Comparison of Proseal Laryngeal Mask Airway (Proseal LMA™) with I-Gel by Fireoptic View of Glottic Aperture in Anaesthetised Adult Patients

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Abstract

Background: The i-gel, a new supraglottic airway device, has been touted to have acceptable airway seal pressure and better ventilatory parameters than Proseal laryngeal mask airway (PLMA) in adults. We propose to test this hypothesis objectively, by comparing fibreoptic grading of positioning of the above airways in adult patients.

Methods: Ninety two adult patients undergoing minor surgeries were randomly assigned to either the PLMA or the i-gel group for airway management. Fibreoptic bronchoscope was inserted through airway tube and glottis view was graded according to established scoring system. Other parameters noted include effective airway time, failed insertions, oropharyngeal leak pressure, ease of gastric tube insertion, airway morbidity. The incidence of sore throat, dysphonia, dysphagia was assessed after 24 hours.

Results: There was no statistical difference between both groups with respect to effective airway time, success rates at first attempt of insertion, ease of gastric tube insertion, airway trauma during insertion and postoperative airway morbidity. Proseal laryngeal mask airway was placed better than i-gel as confirmed by fibreoptic scoring of glottic view. Oropharyngeal leak pressure was better with PLMA group than i-gel.

Conclusion: We conclude that PLMA was placed better than i-gel as confirmed by better fibreoptic scores and had higher oropharyngeal leak pressure.

Keywords: Proseal laryngeal mask airway, Fibreoptic view of glottis, igel, Oropharyngeal leak pressure

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Introduction

Management of airway is one of the primary responsibility of anaesthesiologists. Tracheal intubation has been used to maintain airway and provide positive pressure ventilation during anaesthesia for a long time. However, introduction of supraglottic airway devices with gastric emptying tube like Proseal Laryngeal mask airway (Proseal LMA) and I-Gel has revolutionized airway management.

Proseal Laryngeal Mask Airway (Proseal LMA) has been used for managing controlled and spontaneous ventilation in both adult and pediatric patients. But Proseal LMA has few disadvantages like lesser success rates of placement, difficulty in insertion and increased airway morbidity[1].

The i-gel (Intersurgical Ltd, Wokingham, Berkshire, U.K) is a new single use, supraglottic airway device with a non inflatable cuff made of medical grade thermoplastic elastomer. The cuff is designed to have a mirrored impression of pharyngeal and laryngeal structures and to provide a perilaryngeal seal without inflation. It also has drain tube which allows insertion of gastric tube. It has buccal cavity stabilizer which prevents malrotation and helps in alignment of device with oropharynx. The i-gel also has epiglottic rest to prevent downfolding of epiglottis during insertion. The i-gel has been touted to have better success rates and lesser airway morbidity[2,3,4].

Few studies have been done to compare i-gel and Proseal LMA in adult patients based on clinical parameters. Comparison of fibreoptic positioning of airways provides an objective way of assessing the efficacy of airways. However careful review of literature has revealed that comparison of fibreoptic positioning of the above airways has not been done yet. Hence we have conceptualized the study to compare fibreoptic positioning of Proseal LMA and i-gel.

Aim

To compare Proseal Laryngeal Mask Airway with i-gel in anaesthetized adult patients with respect to fibreoptic grading of position, oropharyngeal leak pressure, effective airway time, success rates for first attempt of insertion, ease of gastric tube insertion, airway trauma during insertion and postoperative airway morbidity.

Methods

The study was approved by the Institutional ethics committee (Ref: 13/IEC/09) and registered with Australian NewZealand Clinical Trial Registry (ACTRN12610000105044 / U-1111-1113-5300). After obtaining written informed consent, 92 patients of ASA (American Society of Anesthesiologists) Grade I and II

were enrolled into this randomized, prospective, comparative study. Sample size was determined based on pilot study done on 10 patients in each group. Patients were randomly allocated into either Group P (Proseal LMA) or Group I (i-gel) by sealed envelope method. All intraoperative data were collected by unblinded observers while postoperative data were collected by blinded observers.

Patients with increased risk of aspiration like hiatus hernia, gastro- esophageal reflux disease, obesity, pregnancy and patients with anticipated difficult airway were excluded from this study. The investigators were Anaesthesiology consultants who have performed at least 20 i-gel and Proseal LMA insertions prior to this study. All patients were kept nil per oral overnight and aspiration prophylaxis with Inj. Ranitidine 50mg IV and Inj. Metoclopromide 10mg IV was given 1 hour before surgery. Patients were premedicated with Inj. Glycopyrrolate 0.2 mg IV 1 hr before surgery. After the placement of standard minimum monitoring devices [ECG, SpO_2, NIBP, Capnography] and preoxygenation, all the patients were induced with Inj.Fentanyl 2 mcg / kg IV, Inj.Lignocaine 1.5 mg/ kg, Inj.Propofol 3 mg / kg I.V. PLMA and I-Gel were inserted as per manufacturer's recommendation.

Three attempts were allowed before insertion is considered a failure. Criteria for failed insertion include airleak over oropharynx, stomach and ineffective ventilation (Exhaled tidal volume <8ml/kg, E_TCO_2>45mmHg. In the event of failed insertion after three attempts, patients were intubated with endotracheal tube and surgery was allowed to proceed.

Fibreoptic bronchoscope will be introduced through airway tube of Proseal LMA and i-gel and the fibreoptic view was scored according to an established scoring system: Grade 4 -only vocal cords seen, Grade 3-vocal cords plus posterior epiglottis seen, Grade 2 - vocal cords plus anterior epiglottis seen, Grade 1-cords not seen but functions adequately[2].

Oropharyngeal leak pressure was defined as the pressure at which audible leak is heard at a constant flow of 6L/min with Adjustable Pressure Leak valve kept closed. After the airway was secured in position, gastric tube (12F Gauge) was inserted through drain tube of Proseal LMA and i-gel. After recovery criteria were met, PLMA and i-gel were removed at the end of procedure.

The sample size for the study was based on a pilot study on ten patients. The outcome of pilot study indicated that a sample size of 46 in each group would give enough power of more than 85%. However results of the pilot study are not included in the results of main study. The results were analysed statistically using student t test and chi square test, wherever appropriate. Differences were considered to be statistically significant when p value was <0.05.

Results

Ninety two patients were enrolled into this study. Both the groups were statistically comparable with respect to demographic variables like age, sex and weight. Mean time taken to secure airway (Effective airway time) was 23.73 (Standard deviation SD 8.5) seconds in PLMA group and 22.26 (SD 5.9) seconds in i-gel group (p=0.339, Not significant [NS]). Insertion attempts were successful in 89.1% of patients (41/46) in PLMA group and 93.5% of patients (43/46) in i-gel group(p=0.141, NS).

Patients in the PLMA group had mean oropharyngeal leak pressure of 27.33 (SD 8.13) mmHg while that in i-gel group was 20.46 (SD 6.5) mmHg. On assessing the position of airway devices with fibreoptic bronchoscope, 80.4% of patients had Grade 4 or 3 glottic view in PLMA group while only 60.9% of patients in i-gel group had similar view (p=0.04, significant). Gastric tube insertion was possible in 86.9% (40/46) of patients in i-gel group and 95.6% (44/46) of patients in PLMA group (p=1.0, NS). Oral trauma (lips or tongue) during insertion occurred in 6.5% (3/46) of patients in i-gel group and 10.9% (5/46) of patients in PLMA group (p=0.465, NS). Postoperative airway morbidity like sorethroat, dysphagia or dysphonia occurred in 15.2%(7/46) of patients in i-gel group and 4.3% (2/46) of patients in PLMA group(p=0.459, NS)

Tables: **Comparative data for Proseal LMA and i-gel**

Values are given as mean (SD) and number (n)

Variables	Group P	Group I	P Value
1) No of patients	46	46	
2) Demographic data			
Age (years)	39.3 (13.8)	35.2 (12.1)	P=0.128 Not significant
Male : Female (n)	24:22	27:19	P=0.408 Not significant
Weight (Kg)	59.5 (10.2)	58.5 (10.8)	P=0.651 Not significant
3) Effective Airway Time (Sec)	23.7 (8.5)	22.2 (5.9)	P=0.339 Not significant

4) Number of attempts (1/2/3)	43/3/0	41/5/0	
5) Fibreoptic grading of airway			
Grade 4	5	13	$\chi 2 = 8.077$
Grade 3	23	24	P = 0.044
Grade 2	17	7	Significant
Grade1	1	2	
6) OP Leak pressure (mmHg)	27.3 (8.1)	20.4 (6.5)	P= 0.0001 Significant
7) Ease of gastric tube insertion			
Not passed	2	6	$\chi 2 = 5.798$
Difficult	13	5	P=1.00
Easy	31	35	Not significant
8) Airway Trauma During Insertion			
Yes	5	3	$\chi 2= 0.548$
No	41	43	P= 0.459 Not significant
9) Postoperative airway morbidity			
Sorethroat	2	3	$\chi 2= 4.501$
Dysphonia	0	3	P= 0.212
Dysphagia	0	1	Not significant

Discussion

Our study showed that PLMA was placed better than i-gel as confirmed by fibreoptic bronchoscope grading and easier insertion of gastric tube. This is probably due to the presence of dorsal cuff in PLMA, which improves position by pushing against ventral cuff. There are no previous studies where fibreoptic grading of position of either PLMA or i-gel were observed. Success rates for gastric tube placement in i-gel was 87% in our study, but was better in (100%) other studies[3,5]. Successful insertion of gastric tube requires the tip of mask to be placed near upper oesophageal sphincter. Hence, gastric tube insertion is bound to be difficult in view of suboptimal positioning of i-gel as confirmed by FOB.

There was no statistically significant difference in effective airway time between both the groups. The airway time for i-gel was slightly more compared to other studies wherein insertion time varied from 11-16 sec [5,6.] Success rates for first attempt of insertion was slightly better in i-gel group (93% vs 89% for PLMA group) but was statistically insignificant. Other studies have shown similar success rates for i-gel insertion from 86 to 97%[4,5,6,7]. Oropharyngeal leak pressure for PLMA group was significantly higher than i-gel group, since the dorsal cuff in PLMA pushes against the ventral cuff and forms better seal.

Airway trauma during insertion was higher in PLMA group since PLMA has bigger cuff and difficult to insert. This is similar to other studies where airway trauma during PLMA insertion varies between 11.6% to 16.6%[9]. Incidence of dysphonia, dysphagia and sore throat after Proseal LMA insertion was more than i-gel group because of presence of double cuff and trauma during insertion.

Hence we conclude that Proseal LMA is better compared to i-gel with respect to airway position as confirmed by fibreoptic bronchoscope, higher oropharyngeal leak pressure and ease of gastric tube insertion. However i-gel had better success rates, quicker insertion time, lesser airway trauma during insertion and lesser postoperative airway morbidity.

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