Comparison of i-gel versus Proseal Laryngeal Mask Airway in Elective Procedures of Short Duration Requiring General Anaesthesia without Muscle Relaxants

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ABSTRACT

BACKGROUND

Supraglottic airway devices (SADs) have been widely used as an alternative to tracheal intubation during general anaesthesia. They are easily inserted, better tolerated, with fewer haemodynamic changes and decreased airway morbidity. The Proseal Laryngeal Mask Airway (PLMA) and the i-gel airway are the two SADs which provide higher airway leak pressures than the classic LMA. Both these devices have separate channels for gastric tube insertion and are recommended for spontaneous as well as controlled ventilation.

METHODS

A prospective randomized study was conducted on 76 patients who were posted for various elective short duration surgical / diagnostic procedures under general anaesthesia. They were randomly divided by closed envelope method into two groups of 38 patients each, Group I (i-gel) and Group P (PLMA). All the patients were induced with general anaesthesia and the planned supraglottic airway was inserted with head in neutral position. Ease of insertion, number of insertion attempts and incidence of adverse effects were assessed.

RESULTS

There was no statistically significant difference between the two groups in terms of ease of insertion, number of insertion attempts and incidence of adverse effects but there was significant statistical difference in the mean duration of insertion between the two groups.

CONCLUSIONS

Insertion of i-gel was significantly easier and more rapid than insertion of PLMA. Both supraglottic airway devices are ideal and can be recommended as effective alternatives to endotracheal tube for short duration surgeries under general anaesthesia without muscle relaxation.

KEYWORDS

Supraglottic Airway Devices, i-gel, Proseal Laryngeal Mask Airway

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BACKGROUND

Securing patient airway is the primary responsibility of an anaesthesiologist. Failure to establish or maintain a patent airway can cause asphyxia and death. Endotracheal intubation is conventionally performed for almost all cases under general anaesthesia. Laryngeal mask airway (LMA) and its variants are SADs which do not require the use of laryngoscope and have several other advantages including easier insertion and minimal risk of tissue compression or injury when compared to the endotracheal tube.[1] i-gel is a novel SAD having a non-inflatable anatomical seal of the pharyngeal, laryngeal and perilaryngeal structures when compared to inflatable seal of PLMA.[2] Hence, we conducted this study to compare ease of insertion, number of insertion attempts and incidence of adverse effects amongst both these SADs.

METHODS

After obtaining ethical committee clearance, this study was conducted in our hospital from December 2019 to February 2020. After taking informed consent, seventy-six patients of either gender belonging to American society of Anaesthesiology (ASA) physical status 1 & 2, aged between 18 to 60 years, scheduled for elective short duration surgical/diagnostic procedures under general anaesthesia were recruited for the prospective randomized study. Patients were divided into two groups by closed envelope method. Group I (i-gel): 38 patients, Group P (PLMA): 38 patients.

Exclusion criteria included patient refusal, anticipated difficult airway, intra-oral pathologies, mouth opening less than 3 cm, edentulous patients and patients with risk of pulmonary aspiration. A thorough pre anaesthetic evaluation was done on the previous evening of surgery. Premedication with Tab Ranitidine 150 mg at night before and on the morning of the surgery & Tab Alprazolam 0.5 mg at night before surgery was prescribed. After shifting to the operating room, routine monitoring were employed for the following parameters: Electrocardiogram (ECG), Heart Rate (HR), Blood pressure (NIBP) & Oxygen saturation (SpO2). An appropriate sized peripheral cannula was secured. Intravenous infusion of Ringers Lactate was started. Intravenous midazolam 1-2 mg and intravenous fentanyl 1.0 mcg/kg was administered. After pre-oxygenation with 100% oxygen for 3 minutes, patient was induced with intravenous propofol 2 mg/kg. Patient's head was kept in neutral position. An additional dose of propofol, if needed, was administered to achieve adequate depth of anaesthesia prior to the device insertion. Adequate depth of anaesthesia was assessed by jaw relaxation and loss of verbal contact with the patient. An appropriately sized and prior lubricated (water-based jelly) i-gel or PLMA was inserted in the Group I and Group P, respectively, by non-blinded anaesthesiologist who had >3 years' experience. A lubricated nasogastric tube (12 F) was placed in the stomach through the gastric channel. The ease of insertion & number of attempts for insertion was noted and documented. Anaesthesia was maintained with sevoflurane 1 MAC and nitrous oxide in oxygen (70:30) with spontaneous respiration using Bain's circuit. Proper placement of the inserted device was confirmed by square wave capnograph trace, normal chest movement and by auscultation. The factors considered for the failure for the proper placement of the device are failure to introduce into the pharynx, ineffective ventilation (inadequate chest rise, abnormal capnogram), drop in SpO2 <95% on commencing ventilation, time taken to insert device exceeding 60 s and malposition. Of the three attempts, second and third attempt was done by senior consultant. In case of failure by senior consultant, based on the need of procedure, the patient was either woken up or surgery was done through mask ventilation as per the difficult airway guidelines. These kind of patients were excluded from our study. Ease of insertion is defined as no resistance to the insertion of device in the pharynx in single attempt. The time taken for the insertion of device was noted as the time from the end of the propofol bolus to the connection of the airway to the breathing circuit and appearance of square wave capnograph. At end of the procedure, all the patients were ventilated with 100% oxygen during emergence from anaesthesia. The device was removed when the patient was able to open the mouth on command. The patients were inspected for any injury to lips, teeth or tongue and the device was inspected for the presence of any blood stains. The mask of the supraglottic device was checked for the presence of any gastric contents to confirm regurgitation. All the patients were observed for a period of 24 h for any complaints of sore throat. Sore throat in the postoperative period was treated using warm saline nebulization and in patients with sore throat 24 h later, warm saline gargles was advised. Laryngospasm, if occurred, was treated as per protocol. Any other complications were noted and duly treated.

Post-operative sore throat was graded as- Grade 0: No sore throat, Grade 1: Mild sore throat- Pain on swallowing solids, Grade 2: Moderate sore throat- Pain on swallowing liquids, Grade 3: Severe sore throat- Pain even on swallowing saliva.[3]

Statistical Analysis

Sample size was calculated using the formula, Total sample n=76.

$$n = \frac{2\,\sigma^2 (Z_{\alpha/2} + Z_{\beta})^2}{d^2}$$

α=0.05, power (1-β) = 0.8.

Data were analyzed using SPSS version 20.0. Results were analysed using Chi square test and Independent t-test. Demographic data, time for successful insertion were compared between the groups using Independent 't' test. The ease of insertion, number of attempts for successful device insertion and the incidence of adverse events were compared using Chi-square test. $p<0.05$ was considered as significant and $p<0.01$ was considered as highly significant.

RESULTS

The minimum age in both groups was 18 years. The maximum age in both groups were 50 years. The mean age in group I and P were 36.9±10.21 and 36.52±10.60 years respectively. There was no significant difference in the age of the patients between Group I and Group P (p=0.84). The mean body weight in Group I was 54.94±13.68 kg and in Group P it was 56.34±14.16 kg. There was no significant difference in the body weight of patients between the Group I and Group P (p=0.54). The ease of insertion of i-gel was very easy in 37 (98%) patients and was difficult in only 1 (2%) patient. In group P, insertion of PLMA was very easy in 30 (84%), easy in 3 (6%) and difficult in 5 (10%) patients. There was no statistically significant difference among the two groups.

Age (Years)	Group I (i-gel) No. of Patients	%	Group P (PLMA) No. of Patients	%
<20	02	5	03	6
21-30	08	21	06	17
31-40	10	26	09	24
41-50	18	47	20	52
Total	38		38	
Mean age in years ±SD	36.9٠10.21		36.52٠10.60	
t-value	0.091			
p-value	0.84 (NS)			

Table 1. Age Group Distribution among Both Groups

NS– Not significant

Sex	Group I (i-gel) No. of Patients	%	Group P (PLMA) No. of Patients	%
Male	18	47	20	53
Female	20	53	18	47
Total	38	100	38	100

Table 2. Sex Distribution among Both Groups

Body Weight (Kg)	Group 1 (i-gel) No. of Patients	%	Group P (PLMA) No. of Patients	%
30-39	4	11	3	8
40-49	10	26	8	22
50-59	12	32	9	23
60-69	6	16	10	26
70-79	5	13	6	16
80-89	1	2	2	5
Total	38	100	38	100
Mean body weight in kg ٠٠SD	54.94٠13.68		56.34٠14.16	
Minimum body weight in kg	35		36	
Maximum body weight in kg	86		84	
t-value	0.197			
p-value	0.544 (NS)			

Table 3. Body Weight Distribution

NS – Not significant

Type of Surgery	Group I (i-gel) No. of Patients	Group P (PLMA) No. of Patients
MRI	4	2
Wound debridement	13	12
Fibroadenoma breast	6	8
Implant removal upper limb	3	2
Colonoscopy	6	4
Lipoma excision	2	3
Incision and Drainage of carbuncle (Neck)	3	5
Cervical lymph node biopsy	1	2
Total	38	38

Table 4. Various Diagnostic/Surgical Procedures among the Two Groups

The first attempt success rate in Group I was higher as 37 (98%) of 38 patients required one attempt, second attempt was required in only 1(2%) patient. In group P, when compared to i-gel group, first attempt success rate was low, as 30 (84%) of 38 patients required one attempt, second attempt was required in 5 (10%) patients. But there was no statistically significant difference between the two groups. The mean duration of insertion of i-gel in group I patients and PLMA in group P patients were 17.12±3.42 and 25.62±5.28 seconds respectively and was statistically highly significant. (p<0.001).

Lip injury was noted in 3 patients in group I (i-gel) out of 38 and in 4 patients out of 38 in group P (PLMA). The incidence was not statistically significant (p=0.695) when compared between both the groups. Only 1 patient in group I had developed sore throat post operatively compared to 4 patients in group P. The incidence was not statistically different (p=0.169) when compared between the groups. The sore throat in all the 5 cases were mild requiring no treatment.

Ease of Insertion	Group I (i-gel) No. of Patients	%	Group P (PLMA) No. of Patients	%
Very easy	37	98	30	84
Easy	0	0	3	6
Difficult	1	2	5	10
Total	38	100	38	100
p value	0.079 (NS)			

Table 5. Comparison of Ease of Insertion between the Two Groups

NS – Not Significant

Insertion Attempts	Group I (i-gel) No. of Patients	%	Group P (PLMA) No. of Patients	%
First attempt	37	98	32	90
Second attempt	1	2	5	10
Total	38	100	38	100

Table 6. Number of Attempts for Insertion of Devices among the Two Groups

	Mean Duration of Insertion (Seconds)
Group I	17.12±3.42
Group P	25.62±5.28
p value	0.000 (HS)

Table 7. Mean Duration for Insertion among the Two Groups

HS – Highly significant

Adverse Effects	Group I (i-gel) No. of Patients (38)	%	Group P (PLMA) No. of Patients (38)	%	p
Tongue/lip injury	3	7	4	10	0.695 (NS)
Sore throat	1	2	4	10	0.169 (NS)
Laryngospasm	0	-	0	-	-
Hiccups	0	-	0	-	-
Aspiration	0	-	0	-	-
Coughing	0	-	0	-	-
Regurgitation	0	-	0	-	-

Table 8. Incidence of Adverse Effects among the Two Groups

NS – Not significant

DISCUSSION

i-gel, an anatomically designed non-inflatable SADs is safe for procedures lasting < 60-120 minutes.[4] PLMA is a complex device requiring an introducer for its insertion, while an i-gel can be inserted without an introducer.[5] Shorter time is expected to achieve an effective airway in i-gel because there is no requirement of cuff inflation.[6]

Ease of Insertion

One of the primary objectives was to compare the ease of insertion between the two devices. The grading of insertion was done similar to the study done by Siddiqui et al,[7] where insertion of device was recorded as: very easy (when assistant help was not required), easy (when jaw thrust was provided by the assistant) and difficult (when jaw thrust and deep rotation or second attempt was used for proper device insertion). In our study, the ease of insertion of i-gel was very easy in 37 (98%) patients and was difficult in only 1 (2%) patient. In group P, insertion of PLMA was very easy in 30 (84%) patients, easy in 3 (6%) patients and difficult in 5 (10%) patients. There was no statistically significant difference between the two groups with respect to ease of insertion as ($p>0.05$). The insertion of i-gel was found comparatively easier and required less skill as compared to PLMA but the results were not statistically significant.[8]

Mean Duration of Insertion

We found that mean time required for successful insertion of i-gel (17.12 s) was significantly shorter than PLMA (25.62 s). Mean time for insertion of the device was noted and found to be significantly less in i-gel group (9.697 ± 2.422 sec) compared to PLMA group (11.696 ± 2.992).[9] This could be partly due to the extra time required for cuff inflation of PLMA after its insertion.

Number of Insertion Attempts

Ishwar Singh et al, studied clinical performance of i-gel for elective surgical procedures. They found that the ease to insert i-gel was better than PLMA, the first attempt success rate was higher with i-gel compared to PLMA and gastric tube being easy to insert in both groups.[5] Results of our study were in accordance with the above study.

Post-Operative Adverse Effects

We compared the incidence of adverse effects intraoperatively, during emergence and in the postoperative period. There was no evidence of regurgitation and aspiration, laryngospasm, hiccups, coughing with either of the devices. In our study, we included only elective patients who were adequately fasting preoperatively, so none of the patients had episode of regurgitation. There were evidences of injury to lip & tongue which was comparatively higher in the PLMA group. In the i-gel group, only 2.6% cases complained of sore throat immediately in the postoperative period whereas in the PLMA group 10.5% patients complained of sore throat.

Various studies have reported similar findings wherein the incidence of sore throat was minimal with i-gel in comparison with other SADs.[10] The lower incidence of sore throat in our study can be attributed to the soft seal, non-inflatable mask of i-gel. So i-gel has some added advantage of easier insertion and minimal tissue compression,[11] whereas PLMA has an inflatable cuff which can absorb anaesthetic gases leading to increased mucosal pressure.[12]

One of the limitations of our study was inability to blind the anaesthesiologist, inserting the SADs among the allotted group of patients.

CONCLUSIONS

Insertion of i-gel was significantly easier and more rapid than insertion of PLMA. Both the supraglottic airway devices are ideal and can be recommended as an effective alternatives to endotracheal tube for short duration surgeries under general anaesthesia without muscle relaxation.

REFERENCES

[1] Levitan RM, Kinkle WC. Initial anatomic investigations of the i-gel airway: a novel supraglottic airway without inflatable cuff. Anaesthesia 2005;60(10):1022-1026.
[2] Kannaujia A, Srivastava U, Saraswat N, et al. A preliminary study of i-gel: a new supraglottic airway device. Indian J Anaesth 2009;53(1):52-56.
[3] Figueredo E, Martinez, Pintanel T. A comparison of the Proseal laryngeal mask and the laryngeal tube in spontaneously breathing anaesthetized patients. anaesth Analg 2003;96(2):600-605.
[4] Uppal V, Gangaiah S, Fletcher G, et al. Randomised crossover comparison between the i-gel and the LMA-unique in anaesthetized, paralysed adults. Br J Anaesth 2009;103(6):882-885.
[5] Singh I, Gupta M, Tandon M. Comparison of clinical performance of I-Gel™ with LMA-Proseal™ in elective surgeries. Indian J Anaesth 2009;53(3):302-305.
[6] Wharton NM, Gibbison B, Gabbott DA, et al. i-gel insertion by novices in manikins and patients. Anaesthesia 2008;63(9):991-995.
[7] Siddiqui AS, Raees US, Siddiqui SZ, et al. Comparison of performance and safety of i-gel with laryngeal mask airway (classic) for general anaesthesia with controlled ventilation. Anaesth Pain Intensive Care 2010;14(1):17-20.
[8] Kini G, Devanna GM, Mukkapati KR, et al. Comparison of i-gel with proseal LMA in adult patients undergoing elective surgical procedures under general anaesthesia without paralysis: a prospective randomized study. J Anaesthesiol Clin Pharmacol 2014;30(2):183-187.
[9] Pratibha SD, Patil V, Patil B, et al. Comparison of two supraglottic airways-i-gel and Proseal laryngeal mask airway for ease of insertion and hemodynamic stability. Indian J Clin Anaesth 2017;4(3):400-405.
[10] Gatward JJ, Cook TM, Seller C, et al. Evaluation of the size 4 i-gel airway in one hundred non-paralysed patients. Anaesthesia 2008;63(10):1124-1130.
[11] Jadhav PA, Dalvi NP, Tendolkar BA. i-gel versus laryngeal mask airway-Proseal: comparison of two supraglottic airway devices in short surgical procedures. J Anaesthesiol Clin Pharmacol 2015;31(2):221-225.
[12] Ouellette RG. The effect of nitrous oxide on laryngeal mask cuff pressure. AANA J 2000;68(5):411-414.