



COMPARATIVE EVALUATION OF AMBU AURAGAIN, i-gel & LMA PROSEAL IN PATIENTS UNDERGOING LAPAROSCOPIC CHOLECYSTECTOMY UNDER GENERAL ANAESTHESIA

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ABSTRACT

In this study, we have compared and evaluated the performance of three supraglottic devices Ambu AuraGain (AAG), i-gel and Proseal LMA (PLMA) regarding their oropharyngeal leak pressure (OLP), ease of insertion, perioperative complications (oropharyngeal trauma and sorethroat) and effects on hemodynamic and ventilatory parameters in patients undergoing laparoscopic cholecystectomy. This randomised comparative study was conducted in GTB Hospital, Delhi from November 2019 to November 2021 in 30 patients aged 18-60 years of ASA I-II grade for laparoscopic cholecystectomy. The patients were randomly allocated into Ambu AuraGain (Group A), i-gel (Group I) or LMA Proseal (Group P) group (10 patients in each group). OLP was measured at various time points. OLP was significantly higher in group I compared to group P before abdominal CO₂ insufflation ($p=0.043$), just after insufflation ($p=0.048$) and 45 mins after insufflation ($p=0.201$). OLP was significantly higher in Group A compared to group P after deflation of abdomen ($p=0.029$). OLP in group A and I were comparable at all time points. OLP was statistically significant among the three groups ($p=0.017$). Time taken for successful device insertion was significantly lesser in group I compared to group P ($p=0.001$) and group A ($p<0.001$). Time taken for insertion of device was comparable between group A and group P ($p=0.984$). Ease of insertion of device, number of attempts, ease of gastric tube placement, hemodynamic and ventilator parameters were comparable among the three groups. Based on our study, we conclude that all the three devices are safe for use in laparoscopic surgery. On comparison of the three devices, OLP was higher in i-gel and Ambu AuraGain in comparison to LMA Proseal. The time taken for successful device insertion was significantly less with i gel as compared to AAG and PLMA.

KEYWORDS : Ambu AuraGain, i-gel, Proseal LMA, Oropharyngeal Leak Pressure.

INTRODUCTION

Laparoscopic surgery is a minimally invasive surgery which offers major benefits to the patient such as minimized incision size, lower incidence of postoperative wound infections, shorter in-patient stay and reduced perioperative morbidity.

Laparoscopic surgeries produce significant physiological changes which are due to the result of patient position, CO₂ insufflation, pneumoperitoneum and increased intrabdominal pressure.¹ Pneumoperitoneum shifts the diaphragm upwards, resulting in increased airway pressure leading to gastric insufflation, air leakage and insufficient ventilation, therefore, cuffed Endotracheal tube (ETT) is gold standard and preferred technique in terms of safety. But with the advent of supraglottic devices (SGDs), their safety and ease of insertion has led to more and more surgeries being carried out using SGDs.

Ambu® AuraGain™ (AAG) is a disposable, single use, cuffed and it has a preformed curvature which resembles human anatomic airway that facilitates rapid establishment of safe airway. It provides an OLP in the range of 24 to 30 cmH₂O^{2,3,4}.

i-gel® is a single use, cuffless with low frictional properties. It has a short wide bore airway tube, elliptical shaped stem, anatomical shaped bowl, integral bite block and a drain tube. It is made up of a thermoplastic elastomer with gel-like feel. The mask is designed anatomically to fit the perilaryngeal and hypopharyngeal structures without the use of an inflatable cuff. It is easy to insert and provides stability after insertion. It has been reported to have OLP in the range of 20 to 30 cmH₂O^{5,6,7}.

LMA Proseal™ (PLMA) is considered to be a prototype for second generation devices and it has two parallel tubes: one for the airway maintenance and the other for gastric drain. It requires an introducer tool for its easy insertion. It has been

reported to have OLP in the range of 20 to 30 cm H₂O^{5,6,8}.

MATERIALS AND METHODS

After institutional ethics committee approval, this randomized controlled study was done from November 2019 to November 2021, at UCMS and GTB Hospital, Delhi. Thirty patients of 18-60 years of age of both sex, ASA I-II grade scheduled for laparoscopic cholecystectomy.

The exclusion criteria were patients with known case of COPD or asthma, known or predicted difficult airway, at risk for pulmonary aspiration and BMI > 30 kg/m².

The patients were randomly allocated into three groups Group A (Ambu AuraGain), Group I i-gel and Group P (LMA Proseal) with 10 patients in each group by using computer-generated random number table. Pre anaesthetic checkup of the participants was done a day before the surgery and written informed consent was taken. All patients were kept nil per orally as per ASA guidelines. OT was prepared and routine monitors including NIBP, pulse oximeter, ECG was attached and baseline parameters were recorded. An 18G intravenous cannula was placed and ringer's lactate solution was started.

One of the three devices AAG, i-gel or PLMA was prepared as per randomization. In the OT, inj morphine 0.1 mg/kg iv was given as pre medication followed by induction by inj. propofol 1.5-2.5 mg/kg iv. After ensuring adequate bag and mask ventilation, inj vecuronium bromide 0.1 mg/kg iv was given for muscle relaxation. The selected SGD was inserted with the patient's head in sniffing position. Time taken for device insertion, ease of device insertion and number of attempts were noted and grading was done. After insertion, cuff of the device was inflated with a manometer and cuff pressure was set to 60 cmH₂O (AAG & PLMA). Mechanical ventilation was started and a lubricated orogastric tube of appropriate size

was introduced via the drain tube of the device. Anaesthesia was maintained with O₂, N₂O, Isoflurane. OLP was measured by keeping a fixed gas flow of 4L/min and closing the circuit's APL valve 5 mins after securing the airway. Then, the highest anaesthesia circuit pressure at which the leak around the seal of SGD developed was noted at the following time points: following insertion of a device (T1), before abdominal CO₂ insufflation (T2), just after insufflation (T3) and every 15 mins after insufflations T4, T5 and so on till the duration of pneumoperitoneum. Last value of OLP was taken at the time of pneumoperitoneum release (TD). At the end of surgery neuromuscular blockade was reversed SGD was removed after adequate recovery of patient. The device was carefully observed for any blood stains and post-operative sore throat after 24 hrs.

RESULTS

Thirty patients were allocated for the study between November 2019 and November 2021. Age, gender, weight, BMI, ASA physical status and size of device were not statistically significant between the groups.

OLP was measured at various time points. OLP was significantly higher in group I compared to group P at T2 (Before abdominal CO₂ insufflation) (p=0.043), at T3 (Just after insufflation) (p=0.048) and at T6 (45 mins after insufflation) (p=0.201). OLP was significantly higher in Group A compared to group P at TD (After deflation of abdomen) (p=0.029). OLP in group A and I were comparable at all time points OLP was statistically significant between the three groups (p=0.017) [Table -1].

Table 1: Comparison Of Oropharyngeal Leak Pressure

OLP (cm H ₂ O)	A (n=10) (Mean±SD)	I (n=10) (Mean±SD)	P (n=10) (Mean±SD)	P-value	P-value (intergroup)		
					A vs P	I vs A	P vs I
OLP T1	33.33±4.39	29.20 ± 1.68	28.50 ± 1.26	0.017*	0.995	0.751	0.574
OLP T2	30.17±2.48	30.00± 1.05	28.50 ± 0.85		0.375	0.468	0.043*
OLP T3	30.17±2.48	29.90 ± 1.52	28.30± 0.94		0.217	0.718	0.048*
OLP T4	29.60±1.83	29.80±1.54	28.40± 1.17		0.210	0.955	0.125
OLP T5	30.00±2.00	30.10 ± 1.10	28.50± 1.35		0.091	0.988	0.068
OLP T6	29.60±1.35	30.40 ± 1.26	28.60 ± 1.07		0.185	0.331	0.008*
OLP TD	29.90±1.66	29.30±1.33	28.20± 1.13		0.029*	0.607	0.201
P-value	0.118						

(p <0.05 significant)*

Time taken for successful device insertion was significantly lesser in group I compared to group P (p=0.001) and group A (p<0.001). Insertion time of device was comparable between group A and group P (p=0.984) [Table -2].

Table 2: Time Taken For Successful Device Insertion

Insertion time (secs)	A (n=10)	I (n=10)	P (n=10)	P-value	P-value (Inter group)		
					A vs P	P vs I	A vs I
	28.20 ± 4.05	20.60 ± 4.57	27.90±2.80	<0.001	0.984	0.001	<0.001

(p <0.05 significant)*

Other parameters like ease of insertion of device, number of attempts required for successful device insertion, ease of

insertion of gastric tube and complications after removal of device were statistically comparable in the three groups.

Hemodynamic variables (HR, SBP & DBP) and ventilator parameters (EtCO₂ and SpO₂) were statistically comparable in the three groups.

DISCUSSION

Due to high airway pressure created by pneumoperitoneum in laparoscopic cholecystectomy there is increased risk of aspiration and loss of the airway can be encountered with the use of SGDs. But second generation SGDs allow higher airway pressures due to their effective seal and is considered as a measure of successful placement of SGD. A higher OLP is a marker of efficacy and safety when using SGDs⁹.

In the present study, OLP was significantly higher in AAG as compared to PLMA after deflation of abdomen (p=0.029) whereas, Singh K et al reported that OLP was found to be comparable while using AAG and PLMA for laparoscopic cholecystectomy¹⁰.

We observed that OLP in i-gel and AAG were comparable at all time points. Our results are similar to that reported by Sabuncu U et al who reported OLPs are comparable while using i-gel and AAG for laparoscopic cholecystectomy⁴.

In present study, OLP was significantly higher in i-gel as compared to PLMA before abdominal CO₂ insufflation (p=0.043), just after insufflation (p=0.048) and at 45mins after insufflation (p=0.201). Our results are similar to a study by Liew GHC et al⁵ in which i-gel and PLMA were compared in elective surgery. In earlier studies conducted by Sharma B et al and Ekinci O et al, OLP was found to be higher in PLMA than i-gel^{8,11}.

The i-gel is known to provide better OLP which improves over time and this may be due to the thermoplastic properties of i-gel cuff which forms an effective seal around the larynx after warming to body temperature¹².

PLMA has been reported to have higher OLP in comparison to i-gel by various authors^{8,13}. However, in the present study, we did not find PLMA to be superior to i-gel. Previous studies reported higher OLP for PLMA due to its bigger dorsal and ventral cuff, deeper bowl, the proximal wedge shape of the cuff, corresponding larger surface area and inflatable nature in comparison with i-gel⁸.

In the present study, mean insertion time for successful device insertion was significantly longer in PLMA as compared to i-gel. Similar results have been reported by many authors^{11,13}. However, Sharma B et al reported that the mean insertion time of PLMA was comparable to that of i-gel in laparoscopic cholecystectomy¹⁴.

In our study, time taken for successful device insertion was significantly longer in AAG as compared to i-gel. The mean insertion time of AAG and i-gel reported in their study by Sabuncu U et al was comparable⁴.

We observed that time taken for insertion of device was comparable between AAG and PLMA whereas, Singh K et al reported a longer insertion time with AAG¹⁰. The longer insertion time for AAG has been attributed to its rigid structure in contrast to flexible silicone structure of PLMA¹⁰.

The placement of AAG and PLMA takes longer time in comparison to i-gel, this could be due to extra time required for cuff inflation in AAG and PLMA after the insertion of device, also PLMA is inserted with an introducer, removal of which is required following insertion of the device whereas i-gel and AAG do not require any introducer for insertion^{15,16}.

CONCLUSIONS

Based on our study, we conclude that all the three devices are safe for use in laparoscopic surgery. On comparison of the three devices, OLP was higher in i-gel and Ambu AuraGain in comparison to PLMA. The time taken for successful device insertion was significantly less with i gel as compared to AAG and PLMA. However, more studies with larger number of patients are required to establish the superiority of one device over another for use during laparoscopic cholecystectomy.

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