Ambu AuraGain versus intubating laryngeal tube suction as a conduit for endotracheal intubation

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Abstract

Background and Aims: Newly developed supraglottic airway devices (SGAs) are designed to be used both for ventilation and as conduits for endotracheal intubation with standard endotracheal tubes (ETTs). We compared the efficacy of the Ambu AuraGain (AAG) and the newly developed intubating laryngeal tube suction disposable (ILTS-D) as conduits for blind and fiber-optically guided endotracheal intubation in an airway mannequin.
Material and Methods: This is a prospective, randomized, crossover study in an airway mannequin, with two arms: blind ETT insertion by medical students and fiber-optically guided ETT insertion by anesthesiologists. The primary outcome variable was the time to achieve an effective airway through an ETT using AAG and ILTS-D as conduits. Secondary outcome variables were the time to achieve effective supraglottic ventilation and successful exchange with an ETT, and the success rates for blind endotracheal intubation and fiber-optically guided intubation techniques for both SGAs.
Results: Forty participants were recruited to each group. All participants were able to insert both devices successfully on the first attempt. For *blind intubation*, the success rate for establishing a definitive airway with an ETT using the SGA as a conduit was significantly higher with ILTS-D (82.5%) compared with AAG (20.0%) ($P < 0.001$). None of the participants were able to successfully complete the exchange of the SGA for the ETT with the AAG. In the *fiber optic guided intubation group*, the rate of successful exchange was significantly higher with ILTS-D (84.6%) compared with AAG (61.5%) ($P = 0.041$).
Conclusion: The ILTS-D successfully performs in an airway mannequin with higher success rate and shorter time for blindly establishing an airway with an ETT using the SGA as a conduit, compared with AAG. Further clinical trials are warranted.

Keywords: Intubation conduit, laryngeal mask, laryngeal tube, supraglottic airway

Introduction

Supraglottic airway devices (SGAs) are used increasingly in patients with difficult airways, or as bridging devices before a definite airway can be established. With recent developments, SGAs now have the capability of being used as conduits for endotracheal intubation with standard endotracheal tubes (ETTs). The Ambu AuraGain (AAG) disposable laryngeal mask is an SGA with an anatomical curve and wide ventilator lumen, allowing the passage of up to size 8-mm ETT.[1] It has been successfully used as a conduit for fiber-optically guided endotracheal intubation both in mannequins and in clinical settings.[1-3] The intubating laryngeal tube suction disposable (ILTS-D) is a new SGA that allows ventilation and endotracheal intubation also up to size 8-mm ETT. In a recent study, the ILTS-D was found to have a high success rate in a clinical setting for both blind endotracheal intubation and fiber-optically guided intubation.[4] Both SGAs have an integrated gastric

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access channel. Although the manufacturers for both devices recommend the use of a flexible bronchoscope for intubation, there is not a specific recommendation made regarding the use of these SGAs as a conduit for blind endotracheal intubation.

The primary aim of our study is to compare the efficacy of AAG and ILTS-D as conduits for endotracheal intubation in a simulation setting. We investigated both the blind insertion and fiber-optically guided techniques of an ETT intubation using both devices as conduits. Our hypothesis was that the time to achieve an effective airway with an ETT through an AAG will be faster than with the ILTS-D. The primary outcome variable was the time to achieve an effective airway through an ETT using AAG and ILTS-D as conduits. The secondary outcome variables were the time to achieve effective supraglottic ventilation with the AAG or ILTS-D, time to achieve a successful exchange with an ETT, and the success rates for blind endotracheal intubation and fiber-optically guided intubation techniques for both SGAs.

Material and Methods

The Human Subject Protection Office at our institution waived the need for formal written consent for this mannequin study. This is a prospective, randomized, crossover study with 2 arms: (1) blind ETT insertion by medical students (blind intubation group) and (2) fiber-optically guided ETT insertion by anesthesiologists (fiber-optically guided group). For both arms of the study, the order of inserting the SGAs was randomized using a computer-generated randomization table and timing was done with a stopwatch.

The study was performed on a Laerdal Airway Management Trainer (Laerdal Medical, Wappinger Falls, NY) [Figure 1a]. The devices used by all subjects were a size 5 AAG (Ambu, Ballerup, Denmark) [Figure 1b], a size 5 ILTS-D (VBM Medizintechnik GmbH, Sulz am Neckar, Germany) [Figure 1c], and a reinforced 7.5-mm ETT (VBM Medizintechnik GmbH) [Figure 1c].

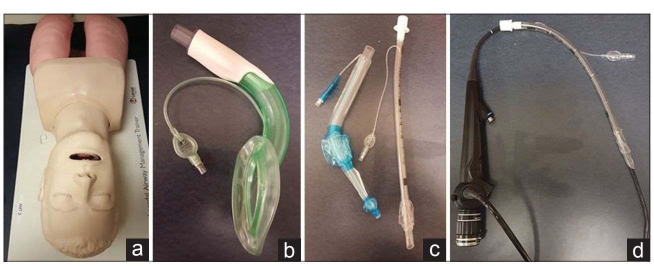

Figure 1: (a) Laerdal airway management trainer; (b) Ambu AuraGain, size 5; (c) intubating laryngeal tube suction disposable, size 5; and (d) fiber-optic bronchoscope preloaded with a 7.5-mm endotracheal tube

Study participants (medical students for the blind intubation group and anesthesiologists for the fiber-optically guided group) were allowed to familiarize themselves with the AAG and ILTS-D, with no time limit but without practicing the technique, before starting the study. The steps were verbally explained by one of the investigators. The devices were inserted per manufacturer's recommendations, the cuffs inflated and proper position confirmed by mannequin lung expansion.

The time to achieve effective supraglottic ventilation with the AAG or ILTS-D was defined as the time (in seconds) from picking up the device until adequate ventilation was confirmed by expansion of the mannequin's lungs using a self-inflating bag. A maximum of three attempts to successfully insert the SGAs were allowed.

The time to achieve an effective airway with an ETT using the SGA as a conduit was defined as the time from picking up the ETT or the fiber-optic bronchoscope to successful intubation, as confirmed by expansion of the mannequin's lungs for the blind intubation and the fiber-optically guided groups respectively.

Blind intubation group

For this part of the study we recruited 40 medical students with no previous experience with the AAG or the ILTS-D. After confirming effective placement of the SGA, participants blindly inserted the reinforced ETT through the ventilation channel of the device. After placement in the trachea, the ETT cuff was inflated and ventilation was confirmed by expansion of the mannequin's lungs using a self-inflating bag. The maximum time allowed for successful intubation by blind intubation was 180 seconds.

Fiber-optically guided intubation

A fiber-optic bronchoscope (Olympus Corporation of the Americas, PA) preloaded with a 7.5-mm ETT [Figure 1d] was used as a guide for the placement of an ETT. Following confirmation of effective placement of the SGA, a flexible bronchoscope loaded with an ETT was inserted into the trachea through the ventilation channel of the device. The ETT was railroaded into the trachea and the cuff of the ETT was then inflated. Ventilation was confirmed by expansion of the mannequin's lungs using a self-inflating bag. The maximum time allowed for successful intubation by fiber-optically guided intubation was 180 seconds.

Successful removal of the supraglottic airway

Finally, in both arms of the study, medical students and anesthesiologists were asked to deflate the SGA cuff and remove the SGA while leaving the ETT in the trachea.

Correct position of the ETT was confirmed by ventilation though the ETT via self-inflating bag with expansion of the mannequin's lungs.

In both groups a gastric drain tube was inserted.

Statistical analysis

A difference in time to intubation, as confirmed by effective ventilation of 10 seconds or greater, was considered significant.[5] Based on a previously reported standard deviation of 11 seconds[3] along with a significant *P* value and power of 80%, it was decided that 40 participants would be an adequate sample size to yield significant results. A *P* value <0.05 was considered statistically significant. Normality was tested using the Shapiro–Wilk test. Since it is a randomized crossover study, an analysis of variance (ANOVA) was performed to compare the times of first successful ventilation and intubation time as well as exchange time. Data are presented as mean (standard deviation) for normally distributed data and median (interquartile range) for data that are not normally distributed. A Chi-squared test was used for proportion of successful completion of each step of the trial in both groups. All times were compared using a Kruskal–Wallis one-way ANOVA.

Results

In the fiber-optically guided arm, there were 40 anesthesia providers: 6 attending anesthesiologists (with a mean experience of 13 ± 10 years), 6 certified registered nurse anesthetists, and 28 anesthesia residents (5 in post graduate year (PGY) 1, 6 PGY-2, 8 PGY-3, and 9 PGY-4). All participants had previous experience with the AAG and no experience with the intubating ILTS-D. Incomplete data were obtained for one of the participants in the fiber-optically guided group, and were therefore excluded from the final analysis.

All candidates in both arms of the study were able to insert both devices successfully on their first attempt.

In the *blind intubation* group, the median time to achieve effective supraglottic ventilation with the SGA and time to achieve an effective airway through an ETT using the SGA as conduits were lower with ILTS-D than with the AAG, but this was not statistically significant [Table 1]. None of the participants were able to successfully complete the exchange of the SGA for the ETT with the AAG. The success rate for establishing a definitive airway with an ETT using the SGA as a conduit was significantly higher with ILTS-D (82.5%) compared with AAG (20.0%) ($P < 0.001$). Success rates of blind intubation for the three steps are presented in Table 2.

In the *fiber-optically guided* group, the median time to achieve effective supraglottic ventilation with the SGA was lower with the AAG than with the ILTS-D. The median time to achieve an effective airway through an ETT using SGA as a conduit, and time to achieve a successful exchange were lower with the ILTS-D than with the AAG. However, time differences were not statistically significant [Table 3]. The success rate for establishing a definitive airway with an ETT using the SGA as a conduit was higher with ILTS-D (84.6 + 33%) compared with the AAG (71.8 + 28%), but was not statistically significant ($P = 0.273$). The rate of successful exchange was significantly higher with ILTS-D (84.6%) compared with AAG (61.5%) ($P = 0.041$). Success rates of blind intubation for the three steps are presented in Table 4.

Discussion

SGAs designed as conduits for endotracheal intubation add significant safety features to the difficult airway management. The intubating laryngeal mask airway, the most frequently studied SGA designed to serve as a conduit to endotracheal intubation, proved to be successfully used by inexperienced medical personnel.[6-8] The recent addition of AAG and i-LTS-D broaden the armamentarium of airway equipment for difficult airway.[1-4,9]

In our study, all participants were able to successfully establish a primary airway with both SGA devices. However, there was a greater rate of success using the ILTS-D as a conduit in both blind and fiber-optic guided intubation techniques. This was statistically significant in the case of the blind intubation arm, but not on the fiber-optically guided limb of the study. In both the blind intubation arm as well as the fiber-optically guided arm of our study, participants were able to establish an effective airway through an ETT, faster with

Table 1: Times for blind intubation (s)

	Median time (IQR)		*P*
	AAG	ILTS-D	
Time to achieve effective supraglottic ventilation	25.2 (19.3-30.2)	22.3 (19.9-27.1)	0.447
Time to achieve an effective airway through an ETT	92.1 (52.9-142.8)	65.5 (55.5-78.9)	0.167
Time to achieve a successful exchange	N/A	127.8 (105.6-145.04)	N/A

AAG=Ambu AuraGain, ILTS-D=Intubating laryngeal tube suction disposable, ETT=Endotracheal tube, IQR=Interquartile range, N/A=Not available

Table 2: Success rates of blind intubation

	AAG (*n*=40), *n* (%)	ILTS-D (*n*=40), *n* (%)	*P*
Step 1: Primary airway using SGA	40 (100)	40 (100)	NA
Step 2: Blind intubation through SGA	8 (20)	33 (82.5)	<0.001*
Step 3: Removal of SGA for exchange	0	31 (77.5)	<0.001*

**Denotes a significant value. AAG=Ambu AuraGain, ILTS-D=Intubating laryngeal tube suction disposable, SGA=Supraglottic device, NA=Not applicable*

Table 3: Times for fiber-optically guided intubation (s)

	Median time (IQR)		*P*
	AAG	ILTS-D	
Time to achieve effective supraglottic ventilation	16.8 (12.6-20)	17.3 (14.4-22.4)	0.199
Time to achieve an effective airway through an ETT	102.8 (68.3-127.9)	76.2 (56.6-111.1)	0.116
Time to achieve a successful exchange	46.9 (11.8)	45.4 (13.12)	0.648

AAG=Ambu AuraGain, ILTS-D=Intubating laryngeal tube suction disposable, ETT=Endotracheal tube, IQR=Interquartile range

Table 4: Success rates of fiber-optically guided intubation

	AAG (*n*=39)	ILTS-D (*n*=39)	*P*
Step 1: Primary airway using SGA	39 (100)	39 (100)	NA
Step 2: Blind intubation through SGA	28 (71.8)	33 (84.6)	0.273
Step 3: Removal of SGA after exchange	24 (61.5)	33 (84.6)	0.041*
Insertion of gastric drain tube	39 (100)	39 (100)	1.00

**Denotes a significant value. AAG=Ambu AuraGain, ILTS-D=Intubating laryngeal tube suction disposable, SGA=Supraglottic device, NA=Not applicable*

the ILTS-D than with the AAG. However, the difference was not statistically significant. Although not statistically significant, this difference may be clinically significant in terms of rapidly improving oxygenation.

The manufacturers' brochures for each device only mention the use of fiber-optically guided intubation for both the AAG as well as the ILTS-D.[10,11] However, the ability to insert an ETT blindly into the trachea through an SGA is especially important in the prehospital area, with poor or no access to fiber-optic guided intubation. Our results indicate that further study of ILTS-D as a conduit for blind intubation would be worthwhile as it could prove to be an effective tool for airway management for inexperienced practitioners.

Our analysis showed that participants in both arms of the study had similar success with both devices in relation to the secondary outcome variables. There was no significant difference in the rate of success or time required to establish a primary airway using the SGAs. However, comparisons of the exchange of the SGA for an ETT merit discussion in both cases. In the case of blind intubation, there was no available comparison as none of the participants were able to exchange the AAG. In the case of fiber-optic guided intubation, participants were more successful completing the exchange using the ILTS-D. This was found to be statistically significant. This would suggest that in both blind and fiber-optically guided use of these SGAs, the ILTS-D would be a better choice to complete an exchange for an ETT.

One of the observed differences between the AAG and the ILTS-D during the fiber-optically guided and blind intubations was that the AAG is not designed with a rigid, anatomically curved tube. This is a factor that may have contributed to the difficulty of sliding the ETT down the trachea and over the flexible section of the bronchoscope after visualizing and passing the tip through the glottis. In a recently published study by de Lloyd *et al.*,[2] participants reported significant resistance to sliding the ETT down the trachea. On the other hand, the ILTS-D provided a slightly more rigid, curved structure that allowed better advancement of the ETT. Despite the fact that this mechanical difficulty was not reflected in the fiber-optically guided arm of the study, perhaps this may have implications in clinical settings and warrants further clinical studies.

In contrast, participants using the ILTS-D in the fiber-optically guided limb of the study experienced visualization difficulties when attempting to pass the tip of the fiber-optic bronchoscope through the glottis. This was a potential key factor for participants who ran out of time and possible cause for the lack of a significant difference between the ILTS-D and AAG in the fiber-optically guided arm of the study. In summary, failures to intubate through the AAG were associated with difficulty in sliding the ETT, while failures to intubate using the ILTS-D were associated with poor visualization of the glottis.

Our study has some limitations. Our study was performed in mannequins, and it is not applicable to clinical situations where the insertion of SGAs may be more difficult, and upper airway edema and bleeding may significantly impair the fiber-optic view. However, it is recognized that mannequin studies can serve as a safe method of evaluation before proceeding to researching airway devices with patients.[12]

Conclusion

We conclude that the ILTS-D performed better than the AAG as a conduit for endotracheal intubation, both with blind and fiber-optic guided intubation in mannequins.

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Conflicts of interest

There are no conflicts of interest.

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