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Evaluation of the new supraglottic airway S.A.L.T to aid blind orotracheal intubation: A pilot study

Vijay G Anand, Girinivasan, Leelakrishna, and Thavamani

Abstract

Background and Objective:

Supraglottic Airway Laryngopharyngeal Tube (S.A.L.T) is a new airway gadget conceived as an effective device to facilitate blind oro-tracheal intubation. Literature review showed no available clinical study on human subjects. The aim of our study was to evaluate S.A.L.T as an adjunct to blind oro-tracheal intubation.

Methods:

Study design: Single centre, Single group, Open label, Prospective, Interventional pilot study. Study Group: 30 adult patients of either sex belonging to ASA I and II, scheduled for elective surgery under General anaesthesia. Patients were pre-medicated with inj. Glycopyrrolate 0.2 mg and inj. Midazolam 2 mg and induced with Inj. Propofol 2 mg/kg IV. After inj. Suxamethonium 1.5 mg/kg IV, S.A.L.T was inserted and a size 7.0 ID cuffed ETT was inserted through it immediately. The time period, from insertion of the S.A.L.T to the insertion of the ETT was noted. A successful intubation was defined as to insert SALT and intubate through it within 2 minutes irrespective of the number of attempts. Airway trauma, if any was recorded.

Results:

Only 40% of the patients were successfully intubated [(20.4% to 59.6% with 95% confidence interval (CI)]. The mean number of attempts required for intubation was 1.4 ± 0.67 (CI - 0.99 to 1.8) and the mean time for intubation was 26.3 ± 19.0 seconds (CI - 14.3 to 38.4 sec). Mallampati class I had more success rate than class III ($P < 0.05$). No airway trauma was recorded.

Conclusion:

S.A.L.T shows limited usefulness as an adjunct for aided blind oro-tracheal intubation.

Keywords: Airway management, emergencies, intubation, laryngoscopy

BACKGROUND

Supraglottic airway devices have been developed since 1908, to secure the airway and/or allow blind endotracheal intubation (ETI). Many devices have been developed, tested, and used for this purpose, but only a few have stood the test of time.[1,2] Each device has its own strength/shortcoming. ETI with direct laryngoscopy (DL) needs expertise and all the emergency service providers/paramedics may not have adequate training to secure the airway with laryngoscopy. However, the increasing need for emergency intubation, employment of paramedics in emergencies,[3,4] difficulty in mastering the technique of ETI using DL,[5,6] urge for a safe, simple and easy alternative for airway management. New gadgets are evolving round the year, each fitting the variable anatomy of human laryngeal complex in a better way.[7]

Supraglottic airway laryngopharyngeal tube (S.A.L.T), bioengineered by Medical Devices International and marketed by Ecolabs is one such new airway gadget. It was invented by Pat Miller and Michael Hall, both paramedics based in Atlanta. It is registered with Food and Drug Administration as class I medical device. The device comes in a prepackaged kit that includes a tongue blade and a harness [Figure 1]. The airway is a hollow tube-like device with a sleek curved design fitting the airway anatomy, midline indicator, a proximal collar with secure points, and a distal epiglottic rest. *In situ*, the blunt end occludes the esophagus and seats against the corniculate cartilages, with the distal opening facing and aligning with the glottis. Moreover, it acts as an oropharyngeal airway, a bite block, provides additional stabilization of the tube when harnessed and prevents accidental

extubation when the cuff is inflated. It is currently available in only one standard adult size which would accommodate endotracheal (ET) tubes of sizes of 6.5-9.0 mm internal diameter (ID). It is conceived as an easy and effective device for basic life support, that is, ventilation and advanced life support, that is, intubation and airway maintenance. It provides rapid, safe, and effective intubation without laryngoscopy.

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Figure 1

S.A.L.T airway gadget with tongue blade and harness

Since it is such a new device, there is not yet much data published regarding successful intubation rates in human subjects. A meticulous internet search into the available literature revealed no clinical study on human subjects and no

published peer reviewed articles studying the efficacy of the S.A.L.T. Available literature presented only two studies, one from the University of Tennessee, on manikin[8] and other using cadavers, from the University of Nevada, School of Medicine, Las Vegas.[9] The variable anatomy of airway in live human subjects would considerably influence the placement and intubation using S.A.L.T.

OBJECTIVE

The aim of our study was to evaluate S.A.L.T as an adjunct for blind orotracheal intubation in human subjects.

MATERIALS AND METHODS

Setting: The study was carried out in a single center, in a tertiary teaching hospital.

Study design: Single group, open label, prospective, interventional pilot study.

Study Group: Thirty adult patients of either sex, belonging to the American Society of Anesthesiologists (ASA) physical status I and II, who were scheduled to undergo elective surgery under general anesthesia.

Inclusion criteria

- Adult patients (20-65 years of age)
- ASA physical status I and II
- Body weight 45-75 kg

Exclusion criteria

- Obesity (body mass index >35 kg/m^2)
- At increased risk of aspiration (gastroesophageal reflux disease, hiatus hernia, and pregnant patients)
- Cervical spine fracture or instability
- Burns cases and postburn contracture cases
- Distorted airway anatomy
- Anticipated difficult airway

Materials

- S.A.L.T airway with tongue blade and harness.
- Size 7.0 ID cuffed Endo-tracheal Tube (ETT).
- A DVD, produced with a standardized set of instructions consistent with those recommended by the manufacturer of S.A.L.T

Method

After Institutional Research Ethics Committee (TIREC) approval, informed consent was obtained from the patients. Placement and intubation through S.A.L.T was attempted by three anesthesiologists with varying profiles; a professor, an assistant professor, and a senior resident with 30, 10, and 3 years of experience in airway management, respectively. They had trained themselves on an intubating manikin adhering to the instructions provided by the manufacturer through a DVD. The anesthesiologists who performed the intubation were given equal chances for the intervention, and each one of them attempted at least 8 times at placement and intubation through the S.A.L.T.

Standard monitoring was instituted which included non-invasive blood pressure, pulse oximeter, electrocardiograph, capnograph, and temperature. Patients were premedicated with inj. glycopyrrolate 0.2 mg and inj. midazolam 2 mg, intramuscular 45 min before the procedure. A size 7.0 ID cuffed ETT was chosen as a standard for every patient. After adequate preoxygenation, the patients were induced with inj. propofol 2 mg/kg intravenous (IV), and inj. suxamethonium 1.5 mg/kg IV was administered to aid muscle relaxation. S.A.L.T was inserted by the anesthesiologist according to the instructions given by the manufacturer. The ETT was then inserted through it immediately [Figure 2]. ETI was confirmed with manual ventilation by visualizing bilaterally equal chest movements, equal air entry on auscultation, and square wave capnography.

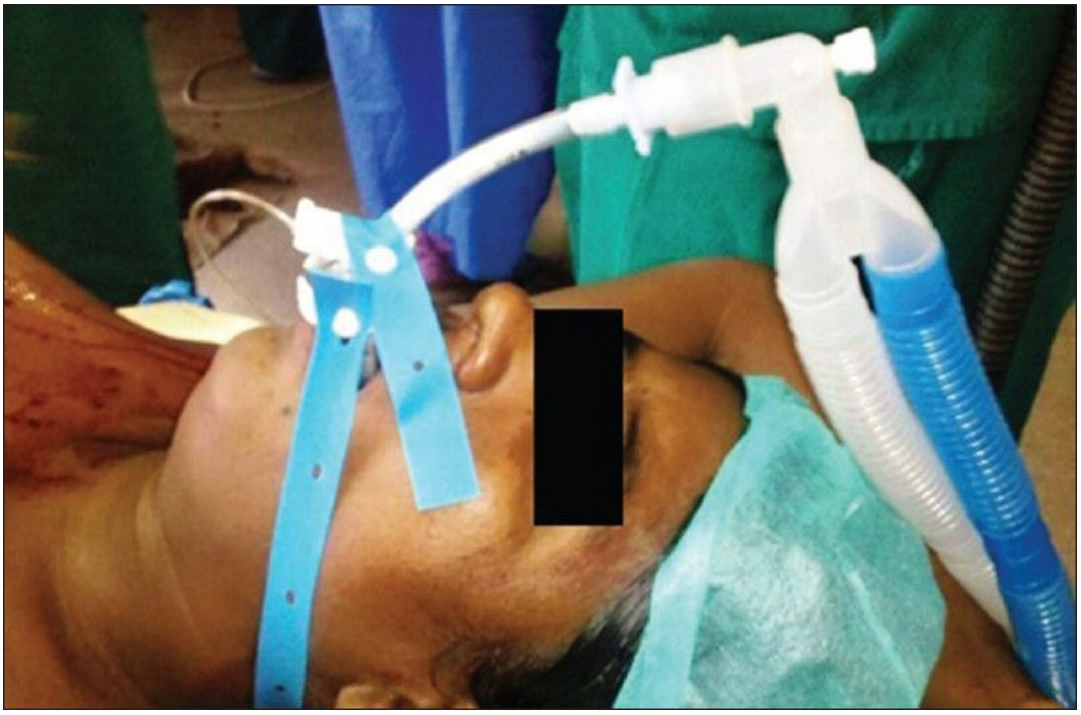

Figure 2

Insertion and intubation through S.A.L.T *in situ*

The time period, from insertion of the S.A.L.T to the insertion of the ETT was noted. A successful intubation was defined as to insert S.A.L.T and to intubate through it within a period of 2 min irrespective of the number of attempts. Airway trauma, if any was recorded.

Statistical analysis

The data were analyzed with the help of the IBM SPSS statistics 20 (IBM Corporation 1989, 2011). The age and weight of the patients were compared between the success and failure by independent student's "*t*" test. The gender and Mallampati class associated with success and failure was analyzed by χ^2 (Chi-square) test. The success of the intervention was estimated by "*t*" test of proportion. The time and attempts for placement were estimated by "*t*" test of means. *P* value of less than 0.05 ($P < 0.05$) was considered as significant in two-tailed situation.

RESULTS

The age, weight, and gender were comparable and did not have any significant association with the placement of S.A.L.T [Tables 1 and 2]. The Mallampati class I was associated with success of intubation ($P < 0.05$) and Mallampati class III was associated with failure of intubation ($P < 0.05$) [Table 2]. The mean time for intubation of the sample was 26.3 ± 19.0 s and the time for intubation for the population was estimated in between 14.3 and 38.4 s. The mean number of attempts required for intubation was 1.4 ± 0.67 attempts and the number of attempts required for intubation for the population was estimated in between 0.99 and 1.8 attempts. The percentage of success in the study was 40%. The estimated population parameter for success of intubation of S.A.L.T is 20.4%-59.6% with 95% confidence interval (CI) [Table 3]. No airway trauma or desaturation was recorded in any subject during the study.

Table 1

The age and weight of the subjects compared between success and failure

Variable	Success ($n = 12$)		Failure ($n = 18$)		Significance
	Mean	SD	Mean	SD	
Age(yrs)	34.4	10.9	41.7	13.1	$P > 0.05$
Weight (kg)	63.2	8.8	65.4	8.7	$P > 0.05$

SD: Standard deviation

Table 2

Association between gender, Mallampatti, and intubation

	Intubation			*P* value	Significance
	Success	Failure	Total		
Gender					
Male	7	12	19	0.711	$P>0.05$
Female	5	6	11		
Total	12	18	30		
Mallampatti					
I	6	5	11	0.0465	$P<0.05$
II	6	6	12		
III	0	7	7		
Total	12	18	30		

Table 3

Estimation of population proportion for success and population parameter of time and number of attempts required for intubation

Parameter	Mean	Std. dev	Confidence interval at 95%
Time (s)	26.3	19.0	14.3-38.4
Attempts	1.4	0.67	0.99-1.8
Proportion of success (%)	40.0		20.4-59.6

DISCUSSION

This new airway gadget S.A.L.T is designed to be used by the paramedics and not the experts. Huffstutter *et al*.,[8] in their study on manikin, 66.4% were successful on the first attempt, 92% with two attempts, and 96% succeeded in intubating within three attempts. They concluded that intubation using the

S.A.L.T. device was simple and effective in the simulated environment requiring few attempts for success. Bledsoe *et al*.,[9] in another study on unembalmed human cadavers involving emergency medical professionals; successful blind placement of an ETT through the S.A.L.T by basic and intermediate emergency medical technician-level providers was 48.1% (95% CI: 34-62), with 37% (95% CI: 24-51) placing the ETT on the first attempt. Whereas the paramedic-level providers, 20 subjects (91% 95% CI: 71-99) were able to successfully place an ETT through the S.A.L.T, with 13 (59% 95% CI: 36-79) doing so on the first attempt. They concluded that Emergency Medical Services providers of varying levels can successfully and rapidly place the S.A.L.T and ventilate a cadaver specimen, but the success rate for blind placement of an ETT through the S.A.L.T was suboptimal.

The pilot experiments so far published, were done only with manikin and cadavers. We sought to test this S.A.L.T in human subjects – what it is really intended for. Thirty years ago, A.J. Brain had published a pilot study on laryngeal mask airway, as an alternative for airway management, with a sample size of only 23 patients. We assumed a sample size of 30 would suffice for a similar pilot study using the S.A.L.T. As the concept and design of this gadget is unique, we could not think of a comparable control group. Hence, we planned this study as a pilot experiment to evaluate the efficacy of this new gadget. At first, we planned to compare two groups, one expert group and the other untrained group (junior residents, interns). The expert group comprised of three anesthesiologists–Professor, assistant professor, and a senior resident with considerable differences in their experiences in airway management. The placement was easy in all the cases, just like sliding any other airway device. But the intubation through S.A.L.T was not as easy on the patients as on the manikin. The time taken by the anesthesiologists to complete the task was similar. The varying experience of the anesthesiologists seemed to have no influence on the intubation through S.A.L.T in any way. Though S.A.L.T was conceptualized to aid in blind orotracheal intubation with much ease, but the supposed to be expert group experienced little ease or success with the device.

The results of our study show that only 40% of the patients were successfully intubated. The intubating rate is very low compared with more than 90% success rate in the above-discussed studies. This could be due to the following:

1. Variable anatomy in human subjects compared to the standard rigid anatomical configurations in the manikin.

2. The muscle relaxation given could have influenced the placement of S.A.L.T and further intubation through it.

3. The learning curve needed to acquaint with the new airway device.

The Mallampati class of the airway also influenced the successful placement of S.A.L.T [Table - 2]. Mallampati class I had more success rate than class III, which shows that S.A.L.T may not help in difficult airway scenarios. Maneuvers such as optimal external laryngeal manipulation could be tried to improve ET placement when the first attempt at intubation fails. Absence of airway trauma during the entire study implies S.A.L.T is safe to handle, at least for further evaluation.

Limitations of the study

The study is limited by the sample size and the design itself. As the experienced anesthesiologists witnessed little ease and lesser success with the patients compared to the manikin, the untrained group was not allowed for further experiment. Hence, we had to settle with a single study group and a small sample size. Thus, the study had to be completed as a feasibility study and the consequent pre-experimental design has limited the probability of randomization, masking, and allocation of control groups, posing a threat to the external validity. As proper randomization was not done, only a convenience sample was taken which has an inherent bias that is unlikely to be representative of the population being studied. The small sample size and the sampling technique also have limited the generalizations of the outcome. To overcome these shortcomings, future studies would require a larger randomized sample size; allocation of an appropriate control group like employing paramedics or other airway gadgets for the intervention would help yield a better statistical outcome.

CONCLUSION

S.A.L.T conceived as an effective device for both basic and advanced life support, shows limited usefulness as an adjunct for aided blind orotracheal intubation. As this was the first study using S.A.L.T. on live human subjects in our institute, to comment on the routine use of this gadget in any emergency or elective set-up is premature. Definitive opinion would be obtained only after further research, with a large sample size, comparison with other airway gadgets, meanwhile understanding the learning curve for the new gadget.

Footnotes

Source of Support: Nil

Conflict of Interest: None declared.

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