

COMPARISON OF OLP (OROPHARYNGEAL LEAK PRESSURE) AND PERFORMANCE CHARACTERISTICS OF I-GEL AND AMBU AURA IN PATIENTS UNDERGOING LAPAROSCOPIC APPENDICECTOMY UNDER GENERAL ANAESTHESIA

Anaesthesiology

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ABSTRACT

Background: Oropharyngeal Leak Pressure (OLP) and safety profile for different Supraglottic Airway Devices in laparoscopic surgeries still needs to be investigated. So, we compared novel 2nd generation Ambuaura (with cuff and built-in gastric channel) and I-gel (characteristically different) in above regards. **Methodology:** After ethical clearance and CTRI registration, 50 ASA I & II patients of 18-60 years undergoing laparoscopic appendectomy under conventional GA, randomly allocated to either of the SGD of study groups (Group A – Ambu AuraGain) and (Group I – I-gel). OLP measured for both devices 5 minutes (T0), and 10 minutes after insertion (T1) and after pneumoperitoneum (T2). Secondary outcomes like number of attempts, insert time, ease of insertion of device and RT, airway manipulation required, signs of airway obstruction and post removal complications noted. Data compared in regards to mean, SD, and appropriate statistical test. **Results:** When compared with I-gel, Ambu AuraGain produced significantly higher sealing pressures (OLP in cmH₂O) [Mean $\pm$ SD] at T0 (Ambu : 25.64 $\pm$ 1.32, i-gel 21.68 $\pm$ 2.14, p<0.00001), T1 (Ambu: 26.6 $\pm$ 1.26, i-gel : 23.2 $\pm$ 1.91, p<0.00001) and T2 (Ambu 27.16 $\pm$ 1.12, i-gel 23.88 $\pm$ 1.77, p<0.00001). Secondary outcomes like time to insert, number of attempts, ease of insertion of device and RT were comparable statistically. Airway manipulation was required in one patient in Group I and one patient had sore throat two hours after removal in Group A. **Conclusion:** I-gel and Ambu AuraGain, suitably acceptable for laparoscopic surgeries. Ambu AuraGain provides higher sealing pressure than I-gel, with overall success as in ease of insertion, number of attempts and less complications.

KEYWORDS

Oropharyngeal Leak Pressure (OLP), Ambu AuraGain, I-gel

INTRODUCTION

The endotracheal tube is always considered to be the gold standard for laparoscopic surgeries. One of the main disadvantages associated with tracheal intubation has been the enhanced pressor response. Supraglottic airway Devices (SGDs) are suitable alternative of ET tube.

SGDs are used to secure and maintain airways in patients during surgery and unexpected difficult airway⁽³⁾ with lower hemodynamic changes during placement. Second generation SGDs have gained popularity owing to better compliance and safety profile of additional gastric port. I-gel is a cuffless SGD made up of thermoelastic elastomer which expands by body heat from the patient after placement and fill the void in hypopharynx⁽⁸⁾

Ambu Aura Gain is a novel cuffed SGD that has preformed smooth rounded curve to follow the anatomy of the human airway allows easy insertion.⁽¹¹⁾ Oropharyngeal leak pressure (OLP) indicates airway protection, successful SGD placement, and Positive Pressure ventilation. A higher OLP suggests a better seal and is thought to allow for greater levels of positive pressure ventilation and improved gastric aspiration protection.

Sealing Pressure, efficacy & safety profile of different SGDs in laparoscopic surgeries are being studied. There are limited literatures available comparing I-gel and Ambu AuraGain in the laparoscopic surgeries.^(6,7) With this context, we hereby tried to explore the use of these two SGDs and compare the overall performance in laparoscopic appendectomy under general anaesthesia.

METHODS

After getting approval from IHEC, GMERS Medical College, Gotri, Vadodara (IHEC/21/OUT/SRFG013) and CTRI registration CTRI(2022/04/041651), Prospective randomized clinical study was carried out at GMERS medical college and Hospital, Gotri, Vadodara from April 2022 to November 2022 50 patients of 18 to 60 years with ASA I and ASA II status, of either sex, undergoing elective laparoscopic appendectomy were enrolled.

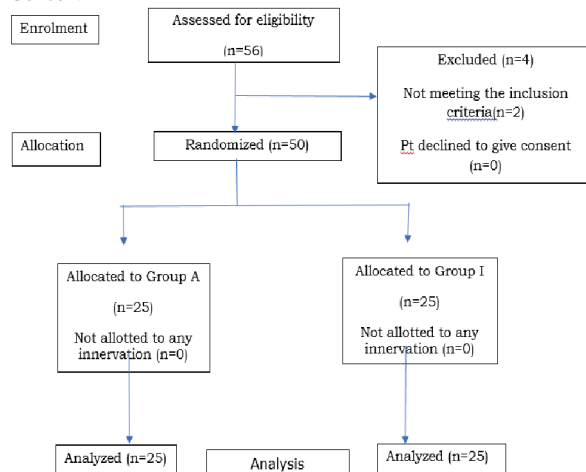
Patient who did not comply to minimum 8 hour fasting before surgery, with potentially difficult airway, active upper respiratory tract infection and having high risk of aspiration were excluded from the

study. Written informed consent was obtained from all the patients and were randomly divided into two groups via envelope method : Group-A (n=25): Ambu AuraGain was used, Group- I (n=25): I-Gel was used to secure airway. After ensuring standard fasting guidelines, IV line cannulated and patients were premedicated.

In the OR under ASA standard monitoring patients were induced with conventional GA technique. Both devices selected according to manufacturer's recommendation and inserted after achieving adequate depth of anesthesia. Appropriate size of gastric tube inserted via gastric port given in the devices. After confirming proper placement non depolarizing muscle relaxant was given.

OLP was measured by transiently stopping ventilation and providing a fresh gas flow of 3 L/min with APL valve closed at 40 cmH₂O. The airway pressure till it reached a Plateau or audible leak around the device started was observed it was considered as the Oropharyngeal Leak Pressure (OLP). Readings were taken for both SGDs at predetermined intervals post insertion : 5 mins. (T0), 10 mins. (T1), After pneumoperitoneum (T2).

Consort

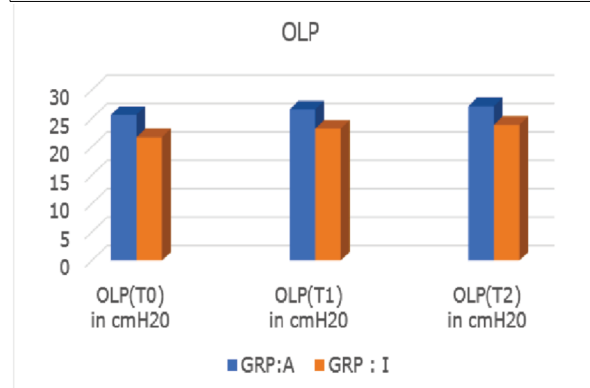


Comparative evaluation of performance characteristics in regards of No. of attempts, Insertion Time, Ease of insertion of device and RT, Airway manipulation required, Signs of airway obstruction and post removal complications was done. After completion of surgery inhalational agent was stopped and patient was reversed with reversal agents.

Table 1 : Oropharyngeal leak pressure(OLP)

Time interval	GROUP A		GROUP I		P -value
	Mean in cmH ₂ O	Median (IQR)	Mean in cmH ₂ O	Median (IQR)	
OLP T(0)	25.64±1.32	25 [25-27]	21.68±2.14	22 [20-23]	<0.01
OLP T(1)	26.6±1.26	26 [26-28]	23.2±1.91	23 [22-24]	<0.01
OLP T(2)	27.16±1.12	27 [26-28]	23.88±1.77	23 [23-25]	<0.01

p value < 0.01 ,so values are highly significant(S) between the groups



T0-Pre-induction,T1- Post Device Insertion T2- Post Pneumoperitoneum

Graph 1: Comparison Of OLP Between (GRP:A) And (GRP:I)

Table 2 : Demographics and secondary outcomes			
Demographic Data	Grp A (n=25)	Grp I (n=25)	p value
Age(years)	29.2±11.38	26.68±9.10	0.38NS
Gender(M:F)	15:10	17:8	0.76 NS
ASA(1/2)	21:4	18:7	0.49 NS
Weight(kg)	56.52±10.04	56.6±7.84	0.97 NS
Duration of Anaesthesia (In min)	53±6.48	53.2±6.14	0.91 NS
Attempts(times)	1.08±0.27	1.04±0.19	0.09 NS
Device insertion time (seconds)	14.8±1.76	14.76±2.43	0.12 NS
Ease of SGD insertion 1/2/3/4	25(100%)0/0/0	25(100%)0/0/0	-
Ease of RT insertion 1/2/3	25(100%)0/0	25(100%)0/0	-
Manipulation required	1/25(4%)	2/25(8%)	0.55NS
Signs of airway obstruction(%)	0%	0%	-
Post removal complication	2/25 (8%)	1/25(4%)	0.55 NS

p value >0.05 ,so data values are not significant(NS) between the groups

DISCUSSION

During controlled and mechanical ventilation, it is essential to maintain adequate airway seal to provide adequate ventilation. For this, OLP should be monitored. A higher OLP signifies efficiency and safety.^(5,6)

In our study OLP achieved with Ambu AuraGain was significantly higher as compared to I-gel at 5 minutes, 10 minutes after insertion and after creating pneumoperitoneum. [p=0.00001]. Sabuncu et al. and Deepak GP et al. study on the contrary didn't observe statistical difference in OLP between the groups [p=0.94].^(3,8) Laxmi TC et al. observed that OLP achieved Ambu AuraGain was significantly higher than that of Igel and LMA Supreme which was in consonance with our study.⁽⁵⁾ The wider airway tube and prominent posterior cuff design of the Ambu AuraGain provides a tighter and more consistent Perilaryngeal seal and might have high OLP which was discussed in previous study also. Manipulation in the form of Head extension, device Adjustment and Jaw thrust provided if device didn't place properly. In our study 1 patient in Group Ambuaura and 2 patients in

group Igel required jaw thrust as manipulation. Deepak GP et al. study also device inserted easily in majority of cases and when required, jaw thrust was the most effective of the manoeuvres in each group. These were subjective findings Pharyngeal anatomy; large epiglottis may sometimes hinder with the proper placement of the SGDs.

No signs of airway obstruction like abnormal chest/ abdominal movement, occlusion sound, inadequate ventilation (tidal volume <6 ml kg), oxygen desaturation (SpO₂ < 90%) or changes in the capnography curve were observed during the procedure. 1 patient in Group A and 1 patient in group I had blood stain on the device after removal, whereas 1 patient in Ambu Aura Group was having sore throat post removal. In Sabuncu et al. study One patient in the AuraGain and one in the i-Gel group had blood-stained SGDs after removal.⁽²³⁾

During laparoscopic surgeries, the risk of passive regurgitation from the stomach increases due to the gastric insufflation or aerophagia. Sabuncu et al followed the 'Rule of 15' to avoid regurgitation while using SGDs in laparoscopic surgeries (Trendelenburg tilt <15°, peritoneal insufflation < 15 cm of H₂O). Aspiration was not observed in any of the cases in our study – IAP maintained <14 cm of H₂O and Trendelenburg position.

Despite of the best we could do, certain areas need to be more emphasized for getting unbiased results. Our study only included subjects undergoing laparoscopic appendicectomy but more studies in context of other laparoscopic surgeries comparing other newer SGDs are required for conclusive evidence. Additionally, it was logistically not feasible to perform Fiberoptic bronchoscopy in all cases to assess the anatomical position.

CONCLUSION

Ambu AuraGain and I-gel suitably acceptable for Laparoscopic Appendicectomy as both the devices provide adequate pharyngeal seal and stability during the surgery with Ambu AuraGain having edge over I-gel considering the higher sealing pressure. Both devices are easy to insert, atraumatic and having less complications like sore throat, or bleeding.

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