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Original research article

A comparative study to evaluate the efficacy of two types of supraglottic airway devices- I-gel and cLMA

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Abstract

Supraglottic airway devices have become a standard fixture in airway management, in the last two decades filling a niche between facemask and tracheal tube in terms of both anatomical position and degree of invasiveness. These devices sit outside trachea but provide a hands free means of achieving a gas tight airway. After obtaining written informed consent, 60 adult patients of both sexes belonging to ASA Grade I and II planned various elective procedures lasting for 45min to 1hour duration, were randomly selected. In 90% patients, I-gel was inserted in 1st attempt and also cLMA was inserted in 90% patients. 3 cases (10%) required 2nd attempt for I-gel insertion as compared to 2 cases (6.7%) for cLMA insertion. However, no 3rd attempt was required for Group I but, 1 case (3.3%) in Group II and the difference was statistically similar with p=1.000.

Keywords: Supraglottic airway devices, I-gel, cLMA

Introduction

Airway management is one of the most important skills in the field of anesthesiology. The major responsibility of an anesthesiologist is to provide adequate ventilation to a patient. The most vital element in providing functional respiration is the airway. Management of the airway has come a long way since the development of endotracheal intubation by Macewan in 1880 to the present day usage of sophisticated devices. It has been established that inability to successfully manage a difficult airway has been responsible for as many as 30% of death totally attributable to anaesthesia [1]. The face mask and the endotracheal tube (ETT) have been the two traditional methods established for providing airway management for a long time.

Supraglottic airway devices have become a standard fixture in airway management, in the last two decades filling a niche between facemask and tracheal tube in terms of both anatomical position and degree of invasiveness. These devices sit outside trachea but provide a hands free means of achieving a gas tight airway. The first successful supraglottic airway device, the laryngeal mask airway (LMA) classic became available in 1989, first described by Dr.Archie Brain [2]. LMA are being used in spontaneous and controlled ventilation. Apart from anaesthesia, various variants of LMA can potentially be useful in other clinical situations i.e cardiopulmonary resuscitation (CPR) [3-6] pre-hospital emergency use, and management of a difficult airway [7]. In spite of this LMA are contraindicated in situations like low pulmonary compliance [8], high airway resistance or conditions where there is increase risk of regurgitation. It is also contraindicated in patients with pregnancy of greater than 14 weeks, morbid obesity, hiatus hernia or any factor associated with delayed gastric emptying careful observations and clinical experience have led to several refinements of Brian's original prototype leading to the development of newer supraglottic airway devices with better airway maintenances such as Proseal LMA, combitube and I- gel LMA.

The primary limitation of the LMA is that it does not reliably protect the lungs from regurgitated stomach contents, although it may act as a barrier at the level of the upper esophageal sphincter if it is correctly positioned. The incidence of aspiration with the LMA has been estimated at 0.02%, which is similar to tracheal intubation in elective patients [9].

The I-gel is the most recent development in supraglottic airway devices. Great contribution in the development of this device was made by Dr. Mohammad Aslam Nasir in January 2007 [10]. The I-gel is a truly anatomical device. The soft non inflatable cuff fits snugly on to the perilaryngeal frame work,

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mirroring the shape of the epiglottis, aryepiglottic folds, piriform fossae, perithyroid, pericricoid, posterior cartilages and spaces [10, 11]. The seal created is sufficient for both spontaneously breathing patients and for intermittent positive pressure ventilation. A drain tube is placed lateral to the airway tube which allows insertion of the gastric tube [12].

Methodology:
After obtaining written informed consent, 60 adult patients of both sexes belonging to ASA Grade I and II planned various elective procedures lasting for 45min to 1hour duration, were randomly selected.
The study group was divided in two groups of 30 each (n=30):
Group I: (30 cases where I- gel was used).
Group II: (30 cases where cLMA was used).

Inclusion criteria were
- ASA Grade I & II patients
- Age between 18 to 55 years of both sexes
- Planned for elective surgical interventions where spontaneous ventilation is ideal.

Exclusion criteria were
- Patients' refusal
- ASA Grade III & IV patients
- Mouth opening < 2.5 cm
- Obese patients with BMI > 28kg/m^2
- Emergency surgical interventions
- Patients with history of allergy or sensitivity to latex or egg
- History of Gastro esophageal reflux disorder
- Patients with risk factors like pregnancy more than14weeks
- K/C/O Hypertension or Blood Pressure $\geq$150/90
- Patients posted for head and neck surgery
- Impaired ability to communicate (eg. Confusion, poor hearing or language barrier)
- Patients with distorted or abnormal anatomy of pharynx.
- Patients with obstruction of the airway beyond the larynx.
- Patients with decreased compliance of the lung.

Study procedure
60 patients who satisfied inclusion criteria were divided in two groups as mentioned previously.
All the patients were subjected to through pre-anesthetic checkup and evaluation was done pre-operatively which included:
- Detailed airway assessment.
- Nutritional status and body weight of the patient.
- Detailed medical history
- Surgical history
- Detailed examination of cardio-vascular and respiratory system.
- Drug therapy
- History of any allergy
- Any addiction (if any)

Relevant baseline investigation including complete blood count, urine routine, serum creatinine, blood urea nitrogen, serum electrolytes, random blood sugar, blood grouping and Rh typing, chest-ray PA view and 12 lead ECG. They were also screened for HIV and HbsAg.
Study procedure including the risks/ benefits was explained to patients and informed written consent was taken in patients own understandable language. All patients were kept nil by mouth overnight and pre-medicated with Tab. Alprazolam 0.5mg and Tab. Ranitidine 150mg the night before surgery.

Results

Table 1: Comparison of MPG

MPG	Group I		Group II	
	No	%	No	%
I	18	60.0	22	73.3
II	12	40.0	8	26.7
Total	30	100.0	30	100.0

Interpretation: In the above table the mallampati grading for airway assessment was done for both the

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groups and it was found to be statistically non-significant (p=0.273).

Table 2: Surgery

Surgery	Group I		Group II	
	No	%	No	%
1.Bilateral Hernia	2	6.7	3	10.0
2.Closed Reduction	1	3.3	1	3.3
3.Contracture Release	2	6.7	2	6.7
4.Fibroadenoma	1	3.3	4	13.3
5.Implant Removal	5	16.7	3	10.0
6.Perianal Abscess	0	0.0	2	6.7
7.Screw Removal	2	6.7	1	3.3
8.Secondary Suturing	3	10.0	2	6.7
9.Split Skin Grafting	2	6.7	0	0.0
10.Umbilical abscess	1	3.3	1	3.3
11.Abscess hand	0	0.0	1	3.3
12.Amputation (LL)	1	3.3	0	0.0
13.Tubectomy	2	6.7	3	10.0
14.Calcification foot excision	1	3.3	0	0.0
15.Circumcision	0	0.0	1	3.3
16.Flush ligation	1	3.3	0	0.0
17.Gynaecomastia Excision	1	3.3	0	0.0
18.Jaboulay's procedure	2	6.7	0	0.0
19.K Wire fixation (forearm)	0	0.0	1	3.3
20.Lipoma Excision	1	3.3	4	13.3
21.Fibrocystic Disease	0	0.0	1	3.3
22. Fracture clavicle	1	3.3	0	0.0
23.Wound debridement	1	3.3	0	0.0

Table 3: Jaw relaxation (secs)

Jaw relaxation (secs)	Group I		Group II	
	No	%	No	%
<100	29	96.7	5	16.7
>100	1	3.3	25	83.3
Total	30	100.0	30	100.0
Mean ± SD	76.33±15.25		124.50±26.17	

Interpretation: The mean jaw relaxation is significantly less in Group I (76.33±15.25) with p <0.001 which signifies that Group I achieved jaw relaxation in shorter duration than Group II (124.50±26.17).

Table 4: Ease of Insertion

Ease of Insertion	Group I		Group II	
	No	%	No	%
Poor	3	10.0	4	13.3
Good	25	83.3	26	86.7
Excellent	2	6.7	0	0.0
Total	30	100.0	30	100.0

Interpretation: The ease of insertion was found to be statistically similar in two groups with P=0.543

Table 5: Duration of insertion (secs)

Duration of insertion (secs)	Group I		Group II	
	No	%	No	%
6-10	21	70.0	21	70.0
11-20	7	23.3	7	23.3
21-30	2	6.7	2	6.7
Total	30	100.0	30	100.0
Mean ± SD	11.03±4.61		11.10±5.32	

Interpretation: The mean duration of insertion of group I and group II were (11.03±4.61) and (11.10±5.32) respectively. There was no difference statistically in both the groups with p =0.959

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Table 6: No. of Insertion Attempts

No. of Insertion Attempts	Group I		Group II	
	No	%	No	%
1	27	90.0	27	90.0
2	3	10.0	2	6.7
3	0	0.0	1	3.3
Total	30	100.0	30	100.0

Interpretation: From the above table it is interpreted that in 90% patients, I-gel was inserted in 1st attempt and also cLMA was inserted in 90% patients. 3 cases (10%) required 2nd attempt for I-gel insertion as compared to 2 cases (6.7%) for cLMA insertion. However, no 3rd attempt was required for Group I but, 1 case (3.3%) in Group II and the difference was statistically similar with p=1.000.

Table 7: Air leak

Air leak	Group I		Group II	
	No	%	No	%
No	29	96.7	30	100.0
Yes	1	3.3	0	0.0
Total	30	100.0	30	100.0

Interpretation: The distribution of air leak is statistically similar in both the groups with P=1.000

Table 8: Ease of removal

Ease of removal	Group I		Group II	
	No	%	No	%
Poor	0	0.0	2	6.7
Good	30	100.0	28	93.3
Total	30	100.0	30	100.0

Interpretation: The ease of removal was found to be statistically insignificant between both the groups with p= 0.492.

Table 9: Local injury

Local injury	Group I (n=30)		Group II (n=30)	
	No	%	No	%
Nil	28	93.3	26	86.7
Yes	2	6.7	4	13.3
Palate	2	6.7	3	10.0
Teeth	0	0.0	1	3.3

Interpretation: In the above table, palate injury was seen in 2 cases (6.7%) and 3 cases (10%) in Group I and Group II, respectively while injury to teeth was seen only in 1 case (3.3%) in Group II. Statistically, both the groups were found to be insignificant with p= 0.671.

Table 10: Post Extubation

Post Extubation	Group I (n=30)		Group II (n=30)	
	No	%	No	%
Nil	30	100.0	28	93.3
Yes	0	0.0	2	6.7
Vomiting	0	0.0	2	6.7

Interpretation: From the above table, post extubation result was statistically insignificant in both the groups with p=0.492.

Table 11: Post Op. after 24 Hr.

Post Op. after 24 Hr.	Group I (n=30)		Group II (n=30)	
	No	%	No	%
Nil	27	90.0	25	83.3
Yes	3	10.0	5	16.7
DC	2	6.7	2	6.7
ST	1	3.3	3	10.0

Interpretation: From the above table, post-operative result after 24hrs was statistically insignificant in

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both the groups with p=0.706.

Discussion:

After premedication, the induction was achieved by Inj. Propofol and the depth of anesthesia was assessed by jaw relaxation and loss of eyelash reflex. As Drage MP *et al*. [13] also said so about the assessment of adequate depth. Once adequate depth was achieved, device was inserted by the technique as recommended by the manufacturers in the instruction manuals, and insertion characteristics of both the devices were assessed as duration and number of attempts while securing the airway. No cricoid pressure was applied while securing the airway. It was also stated that application of cricoid pressure hampered the proper placement of the device. This was the reason for not using the cricoid pressure in our study as well while inserting the device.

One of the primary objective of the study was to compare the ease of insertion of both the devices. The grading of insertion was done similar to the study conducted by Siddiqui *et al*. [14] where insertion of device was recorded as; excellent (when assistant help was not required), good (when jaw thrust was needed by assistant) and poor (when jaw thrust and deep rotation or second attempt was used for proper device insertion. So, in our study 10% of Group I had a poor insertion as compared to 13.3% in Group II, further, 83.3% and 86.7% had a good insertion in Group I and Group II, respectively? Whereas, Group I had excellent insertion of 6.7% which was not observed in Group II. Thus, the distribution of ease of insertion was statistically similar in both the groups. The insertion of I-gel was found comparatively easier and required less skill as compared to LMA but the results were not significant statistically. The I-gel having a non-inflatable cuff and firm in consistency is much easier for insertion as compared to LMA.

The patients were assessed post extubation for airway morbidities (sore throat, vomiting, cough, bronchospasm, laryngospasm). Post extubation complication in the form of vomiting was found in 2 cases (6.67%) in group II and none in group I, which was statistically insignificant.

24 hours after the surgery, patients were interviewed for any post-operative complications like sore throat, dysphagia and hoarseness. Only 2 patients in each of the groups complained of discomfort in the throat, whereas, 1 patient in group I (3.3%) and 3 patients in group II (10%) had complaints of sore throat. The incidence was statistically not different (p= 0.706) when compared between the two groups. The sore throat in all the 4 cases were mild requiring no treatment. None of the patients in both the groups developed postoperative hoarseness and dysphagia.

Our studies were consistent with the studies done by Siddiqui AS, *et al*. [14], Helmy AM, *et al*. [1], Franksen H, *et al*. [15], where the difference between I-gel and cLMA regarding postoperative complication was statistically not significant except nausea and vomiting which was significantly higher in LMA due to the high incidence of gastric insufflations.

Keizer C *et al*. [16], in their study compared the postoperative throat and neck complications between Lma and I-gel. There was a high incidence of post-operative sore throat and dysphagia at 1, 24 and 48 hrs in the LMA group. Because of the absence of an inflatable cuff, the authors hypothesized that the use of the I-gel produced fewer postoperative sore throat and neck complications compared with a standard LMA.

Thus we conclude that airway can be secured in lesser duration and lesser number of attempts with I-gel as compared to cLMA with hemodynamic stability and minimal post-operative complications.

Conclusion

Classic- LMA and I-gel can be used safely and effectively during general anaesthesia with spontaneous ventilation in selected patients. Both devices are easy to insert. The duration of insertion and number of attempts at insertion was definitely less with I-gel as compared to cLMA, though not statistically very significant. I-gel thus, proved to be better & efficient than cLMA in this regard. The time taken for insertion was, also, considerably less for the I-gel highlighting its efficacy in controlled & spontaneous ventilation conditions and also in resuscitative scenarios. Hemodynamic responses elicited by each device were comparable.

Thus the I-gel is a better alternative to cLMA for airway maintenance during general anesthesia for spontaneous ventilation and can be recommended for controlled ventilation also.

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