



## Clinical trial for comparison of clinical performance of I-Gel with LMA-proseal in elective surgeries

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### ABSTRACT

The I-gel is genuinely interesting second era supraglottic aviation route gadget with delicate gel like non inflatable sleeve. The objective of this study was to evaluate and compare the ease of insertion and number of insertion attempts, airway sealing pressure, and fibrotic evaluation of device position and occurrence of complication. A Total 70 adult patients were allocated to either i-gel group or P-LMA group with 35 patients in each group. Both i-gel and P-LMA were introduced with standard technique. The outcomes measured were ease of insertion, number of insertion attempts, airway sealing pressure, haemodynamic changes, fibrotic evaluation of device position and complications. For the i-gel group the success rate at ease of insertion was greater (97% vs 72% respectively;  $P=0.012$ ). Airway sealing pressure was lesser ( $24.72 \pm 1.37$  cm H<sub>2</sub>O vs  $30.09 \pm 2.64$  cm H<sub>2</sub>O respectively;  $P=0.0003$ ). The incidence of postoperative sore throat was lower (2.8% vs 25.7% respectively;  $P=0.01$ ). Changes in haemodynamic parameters were not clinically significant. The i-gel is easier to insert than P-LMA however with a lower airway sealing pressure. It has a lower incidence of postoperative complications.

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### INTRODUCTION

Till date, the bound tracheal cylinder was considered as the best quality level for giving a safe glottic seal, particularly for laparoscopic methodology under general anaesthesia (Sharma *et al.*, 2003). The burdens of tracheal intubation, which includes unbending laryngoscopy, are as far as attendant haemodynamic reactions and harm to the oropharyngeal structures at inclusion. Postoperative sore throat is additionally a genuine concern. This blocks the worldwide utility of the tracheal cylinder and requires a superior alternative (Misra and Ramamurthy, 2008). Over a time frame, new aviation route gadgets have been added to the anaesthesiologist's armamentarium. The supraglottic aviation route gadget is a novel gadget that fills the hole in aviation route the executives between tracheal intubation and utilization of face veil. Dr Archie Brain, a British anaesthesiologist, just because presented the laryngeal veil aviation route in 1983, intended to be situated around the laryngeal delta that could beat the confusions related with endotracheal intubation, but then, be straightforward and a traumatic to insert (Biebuyck *et al.*, 1993). Careful perceptions and clinical experience have prompted a few refinements of Brain's unique model prompting advancement of more up to date supraglottic aviation route gadgets with better highlights for aviation route maintenance (Biebuyck *et al.*, 1993). The wide assortment of aviation route gadgets accessi-

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ble today may comprehensively be named intraglottic and extraglottic aviation route gadgets, which are utilized to ensure the aviation route in both elective just as crisis situations (Atef *et al.*, 2010). As time went on, extra gadgets were added to the LMA family to fulfil explicit necessities, and various different gadgets were created. There are countless supraglottic aviation route gadgets, some of which seem like the LMA family and others that work under an alternate concept (Dorsch, 2012).

Laryngeal cover aviation route is a supraglottic aviation route gadget with an inflatable sleeve shaping a low weight seal around the laryngeal delta and allowing ventilation (Biebuyck *et al.*, 1993). With the job of a LMA, being confined to the troublesome aviation route calculations and a couple of other particular cases, Dr Archie Brain thought of another development, or rather an alteration of the Laryngeal Mask Airway (LMA) in year 2001. This device was called the Proseal-Laryngeal mask airway (Richez *et al.*, 2008). This double lumen, double cuff LMA has some clear advantages over its predecessor. The double tube design separated the respiratory and alimentary tracts, providing a safe escape channel for the regurgitated fluids. The double cuff of the P-LMA gave a better seal around the glottis (Brain *et al.*, 2000; Keller and Brimacombe, 2000), hence establishing its superiority in IPPV. It is designed to achieve a mirror impression of pharyngeal and laryngeal structures and to provide aperilaryngeal seal without cuff inflation. A drain tube is placed lateral to the airway tube, which allows insertion of gastric tube (Richez *et al.*, 2008).

This more up to date supraglottic aviation route gadget, I-gel was presented by Dr Muhammed Aslam Nasir in 2007. It has the potential points of interest including simpler inclusion, insignificant danger of tissue pressure, steadiness after addition and an inbuilt chomp block (Kannaujia *et al.*, 2009).

The problem statement is "a prospective randomised clinical trial for comparison of clinical performance of i-gel with lma-proseal in elective Surgeries. The objective of the study was Comparison of effectiveness between i-gel with P-LMA with respect to,

1. Ease of insertion and number of insertion attempts,
2. The airway sealing pressure,
3. Hemodynamic changes ,
4. Bronchospasm/ Laryngospasm and Regurgitation/ aspiration, airway trauma & post-operative airway morbidity and

5. Fibre optic evaluation used to determine the device's position.

## MATERIALS AND METHODS

Present study was quantitative, comparative evaluative survey design clinical trial for comparison of clinical performance of I-GEL with P-LMA in elective surgeries. The study was undertaken in Krishna Institute of Medical Sciences Karad during the period 2012 to 2014. The study was undertaken after obtaining ethical committee clearance from KIMSDU, IEC, Committee as well as informed consent from all patients. The total sample size was (Seventy) patients, scheduled for various elective surgical procedures under general anaesthesia belonging to ASA class I and II were included in the study.

The 70 adult patients of each gender, randomly divided into two groups of 35 each by Computer generated random numbers) were included in the study: Group 1 – I GEL (n=35) and Group 2 – P-LMA (n=35) Pre-anaesthetic evaluation was done on the evening before surgery. The i-gel supraglottic airway was used in Group 1 patients and P-LMA was Used in group 2 patients. Various observations were made and recorded in tabular form. Fibre optic (FO) evaluation of the SAD position was performed after successful insertion and determination of the airway pressures and tidal volumes. The position was assessed using at present points score (1 = clear view of vocal cords seen; 2 = only arytenoids cartilages seen; 3 = only epiglottis seen; 4 = no laryngeal structures visible). The ease of insertion of device was also recorded. All study variables were recorded by indifferent anesthesia colleague. Followed the protocol of ETT insertion.

The SPSS tool was used for statistical analysis with parametric data were expressed as mean and standard deviation (SD) and analysed using the independent t test. (Grapd Pad InStat 3.06 software) and Non parametric data was analysed using Mann Whitney U test and Fischer's exact test. (Grapd Pad InStat 3.06 software).

## RESULTS AND DISCUSSION

Table 1 shows age distribution of the patients in both the groups. The minimum age in group 1 and group 2 were 20 and 18 years. The maximum age in group 1 and group 2 were 60 years respectively. The mean age in group 1 and 2 were  $33.37 \pm 12.66$  and  $30.14 \pm 11.95$  years respectively. There was no significant difference in the age of the patients between Group 1 and Group 2 ( $P=0.27$ ).

Table 2 shows gender wise distribution in group 1

**Table 1: Comparison of age distribution of both groups**

Age in years	Group I		Group II		't'	'p'
	F	%	F	%		
Less than 20	6	17.14	3	8.50	1.09	0.27
21-30	17	48.57	16	45.8		
31-40	5	14.3	6	17.14		
41-50	3	8.56	6	17.4		
51-60	4	11.43	4	11.4		

**Table 2: Comparison of gender distribution in both study groups**

Gender	Group I (I-gel)		Group II (P-LMA)	
	F	%	F	%
Male	16	54.29	17	48.57
Female	19	45.71	18	51.43

and group 2. Group 1 showed 46% (males) and 54% (females) and group 2 showed 49% (males) and 51% (females).

Table 3 shows the body weight distribution of the patients. The minimum body weight in groups 1 and 2 were 50 kgs and 40 kgs respectively. The maximum body weight in groups 1 and 2 were 74 kgs and 81 kgs respectively. The mean body weight in Group 1 was  $60.71 \pm 6.96$  kgs and in Group 2 it was  $58.05 \pm 11.07$  kg. There was no statistical significant difference in the body weight of patients between the Group 1 and Group 2 (P-value:0.233).

Table 4 shows distribution of patients according to the type of surgeries in group 1 (i-gel) and group 2 (P-LMA). The difference in the type of surgery between the two groups is comparable.

Table 5 shows the insertion of i-gel in group 1 patients was graded very easy in 34 patients and was difficult in 1 patient. The insertion of PLMA in group 2 patients was graded very easy in 25 patients, easy in 2 patients and difficult in 8 patients. The ease of insertion was statistically significant between the two groups (P-value:0.012).

Table 6 shows number of insertion attempts between both the groups. 34 of 35 (97.14%) insertions in group 1 were in the first attempt and only 1 patient required 2nd attempt. 30 of 35 (85.71%) in the group 2 required only one attempt and 5 patients required 2nd attempt. In 2nd attempt for insertion, airway manipulation with jaw thrust was required in both the groups. Number of attempts was not significant between the two groups (P-value:0.19).

Table 7 shows fiberoptic view grading between both the groups. 20 of 35 (57.15%) showing grade 1 in

group 1, 08 patients showing grade 2 and 07 patients showing grade 3. 19 of 35 (54.3%) in the group 2 showing grade 1, 06 patients showing grade 2, 06 patients showing grade 3 and 04 patients showing grade 4. The values for the fiberoptic view were not statistically significant between the two groups (P-value:0.22).

Table 8 shows distribution of patients according to their complications in group 1 and group 2. The incidence of blood staining of device at removal in group 1 (i-gel) was in 2 patients (5.7%) and in group 2 (P-LMA) was in 07 patients (20%). However, the incidence was not statistically significant ( $p=0.15$ ) when compared between both the groups. The incidence of trauma to lip, teeth and tongue at removal in group 1 (i-gel) was in 02 patients (5.7%) and in group 2 (P-LMA) was in 06 patients (17.14%). However, the incidence was not statistically significant ( $P=0.25$ ) when compared between both the groups. There was no incidence of bronchospasm and laryngospasm in both the groups.

Table 9 shows distribution of patients according to their postoperative complications in group 1 and group 2. The incidence of sore throat in group 1 (i-gel) was in 1 patient only (2.85%) and in group 2 (P-LMA) was in 9 patients (25.71%). The incidence of sore throat was statistically significant (P-value:0.01) when compared between both the groups. There was no incidence of dysphagia, dysphonia, dysarthria in both the groups.

Table 10 shows comparison of mean pulse rate in group 1 and group 2. Statistical evaluation done between two groups showed no statistical significant difference in mean pulse rate at any interval (P-value:0.237)

**Table 3: Comparison of body weight distribution in both study groups**

BodyWt	Group I I-gel		Group IIP-LMA		't' value	'p' value
	F	%	F	%		
40-49	00	00	07	20	1.201	0.233
50-59	17	48.6	12	34.25		
60-69	12	34.25	10	28.6		
70-79	06	17.15	04	11.42		
80-89	00	00	02	5.73		
Min.	50		40			
Max.	74		81			

**Table 4: Comparison of distribution of patients with respect to type of surgeries in both study groups**

Type of surgery	Group I (I-gel)		Group II (P-LMA)	
	F	%	F	%
L.A	5	14.3	4	11.5
Hernia repair	9	25.8	7	20
Breast lump excision	3	8.5	2	5.7
UL Faciotomy	1	2.8	2	5.7
Abd.TL	7	20	9	25.7
Laposcopic TL	4	11.5	5	14.2
Open appendisectomy	5	14.3	4	11.5
Radius platting	1	2.8	2	5.7

**Table 5: Comparison of ease of insertion in both study groups**

Ease of insertion	Group I (I-gel)		Group II (P-LMA)		'p' value
	F	%	F	%	
Very easy	34	97.14	25	71.42	0.012
Easy	00	00	02	5.72	
Difficult	01	2.86	08	22.56	

**Table 6: Comparison of attempts of insertion in both study groups**

Attempt	Group I (I-gel)		Group II (P-LMA)		'p' value
	F	%	F	%	
First	34	97.14	30	85.71	0.019
Second	01	2.86	05	14.29	

**Table 7: Comparison of fiberoptic viewin both study groups**

Grading	Group I (I-gel)		Group II (P-LMA)		'p' value
	F	%	F	%	
Grade 1	20	57.15	19	54.3	0.22
Grade 2	08	22.85	06	17.14	
Grade 3	07	20	06	17.14	
Grade 4	00	00	04	11.42	

**Table 8: Comparison of complications at removal in both study groups**

Complications	Group I (I-gel)		Group II (P-LMA)		'p' value
	F	%	F	%	
Blood stained of device	02	5.7	7	20	0.15
Trauma to oral parts	02	5.7	6	17.14	0.15

**Table 9: Comparison of post operative complications in both study groups**

Complications	Group I (I-gelx)		Group II (P-LMA)		'p' value
	F	%	F	%	
Sore throat	01	2.85	09	25.71	0.01

**Table 10: Comparison of mean vital signs in both study groups**

Vital signs	Group I (I-gel)		Group II (P-LMA)		'p' value
	Before	After	Before	After	
Heart rate	77.08±8.47	78.31±7.59	74±8.38	76.2±8.40	0.237
Systolic BP	121.97±10.33	121.91±11.84	116.25±12.04	117.77±12.65	0.475
Diastolic BP	75.08±6.84	75.57±7.36	71.02±7.82	72.37±7.58	0.514

Statistical evaluation done between two groups showed no significant difference in mean systolic blood pressure at any interval (P-value:0.475)

Statistical evaluation done between two groups showed no significant difference in mean diastolic blood pressure at any interval (P-value:0.514).

The present forth coming, randomized investigation was embraced to think about two supraglottic aviation route gadgets I-gel and P-LMA in anesthetized incapacitated patients without hardly lifting a finger of inclusion, number of endeavors of addition, aviation route spill pressure, haemodynamic changes and intra and post employable difficulties.

The study population consisted of 70 patients divided into two groups randomly using simple closed envelope method with 35 patients in each group. Group1 consisted of 35 patients in whom i-gel supraglottic airway device was used and group 2 consisted of 35 patients in whom P-LMA was used.

Both the groups were comparable with respect to demographic variables and there was no statistically significant difference with regards to mean age, sex and weight. Also, both the groups were comparable with respect to type and duration of surgery.

One of the primary objectives was to compare the ease of insertion between the two devices. The grading of insertion was done in a similar way as in a study conducted by Siddiqui et al.

In present study, the ease of insertion of i-gel was very easy (score 1) in 34(97.1%) patients and difficult (score 3) only in 1 (2.8%) patient. In

group 2 insertion of P-LMA was very easy (score 1) in 25 (71.4%) patients, easy (score 2) in 2 (5.7%)patients and difficult (score 3) in 8 (22.5%) patients. (Schmidbauer *et al.*, 2009) There was a statistically significant difference between the two groups with respect to ease of insertion(P<0.05). Present study is comparable with the study conducted by Ishwar Singh et al (Singh *et al.*, 2009) . In present study, insertion of i-gel was successful in first attempt in 97.1% patients as compared to 85.7% first time insertion with P-LMA. Airway manipulation like jawthrust was required during second attempt insertion in one patient of i-gel insertion and 5 patients with P-LMA insertions. In a study conducted by Ishwar Singh et al, (Singh *et al.*, 2009) on sixty patients showed the success rate of first attempt of insertion in i-gel group was 100% vs 93.3% in P-LMA group. (Gatward *et al.*, 2008) Another study conducted by L. Gasteigere-tal, on 152 patients showed first attempt and overall insertion success were similar(P-LMA 75 / 76 (99%) and 76 / 76 (100%); i-gel 73 / 75 (97%) and 75 (100%),respectively). Present study result is in consonance with above mentioned studies (Uppal *et al.*, 2009).

Airway leak pressure detection was performed in a similar manner done by Ishwar Singh et al, (Singh *et al.*, 2009) in their study. The difference in the sealing pressures between igel group (24.72±1.37 cm H2O vs 30.09±2.64 cm H2O)in P-LMA group which were statistically significant in present study (P=0.0003). Ishwar Singh et al., (Francksen *et al.*,

2009) , conducted a study on sixty patients showing mean airway sealing pressure was higher with PLMA( $29.6 \pm 5.62$  cm H<sub>2</sub>O) than with i-gel ( $25.27 \pm 6.44$  cm H<sub>2</sub>O) a statistically significant finding but the airway sealing pressure of i-gel was also within normal limit and effective in preventing aspiration. Present study results concur with above mentioned study. Bikramjit Das et al (Das et al., 2012) in his study on 90 children, 1–6 years of age,

ASA physical status I–II, weighing 10–20 kgs showed that the airway leak pressure of the i-gel group ( $27.1 \pm 2.6$  cmH<sub>2</sub>O) was significantly higher than that of the P-LMA group ( $22.73 \pm 1.2$  cmH<sub>2</sub>O), ( $P < 0.05$ ). This is in contrast to present study.

In present study, fiberoptic view to assess the position of the supraglottic airway device showed Grade 1 view in 54% patients in P-LMA group compared to 57% patients in i-gel group, Grade 2 view in 17% patients in P-LMA group compared to 23% patients in i-gel group, (Gasteiger et al., 2010) Grade 3 view in 17% patients in P-LMA group compared to 20% patients in i-gel group, and Grade 4 view in 12% patients in P-LMA group compared to 0% patients in i-gel group which was statistically non significant ( $P = 0.22$ ).

Present study results are in consonance with the previous studies of Ishwar Singh et al, (Francksen et al., 2009) , In present study, the patients were inspected for any injury of the lips, teeth or tongue and the device for blood stain after its removal at the end of the surgery similar to study done by Ishwar Singh et al, (Singh et al., 2009). Injury to lip, teeth and tongue was noted in 2 patients in group 1 (i-gel) out of 35 and in 6 patients out of 35 in group 2 (P-LMA).

However the incidence was not statistically significant ( $P = 0.25$ ). 2 patients in the i-gel group had blood stain on the device on removal compared to 7 patients in group 2 (PLMA)

which was not statistically significant ( $P = 0.15$ ). There was no incidence of bronchospasm and laryngospasm in both groups. Ishwar Singh et al, (Francksen et al., 2009) in his study reported that the incidence of blood staining of the device was more with P-LMA(6/30) than with i-gel (1/30) & tongue, lip and dental trauma was more with P-LMA(5/30) than with i-gel (1/30) which was otherwise statistically not significant (McHardy and Chung, 1999) .

Levitan&Kinkle (Levitan and Kinkle, 2005) presumed that the inflatable supra glottis airway devices, during insertion, (Burgard et al., 1996) the deflated leading edge of the mask can catch the epiglottis edge and cause it to down-fold or impede

proper placement beneath the tongue and can cause pharyngeal injury. The incidence was statistically significant ( $P = 0.01$ ) when compared between the groups (Nott et al., 1998).

In present study, there was no statistically significant difference between i-gel and P-LMA with regard to heart rate, systolic and diastolic blood pressure, arterial saturation (SpO<sub>2</sub>) and End tidal carbon dioxide (EtCO<sub>2</sub>). V Trivedi et al and Bikramjit Das et al, (Das et al., 2012) in their studies found no significant difference between I-gel and P-LMA with regard to heart rate, arterial BP, SpO<sub>2</sub> and EtCO<sub>2</sub>. Another study conducted by Dheer Singh et al, (Brimacombe et al., 2000) showed mean pulse rate changes were comparable in both groups but the mean arterial pressure changes were significantly higher in PLMA group than I-gel group. This is in contrast to present study. Although they claim that the blood pressure effect was statistically significant but the quantum of change was  $< 5$  mm Hg; ( $p < 0.05$ ) which was of no clinical significance.

## CONCLUSION

Study concluded that in a detailed study of 70 patients, insertion of I-gel was found to be much simpler and easier than the P-LMA insertion. Airway sealing pressure was high in P-LMA patients compared to I-gel patients providing a relatively better seal against aspiration or regurgitation. However, there was no incidence of aspiration and regurgitation in either groups. Blood staining of device and trauma to lips, teeth and tongue was more with P-LMA. Postoperative pharyngolaryngeal morbidity was more with the use of P-LMA.

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## Conflicts of interest

The authors declare that they have no conflict of interest for this study.

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