Research Article

Comparison of i-gel with LMA ProSeal for ease of insertion in adult anaesthetised paralysed patients: a prospective randomized trial

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Abstract

Background: i-gel,a recently developed non-inflatable supraglottic airway device, a suitable better alternative to cuffed inflatable suprglottic airway device like LMA ProSeal.**Aim and objectives:** This study aimed to compare the ease of insertion to achieve early successful airway between LMA ProSeal and i-gel. The secondary objectives were to compare hemodynamic parameters and any airway complications.**Materials and methods:** This prospective randomized study done in fifty (n=25, each group) ASA I and II adult patients, aged between 20 and 65 years of either sex scheduled for elective surgeries. Patients airway was secured with appropriate size eitherLMA ProSeal or i-gel. The time taken for successful insertion, number of attempts and ease ofgastric tube placement were recorded. Hemodynamic parameters at basal (pre operative), 1, 3 & 5 minutes after insertion were recorded. Blood stain of device and any postoperative airway complications were noted.**Results:** Time taken for successful insertion was significantly less in i-gel group [Group 1(LMA ProSeal) 20.56±2.00, Group 2 (i-gel) 12.08±1.53, p=0.001*]. Time taken for gastric tube placement was significantly less in i-gel group [Group 1(LMA ProSeal) 31.96±4.58, Group 2 (i-gel) 21.48±2.55, p=0.001*]. Among hemodynamic parameters, heart rate immediately after insertion of device was stable in i-gel group. The numbers of insertion attempts were also less with i-gel group.**Conclusion:** In our study, ease ofinsertion with less number of attempts was observed with i-gel group.So i-gel found to be the better alternative to LMA ProSeal.

Keywords: LMA ProSeal, i-gel, ease of insertion

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Introduction

In recent past, supraglottic airway devices gained much importance and widely used in day care short surgical procedures under general anaesthesia. By avoiding laryngoscopy and endotracheal intubation, stress response and other complications (like bronchospasm, cough, sore throat and airway trauma) were minimal with these supraglottic airway devices. LMA ProSeal and i-gel are recently developed second generation airway devices with integrated gastric channel. The LMA ProSeal was introduced by Archie Brain[1] in clinical practice in 2000, with a modified cuffto improve the laryngeal seal and an integrated gastric channel to (i) prevent gastric aspiration (ii) prevent gastric inflation(iii) facilitate gastric tube insertion and (iv) provide information about position. The i-gel was launched in 2007 by intersurgical, it has a soft, gel-like, non-inflatable cuff, designed to provide an anatomical impression fit over the laryngeal inlet.[2] A supraglottic airway devicewithout an inflatable cuff has several potential advantageslike easier insertion, minimal risk of tissue compression and stability after insertion. Hence,i-gelcan be an alternative option to LMA ProSeal with advantages like easyinsertion, required less skill than LMA ProSeal[3]. So we designed this study to compare i-geland LMA Pro Sealin anaesthetisedparalysed patients undergoing short general surgical procedures. Our primary objective was to compare the ease of insertion and early successful ventilation without hemodynamic changes. Secondary objectives were to compare ease of gastric tube

Manuscript received: 26th Feb 2016
Reviewed: 14th March 2016
Author Corrected: 22nd March 2016
Accepted for Publication 4th April 2016

placement, airway trauma and any perioperative airway complications.

Materials and Methods

After approval from our institutional ethical committee, this prospective randomized comparative non-crossover study was done in fifty ASA I and II adult patients, aged between 20 and 65 years of either sex scheduled for elective surgeries like hernioplasty, fibroadenoma breast excision, Webster's procedure, Orchidectomy, eversion of sac and skin grafting.Exclusion criteria includes: 1. Patients with anticipated difficult airway, GERD and Hiatus hernia. 2. Laparoscopic and Head and Neck surgeries. 3. Surgeries likely to extend beyond 2 hours duration. 4. Body mass index greater than 35 kg/m^2. 5. Upper respiratory tract infections in the previous ten days.6. Pregnancy.

After routine preanaesthetic assessment and written informed consent from selected patients, theywere allocated into two groups as Group 1: LMA ProSeal & Group 2: i-gel by simple randomization using sequentially numbered opaque sealed envelopes.

A standardized anesthetic protocol was followed in all cases. All patients were kept 8 hours fasting, and premedicated with inj. Midazolam 1.5mg & inj. Glycopyrrolate 0.2mg intravenously 15 minutes prior to induction of anaesthesia. A Standard monitoring of pulse oximetry, electrocardiography, noninvasive blood pressure, temperature and capnography was done in all cases by the same monitor system. All patients were preoxygenated for 3 minutes and induction of anaesthesia commenced with inj. Fentanyl 2 µg/kg and inj. Propofol 2.5 mg/kg followed by inj. Succinylcholine 1.5mg/kg I.V bolus.

Then the patients airway was secured with appropriate size lubricated (using water-soluble gel) LMA ProSealin Group 1 and i-gel in Group 2. Manufacturer's guidelines were followed in size selection of both device and cuff inflation of LMA ProSeal. For Group 1 (LMA ProSeal), size 3 was used for 30-50 kg, size 4 for 50-70kg, and size 5 for 70-100kg body weight. For Group 2 (i-gel), size 3 was used for 30-60 kg, size 4 for 50-90kg, size 5 for >90kg body weight. A standard insertion technique was followed in all cases as per guideline according to the device. Both the devices were fixed by taping. Maintenance was achieved by oxygen 33%, nitrous oxide 66 %and Isoflurane 0.8 -1%. Once the effect of succinylcholine was overinitial dose of intravenous vecuronium 0.08 mg/kg followed by intermittent dose of 0.02 mg/kg was given when required. Heart rate and non-invasive blood pressure were recorded at 1, 3 and 5 minutes after insertion of device. Surgeons were requested not to clean, drape or positionthe patient till 5 minutes after placement of supraglottic devices so as to avoid any stimuli which likely to interfere with the findings.

Duration of insertion was measured from the time the facemask was taken away from the face until successful ventilation of the patient. Successful ventilation was judged by a square wave capnograph trace, normal thoraco - abdominal movement and absence of leak. Ease of insertion was defined as correct placement of device in sniffing positionwithout any requirement of airway manipulation like chin lift, jaw thrust, head extension and neck flexion. If an effective airway could not be achieved the device was removed and reinserted. Three attempts were permitted before the failure of insertion was recorded. If three attempts were unsuccessful or any desaturation (SpO_2<95%), further plan was to intubate the trachea with appropriate size endotracheal tube without delay. The numbers of insertion attempts along with airway manipulation required for correct placement were recorded.

After successful airway confirmation with adequateventilation, a lubricated gastric tube was placed in the stomach through the gastric channel (size 14Fr for LMA ProSeal and 12Fr for i-gel). The time taken for the placement of gastric tube was also recorded and its correct placement was confirmed by injection of air and epigastric auscultation or aspiration of gastric contents. Two attempts were allowed before gastric tube placement was considered as failure.

At the end of surgical procedure anaesthesia was discontinued, the effect of non-depolarizing muscle relaxant in the patient was reversedwith inj. Neostigmine 60 µg/kg and inj.Glycopyrrolate 10 µg/kg. The device was removed after recovery of the patient from anaesthesia and muscle relaxant.Blood staining of the device, tongue, lip and any airway trauma along with hoarseness of voice, sore throat and dysphagia in next 24 hours were noted. Standard protocol was followed in recovery, postoperative monitoring and postoperative analgesia.

Statistical analysis was done using SPSS (17.0) software. Continuous variables were presented as mean ±SD; Ordinal and Nominal data were presented as

number or percentage of incidents. Comparison between the groups was made using student's t test for quantitative data and chi-square test for qualitative data. Hemodynamic parameters wereanalyzedusing one-way ANOVA to find statistical difference within and between groups.Fisher's exact test was used to analyzenumber of insertion attempts. P value (<0.05) was considered statistically significant.

Results

There was no significant difference in demographic data between Group 1 (LMA ProSeal) and Group 2 (i-gel).[Table 1] The mean time taken for successful insertion of a device in Group 1 (LMA ProSeal) was 20.56 ± 2 s and for Group 2 (i-gel) was 12.08 ± 1.53 s. The time taken for successful insertion in Group 2 (i-gel) was significantly (p=0.001*) less compared to Group 1 (LMA ProSeal).

The success rate at first attempt of insertion was(84%) 21/25 in Group 2 (i-gel) and (72%) 18/25 in Group 1 (LMA ProSeal). In patients requiring second and third attempts Group 2 (i-gel) performed better thanGroup 1 (LMA ProSeal).[Table 2] The number of attempts was not significant (p=0.587) between the groups. The number of patients who required airway manipulation in Group1 (LMA ProSeal) was 11and in Group 2 (i-gel) was 5.

The requirement of airway manipulation was higher with (Group1) LMA ProSeal when compared to Group 2 (i-gel).[Table 2]

Table-1: Comparison of demographic data & duration of surgery

Variables	Group 1(LMA ProSeal)	Group 2(i-gel)	P value
No of patients(n)†	25	25	
Sex(M\F)†	19\6	18\7	
ASA (I\II)†	17\8	19\6	
Age(years)††	38.52±14.96	34.80±12.85	0.351
Weight(kg)††	67.48±13.77	68.44±13.35	0.803
Height(cm)††	158.48±9.16	160.24±10.43	0.529
Duration of surgery (minutes)††	66.00±24.36	73.80±36.69	0.38

Values as numbers†,mean ± SD††.

Table 2:Comparison of ease of insertion

Variables	Group 1 (LMA ProSeal) (n=25)	Group 2 (i-gel) (n=25)	P value
Time taken for successful insertion(s)†	20.56±2.00	12.08±1.53	0.001*
Success in first attempt	18	21	0.587‡
Success in second attempt	5	3	
Success in third attempt	2	1	
Airway manipulation required	11	5	
Time taken for gastric tube placement(s)†	31.96±4.58	21.48±2.55	0.001*
No of attempt for gastric tube placement(1st\2nd)	(23\2)	(25\0)	

Values as mean ± SD†,*Significant (p<0.05),‡Fisher's exact test.

Table 3: Comparison of hemodynamic parameters

Parameter	variables	Group 1 (LMA ProSeal) (n=25)	Group 2 (i-gel) (n=25)	P value
Heart Rate (beats per minute)	Basal (pre op)	80.48 + 6.94	78.60 + 6.69	0.334
	after insertion at 1mt	97.80 + 6.63	82.04 + 5.97	.002*
	after insertion at 3mt	94.56 + 6.82	81.64 + 6.79	.003*
	after insertion at 5mt	95.44 + 7.77	78.48 + 7.81	.003*
Mean Blood Pressure (mmHg)	Basal (pre op)	96.00 + 6.71	94.48 + 6.71	0.39
	after insertion at 1mt	95.92 + 8.52	94.48 + 5.63	0.567
	after insertion at 3mt	98.20+ 4.32	94.36+ 4.22	0.126
	after insertion at 5mt	94.00+ 5.35	90.96+ 4.95	0.193

Values as mean ± SD,*Significant ($p<0.05$).

Table 4:Comparison of blood stain on device after removal.

Blood stain on device	Group 1 (LMA ProSeal) (n=25)	Group 2 (i-gel) (n=25)
Yes	3	0
No	22	25

The mean time taken for gastric tube placement was 31.96 + 4.58 s for Group 1(LMA ProSeal) and 21.48± 2.55 s for Group 2 (i-gel).The mean time taken for gastric tube placement was significantly (p=0.001*) less inGroup 2 (i-gel) when compared to Group1 (LMA ProSeal). The success rateforgastric tube placement was 100 %(25/25) in Group 2 (i-gel) and 92 %(23/25) in Group 1 (LMA ProSeal).[Table 2].

The Heart Rate and Mean Blood Pressure values did not differ among the groups preoperatively. Heart rate was significantly ($p<0.05$) stable in Group2(i-gel) compared to Group 1 (LMA ProSeal) at all time after insertion. The mean blood pressure after insertion of device was comparable between the groups.[Table 3].

Blood staining of device was observed only in Group 1 (LMA ProSeal) (3/25).[Table 4] There were no complications such as cough, sore throat, incidence of bronchospasm andlaryngospasm in both the groups.

Discussion

Each airway device has unique property that may be advantageous in certain situations yet may have limitations in others. Successful airway managementrequires the combination of proper deviceselection and technique. Stress response and chances of hypoxia increased with the number of attempts and timetaken to secure the airway.In our study we compared the recently developed supraglottic airway devicei-gel with LMA ProSeal in the aspect of ease of insertion, ease of gastric tube placement, andcomplications in elective short surgical procedures.

In our study successful placement of the device in first attempt was higher with i-gel group (84%) than LMA ProSeal group (72%).The requirement of 2nd and 3rd attempt to achieve effectiveairway wasless in i-gel when compared to LMA ProSeal. The mean time taken to insert LMA ProSealwas 20.56 ± 2.00s andfor i-gelwas 12.08 ± 1.53s, p=0.001*. The mean time required to achieve effectiveairway was significantly less in i-gel group than LMA ProSeal. These findings were similar with Kannaujia, et al[4] and Singh, et al[5] studies.Kannaujia, et al study with i-gel in 50 patients

recordedsuccess rate at first attempt was 90%(45/50) with a median insertion time of 11 s (range 8 - 45s). Five patients (10%) needed second attempt while none needed 3 rdattempts or had failure of insertion. Singh, et al found higher success rate of insertion with 1-gel (29/30) than with LMA ProSeal (23/30) which was statistically significant ($p<0.05$).

Kini, et al[6] observed significantly lower insertion time with i-gel (21.98±5.42*s) when compared to LMA ProSeal (30.60±8.51s), but the findings were not similar to our study (i-gel group 12.08 ± 1.53*s and LMA ProSeal group 20.56 ± 2.00s). The reason might be that they studied these devices in spontaneously ventilated non paralysed patients, but we studied in paralysed patients. The need for airway manipulation during insertion was high in LMA ProSeal group than i-gel in our study, which is similar to Chauhan, et al[7].

Singh, et al[5] observed that ease of insertion of gastric tube was more with i-gel (30/30) than with LMA - ProSeal (26/30). Brimacombe, et al[8] observed LMA ProSeal gastric tube was inserted in 88% of casesin first attemptandtime taken for placement was 22 ± 18 s. These results were similar to our studies. In our study the time taken for placement of gastric tube in LMA ProSeal was 31.96 ± 4.58 s andin i-gel,it was 21.48± 2.55s. The number of attempts andtime taken forgastric tube placement was more withLMA ProSeal compared to i-gel. The possible cause may be due to the larger cuffof LMA ProSael that tends to fold and obstruct the passage ofgastric tube.

Shin, et al[9] compared i-gel with classic laryngeal mask airway (cLMA) and ProSeal laryngeal mask airway (PLMA) in anaesthetisedparalysed patients. He concluded that there were no differences in the haemodynamic data immediately after insertion of devices among the three groups. i-gel was effective as LMA ProSeal which was similar to our data. In our study increase in heart rate was present in LMA ProSeal at 1,3 and 5 minutes that may be attributed to the increase need for airway manipulation, the increase number ofattempts,and large inflatable cuff (which stimulate sympathetic response while inflation of cuff) of the LMA ProSeal.

In our study, blood stain on device was observed only in cases with LMA ProSeal(3/25) and none with i-gel. These findings were similar with Das et al[10] (blood stain in LMA ProSeal 4/30 and i-gel1/30). There were no other complications like coughing, sore throat andhoarseness of voice in either group.

Conclusion

In our study,i-gel insertion was very easy to achieve effective airway with minimal airway manipulation and less number of attempts than LMA ProSeal. The successful gastric tube placement was higher with i-gel than LMA ProSeal. So i-gel is the superior and better alternative to LMA ProSeal.

Funding: Nil,
Conflict of interest: None.
Permission of IRB: Yes

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How to cite this article?

Raajaram Mu, Suresh Rajkumar, Ezhilrajan V, Comparison of i-gel with LMA ProSeal for ease of insertion in adult anaesthetised paralysed patients: a prospective randomized trial: *Int J Med Res Rev* 2016;4(4):531-536. doi: 10.17511/ijmrr.2016.i04.10.

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