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A COMPARATIVE STUDY TO EVALUATE THE EFFICACY OF PROSEAL LARYNGEAL MASK AIRWAY AND I-GEL IN INDIVIDUALS UNDERGOING LAPAROSCOPIC SURGERY.

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ABSTRACT

Background: Airway management of patients has evolved from ventilation through endotracheal tube to Laryngeal Mask Airway but their role is limited in laparoscopic surgery. In this study we compared the efficacy of I-gel and Proseal LMA during general anaesthesia in patients undergoing laparoscopic surgery.

Materials and method: This prospective randomised observational study was conducted on 60 patients of 18-65 years, divided into two groups i.e. Group P (Proseal LMA) and Group I (I-gel) of 30 patients each. Sealing adequacy, insertion characteristics, hemodynamic alterations, and postoperative complications were assessed.

Result: Leak pressure of Proseal LMA was higher as compared to I-gel. Leak fraction and leak volume was lower in Proseal LMA as compared to I-gel. I-gel requires lesser time for insertion. Haemodynamic parameters were comparable between the two groups.

Conclusion: Proseal LMA provides better sealing adequacy than I-gel.

KEYWORDS : Proseal Laryngeal Mask Airway, I-gel, Leak Pressure, Leak fraction.

INTRODUCTION:

The development of laparoscopic surgery has revolutionized the field of surgery.[1] A ventilatory strategy that provides adequate oxygenation and ventilation is required during laparoscopic surgery to overcome the problems of increased airway pressure and decreased airway compliance.[2] Endotracheal tube, the time tested airway securing device has certain demerits such as trauma to vocal cords/oral cavity, exaggerated pressor response and sore throat.[3] Newer airway devices have been added to the anaesthesiologist's armamentarium to tackle these problems and thus ultimately led to the development of second generation supra-glottic airway devices.[4]

Proseal LMA made up of silicon with a softer, deeper mask bowl, a dorsal and peripheral cuff provides better seal around the glottic aperture and permits high airway pressures without leak. The drain tube permits drainage of passively regurgitated gastric fluid.[5]

I-gel™, a novel single-use airway device made of a medical grade thermoplastic elastomer with latex free and gel like material[6] designed to fit the peri-laryngeal and hypo-pharyngeal structures without an inflatable cuff.[7]

These devices provide low resistance to gas flow, more stability, potential for good access to the airway as a conduit, improved pharyngeal seal and decreased risks of airway occlusion or aspiration.[8] Use of supra-glottic airway device is a challenge in laparoscopic surgeries. The cardiopulmonary changes during laparoscopy are complex and depend on the interaction of the patient's pre-existing cardiopulmonary status, the anaesthetic technique and several surgical factors.[9]

Our objective was to evaluate the sealing adequacy, insertion characteristics, hemodynamic changes, and postoperative complications during insertion of I-gel and Proseal LMA in patients undergoing laparoscopic surgeries.

MATERIALS AND METHODS:

After obtaining approval from the institutional ethical committee, this prospective observational study was conducted at BPS GMC (W) Khanpur Kalan, Sonipat on 60 ASA I-II patients of age 18-65 years. Sample size was calculated using α-error of 5% and 90% power. Patients with ASA III-IV, anticipated difficult airway, mouth opening <2.5 cm, obese, oropharyngeal pathology, cervical spine instability, pregnant patients, history of lung diseases were excluded from the study. Patients were randomly divided into two groups i.e. Group P (Proseal LMA) and Group I (I-gel) of 30 each by using sealed opaque envelope technique.

Patients were pre-medicated with ranitidine 50 mg (i.v) and ondansetron 4 mg (i.v), 45 min before surgery. In the operation theatre, vital parameter monitoring was initiated and baseline readings were recorded. Midazolam 0.02 mg/kg i.v, Glycopyrrolate 0.005mg/kg i.v and Fentanyl 1.5 mcg/kg i.v were administered. After pre-oxygenation with 100% oxygen, induction was done with Propofol 2-2.5 mg/kg i.v and Vecuronium Bromide 0.1-0.2 mg/kg i.v. Depending on the randomisation corresponding airway device was inserted by experienced anaesthesiologist in each group. Size of Proseal Laryngeal Mask Airway and I-gel was decided by patient's age, sex and mallampati grading. After insertion, the device was confirmed for correct placement and then connected to the ventilation system.

A 14 F gastric tube for Proseal LMA and 12 F for I-gel was inserted through the gastric channel. Ease of insertion and time to insertion of gastric tube was recorded.

The number of attempts and ease of airway device insertion were recorded and defined as:

- Easy insertion - Insertion at first attempt with no resistance
- Difficult insertion - Insertion with resistance or requiring second attempt
- Failed insertion- Insertion not possible

Two attempts of supraglottic airway device were allowed before considering failed attempt. If a second attempt was needed, a different device size was used. In case of ineffective ventilation (TV<6ml/kg) or hypercarbia (>45 mm Hg), despite a successful placement, the device was removed and re-inserted performing corrective manoeuvres. If ventilation continued to be ineffective after repositioning the device, it was considered as ventilation failure and endotracheal intubation was performed. Time taken during insertion of both devices was recorded. Anaesthesia was maintained with controlled intermittent positive pressure ventilation using oxygen, nitrous oxide, sevoflurane and intermittent doses of vecuronium bromide 0.02mg/kg. Paracetamol 15mg/kg i.v was administered for intra-operative analgesia.

Oropharyngeal leak pressure was measured by closing the expiratory valve of circle system at a fixed gas flow of 3 L/min and recording airway pressure (between 20-40 cm H_2O and not exceeding beyond 40 cm H_2O) at which equilibrium was achieved. Pressure below 20 cm H_2O signifies significant leak and pressure >40 cm H_2O leads to barotrauma. Equilibrium point was identified by either:

(1) Auscultation- measuring the minimal airway pressure at which an audible gas leak occurred using a stethoscope placed just lateral to thyroid cartilage.

(2) Manometer stability- observing the manometer dial as the pressure from the breathing system increased and noting the airway pressure at which the dial reached stability.

Leak volume was calculated by the difference between inspired and expired tidal volume. The leak fraction was calculated by dividing leak volume by the inspired tidal volume.

Vital parameters were recorded before induction (baseline), just after intubation, before and after pneumoperitoneum, after gastric tube insertion, after change of position, after extubating to maintain target SpO_2 (>95%) and $EtCO_2$ (<45 mm Hg). Patients were extubated using standard protocol. Complications such as sore throat, laryngospasm, regurgitation, aspiration, stridor, hoarseness of voice, blood on device, injuries (to lip, teeth, and gum) and dysphagia were recorded during intra and postoperative period.

The statistical analysis was done using unpaired't' test, ANOVA and chi-square test. The statistical test was applied using SPSS version 18. The *P* value of <0.05 was considered to be statistically significant.

RESULTS:

Both groups were comparable with respect to demographic profile. Leak pressure was significantly higher in Proseal LMA (after induction, after pneumoperitoneum and after positioning) as compared to I-gel (Table 1).

TIME	Leak Pressure in cm H_2O		*P* value	SIGNIFICANCE
	PROSEAL LMA	I-GEL		
After induction (5 min)	31.2 ± 6.16	23.13 ± 4.25	0.0001	Significant
Pneumoperitoneum (10 min)	32.53 ± 5.94	24.33 ± 4.72	0.0001	Significant
After positioning (15min)	32.33 ± 5.99	24.93 ± 4.22	0.0001	Significant

Table 1

Leak volume in Proseal LMA was found to be significantly lower than I-gel immediately after induction, after pneumoperitoneum and at 25 min interval (Figure 1).

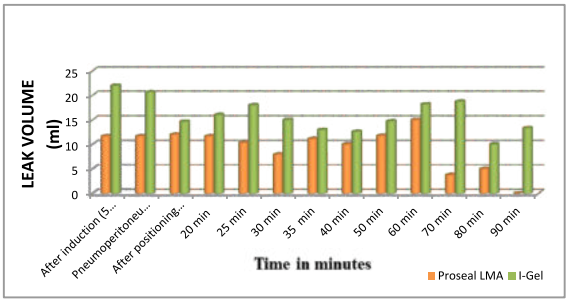

Figure 1

Leak fraction was also found to be significantly lower in Proseal LMA than I-gel after induction, after pneumoperitoneum and at 25 min interval (Figure 2).

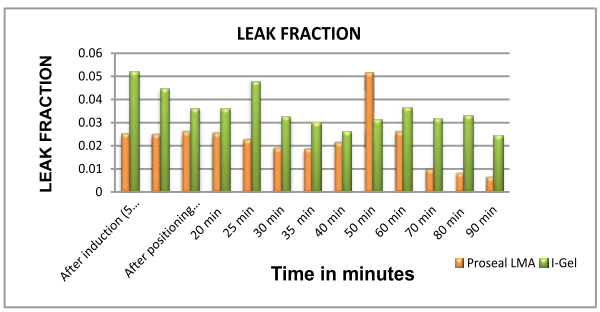

Figure 2

Attempts of insertion of airway devices and Ryle's tube were comparable in both groups. Mean time required for successful insertion of I-gel (14.96 ± 12.41s) was significantly shorter than Proseal LMA (25.03 ± 20.65s). Mean time required for successful insertion of Ryle's tube in I-gel (6.76 ± 4.91s) was significantly shorter than that in Proseal LMA (9.06 ± 4.89s). On comparing the hemodynamic trends there was no statistically significant difference. There was more incidence of blood staining of device in Proseal LMA group as compared to I-gel. Incidence of mild sore throat was noted in Proseal group. There was no evidence of stridor, hoarseness of voice, regurgitation, dysphagia and injury to tongue, lip and teeth among both groups.

DISCUSSION:

Sealing adequacy was comparable among both groups throughout the surgery except at the time of insertion, during pneumoperitoneum and at 25 minutes interval where results showed statistically significant difference. Leak pressure of Proseal LMA was higher as compared to I-gel but the leak pressure of I-gel was within the normal limit to provide adequate ventilation and to prevent aspiration. Leak pressure indicates the success of positive pressure ventilation and the degree of airway protection. It is regarded as the most important value for testing suitability of supraglottic airway device in laparoscopic surgery.[10] Our finding corelate well with Jose M. Belena et al who found that Proseal LMA has better leak pressure than I-gel (P= 0.027)[11]. We observed a lower leak fraction in I-gel as compared to Proseal LMA during the initial period of surgery which was later found to be comparable throughout the surgery. Proseal LMA was easier to insert in first attempt (100%) than I-gel (96.7%) but it was statistically insignificant. Mean time of insertion of I-gel was significantly shorter than Proseal LMA. Since no cuff inflation is required in the I-gel™, time required to achieve an effective airway was shorter, and does not require an introducer, the device can be simply pushed into place.[12,13] This went in agreement with the study performed by Sanli Mukadder et al.[14] Insertion time of gastric tube was significantly shorter in I-gel as compared to Proseal LMA. Proseal LMA and I-gel rests above the hypopharynx and mucosal pressures achieved are usually below the pharyngeal perfusion pressure[15,16,] so they cause less haemodynamic disturbances. Insertion of supraglottic device is a blind technique which leads to blood staining of device. Levitan & Kinkle presumed that inflatable mask of these device has the potential to cause tissue distortion, venous compression & nerve injury.[15] Trauma on insertion, multiple insertions, and pressure exerted by cuff against the pharyngeal mucosa, cuff volumes and pressure have all been incriminated for postoperative complications.[17,18,19]

CONCLUSION:

Proseal LMA provides better sealing adequacy however, it is equally efficacious as I-gel with respect to ease of insertion, haemodynamic stability, ventilation parameters and has lower rate of complications.

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