Journal of Anesthesia & Clinical Research

Mogahed and Anwar, J Anesth Clin Res 2017, 8:6
DOI: 10.4172/2155-6148.1000733

Research Article Open Access

The Efficacy Of Non Inflatable Cuff (I-gel and SLIPA) Versus Inflatable Cuff (Soft Seal LMA) Supraglottic Airways In Paralyzed Adult Patients

Mona Mohamed Mogahed* **and Atteia Gad Anwar**

Faculty of Medicine, Tanta University, Tanta, Egypt

***Corresponding author:** Mogahed MM, Anesthiology and Surgical Intensive Care, El Moatasem St, Faculty of Medicine, Tanta University, Tanta, Egypt, Tel: 0201145130150; Fax: 020403292202; E-mail: monamogahedfr@hotmail.com

Received date: May 31, 2017; **Accepted date:** June 15, 2017; **Published date:** June 19, 2017

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Abstract

Aim: To compare the efficacy of non-inflatable cuff supraglottic airways (I-gel and SLIPA) to inflatable cuff soft seal Laryngeal mask airway (SSLMA) in patients requiring general anesthesia and controlled ventilation during elective surgical procedures.

Patients and methods: An experimental study design was used, with comparison of three groups of patients using i-gel, SLIPA and SSLMA. Patients with risk of gastro esophageal reflux were excluded. Ease of insertion, quality of seal, effective ventilation, hemodynamic responses, side effects and surgical time were assessed. . An Oropharyngeal sealing pressure or 'leak' test was performed with the airway devices to quantify the efficacy of the seal with the patient airway. Airway sealing pressure tests claimed to be excellent for clinical purposes.

Results: Overall success of insertion was 100% in i-gel, 97.5% and 95% in SSLMA and SLIPA respectively. The i-gel permitted ventilation with a significantly high tidal volume (485 ± 82 ml) at a significantly low peak airway pressure (12 ± 3 cmH_2O) and a significantly high leak pressure (26 ± 6.3 cmH_2O). All groups show stable hemodynamic responses to insertion and removal of the devices. Insertion time was significantly shorter with i-gel (15 ± 2.5 sec.) compared to SLIPA and SSLMA, 22 ± 4.6 sec. and 19 ± 3.85 sec, respectively. Sore throat was significantly high in SSLMA 30%. Whereas, blood traces on the device and gastric air insufflations were highly significant with SLIPA 8% and 10% respectively.

Conclusion: The three disposable SGAs proved to be suitable for controlled ventilation during elective short surgical operations. The i-gel provides effective ventilation with minimal side effects. Whereas, SLIPA is associated with a high incidence of gastric air insufflations, The Soft Seal LMA provides high leakage volume and incidence of sore throat postoperatively.

Keywords: Laryngeal masks; i-gel; SLIPA; SSLMA; Comparison

Introduction

The supraglottic airway devices (SGAs) are devices that designed to be inserted above the level of the vocal cord for ventilation during spontaneous or intermittent positive pressure ventilation [1]. SGAs provide a possible alternative technique to the use of tracheal tubes during elective surgical procedures. Blind insertion and effective positive pressure ventilation are the advantages of SGAs. The The supraglottic airways are established devices during general anesthesia, for difficult airway management and for airway management during cardiopulmonary resuscitation [2]. SGAs with non-inflatable cuff include The i-gel (Intersurgical Ltd., Wokingham, Berkshire, UK) which is a single-use supraglottic airway device provides a seal without cuff inflation. Its drain tube prevents both gastric insufflations and aspiration, facilitates gastric tube insertion [3]. And the streamlined liner of the pharynx airway (SLIPA Medical Ltd, Douglas, Isle of Man, UK) which is a disposable SAD made of plastic material. It is a hollow boot shaped chamber similar to the contour of the pharynx [4]. SLIPA is designed to decrease the risk of aspiration during positive pressure ventilation [5]. This relates to the large capacity of its hollow structure (50 mL) which is almost double the volume of the stomach contents (26 mL) in fasted patients [6]. The LMA challenged the gold standard of endotracheal intubation with a cuffed tube to maintain a clear airway and provide positive pressure ventilation with a lower risk of trauma [7]. A new single-use disposable supraglottic airway device, the Soft Seal LM (Portex Ltd., Hythe Kent, United Kingdom), has been introduced recently. It is fabricated from latex-free medical-grade plasticized polyvinyl chloride (PVC) [8].

Patients and Methods

A total of 120 patients scheduled for elective general surgery were consecutively recruited in the study. Only patients classified as ASA I and II were eligible for inclusion. The exclusion criteria were high risk for pulmonary aspiration: diabetic, obese and pregnant women. Patients having lung disease, difficult airway, surgery performed in non supine position, oral or nasal surgery and preoperative sore throat were also excluded.

Approval was given by the Hospital Ethics Committee prior to study commencement. Informed signed consent was obtained from each patient participating in the study. The maneuvers and medications used are not harmful to the patients when professionally used, and have been used in the management of similar cases.

During pre-anesthetic evaluation, the patient's age, gender, heights, weights, Mallampati grade mouth opening and thyromental distance were recorded. After placement of pulse oximeter (SPO_2), electrocardiogram (ECG) and non-invasive blood pressure (NIBP) monitor, intravenous 1 μg/kg fentanyl was given. Following pre-oxygenation for 3 min, anesthesia was induced with 3 mg/kg propofol and 0.5 mg/kg rocuronium. The lungs were ventilated manually with sevoflurane (2%-3%) and O_2 100% via a facemask with or without the use of an oral airway. One minute later a single anesthesiologist inserted the airway device as out-lined in the manufacturer's instructions. Before insertion, a water-soluble lubricant was applied to all devices. The i-gel was grasped along the integral bite block and was introduced into the mouth towards the hard palate until resistance was felt. The SLIPATM was introduced into the pharynx. The SSLMA was introduced with the cuff partially inflated till a definite resistance was felt as the tip entered the hypopharynx. The cuff was inflated to a 'just seal' pressure, defined as no leak on gentle manual ventilation. If substantial leakage occurred despite optimal placement another 10 ml of air was added. Then the SGA was secured after successful placement.

Successful placement and adequate ventilation was confirmed by clinically observing bilateral chest wall movement, square capnogram waveform during manual ventilation, and silent epigastrium by auscultation. An Oropharyngeal sealing pressure tests were performed using continuous fresh gas flow of 3 L/min was set with the adjustable pressure-limiting valve closed and the circuit connected to the reservoir bag. Stopping ventilation, keeping the patient apneic, and recording the airway pressure at which equilibrium was achieved. At this time, air leak can be detected at the mouth by hearing an audible noise coming from the mouth or by putting a stethoscope just lateral to the thyroid cartilage The leak volume was calculated as the difference between the inspired and the expired tidal volumes [9]. Intermittent positive pressure ventilation with tidal volume 8ml/kg and respiratory rate of 10/min, then started. Tidal volume and respiratory rate were adjusted to maintain $ETCO_2$ between 35 and 40 mmHg. Anesthesia was maintained with sevoflurane (2%-3%). Intraoperative analgesia was maintained with intravenous infusion of diclofenac sodium 75 mg in 100 ml normal saline, with supplementary fentanyl 25-50 μg iv given as required. Rocuronium 0.1mg every 20 min was given.

If the first insertion was unsuccessful, the patient received a supplementary dose of propofol up to 1 mg/kg and the head was repositioned to permit another attempt. If the third attempt was unsuccessful, it was to be recorded as a failure and the patient had an endotracheal tube inserted. An unsuccessful attempt of insertion was defined as placement of the device into the mouth and withdrawal from the mouth. Insertion time was noted i.e. the time (in sec) taken from opening the patient's mouth to successful SGAs insertion. The size of the SSLMA and i-gel were chosen, based upon body weight, according to the manufacturer's recommendations. The SLIPA size was chosen by matching the width across the thyroid cartilage with that of the bridge of the SLIPA. Blood pressure, heart rate and O_2 saturation were measured before anesthesia, immediately before airway placement, and five minutes after placing the airway. Gastric air insufflations were monitored by auscultation of the patient's stomach, immediately after insertion of the airway, after positioning, and at the end of surgery. After surgery, muscle relaxant was reversed by atropine and neostigmine. Once consciousness is regained and protective reflexes have returned, gentle suction around the airway device in the pharynx and hypopharynx, by asking the patient to open his/her mouth wide, was done. SGA was removed and replaced with oxygen facemask. The blood or gastric fluids on SGA devices were noted. In the recovery room, the patient continued to breathe oxygen and was monitored for 30 minutes. Presence of sore throat was enquired at 2 and 24 hours after surgery.

Thereafter, the single anesthesiologist who inserted the devices gave a subjective assessment of the insertion procedure and the handling of each device. The overall performance was rated as high, moderate, low and poor.

Results

Table 1 shows the demographic data of the patients. All groups were similar as regards age and sex distribution. No statistically significant differences were revealed regarding their body weight and height, ASA classification, predictors of difficult airway and duration of surgeries.

	i-gel (n _40)	SLIPA (n _40)	SSLMA (n_40)	P value
Height (cm)	165 ± 5	169 ± 5	170 ± 6	0.214
Weight (kg)	786	75 ± 4	74 ± 6	0.986
Age (yr)	55 ± 10	49 ± 13	52 ± 12	0.241
Sex (M – F)	30-Oct	25/15	21/19	0.112
ASA I/II	23/17	25/15	22/18	0.78
Mallampati I/II/III /IV	20/16/4/0	21/16/3/0	19/18/3 /0	-
Mouth opening (mm)	49 ± 10	50 ± 9	44 ± 10	0.542
Thyromental Distance(mm)	64 ± 14	70 ± 12	69 ± 13	0.754
Duration of surgery (min)	32.20 ± 5.36	33.25 ± 6.87	31 ± 4.36	0.639

Table 1: Description of patients in the three study groups.

As shown in Table 2 The seal quality in all devices ('I-gel', SLIPA^{TM} and the SSLMA) permitted the use of low flows tidal volumes , 485 ± 82 and 451 ± 30 and 402 ± 23 mL (P=0.2) respectively. The peak pressure was significantly high in the SLIPA group (16 ± 3 cm H_2O), while leak pressure was significantly high in i-gel group (26 ± 6.3 cm H_2O). End tidal CO_2 was significantly higher in SSLMA group (40 ± 3 mm Hg).

	i-gel (n _40)	SLIPA (n _40)	SSLMA (n _40)	p value
Tidal volume (mL)	485 ± 82	451 ± 30	402 ± 23	**0.028***
Respiratory rate (bpm)	11 ± 1	13 ± 2	11 ± 2	**0.079**

End-tidal CO_2 (mm Hg)	36 ± 4	38 ± 2	40 ± 3	**0.022***
Peak pressure (cm H_2O)	12 ± 3	16 ± 3	14 ± 4	**0.041***
Leak volume (ml)	20 ± 2	24 ± 1.5	26 ± 6.3	**0.044***
Oropharyngeal sealing pressure (cm H_2O)	28 ± 3	24 ± 7	19 ± 2	**<0.001***
(*)Significant p. value <0.05				

Table 2: Ventilation parameters, peak pressure and leak pressure.

There were no significant differences in hemodynamic variables and oxygen saturation percent (S_pO_2) values between the three groups at any time (Figure 1).

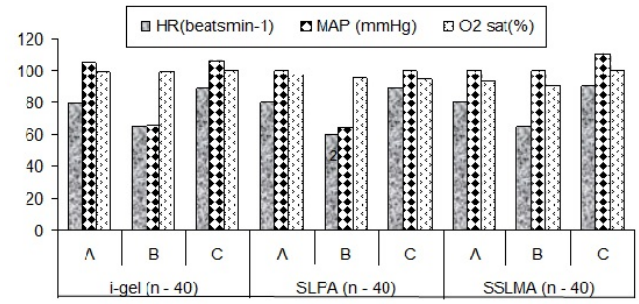

Figure 1: Hemodynamic variables between the three groups, A= before anesthesia , B= immediately before airway placement , C= five minutes after placing SGAs.

In the i-gel group, a significantly high successful placement was established in 38 patients (95%) on the first attempt and in the remaining 2 patients (100%) on the second attempt. In the SLIPA group, device insertion was successful in 34 patients (85%) on the first attempt, in four patients (95%) on the second attempt and in two patient (5%) failed attempts. In LMA group, insertion was successful in 35 patients (87.5%) on the first attempt, in three patients (95%) on the second attempt, in one patient (97.5%) after three attempts and one failed (2.5%). Time of insertion was comparable with the SLIPA (22 ± 4.6 sec.) and the SSLMA (19 ± 3.85 sec.), it was significantly (p=0.033) shorter in the i-gel group (15 ± 2.5 sec) (Table 3).

Insertion of the airway device was generally easier in the i-gel and SSLMA groups compared to the SLIPA. A high performance was noted in the i-gel group 26 patients compared with 22,24 in the SLIPA and SSLMA group respsectively (Figure 2).

	i-gel	SLIPA	SSLMA	P value
1st attempt success rate	95%	85%	87.50%	0.038*
Overall success rate	100%	95%	97.50%	0.248
Insertion time (sec.)	15 ± 2.5	22 ± 4.6	19 ± 3.85	0.033*
(*) Significant p. value <0.05				

Table 3: Success rate (%) and insertion time: I-gel , SLIPA and SSLMA.

Maximum airway sealing pressure was 28 ± 3 cm H2O , 24 ± 7 cmH2O and 19 ± 2 cmH_2O in the i-gel and the SLIPA and SSLMA groups, respectively. No major adverse event occurred during the perioperative period in any patient in our study. However, one patient in the SLIPA and two in the SSLMA groups experienced bronchospasm and airway obstruction two min. after device insertion. In second attempt, airway was replaced by a smaller device in two patients in the SLIPA group and in three patients in the SSLMA group. The airway was replaced by a larger device in two patients in the SLIPA group and in one patient in the SSLMA group.

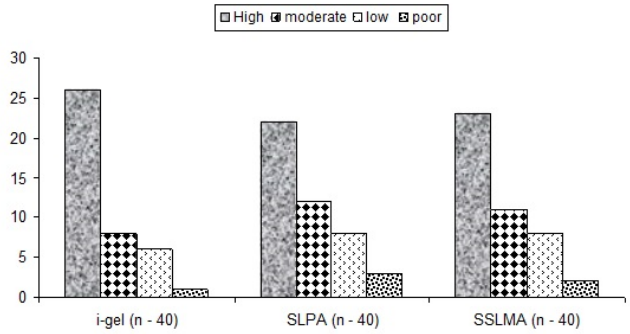

Figure 2: Subjective assessment of overall performance.

Group	i-gel	SLIPA	SSLMA	p value
Gastric air insufflations (%)	0	10	5	0.042*
Blood traces on airway device (%)	4	8	6	0.033*
Incidence of sore throat (%)	8	20	30	0.028*
(*)Significant p. value <0.05				

Table 4: Side effects associated with i-gel, SLIPA and SSLMA.

Side effects associated with i-gel, SLIPA and SSLMA are shown in (Table 4). Gastric air insufflations and blood trace were significantly high in the SLIPA group (10, p=0.042 and 8, p=0.033 respectively). No gastric fluids were found. Sore throat in the postoperative period was

significantly high in SSLMA group (30, p=0.028) after 2 hours. No complain was recorded after 24 h in the three groups.

Discussion

SGA devices have become widely used in the anesthesia practice and airway management as an alternative to tracheal intubation during spontaneous or controlled ventilation [10].

In our study, the overall success rates were 100% of patients using i-gel, 97.5% using LMA and 95% using the SLIPA and in a relatively high number of patients, insertion of the supraglottic airway devices was successful on first attempt (95%, 85% and 87.5% in i-gel, SLIPA and SSLMA respectively). Although these results are lower than the findings of Jeon et al. [11] who reported a first insertion success rate of 100% with both PLMA and I-gel devices on the first insertion attempt, and other studies that reported insertion success rates of 84-100% for the i-gel [12] and 96-100% for the SLIPA [13].

A high performance was noted with the i-gel group patients compared with supraglottic devices including SLIPA [14] on the other hand SSLMA was more likely to be rated inferior regarding handling [15].

Castl et al. in their study comparing the I-gel with LMA and showed that the I-gel had shortest insertion time [16]. Gatward et al. found that I-gel was inserted approximately 50% faster than the other devices as PLMA manikin during resuscitation [17]. Xu et al. compared SLIPA, PLMA, and standard endotracheal intubation and recorded a first insertion success rate of 96% and 98% for the PLMA and SLIPA respectively [18]. In the opposite of our result Chio et al. compared SLIPA with PLMA in 60 patients undergoing surgeries under general anesthesia. And found that, the first insertion success rates for PLMA and SLIPA were 93.3% and 73.3%, respectively. This variation in results might be due to the relative experience of the anesthesiologist who has selected inappropriate size of SLIPA airway. Hence correct size selection is necessary for successful insertion [19]. Atef et al. showed that insertion of I-gel was significantly faster than insertion of LMA [20]. Goyal et al. on comparing size 2 i-gel with PLMA and cLMA in spontaneously breathing children undergoing elective surgery, showed that the success rate for first attempt was 95% for the i-gel group and 90% for the two laryngeal mask airway groups [21].

Time of insertion was with the SLIPA (22 ± 4.6 sec.) and the SSLMA (19 ± 3.85 sec). It was significantly (p=0.033) shorter in i-gel group (15 ± 2.5 sec.). Time of insertion of SSLMA was almost similar to other study (median of 20 sec.) [22] Meanwhile, time of insertion of SLIPA and i-gel were longer than other studies 10.5 ± 6.7 sec and 8.5 ± 6.3 sec. respectively [23].

Although, we used optimal conditions for easy SGAs insertion, we had higher incidence of low successful first attempts and longer insertion time. Frequently, we encountered difficulty in passing the SGAs between the patient front incisors, which was attributed to ethnic characters. In addition, choosing the correct size of SGAs is very important. Matching of the thyroid cartilage width to the SLIPA bridge was reliable indicator of right size, though there were still errors in choosing size (4/40) [24]. Choosing SSLMA size according to body weight resulted in few errors (4/40), probably because of cumbersome size of the semi-inflated cuff during insertion and the wide, stiff tube which restrict oral manipulation leading to impaction at the back of the mouth and more malposition [25], optimal insertion, adequate lubrication, optimal cuff inflation, proper patient's head and neck position and the device insertion until a definitive resistance is felt [26].

In our study SSLMA, contrary to other study [27], has significantly low leak volume compared to i-gel and SLIPA. Moreover, SSLMA provided our patients with significantly low tidal volume resulted in significantly high end tidal volume CO_2. Peak airway pressure was, also, significantly higher than i-gel. Our results can be attributed to the fact that volume cycled modes cannot ventilate effectively and constantly in the presence of airway leaks. Moreover, rising airway pressure can force compressible air volume in the circuit to rise and effective tidal volume to fall [28].

The i-gel, in our study, provided effective ventilation with significantly high leak volume. The gel like cuff seems to create a perfect fit to peri-laryngeal structures, though enables reliable application [28].

Theoretically a supraglottic airway device with higher sealing pressures should better protect the airway from aspiration, however, the use of SGA devices equipped with an additional esophageal lumen often prevents tracheal aspiration of gastric content .So Pulmonary aspiration of gastric contents remains a major concern when using SGA devices [29].

Zanfaly et al. found in their study that the mean airway sealing pressure was lower in the i-gel group (24.8 ± 5.8 cmH_2O) than in the LMA group (27.33 ± 6.5 cmH_2O) and the
ETT group (28.5 ± 5.7 cmH_2O), but the difference was statistically nonsignifcant [30].

No regurgitation of gastric contents was observed in any group in our study. Contrary to our results, in some paralysed patients reflux occurred during maintenance and emergence without clinical consequences [24]. The tendency to reflux is related to lower esophageal sphincter (LOS) pressure and the barrier pressure (BrP), which is the difference between gastric and sphincter pressures. Patient factors, operation factors, anesthesia factors, and device factors affect LOS tone and predispose the patient to insufflations, regurgitation and aspiration [31].

The i-gel has a drainage tube that allows escape of both ventilating gases and regurgitated fluid. The i-gel appears to be an improvement on the standard LMA for preventing aspiration. However, studies on Pro-Seal LMA imply that its effectiveness varies with the flow rate of regurgitated fluid, with greater probability of aspiration at higher flow rates [24]. Thus, risk of aspiration using i-gel might be similar to that for the standard LMA, but with smaller volumes actually aspirated.

The absence of inflatable cuff might increase the risk of gastric insufflations [6]. However, the ability of the SLIPA to protect against aspiration is limited to the storage capacity of the device, which exceeds the volume of gastric contents of fasted patients [6].

Although blood traces were significantly high in SLIPA group, postoperative sore throat was significantly higher in SSLMA group. The rigid material of the SLIPA appears to be more traumatic to the pharynx. The pressure-induced mucosal trauma resulted from SSLMA inflatable cuff seems to be more prevalent.

The postoperative sore throat percent was (30%). A systematic review and meta-analysis of the i-gel_ vs laryngeal mask airway in adults also showed a reduced the rate of postoperative sore throat [32].

Conclusion

The three disposable SGAs proved to be suitable for controlled ventilation during elective short surgical operations. The i-gel provides effective ventilation with minimal side effects and provide the best sealing quality, and the least leakage volume . Whereas, SLIPA is associated with a high incidence of gastric air insufflations, However, SSLMA associated with mild sore throat postoperatively.

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