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±1.37 cmH2O vs 30.09±2.64 cmH2O 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 accessible today may comprehensively be named intraglot-
tic 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 fulfill 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.

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

RESULTS AND DISCUSSION

Table 1 shows age distribution of the patients in both the groups. The minimum age in group1 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±12.66 and 30.14±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 | 17.14| 0.27 |
| 31-40       | 5       | 14.3 | 6       | 17.14| 1.09 | 0.27 |
| 41-50       | 3       | 8.56 | 6       | 17.14| 1.09 | 0.27 |
| 51-60       | 4       | 11.43| 4       | 11.43| 1.09 | 0.27 |

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±6.96 kgs and in Group 2 it was 58.05±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

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 7 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 2 patients (5.7%) and in group 2 (P-LMA) was in 6 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 dysphasia, 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

| Body Wt | Group I (I-gel) | Group II (P-LMA) | ‘t’ value | ‘p’ value |
|---------|-----------------|------------------|-----------|-----------|
| 40-49   | 00              | 07               | 1.201     | 0.233     |
| 50-59   | 17              | 12               | 34.25     |           |
| 60-69   | 12              | 10               | 28.6      |           |
| 70-79   | 06              | 04               | 11.42     |           |
| 80-89   | 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) |
|--------------------------|-----------------|------------------|
| LA                       | 5 F 14.3%       | 4 F 11.5%        |
| Hernia repair            | 9 F 25.8%       | 7 F 20%          |
| Breast lump excision     | 3 F 8.5%        | 2 F 5.7%         |
| UL Faciotomy              | 1 F 2.8%        | 2 F 5.7%         |
| Abd.TL                    | 7 F 20%         | 9 F 25.7%        |
| Laproscopic TL            | 4 F 11.5%       | 5 F 14.2%        |
| Open appendicectomy      | 5 F 14.3%       | 4 F 11.5%        |
| Radius platting          | 1 F 2.8%        | 2 F 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 |
|-------------------|-----------------|------------------|-----------|
| Very easy         | 34 F 97.14%     | 25 F 71.42%     | 0.012     |
| Easy              | 00 F 00%        | 02 F 5.72%      |           |
| Difficult         | 01 F 2.86%      | 08 F 22.56%     |           |

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

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

### Table 7: Comparison of fiberoptic view in both study groups

| Grading | Group I (I-gel) | Group II (P-LMA) | ‘p’ value |
|---------|-----------------|------------------|-----------|
| Grade 1 | 20 F 57.15%     | 19 F 54.3%      | 0.22      |
| Grade 2 | 08 F 22.85%     | 06 F 17.14%     |           |
| Grade 3 | 07 F 20%        | 06 F 17.14%     |           |
| Grade 4 | 00 F 00%        | 04 F 11.42%     |           |
Table 8: Comparison of complications at removal in both study groups

| Complications          | Group I (I-gel) F | Group I (I-gel) % | Group II (P-LMA) F | Group II (P-LMA) % | ‘p’ value |
|------------------------|-------------------|-------------------|--------------------|--------------------|-----------|
| 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-gel) F | Group I (I-gel) % | Group II (P-LMA) F | Group II (P-LMA) % | ‘p’ value |
|---------------|-------------------|-------------------|--------------------|--------------------|-----------|
| 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) Before | Group I (I-gel) After | Group II (P-LMA) Before | Group II (P-LMA) After | ‘p’ value |
|------------------|------------------------|-----------------------|-------------------------|------------------------|-----------|
| 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 forthcoming, randomized investigation was embraced to think about two supraglottic airway route gadgets I-gel and P-LMA in anesthetized incapacitated patients without hardly lifting a finger of inclusion, number of endeavors of addition, airway 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%); 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,
In a study conducted by Francksen et al. (2009), 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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