INTRODUCTION

Providing a safe airway is the prime responsibility of an anaesthesiologist. Supraglottic airway devices are commonly used airway adjuncts during anaesthesia or resuscitation and have become an integral part of difficult airway algorithm. In current scenario they are not only used as a ventilating device but also act as conduit for planned blind as well as fiberoptic guided intubation in anticipated or unanticipated difficult laryngoscopies.

Almost all SADs have been tried for endotracheal intubation, but very few stood the test of time with excellent outcomes. Classic and unique LMA fail to serve as conduit for intubation owing to narrow lumen and long length of their airway tube which does not accommodate an adult size endotracheal tube. The intubating LMA (ILMA) is being widely used as conduit for blind as well as fiberoptic guided ETI. It comes with a specially designed armoured endotracheal tube with silicon tip which facilitates its insertion but at the same time adds on to the cost. I-Gel (manufactured by Intersurgical) is another promising SAD which has gained popularity over last decade because of its anatomical shape and gel filled cuff. The airway channel of I-Gel is shorter and broader compared to that of the other SADs, allowing the adult size endotracheal tube to be inserted without any difficulty.

ABSTRACT

Background and Aims: I-Gel, a novel SAD has been introduced as a ventilating device but has widely gained popularity as conduit for intubation. Unlike intubating laryngeal mask airway (ILMA), I-Gel does not have an endotracheal tube specially designed for it. Hence the aim of this study was to compare the rate of successful intubation via I-Gel using three different types of endotracheal tubes. Methods: We randomised 75 American Society of Anesthesiologists (ASA) physical status I and II patients, between the age group 18-60 years of either sex undergoing elective surgery under general anaesthesia into three groups on the basis of endotracheal tube (ETT), used for intubation via I-Gel: Group P (Polyvinyl chloride ETT), Group I (Intubating laryngeal mask airway ETT), Group F (flexometallic ETT). After following the standard induction protocol, appropriate size I Gel was inserted in all patients. Thereafter group specific ETT was inserted via I-Gel. We recorded and compared the time taken for successful intubation, the success rate, number of attempts taken, manoeuvres used, and complications among three different types of ETT. Quantitative variables were compared using Kruskal Wallis test and the qualitative variables were compared using Chi-square test. Results: The time taken for successful intubation was least in group P (10.51 ± 3.82 seconds). Group P also had the highest first attempt (68%) and overall rate of successful intubation (88%). Conclusion: PVC ETT had highest first attempt success rate and required minimum time for endotracheal intubation via I-Gel when compared to ILMA ETT and Flexible ETT.

Key words: Endotracheal tubes, I-Gel, intubation
tube to easily pass through it. Unlike ILMA, I-Gel® neither comes with a designated endotracheal tube nor does the manufacturer provides any information regarding the type of endotracheal tube most suitable while using the device as a conduit for intubation. Previous studies have compared the success rate of intubation via I-Gel® and other SADs using either polyvinyl chloride endotracheal tubes (PVC ETT) or ILMA ETT. To the best of our knowledge we could not find any published study comparing the success rate of ETI comparing different endotracheal tubes using I-Gel® as conduit for intubation.

Hence, we proposed to conduct a study to evaluate the success rate of ETI with three different types of endotracheal tubes using I-Gel® as conduit for intubation to ascertain which type of ETT has the highest success rate.

METHODS

This was a randomised comparative study conducted in a tertiary care hospital after prior approval from the institutional ethics committee. Written and informed consent was obtained from all the patients after explaining about the objective of the study, the technique and its related complications.

Seventy-five ASA I and II patients between 18-60 years of age of either sex with modified Mallampati grade I and II, mouth opening of more than 3 cm with BMI ≤30 Kg/m² posted for elective surgery under general anaesthesia were included in this study.

Patients with anticipated difficult ventilation and intubation, contraindication to the use of muscle relaxants, increased risk of aspiration and those who refused to participate in the study were excluded from the study.

Based on computer generated randomisation table, all patients were randomly allocated into three groups namely, group P (PVC ETT was used), group F (flexometallic ETT was used), group I (ILMA ETT was used). Subsequently, the number slips were placed in opaque envelopes and sealed. The final group allocation was performed just before the procedure by opening the opaque sealed envelope by the staff nurse present.

All patients underwent a thorough preoperative examination and were kept NPO as per standard ASA guidelines. All patients were premedicated with oral alprazolam 0.25 mg on the night before and on the day of surgery. On the day of surgery the patients were shifted inside the operation theatre and standard ASA monitors were attached (Noninvasive blood pressure, oxygen saturation and electrocardiogram). Baseline vital parameters were recorded. An 18 G venous cannula was secured over non dominant hand and Ringer lactate/normal saline solution was started. Inj. midazolam 0.04 mg/kg and Inj. fentanyl 2 mcg/kg intravenously was given to all patients as preanaesthetic medication. Anaesthesia was induced with titrated doses of propofol intravenously till loss of verbal response was attained. After check ventilation, muscle relaxation was achieved with vecuronium 0.1 mg/kg intravenously. In concordance to patient’s weight, adequate size I-Gel® was inserted. Correct placement was ensured with adequate chest rise and appearance of square shaped capnograph.

Thereafter, an adult fiberoptic bronchoscope was used to grade the glottic view through the I-Gel® using Brimacombe score [10] (grade 1- vocal cords not visible; grade 2- anterior surface of epiglottis visible with part of vocal cords visible; grade 3- posterior surface of epiglottis with vocal cords; grade 4- only vocal cords visible). In cases where the Brimacombe score was 1 and 2, the I-Gel® was removed, reinserted and repeat Brimacombe scoring was done. If the score persisted to be 1 or 2, the patient was excluded from the study. The patients which had Brimacombe score of 3 or 4, the fiberoptic bronchoscope was withdrawn from the lumen of I-Gel®. Thereafter the group specific ETT of appropriate size (I-Gel® size 3 - ETT 7 mm; I-Gel® size 4 - ETT 7.5 mm) was properly lubricated with water based jelly and was passed through the airway tube of I-Gel® blindly. A total of three attempts were taken to intubate the patient. During the first attempt no manoeuvre was done, in the second attempt lateral displacement of larynx was done externally while trying to intubate, and in the last attempt ETI size was stepped down by one size to aid in intubation. The lateral displacement of the larynx was a blind technique wherein first a gentle rightward displacement of larynx was attempted while trying to intubate through the I-Gel® which if failed a gentle leftward displacement of larynx was attempted while trying to intubate via I-Gel®. Gentle displacement of larynx was done to avoid any untoward displacement of I-Gel® while trying to intubate through it. Only one attempt was taken applying each respective manoeuvre. The number of attempts required for

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successful intubation was noted and the effect of manoeuvres on the success of intubation was also recorded. While trying to intubate through the I-Gel®, if there was resistance encountered during the passage of tube or there was oesophageal intubation; the endotracheal tube was withdrawn from the I-Gel® and the patient was ventilated through the I-Gel® for at least one minute before further attempt was made. After successful intubation via I-Gel®, the I-Gel® was removed over the endotracheal tube. The position of the endotracheal tube was reconfirmed and the tube was fixed. Oxygen saturation (SpO₂), heart rate and mean arterial pressure were continuously monitored throughout the study period. Any haemodynamic fluctuations were managed as per standard ASA guidelines. At any point of time if SpO₂ <94%, patient was oxygenated till it reaches to 100% which was fixed as one minute of mask ventilation before second attempt is taken. Total time taken for intubation was recorded in all the patients. The procedure was performed by a single operator who was routinely performing endotracheal intubation and SAD placement in patients. The operator had no previous experience of using I-Gel® as intubation conduit. The operator was required to gain experience of at least 20 successful intubation via I-Gel® with each type of ETT before enrolment of the study subjects. Subsequently, anaesthesia was maintained according to the standard technique. Complication like blood on the I-Gel®, ETT, sore throat, dental injury were observed and compared. The patient was observed for next 24 hours by staff nurse at PACU and was informed at timed intervals.

During this study the parameters evaluated and recorded were a) Time taken for intubation- It was time taken from the point of introducing the group specific ETT in airway tube of I-Gel® till the first appearance of square waveform on capnograph (ventilation time in between the attempts were excluded); b) First attempt rate of successful intubation; c) Overall rate of successful intubation; d) Total number of attempts taken and the manoeuvres required; e) Cause for failed intubation (oesophageal intubation, resistance during intubation) and f) Any complication- trauma, sore throat, dental injury etc.

As we could not find any previous study comparing intubation using three different types of endotracheal tubes with I-Gel® as a conduit we decided to conduct a pilot study. Following a benchmark study published by Julious SA et al.,[11] we conducted a pilot study taking 12 patients in each group where we performed intubation through I-Gel® using PVC, ILMA and flexometallic ETT. We analysed the data obtained from the pilot study using Statistical Package for Social Science (SPSS 20.0 evaluation version) software. The success rates for intubation were 92%, 86% and 88% in respective groups. Considering the success rate of intubation from the pilot study, the effect size was calculated to be 0.42. For execution of 90% power of study and 95% confidence interval using the effect size we calculated the final sample size with G power statistical analysis software (version 3.1.a) using proportions obtained from the pilot study. Finally the sample size came out to be 75 (25 in each group) with mentioned effect size. The data obtained was tabulated and analysed using Statistical Package for Social Science (SPSS 20.0 evaluation version). Data set was analysed with Shapiro-Wilk test for assessment of normality. The data set was found to have non-normal distribution. Quantitative variables like age, height, weight, time taken for intubation were compared using Kruskal Wallis test. Qualitative variables like sex, ASA grading, MMP grading, Brimacombe score, number of attempts, rate of successful intubation, cause of intubation failure and complication rate were compared using Chi-square test.

**RESULTS**

The flow of the patients enrolled in the study is represented in the CONSORT-flow diagram [Figure 1]. The three groups were comparable with respect to demographic profile [Table 1].

In all the patients enrolled in this study, I-Gel® of sizes 3 and 4 were used and the data was comparable in the three groups. The Brimacombe score of 3 and 4 were comparable in the three groups. Total of 3 patients had Brimacombe score 1 or 2, which on second attempt improved to 3 or 4.

The first attempt success rate and overall success rate of intubation were highest in group P (68%; 88%)

| Parameter | Group P (n) | Group I (n) | Group F (n) | P       |
|-----------|-------------|-------------|-------------|---------|
| Age (years) | 31±9±6.13 | 31±4±14.07 | 32±4±5.64 | 0.654   |
| Sex (M/F)  | 21/4        | 20/5        | 22/3        | 0.177   |
| Weight (kgs) | 60.7±5.3 | 58±4.22     | 59.6±5.1   | 0.194   |
| Height (cm) | 159.4±4.15 | 157.2±4.52 | 158.6±4.24 | 0.177   |
| ASA grade (I/II) | 22/3   | 21/4        | 19/6        | 0.101   |
| MMP (I/II) | 21/4        | 20/5        | 22/3        | 0.177   |

n – Number of patients, MMP – Modified Mallampati, M – Male, F – Female
[Table 2]. The mean (SD) time to intubation was least with group P (10.51 ± 3.82 seconds) and greatest with group I (13.25 ± 5.83 seconds) [Table 2]. There were no oesophageal intubation in group P unlike group I and F [Table 2]. The airway trauma in the form of blood over the device was minimal and was comparable in the three groups [Table 2]. No significant haemodynamic fluctuations or any episode of desaturation was observed in any of the study group.

**DISCUSSION**

Although direct laryngoscopy followed by endotracheal intubation has been the gold standard for securing the definitive airway since ages but cases of anticipated difficult airways are on the rise worldwide. In such cases fiberoptic bronchoscopy (FOB) or video laryngoscope guided intubations have been studied by various clinicians and investigators but their availability and cost remains the key concern.

The SADs are now routinely used in the operation theatre for administering general anaesthesia to patients. In past two decades manufacturers have come up with many newer SADs with slight innovation or modification. I-Gel® was introduced as a ventilating device and subsequently became one of the few SADs which can be used as a conduit for intubation.

There is published literature in both mannequin as well as humans where I-Gel® has been used as a conduit for endotracheal intubation.[12,13] The shape of the cuff mirrors the laryngeal anatomy, thus provides a better apposition to glottis structures and increases the success rate of endotracheal intubation when compared to other SADs. The large airway diameter of

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**Table 2: Parameters evaluated**

| Variables                        | Group P (n) | Group I (n) | Group F (n) | P    |
|----------------------------------|-------------|-------------|-------------|------|
| 1st attempt success rate, %     | 68 (17)     | 48 (12)     | 52 (13)     | 0.041|
| Maneuvers used                   | Lateral displacement of larynx | 12 (3)     | 16 (4)     | 12 (3) | 0.897|
|                                  | Downsizing of ETT         | 8 (2)      | 8 (2)      | 12 (3) | 0.913|
| Overall success rate, %         | 88 (22)     | 72 (18)     | 76 (19)     | 0.037|
| Time taken for intubation, sec (mean±SD) | 10.51±3.82 | 13.25±5.83 | 12.79±4.91 | 0.173|
| Cause of failed intubation       | Resistance     | 3           | 2           | 2     | 0.913|
|                                  | Oesophageal intubation   | 0           | 5           | 4     | <0.001|
| Complications                    | 2            | 1           | 1           | 0.917|

n – Number of patients, SD – Standard deviation, sec – seconds, % – percentage
its airway tube facilitates the easy introduction of the endotracheal tube (ETT) through it.[12]

Unlike ILMA which is another SAD widely used for tracheal intubations, we don’t have any designated ETT for intubations through I-Gel®. Most of the investigators have used PVC ETT for intubations through the I-Gel®. This thought stimulated us to conduct this study where we compared the rate of successful endotracheal intubation via I-Gel® using three different types of ETTs routinely available in our hospital set up. We used PVC, ILMA ETT and flexometallic ETT for intubation via I-Gel®.

In this study, we found that overall success rate was highest with PVC ETT (88%) when compared to other two types of ETT. The first attempt success rate was also found to be highest with PVC ETT. A previous study found overall success rate of 77.5% and first attempt success rate of 65% with I-Gel® using PVC ETT.[14] The authors also assessed Brimacombe scoring in their patients but their methodology did not exclude the patient with score 1 and 2. Halgawi et al. found first attempt success rate of 69% and overall success rate of 73% during blind intubation using PVC ETT via I-Gel®.[14] Another group of investigators found a success rate of 15% with I-Gel® using Magill’s PVC ETT; such low success rate may be attributed to the fact that their study population consisted of patients with at least one predictor of difficult airway.[15] Contrary results were observed in a different study with 100% success rate with PVC ETT using I-Gel® as a conduit in patients with at least one predictor of difficult laryngoscopy.[16] This improved success rate may be attributed to the fact that they used FOB for guiding the ETT through the airway channel of I-Gel®. The first attempt success rate of 66% and overall success rate of 82% using PVC ETT was observed in one study but the authors did not grade the laryngeal view using a fibroptic bronchoscope hence there is a possibility of improper placement of I-Gel® with limited glottic opening as one of the possible reason for failed intubations.[17] Fiberoptic bronchoscope may not be available at some of the setups where anaesthesiologist has to rely on clinical parameter (adequate chest rise, square shaped capnograph, correct placement of nasogastric tube) for the successful placement of the I-Gel®.

Three different tubes (silicone wire-reinforced tube, parker tube and PVC ETT) were compared in a previous study for intubation through ILMA and the highest success rate was found with silicone wire-reinforced tube and least with PVC ETT.[18] The difference in the success rate could be because the ILMA has an inbuilt v-shaped guiding ramp in the laryngeal bowl which guides the tube towards the laryngeal inlet which in case of PVC ETT might have exaggerated the exit angle and the tube could have hit the anterior commissure resulting in increased failure rate.

In our study to increase the success rate of intubation we also inculcated some maneuvers like lateral displacement of larynx and downsizing the ETT. These manoeuvres did improve the rate of successful intubation but we did not find any maneuver more favourable for a particular type of ETT. In some previous studies, clockwise and counter clockwise manipulation of the PVC ETT[14,18] was performed with the rationale that it would help in negotiating the bevel in case it is hitting the anterior commissure. We don’t recommend such practices while doing blind intubations as they may lead to trauma to airway structures. Kapoor et al. in their study also mentioned about reverse insertion of ETT.[17] But we found that it was difficult to rotate the tube once it has already crossed the entire length of I-Gel®. Also we were not sure whether the rotation of the shaft of the ETT would result in movement at distal tip of the ETT or not. Prewarming of PVC ETT could also improve the success rate of intubation.[19]

In our study, the time taken for intubation was least with PVC ETT and maximum with ILMA ETT. In case of PVC ETT, its inbuilt curvature provided little resistance while passing it through I-Gel® but a thorough lubrication had successfully overcome it. Our observations say that once the tube exited from the I-Gel®, this inbuilt curvature of PVC ETT had rather helped in negotiating the ETT through the vocal cords. The ILMA ETT is straight and the cuff merges with the wall thereby producing minimum friction while passing through the I-Gel®. However while exiting the I-Gel®, the floppy body of the tube, lack of intrinsic curvature and the round blunt tip made it difficult to pass the tube through the vocal cords. In Figures 2-4 we can very well observe the angle at which the three tubes exit from the mask of I-Gel®. The inbuilt radius of curvature of PVC ETT helps in directing the tube towards the laryngeal inlet while the other two tubes tend to sag down after exiting the I-Gel®.

In our study, there was no oesophageal intubation with PVC ETT whereas with other two tubes, there
was significant incidence of oesophageal intubation \((P < 0.001)\). The only complication we observed was trauma to the airway which was seen more with PVC ETT compared to others but it was neither statistically nor clinically significant. None of the patient complained of postoperative sore throat.

However, our study population consisted of patients with normal airway therefore the findings of our study may not be extrapolated to patients with anticipated difficult airway.

**CONCLUSION**

Polyvinyl chloride endotracheal tube provides the highest first attempt success rate and the overall rate of successful intubation via I-Gel®. Also the mean time taken for intubation is least with PVC ETT. Manoeuvres like lateral displacement of larynx and reducing the size of ETT may improve the rate of successful intubation. Further studies are required to apply these results in patients with anticipated difficult airway.

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**Conflicts of interest**

There are no conflicts of interest.

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