows the demographic data, type of surgery and duration of anaesthesia. There were no statistical differences in both groups with respect to age, gender, weight, height, BMI, race distribution, type of surgery and duration of anaesthesia.

Table 1

Demographic Data of Patients. Values are expressed as mean ± standard deviation or n, number of patients and percentage in parenthesis.

Parameters	I-gel™ n = 60	LMA-Supreme™ n = 60
Age (yrs)	40.85 ± 16.36	42.00 ± 18.82
Gender		
Male	22 (36.7)	23 (38.3)
Female	38 (63.3)	37 (61.7)
Weight (kg)	64.64 ± 11.22	61.66± 12.40
Height (metres)	1.64 ± 0.17	1.59 ± 0.28
Body mass index (kg/m^2)	22.86 ± 3.84	24.91± 4.30
Race distribution		
Malay	32 (53.3)	38 (63.3)
Chinese	18 (30.0)	13 (21.7)
Indian	6 (10.0)	7 (11.7)
Others	4 (6.7)	2 (3.3)
Type of operation		
General Surgery	25 (41.7)	31 (51.7)
Orthopaedic	19 (31.7)	16 (26.7)
Gynaecology	11 (18.3)	8 (13.3)
Urology	5 (8.3)	5 (8.3)
Duration of operation (hours)	1.10 ± 0.36	1.17 ± 0.39

* p<0.05

Table II shows the sizes of supraglottic airway device used for both groups. Ninety per cent of I-gelTM group used size 4 as compared to 63.3% in LMA-SupremeTM group. The success rate of the first attempt was higher for the I-gelTM (95%) than for the LMA-SupremeTM (81.7%), but both these differences were not statistically significant. There was no failure of insertion in both groups. With regards to insertion time, I-gelTM showed a shorter time with a median of 14 seconds as compared 16 seconds in the LMA-SupremeTM group (p = 0.001).

Table 2

Sizes of Supraglottic Devices Use, Insertion Attempts and Insertion Times. Result presented as n, number of patients and percentage in parenthesis or median with range in parenthesis.

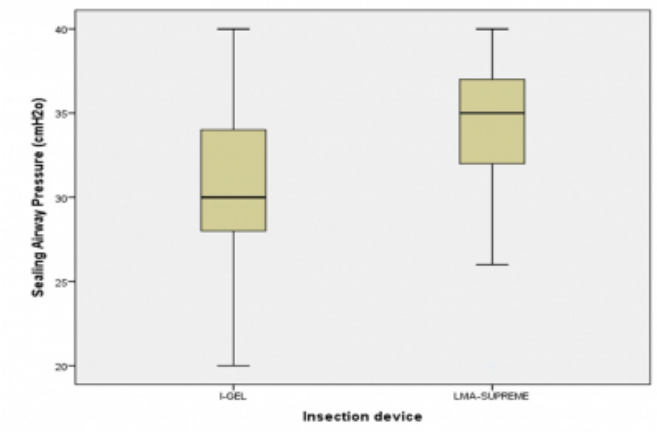
	I-gel™ n = 60	LMA-Supreme™ n = 60
Size of Supraglottic Device		
3	5 (8.3)	16 (26.7)
4	54 (90.0)	38 (63.3)
5	1 (1.7)	6 (10.0)
Insertion attempt /attempts		
1	57 (95.0)	49 (81.7)
2	3 (5.0)	9 (15.0)
3	0	2 (3.3)
Failed	0	0
Insertion time (seconds)	14 (14 – 17)*	16 (16 – 19)*

* p<0.05

The median sealing airway pressure was higher for LMA-SupremeTM group (35 cmH2O) as compared to the I-gelTM group (30 cmH2O), as seen in Figure 1. The difference in sealing airway pressure was statistically significant (p = 0.001).

Figure 1

Comparison of Sealing Airway Pressure. Result presented as median with range.



Overall incidence of sore throat and throat related complaints were higher in LMA-SupremeTM group at one hour, 12 hours and 24 hours postoperatively and were statistically significant, as shown in Tables III and IV. None of the patients required treatment for postoperative sore throat.

Table 3

Incidence of Postoperative Sore Throat at 1, 12 and 24 Hours Postoperatively. Values are expressed as n, number of patients and percentage in parenthesis.

Time	Throats Complaints		I-gel™ n = 60	LMA Supreme™ n = 60
One Hour	Sore throat	No	56 (93.3)	45 (75.0)
		Yes	4 (6.7)*	15 (25.0)*
	Severity (VAS 1–10)			
	1		0 (0)	0 (0)
	2		2 (50.0)*	0 (0)
	3		2 (50.0)*	4 (26.7)*
	4		0 (0)	5 (33.3)*
	≥5		0 (0)	6 (40.0)*
12 Hours	Sore throat	No	60 (100)	50 (83.3)
		Yes	0 (0)	10 (16.7)*
	Severity(VAS 1–10)			
	1			0 (0)
	2			7 (70.0)*
	3			2 (20.0)*
	4			1 (10.0)*
	≥5			
24 Hours	Sore throat	No	60 (100)	53 (88.3)
		Yes	0 (0)	7 (11.7)*
	Severity (VAS 1–10)			
	1			5 (71.4)*
	2			2 (28.6)*
	3			0 (0)
	4			0 (0)
	≥5			0 (0)

* p<0.05

Table 4

Incidence of Postoperative Throat Complaints at 1, 12 and 24 Hours Postoperatively. Values are expressed as n, number of patients and percentage in parenthesis.

Time	Throats Complaints		I-gel™ n = 60	LMA Supreme™ n = 60
One Hour	Throat Dryness	No	59 (98.3)	49 (81.7)
		Yes	1 (1.7)*	11 (18.3)*
	Hoarseness	No	60 (100)	59 (98.3)
		Yes	0 (0)	1 (1.7)
	Cough	No	57 (95.0)	53 (88.3)
		Yes	3 (5.0)	7 (11.7)
12 Hours	Throat Dryness	No	60 (100)	52 (86.7)
		Yes	0 (0)	8 (13.3)*
	Hoarseness	No	60 (100)	60 (100)
		Yes	0 (0)	0 (0)
	Cough	No	59 (98.3)	56 (93.3)
		Yes	1 (1.7)	4 (6.7)
24 Hours	Throat Dryness	No	60 (100)	55 (91.7)
		Yes	0 (0)	5 (8.3)
	Hoarseness	No	60 (100)	60 (100)
		Yes	0 (0)	0 (0)
	Cough	No	60 (100)	58 (96.7)
		Yes	0 (0)	2 (3.3)

* p<0.05

DISCUSSION

We found that there was no significant difference between I-

gelTM and LMA-SupremeTM groups in the success rate at first attempt insertion of the devices. Our finding is consistent with a study by Teoh et al which demonstrated that 47 (94%) LMA-SupremeTM and 48 (96%) I-gelTM patients had the devices successfully inserted at the first attempt (12). However, Ragazzi et al found that the first-time insertion success rate was significantly higher in novice operators for the LMA-SupremeTM (77%) group as compared to the I-gelTM (54%) group. They postulated that the performance of the LMA-SupremeTM was better because the bulky design of I-gelTM makes its insertion less predictable and tongue size more influential (13). In our study, there was no failure of insertion in both groups although the operator had limited experience. Hence we conclude that these devices are easy to use.

I-gelTM group had a shorter insertion time as compared to the LMA-SupremeTM group with a median time of 14 and 16 seconds respectively. Teoh et al determined insertion time by measuring the time from which the device was taken for insertion until the first appearance of the square wave on the capnograph. They demonstrated that the I-gelTM group had a shorter insertion time with a mean of 14.3 seconds as compared 15.4 seconds in the LMA-SupremeTM group (12). Insertion time for LMA-SupremeTM was longer possibly because extra time was taken to inflate the cuff. However, Fernandez et al reported that insertion time for I-gelTM was longer as compared to LMA-SupremeTM. They concluded that the bulky design of the I-gelTM made insertion time longer (14).

This study found that the sealing airway pressure was significantly lower in the I-gelTM group with a median of 30 cmH2O as compared to 35 cmH2O in the LMA-SupremeTM. Teoh et al studied patients undergoing gynaecological laparoscopic surgery also showed that there was no significant difference in sealing airway pressure between the I-gelTM and the LMA-SupremeTM group but a significant air leak in the I-gelTM group was noted with a mean difference of 10 ml between expired and inspired tidal volume after the creation of pneumoperitonium. They suggested that the non-inflatable cuff is more susceptible to airway leaks especially if a wrong size is chosen and anatomical fit is not achieve (12). I-gelTM was postulated to expand with temperature because it is made from thermoplastic elastomer and hence is expected to provide a better airway seal with time during usage (5). Fernandez et al in measuring sealing airway pressure of I-gelTM during surgery found that there was no significant difference in sealing airway pressure at 10, 30, and 60 minutes after I-gelTM insertion (14).

Our results showed that the incidence of sore throat and throat complaints were lower in the I-gelTM group, and this was similar to a meta-analysis finding in 2012 (15). The cuff of I-gelTM being non-inflatable probably decrease the risk of airway tissue compression and hence tissue ischaemia. This study did not limit, standardise or record the use of perioperative of analgesia. We also assumed that the volume of cuff of LMA-SupremeTM or the of I-gelTM were not pressing on the surrounding area of the throat as there were no direct vision done to confirm the placement of the devices after insertion. These factors may have contributed to the throat complaints.

ACKNOWLEDGEMENT

The authors wish to thank the staff of Department of Anaesthesiology & Intensive Care, Universiti Kebangsaan Malaysia Medical Centre for their support.

This research was financially supported by Universiti Kebangsaan Malaysia Medical Centre, Kuala Lumpur, Malaysia.

References

1. Jolliffe L, Jackson I. Airway management in the outpatient setting: new devices and techniques. Curr Opin Anesthesiol 2008; 21:719-22.

2. Brimacombe J, Keller C, Fullekrug B, Agrò F, Rosenblatt W, Dierdorf SF, Lucas EG, Capdevilla X, Brimacombe N. A multicenter study comparing the prosealTM and classicTM laryngeal mask airway in anesthetized, non paralyzed patients. Anesthesiology 2002; 96: 289-95.

3. Theiler LG, Kleine-Brueggeney M, Kaiser D, Urwyler N, Luyet C, Vogt A, Greif R. Crossover comparison of the laryngeal mask supremeTM and the I-gelTM in simulated difficult airway scenario in anesthetized patients. Anesthesiology 2009; 111: 55-62.

4. Verghese C, Ramaswamy B. LMA-SupremeTM: a new single-use LMATM with gastric access: a report on its clinical efficacy. Br J Anaesth 2008; 101(3):405-10.

5. Anon. I-gelTM Single use supraglottic airway: User guide. Berkshire: Intersurgical Ltd; 2007.p.3-17.

6. Kannaujia A, Srivastava U, Saraswat N, Mishra A, Kumar A, Saxena S. A preliminary study of I-gelTM: a new supraglottic airway device. Indian J Anaesth 2009; 53(1):52-6.

7. Shin WJ, Cheong YS, Yang HS, Nishiyama T. The supraglottic airway I-gelTM in comparison with proseal laryngeal mask airway and classic laryngeal mask airway in anaesthetized patients. Eur J Anaesthesiol 2010; 27: 598-600.

8. Richez B, Saltel L, Branchereau F, Torrielli R, Cros AM. A new single use supraglottic airway device with a non inflatable cuff and an esophageal vent: an observational study of the I-gelTM. Anesth Analg 2008; 106(4): 1137-39.

9. Bamgbade OA, Macnah WR, Khalaf WM. Evaluation of the I-gelTM airway in 300 patients. Eur J Anaesthesiol 2008; 25: 865-66.

10. Uppal V, Gangaiah S, Fletcher G, Kinsella J. Randomized crossover comparison between the I-gelTM and the LMA-UniqueTM in anaesthetized, paralysed adults. Br J Anaesth 2009; 103: 882-85.

11. Brimacombe J, Keller C, Brimacombe L. A comparison of the laryngeal mask airway prosealTM and the laryngeal tube airway in paralyzed anesthetized adult patients undergoing pressure-controlled ventilation. Anesth Analg 2002; 95: 770-76.

12. Teoh WHL, Lee KM, Suhitharan T, Yahaya Z, Teo MM, Sia ATH. Comparison of the LMA-SupremeTM vs the I-gelTM in paralysed patients undergoing gynaecological laparoscopic surgery with controlled ventilation. Anaesthesia 2010; 65: 1173-79.

13. Ragazzi R, Finessi L, Farinelli I, Alvisi R, Volta CA. LMA-SupremeTM versus I-gelTM a comparison of insertion success in novices. Anaesthesia 2012; 67(4): 384-88.

14. Fernandez DA, Pacrez VA, Bermenjo GJC, Marcos VJM. SupremeTM laryngeal mask airway vs the I-gelTM supraglottic airway in patients under general anesthesia and mechanical ventilation with no neuromuscular block: a randomized clinical trial. Rev Esp Anestesiol Reanim 2009; 56(8): 474-78.

15. Chen X, Jiao J, Liu L, Wu X. A comparison of the performance of I-gelTM vs the LMA-SupremeTM during anesthesia: A meta-analysis of randomized controlled trials. PLoS ONE 2013; 8(8): e71910

Author Information

Mahmud Zuhdi Abdullah
Department of Anaesthesia and Intensive Care, Sibu Hospital
Sarawak, Malaysia

Azarinah Izaham
Department of Anaesthesiology & Intensive Care, Universiti Kebangsaan Malaysia Medical Centre
Kuala Lumpur, Malaysia

Norsidah Abdul Manap
Department of Anaesthesiology & Intensive Care, Universiti Kebangsaan Malaysia Medical Centre
Kuala Lumpur, Malaysia

Raha Abdul Rahman
Department of Anaesthesiology & Intensive Care, Universiti Kebangsaan Malaysia Medical Centre
Kuala Lumpur, Malaysia

Jaafar Md Zain
Department of Anaesthesiology & Intensive Care, Universiti Kebangsaan Malaysia Medical Centre
Kuala Lumpur, Malaysia

Adnan Dan
Department of Anaesthesiology & Intensive Care, Universiti Kebangsaan Malaysia Medical Centre
Kuala Lumpur, Malaysia