Randamosied Control Study to Evaluate and Compare, Two Supraglottic Airway Devices Classic LMA and I-Gel in Anaesthetized Spontaneously Breathing Adult Patients Posted for Minor Day Care Gynecological Surgeries Under General Anaesthesia

A. Rajendran[1], P. Sridhar[2], Heber Anandan[3]

ABSTRACT

Introduction: The major responsibility of an anesthesiologist is to provide adequate ventilation to the patient. There are wide varieties of supraglottic airway devices available which are used for surgeries requiring general anesthesia, so as to avoid the hemodynamic response associated with endotracheal intubation. Study aimed to record the functional difference exists between classic LMA and I –gel in anaesthetized spontaneously breathing adult patients posted for minor day care gynecological surgeries under general anaesthesia.

Material and Methods: Patients undergoing short surgical procedures were randomly assigned to I-gel or classic LMA. Anesthesia was induced with standard doses of propofol and the supraglottic airway device was inserted. The functional difference exists between classic–LMA and I –gel in terms of ease of insertion, airway leak pressure, hemodynamic stability and the complications were studied.

Results: There was a significant difference in easiness of insertion. The mean time required for insertion of classic LMA was 25.88 seconds as against the mean time of 22.82 seconds required in case of I-gel. Heart rate, Systolic Blood Pressure and Diastolic blood pressure in classic LMA and I-gel cases had not showed any important difference statistically. In terms of development of either intraoperative or postoperative complications, the difference between the two groups was not found to be significant.

Conclusion: Successful and shorter duration of insertion, with less hemodynamic response makes i-gel a suitable alternative to LMA Classic during general anesthesia.

Keywords: Diastolic Blood Pressure, Heart Rate, I-gel Ease of Insertion, Laryngeal Mask Airway Classic, Systolic Blood Pressure

INTRODUCTION

The supraglottic airway device is a novel device that fills the gap in airway management between tracheal intubation and use of face mask. Classic LMA has been a definitive alternative to endotracheal intubation in the past few years. But it has got its limitation in restricted mouth opening, with less airway leak pressure and lack of gastric port. I-gel is a new extra glottis mask airway device with gastric access. It provides a reliable perilaryngeal seal and does not produce compressive trauma.[1,2] The other second-generation newer airway device i-gel™ is a new supraglottic airway device designed to fit the peri-laryngeal and hypo-pharyngeal structures without the use of an inflatable cuff, made of a thermoplastic elastomer (styrene ethylene butadiene styrene) with a soft durometer (hardness) and gel-like, provides a seal in patients with a wide range of anatomical variation. The claimed potential advantages include ease of insertion and use with minimal tissue compression and congestion, airway complications and stability following insertion.[3,4] A previous anatomical study in cadavers has shown that the i-gel™ is capable of achieving a good peri-laryngeal seal without the requirement for an inflatable cuff. It also has features designed to allow a gastric tube to be passed into the stomach.[5-7]

Study aimed to record the functional difference exists between classic LMA and I –gel in anaesthetized spontaneously breathing adult patients posted for minor day care gynecological surgeries under general anaesthesia.

MATERIAL AND METHODS

Study was conducted after obtaining institutional ethics committee approval. Its single centre and single blinded study. ASA 1 and 2 patients with age between 18 and 60 years, with BMI of 20 to 25 kilogram/meter^2 undergoing day care minor gynecological patients were included in the study. Patients with difficult airway, with history of GERD and OSA and ASA 3 and 4 were excluded from study. 80 patients were divided into two groups of 40 each. Pre-anaesthetic evaluation was done on the evening before surgery. Patient premedicated with, Injection Ranitidine 50mg (iv), Injection metoclopramide 10mg (iv), Injection Glycopyrrolate 0.2mg (im) was give 30mins prior to surgery. The patient was pre-medicated with injection midazolam 2mg (iv), injection Fentanyl 1mcg/Kg (iv). Pre induction baseline cardio- respiratory parameters like Heart Rate(H.R), Blood

[1]Assistant Professor, Department of Anesthesiology, Government Dharmapuri Medical College and Hospital, [2]Assistant Professor, Institute of Obstetric and Gynaecology, Madras Medical College, [3]Senior Clinical Scientist, Dr. Agarwal's Healthcare Limited, Tamilnadu, India

Corresponding author: P. Sridhar, Assistant Professor, Institute of Obstetric and Gynaecology, Madras Medical College, Tamilnadu, India

How to cite this article: A. Rajendran, P. Sridhar, Heber Anandan. Randamosied control study to evaluate and compare, two supraglottic airway devices classic LMA and I-Gel in anaesthetized spontaneously breathing adult patients posted for minor day care gynecological surgeries under general anaesthesia. International Journal of Contemporary Medical Research 2018;5(2):B18-B21.

Pressor (B.P) and oxygen saturation (SpO2) were recorded. Anaesthesia was induced with Injection propofol 2mg/kg. It was confirmed by loss of verbal communication and loss of eye-lash reflex. Modified Muzi and colleagues scoring system is used to assess the tolerance of LMA insertion. Ideal score for LMA insertion was less than 2. Size of LMA and I- gel was selected according to weight of the patient. Ideal placements of airway was confirmed by presence of good bilateral symmetrical chest movements, square wave form on capnograph, normal end tidal co2 and stable spo2 (more than 95%). Immediately after insertion patient was ventilated with IPPV until resuming spontaneous breathing then patient was allowed to breath spontaneously till the end of surgery. Anaesthesia should be maintained with using 66% N_2O, 33% O_2 with one to two percent sevoflurane and without any neuromuscular blocking agents. The device was removed after resumed conscious, spontaneously and responded to oral commands. The oral cavity was examined for any injuries like lip, dental, tongue and also device was inspected for blood staining which indicate pharyngolaryngeal injury.18-24 hours after surgery patient was interviewed for any post-operative morbidity like irritation in throat, difficulty in swallowing and any change in voice. In case of failure to insert the LMA properly as judged by an audible leak or inability to achieve adequate chest expansion, the device was removed and reinserted. Maximum three attempts were allowed and if effective ventilation could not be achieved endotracheal intubation was planned and, proposed surgical procedure will be carried out. That case will be excluded from the study.

Ease of intubation (Table 3), time taken and number attempts were noted. Airway leak pressure was measured by determined by closing the adjustable pressure limiting valve(APL) of the circle system at fixed gas flow of 3 lit/ min and pressure at which audible leak was heard, was taken as the leak pressure. Gastric insufflation was epigastric auscultation with help of stethoscope, during inspiration. Hemodynamic parameters (Heart rate and Blood Pressure) were measured at baseline, induction, first and fifth minute.

STATISTICAL ANALYSIS

Microsoft office 2007 was used for the analysis. Descriptive statistics like mean and percentages were used for interpretation of data. Chi square test was used for the comparison.

RESULTS

Age, Body Mass Index and Size of LMA were statistically similar in both the groups (Table 1). Out of total number of 80 patients, the insertion were achieved in first attempts in 73 patients and second attempts were required only in 7 patients out of which 4 were for classic- LMA and 3 were for I-gel. The difference were not important statistically (p=0.69%). Insertion of I-gel was very easy in 37 patients and easy in 3 patients, whereas in C-LMA it was very easy in 30 patients and easy in 10 patients (Table 4). There were no cases of failure of insertion in both the groups. The p – value is 0.033883. There was a significant difference in easiness of insertion. The mean time required for insertion of classic LMA was 25.88 seconds as against the mean time of 22.82 seconds required in case of I- gel. The p value was 0.002. There was a statistical difference in time taken for insertion. The mean airway leak pressure with I-gel in group 2 patients was 23.82±2.47 cm H_2O and with c-LMA in group 1 was19.12±2.23 cm H_2O and was highly significant statistically (p=0.000). Out of total number of 80 patients the gastric insufflation was not seen in 64 cases and was seen in only 16 cases out of which 10 were for classic LMA and 6 was for I-gel(Table 4). The p value was 0.26. The difference between the two groups were not important statistically (p=0.26).

Comparison of pre insertion, 1 min post insertion, 5 min post insertion Heart rate, Systolic Blood Pressure and Diastolic blood pressure in classic LMA and i- gel cases had not showed any important difference statistically. All

Characteristics	Group I	Group II	P- value
Mean age in years	38.60	39.35	0.72
Mean BMI	22.96	23.28	0.14
Ease of insertion(1/2/3)	30/10/0	37/3/0	0.033
Number of attempts (I/II)	36/4	37/3	-
Duration of insertion (seconds)	25.88	22.82	0.002
Airway leak pressure (cmH2O)	19.12	23.82	0.00
Gastric insufflation(cases)	10	6	0.26
Lip injury (cases)	5	1	Nil
Blood on device (cases)	7	6	Nil
Post extubation cough	4	-	Nil
Post op dysphagia (cases)	0	2	Nil
Post op nausea, vomiting (cases)	1	2	Nil

Vitals	Pre-induction		1 Minute		5 Minutes	
	Group I	Group II	Group I	Group II	Group I	Group II
HR	88.6	82.28	89.4	83.75	84.8	80.9
SBP	122.12	122.755	121.62	123.88	118.52	118.65
DBP	77.72	77	77.77	77.12	72.98	74.42

Table-1: Characteristics

the above mentioned parameters (HR,SBP,DBP) were found to have marginal peak effect at 1 min post insertion in both the groups. Out of total number of 80 cases, 6 cases had lip injury, 4 cases had post removal cough, 3 cases had nausea and vomiting, 2 cases had dysphagia and 13 cases of blood staining on airway (Table 4).Out of the 6 cases lip injury 5 cases were of group I, while 1 cases was group II. Out of 3 cases with post of nausea and vomiting 1 was on group I while 2 were on group II. Out of 13 cases of blood staining on airway 7 were of group I, while 6 were of group II. Cough on removal of airway (4 cases) was seen only in group I. None of the cases had laryngospasm, pulmonary edema during intra or postoperative. In terms of development of either intraoperative or postoperative complications, the difference between the two groups was not found to be significant.

DISCUSSION

Both the groups were comparable and there were no statistically important difference regarding age, weight, body mass index, size of airway and number of attempts. 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 conducted by Siddiqui et al.[8] There was a significant difference in easiness of insertion. In 2008, Gatward JJ et al concluded that the airway seal given by the I-gel lower than the PLMA, but could be used in IPPV. Insertion of the device into the correct functional and anatomical position was easy and rapid.[9] The time for insertion was considered according to the study conducted by Helmy AM et al. from picking up the device to confirmation of effective ventilation by bilateral chest movement, square wave pattern capnography, normal range end tidal CO_2 and stable arterial SpO_2 (>95%).[10] In our study, the time for insertion of i-gel (22.82s) was shorter compared to c-LMA (25.88 s) which was highly significant statistically (p=0.002). The i-gel SAD is made of thermoplastic elastomer and has no cuff to be inflated after its insertion, hence requires less time for successful insertion as compared to c-LMA which has a cuff to be inflated after its insertion. In Franksen H et al, Amini S et al, Ali A et al studies, though the mean time for i-gel insertion was clinically shorter as compared to c-LMA, it was not statistically significant.[11-13] Airway leak pressure detection was performed in a similar manner done by Uppal V et al in their study.[14] In their study mean leak pressures were 25 and 22 in I-gel and C-LMA group respectively. It was comparable to mean pressures in our study, indicating I-gel can be preferred over C-LMA for IPPV. While inserting and removing the airway devices, the hemodynamic changes are produced because of mechanical contact between device and oropharyngeal structures, pressure over the larynx and pharynx produced by inflated cuff and dome of airway device. The hemodynamic parameters were monitored in the following time interval – Basal before insertion, 1 minute after insertion,, 5 minutes after insertion.[15] In our study, there was no important difference between two groups with regarding to all hemodynamic parameters. The results of our study were similar to the studies done by Helmy AM et al, Franksen H et al who in their studies found no significant difference between two groups regard to all hemodynamic parameters.[10,11] Jindal P et al in their study observed that i-gel produced less hemodynamic changes compared to other SADs.[15] Since I –gel can change its shape according to temperature, at normal body temperature it correctly fit in to perilaryngeal structures. does not produce much pressure over anatomical structures, hence produce less hemodynamic changes as compared to c-LMA which because of an inflatable cuff can produce more hemodynamic changes. 18-24 hours after surgery, patients were interviewed for any postoperative complications like sore throat, dysphagia and hoarseness.[12,16] Only 2 patient in group II had developed dysphagia post operatively compared to none of them in group I. Our results were consistent with the studies done by Siddiqui AS et al, Helmy AM et al, Fanksen H et al where the difference between two groups regarding postoperative morbidity was not statistically important, but there was higher incidence of nausea and vomiting in c –LMA group due to more incidence of gastric insufflation.[8,10,11] Cough, on removal of airway, was seen in C- LMA group. This suggests that cuff of C- LMA causes edema resulting in post extubation cough. I Gel which is a cuffed perilaryngeal sealer produce less trauma thereby causing no cough.

CONCLUSION

We conclude that I- Gel is preferred over C-LMA, as ease and time taken for insertion of airway was much lesser. Since airway leak pressure of I gel is higher it can be used for IPPV as well. I gel has low pharyngolaryngeal morbidity rate as compared to c- LMA. It can be used for CPR by an unskilled worker, as its easy and quick to insert

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Source of Support: Nil; **Conflict of Interest:** None

Submitted: 17-01-2018; **Accepted:** 16-02-2018; **Published:** 28-02-2018