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# Ambu®AuragainTM And I-Gel® In Adult Patients - A Comparative Randomized Controlled Study

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***Abstract:***
***Background****Supraglottic airway devices have evolved as a replacement for ETT for almost all procedures.With the advent of 2nd generation SADs, the apprehensions about aspiration, inadequate ventilation and displacement have been put to rest[1,2].These devicesare nowadays increasingly used because of theease of securingan airway and establishingairway control in a hands-free manner along with minimal hemodynamic side effects.*
***Aim****In this study we have compared the clinical performance of AuraGain and I-gel in 70adult patients aged 18to 65 years, posted for laparoscopic cholecystectomy under general anesthesia.*
***Methods****ASA physical status I & IIpatientswere randomly allocated intotwo groups: Aura Gain group A and I-gel group I.The primary outcome was the requirement ofadditional airway manoeuvresand ease ofinsertion parameters. Secondary outcomes were oropharyngeal leak pressures and peri-operative adverse effects.*
***Results****There was a significant difference in the time taken for the insertion of SAD in GroupA when compared to Group- I (p<0.0001). GroupA had significantly increased grades of ease of insertion of SAD when compared to GroupI (p=0.037). There was alsoa highly significant difference in the Oropharyngeal Leak pressure of GroupA when compared to Group- I (p<0.001)*
***Conclusion****The ease of insertion is better with I Gel which also offers a fasterplacement whereas AuraAmbuGain provides a better seal with higher OLPs.*
***Keywords:*** *Supraglottic airway devices,2nd generation, Laparoscopic Cholecystectomy, Oropharyngeal leak pressure, Ease of insertion.*

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## I. Introduction

I-gel (Inter surgical Ltd., Wokingham, Berkshire, UK) and Ambu AuraGain (Ambu, Ballerup, Denmark) are both 2nd Generation SADs having higheroropharyngeal leak pressures and a 2nd port for gastric tube insertion[3].I-gel is made up of gel-like thermoplastic elastomer which is soft and transparent.It isdesigned to anatomically fit the perilaryngeal and hypopharyngeal structures without an inflatable cuff.[4] It also has a port for gastric tube placement**.**AmbuAuraGainis a cuffed supraglottic airway,having a preformed curve and a built-in gastric port whichcan work as a conduit for intubation. It follows airway anatomy and aids in easy insertion. It can accommodate a comparatively larger endotracheal tube (ETT).[5,6]

Laparoscopic surgeries cause pneumoperitoneum which causes a rise in airway pressure and may increase the risk of regurgitation.[7]2nd generation SADs with their higher OLPs and a drainage port have become a suitable choice for these surgeries.

In this prospective randomised study, we compared these two supraglottic airway devices namely, I-gel and AmbuAuragainbased onadditional manoeuvres required, their ease of insertion, number of attempts, oropharyngeal leak pressures, haemodynamic changes associated with insertion and incidence of any perioperative complications.

## II. Methods:

A prospective randomized comparative,single-blinded study was conducted afterapproval from the Institutional Ethical Committee. ASA physical status I & II patients,70 in number, between 18 to 65 years of

age, weighing between 30-100kgs, with comparable demography posted for laparoscopic cholecystectomy under general anaesthesia were selected for the study. 35 patients in each group were selected after sample size calculation. Patients were randomized using computer-generated code into 2 groups.

**Group A** AmbuAuraGain group of 35 patients.
**Group II-G**el Group of35 patients.

After Pre-anesthetic examination and informed consent, induction was carried out withinjectionPropofol 2mg/kg and 100mcg fentanyl followed by injection vecuronium bromide 0.1mg/kg IV.Hemodynamic monitoring was done throughout the perioperative period.Adequate-sized SAD was selected as per manufacturer guidelines.The airway device insertion was performed by the resident anesthesiologist.In case of any resistance encountered during device placement,certain maneuvers as; jaw lift, head and neck extension, lateral approach etc were attempted. The ease of insertion was graded as Grade1- Easy, Grade2- Easy but with manoeuvre, Grade3- Difficult and Grade 4- Impossible. The AmbuAuragain cuff was inflated with air to attain a cuff pressure not exceeding 60cm H2O.Successful establishment of placement was done with the help of Bubble test,Suprasternal notch test and insertion of Gastric tube.A successful performance was established with the help of the OLP test and MaximumMinuteVentilation test.In case of test failure, the device was removed and reinserted upto three insertion attempts.'Insertion failure' was defined as more than three unsuccessful attempts. In case of Insertion failure, endotracheal intubation was done.

Oropharyngeal leak pressure was measured after closing the pressure limiting valve, with a fresh gas flow of 3L/min, monitoring the airway pressure at equilibrium or when an audible leak from the throat was heard.MMV test was done using normal and then double the tidal volume to establish an acceptable rise in minute ventilation.Post-surgery, patients were inquired about sore throat, hoarseness of voice or any other complaints at 1 hour and 24 hours.

A p-value < 0.05 was considered significant and a p-value <0.001 was considered highly significant at a 95% confidence interval.

Patients with ananticipated difficult airway MPC III or IV,Pregnant Patients,and Patients with Respiratory tract pathology or bleeding disorder were excluded from the study.Two patients could not complete the study due to follow-up loss;so a total of 68 patients were analysed with 34 patients in each group.

## III. Results:

The 2 groups werecomparable in terms of age, gender, ASA grades, BMI, Malampatti scores, type and duration of surgery.

The time taken for the insertion of SAD was 71.03±20.21 seconds in GroupA and a statistically significant,lesser time of 49.53±13.52 seconds in Group- I.

Ease of insertion of SAD in Group- I had a median grade of 1 Vs a median grade of 2 in Group- A. It was statistically significant ($p<0.05$). GroupA had significantly increased grades of ease of insertion at 1.85±0.59 when compared to GroupI at 1.46±0.59 ($p=0.04$).

There was a highly significant difference in the Oropharyngeal Leak pressure of GroupA when compared to Group- I ($p<0.001$). MeanOropharyngeal leak pressures were; (cmH2O) in A group31.53(±2.56) and I gel Group26.17(±2.24)

There was no statistically significant difference in the number of attempts required for the insertion of the SADs in the 2 groups($p>0.05$). Pre and post-insertion vitals were comparable in the two groups.

No complications were noted intraoperatively (like displacement, leaks, regurgitation, aspiration, accidental removal etc.) Postoperative complications like blood stains on removal, sore throat, cough, hoarseness, dysphonia, stridor etc were also monitored,if any within one hour and after 24 hours of removal postoperatively. None of the patients in both groups had blood stains on the SAD or complaints of sore throat or any other complaint.

## IV. DISCUSSION

This prospective randomized comparative study was conducted to compare the performance ofAmbuAuragain and I-gel in laparoscopic cholecystectomy under general anaesthesia. The time for insertion of SAD was calculated from the time,the resident anaesthesiologist picked up the SAD, to the confirmation of a successful placement confirmed by capnography and auscultation.The time taken for insertion of SAD was 71.03±20.21 seconds in Group Vs 49.53±13.52 seconds in Group- I, which was statistically highly significant ($p<0.001$).

Regarding the ease of insertion,AmbuAuragainwas observed to be relatively difficult to insert as compared to Igel. 80% of cases in Group- I and 67% of cases in GroupA had single attempt successful insertion of respective SADs ($p=0.020$). None of the groups had insertion failure (failure with 3 attempts) or conversion to endotracheal intubation.

Our study findings were quite similar to those of Wharton NM, who in their study of I-gel insertion by novices in manikins and patients noted that eighty-eight percent (44/50) were placed in the first attempt in manikins with a median insertion time of 14 seconds (range 7–45).[8]Success on the first attempt in healthy anaesthetized patients was 82.5% (33/40) and on the second attempt 15% (6/40). After three attempts there were no failures.

There was a highly significant difference in the Oropharyngeal Leak pressure of GroupA[9] compared toGroup I[10](p<0.001).Mean Oropharyngeal leak pressures were; (cmH2O) in A group 31.53(±2.56) and I gel Group 26.17(±2.24).

None of the patients in either group had any intraoperative or post-operative complaints.

## V. CONCLUSION

AmbuAuraGain provides a better oropharyngeal seal and has higher leak pressurescompared to I-gel. AmbuAuraGain can also be used as a conduit for the passage of an adequately sized endotracheal tube. Compared with the I gel group,Ambuauragainrequired more additional airway manoeuvres during the placement of the device andmaintenance of ventilation.However,the time for insertion was significantly less with a better ease of insertion in Igel.

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