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Original Research Article.

To Compare the Ease of Intubation Through an I-gel Versus AMBU AuraGain: A Prospective Randomised Study

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ABSTRACT

Background: Supraglottic Airway Devices (SAD) have become a fundamental part of difficult airway algorithms and are attaining popularity as airway management device during general anaesthesia. These devices can also be used as conduit for endotracheal intubation. The study aimed to evaluate the success and ease of I-gel and Ambu AuraGain (AAG) as conduit for endotracheal intubation.

Methods: 100 patients (20-60 years) were registered in this prospective, randomized study. After induction, appropriate size Ambu AuraGain/ I-gel were inserted. After confirmation of proper placement of SAD, endotracheal tube was inserted. The number of successful blind intubations, time taken for intubation through either of the SADs, number of attempts taken for effective SAD placement, time to achieve effective ventilation after SAD placement, number of attempts taken for blind endotracheal intubation, number of cases in which fiberoptic scope is used, hemodynamics and complications were recorded. Data was analyzed using chi square test and Fisher Exact Test.

Results: The overall success rate for SAD placement was 100% in both the groups however insertion time was significantly shorter with I-gel(17.58±1.31seconds) compared to Ambu AuraGain (21.34±1.65seconds) (p<0.001). Success rate for blind intubation through SAD was significantly higher in I-gel group (40% in AAG and 74% in I-gel, p=0.002). The use of fiberoptic scope for intubation was similar in both the groups (60% in AAG and 76.9% in I-gel, p=0.284). Overall intubation success for I-gel was 94% and AAG was 76% (p=0.011) and time taken for successful intubation through I-gel was significantly less as compared to Ambu AuraGain (p<0.001).

Conclusion: I-gel is a better conduit for endotracheal intubation than Ambu AuraGain with higher success rate and less time required for endotracheal intubation.

Keywords: Supraglottic Airway Devices (SAD), Ambu AuraGain (AAG), I-gel.

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INTRODUCTION

Supraglottic Airway Devices (SAD) are popular airway management tools during general anaesthesia.[1-3] These also have become a fundamental part of difficult airway algorithms. SAD has a disadvantage as it provides less protection of airway from gastric aspiration risk compared to endotracheal intubation however it can be used as a conduit for intubation.[4]

Ambu AuraGain (AAG) is a recently introduced, second generation SAD device with intubation capability.[5] Its rapid placement is ensured owing to its soft rounded curve which follows the airway anatomy. Soft rounded curve of AAG follows anatomy of human airway and ensures rapid placement. Moreover, wider airway tube facilitates use of bigger size ETT (endotracheal tube). The standard technique of insertion is same as that of Intubating Laryngeal mask Airway (ILMA).[6] Thus, AAG offers a versatile array of integrated features making it a safe choice for both routine and advanced cases.

I-gel, a well known, second generation SAD commonly used to secure airway has advantage due to its thermoplastic elastomer. The shape of the cuff mirrors the laryngeal anatomy[7,8] thus providing better compatibility to the glottic structures without any compression or displacement trauma to structures in vicinity. Moreover, large diameter of airway tube expedites easy passage of ETT (endotracheal tube) through it.

Both of these devices have been used as rescue devices in case of failed endotracheal intubation in unanticipated difficult airway, but the dilemma persists in managing the patient who has a SAD in place, but still requires the airway secured by an ETT. Previous studies have shown different Supraglottic Airway Devices (SAD) as conduit for intubation including Ambu AuraGain. However, there is very scarce literature available regarding the comparison of clinical performance as conduit for intubation through Ambu AuraGain and more widely used I-Gel. Hence, to learn a better

device to be used as a conduit for endotracheal intubation we propose to compare the ease of insertion of ETT through I-Gel and Ambu AuraGain. Our primary aim was to compare I-Gel and Ambu AuraGain in terms of number of successful blind intubations. The secondary aim was to compare the time taken for endotracheal intubation through either of the SADs, the number of attempts taken for effective SAD placement, time to achieve effective ventilation after SAD placement, number of attempts for blind endotracheal intubation, number of cases in which fiberoptic scope is used, and post operative sore throat. Hemodynamics and complications with the use of two SADs as conduit for endotracheal intubation were recorded.

METHODS

This prospective randomized study was conducted on 100 patients divided into two groups of age group 20-60 years of either sex with ASA (American Society of Anaesthesiologist) physical status I/II scheduled for elective surgery under GA (general anaesthesia) after obtaining approval from Institutional Ethical Committee at a tertiary care centre. Trial is registered with CTRI no. CTRI/2021/03/031714. A written informed consent was obtained from each patient after explaining the technique prior to inclusion in this study. Exclusion criteria included anticipated difficult airway, history of gastroesophageal reflux disease, any contraindications to muscle relaxants, increased aspiration risk, oropharyngeal pathology and poor lung compliance.

Patients were randomly allocated in 2 groups based on computer generated random number tables. In Group A (n=50): Appropriate size Ambu AuraGain was inserted and in Group I (n=50): Appropriate size I-gel was inserted.

Preoperatively, detailed history was obtained and systemic examination with airway assessment of each patient was done. All required routine investigations were done. Standard ASA monitoring included NIBP (non-invasive blood pressure), pulse oximetry, ECG, capnography and core temperature. Baseline values of all parameters were recorded and i.v. line was secured and maintained.

After pre-oxygenation with 100 % O_2, patient was induced with fentanyl 2µg/kg and titrated dose of1% Propofol. After assessing adequate mask ventilation, muscle relaxation was achieved with vecuronium 0.1mg / kg. The patient was ventilated through facemask with isoflurane in O_2, for 4 minutes achieving a MAC of 0.8-1. According to the allocated group and patient's weight, adequately sized I-gel / Ambu AuraGain (table 1) was inserted keeping the head in neutral position. Prior to insertion, standard pre use tests were performed for both devices and lubricated using 2% lignocaine jelly. Correct placement of SAD was ensured by adequate chest rise and capnography, air entry on chest auscultation, absence of audible leak during IPPV and absence of gastric insufflation. In case of absence of any of these criteria, SAD was repositioned by doing up and down movement and head and neck maneuvers and counted as second attempt. If unsuccessful, a third attempt was done using larger size SADs. The time from the discontinuation of facemask ventilation till appropriate SAD placement with capnography confirmation was noted as SAD insertion time. The time was recorded with the help of a stopwatch Number of attempts for SAD placement was also noted. A failed attempt was defined as removal of the SAD from the mouth before reinsertion. If successful ventilation couldn't be achieved even after third attempt this was recorded as failure of SAD insertion.

Following confirmation of effective placement of SAD, closed circuit was detached and an appropriately sized (table 1), lubricated and pre warmed ETT was gently inserted to length, through ventilation port of the device and the cuff of ETT was inflated. If no resistance was felt ETT was advanced fully into the SAD. The correct placement of ETT was confirmed by auscultation and capnography. When resistance was felt during ET tube insertion, jaw lifting, rotation of ETT and slight withdrawal of device was done to improve second attempt. If blind intubation could not be done in two attempts through SAD, the same size ETT was railroaded over fiberoptic scope (OlympusBF-PE2 with 4.9mm outer diameter), which was connected to camera and closed-circuit television monitor. Endotracheal intubation was done with the help of fiberoptic scope passing through the SAD. ETT insertion time was recorded as the time from disconnection of circuit for endotracheal tube insertion to the time ventilation was achieved through ETT with $EtCO_2$ confirmation. The total intubation time was also computed by SAD insertion time and ETT insertion time. After confirming proper insertion of ETT, the SAD was removed by railroading it over another small sized ETT used as a stabilizing rod.

Correct position of ETT was confirmed by auscultation and capnography. If intubation could not be done with fiberoptic bronchoscope then after removing the SAD, intubation was done by direct / video laryngoscopy as rescue intervention and labeled as failed intubation. Anaesthesia was maintained on O_2 and N_2O mixture, isoflurane, and intermittent vecuronium boluses. Fentanyl 1 µg/kg will be administered if required based on hemodynamic parameters. Haemodynamic parameters were monitored continuously till the end of surgery and recorded for every 3 minutes for first 10 minutes and every 5 minutes for 30 minutes. Any complications like hypoxia (SpO2<94%), bradycardia, bronchospasm, oesophageal or laryngeal trauma, sore throat or hoarseness of voice and aspiration were recorded.

Sample Size calculation and Statistical analysis:

A pilot study was conducted taking 12 patients in each group where intubation through Ambu Auragain and I-gel was performed. We blindly intubated 5 patients with Ambu AuraGain and 8 patients with I-gel. Data obtained from pilot study was analysed using SPSS version 22 and Microsoft Excel. Using the effect size for success rate of intubation as p1=40% and p2 = 68% for execution of 80% power and confidence level of 95%, sample size was calculated as 46. To increase the power of the test, sample was taken 50 for each group. Descriptive statistics were applied, and data was reported in terms of mean, S.D and percentages. Appropriate statistical tests of comparison were applied. Categorical variables were analyzed with the help of chi square test and Fisher Exact Test. Continuous variables were analyzed with t-Test and Mann Whitney U test where applicable. Statistical significance was taken as $p<0.05$.

RESULTS

A total of 122 patients were assessed for eligibility. After exclusion of 22 patients based on exclusion criteria 100 patients were recruited in the study and their data has been included in analysis (Figure 1). Data obtained from pilot study was not included in the main study.

In this study, distribution of patients according to age, gender, height, weight, ASA status, MP (mallampati) grading was similar in both the groups and statistically no significant difference was seen between the two groups (Table 2).

The I gel and Ambu AuraGain were successfully inserted in first attempt in 92% (46/50) and 78% (39/50) patients respectively, while second attempt was required in 8% (4/50) patients in I-gel and 18% (9/50) in Ambu AuraGain. The third attempt was required only in Ambu AuraGain in 4% (2/50) patients and not required in I-gel. The difference was statistically non-significant in Group A and Group I ($p>0.05$) However the overall success rate of insertion of I-gel and Ambu AuraGain was 100%.(Table 3) We compared time taken for SAD placement (time from the removal of facemask to the time ventilation was achieved through SAD with EtCO2 confirmation) in both the groups and the difference between the groups was statistically significant. The time taken for successful placement of I-gel was 17.58±1.31 sec which was significantly less as compared to 21.34 ± 1.65 sec with Ambu AuraGain ($p<0.001$). This is likely due to the less flexible stem of I-gel that makes its insertion easier and avoids the need for cuff inflation (Table 4). The first pass success rate for blind intubation through I-gel and Ambu Auragain was 44% (22/50) and 12% (6/50) respectively while the second attempt for blind intubation was successful in 30% (15/50) and 28% (14/50) patients respectively. The overall rate for successful blind intubation was 74% in I-Gel and 40 % in AAG. The difference was statistically significant in Group A and Group I ($p=0.002$). Thus I-gel as a conduit for blind intubation had a higher success rate as compared to AAG.

The failure rate for blind intubation through I-gel and Ambu Auragain was 26% (13/50) and 60% (30/50) respectively. Fiberoptic bronchoscope was used in these patients to aid endotracheal intubation. The success rate for fiberoptic guided intubation through I-gel and Ambu AuraGain was 76.9% (10/13) and 60% (18/30) respectively ($p=0.284$). The overall success rate of intubation in I-gel was 94% (47/50) and Ambu AuraGain was 76% (38/50) respectively ($p=0.011$).

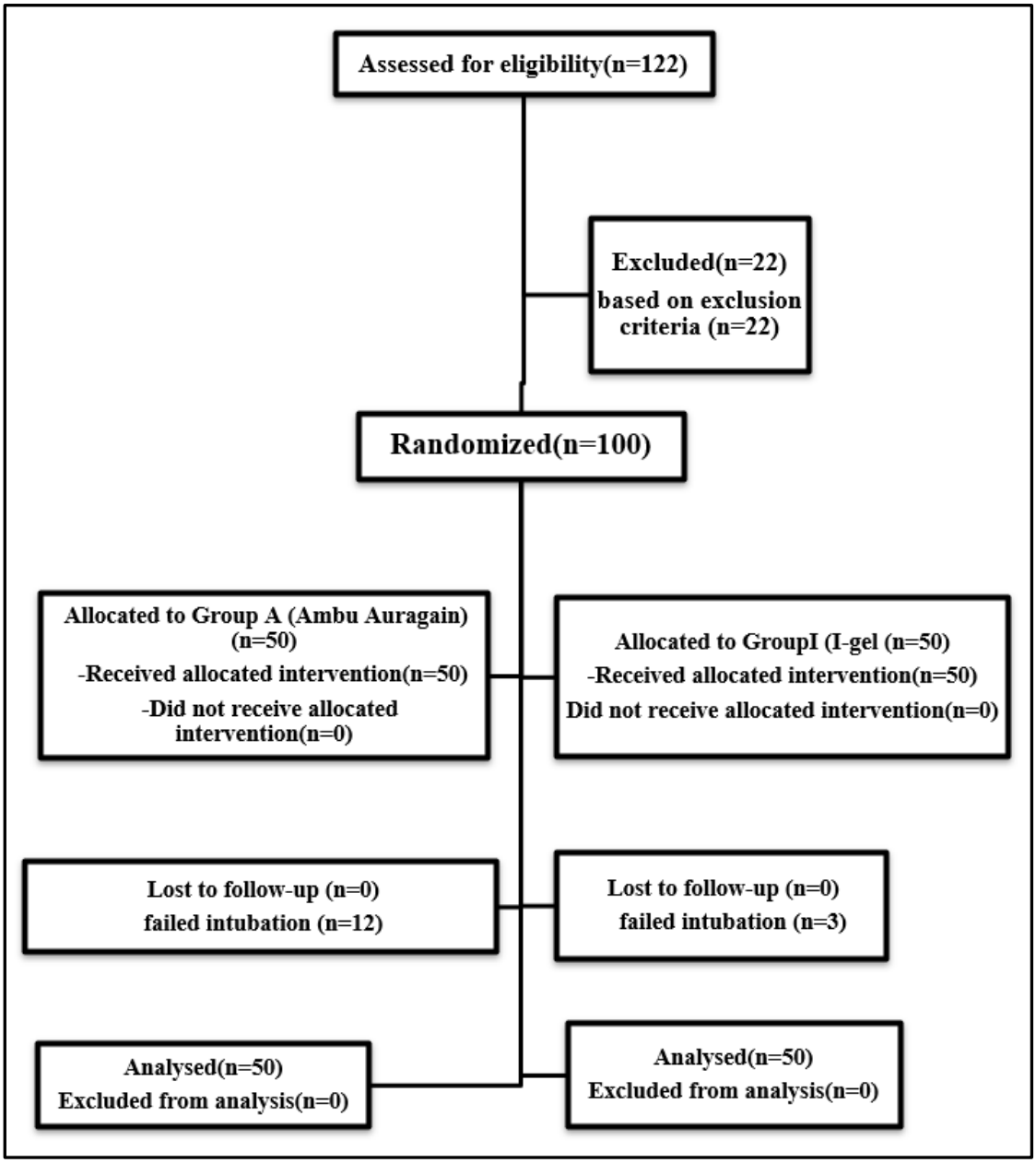

Figure 1: CONSORT flow diagram

Table 1: *SAD and †ETT size used in the study based on weight of patients

	Ambu Aura gain			I gel		
Body weight (kg)	**30-50**	**50-70**	**>70**	**30-50**	**50-70**	**>70**
SAD size used	3	4	5	3	4	5
ETT size used	6	7	7.5	6	7	7.5

*SAD- Supraglottic Airway device, †ETT- Endotracheal tube

Table 2: Demographic data, ASA status, and malampatti grade

Demographic data	Group A (n=50)	Group I (n=50)	P value
Age(years) mean± SD	41.44 ± 11.49	42.88 ± 10.78	0.570
***Gender (M:F)**	(16/34)	(15/35)	0.829
Height(cm) mean± SD	163.94±6.06	163.44±5.31	0.662
Weight(kg) mean± SD	67.56±8.27	66.649.41	0.605
***ASA status (I/II)**	(24/26)	(23/27)	0.841
***MP grade(I/II/III)**	(22/22/6)	(23/22/5)	0.945

*values are absolute values.

Table 3: Intubation success rate through SAD in both groups

	Group A		Group I		P value
	n	**%**	**n**	**%**	
Blind Intubation through SAD	20	40.0*	37	74.0*	0.002
Fiberoptic Guided intubation through SAD	18	60†	10	76.9‡	0.284
Overall intubation success	38	76	47	94	0.011

*n=50 taken as denominator

†18/30. 30 is the unsuccessful blind intubation patients

‡10/13. 13 is the unsuccessful blind intubation patients

Table 4: Time taken for SAD placement and intubation in both groups

Time (in seconds)	Group A	Group I	p value
	Mean±SD	**Mean±SD**	
Time taken for SAD placement	21.34±1.65	17.58±1.31	<0.001*
Time taken for intubation through SAD	32.44±2.30	21.28±2.57	<0.001*
Total intubation time	53.78±2.64	38.86±2.95	<0.001*

*P<0.05 significant

Table 5: Intraoperative complications and Postoperative interview about the different types of patient discomfort (pain in throat, hoarseness) in both groups

Complications	Group A	Group I	P value
Hypoxia (SpO2< 94%),	0/50	0/50	
Aspiration	0/50	0/50	
Bronchospasm	0/50	0/50	
Trauma (blood stain on SAD/ ETT)	5/50	3/50	0.4609
Hoarseness	5/50	2/50	0.239
Pain in throat	5/50	2/50	0.239

Values are absolute values

The mean time for successful intubation through SAD and total intubation time were compared in both the groups and the difference between the groups was statistically significant. The mean time for intubation time through I-gel was 21.28±2.57 seconds and for Ambu AuraGain was 32.44±2.30 seconds and the total intubation time for Group I and Group A was 38.86±2.95 seconds and 53.78±2.64 seconds respectively ($p<0.001$). Therefore, the total intubation time was significantly less with I-gel as compared to Ambu AuraGain.

Hemodynamic parameters including heart rate, systolic blood pressure, and diastolic blood pressure were comparable in both groups. There was no significant difference between the two groups.

There was no incidence of hypoxia (SpO2< 94%) and bronchospasm in the two groups. In Group A, 5 patients had blood stain on SAD/ ETT and same patients developed hoarseness and throat pain post-operatively which was mild and relieved with gargles. In group I, 3 patients had blood stain on SAD/ ETT and 2 patients developed hoarseness and throat pain post-operatively (Table 5). Symptoms were mild in both the groups and relieved with gargles.

DISCUSSION

The primary endpoint of our study was to compare I-Gel and Ambu AuraGain in terms of number of successful blind intubations. We observed significant difference in the two groups with higher number of successful blind intubations with the I-gel.

Fiberoptic scope was used in unsuccessful blind intubation patients to aid endotracheal intubation. The use of fiberoptic scope for intubation was comparable in both the groups. Results of our study are supported by studies by Sethi S et al[9] Preece G et al[10] and de Llyod et al.[11] In a recent study, Sarma et al[12] observed 40% success rate through I-gel while no patient could be intubated blindly through Ambu AuraGain, where they used ILMA-ETT (endotracheal tube) in all the patients. They chose size 3 SAD for all female patients and size 4 for all male patients as first choice and also used ILMA-ETT (#6.5) in all female patients and ILMA-ETT (#7) in all male patients. In another study by Svendsen CN et al[13], they observed 92% success rate using I- gel and 82% success rate using Ambu AuraGain for flexible bronchoscopic intubation.

Time taken for successful intubation and total intubation time was significantly less in I gel compared to Ambu AuraGain. Somri et al[14] and Choudhary B et al[15] also showed comparable results to our study. Both I gel and Ambu AuraGain were successfully inserted in all the patients. I gel required maximum of two attempts while Ambu AuraGain required third attempt in 4% of the patients. Previous studies by Sudheesh K et al[16] and Moser B et al[17] have also reported similar success rate.

I-gel also has significantly shorter insertion time as compared to Ambu Auragain. Studies by Hur M et al[18] and Dhimar AA et al[19] showed similar results. This is likely due to the less flexible stem of I-gel which makes its insertion easier and avoids the need for cuff inflation.

Concerning airway discomfort postoperatively, symptoms were mild in both the groups and showed no significant difference in both groups, despite more attempts in insertion and intubation (unsuccessful blind) in Ambu AuraGain group. Hemodynamic parameters were comparable in both groups.

I-gel and Ambu AuraGain are reliable conduits for intubation. Our data shows that I-gel due to its less flexible stem and non-inflatable cuff shows significantly lesser time for placement as well as for ETT insertion. The lower success rate of intubation through Ambu AuraGain may be due to non-rigid and not anatomically curved tube causing difficulty in sliding of ETT down the trachea. Secondly, the pilot balloon of ETT gets stuck in the middle of ventilation channel of Ambu AuraGain. We propose that the chances of failure can be reduced by proper lubrication of the ETT and using a lower size ETT.

Our data suggests I gel to be more appropriate to be used as a rescue device, where intubation is required to secure airway in unanticipated difficult airway due to its higher success rate and lesser time required for endotracheal intubation.

This study has four major limitations. Firstly, all patients with anticipated difficult airway were excluded from the study. Secondly, efficacy of these devices was tested by experienced users and our results might not necessarily apply to less experienced personnel. Thirdly, the data was collected in an unblinded manner which might be a possible source of bias. And lastly, we compared the two devices for blind intubation also, while recommendations are for using FOB (fiberoptic bronchoscopy) guidance when intubating using SAD. Future studies involving larger sample size and including anticipated difficult airway patients may help in assessing the helpfulness of Ambu AuraGain and I Gel in emergency situations as well.

CONCLUSION

In conclusion, the results of our study suggest that both I-gel and Ambu AuraGain are reliable devices for airway management and adequate ventilation. However, I-gel is a better conduit for endotracheal intubation than Ambu AuraGain with a higher success rate and less time required for endotracheal intubation.

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