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COMPARATIVE CLINICAL EVALUATION OF PROSEAL LMA WITH I - GEL AIRWAY IN PATIENTS UNDERGOING ELECTIVE SURGICAL PROCEDURES UNDER GENERAL ANAESTHESIA

Sugata Dasgupta¹, *Dipasri Bhattacharya¹ and Saswati Paul²

¹*Department of Anaesthesiology, R.G.Kar Medical College, Kolkata, West Bengal*

²*Department of Anaesthesiology, N. R. S. Medical College Kolkata, West Bengal*

**Author for Correspondence*

ABSTRACT

The laryngeal mask airway devices dominate the field of supraglottic airway management and are widely being used in clinical practice. The disposable one is the preferred variety because it avoids the risk of contamination.

A new disposable supraglottic airway device the i-gel airway has been introduced recently. We have compared the disposable soft seal LMA with i-gel airway in terms of various clinical parameters.

200 patients aged 20-50 years, body weight 50 to 80 kg, ASA I and II were randomly assigned into two equal groups for airway management during surgery, group A (n=100) for disposable soft seal LMA and group B (n=100) for i-gel airway. Anaesthesia was induced with fentanyl 2µg/kg + propofol 3mg/kg and midazolam 0.05mg/kg, maintained with nitrous oxide 66%, oxygen 33% and halothane 2 to 3%. The variables studied were ease of insertion and insertion time, presence of blood on the device on withdrawal and postoperative sore throat at 2 and 24 hours.

Successful insertion at first attempt was performed in 80% of group A and 98% of group B (p<0.05) within 15 seconds. Macroscopic blood was seen in 6% of group A and none in group B (p<0.05). Incidence of sore throat at 2 hours post operatively was 18% in group A and 6% in group B (p< 0.05). However, there was no such difference at 24 hours.

To conclude, i-gel airway is a better and useful alternative to disposable soft seal LMA regarding ease of insertion and less incidence of sore throat in the postoperative period.

Keywords: Disposable Soft Seal LMA, I-Gel Airway, Clinical Evaluation

INTRODUCTION

The single use soft seal Laryngeal Mask Airway (LMA) is an effective supraglottic device and is widely used for securing airway in patients undergoing elective surgery under general anaesthesia (Andre *et al.*, 2003). This new disposable device is an acceptable alternative to the reusable LMA Classic resulting in a good laryngeal seal, offering similar clinical performance and less chance of contamination (Andre *et al.*, 2003; Brimacombe *et al.*, 1998; Verghese *et al.*, 1998; Dingley *et al.*, 1994). The disposable soft seal variety cause less trauma during insertion and minimize the incidence of postoperative sore throat (Peach *et al.*, 2005). Only drawback is its difficult insertion in some cases compared to classic LMA (Brimacombe *et al.*, 1998; Peach *et al.*, 2005). The i -gel airway is the most recent novel supraglottic airway device made up of a latex free thermo plastic elastomer with a soft durometer and gel like feel (Levitan and Kinkle, 2005). The mask of i-gel is designed anatomically to fit the hypopharyngeal and perilaryngeal aperture without the use of an inflatable cuff. A supraglottic airway without an inflatable cuff has potential advantages including easier insertion, use with minimal risk of tissue compression and stability after insertion (Levitan and Kinkle, 2005). The integrated gastric channel actively reduce gastric insufflation and risk of aspiration (Levitan and Kinkle, 2005).

The aim of this study was to evaluate the clinical acceptability of the i-gel airway as an alternative to the soft seal disposable LMA. We have compared them in terms of ease of insertion, insertion time, postoperative complications like sore throat, at 2 and 24 hours following surgery. Since the i-gel airway is now available in India, this study is all the more relevant and worthwhile

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MATERIALS AND METHODS

After obtaining approval from the institutional ethical committee and informed written consent, 200 patients (ASA I and II), aged 20 to 50 years, body weight 50 to 80 kg of both sexes undergoing elective surgery under general anaesthesia with spontaneous ventilation using either LMA or i- gel airway (3 or 4 size according to body weight), were randomly allocated into two equal groups. Patients of ASA III, predicted difficult airway, requiring surgery in nonsupine position, undergoing oral or nasal surgery and patients having history of preoperative sore throat were excluded from the study. Patients were randomly allocated according to computer – generated random number sequences and sealed opaque envelopes, to placement of either the disposable soft seal LMA or i- gel airway. Group A (n=100) had disposable LMA insertion and group B (n=100) had i-gel airway insertion for elective surgical procedures of one to one and half hour duration. Patients of group A weighing 50 to 70kg were assigned a size 3 and more than 70kg were assigned size 4 LMA. In group B, patients of body weight less than 60 kg had size 3 and more than 60kg had size 4 i-gel airway insertion (according to i-gel user guide). Patients were unaware of the type of airway device used. The same anaesthesiologist inserted the device in all patients. In group A routine pre insertion test of the cuff for leaks were done immediately before use. The tip of LMA and posterior aspect of the mask was coated with water-soluble lubricant, which is the normal practice in our institution. The cuff was inflated before insertion with ambient room air at 10mm of Hg or 415 cm of H₂O above atmospheric pressure, which is the standard practice in our institution and advocated by many authors who believe, insertion of laryngeal mask with cuff partially inflated result in a lower incidence of sore throat and pharyngeal mucosal bleeding (Matta *et al.*, 1995). The i-gel airway was inserted according to the instructions mentioned in the i-gel User Guide. No premeditation was used and all patients were preoxygenated for 3 minutes before intravenous induction which consisted of 2 ug / kg of fentanyl, 3 mg/kg of propofol and 0.05 mg/kg of midazolam. The laryngeal mask airway or i-gel airway was inserted after loss of eyelash reflex and the relaxation of the jaw (Drage *et al.*, 1996). The LMA was held at the mask-tube junction in pen holding fashion and was inserted in sniffing position to facilitate passage around the back of the mouth in the line of palatopharyngeal curve. The mask was introduced till a definite resistance was felt as the tip entered the hypopharynx and backline of the airway tube faced upper lip. The mask was then inflated with the recommended volume and the position was secured with tape and bite block. The i- gel was lubricated with a non anaesthetic water soluble lubricant and then held along the integral bite block with the mask facing towards the chin of the patient. The airway was introduced in sniffing position into the mouth of the patient in a direction towards the hard palate downwards and backwards till a definite resistance was felt. At this point the tip of the airway should be located into the upper oesophageal opening, the mask should be located against the laryngeal framework and the incisors should be resting on the integral bite block. The position was secured with tape. An unsuccessful attempt at insertion was defined as placement of the mask into the mouth and withdrawal from the mouth. Successful placement and adequate ventilation was confirmed by clinical observation of clear airway, observing chest wall movement with manual ventilation, listening to escape of gas from the mouth, observing the square wave trace capnograph and satisfactory movement of the reservoir bag on spontaneous ventilation. Anaesthesia was maintained with N₂O + O₂ (2:1) and halothane 2 to 3% with Mapleson A circuit. The insertion time was noted (i.e. the time in seconds taken from loss of eyelash reflex to successful airway insertion) in both the groups.

The ease of insertion was graded as:

- 1 - very easy insertion at first attempt with no resistance,
- 2 - easy at first attempt with little resistance,
- 3 - some difficulty, but successful at second attempt and
- 4 - Failed insertion.

The monitors used were SpO₂, NIBP, continuous ECG and capnography. At the end of surgery nitrous oxide and halothane were discontinued to allow the patient to resume full recovery. When the protective reflexes had returned to normal, the airway was removed (after deflation of the cuff in case of LMA) and presence of blood on the airway if any was noted. Presence of sore throat was enquired and the patients

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were requested to grade the sore throat (none, mild, moderate and severe) at 2 and 24 hours after surgery by another anaesthesiologist. The following parameters were recorded: patient's demographic data (Sex, age, body weight), duration of surgery (from the time of skin incision to skin closure), duration of anaesthesia (from the time of induction to the removal of airway), time to insert airway, number of insertions.

Two groups were chosen. Statistical analysis was done. Sample size calculation was performed using Sampsiz version 2.0 (Sample size tables for clinical studies; Blackwell Science Ltd., Oxford, United Kingdom).

The study had a power of 90% ($\beta = 10\%$, $\alpha = 0.05$) and the standardized difference was 0.35 (SD, 0.86). The estimated sample size was 88 patients per group. Two groups each of 100 patients were chosen. Comparison were performed using Mann – Whitney and Wisconsin tests as appropriate for paired and independent observations and Chi-square test for comparison of categorical outcomes. All data were presented as mean \pm SD and $p < 0.05$ was considered to be significant

RESULTS AND DISCUSSION

Results

The two groups were similar with respect to age, sex, body weight, height, duration of surgery and anaesthesia (Table – 1). The overall insertion time of the airway in both the group was within 15 seconds and successful insertion at first attempt was performed in 80% of group A (LMA disposable) and in 98% of group B (i-gel airway) (Table – 2). In none of the cases there was laryngospasm, retching or any haemodynamic or respiratory side effects. None of the patient had aspiration or regurgitation. Macroscopic blood on the airway was seen on removal in 6% of group A but none in group B. The incidence of sore throat at 2 hour was 18% in group A and in 6% in group B. $p < 0.05$. Figure 1. There was no significant difference in sore throat in between two groups after 24 hours (Figure 1).

Discussion

LMA is the most important milestone in the development of airway devices in the past 20 years. It was originally developed for airway management of routine cases with spontaneous ventilation (Sarma, 1990). The soft seal disposable LMA made primarily of medical grade polyvinyl chloride is available in three sizes 3, 4 and 5 (Brimacombe, 2005). They are used once and thereby contamination can be avoided in contrast to LMA classic (Brimacombe, 2005). First reports on the use of a disposable soft seal laryngeal mask when compared with LMA classic proved that both LMA provided an adequate airway and similar clinical performance in spontaneously breathing patients with less incidence of sore throat in disposable soft seal LMA probably due to less chance of cuff pressure rise during nitrous oxide anaesthesia (Andre et al., 2003; Brimacombe, 2005).

The i-gel is a new single use device manufactured by Intersurgical, now available in India. It has some distinctive features that set it apart from other supraglottic airway devices (Gabbot and Beringer, 2007). The supraglottic component that covers the larynx is made of an elastomer gel (styrene ethylene butadiene styrene (SEBS)) which does not require inflation. There is a provision for an independent gastric drainage tube and an integral bite block. It is available in sizes 3, 4 and 5 (Gabbot and Beringer, 2007)

We found that i-gel is very easy to use. Insertion does not require an introducer or placement of the finger into the mouth as the device is simply pushed into place. In our study 98% of i-gel group had insertion at first attempt which conforms to the study of Gabbot and Boringer (Gabbot and Beringer, 2007).

The introduction of laryngeal mask airway sometimes needs index finger guidance to keep it in proper place. In our study all the patients who needed more than one attempt in LMA group needed index finger guidance (Matta et al., 1995; Gabbot and Beringer, 2007) for proper insertion. Inflation using the recommended volumes increases masks rigidity, decreases conformity with perilaryngeal structures (Brimacombe and Keller, 1998). Mechanically, inflation can cause movement of the device because the distal wedge shape of the mask is forced out of the upper oesophagus (Keller et al., 1998). Inflatable masks also have the potential to cause tissue distortion, venous compression and nerve injury (Twigg et

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al., 2000; Stewart and Lindsay, 2002; Lowinger *et al.*, 1999). Finally, depending upon their materials, they can absorb anaesthetic gases, leading to increased mucosal pressures (Ouellette, 2000).

A supraglottic airway without an inflatable cuff has certain advantages. There is no change of position (as may occur following insertion of LMA) following insertion, the problem of absorption of nitrous oxide and increase in cuff pressure does not arise (Levitan and Kinkle, 2005; Soar, 2007).

Table 1: Patient's demographic data

	Group A, n=100, Disposable LMA	Group B, n=100, i-gel airway	p value
Age (yrs)	40.3 ±10.3	40.1 ± 10.2	NS
Sex: M/F	52 / 48	56 / 44	NS
Body weight (kg)	64.12 ± 10.12	62.30 ± 9.98	NS
Height (cms)	155 ±10.23	154 ±10.22	NS
Duration of Surgery (mins)	70 ±10.30	70 ± 9.50	NS
Duration of anaesthesia (mins)	80 ± 10.24	80 ± 11.02	NS

Table 2: Type of surgeries in both the groups

	Group A n=100 Disposable LMA	Group B n=100 i- gel airway	p value
Inguinal Herniorraphy	55	51	NS
Epigastric hernia	5	9	NS
Bilateral hydrocoele	14	15	NS
Hypospadias	6	5	NS
Skin grafting	10	10	NS
Lipoma excision	3	3	NS
Dermoid cyst excision	2	2	NS
Tendon repair	2	3	NS
Bilateral release of carpal tunnel	3	2	NS

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Table 3: Insertion time and No. of attempts of insertion

	Group A, n=100, Disposable LMA	Group B, n=100, i-gel airway	p value
insertion time (sec)	15.10 ± 5.0	14.12 ± 6.0	NS
insertion 1st attempt without any resistance	60/100(60%)	70/100(70%)	p<0.05
1st attempt with resistance	20/100(20%)	28/100(28%)	
2 nd attempt	10/100 (10%)	2/100 (2%)	p<0.05
3 rd attempt	10/100 (10%)	0	p<0.05

Table 4: Post operative complications in between two groups

	Group A Disposable LMA n=100	Group B i-gel airway n=100	p value
Evidence of tissue trauma as proved by presence of macroscopic blood on airway	6% ¹	nil	<0.05
Incidence of postoperative sore throat 2hr			
None			
Mild	80/100(80%)	95/100(95%)	<0.05 significant
Moderate	10/100(10%)	3/100(3%)	<0.05 significant
Severe	5/100(5%) 5/100(5%)	2/100(2%) 0	
24hr			
Mild	3/100(3%)	2/100(2%)	NS

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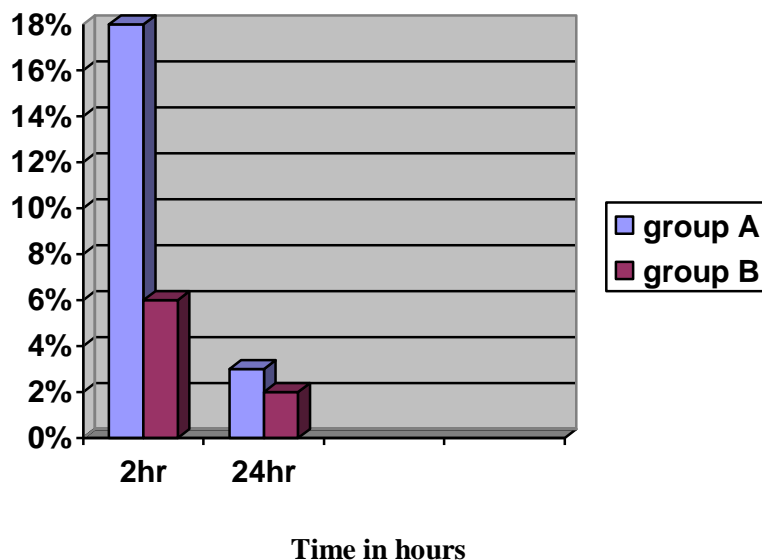


Figure 1: Incidence of sore throat (in %) at 2hr and 24hr period following insertion in both the groups

The tensile properties of the i-gel bowl, along with its shape and the ridge at its proximal end, contribute to the stability of the device upon insertion (Levitan and Kinkle, 2005; Soar, 2007). The i-gel is a supraglottic airway competing to be the easiest and simplest device for non-airway experts to use during cardiopulmonary resuscitation (Soar, 2007; Cook and Hommers, 2006). Jackson and Cook (2007) in their Trucorp manikin study for all supraglottic airway devices have seen that i-gel insertion was significantly the easiest (Jackson and Cook, 2007).

Airway trauma demonstrated by visible blood on the i-gel on removal was not detected in any case in our study. The incidence of sore throat was also less in i-gel group than in comparison to LMA group. Sharma *et al.*, (2007), Gibbison *et al.*, (2008) have similar experience with the i-gel (Sharma *et al.*, 2007). The i-gel has features designed to separate the airway and gastro-intestinal tracts and as such should offer some protection against aspiration (Gibbison *et al.*, 2008). In our study no patients in any group had regurgitation or aspiration.

At this point of time the i-gel device costs twice the amount of disposable soft – seal LMA. Gradually as airway experts or the anaesthesiologist realizes the advantages of i –gel and with widespread acceptance the prices bound to come down in near future.

To conclude, the result of the study shows that i-gel airway provides an easy insertion and reliable clear airway with minimum complications.

So it can be a better alternative to disposable soft seal LMA in patients undergoing elective surgical procedures under general anaesthesia.

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