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Comparison of Insertion Characteristics of I-Gel and Classic LMA by First Time Users.

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ABSTRACT

Background: To compare Classical Laryngeal mask airway (LMA classic) and I-Gel with regard to ease of insertion, number of attempts taken for optimal positioning, leak pressure, gastric dilation, and post device removal complications by first time users in patients undergoing elective ENT procedures. **Methods**: 100 adult patients who underwent elective ENT procedures under general anesthesia with spontaneous ventilation were randomly assigned into two groups: I-gel and LMA groups by draw method. Device insertion was done by first time users; in our study interns and anesthesia technicians were involved. Parameters compared were number and duration of insertion attempts for optimal positioning, gastric dilation, leak pressure and airway assessment after removal of the device by indirect laryngoscopy. **Results:** There were no statistically significant differences between the groups, with regard to hemodynamics and ventilation parameters. The mean time taken for insertion was 13.6 ± 3.9 seconds in the I-gel group, while it was 23.2 ± 7.9seconds in the LMA classic group and it was statistically significant (P <0.05). The number of insertion attempts between groups were statistically significant (P=0.027746). Leak pressure was 23.62 ± 4.9 cm H2O in the I-gel group compared to 18.2 ± 5.7 cm H2O in the LMA classic group (P<0.05). Incidence of gastric dilation was significantly more with LMA classic group 12(24%) compared to I-gel group 4(8%) (P=0.02926). Post device removal, presence of blood on the device and trauma to epiglottis and posterior pharyngeal wall was less in I-Gel group compared to LMA classic group. **Conclusion**: I-gel is better than Classic LMA with respect to ease of insertion, other insertion characteristics and trauma, especially in first time users.

Keywords: LMA classic, I-Gel, insertion time, leak pressure, gastric dilation, Post device removal.

INTRODUCTION

The tracheal tube has generally been considered the optimal method of managing the airway and there is evidence that, without adequate training and experience, the incidence of complications, such as unrecognised oesophageal intubation (2.4–17% in several studies involving paramedics) and dislodgement, is unacceptably high.[1-3] The Supra Glottic Airway devices are easier to insert than a tracheal tube. Laryngeal Mask Airway (LMA) invented by Archie Brain was the first of its kind. The I-gel Supraglottic Airway device (Intersurgical Ltd, Wokingham, Berkshire, UK) was invented in 2007 by Dr.Muhammed Aslam Nasir which could overcome the undesirable laryngeal and tracheal trauma side effects. It is made up of a thermoplastic elastomer, which has a gel-like feel.[4] The shape, softness and contour accurately mirror the perilaryngeal anatomy to create the perfect fit, so that compression and displacement trauma are significantly reduced and has cheaper manufacturing costs due to the simplicity of design.[5,6] Safety of I-gel has been established by various studies.[7] Misplaced tracheal tubes in difficult circumstances outside operating room may cause brain damage or death of patient. European guidelines for resuscitation accepted the relatively safe and easy use of supraglottic airway devices (SAD's) by operators with limited airway management experience.[8] To decrease the "hands-off" time, emphasis on tracheal intubation was reduced in favor of supraglottic devices.[9]

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We conducted this study to compare Laryngeal mask airway classic (LMA classic) and I-Gel, with regard to various insertion characteristics by first time users in anesthetized, spontaneously breathing/ventilated adult patients undergoing elective ENT procedures.

MATERIALS AND METHODS

After obtaining approval from the hospital ethical committee and written/informed consent, this prospective randomized study was conducted in KMCT Medical college between May 2012- August

2014 on 100 patients of ASA physical status I/II, of either sex in the age group of 18-50 years, who were scheduled to undergo elective ENT surgery in the supine position requiring general anesthesia with spontaneous breathing or ventilation. The exclusion criteria were patients with anticipated difficult airway, pregnancy, history of obstructive sleep apnea, any pathology of the neck and upper respiratory tract or upper alimentary tract, mouth opening <2.5 cm, patients at risk of aspiration, cervical spine disease, all emergency and head and neck surgical procedures. The patients were equally randomized into two groups: group 1 (I-gel group) and group 2 (LMA group). Correct method of device (I-Gel or LMA Classic) insertion was shown to first time users prior to the procedure with the help of pictures, video and manikin.

All patients were kept NPO for 8hours prior to surgery. Patients were given lorazepam 1 mg, ranitidine 150mg and metoclopramide 10mg orally night before and morning of surgery. Pre induction monitors were ECG, pulse oximetry & NIBP. Baseline parameters noted. After preoxygenating with 100% oxygen, anesthesia was induced with midazolam 1mg, fentanyl 2 µg/kg and propofol 2-2.5 mg/kg IV. Once adequate depth of anesthesia was achieved, either of the 2 devices of appropriate size for body weight of the patients, selected using a random computerized table, was inserted by a first time user under the close supervision of an experienced anesthesiologist. Post induction monitors included preinduction monitors plus ETCO2. Maintenance of anesthesia was achieved with the nitrous oxide: oxygen mixture and 1.5-2% isoflurane. Baseline hemodynamic parameters were noted prior to insertion of the device and then at 1, 5, 10, and 15 minutes post insertion and then at 15-minute intervals till the end of surgery. Insertion time was recorded by an independent observer and defined as time interval between beginning of insertion and appearance of capnograph. However, if insertion failed at the second attempt, it was recorded as a failure and a cuffed endotracheal tube of appropriate size was inserted. Optimal anatomical position of the device was confirmed by introducing a flexible fibreoptic bronchoscope. Leak pressure was determined by closing the expiratory valve of the circle system at a fixed gas flow of 3L/min and noting the airway pressure at which equilibrium was reached. At the end of the surgical procedure, anesthesia was discontinued and the device was removed. Post device removal, incidence of cough/spasm, sore throat, postoperative nausea and vomiting, gastric dilatation, blood staining and indirect Laryngoscopy findings (done by ENT surgeon 24 hours postoperative to assess the trauma) were recorded.

Statistical analysis

Statistical analyses were done using ANOVA calculator, Fisher exact test calculator and Z Test Calculator. P values of ≤ 0.05 were considered significant.

RESULTS

Demographic data (age, gender, body mass index) between groups were statistically insignificant [Table 1]. The insertion time for I-Gel was significantly shorter than that for the LMA Classic. No statistically significant differences were observed between both groups of the study with regard to systolic BP, diastolic BP, heart rate, SPO2 and end-tidal CO2 throughout the surgery. [Table 2] shows that insertion and ventilation was possible at the first attempt in 96% of patients in the I-Gel group and in 80% in LMA classic group & more than one attempt was required in 4% of I-Gel group and 20% of the LMA classic group, which was statistically significant (P=0.0277). The mean duration of insertion attempt was 11.6 ± 3.2 seconds in I-gel group, while it was 21.2 ± 5.3 seconds in LMA classic group. The difference between both groups regarding duration of insertion attempts was statistically significant. Leak pressure was significantly higher among patients of the I-Gel group (23.62 ± 4.9 versus 18.2 ± 5.7 cm H2O) than in LMA classic group. The incidence of gastric insufflation was significantly more with LMA classic (12% versus 4% in I-Gel group; P<0.05). With respect to post device removal complications [Table 3] presence of blood on device (14% versus 2%) and trauma to epiglottis and posterior pharyngeal wall, was statistically significant in LMA classic group (P < 0.05).

Table 1: Demographic Data.

Characteristic	I-gel group (*n*=50)	LMA group (*n*=50)	P value
Age	28.29±10.4	31.62±11.4	0.130
Gender			
Male	26 (52%)	28 (56%)	
Female	24 (48%)	22 (44%)	0.841116
BMI (kg/m^2)	22.13±2.15	21.81±4.13	0.628

Table 2: Comparison between I-gel and LMA groups with respect to different parameters.

Parameter	I-gel group (n=50)	LMA group (n=50)	*P* value
Number of insertion attempts (Fisher exact test)			
One attempt	48 (96%)	40 (80%)	
Two attempts	2 (4%)	10 (20%)	0.027746
Duration of insertion attempts (seconds) (ANOVA test)	13.6 ± 3.9	23.2 ± 7.9	<0.05
Leak pressure (cm H_2O) (ANOVA test)	23.62 ± 4.9	18.2 ± 5.7	<0.05
Incidence of gastric insufflation (Z score calculator)	4 (8%)	12(24%)	0.02926

Table 3: Comparison of post device removal complications.

	I-Gel (n=50)	LMA (n=50)	P Value
Post removal cough	1 (2%)	3 (6%)	0.30772
Sore throat	8 (16%)	9 (18%)	0.78716
Laryngeal Spasm	0	3 (6%)	0.0784
Presence of blood on airway device	1 (2%)	7 (14%)	0.0271
Dysphagia/ Dysphonia	2 (4%)	4(8%)	0.4009
Ear pain	0	1 (2%)	0.3125
Trauma to epiglottis and posterior pharyngeal wall	1 (2%)	7 (14%)	0.0271

DISCUSSION

Our results demonstrated that I-gel has many advantages over LMA Classic especially in first time users.

Jindal et al.[10] and Amar M. Helmy et al.[11] reported hemodynamic stability with both LMA and I-gel, with no statistically significant difference, which is consistent with our findings. In most of the previous studies, mean insertion time was statistically insignificant. But in our study, mean duration of insertion attempt was 13.6 ± 3.9 seconds in I-Gel group, while it was 23.2 ± 7.9 seconds in LMA classic group which was statistically significant. Our findings were similar to studies by Amar M Helmy et al,[11] (mean insertion time of 15.62 ± 4.9 sec in I-Gel group and 26.2 ± 17.7 sec in LMA group P= 0.0023) and Jeaven Singh et al,[12] (Mean insertion time 19.3 sec in I-Gel and 26.3 sec in LMA group P= 0.000). In our study, insertion and ventilation was possible at the first attempt in 96% of patients in the I-Gel group and in 80% in LMA classic group & more than one attempt was required in 4% of I-Gel group and 20% of the LMA classic group, which were statistically significant (P=0.0277). Unlike our study, in most of the previous studies, first attempt success rates were comparable in both groups. However, Janakiraman et al,[13] had first attempt success rate significantly higher in LMA group 86% than in I-Gel group 54%. The mean leak pressure has been reported as 25.6 ± 4.9 with the use of I-Gel.[11,15] This was consistent with our findings of 24.42 ± 4.9. In our study, Post removal cough/spasm, Sore throat, Postoperative nausea or vomiting were slightly more in LMA classic group, but not statistically significant. But in most of the previous studies post removal cough was seen more in case of I-Gel,[16,17] but the difference was statistically insignificant. Presence of blood on device (14% versus 2%) on removal and trauma to epiglottis and posterior pharyngeal wall seen by ILS after 24 hours, were statistically significant in LMA classic group (P < 0.05). Chauhan et al,[14] study also showed higher incidence of pharyngolaryngeal morbidity with Proseal LMA (blood staining of the device, sore throat, and dysphagia) in comparison to the I-gel which supported our findings.

CONCLUSION

Both LMA and I-gel do not cause any significant changes in the hemodynamics or ventilation parameters. Insertion time for I-gel was significantly less than that of LMA classic in first time users. Leak pressure was significantly higher with I-gel than LMA and thus incidence of gastric dilation was significantly lower with I-gel. The post device removal complications were not significantly different except presence of blood on device on removal and trauma to epiglottis and posterior pharyngeal wall, which was statistically significant in LMA group.

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