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Comparative Study Between I-Gel and Classic Lma in Anaesthetized, Spontaneously Ventilating Patients

KEYWORDS: 1.Laryngeal mask airway 2. i-gel 3. supraglottic airway device 4. c-LMA

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ABSTRACT *Maintenance of airway is an integral part of general anaesthesia. Hemodynamic changes are major hazards of general endotracheal anesthesia and are probably generated by direct laryngoscopy and endotracheal intubation. Supraglottic airway devices have been widely used as an alternative to tracheal intubation during general anaesthesia. Laryngeal mask airway is a supraglottic airway device with an inflatable cuff forming a low pressure seal around the laryngeal inlet and permitting ventilation. The i-gel is a novel supraglottic airway device made of thermoplastic elastomer which is soft, gel-like and transparent and does not have an inflatable cuff. In view of this, the present study was undertaken to compare the performance of two supraglottic airway devices classic laryngeal mask airway and i-gel in anaesthetized, spontaneously ventilating adult patients posted for elective surgeries under general anaesthesia.*

One hundred patients, scheduled for various elective surgical procedures under general anaesthesia belonging to ASA class I and II were included in the study and were randomly divided into two groups with 50 patients in each group. Both the devices were compared in relation to the ease of insertion, number of insertion attempts, time of insertion, airway leak pressure, haemodynamic changes, intra and post operative complications.

The demographic and hemodynamic parameters did not show any difference between the two devices. Statiscally the times of insertion (17.12±3.42 vs. 25.62±5.28 seconds) and airway leak pressure (26.38±2.76 vs. 19.70±2.10 cm of H20) were lower for i-gel compared to c-LMA

INTRODUCTION

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.

LMA-classic is the gold standard for supraglottic airway devices and is in use since 1983. It consists of an inflatable cuff and apertures for delivery of gases. It has been used in cases with spontaneously ventilation as well.

The i-gel is a new supraglottic airway device with a non inflatable cuff, composed of soft gel like, transparent thermoplastic elastomer. A drain tube is placed lateral to the airway tube, which allows insertion of gastric tube. I-gel was introduced by Dr Muhammed Aslam Nasir in 2007. It has the potential advantages including easier insertion and inbuilt bite block. It seals the laryngo-pharyngeal space without any air being insufflated and additionally has an oesophageal lumen

Materials and methods:

One hundred patients, scheduled for various elective surgical procedures under general anaesthesia belonging to ASA class I and II were included in the study

The inclusion criteria were:

- Adult normotensive patients aged between 15 and 50 years of both sex.
- Mallampati grade I and II.
- Elective surgeries under general anaesthesia with spontaneous ventilation.
- Duration of surgery less than 60 minutes.

The exclusion criteria were:

- Age <15 years and > 50 years.
- Mallampati grade III and above.
- Emergency surgeries.
- Head and neck surgeries.
- Patients with decreased mouth opening.
- Patients with increased risk of aspiration.
- Patients with abnormal or distorted anatomy of the pharynx.
- Patients with obstruction of the airway beyond the larynx.
- Patients with decreased compliance of the lungs.
- Obese patients with BMI >28 kg/m2.

The study population was randomly divided into two groups with 50 patients in each group using sealed envelopes containing the name of the group and the patient was asked to pick up the envelope. The envelope was opened by senior anaesthesiologist who was not involved with the study.

Pre-anaesthetic evaluation was done on the evening before surgery.

After pre operative preparation, the patient was brought into the operating theatre and the head was placed on a soft pillow of 10 cms before induction of anaesthesia with the neck flexed and head extended. The patient was connected to multiparameter monitor, which records heart rate, non- invasive measurements of SBP, DBP, MAP,

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etCO2 and continuous ECG monitoring and oxygen saturation.

The size of the device was decided by anaesthetist based on patient's body weight and manufacturer's recommendation. The standard pre use tests for both devices were performed. Both devices were lubricated using Lignocaine jelly on the tip and posterior surface as recommended by the manufacturer and the c- LMA fully deflated prior to insertion.

After recording the baseline reading of various hemodynamic parameters, the patient was premedicated with injection Midazolam 0.02 mg/kg body weight. Analgesia was provided by giving paracetamol 15 mg/kg half an hour before surgery. Then the patient was preoxygenated with 100% oxygen for 3 minutes via a face mask with Bain's circuit. Intravenous lignocaine (2%) 2 ml was given to prevent pain on injection of propofol. Anaesthesia was induced with propofol 2.5 mg/kg body weight. Induction of anaesthesia was confirmed by loss of verbal communication with the patient and loss of eyelash reflex. Once an adequate depth of anaesthesia was achieved, the allotted device was inserted. The standard insertion technique uses a midline or slightly diagonal approach (with the cuff fully deflated for c-LMA). The head should be extended and the neck flexed (sniffing position).

The device was connected to breathing circuit and patient ventilated spontaneously. An effective airway was confirmed by bilateral symmetrical chest movement, normal end tidal CO2 and stable SpO2 (>95%). The device was secured with adhesive tape. Anaesthesia was maintained using 66% nitrous oxide and 33% of oxygen with 0.8-1% Sevoflurane. The patient is recovered from anaesthesia by discontinuing sevoflurane five minutes before the end of surgery. The patient remained in the supine position and the device removed after the patient was fully awake and met all the reliable signs of recovery. The patient was inspected for any injury of the lips, teeth or tongue and the device for blood stain. 18-24 hours after surgery, patient was interviewed for any post operative complications like sore throat, dysphagia and hoarseness.

2.1. Parameters studied in this study

2.1.1. Ease of insertion

Graded subjectively on a scale from 1 to 3. The grading of insertion was done as; very easy (when assistant help was not required), easy (when jaw thrust was needed by assistant) and difficult (when jaw thrust and deep rotation or second attempt was used for proper device insertion).

2.1.2. Time of insertion

Time from picking up the device, to the time of confirmation of effective ventilation by bilateral symmetrical chest movement, square waveform on capnograph, normal range end tidal CO2 and stable arterial SpO2 (>95%).

2.1.3. Number of insertion attempts.

2.1.4. Airway leak pressure

The leak pressure found out by closing the expiratory valve of the circle system at a fixed low gas flow (3L/min), observing air way pressure at which equilibirium was reached. At this point, gas leakage was heard at the mouth, at the epigastrium by auscultation or coming out of the drainage tube (i-gel group)

2.1.5. Haemodynamic Parameters

They included heart rate, Systolic blood pressure, Diastolic blood Mean arterial pressure, oxygen saturation.

The above haemodynamic parameters were monitored in intervals of basal before premedication, at the time of insertion, 1 minute after insertion, 2 minutes after insertion, 5 minutes after insertion, at the time of removal, 1 minute after removal

2.1.6. Injuries

The patient was inspected for any injury of the lips, teeth or tongue and the device for blood stain after its removal at the end of the surgery.

2.1.7. Post Operative Complications

18-24 hours after surgery, patient was interviewed for any post operative complications like sore throat, dysphagia and hoarseness. Post operative sore throat was graded as nil, mild, moderate and severe.

OBSERVATION AND RESULTS

Demographic parameters:

There was no significant difference in the demographic criteria that included age of the patients (p=0.84), sex distribution, weight of the patients (p=0.544) between Group 1 and Group 2.

Ease of utility:

There was no statistically significant difference in the ease of insertion of both the devices (P=0.79). The attempts at insertion were lesser for I-gel than c-LMA. However it was found to be non significant since the p value was 0.66 The means of duration of insertion of i-gel in group 1 patients and c-LMA in group 2 patients were 17.12±3.42 and 25.62±5.28 seconds respectively and was also statistically highly significant (p<0.001). the mean airway leak pressure with i-gel in group 1 patients was 26.38±2.76 9 (cm H2O) and with c-LMA in group 2 patients was 19.70±2.10 (cm H2O) and was highly significant statistically. (p<0.01).

Hemodynamic parameters:

There was no statistical significance in the changes in heart rate, systolic blood pressure, diastolic blood pressure, mean blood pressure, oxygen saturation noted at various intervals were not significantly different. In the i-gel group, more number of patients suffered injuries to oral cavity and sore throat (8 cases) compared to the classic LMA group (4) which was found to be non significant.

DISCUSSION

In many studies conducted comparing both these devices, the demographic criteria (age, sex, body weight) were not found to influence the outcome nor did they show a difference.

The results of our study with regard to the ease of insertion were similar to those done by Ansar Ali et al., and Iswar Singh et al.

The attempts of insertion were comparable to studies done by Siddiqui S et al., and Helmy M et al. However, in a study done by Uppal V et al., 100% of C-LMA insertions were successful as compared to 90% in our study.

The time of insertion was shorter for i-gel in our study which was consistent with studies done by Helmy M et al., and Parul J et al. Also, the airway leak pressures were significantly low for i-gel compared to c-LMA in our study which was comparable to results of Janakiraman et al., and Franksen et al studies.

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In many studies, it has been found there was no difference in the change of the hemodynamic parameters when these two devices were compared. Also there were minimal incidences of injuries to oral cavity and sore throat in all the studies and were comparable to our study.

CONCLUSION

- The demographic parameters like age, sex and weight did not influence the ease of using either supraglottic airway devices.
- There were no significant differences in the changes of heart rate, blood pressures (systolic, diastolic, mean) and oxygen saturation at all intervals between the two devices.
- There was however reduction in the insertion time and airway leak pressure for i-gel compared to c-LMA.

SUMMARY

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.

Laryngeal mask airway is a supraglottic airway device with an inflatable cuff forming low pressure seal around the laryngeal inlet and permitting ventilation. The i-gel is a new supraglottic airway device with a non inflatable cuff, composed of soft gel like, transparent thermoplastic elastomer.

This randomised study included 100 patients divided into 2 groups for elective surgeries. The i-gel and c-LMA were used and the patients were spontaneously ventilated.

Various parameters were taken into consideration which included age, sex, body weight, hemodynamic parameters, ease of insertion, time of insertion, airway leak pressures and post operative injuries and sore throat.

From this study it can be summarised that classic-LMA and i-gel can be used safely and effectively during general anaesthesia with spontaneous ventilation in selected patients. Both devices are easy to insert. The i-gel provides a better airway sealing pressure and faster time of insertion compared to c LMA.

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