Comparing the efficacy and safety of laryngeal mask airway, streamlined liner of the pharyngeal airway and I-gel following tracheal extubation

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Abstract

Adverse events following surgical operations are common complications due to removal of tracheal tube in contrast to the tracheal intubation. Awareness about the new methods and strategies for tracheal tube extubation is necessary for a safe and successful extubation. Therefore, we aimed to assess the safety and efficacy of laryngeal mask airway (LMA), streamlined liner of the pharyngeal airway (SLIPA) and I-gel in extubation time of tracheal tube. A one-single randomized clinical trial was conducted in 105 eligible patients in three groups including LMA, SLIPA and I-gel. The patients were under surgery after general anesthesia with propofol (2–3 mg/kg) and fentanyl (1–2 μg/kg). Hemodynamic responses and extubation consequences including coughing rate, laryngospasm, airway obstruction, apnea, breath holding and straining of patients, vomiting, and need for re-intubation were recorded every 5 minutes since inserting of supraglottic airway devices (SADs) until patients restore consciousness. Analysis of data was conducted in SPSS software by analysis of variance (ANOVA) and ANOVA for repeated measurements tests. The overall successful insertion was 100% for LMA and I-Gel and this rate was 97.1% for SLIPA method. A significant decrease was observed in trend of hemodynamic responses in all three groups. Nevertheless, the MBP was lower in LMA group and lower HR was observed in I-Gel and higher HR occurred in SLIPA ($P < 0.05$). Three groups was same statistically regarding sore throat, vomiting, coughing, breath holding, apnea, laryngospasm, and re-intubation need ($P > 0.05$). However, the incidence rate of apnea, and laryngospasm, as well as re-intubation need in SLIPA group was 2.9%, respectively. LMA, I-GEL and SLIPA could be considered as useful and safe devices for ventilation control after tracheal tube removal at the end of operation. Three devices were same regarding to sore throat, vomiting, coughing, and breath holding. However, LMA showed lower side effects while SLIPA was related to more occurrences of apnea, laryngospasm, and re-intubation need.

Key words: anesthesia; extubation; I-Gel; Intubation; laryngeal mask airway; pharyngeal airway; streamlined liner of the pharyngeal airway; supraglottic airway devices

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Introduction

Removal of endotracheal tubes is an important stage in the recovery from general anesthesia and may have some potential risks.[1] Early extubation could reduce the incidence of ventilator associated pneumonia (VAP) in patients who have been intubated and undergoing mechanical ventilation. Moreover, it increases the patient comfort and the ability of airway cleaning due to effective coughing. However, defeat in extubation and re-intubation is one cause of prolonging stay of patients under mechanical ventilation and increasing the mortality, treatment costs and need for tracheostomy.[2] According to studies by the American Society of Anesthesiologist (ASA), obese patients with obstructive sleep apnea (OSA) are at higher risk in complications during extuba-

tion.[3,4] In addition, aging, long staying under mechanical ventilation, anemia, increased underlying disease severity, continuous intravenous sedation, and extubation without previous planning are associated with the increased risk of extubation failure in patients in the intensive care unit (ICU).[5-7]

In common surgical operations the adverse events are more common after removal of tracheal tube in contrast to the tracheal intubation.[8] Moreover, these extubation complications including tachycardia, hypertension and hypotension occur in patients with ischemic heart disease at the time of patient extubation and recovery period.[9,10] Moreover, respiratory complications including trauma around the pharynx and larynx, coughing, decreased oxygen saturation of the blood, breath holding, masseter spasm, laryngospasm, airway obstruction, and aspiration may occur.[11,12]

Increase awareness about the new methods and strategies for tracheal tube extubation are necessary for a safe and successful extubation with regard to increasing consequences of tube removal. Therefore, using standard tools for extubation should be have minimum characteristics such as the ability to ventilate and oxygenate, help to re-intubation in emergency times, access to the airway, non-interference with the patient's comfort and without side effects. For this reason, use of supraglottic airway devices (SADs), Stylet, or endotracheal tube exchanger are recommended by the ASA for high-risk patients.[3] Advantages of using SADs are the lack of laryngoscopy, less invasion of the respiratory tract, better patient tolerance, ease of insertation and less coughing.[13] Laryngeal mask airway (LMA) and Streamlined liner of the pharyngeal airway (SLIPA) and I-gel are some various types of SADs. Currently, the LMA method has been widely used after extubation with reasonable results.[14,15]

The LMA method used in the current study is "The Bailey Maneuver" that developed by Bailey for the first time.[16,17] This Maneuver is used for prevention of some complications that may occur such as laryngospasm, laryngeal edema, hemorrhage, trauma and vocal cord paralysis/dysfunction. However, the tracheal tube is considered as an external object in the airway. Therefore, sometimes by awakening the patients at the end of the procedure, some complications might be occurring despite the fact that the tracheal extubation criteria are met. However, since there were no comparative studies the safety and effectiveness of SLIPA and I-gel, we aimed to assess the safety and efficacy of using SLIPA and I-gel with laryngeal mask in extubation time of tracheal tube.

Materials and Methods

This study is a one-single randomized clinical trial that conducted on patients undergoing elective surgery in lower limbs after general anesthesia. The study setting was Vali-Asr Hospital of Arak, Iran. The sample size was calculated based on incidence rate of cough in two groups of another study including LMA and Guedel airway equal 3.8% and 26.9% respectively.[18] Moreover, the power and type 1 error were considered as 80% and 5% respectively. Furthermore, at least 32 patients were needed in each arm of study.

Age of patients between 15–70 years old, ASA I–II,[19] supine position, surgery duration between 120 to 180 minutes were the inclusion criteria. However, patients with body mass index (BMI) > 30, difficult airway (Mallampati Class III and IV),[20,21] history of gastric reflux, chronic obstructive pulmonary disease (COPD), head and neck surgery, pregnancy and operation that taken lower 120 minutes or higher 180 minutes were excluded from the study. The eligible patients were enrolled in study after receiving written informed consent according to inclusion and exclusion criteria. The ethical committee of Arak University of Medical Sciences approved the study protocol by IR.Arakmu.rec.1395.165 number. Moreover, this RCT is registered in Iranian Registry of Clinical Trial Center by IRCT2016100514056N10 code.

After hospitalized the enrolled eligible patients and placing on the bed, an intravenous line was considered and all of the patients were under standard monitoring for blood pressure, heart rate (HR), arterial oxygen saturation (SaO_2) and respiratory rate (RR). Block random allocation was used by an anesthesiologist for patient's assignment in three study groups including LMA, SLIPA and I-gel (**Figure 1**). The block size was considered as six and all combination of blocks used randomly.

General anesthesia was applied for all patients with propofol (2–3 mg/kg) and fentanyl (1–2 μg/kg). Moreover, intravenous Atracurium was injected for sufficient muscle relaxation. After 2 minutes, all patients underwent intubation. Isoflurane and mixed 50% of nitrous oxide and oxygen were used to continue the general anesthesia, at the end of the surgery and after the anesthetic gases have stopped and throat suctioned under direct vision the Laryngeal mask placed behind the trachea with empty cuff in the first group. All the SADs were inserted by the same anesthesiologist with good experience. The tracheal tube was removed after ensuring the location of LMA and ventilation with LMA. In the SLIPA and I-gel groups acted as the first group. Then ventilation was continued by 100% oxygen and the patient was transferred to recovery. In each group, after vigilance, superglot devices were removed. Systolic and diastolic blood pressure, mean blood pressure (MBP), HR, SaO_2 and number of breaths/RR were recorded in 5, 10, 15, 20, 25, 30, 35, 40, 45 and 50 minutes after inserting of SADs in all patients as long as patients recovered from anesthesia. Moreover, coughing rate, laryngospasm, airway obstruction,

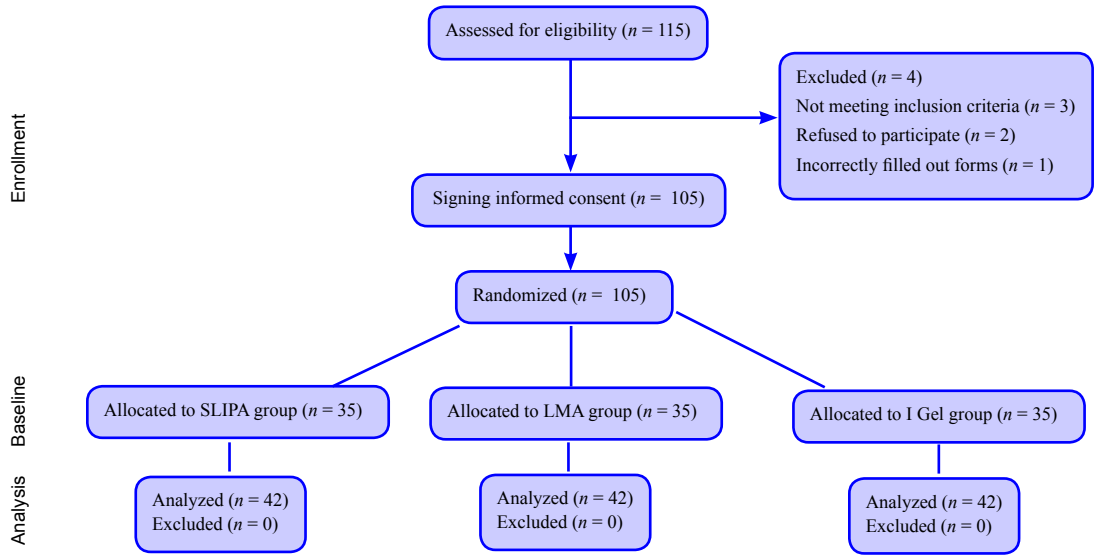

Figure 1: CONSORT diagram showing the flow of participants through each stage of a randomized trial.
Note: LMA: Laryngeal mask airway; SLIPA: streamlined liner of the pharyngeal airway.

apnea, breathe holding and straining of patients, vomiting, and need for re-intubation, was recorded in each patient to vigilance. Data were analyzed by analysis of variance (ANOVA) in each time after inserting of SADs. In addition, the trend of MBP, HR, SaO_2 and RR from placing of SADs to the 50th minute after insertion was assessed by ANOVA for repeated measurements. The significant value was considered as 0.05. All statistical analyses were conducted using SPSS 18.0 software (SPSS Inc., Chicago, IL, USA).

Results

The current study was conducted on 105 patients in 3 groups with 35 patients in each group. The overall successful insertion rate was 100% for LMA and I-Gel and this rate was 97.1% for SLIPA method. The mean age of patients was 42.3 ± 9.39 years (range 20–65 years) and 51.4% were male. Moreover, the mean of BMI calculated for patients as 25.06 ± 2.55 kg/m^2. Laryngospasm and apnea was observed in one patient and one of them need to re-intubation due to airway spasm. Baseline measurement showed that three group was same regarding to age ($P = 0.92$) and gender ($P = 0.91$). Moreover, the MBP, HR, SaO_2 and PR at baseline and before any intervention were same among three studied groups ($P < 0.05$).

The analysis of variance showed that there was a significant difference in MBP at all 10 measurements among the three groups. Moreover, a significant decrease (**Figure 2**) was observed in trend of MBP by analysis of variance for repeated measurements in three groups ($P < 0.001$). Moreover, the Tukey *post hoc* test showed that there was a significant difference among three groups, in a way that the MBP was higher in I-Gel group and the mean of MBP was lower in LMA at 50 minutes after placing of SADs ($P = 0.002$).

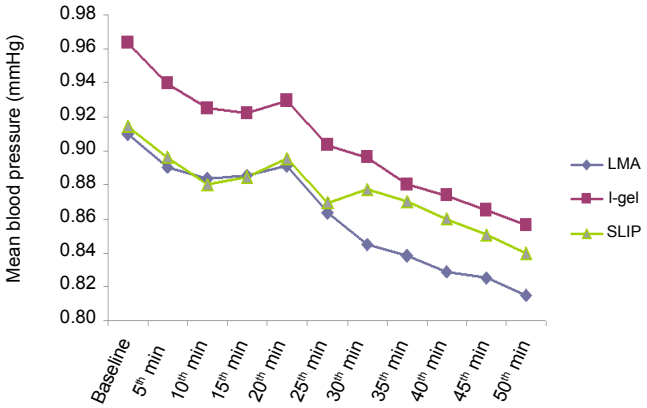

Figure 2: Comparing the mean blood pressure among LMA, I-Gel and SLIPA groups and its trend until the 50th minute after inserting of supraglottic airway devices.
Note: Data are expressed as mean (n = 35), and analyzed by analysis of variance followed by Tukey post hoc test. LMA: Laryngeal mask airway; SLIPA: streamlined liner of the pharyngeal airway; min: minute.

Based on analysis of variance there was a significant difference in HR of patients among LMA, I-Gel and SLIPA groups at the different times. Lower HR was observed in I-Gel and higher HR occurred in SLIPA method ($P < 0.05$). The analysis of variance repeated measurements showed that LMA, I-Gel and SLIPA groups have had decreasing trend in HR ($P < 0.001$; **Figure 3**).

Comparing the mean of SaO_2 among LMA, I-Gel and SLIPA groups are shown in **Table 1**. The analysis of variance showed that there was a significant difference among three groups in mean of SaO_2 at the 5th, 15th, 25th, 45th and

50th minutes after inserting of SADs ($P < 0.05$). Moreover, the ANOVA for repeated measurements showed that the decreasing trend in three groups was significant after placing of SADs until 50th minute ($P < 0.001$). ANOVA showed that there was no significant difference in RR among three groups in most time except in the 10th, 30th and 35th minutes. However, the ANOVA for repeated measurements showed that trend of decreasing in RR was significant in each group ($P < 0.05$; **Table 2**).

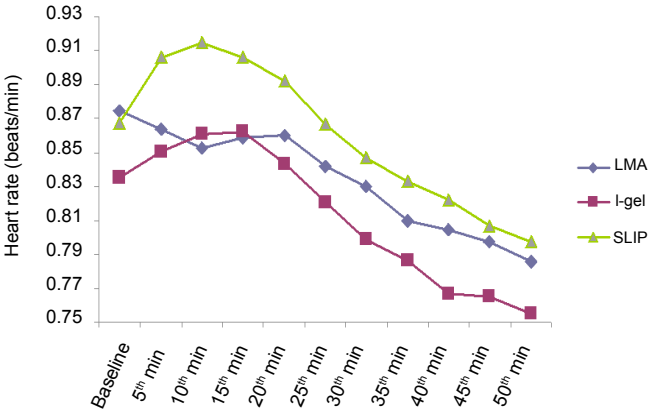

Figure 3: Comparing the heart rate among LMA, I-Gel and SLIPA groups and its trend until the 50th minutes after SADs insertion.
Note: Data are expressed as mean (n = 35), and analyzed by analysis of variance followed by Tukey post hoc test. LMA: Laryngeal mask airway; SLIPA: streamlined liner of the pharyngeal airway; SADs: supraglottic airway devices; min:minute.

Table 1: Comparing the mean of SaO_2 (%) among LMA, I-Gel and SLIPA groups and its trend until the 50th minute after inserting of SADs

Time	LMA	I-gel	SLIPA	*P* value[a]
Baseline	96.7±0.72	96.3±0.57	96.5±0.74	0.053
5th minute	96.5±1.07	95.3±1.28	94.8±1.99	< 0.001
10th minute	95.7±0.94	95.6±0.85	95.2±0.80	0.059
15th minute	94.9±1.11	95.6±1.06	95.4±1.03	0.028
20th minute	95.0±0.77	95.1±0.81	95.2±0.68	0.522
25th minute	95.7±0.80	96.1±0.74	95.8±0.55	0.048
30th minute	96.2±0.63	96.5±0.56	96.4±0.55	0.052
35th minute	96.4±0.78	96.1±0.87	96.2±0.58	0.268
40th minute	96.6±0.60	96.6±0.69	96.5±0.51	0.714
45th minute	96.4±0.61	96.8±0.51	96.5±0.56	0.009
50th minute	96.7±0.63	97.2±0.43	97.1±0.59	0.001
P value[b]	< 0.001	< 0.001	< 0.001	

Note: Data are expressed as the mean ± SD (n = 35). SaO_2: Arterial oxygen saturation; LMA: laryngeal mask airway; SLIPA: streamlined liner of the pharyngeal airway; SADs: supraglottic airway devices. [a]ANOVA; [b]ANOVA for repeated measurements.

There was not report sore throat and vomiting in each group. Moreover, there was only 2.9% (1 patient) apnea, laryngospasm, and re-intubation need in SLIPA group and these complications did not observe in other groups. Nev

Table 2: Comparing the mean of RR among LMA, I-Gel and SLIPA groups and its trend until the 50th minute after inserting of SADs

Time	LMA	I-gel	SLIPA	*P* value[a]
Baseline	20.34±2.99	20.23±1.57	19.91±2.21	0.729
5th minute	19.29±2.08	19.97±1.79	19.86±2.60	0.375
10th minute	20.20±1.84	19.86±1.24	19.11±1.59	0.016
15th minute	19.60±1.96	20.23±2.12	20.40±1.67	0.191
20th minute	20.14±1.70	19.94±1.66	19.54±1.67	0.317
25th minute	19.66±1.61	20.09±0.89	20.46±1.56	0.060
30th minute	19.77±1.11	20.49±1.20	20.11±1.49	0.070
35th minute	20.14±1.35	18.97±1.32	20.51±1.24	0.001
40th minute	19.71±1.07	19.49±1.04	19.31±1.16	0.310
45th minute	19.11±1.23	19.40±1.00	18.77±1.39	0.103
50th minute	18.23±1.09	18.49±0.89	18.94±1.14	0.017
P value[b]	0.002	< 0.001	0.035	

Note: Data are expressed as the mean ± SD (n = 35). RR: respiratory rate; LMA: laryngeal mask airway; SLIPA: streamlined liner of the pharyngeal airway; SADs: supraglottic airway devices. [a]ANOVA; [b]ANOVA for repeated measurements.

Table 3: Comparing the outcomes and complications of LMA, I-gel and SLIPA among three groups

Item	LMA	I-gel	SLIPA	*P* value
Surgery duration (minute)	143.66±12.5	153.00±14.3	152.57±9.8	0.002
Aldrete score	9.57±0.5	9.54±0.5	9.57±0.5	0.963
Recovery time (minute)	37.54±5.8	38.40±4.9	36.51±4.8	0.322
Coughing	2(6)	4(11)	7(20)	0.189
Breath holding	1(3)	2(6)	3(8.6)	0.588

Note: Data are expressed as mean ± SD or n(percent) (n = 35), and analyzed by analysis of variance followed by Tukey *post hoc* test. LMA: Laryngeal mask airway; SLIPA: streamlined liner of the pharyngeal airway.

ertheless, there was no significant difference among study groups regarding to consequences of interventions regarding to coughing, breath holding, apnea, laryngospasm, and re-intubation need ($P > 0.05$). However, the mean of surgery duration was lower in LMA group ($P = 0.002$). The Aldrete score and recovery time were same statistically in three groups ($P > 0.05$; **Table 3**).

Discussion

Based on our results and repeated measurements test, three-studied interventions have decreasing effect in the blood pressure. However, the MBP was lower in LMA group at all times after placing of supraglottic device to the 50th minute while it is higher in I-Gel. However, the hypotension effect of LMA versus I-Gel and SLIPA could help in management of bleeding and hemodynamic responses of patients. Another study showed that using of

LMA during general anesthesia is a best approach to slake the hemodynamic changes in patients after laryngoscopy and endotracheal intubation especially for patients with hypertension.[22] Moreover, another study showed that for airway management the insertion of LMA caused lower hemodynamic responses compared to comb-tube in under operation patients.[23] However, LMA is a safer method for cardiovascular patients.[22,23] Russo et al.[15] study in 48 patients in Germany showed that using LMA after surgery as a replacement for tracheal tube could create lower cardiovascular changes. Moreover, they showed that LMA is useful for ventilation without any side effect.[15]

All three methods decreased the HR but the trend in LMA group was decreasing exactly after the placing of SADs. However, the HR in SLIPA and I-Gel first increased and then decreased. Comparing the mean of SaO_2 and RR among LMA, I-Gel and SLIPA groups, we found that the decreasing trend of SaO_2 and RR in three groups was significant. However, other studies showed that LMA, I-Gel, and SLIPA groups create stable hemodynamic responses regarding to the insertion and removal of the supraglottic airways devices.[22-24] In addition, in Koga et al.[25] study the incidence of respiratory side effects was significantly lower in LMA group.

The mean of surgery duration was lower in LMA group and have the lowest side effects in comparison with I-Gel and SLIPA. The same results observed in another studies.[15,23] This fact shows that the LMA is a faster method among the studied SADs. However, the insertion time of Mogahed's study[24] was lower in I-Gel and LMA and SLIPA placed in the second and third rank. Moreover, the incidence of sore throat was 30% in LMA device in Mogahed's study. The difference of our study from the Mogahed's study[24] was that the surgery time and the mean of surgery time in our study were five folds that of the Mogahed's study.

The incidence of apnea, laryngospasm, and need to re-intubation was 2.9% in SLIPA. However, these complications did not observe in LMA and I-Gel groups. Moreover, sore throat and vomiting did not occur in each group and three groups was same statistically regarding to consequences of insertion of supraglottic airways to coughing, breath holding, apnea, laryngospasm, and re-intubation need. The Mogahed et al study showed that blood traces on the device and gastric air insufflations were higher in SLIPA method in comparison with LMA and I-Gel.[24] Another study showed that video laryngoscopy was an easier method and has a shorter intubation time than LMA using bougie, although the authors suggested that the LMA could be used as replacement of video laryngoscopy in hard situations.[22]

All three disposable SADs that studied in current study including LMA, I-Gel and SLIPA are useful devices for ventilation control in elective surgical operations regarding to the hemodynamic responses. However, LMA is the safer device regarding to lower side effects. Whereas, SLIPA is related to higher incidence in apnea, laryngospasm, and re-intubation need, although three SADs are same regarding to sore throat, vomiting, coughing and breath holding.

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Author contributions

HM contributed to the conception or design of the interpretation of data for the work. EM was responsible for the conception or design of the work. BY contributed to the acquisition and analysis of data for the work and drafted the article. A Mohammadbeigi contributed to the conception or design of the work analysis, or interpretation of data for the work. A Modir contributed to the conception or design. All the authors approved the final version of the manuscript for publication.

Conflicts of interest

There is no conflict of interest.

Research ethics

The ethical committee of Arak University of Medical Sciences approved this project by IR.ARAKMU.REC.1395.165. The study followed international and national regulations in accordance with the *Declaration of Helsinki*. The trial was registered with Iranian Registry Clinical Trial Center (identifier: IRCT2016100514056N10).

Data sharing statement

Datasets analyzed during the current study are available from the corresponding author on reasonable request.

Plagiarism check

Checked twice by iThenticate.

Peer review

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