Original Article

Comparison of Ambu AuraGain at low cuff pressure, Ambu AuraGain at high cuff pressure and i-gel in relation to incidence of postoperative upper airway complications

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ABSTRACT

Background and Aims: Postoperative upper airway complications are frequently encountered with the use of supraglottic airway devices (SADs). Cuff pressure is one of the risk factors for upper airway complications with SADs. Among SADs, i-gel has shown lesser incidence. The effect of different cuff pressures on the incidence of postoperative upper airway complications is not known with Ambu AuraGain and nor has Ambu AuraGain been compared with i-gel in this regard. So, we undertook this study. **Methods:** A total of 200 patients undergoing elective laparoscopic surgery were randomised into 3 groups based on the SAD used and intra-cuff pressure: i-gel (IG) ($n = 66$); Ambu AuraGain at 25 cmH_2O cuff pressure (AL) ($n = 67$); and Ambu AuraGain at 60 cmH_2O cuff pressure (AH) ($n = 67$). The oropharyngeal leak pressures (OLPs) were measured after insertion and generation of carboperitoneum. An observer who was blind to the intraoperative details assessed the patients for two postoperative days for sore throat, dysphagia, dysphonia, or any other upper airway complications. **Results:** The OLPs before and after carboperitoneum in the 3 groups were (IG-24.22 ± 7.87 and 28.31 ± 8.52, AL-24.40 ± 5.84 and 26.94 ± 5.93, AH-25.02 ± 5.02 and 28.91 ± 5.6) cmH_2O ($P = 0.747$ and $P = 0.231$). The overall incidence of postoperative sore throat among the 3 groups was: IG-5.7%, AL-14.9%, and AH-17.9%; $P = 0.135$. Dysphagia was seen only with Ambu AuraGain at high pressure in 4 patients (5.97%) ($P = 0.017$). **Conclusion:** Limiting cuff pressure in Ambu AuraGain to 25, as against 60 cmH_2O, does not affect the OLP but has the potential of reducing the incidence of dysphagia.

Key words: Laryngeal masks, pharyngitis, postoperative complications.

INTRODUCTION

Supraglottic airway devices (SAD) are being used in the majority of cases under general anaesthesia. Insertion of these devices is easy and involves minimal manipulation of the airway as compared to the endotracheal tube (ETT). Also, the ventilatory functions and prevention of gastric aspiration are almost similar with an added advantage of relatively fewer postoperative complications (ETT 14.4% to 50% and SAD 5.8% to 34%).[1,2] Considering the extensive use of SADs these days, incidence of sore throat associated with its use is still bothersome. Cuff pressure is one of the risk factors

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with the use of SADs and studies done with various types of SADs have shown decreased incidence when the cuff pressure is kept low.[3,4] Ambu AuraGain® (Ambu, India) (AAG) is a useful alternative to other SADs with considerable ease of insertion and similar clinical performance even at low cuff pressures.[5] i-gel® (Intersurgical, India), a second-generation SAD is now widely used in anaesthesia and resuscitation. It has also shown higher oropharyngeal leak pressure (OLP) and lesser incidence of a postoperative sore throat when compared with other SADs.[6] The effect of low cuff pressures on the incidence of postoperative upper airway complications is not known with Ambu AuraGain and also it has not been compared with i-gel in this regard. Hence, we planned this study.

METHODS

After institutional review board approval and ethical clearance (F. No./11/IEC/MAMC/2016/113) this prospective, double-blind, randomised study was conducted during the period from 01/01/2017 to 31/12/2017. Written informed consent was taken from all the patients.

The study included all patients undergoing elective laparoscopic surgery aged between 18 to 60 years of either sex and American Society of Anesthesiologists (ASA) physical status grade 1 or 2. Patients with neurological or psychiatric disorders, hoarseness of voice, history of respiratory infection within a month, allergy to soya bean oil or egg and any of the study drugs, any contraindications for using SAD were not enroled for the study. The patients were randomly divided into three groups by computer-generated random numbers, depending upon the SAD that was allocated to them: Group-IG (66) where i-gel, Group-AL (67) where Ambu AuraGain (AAG) at low cuff pressure, and Group-AH (67) where AAG at high cuff pressure was used. The primary objective of the study included comparison of postoperative sore throat and the secondary objectives included dysphagia, hoarseness of voice or any upper airway related complications among the three groups. Two senior anaesthesiologists not otherwise involved in the study were aware of the group allocation and they communicated this to the operator, who stayed with the patient throughout the intraoperative period, just before the case was being anaesthetised. Operator had experience of inserting both devices atleast 50 times. Standard monitors [peripheral oxygen saturation (SpO2), non-invasive blood pressure (NIBP), and electrocardiography(ECG)] were attached to the patients and balanced anaesthesia was administered. Attempts at the insertion of the SAD were made after 3 minutes of giving muscle relaxant.

The SAD size was determined by the patient's body weight following the manufacturer guidelines: <50 kg, size 3; 50–70 kg, size 4. Standard pre-use checks were performed on all the devices. The SADs were inserted by a single-hand insertion technique with the patient's head in sniffing position over a 7 cm pillow at the edge of the operation theatre (OT) table and the patient's face at a vertical level of the operator's umbilicus. The cuff of the AAG was completely deflated before insertion and its dorsal surface was lubricated with a water-soluble jelly. For i-gel, the dorsal and the lateral surfaces were lubricated. After insertion, the AAG cuff was inflated with air (half the maximum recommended volume for that size). After insertion, if ventilation was found inadequate, slight up-down or side-to-side adjustment of the device was performed as the first manoeuvre. If this manoeuvre failed, the device was pulled out without deflating the cuff (for AAG) 6 cm and reinserted again as a second manoeuvre. Since both the manoeuvres were done with some part of SAD within the oral cavity, the attempt was considered as one. When both the manoeuvres failed, the device was completely taken out. An assistant was asked to provide jaw thrust and the SAD was reinserted, this was considered as the second attempt. The successful SAD insertion was defined as the synchronised expansion of the chest wall with unobstructed inspiratory and expiratory flow, normal capnograph tracing at positive pressure ventilation and no audible leak after SAD insertion and cuff inflation (for AAG).

Bubble test, suprasternal notch test, and nasogastric tube (NGT) placement were performed thereafter. In the 'bubble test', a small drop of lidocaine jelly was placed at the machine end of the drain tube and intermittent positive pressure ventilation (IPPV) was performed. A gentle movement in the jelly without air bubbling through confirmed good positioning. In the suprasternal notch test, the machine end of the drain tube was filled with about an inch of jelly, and repeated gentle pressure was applied over the trachea at the level of the suprasternal notch. A gentle bounce of jelly with suprasternal pressure indicated good SAD positioning.

Finally, a smooth and successful placement of NGT into the stomach through the drain tube provided

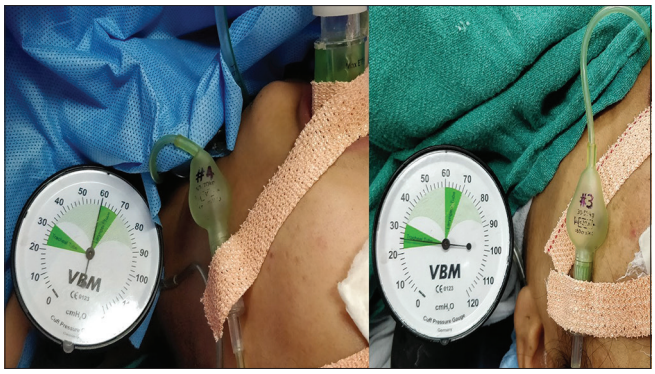

Figure 1: Cuff pressure setting in group AL and AH

further confirmation of the SAD positioning. Once the insertion was successful, the cuff pressure of AAG was adjusted using a manometer. The cuff pressure was kept at 25 cmH_2O in the AL (low-pressure) group and 60 cmH_2O in the AH (high-pressure) group [Figure 1]. The number of attempts and manoeuvres required until successful SAD insertion was recorded. An attempt was defined by SAD placement in the mouth till it was either successfully placed or it was removed from the mouth. If the criteria of successful insertion were not achieved after 3 attempts at SAD insertion, the airway was secured according to the decision of the attending anaesthesiologists and the case was defined as a SAD insertion failure. The causes of SAD insertion failure were noted (insertion failure into the airway, persistent air leak, or ineffective ventilation).

After successful SAD insertion, the patient's head was placed in a neutral position and the OLP was measured. The adjustable pressure-limiting (APL) valve of the anaesthesia circuit was fully closed and the oxygen was run at a fixed flow of 3 L/min. The OLP was defined as the pressure at which the manometer reading stabilised for >10 seconds. After anaesthesia induction and OLP measurement, volume-controlled ventilation with tidal volume 6-8 mL/kg of ideal body weight and no positive end-expiratory pressure was applied. The respiratory rate was adjusted to keep the end tidal carbon dioxide (ETCO2) between 35 and 40 mmHg. Anaesthesia was maintained with isoflurane oxygen (O_2) + nitrous oxide (N_2O) (33 + 67%). The surgeons were asked to generate carboperitoneum by CO_2 insufflation to a maximum insufflation pressure of 12 mmHg and the OLP measurement was repeated after CO_2 insufflation. After SAD removal, the device was inspected for blood on the inside or outside surface and the patient was transferred to the post-anaesthesia care unit (PACU). If there was a situation of ventilation failure during the anaesthesia, the SAD was removed and the airway was secured according to the decision of the attending anaesthesiologists and the case was dropped from the study.

Trained observers who were not involved in intraoperative management and blind to the group allocation collected all the data postoperatively. Postoperative upper airway adverse events were assessed: sore throat was defined as constant pain or discomfort in the throat independent of swallowing; dysphonia was defined as difficulty in speaking or pain on speaking; dysphagia was defined as difficulty or pain provoked by swallowing. The incidence of postoperative upper airway adverse events was recorded immediately after shifting to the post-anaesthesia care unit (PACU), at discharge from the PACU, and in the morning for the next two days (postoperative day (POD)-1 and POD-2). Any other complication related to the upper airway was also recorded at the same time.

The total sample size was calculated as 158 with a 5% significance and 80% power. 200 patients were included considering the loss to follow up of <20% and available time frame [Figure 2]. The qualitative and quantitative variables were analysed using the Chi-square test and two-way Analysis of Variance (ANOVA) respectively. OLP at two different time-intervals in the same group was analysed using paired *t*-test. Postoperative upper airway complications and unforeseen difficulty during insertion were expressed as percentages and analysed using Fisher exact test. Statistical analysis was done with Statistical Package for the Social Sciences(SPSS) software version 23.0 and a P value < 0.05 was taken to indicate a significant difference.

RESULTS

Demographics did not show any significant statistical difference among the three groups [Table 1]. Insertion of respective SAD could be achieved in all 200 cases and required one attempt without any manoeuvring in a majority of cases and when required, jaw thrust was the most effective of the manoeuvres in each group [Table 2]. There was no significant difference in the OLP among the 3 groups measured at two different times; after one successful insertion and after carboperitoneum. There was a statistically significant increase in OLP after creating carboperitoneum in all 3 groups ($P < 0.001$) [Table 2]. There was no statistically significant difference amongst the three groups for the *in situ* duration [Table 2]. Blood on the device was

Table 1: Demography of Patients in the three Groups

	Group IG (*n*=66)	Group AL (*n*=67)	Group AH (*n*=67)	*P*
Age (years) (mean±SD)	33.70±9.56	36.94±10.94	34.05±11.25	0.156
Sex (male (%)/female (%))	55 (83.33)/11 (16.67)	52 (77.61)/15 (22.39)	55 (82.09)/12 (17.91)	0.675
ASA (1(%)/2(%))	59 (89.40)/7 (10.60)	52 (77.61)/15 (22.39)	58 (86.57)/9 (13.43)	0.147
BMI (kg/m^2) (mean±SD)	22.48±4.13	22.27±2.27	23.10±3.66	0.35

ASA-American Society of Anesthesiologists; BMI-Body mass index; SD-Standard deviation

Table 2: Parameters Related to Device Insertion, Performance and Duration

	Group IG (*n*=66)	Group AL (*n*=67)	Group AH (*n*=67)	*P*
Attempts (1/2/3)	49 (74.3%)/ 14 (21.2%)/ 3 (4.5%)	51 (76.1%)/ 14 (20.9%)/ 2 (3.0%)	53 (79.1%)/ 13 (19.4%)/ 1 (1.5%)	0.878
Manoeuvres (0/1/2/3)	49 (74.24%)/ 0/0/17 (25.76%)	50 (85.1%)/ 1 (2.1%)/0/16 (12.8%)	52 (77.61%)/ 0/1 (1.5%)/14 (20.89%)	0.627
OLP-I (cmH_2O)	24.22±7.87	24.40±5.84	25.02±5.02	0.747
OLP-C (cmH_2O)	28.31±8.52	26.94±5.93	28.91±5.6	0.231
P (OLP-I vs. OLP-C)	<0.001	<0.001	<0.001	-
Duration of SAD use (min)	67.82±33.16	75.52±41.93	65.22±31.85	0.227

Data presented as mean (SD) or actual numbers (%age); OLP-I – oropharyngeal leak pressure after SAD insertion; OLP-C – oropharyngeal leak pressure after carboperitoneum; manoeuvre-1=slight side to side and/or up-down adjustment; manoeuvre-2=pull out SAD by 6 cm with cuff inflated (for AAG) and reinsert; manoeuvre-3=jaw thrust. SAD=Supraglottic airway device

Table 3: Pharyngolaryngeal morbidity with the three SADs

	i-gel (*n*=66)	AAG (low pressure) (*n*=67)	AAG (high pressure) (*n*=67)	*P*
Blood on device	2 (3.03%)	4 (5.97%)	9 (13.43%)	0.063
Sore throat	5 (7.57%)	10 (14.92%)	12 (17.91%)	0.135
Dysphagia	0	0	4 (5.9%)	0.017
Hoarseness, Dysphonia	0	0	0	-

SADs=Supraglottic airway devices

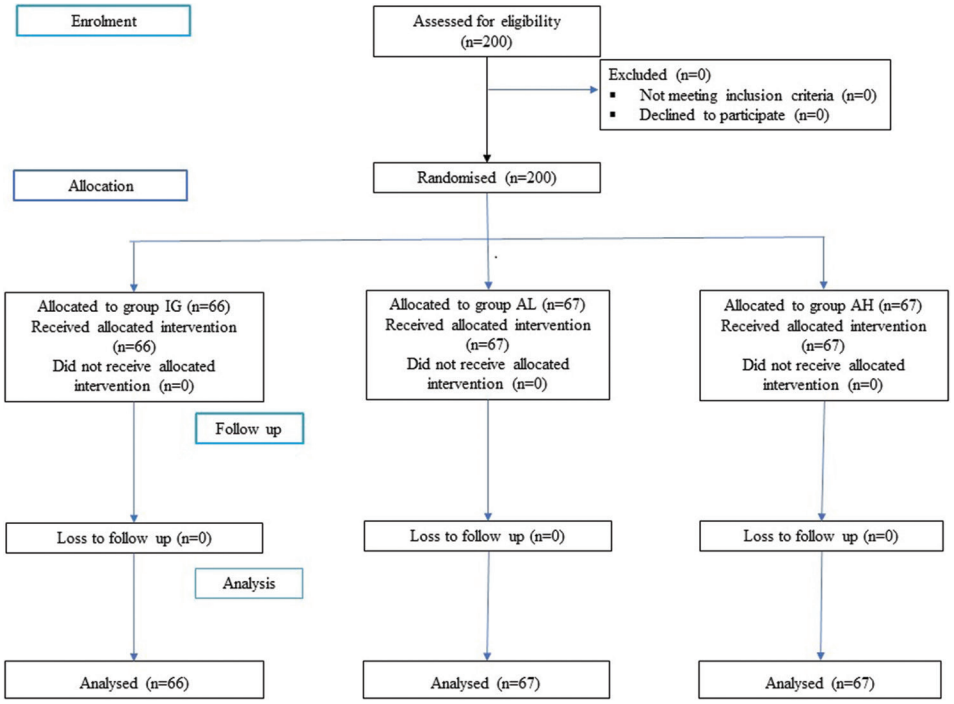

Figure 2: CONSORT flow diagram

observed in 2 cases in group IG, and 4 in group AL, and 9 in AH ($P = 0.063$) [Table 3]. Five patients had sore throat after i-gel use, while 10 and 12 patients complained of sore throat after AAG used at low

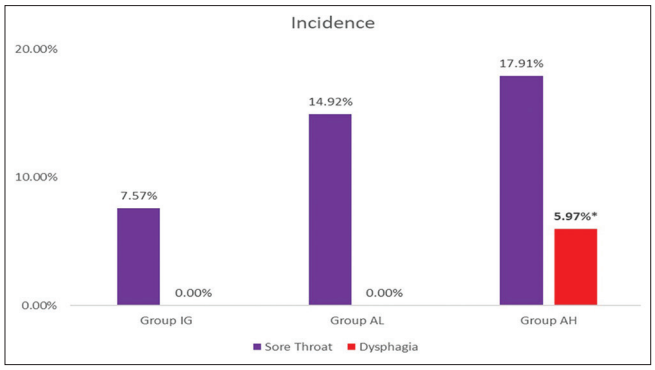

Figure 3: Bar diagram showing incidence of sore throat and dysphagia

and high pressure respectively (P = 0.135) [Table 3]. Dysphagia was observed only in the group whose airway was managed using AAG with high cuff pressure (Group AH) (5.97%) and it was found to be statistically significant (P = 0.017) [Table 3 and Figure 3].

DISCUSSION

El Boghdadly *et al.*,[7] have enumerated risk factors of postoperative sore throat as female sex, younger age, multiple attempts, prolonged duration of anaesthesia and the presence of a bloodstain on SAD after removal. In our study, there was no statistically significant difference among the 3 groups for the above-mentioned factors and we could reduce confounding factors to the minimum [Tables 1 and 2]. We included only laparoscopic surgeries where pain at the surgical site is less and upper airway complaints are more bothering. In previous studies, the overall incidence of postoperative upper airway complications after classic laryngeal mask airway (cLMA) use varied from 5.8% to 34%.[1,2] The wide variation in these figures could be because of many factors like (1) difference in the expertise and technique of anaesthetists, (2) differences between individual anaesthesiologists and patients in the definition of sore throat, (3) difference in the severity of postoperative surgical site pain and morbidities. It was also seen that the method of questioning is an important determinant of the incidence of sore throat. In a study after indirect questioning of 129 patients, only two complained of sore throat, whereas after direct questioning of 113 patients, 28 complained of sore throat.[8] In our study diagnostic laparoscopy and hysteroscopy were the commonest procedures (57.5%) where surgical manipulations were minimal and thus lesser surgical site pain.

Direct questioning was used for the assessment of upper airway complications and pain at the surgical site was also noted. Surgical site pain was assessed using the visual analogue scale (VAS) (0-10) and it was found that the mean score in none of the groups crossed a VAS of 3. Thus, we feel that the inclusion of mostly minimally invasive gynaecological diagnostic laparoscopic surgeries with low postoperative pain scores and direct questioning for post-operative airway morbidities make our study more robust than the previous studies. Although there was no statistically significant difference in the incidence of sore throat amongst the three groups, the incidence was highest with the high pressure cuffed device and the lowest in patients who were in the i-gel group. On the other hand, dysphagia occurred only in the high cuff pressure group and was significantly more than the other two groups (P = 0.017). Since the median duration of SAD *in situ* was 60 minutes in all three groups, it was probably the higher cuff pressures that lead to a significantly more incidence of dysphagia and higher (though not statistically significant) incidence of sore throat in the high cuff pressure group.

Brimacombe *et al.*,[9] showed that the SAD cuff pressure correlates directly with pharyngeal mucosal pressure but the pharyngeal pressures are much lower than the cuff pressures. In our study, the cuff pressure was kept at 25 cm H_2O in the low-pressure group (AL) and 60 cm H_2O in the high-pressure group (AH) after successful insertion of Ambu AuraGain. On the other hand, in the group IG, the pressure was not known as the i-gel is made of medical-grade thermoplastic elastomer and has a non-inflatable anatomical peri-laryngeal seal. Eschertzhuber *et al.*,[10] have shown at lower cuff pressures, cuffed devices may exert even less mucosal pressures than the i-gel. We did not measure the mucosal pressures but found that sore throat was less with i-gel, although not significantly less, than with AAG. In inter-group comparison, there was no statistically significant difference in the OLP amongst the three groups both before and after carboperitoneum. Hence, there was no compromise in ventilatory function even at a reduced cuff pressure of 25 cm H_2O with an added advantage of decreased mucosal pressure as suggested by Brimacombe *et al.*,[9] and Eschertzhuber *et al.*,[10] On the other hand, there was a significant rise in the OLP in all 3 groups after the creation of carboperitoneum ($P < 0.001$ for all three groups). This increase in OLP with carboperitoneum has been noticed regularly by previous investigators as well using other cuffed devices and they attributed

this to altered anatomy of the pharynx.[7] Increase in intra-abdominal pressure is known to push the mediastinum upwards along with the trachea-laryngeal apparatus.[11] Since the SAD is fixed around the mouth of the patient, it cannot shift up as much as the glottis that has been pushed up along with the trachea-laryngeal apparatus. This discrepancy in the relative upward movements of the peri-glottic area and the rim of peri-glottic SADs (like i-gel and Ambu AuraGain) makes the SAD fit more snuggly around the laryngeal inlet thereby improving the seal and increasing the OLP. In our study, we could achieve adequate seal in all three groups to allow adequate ventilation both before and after carboperitoneum. Thus, maintaining cuff pressure at 25 cm H_2O at all times seems more prudent knowing that it is the cuff pressure that determines the mucosal pressure.

The strength of our study lies in our ability to keep the confounding factors to a minimum as mentioned above. However, the mean duration of SADs *in situ* ranged from 65 to 75 minutes only, which may not allow all the benefits of low pressure to be fully expressed and appreciated. A study conducted with a longer duration of SAD use would probably be more useful in this regard.

CONCLUSION

Keeping cuff pressure at 25 cm H_2O and probably as low as possible to achieve adequate ventilation reduces postoperative pharyngo-laryngeal adverse events with cuffed SADs like AAG in surgeries lasting mostly 65-75 minutes without compromising their functional characteristics, even with carboperitoneum. With i-gel, these adverse events are as low as with AAG at low cuff pressure. These attributes of low cuff pressure and i-gel may become even more relevant during the longer *in situ* use of these SADs and should thus make them more suitable for general use.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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