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Comparision of I-Gel, A New Supraglottic Airway Device(SGD) with Classic Laryngeal Mask Airway(LMA) in Performance and Safety During General Anesthesia with Controlled Ventilation.

KEYWORDS: i-gel, Classic LMA, general anaesthesia, controlled ventilation.

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ABSTRACT *Background: I-gel is a new SGDs , differs from others as it has a softer and gel like transparent non-inflatable cuff.*

Aims: To compare ease of insertion, effectiveness of positive pressure ventilation and airway complications of i-gel with classic LMA in general anaesthesia with controlled ventilation.

Methods: A prospective randomized controlled trial was conducted among 100 adult patients of either sex, aged 15-50 yrs, weighing 35-75 kg, ASA-1 and 2 undergoing various elective surgical procedures under general anaesthesia.. Patients were divided into two groups : group 1. I-gel, group 2: classic LMA. .Anaesthesia was given by standard gas-relaxant IPPV technique. Data recorded were ease of insertion, no. of insertion attempts, time taken for successful device insertion, peri-opertive airway complication.

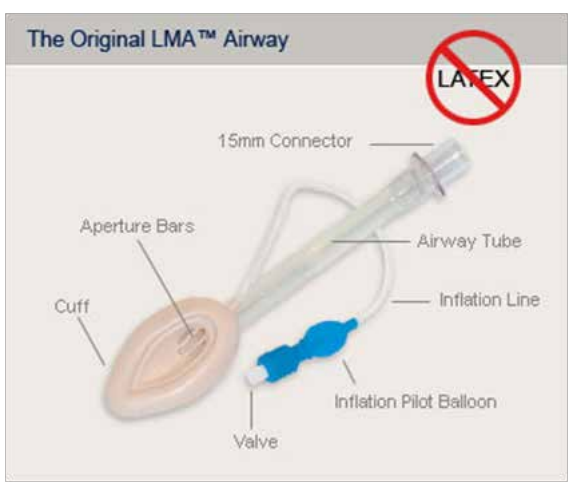
Results: In this study both SGDs were easy to insert and did not require laryngoscope for insertion . Patients of i-gel group had comparatively less pharyngolaryngeal morbidity than patients of LMA group respectively (4% /20%).

Conclusion: I-gel and Classic LMA, both SGDs can be used safely and effectively in selected patients for general anaesthesia with controlled ventilation with less pharyngolaryngeal morbidity.

Introduction

Supraglottic Airway Devices are now widely used for surgery requiring general anaesthesia as an alternative to tracheal intubation. The tracheal intubation is the gold standard method for maintaining a patent airway during anaesthesia[1]However this maneuver requires skill and continuous training and practice and usually required direct laryngoscopy , which may cause laryngopharyngeal lesions. [2].

Supraglottic Airway Devices(SGD) are devices that ventilate patients by delivering anesthetic gases/oxygen above the level of the vocal cords and are designed to overcome the disadvantages of endotracheal intubation such as: soft tissue, tooth, vocal cords, laryngeal and tracheal damage, exaggerated hemodynamic response, barotrauma, etc. The advantages of the supraglottic airway devices include: avoidance of laryngoscopy, less invasive for the respiratory tract, better tolerated by patients, increased ease of placement, improved hemodynamic stability in emergence, less coughing, less sore throat, handsfree airway and easier placement by inexperienced personal .Varieties of SGDs are used for securing and maintaining airway for general anaesthesia in fasted patient during spontaneous and controlled ventilation. The laryngeal mask airway (LMA) classic consists of an inflatable silicon mask and a connecting tube. It is inserted blindly into the pharynx, forming a low pressure seal around laryngeal inlet and allow gentle positive pressure ventilation.



(http://www.lmana.com/pwpcontrol.php?pwpid=6345)

I-gel (intersurgical Ltd, Wokingham, UK) is a novel SGD with an anatomically designed mask made of a gel like thermoelastic -elastomer. It has features designed to separate gastro-intestinal and respiratory tract and allow aspiration of gastric content through gastric tube[3] The tensile property of i-gel bowl, along with its shape and the ridge at its proximal end, contribute stability to the devices. Upon insertion sliding beneath the Pharyngo-epiglottic fold, it become narrower and longer, creating an outward force against tissue. The ridge at the proximal bowl catches the base of the tongue, also keeping the devices from moving upward out of position [4]

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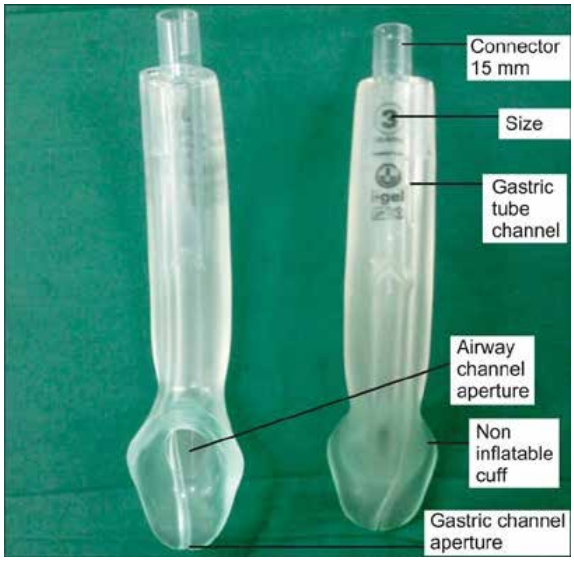

(image of igel taken from department of anesthesia GCS Medical college)

SGDs offers many advantages in carefully selected patients ; allow rapid access to airway , do not require laryngoscope for insertion , provide safe airway for spontaneous and controlled ventilation Some additional benefits of these devices are that they may be used as a rescue airway and fibreoptic conduit , when intubation difficult or unsuccessful.

Aim of our study is to compare ease of insertion, effectiveness of positive pressure ventilation and airway complication of both the devices during general anaesthesia with controlled ventilation

Methods

Prospective randomized controlled trial were conducted among 100 adult patients of either sex, aged 15-50 yrs, weighing 35-75kg, ASA I and II, undergoing various elective surgical procedure under general anaesthesia with controlled ventilation. Patients were randomly allocated to receive i-gel as airway devices for group-I and classic LMA in group-II . Exclusion criteria were the presence of any significant acute or chronic lung disease , pathology of neck or upper respiratory tract, airway deformity, patients with increase risk of aspiration (hiatus hernia, morbid obesity, gastro-oesophageal reflux disease, full stomach or pregnancy). Informed and written consent was taken from each patient. Patients were pre-medicated with inj.Glycopyrolate (0.2 mg), inj. Rantac (1mg/kg), inj,Midazolam (0.01mg/kg), inj. Fentanyl (2µ/kg) intravenously 15 minutes before surgery. Standard monitors were applied prior to induction including electrocardiogram, pulse oxymeter, noninvasive blood pressure(NIBP) and basic vitals were recorded. Intravenous fluid Ringer lactate was started. Patients were placed in the ramp position prior to induction of anaesthesia. All patients were pre-oxygenated with 100% oxygen for 3 minutes then induced with inj.propofol (2mg/kg) and inj.succinylcholine (2mg/kg) intravenously.

In case of classic LMA size 3 was used for adult female patient and size 4 for adult male. Classic LMA was inserted by pushing cuff with index finger along the hard palate. In case of i-gel size selection depended on patient weight, size 3 was used for patients <50kgs, size 4 was used for those between 50 and 90kg. Insertion time was recorded from the moment anaesthetist picked up the devices until the first breath was delivered. The number of attempts required for insertion was recorded. A 'failed attempt' was defined as removal of the device from the mouth before re-insertion. We decided to do maximum two attempts. Adequate placement of device was assessed by gentle squeezing the reservoir bag and bi-lateral chest expansion and observing $ETCO_2$ waveform. If ventilation was inadequate following manipulations were allowed like, gentle pushing or pulling of the device, chin-lift, jaw extension, neck flexion. In case of i-gel, gastric tube no. 10 for size 3 and no.12 for size 4, was inserted to empty stomach. All patients were ventilated with volume controlled ventilation. Tidal volume was set at 6-8ml/kg and respiratory rate at 12 to 14 breath per minute. Anaesthesia was maintained with ideal gas-relaxant IPPV technique. Primary aim of study was to compare ease of insertion effectiveness of ventilation and intra or post operative airway complications. Data recorded were as follows: age, weight, height, time of insertion, number of attempts, ease of insertion, inspired tidal volume, expired tidal volume, and complications- during insertion, maintenance and removal . At the end of surgery neuromuscular blockade was reversed with inj. Neostigmine and glycopyrolate intravenously. gastric tube was removed after proper suction. LMA was removed on appearance of airway reflexes and opening of mouth on command.

Any pharyngeo-laryngeal morbidity like sore throat, neck pain, dysphonia were recorded in recovery room.

Results:

Statastical package for social science (SPSS 15) was used to analyze the data .Mean and standard deviation values were estimated for age, weight, duration of surgery, time for successful insertion while frequency and percentage were used for gender, Mallampatti, ASA status, insertion attempts and morbidity.

Table 1 Demographic data and time of duration of surgery. Data are given as mean (SD) or as absolute numbers.

Variable	Group 1 (n=50)	Group 2 (n=50)	P value
Age (years)	37.94±8.47	34.58±9.32	0.078
Sex (male/female)	10/40	17/33	0.176
Weight (kg)	56.08±9.52	56.24±8.88	0.924
Duration of surgery (mins)	70.8±30.26	58.2±24.67	0.045
ASA(I/II)	40/10	39/11	1
Mallampatti (I/II)	47/3	49/1	0.60
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The demographic data is presented in table 1. There was no statistically significant difference when comparing mean age, sex, weight between two groups. ASA physical sta-

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tus and Malampatti score were statistically equal in both the groups. There were statistically significant difference found in duration of surgery .Duration of surgery was longer in case of I gel group than classic LMA group

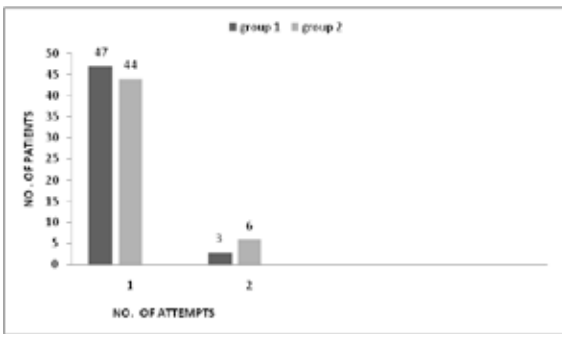

Figure 1.Numbers of attempts for successful device insertion

As per above chart successful device insertion was achieved in one attempt in 94% patient in group-I and 88% in group II , it is not statistically significant (p=0.48). In case of group I, 3 patients were required second attempt and jaw thrust for successful device insertion. In group II, 6 patients required second attempt , among them two patients required laryngoscopic LMA insertion and other required manipulations.

Table-2 Time taken for successful device insertion

Insertion time	Group-1	Group-2	P value
(sec)	11.82±3.23	14.98±12.72	0.089

Above table showing mean time for successful SGDs insertion. Time required for the first adequate ventilation was comparable between groups (Mean value ; i-gel 11.82 sec, classic LMA 14.98 sec : p=0.08: 95% CI of mean difference -6.82 to 0.50).

Ability to ventilate in paralyzed patient with controlled ventilation was comparable in both groups, but ventilator parameters like peak airway pressure and leak pressure was not recorded due to non availability of special instrument for it.

Table 3 Airway complication

Device	Blood on device	Sore throat	Dysphagia	Dysphonia
Group I	02(4)	4(8)	0	0
Group II	10(20)	8(16)	4(8)	0

Pharyngo-laryngeal morbidity like sore throat, dysphagia, dyasphonia was less in both group as shown in table3. Blood on device after extubation was more in group II than group I 20%/4%)respectively.

Discussion

The I-gel is a new SGDs, without an inflatable cuff, designed for use during general anaesthesia [4]. It is a latex free, disposable device, made of a medical grade thermoplastic elastomer. I-gel is anatomically preformed to mirror the perilaryngeal structures. The device contain an epiglottis blocker, which helps to prevent epiglottis from downfolding or obstructing laryngeal inlet. The soft non-inflatable cuff seals anatomically against perilaryngeal structures. [5] I-gel has a gastric channel allowing venting of air and gastric contents or insertion of gasric tube .

As it separate the gastro-intestinal and respiratory tracts, early reports have postulated its use as potential airway for use in resuscitation[6] Many studies compared LMA with i-gel [3,7,8].

Richez et al [9] carried out one of the earliest studies to evaluate the i-gel. They found that insertion success rate was 97%. Insertion was easy and performed at the first attempt in every patient. I-gel is rapidly and easily inserted ;providing a reliable airway in over 90% cases. Acott [10] assessed the use of i-gel as an airway device during general anaesthesia.

Regarding the time of insertion for the i-gel the results of our study are in agreement with the data of Wharton et al .[11,] In their study time to successful insertion and success rate (first attempt 83%; overall 95%) are comparable to our results.

Nandwani et al have shown that increasing the cuff volume of LMA displaces the larynx anteriorly. Higher cuff volume may be observed especially during nitrous oxide administration [12].The wedge shaped tip is then displaced from the wedge shaped hypopharynx causing proximal displacement of cuff, movement of the epiglottis into bowl and exposition of oesophageal inlet. A malposition of SGDs increase the risk of leakage, if leakage is sufficiently large, a ballooning of stomach may lead to deterioration of respiratory mechanics , regurgitation and risk of aspiration. In contrast non-inflatable cuff of the i-gel is semi rigid and can not be folded over or over inflated, thus diminishing the risk of both airway obstruction and mucosal damage.

If a supraglottic airway device lacks the facility of active or passive emptying of stomach , this may put the patient an increased risk of regurgitation and aspiration thereby precluding use of such device in patient with full stomach. [13,14] In our study that's why we had selected planned surgery with proper fasted patient. In our study placement of gastric tube was very easy in all the patients of i-gel group.

Post operative pharyngolaryngeal morbidity has gained wide spread attention. The causes of post operative adverse events such as sore throat, dysphonia, dysphagia with use of SGDs are dependent on the depth of anaesthesia , method of insertion, the numbers of insertion attempts ,done by experienced person. Low airway complication in both groups in our study is noticeable and could have been due to the high rate of first attempt success. According to our study blood on device after removal was observed in (20%) in patients of LMA group and low(4%) in i-gel group, which is statistically significant. Airway complication may be due to inflatable mask having potential to do tissue distortion, venous compression and nerve injury.[4]. Both devices were found equally effective In preventing aspiration and forming adequate seal as also shown by different authors[15,16]. Both devices were found equally effective in preventing aspiration and forming adequate seal as also seen by different authors[17-18].

CONCLUSION

We concluded that both classic LMA and i-gel can be used safely and effectively during general anaesthesia with controlled ventilation in selected patients. Both the devices are easy to insert, but i-gel quicker to insert and fewer manipulation required to insert , have less pharyngolaryngeal

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morbidity than classic LMA.

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