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AIRWAY DEVICE; COMPARISON OF I-GEL SUPRAGLOTTIC WITH LARYNGEAL MASK AIRWAY

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ABSTRACT: Introduction: Intersurgical-gel (I-gel) is a new supraglottic airway device that is widely being used to secure airway during general anaesthesia. **Objectives:** The objective of the study is to compare the ease of insertion of Intersurgical-gel and Laryngeal mask airway (LMA). **Material & Method:** This study was conducted in Department of anaesthesia Hameed Latif Hospital, Lahore. 100 American Society of Anesthesiologists (ASA) I-II, patients were enrolled in this study for elective surgery divided in 2 groups of 50 each. LMA and I-gel were used in groups A and B respectively for intra operative maintenance of airway. Randomization through random number table in Statistical Package for Social Sciences (SPSS) version 17 was used. **Results:** There were 50 patients in both groups. There were no statistical significant difference between the patients age of two groups. There was absolutely no difference between 2 groups regarding ease of insertion because both groups had 84% easy and 16% satisfactory insertions. Insertion time of LMA and I-gel in First and Second attempt were also comparable and statistically nonsignificant. Airway manipulations was required in both groups for insertion of device, in LMA group 30% required and 70% did not require and in i-gel group 48% required and 52% did not require. There is no statistical significant difference between both groups. **Conclusion:** we found that regarding ease of insertion there is statistically no significant difference between I-gel and LMA.

Key words: I-gel, LMA, Ease of insertion, Supraglottic airway device.

INTRODUCTION

Maintenance of airway is an integral part of general anaesthesia. Various airway devices are used for this purpose. Endotracheal tube (ETT) is the gold standard for airway maintenance. Endotracheal intubation is associated with complications (soft tissue trauma, dental injury, haemodynamic instability, esophageal intubation, hypoxia and sore throat) as it requires laryngoscopy and manipulation of the vocal cords^{1,2,3}.

Laryngeal mask airway (LMA) was introduced as an acceptable alternative to endotracheal intubation in selected cases. Its insertion is associated with less haemodynamic instability⁴. Problems with its use include difficulty with correct placement of the device; post operative sore throat, risk of aspiration, and air leak due to inadequate fit, gastric distension and laryngospasm^{3,5}.

I-gel (Intersurgical[®]) airway is a novel supraglottic airway that uses an anatomically designed mask made of a specially developed gel-like thermoplastic elastomer.

The mask of the I-gel is designed to conform anatomically the peri-laryngeal & hypo-pharyngeal structures obviating the need for an inflatable cuff. The claimed advantages include easier insertion, minimal risk of tissue compression, and stability after insertion as well as acting as a bite-block. Provision of drainage tube offers safety from aspiration in patients with no primary aspiration risk, additional reassurance for a correct position and a better stability of the airway^{6,7}. Various studies have established the safety of I-gel as a supraglottic airway device^{8,9}.

We carried out this study to compare the ease of insertion of I-gel vs LMA in our population.

MATERIALS AND METHODS Study Design

Experimental study.

Setting

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Professional Med J Dec 2010;17(4): 643-647.

Duration of Study

The study was completed in 6 months after the approval of synopsis.

Sample Size

100 patients were enrolled in this study divided in 2 groups of 50 each.

Sampling Technique

This study used convenient, non-probability sampling with random allocation.

INCLUSION CRITERIA

- 1. Patients of American society of anesthesiology (ASA) I-II
- 2. Mallampati Score I-II
- 3. Adults (age 16 to 70 years)
- 4. Weight 30 100 kgs
- 5. Fasted patients (> 6 hours solids, >2hours liquids excluding milk)
- 6. Elective procedures
- 7. Non-pregnant
- 8. Non-symptomatic of Regurgitation

EXCLUSION CRITERIA

- 1. Heavy Smokers (>40 cigarettes day)
- 2. Drug/SolventAbusers
- 3. Head & neck, orofacial trauma, thoracic or abdominal trauma
- 4. Anticipated difficult intubation

DATA COLLECTION PROCEDURE

After approval from ethical committee of the hospital and written informed consent, patient fulfilling the inclusion criteria were enrolled. Randomization through random number table in Statistical Package for Social Sciences (SPSS) version 10 was used. In group A "LMA" and in group B "I-gel" was used for intra operative maintenance of airway. The patients were pre-medicated with Midazolam 2.5mg Intravenous (I/V) 15 minutes before shifting to operation theatre. Patients were pre-oxygenated for three minutes with 100% oxygen.

Propofol 1% 2mg/kg I/V were given at induction. I- gel and LMA was lubricated with distilled water. After 1 minute of ventilation with Oxygen and sevoflurane using a face mask, LMA or an I-gel was placed in peri laryngeal area. Anaesthesia was maintained with O2, sevoflurane and with intermittent positive pressure ventilation (IPPV). Injection Tramadol 1.5mg/kg was given for analgesia. Group A and group B was assessed for ease of insertion of LMA and I-gel.

Ease of insertion LMA or I-gel was assessed according to following criteria:

- 1. Easy (no airway manipulation)
- 2. Satisfactory (required less than two maneuvers)
- 3. Difficult (required more than two maneuvers)

DATAANALYSIS PROCEDURE

Statistical analyses were conducted using SPSS v 17.0. T-test is used to compare the mean and Chi square test was used to check the association between qualitative variables. P-value less than or equal to 0.05 consider significant.

RESULTS

There were 50 patients in both groups. There were no statistical significant difference between the patients age of two groups (p-value=0.367) shown in Table I. In LMA group (Group A) 84% insertions were easy and 16% were satisfactory. While in I-gel group (Group B) exactly same percentage was observed i.e. 84% easy and 16% satisfactory. There was no statistically significant association found in ease of insertion between I-gel & LMA (p-value=1) in Table II. Mean insertion time with LMA group was 10.90 ± 5.17 secs while that with I-gel group was 10.76 ± 5.53 secs. There is no statistically significant difference of insertion time between two procedures (p-value=0.92) Table III. Manipulation of the airway was needed in 30% of the cases with LMA and 48% of the cases with I-gel which is no statistical association between both groups of airway manipulation requirements(p-value=0.065) shown in Table IV. 1st attempt insertion in LMA group was 94% while 2nd

Professional Med J Dec 2010;17(4): 643-647.

attempt was required in 6% of the cases. In I-gel group 1st attempt insertion was achieved in 90% and 10% of the cases required 2nd attempt. There is also statistical non-significant association between the insertion attempt of two devices(p-value=0.461) (Table V).Bleeding was only observed in one case of I-gel

Table-I. Comparison of mean age between two groups of the patients			
Study group	Mean age		
Laryngeal mask airway	35.62±10.16		
P-value = 0.367	38.32±12.70		
<i>P-value = 0.367</i>			

Table-II. Comparison of easiness of the procedures in two groups

Easiness	Study group	
	Laryngeal mask airway	I-gel
Easy	42	42
	84%	84%
Satisfactory	8	8
	16%	16%
	100%	100%
	p-vale=1	

Table-V. Comparison of insertion attempts for two devices

Number of attempts	Study group		
	Laryngeal mask airway	l-gel	
One attempt	47	45	
	94%	90%	
Two attempts	3	5	
	6%	10%	
	p-vale = 0.0461		

Professional Med J Dec 2010;17(4): 643-647.

group. Laryngospasm was seen in 2 cases; one in each group. Failure to secure airway with LMA occurred in 3 patients and with I-gel in 2 patients.

DISCUSSION

I-gel is a relatively new device; we found limited data on its usage. Most studies were done on cadavers and manikins. There were only 3 studies done on human beings currently available.

Most of the studies carried out on ease of insertion of supraglottic devices have used number of attempts or need for airway manipulation as indicators of ease of insertion of the different models and makes of the LMA. None of these parameters have been validated for ease of insertion.

Sudhir et al Compared Ambu Aura Once Laryngeal Mask with the CLMA, using the number of attempts as a marker

Table-III. Insertion time with LMA and I-gel devices			
Study group	Mean time (sec)		
Laryngeal mask airway	10.90 ± 5.17		
I-gel	10.76 ± 5.53		
<i>P-value = 0.92</i>			

Table-IV. Comparison of airway manipulation requirement between two groups

Status of airway manipulation	Study group		
	Laryngeal mask airway	I-gel	
Manipulation needed	15	24	
	30%	48%	
Satisfactory	35	26	
	70%	52%	
	<i>p-vale = 0.065</i>		

of ease of insertion. They noticed 92% success rates with the Ambu and 84% with the CLMA regarding insertion with 1st attempt (p = 0.22)¹⁰.

Shariffuddin & Wang compared Ambu AuraOnce Laryngeal Mask with that of the CLMA and their study was based on airway manipulations required for insertion. The ease of insertion was comparable between the groups (p = 0.045)¹¹.

The studies on the ease of insertion of I-gel include that by Soar J who used size 4 I-gels in patients during cardiac arrest and noticed that I-gel was inserted in less than 10 sec from opening the packet. He advocated I-gel as another supraglottic airway device competing to be easy and simple for non-airway experts to use during cardiopulmonary resuscitation¹². In our study mean insertion time with I-gel was 10.76 secs.

Paralkar et al compared the I-gel regarding its ease of insertion, seal pressures, mode of ventilation, efficacy and fit as an airway and performance relative to the LMA and PLMA. They observed that regarding its fit around peri-laryngeal area was equivalent to LMA and there were no complications post operatively. They suggested that I-gel was comparable with these devices in most of the cases and superior to LMA in 63% and PLMA in 17% of the patients¹³. In our study as far as perioperative complications were concerned only one case of bleeding on the device and one case of laryngospasm was seen with I-gel. One case of laryngospasm was also reported in LMA group.

Cook et al conducted a cohort study of I-gel airway in 71 patients in minor elective surgeries and found that insertion and ventilation were possible in 87% patients in 1st attempt, 10% in 2nd attempt and 3% in 3rd attempt. They also recorded the time of insertion and airway maneuvers used to pass airway. Anesthetists overall rated its performance excellent in 93-94%, fair in 3-4% and 1% poor. They concluded that it is a fast and easily inserted device, with good airway maintenance and requiring lesser airway maneuvers¹⁴.

Wharton et al did study in 37 patients regarding

placement time, attempts, airway maneuvers, and failure rate and post operative complications with I-gel airway device. They noticed that 1st attempt insertion was possible in 84% of the patients; rest was achieved in 2nd attempt. Average time needed to place was 17sec and gastric tube was passed in 88% patients. It needed lesser airway manipulations as compared to CLMA and P LMA. They suggested that I-gel might be superior to the CLMA and PLMA¹⁵. In our study 1st attempt insertion was possible in 90% of the cases while 2nd attempt was required in the remaining 10%. Comparable rates were also observed in LMA group.

Our study has failed to show the superiority of either device in ease of insertion, insertion time or number of attempts at insertion. Ease of insertion becomes an important factor when these devices are used by relatively untrained personnel. The insertion was done by experienced anesthetists who had vast experience with LMA insertion and had used I-gel extensively before this study. The results of this study may not be applicable to people relatively untrained in airway management. We need more data to confirm the ease of insertion of I-gel in the hands of people who are asked to manage the airway occasionally.

CONCLUSION

Our study showed that I-gel is comparable to LMA in ease of insertion in the hands of experts in airway management. We recommend more trials of comparison of LMA and I-gel regarding their insertion and airway management.

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Successful people, successful leaders know that no problem or challenge in the workplace is to be fearedit is only to be understood.

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5