Curpod et al. Sri Lankan Journal of Anaesthesiology: 25(1):25-30(2017)
DOI: 10.4038 /slja.v25i1.8195

Comparison of clinical performance of i-gel with laryngeal mask airway pro-seal in elective surgery in adults

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Aim: The present study was performed to compare the clinical performance of i-gel and PLMA in terms of the efficacy and safety management in anaesthetized adult patients undergoing elective surgery.

Materials and Methods: 80 patients of either sex were randomized in two groups. Group I (n=40) for i-gel and Group P (n=40) for Proseal. After induction i-gel or Proseal was inserted. The cuff of PLMA inflated and pressure maintained at 60cmH_2O. Insertion time, ease and number of attempts at insertion, airway sealing pressure, airway sealing quality score (ASQS), fiberoptic assessment, ease and number of attempts at gastric tube placement and complications during insertion, maintenance and removal were noted. Statistical analysis was done using Statistical Package for Social Science (SPSS) 20, the sample size was calculated with 99% power (β error = 1%), 95% confidence(α error = 5%), $p < 0.05$ was considered statistically significant.

Results: Demographic data were comparable. Mean insertion time for i-gel (12.30± 1.018sec) was significantly lower than PLMA (13.82 ± 1.083sec):(p< 0.00), i-gel was easier to insert (p <0.010) and number of attempts were comparable (p <0.644). Airway sealing pressure (cmH_2O) was significantly lower in group-I (23.925±0.729 vs 29 ±0.751, p = 0.000). ASQS were comparable (p< 0.762). 37 (92.5%), 3(7.5%) and 30 (75%), 10 (25%) patients had fiberoptic score of 1/2 in i-gel and PLMA respectively (p < 0.034). Gastric tube placement, haemodynamic parameters and complications were comparable.

Conclusion: i-gel is an effective and safe alternative supraglottic airway device.

Keywords: i-gel; LMA-Proseal; supraglottic airway devices

Introduction

Introduction of Supraglottic airway devices (SAD) has revolutionized the airway management. The first successful supraglottic airway device, the Laryngeal Mask Airway (LMA)-Classic, became available in 1989. Since then the indications for the LMA have evolved rapidly and there is now a far more liberal attitude to indications for laryngeal mask use. It is estimated that over 200 million anaesthetics have now been administered using c-LMA. The constant evolution in device design has encouraged to introduction of various other SADs like ProSeal LMA, Intubating LMA and i-gel to overcome the limitations of c-LMA.[1]

The risk of aspiration with c-LMA is reported to be around 6%-9%, as detected by observations of the oesophagus via fiberoptic bronchoscopy (FOB), or low pulmonary compliance.[2] [(e.g. obesity) requiring peak inspiratory pressure greater than 20 cmH_20] LMA ProSeal (PLMA) was introduced in 2000 to improve performance during controlled ventilation, safety regarding aspiration, and an ability to diagnose misplacement of the device tip. However, both the c-LMA and PLMA have cuff related complications. High cuff pressure in laryngeal mask airways can cause damage to the mucosae on periglottic and supraglottic structures and associated with increased morbidity, such as sore throat, hoarseness of voice and nerve palsies.[3]

Therefore to overcome the limitations of PLMA a new and cheaper SAD called i-gel was developed. i-gel is a novel and innovative, latex free supraglottic device, made up of medical grade thermoplastic elastomer, which is soft, gel

like, transparent and designed to anatomically fit the perilaryngeal and hypo pharyngeal structures with a non inflatable cuff and a channel for gastric suction catheter placement.[4] The potential advantages of the i-gel are that it is compatible with anatomical structures, it can be easily inserted into the mouth, and there is reduced risk of pharyngeal tissue compression due to lack of high cuff pressure.[5]

This study was done to compare the insertion time, ease of insertion, insertion attempts, the airway sealing pressure, airway sealing quality score, fiberoptic assessment, ease of gastric tube placement and complications between i-gel and LMA- pro seal.

Material and methods

The prospective randomized study was conducted after obtaining approval of the hospital ethical committee and written informed consent from the patients from November 2013 to May 2015. The study was conducted on 80 patients, 40 in each group undergoing elective surgery in supine position under general anaesthesia with controlled ventilation with the following inclusion criteria, ASA class 1-2, age 20-60years of either sex posted for elective surgical procedures of duration of 1-1½ hours with no requirement for endotracheal intubation. Patient with risk factors for difficult airway (mouth opening of <2cm, Mallampati class 4, limited neck extension, history of previous difficult intubation), known pulmonary and cardiovascular diseases, risk of aspiration (full stomach, hiatus hernia, gastroesophageal reflex disease, emergency surgery) were excluded from the study.

Following detailed pre-anaesthetic checkup, informed written consent was obtained from patient fulfilling the above required criteria. Patients were randomly allocated into two groups namely group I (i-gel, n=40) and group P (PLMA, n=40) in a sealed envelope. All patients were asked to fast overnight. On the day of surgery, 18g vasofix was inserted and preloaded with 500ml of Ringer Lactate solution. ECG, NIBP, SpO_2 monitors were connected and baseline readings noted. Midazolam 1mg, glycopyrrolate 0.2mg, ranitidine 50mg and ondansetron 4mg intravenously was given to all the patients. All patients were preoxygenated for three minutes and anaesthesia was induced with propofol 2mg/kg and fentanyl 2mcg/kg. Neuromuscular blockade was achieved with veccuronium bromide 0.1mg/kg, and ventilated with oxygen, nitrous oxide and sevoflurane. Once adequate depth was achieved, i-gel or PLMA lubricated with soluble jelly was inserted. The cuff of PLMA was inflated with air and an effective airway was confirmed by bilateral symmetrical chest expansion on manual ventilation, square waveform on capnography, stable oxygen saturation, no audible leak of the gases and lack of gastric insufflation. Intracuff pressure of PLMA was set at $60cmH_2O$ throughout anaesthesia using a manometer. The device was fixed over the chin. Anaesthesia was maintained with oxygen, nitrous oxide and sevoflurane and ventilated with intermittent positive pressure ventilation. A lubricated gastric tube was placed in the stomach through the gastric channel. Haemodynamic parameters were monitored prior to insertion of the device and then at 5, 10 and 15mins after insertion of the device. Thereafter monitoring was done every 15mins till the end of the surgery.

Insertion time was noted as the time interval between picking up the device and securing an effective airway as recorded by an independent observer. The ease of insertion of device was assessed using a subjective scale of 1-4 (1-no resistance, 2- mild resistance, 3-moderate resistance, 4- inability to place a device). Failure of a device was identified as three unsuccessful insertion attempts or inadequate ventilation. Such patients were withdrawn from the study and insertion was recorded as failure and a cuffed endotracheal tube was inserted.

The Airway Sealing Pressure (ASP) was measured at cuff pressure of $60cmH_2O$ (in case of PLMA) by closing the expiratory valve of the circle system at a fixed gas flow of 3L/min and recording the airway pressure at which equilibrium was reached. At this stage an audible leak at the mouth (sound of gas escaping from mouth heard by listening close to patient's mouth) and the stomach (sound of gas escaping into oesophagus heard by auscultation over epigastrium) was ascertained. Tidal volume loss was detected by inspiratory (set) - expiratory (outcome) volume on the ventilator display

screen. Airway seal was scored using Airway Sealing Quality Score (ASQS) as per Table 1.

Table 1: Airway sealing quality score[10]

1	No leak detected
2	Minor leak of tidal volume (Vt loss <20%)
3	Moderate leak of tidal volume (Vt loss 20% - 40%)
4	Insufficient seal (Vt loss >40%)

The anatomical position of the device was assessed by introducing a flexible fiberoptic bronchoscope into the airway tube to a position proximal to the terminal end. The scoring of fiberoptic examination was done by using fiberoptic scoring system as per Table 2.

Table 2: Fiber optic scoring system[6-8]

1	Clear view of vocal cords
2	Only arytenoid cartilages visible
3	Only epiglottis visible
4	No laryngeal structures visible

Ease of placement of gastric tube was recorded as either: easy/difficult/failure. Failure was defined as inability to advance the orogastric tube into the stomach within two attempts. Its correct placement confirmed by injection of air and auscultation over the epigastrium or aspiration of gastric contents. At the end of surgical procedure anaesthesia was discontinued and patient reversed with standard dose of neostigmine and glycopyrrolate and device removed. Complications occurring during insertion, maintenance and removal were noted for each patient. Bronchospasm or laryngospasm, blood staining of tongue, lip and dental trauma, regurgitation and aspiration of gastric contents were evaluated by examining oropharyngeal structures by light source and treated appropriately. Blood staining of the SAD were recorded during removal. Postoperatively patients were questioned for sore throat, dysphagia, dyspnea, hoarseness of voice.

Statistics

In the present study to calculate the sample size, with 99% power (β error = 1%), 95% confidence(α error = 5%) and to minimum detectable difference between the groups as 3.93sec with 2.91 SD required a minimum of 21 subjects.[10] Statistical analysis was done using Statistical Package for Social Science (SPSS) 20. The various appropriate descriptive and inferential statistics had been calculated for the numeric data like age, height, weight, heart rate, SBP, DBP, SpO_2etc. Mean and standard deviations (SD) were calculated for numeric data and expressed as mean ± SD. And for non-numeric data frequency and percentages were calculated.

In order to compare the mean values of two groups (I and P), two tailed unpaired t-test was used and Chi square test was used for association between two attributes like ease of insertion, number of attempts, airway sealing quality score, fiberoptic score, ease and number of attempts of gastric tube insertion, complications etc in both the groups. P value < 0.05 had been considered as significant value.

Results

Table 3: Patient demographic characteristics (Mean ± SD)

	Group I	Group P	p–value
Age (Years)	33.80 ± 9.202	32.00±10.115	0.408
Sex (M/F)	20 / 20	23 /17	0.501
Weight(kgs)	60.48±8.635	59.85±8.267	0.742
Height(cms)	155± 4.14	154.85 ± 4.897	0.886
Type of surgical procedures			
General Surgery	17(42.5%)	13 (32.5%)	0.449
Plastic Surgery	6 (15%)	8 (20%)	
Orthopaedics	17 (42.5)	19 (47.5%)	

There was no difference between the two groups with respect to demographic and surgical details (Table 3). In all the patients the i-gel or PLMA was inserted within two attempts. The mean insertion time for I-gel was 12.30±1.018 seconds and PLMA was 13.82 ±1.083 seconds. It was comparable between the two groups. (p = 0.00, Table 4). With regards to ease of insertion a significant difference (p = 0.010) was found between i gel and PLMA. In group I, 35 (87.5%) and 5 (12.5%) patients and in Group P, 25 (62.5%) and 15 (37.5%) patients had a scale of 1 and 2 respectively (Table 4). In all the patients the device was inserted successfully within two attempts. The first attempt success rate was high

for both groups. [38 (95%) for Group I and 37 (92.5%) for Group P, p = 0.644, Table 4]

Table 4: Insertion characteristics

	Group I	Group P	p-Value
Insertion time(sec)	12.30± 1.018	13.82 ± 1.083	0.00
Ease of insertion 1 2 3 4	 35 (87.5%) 5 (12.5%) 0 0	 25 (62.5%) 15 (37.5%) 0 0	0.010
No of attempts 1 2	 38 (95%) 2 (5%)	 37 (92.5%) 3 (7.5%)	0.644
ASP (cm H_2O)	23.925 ± 0.729	29 ± 0.751	0.000
ASQS 1 2 3 4	 33 (82.5%) 7 (17.5%) 0 0	 34 (85%) 6 (15%) 0 0	0.762
Fiberoptic score 1 2 3 4	 37 (92.5%) 3 (7.5%) 0 0	 30 (75%) 10 (25%) 0 0	0.034

Table 5: Comparison of other parameters

	Group I	Group P	p-Value
Gastric tube insertion			
Ease Easy Difficult Failed	 36 (90%) 4 (10%) 0	 34 (85%) 5 (12.5%) 1 (2.5%)	0.723
Attempts 1 2	 38 (95%) 2 (5%)	 34 (87.2%) 5 (12.8%)	0.285
No. of patients with complications No. of patients without complications	3 (7.5%) 37 (92.5%)	5 (12.5%) 35 (87.5%)	0.456

The average sealing pressure in Group I was 23.925 ± 0.729cm H_2O and in Group P was 29 ± 0.751cm H_2O, with a p value of 0.000 which was significant (Table 4). Adequate ventilation was achieved in both the groups. Airway sealing quality score as determined by percentage loss of delivered tidal volume were comparable between two groups. (Group I 33 (82.5%) and 7 (17.5%) patients and Group P 34 (85%) and 6 (15%), p = 0.762, Table 4)

The i-gel group provided a better fiberoptic view of glottis than proseal LMA. In Group-I 37 (92.5%) and 3 (7.5%) patients and in Group P 30 (75%) and 10 (25%) patients had fiberoptic score of 1 and 2 respectively with a p value of 0.034 which was statistically significant (Table 4). Gastric tube was inserted in all the patients except one patient in Group P. There was no statistically significant difference regarding the ease and attempts of gastric tube insertion between the two groups (Table 5). There was no statistically significant difference between the two groups with regards to complications (Table 5).

Discussion

Our study demonstrated that i-gel and PLMA are equally effective supraglottic airway devices. But i-gel scores over PLMA regarding ease of insertion, airway sealing pressure and good fiberoptic view providing effective anatomical conformity.

Shorter insertion time influence the feasibility of supraglottic devices. Many studies have reported shorter insertion time for i-gel compared to other supraglottic devices because of less flexible stem and no need for cuff inflation.[9] Statistically significant shorter mean insertion time observed in our study correlates with the results of studies of Chauhan et al and Tokgoz et al.[10,11] Sharma B et al found shorter mean insertion time for PLMA when compared to i gel but it was not statistically significant.[12] But these differences in time interval are clinically not significant.

The ease of insertion is better with i-gel than PLMA. Levitan and Kinkle presumed that on insertion of LMA, the deflated leading edge of the mask can catch the edge of the epiglottis and cause it to downfold or impede proper placement beneath the tongue.[5] Brimacombe et al presumed that the difficulties in inserting LMA-ProSeal were caused by larger cuff impeding digital intra-oral positioning and propulsion into the pharynx, the lack of back plate making cuff more likely to

fold over at the back of mouth and the need for more precise tip positioning to prevent air leaks up the drainage tube.[13,14] Chauhan et al and Singh et al observed the ease of insertion was better with i-gel than PLMA. Chauhan et al also observed that number of manipulations required were more in PLMA resulting in haemodynamic changes.[10,15]

In our study the device was inserted successfully in all patients. Insertion attempts of i-gel vs PLMA were not statistically significant. Other studies comparing i-gel and Proseal LMA found similar results. Tokgoz et al has found a high success rate at first attempt and overall success in i-gel when compared to PLMA.[11,15,16]

Airway sealing pressure is used to monitor the quality of airway seal, which prevents gastric insufflation, aspiration and oropharyngeal air leakage. The seal pressure appears to improve over time in number of patients due to thermoplastic properties of the gel cuff, which may form a more efficient seal around the larynx after warming to body temperature. Effective airway leakage pressure is important to provide adequate ventilation in patient with increased airway resistance.[17] Similar to our result, significant lower mean airway sealing pressure with i-gel were observed by Chauhan et al, Tokgoz et al and Singh et al. But there was no statistically significant difference in Airway Sealing Quality Score. i-gel thus provides effective seal and ventilation at relatively lower airway pressures when compared to PLMA which requires higher airway pressures to provide effective seal and ventilation.

In many studies the placement of supraglottic device were confirmed by fiberoptic bronchoscope, has showed that i-gel consistently achieves proper positioning and effectively conforms to the perilaryngeal airway.[10,11] The fiber optic image score depends on hypo pharyngeal device position and folding of epiglottis. Chauhan et al noted i-gel had an excellent anatomical fit (Grade 1 view= 97.5%) which was significantly better than the PLMA (Grade 1 view =75%). Tokgoz et al observed a notably good view of vocal cords in i-gel.

There was no significant statistical difference regarding the ease of placement of gastric tube and number of attempts. Similar results are also found in many studies.[10,11,15] In our study we did not experience any complications during insertion and maintenance. None of the patients in both the groups had postoperatively sore throat, dysphagia, dyspnea, hoarseness of voice. Many studies have recorded the incidence of blood staining of the device, tongue, lip and dental trauma as more with other supraglottic devices.[18,19] Devices with inflatable mask have the potential to cause tissue distortion, venous compression and nerve injury, which explains the high incidence of associated postoperative morbidity.[5]

To conclude the i-gel is comparable to PLMA in securing the airway during controlled ventilation. It is better than PLMA in terms of ease of insertion, with less airway sealing pressure providing better ventilation and effectively conforming to the perilaryngeal anatomy, despite the lack of an inflatable cuff.

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