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Research Article

A comparative evaluation of different supraglottic ventilatory devices during general anesthesia with controlled ventilation: A pilot study

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KEYWORDS

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Abstract *Introduction:* ProSeal Laryngeal mask airway (PLMA), I-gel air way and SLIPA (Streamlined Pharynx Airway liner) are ventilatory devices that are inserted easily and blindly as an alternative method to endotracheal intubations. They allowed safe ventilation with lesser pressor response.

Aim of the study: This study aimed to compare PLMA, I-gel air way and SLIPA during general anesthesia in insertion parameters, cardiovascular response, ventilation parameters and post-removal complications.

Material and methods: Sixty adult patients with mallampati score I and II scheduled for elective inguinal hernia repair under general anesthesia with controlled ventilation. Patients were randomly allocated to three equal groups in controlled pilot study, PLMA was used in the first, I-gel was used in the second and SLIPA was used in the third group. The three devices were compared as regards insertion parameters, cardiovascular responses, adequacy of ventilation (oxygen saturation, end tidal carbon dioxide, air leak), fibreoptic vision and postremoval complications.

Results: Manual manipulations were less in I-gel group (10%) in comparison with PLMA (20%) and SLIPA (30%) groups. However, air leak fraction was more evident in PLMA group. Postoperative sore throat occurred more frequently with SLIPA and PLMA and blood stained was significant in the SLIPA group.

Conclusions: We concluded that the I-gel, PLMA and SLIPA are effective ventilatory devices during controlled ventilation, without major complications. I-gel offers advantage over PLMA and SLIPA in being less manipulation needed during placement, less air leak, less postoperative sore throat and less in blood stained to the device after its removal in comparison with PLMA and SLIPA.

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1. Introduction

Endotracheal intubations have served a golden role in airway management. However, there are many adverse cardiovascular responses to Laryngoscopy and intubation [1], in addition to the problems during usage and postremoval complications as straining, coughing, breath-holding and laryngeal spasm [2].

Proseal Laryngeal mask airway (PLMA), I-gel and SLIPA are ventilatory devices which are inserted easily and blindly without the use of laryngoscope permitting smooth safe ventilation and saving airway crisis during difficult intubation [3].

PLMA provides safe, effective and hand free anesthesia with little risk factors for aspiration in addition to its important position in difficult intubation algorithm [4].

I-gel has a soft, gel-like, non-inflatable cuff, made of a gel-like thermoplastic elastomer, designed to provide an anatomical, impression fit over the laryngeal inlet [5].

SLIPA™ is a latex-free supraglottic airway that is indicated for the use during routine general anesthesia as an alternative to the face mask and laryngeal mask airway [6].

2. Aim of this study

The aim of this study was to compare the three different ventilatory devices with respect to ease of use, airway interventional requirements, insertion complications, fiberoptic view, cardiovascular response, ventilatory parameters and postoperative clinical problems during mechanical ventilation.

3. Material and methods

After approval from the Medical Ethical Committee this study was carried out on sixty patients of both sexes with age range 18–50 years, scheduled for elective hernia repair surgery in Menoufiya university hospital. Preoperative airway evaluation, and only patients with Mallampati score I and II, and those with thyromental distance (patil's test) more than 6.5 cm were included in the study.

Exclusion criteria included known esophageal disease, pulmonary disease, cardiovascular disease (hypertensive, coronary insufficiency), neurological disorders (cerbro vascular accident) and patients with psychiatric disorders. Also patients at risk of regurgitation (obese, pregnant and obstructive hernia) and patients predicted to be difficult intubated as mentioned before, were excluded.

Patients were randomly allocated to three equal groups in a controlled pilot study. **PLMA** was used in **group I**, **I-gel** was used in **group II** and **SLIPA** was used in **group III**.

Monitoring was applied before induction and included an electrocardiogram, pulse oximetry, capnograph and noninvasive blood pressure monitor using Oscar II Datex monitor (Datex, Helsinki, Finland) and tidal volume using the inline spirometer of anesthesia machine.

All patients received premedications with 2 mg midazolam and atropine 0.01 mg/kg given intravenously just before transport to the operating room. After 3 min of preoxygenation, anesthesia was induced with 2 μg/kg of fentanyl and 2.5 mg/kg of propofol slow I.V after loss of eyelash reflex and onset of apnea, insertion of the ventilatory device was done. Insertion of the ventilatory device, in group I, PLMA was inserted by index finger insertion technique and according to Brain's instruction in group II, I-gel was inserted according to the manufacturer's recommendations [7]. In group I and group II a size 4 of each device was used in all patients. In group III we used the size according to the recommendation of the manufacturer, which involved gender and height and inserted according to the manufacturer's recommendations [8].

Effective ventilation was defined as proper chest expansion, a square wave capnograph trace, absence of audible leak, and lack of gastric insufflations.

Anesthesia was maintained using inhalation of 1.2% isoflurane. Neuromuscular blockade was obtained with cisatracurium 0.15 mg/kg and maintained throughout the surgery to train of four count of 1/4, as assessed by peripheral nerve stimulator.

Controlled ventilation using tidal volume (vt) of 8 ml/kg, respiratory rate (RR) 12 cycles/min and I/E ratio of 1:2. VT, RR, and I/E ratio were manipulated so as to optimize Paw not more than 20 cm H_2O.

At the end of operation anesthetic agents were switched off. Reversal of neuromuscular blocking agents using neostigmine and atropine, gentle oral suction was performed and when swallowing recurred deflation of cuff in group PLMA was done. The device was removed after full recovery of muscle relaxant using train of four then effective breathing was assured.

The following parameters were assessed: *Insertion parameters:* first time placement rate and insertion time (from the removal of face mask to attachment of breathing circuit), number of intubation attempts, manipulator after insertion to assure patent airway (chin lift, jaw thrust and head tilt) and complications during insertion (cough, breath holding, biting, laryngeal spasm and lip or teeth injury).

Fiberoptic bronchoscopic view was recorded through the suction opening in the L shape connection between the tube and the Bain circuit, a 2-mm fiberoptic bronchoscope was inserted for evaluating glottic view. The best views from the tip of the orifice of I-gel, PLMA and SLIPA were graded from 1 to 4 follows: 1 (only vocal cords seen), 2 (partial visibility cords and/or arytenoids seen), 3 (only epiglottis seen), 4 (no vocal cords, arytenoids nor epiglottis visible). In addition, epiglottic down-folding was also noted [9]. The good view takes score 1 or 2.

Hemodynamic parameter heart rate, mean arterial blood pressure were measured before induction, after induction and after device insertion.

Ventilation parameters (incidence of oxygen desaturation ($S_P0_2 < 90\%$), hypercarbia ($P_ECO_2 > 45$ mmHg), reliability of air tight seal of the supraglottic airway, auscultation of air leak at antero-lateral neck (oropharyngeal leak) and epigastrium (gastric leak) at peak airway pressure (Paw = 20 cm H_2O), fraction of leak = Exp • V_T (by ventilator spirometry)/ Inspiratory V_T (by ventilator presetting) × 100 and maximum airway sealing pressure were measured by closing the expiratory valve of the breathing circuit and noting the pressure at which a leak developed with fixed fresh gas flow of 3 L/m.

Postremoval complications: (cough, regurgitation, breath holding, laryngeal spasm, oropharyngeal injuries and detection of blood traces on the airway just after the removal of the device and sore throat 6 h after this removal).

Statistical analysis of data was carried out as for all comparisons. $P < 0.05$ was considered significant. The values obtained were expressed as mean ± SD for numerical data.

Comparison of continuous data was made by using one way analysis of variance (ANOVA) for repeated measures. Chi-square test was used to calculate significance of the categorical variables.

4. Results

There were no significant differences between the 3 groups as regards the demographic and clinical characteristics (Table 1). As regards insertion problems (Table 2), the I-gel was inserted in all patients in one attempt, however in PLMA group two patients need second attempt. SLIPA was inserted in 3 patients in the second attempt.

The insertion time and the manual maneuvers were comparable between the three groups, But PLMA and SLIPA needed more manipulation to assure patent airway and there was only one case in PLMA group developed cough, one case developed breath holding and one case developed laryngeal spasm. In SLIPA group, 2 patients developed cough and one case developed tooth injury.

As regards fiberoptic view, the I-gel was the best one but the result of the three groups was comparable between the studied groups as regards the cardiovascular response to the device insertion, there were no significant changes in heart rate and mean arterial blood pressure between the studied groups (Figs. 1 and 2).

There was effective ventilation in the 3 groups as oxygen desaturation or hypercarbia detected in one patient in the PLMA groups (Table 3).

The air leak detected at oropharynx in one patient in every group of the I-gel and PLMA groups and 2 patients in the SLIPA group. SLIPA showed more leak fraction (10%) compared to that in I-gel (4%) and PLMA (6%) in controlled ventilation (Table 3). After the removal of the device, the cough, breath holding, laryngeal spasm and oropharyngeal injuries were comparable between the studied groups (Table 4).

As regards blood stained device, the SLIPA group showed a significant increase. Finally sore throat was significantly occurred in the SLIPA and PLMA respectively in comparison with I-gel group (Table 4).

5. Discussion

This study demonstrates that the three devices are good ventilatory aids to anesthetic practice. In general the three devices are effective in establishing an airway for controlled ventilation.

As regards the insertion criteria in the studied patients, it was found that the rate of the first time insertion was higher in I-gel patients (100%) compared to both PLMA (90%) and SLIPA patients (85%). However, more patients managed with PLMA and SLIPA required manual assistance of head and neck in order to start effective controlled ventilation. This of course, has prolonged the establishment to effective ventilation time for PLMA and SLIPA patients.

In agreement with our result Jackson et al who find that the I gel insertion is the easiest one among 8 supraglottic devices including SLIPA, needs less attempts of insertion [10].

Castl et al. in their study showed that the I-gel was consistently the fastest airway device in comparing the I-gel with LMA. And this made 63% of students in the research chooses the I-gel as their preferred airway device [11].

Gatward et al. during study the time taken for insertion of the airway in manikin during resuscitation found that the I-gel was inserted approximately 50% faster than the other devices as PLMA [12].

Xu et al. compared SLIPA, PLMA, and standard endotracheal intubation in 150 healthy adult females scheduled to undergo laparoscopic, gynecological procedures under general anesthesia and showed a first insertion success rate of 96% and 98% for the PLMA and SLIPA respectively [13].

In the opposite to our result Chio et al., mentioned that, the first insertion success rates for PLMA and SLIPA were 93.3% and 73.3%, respectively on comparing SLIPA with PLMA in 60 patients undergoing surgeries under general anesthesia. It seems that this variation in results is due to the relative experience of the anesthesiologist who has inserted the airway with inappropriate selection of the size of SLIPA airway. Correct size selection is important for successful insertion, as SLIPA comes in a fixed preformed shape and six adult sizes (47–57) [14].

Atef et al. showed that insertion of I-gel was significantly more rapid and easier than insertion of LMA 15.

Goyal et al. on comparing size 2 I-gel with PLMA and cLMA in spontaneously breathing children undergoing elective surgery, mentioned that insertion was easy in the majority of cases in all groups, and success rate for first attempt was 95% for the I-gel group and 90% for the two laryngeal mask airway groups [16].

In our study, the I-gel enabled better fiberoptic bronchoscopic view than SLIPA and PLMA (I-gel 95%, slipa 85% and 75% in PLMA group) in agreement with our result Francksen et al. reports a significant difference between the I-gel and LMA-Unique as regards the fiberoptic visualization of the cords [17].

Also Theiler et al. found less epiglottic downfolding and better fiberoptic visualization in I-gel group in comparing laryngeal mask supreme and the I-gel in anesthetic patients [18].

And also Christiaan et al. in their study comparing the I-gel and the La premiere LMA showed the fiberoptic view score were better for the I gel than the la premier LMA 19.

Table 1 Demographic data.

	pLMA group (mean ± SD)	I-gel group (mean ± SD)	Slipa group (mean ± SD)	Anova test	*P*-value
Age (years)	30.13 ± 5.8	27.6 ± 6.3	29.7 ± 6.61	0.92	0.4
Gender (M/F)	11/9	12/8	14/6	Chi-X = 2.9	0.06
Weight (kg)	78.9 ± 6.78	76.8 ± 7.73	75.1 ± 2.4	1.95	0.15
Duration of surgery (min)	47.4 ± 6.2	50.2 ± 5.7	48.1 ± 4.8	1.36	0.27

Data expressed as mean and standard deviation (Mean ± SD), Anova test.
* Denotes statistical significance ($P < 0.05$). Chi-square test for gender. M/F = male/female.

Table 2 Insertion parameters.

	PLMA group (mean ± SD)	I-gel group (mean ± SD)	Slipa group (mean ± SD)	Chi-square test	*P*-value
First time insertion (y/n)	18/2	20/0	17/3	3.07	0.21
Insertion time (min)	28.75 ± 3.78	26.2 ± 3.57	28.55 ± 3.79	Anova = 2.9	0.06
Manual maneuvers:					
Chin lift (y/n)	2/18	1/19	3/17	1.11	0.57
Head tilt (y/n)	0/20	0/20	1/19	2.03	0.36
Jaw thrust (y/n)	2/18	1/19	3/17	1.11	0.57
Complications:					
Cough (y/n)	1/19	0/20	2/18	2.1	0.35
Breath holding (y/n)	1/19	0/20	0/20	2.03	0.36
Lip or teeth injury (y/n)	0/20	0/20	1/19	2.03	0.36
Laryngeal spasm (y/n)	1/19	0/20	0/20	2.03	0.36
Fiberoptic view (good/bad)	17/3	19/1	15/5	3.1	0.21

Data expressed as number (y/n) Chi-square test.
* Denotes statistical significance ($P < 0.05$). Anova test used for the time of insertion.

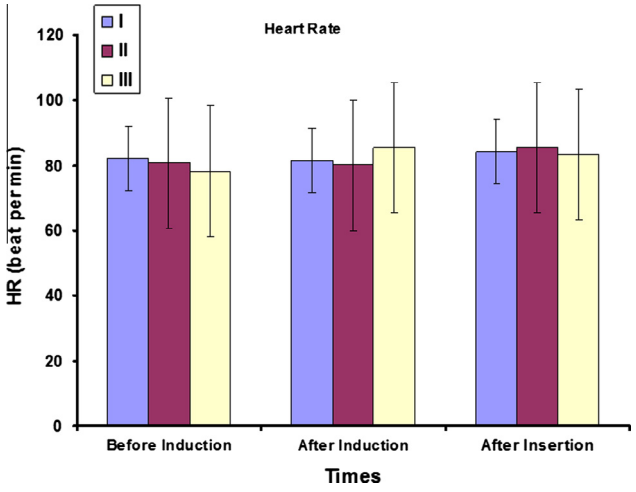

Figure 1 Heart rate changes in the three groups.

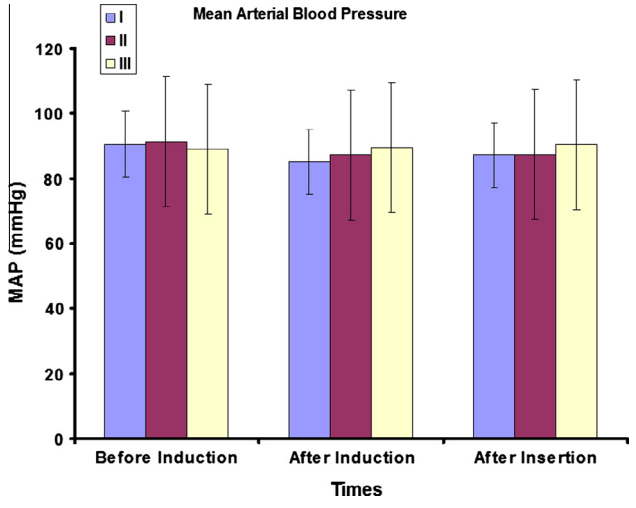

Figure 2 Mean arterial blood pressure changes in the three groups.

Chio et al. at his fiberoptic assessment reported that 60% of PLMAs and 40% of SLIPAs were deemed to be appropriately inserted and they attributed this value to less experience regarding SLIPA insertion [14].

In the present study, there was no significant difference in hemodynamic response to insertion of the three devices. This can be explained by similar stimulation of oropharyngeal and laryngeal tissues in the 3 devices.

Our results are in agreement with the study of Oh et al. who showed that there was no statistically significant difference between the LMA and SLIPA groups in hemodynamic responses [20].

But in opposite to this Puri et al. in comparing the SLIPA with LMA found that the SLIPA insertion was accompanied with significant rise in mean blood pressure in the SLIPA group. And this can explained by the investigator who may be expert at this time in LMA insertion but not with the SLIPA which due to its stiffener plastic material may induce more injury to the mucosa of pharyngeal and laryngeal tissue [21].

Also Shin et al. show no difference as hemodynamics in comparing the I gel with PLMA and cLMA [22].

Teoh et al. showed that the hemodynamic consequences secondary to airway device insertion did not differ significantly on comparing the I-gel versus LMA supreme in a paralyzed patients undergoing gynecological laparoscopic surgery with controlled ventilation [23].

There was good ventilation during usage of the 3 devices with no incidence of oxygen desaturation or hypercarbia except in one case in the PLMA group during controlled ventilation.

Previous study of Lange et al. showed that there is insignificant difference in ventilation, oxygenation in comparing the SLIPA with cLMA in ophthalmic surgery [24].

The incidence of leak at a standardized peak airway pressure of 20 cm H_2O was tested in the present study and found to be more with SLIPA, where two patients experienced oropharyngeal leak with about 10% of their tidal volumes without gastric insufflations, the explanation of this finding it may be due to the inflatable cuff of the PLMA and the soft nature of the pharyngeal part of the I-gel in front of the hard pharyngeal part of the SLIPA which make the PLMA and I gel more adherent to the pharyngeal wall, In agreement with our result Gatward et al. [12] who find that the leak in I-gel is less in com-

Table 3 Ventilation parameters (oxygen desaturation, hypercarbia and air leak).

	pLMA group	I-gel group	Slipa group	Chi-square test	*P*-value
O_2 desaturation (y/n)	0/20	0/20	0/20	1	0.5
Hypercarbia (y/n)	0/20	0/20	0/20	1	0.5
Leak Site – Oropharynx (y/n)	1/19	1/19	1/19	0	1
Leak fraction (%)	6%	4%	10%	3	0.22

Data expressed as number (y/n) Chi-square test.
* Denotes statistical significance ($P < 0.05$).

Table 4 Postremoval complications.

	PLMA group	I-gel group	SLIPA group	Chi-square	*P*-value
Cough (y/n)	1/19	0/20	1/19	1.03	0.59
Breath holding (y/n)	1/19	0/20	0/20	2.03	0.36
Laryngeal spasm (y/n)	0/20	0/20	1/19	2.03	0.36
Oroph. Injuries (y/n)	0/20	0/20	1/19	2.03	0.36
blood stained (y/n)	1/19	0/20	5*/15	7.78	0.02*
Sore throat (y/n)	6*/14	1/19	8*/12	6.9	0.03*

Data expressed as number (y/n) Chi-square test.
* Denotes statistical significance ($P < 0.05$).

paring with the cLMA and also Lange et al. [24] during his study in the ophthalmic surgery comparing SLIPA with cLMA showed that SLIPA is associated with a higher incidence of air leak and gastric air insufflation, which may increase the risk of aspiration. In our study the maximum airway pressure was 20ccH_2O which can protect against gastric insufflation).

As regards the postoperative complications there was a significant difference in the blood stained device in SLIPA group and a significant difference in the presence of sore throat in SLIPA and PLMA in comparison with the I-gel group and this can explained by the firm nature of the slipa and of its pharyngeal part and the jaw manipulation at the start of the procedure and pressure of the inflated cuff in PLMA against the pharyngeal wall.

In agreement with our result Abdellatif and Ali, who found during his comparison of streamlined liner of the pharynx airway (SLIP) with the laryngeal mask airway Proseal for lower abdominal laparoscopic surgeries in paralyzed women that there is a significant increase in the blood traces on the device in SLIPA group [25].

Teoh et al. showed that the I-gel was designed to create a peri-laryngeal anatomical seal without an inflatable cuff, decreasing the risk of compression trauma to the pharynx and because of that the use of the I-gel has been shown clinically to result in fewer postoperative sore throat and neck complaints compared with disposable LMA [23].

Lang et al. noticed that after Removal of the SLIPA or the LMA. Blood traces were noticed on the surface of the device in 20% of the SLIPA group and in 11% of the LMA group. Complaints of a sore throat were significantly higher in the LMA group than in the SLIPA group A significantly higher This might have been due to the pressure exerted on the pharynx by the inflatable cuff of the cLMA [24].

6. Conclusions

We concluded that the I-gel, PLMA and SLIPA are effective ventilatory devices during controlled ventilation, without major complications. I-gel offers advantage over PLMA and SLIPA in being less manipulation needed during placement, less air leak, less postoperative sore throat and less in blood stained to the device after its removal in comparison with PLMA and SLIPA.

Conflict of interest

None declared.

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