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ORIGINAL RESEARCH

Comparison of clinical performance of I-Gel with laryngeal mask airway proseal in elective surgery

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ABSTRACT
Supraglottic airway devices are an intermediate between facemask and an ETT. I-gel and LMA-proseal are second generation SAD designed to reduce the risk of aspiration of gastric contents. This prospective randomized study was taken up to compare the clinical performance of i-gel with laryngeal mask airway proseal in elective surgery in adults. After ethical committee approval, following detailed preanesthetic checkup informed written consent was obtained from all the 94 patients of either sex and were randomized in sealed envelope. I-gel group (n=47) and PLMA group (n=47). Demographically both groups were similar. I-gel was more easily inserted than PLMA(p=0.017), mean insertion time for i-gel (12.47±0.62 sec) was significantly lower than PLMA (13.43±0.68sec), p=0.000 and number of attempts were comparable between two groups (p=0.154). 44(93.6%)/3(6.4%) in i-gel group and 31(70.2%)/16(29.8%) patients in PLMA group had fibreoptic score of 1/2 respectively (p=0.003). Gastric tube placement, complications and hemodynamic parameters were comparable.

Key words: Insertion, I-gel, characteristics, LMA pro-seal

INTRODUCTION

Introduction of supraglottic airway devices (SAD) has revolutionized the airway management. The first successful supraglottic airway device the laryngeal mask airway classic introduced in 1989 and it is found to have risk of aspiration of around 6-9%[1].To overcome the limitation of C-LMA constant evolution in device design has encouraged resulting in introduction of various other SADs like proseal-LMA, intubating-LMA and I-gel[2].

LMA proseal is a reusable supraglottic airway device with both an airway lumen and a drain tube. It achieves high pressure seal for both the airway and oesophagus[3, 4].The drain tube present in LMA proseal helps in drainage of regurgitant matter or decompression of stomach. The LMA proseal is a reliable device for airway maintenance and ventilation of lungs but it has cuff related complications[3, 5].High pressure in laryngeal mask airway can cause damage to the mucosae on periglottic and supraglottic structures resulting in the sore throat, hoarseness of voice and nerve palsies[5].

The I-gel is a newly developed supraglottic airway device. The cuff of I-gel is constructed from medical grade thermoplastic elastomer which eliminates need to inflate the cuff thus reducing the cuff related complications[6].Several studies in adults have shown that the clinical performance ofthe I-gel is comparable with or better than other devices with respect to insertion time, ease of insertion, oropharyngeal leak pressure and vocal cord view via a fiberooptic scope[7, 8].

The present study is to compare the clinical performance of i-gel with LMA pro-seal in patients undergoing elective surgery under general anesthesia.

METHODOLOGY

The prospective randomized study was conducted on 94 patients, 47 in each group undergoing elective surgery in supine position under general anaesthesia with controlled ventilation with the following inclusion and exclusion criteria.

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INCLUSION CRITERIA

1. Patient willing to give informed consent.
2. American society of anesthesiologists (ASA) physical status 1 or 2.
3. Age 18-60 years.
4. Elective surgical procedure of duration less than 2 hours under general anesthesia with no requirement for endotracheal intubation.

EXCLUSION CRITERIA

1. Patients with risk factors for difficult airway (mouth opening <2cm, Mallampatti class 4, limited neck extension, history of previous difficult intubation).
2. ASA physical status 3 and 4.
3. Patients with risk of aspiration (full stomach, hiatus hernia, gastroesophageal reflex disease, emergency surgery).

RESULTS:

Table 1: Comparison of subjective scale of ease of insertion between two groups

Ease of Insertion	I-Gel		PROSEAL-LMA		p-value	Result
	Number of Patients	Percent	Number of patients	Percent		
1(no resistance)	41	87.2%	31	66.0%	0.015	Significant
2(mild resistance)	6	12.8%	16	34.0%		
3(moderate resistance)	0	0	0	0		
4(inability to place a device)	0	0	0	0		

In i-gel group-41(87.2%)/6(12.8%)/0/0 patients and in proseal group-31(66%)/16(34%)/0/0 patients had scale of 1/2/3/4 respectively with p-value of 0.015, which is statistically significant.

Table 2: Comparison of insertion time in seconds between two groups

Group	MEAN (sec)	SD (sec)	p-value	Result
I-Gel	12.47	0.62	0.000	Significant
PROSEAL LMA	13.43	0.68		

The mean insertion time in i-gel group was 12.47sec with SD 0.62 sec and in group proseal was 13.43sec with SD 0.68 sec with p-value 0.000 which is statistically significant.

Table 3: Comparison of number of insertions attempts between two groups

Attempts	I-Gel		PROSEAL-LMA		p-value	Result
	Number of patients	Percent	Number of patients	Percent		
1	44	93.6%	43	91.5%	0.154	Not Significant
2	3	6.4%	4	8.5%		
3	0	0	0	0		
Total	47	100.0%	47	100.0%		

Out of 94 patients, in i-gel group 44(93.6%)/3(6.4%)/0 patients and in proseal group 43(91.5%)/4(8.5%)/0 patients had insertion attempts of 1/2/3 respectively with p-value of 0.154 which is statistically not significant.

Table 4: Comparison of Fiberoptic scoring between two groups

Fibre Optic Scoring	I-GEL		Proseal LMA		P-Value	Result
	Number of patients	Percentage	Number of patients	Percentage		
1	44	93.6%	31	70.2%	0.003	Significant
2	3	6.4%	16	29.8%		
3	0	0	0	0		
4	0	0	0	0		

Fiberoptic scoring for group i-gel was found to be score 1 in 44 patients and score 2 in 3 patients and that for group proseal LMA is found to be score 1 in 33 patients and score 2 in 14 patients. Statistical analysis reveals p-value of 0.003 which is statistically significant.

Table 5: Comparison of Ease of gastric tube insertion between two groups

Ease	I-Gel		Proseal LMA		P-Value	Remark
	Number of patients	Percentage	Number of patients	Percentage		
Easy	42	89.45%	39	83.0%	0.543	Not significant
Difficult	4	8.5%	5	10.6%		
Failed	1	2.1%	3	6.4%		

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In group i-gel -42(89.45%)/4(8.5%)/1(2.1%) and in proseal group 39(83%)/5(10.6%)/3(6.4%) patients were subjectively scored as easy/difficult/failure respectively regarding the ease of insertion with p-value of 0.543 which is statistically not significant.

Table 6: Number of attempts of gastric tube placement between two groups

Gastric Tube Placement Attempts	I-Gel		Proseal-LMA		P-Value	Result
	Number of patients	Percent	Number of patients	Percent		
1	43	93.47%	41	93.1%	0.503	Not Significant
2	3	6.5%	3	6.81%		

In i-gel group 43(93.475)/3(6.5%) patients and in proseal group 41(93.1%)/3(6.81%) patients had a score of 1/2 respectively with p-value of 0.503 which is statistically not significant.

DISCUSSION

Introduction of supraglottic airway devices (SAD) has revolutionized the airway management. The first successful supraglottic airway device the laryngeal mask airway classic introduced in 1989 and it is found to have risk of aspiration of around 6-9% [1].To overcome the limitation of C-LMA constant evolution in device design has encouraged resulting in introduction of various other SADs like proseal-LMA, intubating-LMA and I-gel [2].

LMA proseal is a reusable supraglottic airway device with both an airway lumen and a drain tube. A review of literature done by Cook TM *et al*. showed that proseal LMA achieves high pressure seal for both the airway and esophagus [3, 4].The drain tube present in LMA proseal helps in drainage of regurgitant matter or decompression of stomach there by reducing the risk of aspiration. The LMA proseal is a reliable device for airway maintenance and ventilation of lungs but it has cuff related complications [3,5].High pressure in laryngeal mask airway can cause damage to the mucosae on periglottic and supraglottic structures resulting in the sore throat, hoarseness of voice and nerve palsies [5].

The I-gel is a newly developed supraglottic airway device. The cuff of I-gel is constructed from medical grade thermoplastic elastomer which eliminates need to inflate the cuff thus reducing the cuff related complications [6]. Janakiraman *et al.* noted that oropharyngeal leak pressure for the i-gel is higher than for the LMA classic thereby overcoming the drawback of C-LMA with respect to aspiration of gastric contents [9]. Several studies in adults have shown that the clinical performance of the I-gel is comparable with or better than other devices with respect to insertion time, ease of insertion, oropharyngeal leak pressure and vocal cord view via a fiberooptic scope[7,8].

Chauhan *et al*. and Curpod *et al*. found that i-gel is comparable to the PLMA in securing a patent airway during controlled ventilation and it is better than PLMA in terms of faster insertion and ease of insertion. In our study comparison of clinical performance of i-gel with LMA-Proseal in elective surgery in adults was taken up to compare the efficacy and safety in anesthetized patients on controlled ventilation undergoing elective surgical procedure with respect to the ease of insertion, insertion attempts, fibreoptic assessment, ease of gastric tube placement and complications.

The demographic profile of patients regarding age, gender and weight in both the groups were similar

After insertion of the device the following insertion characteristics were studied insertion time, ease of insertion, number of attempts, fibreoptic score.

In our study ease of insertion was assessed using a subjective scale of 1-4, 1= no resistance, 2= mild resistance, 3= moderate resistance, 4=inability to place a device. In i-gel group 41(87.2%)/6(12.8%)/0/0 and in PLMA group 31(66%)/16(34%)/0/0 patients had a scale of 1/2/3/4 respectively with a p-value of 0.015 which is statistically significant.In a similar study done by Curpod *et al*. they found the ease of insertion in I-gel was 35/5/0/0 and in PLMA was 25/15/0/0 respectively with a p-value <0.05 which was statistically significant[10]. Nirupa *et al*. has graded ease of insertion as very easy/easy/difficult. In i-gel group (n=50) they found 47/1/2 and in PLMA group 40/7/3 patients had a score of very easy/easy/difficult respectively with p value of 0.11 which was statistically insignificant[11].Chauhan *et al*. has graded ease of insertion as 3,2,1,0. 3= insertion at first attempt without any tactile resistance, 2= insertion at first attempt with tactile resistance, 1= insertion successful at second attempt, 0= insertion failed at secondattempt [12]. In i-gel group 32(80%)/8(20%)/0/0 and in PLMA group 25(62.5%)/15(37.5%)/0/0 patients had a scale of 3/2/1/0 respectively with p-value of 0.0004 which was statistically significant. Anjan das *et al*.graded ease of insertion as easy in which there was no resistance to insertion in pharynx in a single maneuver and as difficult where there was resistance to insertion or more than one maneuver was required for correct placement of device [13]. In i-gel group 27(90%)/3(10%) and in PLMA group 25(83.33%)/5(16.67%) patients recorded as easy/difficult respectively with p-value of 0.29 which was statistically not significant. Singh *et al.* graded the ease of insertion as easy/difficult. They found in i-gel 29/1 and in PLMA 23/7 with p-value <0.05 which was statistically significant. The results of our study concur with the results of Curpod *et al*., Chauhan *et al*. and Singh *et al*. but the results of Nirupa *et al*. and

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Anjan das *et al*. did not find any statistical significance between the groups although the ease of insertion was better with i-gel group. I-gel supraglottic airway device should be easier to insert due to its unique gel like material, contour, buccal stabilizer and epiglottis blocker that minimizes epiglottis downfolding. Levitan & Kinkle presumed that on insertion of LMA with inflatable mask the deflated leading edge of the mask can catch edge of the epiglottis and cause it to downfold or impede proper placement beneath the tongue. Brimacombe and colleagues proposed that the difficulties in inserting proseal LMA were due to larger cuff impeding digital intraoral positioning and propulsion into the pharynx.

In our study mean insertion time in I-gel was 12.47±0.62 sec and Proseal 13.43±0.68sec with a p-value of 0.000 which was statistically significant. Similarly, Shiveshi *et al*. found the mean insertion time of i-gel was significantly lower (22.63±5.79sec) than mean insertion time of PLMA (43.26±7.85sec)[9]. Jadhav *et al*. found mean insertion time of i-gel 29.53sec±8.23sec and PLMA 41±9.41sec which was statistically significant[14]. Similar findings noted in Chauhan *et al*.[12]which found the mean insertion time of i-gel was 11.12±1.81sec and that for PLMA was 15.13±2.91sec which was statistically significant[12]. Curpod *et al*.[10] also found similar findings where mean insertion time for i-gel was 12.30± 1.018 sec and for PLMA was 13.82±1.083 sec with p-value <0.05 which was statistically significant[10]. Many other studies have reported shorter insertion time for i-gel compared to other supraglottic airway devices which may be explained by the noninflatable cuff in the i-gel requiring shorter time to achieve an effective airway.

CONCLUSION

In our study comparing the clinical performance of i-gel with LMA proseal in elective surgery in adults the results indicate that i-gel is easier to insert and have good fibreoptic view providing better ventilation and an effective anatomical conformity.

We conclude that i-gel is good alternative to the PLMA since it can be inserted faster and easier and effectively conforming to the perilaryngeal anatomy, despite the lack of an inflatable cuff. I-gel consistently achieved proper positioning for supraglottic ventilation.

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