COMPARATIVE STUDY OF CLINICAL PERFORMANCE OF I-GEL WITH CLASSIC LMA IN ADULT PATIENTS

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ABSTRACT

BACKGROUND

The aim of this study is to compare the I-Gel and Classic LMA (CLMA) in elective surgeries with regard to ease and success rate of insertion, time of insertion, airway sealing pressure and associated complication.

MATERIALS AND METHODS

In a prospective randomised study, 60 adult patients of ASA I-II of either gender between 18 and 60 years presenting for a short surgical procedure under general anaesthesia using either I-Gel or CLMA. An experienced anaesthesiologist inserted appropriate sized I-Gel or CLMA in patients using standard insertion technique and assessed the intraoperative findings of the study regarding time taken for respective device insertion, effective seal and complications were done.

RESULTS

There were no significant differences in demographic and haemodynamic data. Ease of insertion and success rate were comparable. No significant difference in both devices ($P > 0.05$) (Chi-square test). The mean time for insertion was more with CLMA (25.623±5.28 sec) than with I-Gel (16.80±3.336 sec) ($P < 0.05$). Although, the airway sealing pressure was significantly higher with I-Gel (26.07±3.073 cm of H_2O), the airway sealing pressure of CLMA (19.70±2.10 cm of H_2O) was very well within normal limit (Student's 't' test). Incidence of complications were comparable.

CONCLUSION

I-Gel is a supraglottic device with acceptable airway sealing pressure, easier to insert and less sore throat incidence. Hence, I-Gel can be a good alternative to CLMA.

KEYWORDS

Airway Sealing Pressure, I-Gel, CLMA, Time of Insertion.

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BACKGROUND

The supraglottic airway device is a novel device that fills the gap in airway management between tracheal intubation and use of face mask. Dr. Archie Brain, a British anaesthesiologist, for the first time introduced the laryngeal mask airway in 1983, designed to be positioned around the laryngeal inlet that could overcome the complications associated with endotracheal intubation, and yet be simple and atraumatic to insert.[1] Careful observations and clinical experience have led to several refinements of Brain's original prototype leading to development of newer supraglottic airway devices with better features for airway maintenance. The wide variety of airway devices available today may broadly be classified as intraglottic and extraglottic airway devices, which are employed to protect the airway in both elective as well as emergency situations.[2] As time went on, additional devices were added to the LMA family to satisfy specific needs and a number of other devices were developed. There are a large number of supraglottic airway devices, some of which appear similar to the LMA family and others that work under a different concept.[3]

Laryngoscopy and endotracheal intubation produce reflex sympathetic stimulation and are associated with raised levels of plasma catecholamines, hypertension, tachycardia, myocardial ischaemia, depression of myocardial contractility, ventricular arrhythmias and intracranial hypertension. Transitory hypertension and tachycardia are probably of no consequence in healthy individuals, but either or both may be hazardous to those with hypertension, myocardial insufficiency or cerebrovascular diseases.[4] This laryngoscopic reaction in such individuals may predispose to development of pulmonary oedema, myocardial insufficiency and cerebrovascular accident.[5,6] Supraglottic airway devices are now widely used for surgery requiring general anaesthesia, so as to avoid the complications associated with tracheal intubation.[7]

The Laryngeal Mask Airway (LMA) Classic TM (Laryngeal Mask Company Ltd., Henley-on-Thames, UK) was introduced into clinical practice as a first-generation supraglottic airway device in 1983.[8] Since then it has gained popularity for airway management in both anaesthesia and resuscitation due to its ease of use.[8,9,10]

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The LMA-Classic (Standard LMA, Classic LMA, LMA-C, C-LMA) consists of a curved tube (Shaft) connected to an elliptical spoon-shaped mask (cup) at a 30° angle.

There are two flexible vertical bars where the tube enters the mask to prevent the tube from being obstructed by the epiglottis. An inflatable cuff surrounds the inner rim of the mask. An inflation tube and self-sealing pilot balloon are attached to the proximal wider end of the mask. A black line runs longitudinally along the posterior aspect of the tube. At the machine end of the tube is a 15-mm connector. The LMA is made from silicone and contains no latex.

However, insertion of the LMA Classic is not always easy in children due to differences in airway anatomy compared with adults[9] and more complications are related to its use in younger children compared with adults.[11,12,13] The I-Gel TM (Intersurgical Ltd., Wokingham, UK) is a disposable supraglottic airway device with a non-inflatable cuff made of thermoplastic elastomer gel that eliminates the need for cuff inflation and therefore prevents potential complications related to high intracuff pressures. In addition, it has a symmetrical, widened, elliptical and laterally flattened stem which may result in easier insertion and improved stabilisation during maintenance of anaesthesia.[14,15] The newer supraglottic airway device, I-Gel was introduced by Dr. Muhammed Aslam Nasir in 2007. It has the potential advantages including easier insertion, minimal risk of tissue compression, stability after insertion and an inbuilt bite block.

The I-Gel airway is a novel and innovative supraglottic airway management device, made of a medical grade thermoplastic elastomer, which is soft, gel-like and transparent. The I-Gel is designed to create a non-inflatable anatomical seal of the pharyngeal, laryngeal and perilaryngeal structures while avoiding compression trauma. This device has been developed after extensive literature searches related to supraglottic, extraglottic, periglottic and intraglottic airway devices dating back as far as the eighteenth century. Fresh cadaveric neck dissections, direct and indirect pharyngolaryngeal endoscopies, X-rays, CT and MRI imaging data were all utilised in order to ensure the I-Gel's shape, softness and contours accurately mirror those of the pharyngeal, laryngeal and perilaryngeal framework. The I-Gel is a truly anatomical device achieving a mirrored impression of those structures without causing multidirectional forces of compression or displacement trauma to the tissues and structures in the vicinity. The I-Gel has evolved as a device that accurately positions itself over the laryngeal framework providing a reliable perilaryngeal seal and therefore no cuff inflation is necessary.

Hence, this study was undertaken to compare these two supraglottic airway devices in relation to the ease of insertion, number of insertion attempts, time of insertion, airway leak pressure, haemodynamic changes and complications.

MATERIALS AND METHODS

After obtaining the approval of the Institutional Ethics Committee and written informed consent from the patients, 60 patients were included.

Inclusion Criteria

1. Patients belonging to American Society of Anaesthesiologist physical status I and II.
2. Patients undergoing elective surgery under general anaesthesia.
3. Patients between 15 to 60 years of age.
4. Patients of weight 50-90 kg.

Exclusion Criteria

1. Patients with full stomach, hiatus hernia or gastro-oesophageal disorder.
2. Emergency procedures.
3. ASA III and IV.
4. Patients with mouth opening < 2.5 cm or difficult airway.
5. Age < 15 years and > 60 years.
6. Patients with abnormal or distorted anatomy of the pharynx.
7. Patients with decreased compliance of the lungs.

All the patients received injection midazolam 1 mg, glycopyrrolate 0.2 mg, ranitidine 50 mg and metoclopramide 10 mg intravenously 30 minutes before surgery. Anaesthesia induction with propofol 2 mg/kg and fentanyl 1 µg/kg and neuromuscular blockade with scoline 2 mg/kg. Both I-Gel and Classic LMA was lubricated with water soluble jelly. Once adequate depth is achieved, each device was inserted by an experienced anaesthesiologist. Both the devices were fixed by taping the tube over the chin and lubricated gastric tube placed into the stomach through the gastric channel. Maintenance was achieved by oxygen, nitrous oxide, isoflurane and intermittent doses of intravenous vecuronium. Haemodynamic parameters like heart rate, non-invasive blood pressure and oxygen saturation were recorded before induction, at insertion at 1, 5 and 15 minutes after insertion of device, then at end of surgery and 1 minute after removal of device.

The number of insertion attempts and the ease of insertion of device were recorded. Ease defined as no resistance to insertion in the pharynx in a single manoeuvre. In a difficult insertion, there will be resistance to insertion or more than one manoeuvre or attempt required for the correct placement of the device. An effective airway was judged by a square wave capnograph trace, normal thoracoabdominal movement and absence of leak. If an effective airway could not be achieved with the device, then rescue airway with endotracheal tube was achieved after three unsuccessful attempts and failure of insertion recorded.

The airway sealing pressure was determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 L/minute and recording the airway pressure (Pressure gauge) at which equilibrium was achieved. At this time, gas leakage was determined at the mouth by the audible leak or by detection of an audible noise using a stethoscope placed just lateral to thyroid cartilage. At the end of surgical procedure anaesthesia was discontinued, patient was reversed with standard dose of neostigmine and glycopyrrolate and the device was removed. Adverse effects like blood staining of the device and tongue, lip and dental trauma recorded. Regurgitation of gastric contents also assessed. Pharyngolaryngeal morbidity was assessed as sore throat.

The sample size was based on a crossover pilot study of 10 patients and was selected to detect a projected difference of 30% between the groups for airway sealing pressure for type I error of 0.05 and a power of 0.8. Statistical analysis for airway sealing pressure was done by Fisher's t–test. For the

two variables, ease of insertion of gastric tube and bronchospasm/laryngospasm dichotomous nominal scale data correlation was applied.

For the remaining characteristics, Chi square test with Yate's correction was applied. Significance was taken as $p < 0.05$.

RESULTS

There was no difference between the two groups with respect to demographic and surgical details.

Particulars	I-GEL	CLMA
Age	37.87±10.28	36.52±11.24
Sex		
Male	5	6
Female	25	24
Weight	57.13±13.74	56.34±14.16
Duration of Surgery	34.48±10.70	43.92±11.80

Table 1: Demographic Data

Data	I-GEL	CLMA	P value
Airway sealing pressure	26.07±3.073	19.70±2.10	0.001
No. of attempts			0.301
First	29	27	
Second	1	3	
Ease of insertion			0.192
Easy	29	27	
Difficult	1	3	
Time of insertion	16.80±3.336	25.62±5.28	0.001

Table 2: Comparison of Airway Sealing Pressure, Ease of Insertion, Insertion Attempts and Mean Insertion Time

Complications	I-GEL	CLMA
Tongue injury	3	2
Sore throat	1	2

Table 3: Complications

RESULTS

The demographic data were comparable in both the groups. There was no significant difference in I-Gel and CLMA group. Airway sealing pressure in group I-Gel was 26.07±3.073 and in group CLMA was 19.70±2.10, which was statistically significant with P value 0.001. Also the mean time of insertion of group I-Gel was 16.80±3.336 and group CLMA 25.62±5.28, which was significant with P value 0.001. Only 3 patients of 30 in I-Gel group had tongue injury, whereas only 2 in CLMA group. Such as only 1 in I-Gel and 2 in CLMA group had sore throat, which was not statistically significant.

DISCUSSION

Both the groups were comparable and there was no statistically significant difference with regards to mean age, weight, sex and duration of surgery.

In our study, the ease of insertion of I-Gel was easy in 29/30 and difficult in 1/30. In group CLMA, insertion was easy in 27/30 and difficult in 3/30. There was no statistically significant difference between the two groups with respect to ease of insertion. Our study compared the ease of insertion of the devices with the study conducted by Ali A et al, Siddiqui et al, Janakiram et al who also did not find any statistically significant difference.[15,16,17] In this study, insertion of I-Gel was successful in first attempt in 29/30 patients as compared to 27/30 first time insertion with C-LMA. Airway manipulation like jaw thrust was required during second attempt insertion in one patient of I-Gel insertion and 3 patients with C-LMA insertions. Very similar results were found in studies conducted by Helmy AM et al and Uppal V et al.[2,18]

In our study, the time for insertion of I-Gel (16.80s) was shorter compared to C-LMA (25.62s), which was highly significant statistically ($p = 0.000$). 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. Consistent with our results, Helmy AM et al and Uppal V et al also shows significant difference.[2,18]

Airway leak pressure detection was performed in a similar manner done by Uppal V et al[17] in their study. The difference in the leak pressures between I-Gel and C-LMA were statistically significant in our study ($p = 0.000$) similar to the previous studies of Janakiram et al and Helmy AM et al.[2,17,18]

Complications were also comparable in both groups and there was no statistically significant difference.

CONCLUSION

To conclude the I-Gel is a cheap and effective device, which is easier to insert. It has other potential advantages like effective airway sealing pressure, which was within the normal limit. Lack of inflatable cuff also resulted in lower incidence of sore throat. Thus, an I-Gel can be a useful tool for maintaining airway and intermittent positive pressure ventilation.

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