Can Emergency Medical Services Personnel Effectively Place and Use the Supraglottic Airway Laryngopharyngeal Tube (SALT) Airway?

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Abstract

Background. Various alternative airway devices have been developed in the last several years. Among these is the Supraglottic Airway Laryngopharyngeal Tube (SALT), which was designed to function as a basic mechanical airway and as an endotracheal tube (ET) introducer for blind endotracheal intubation (ETI). **Objective.** To determine the rate of successful placement of the SALT and the success rate of subsequent blind ET insertion by a cohort of emergency medical services (EMS) providers of varying levels of EMS certification. **Methods.** This study was a two-phase, two-group nonblinded, prospective time trial using a convenience cohort of prehospital providers to determine the success rate for SALT placement (i.e., the basic life support [*BLS*] *phase*) and ET placement using the SALT (i.e., the advanced life support [*ALS*] *phase*) in an unembalmed human cadaver model. The part 1 cohort (*group 1*) comprised predominantly basic and intermediate emergency medical technician (EMT)-level providers, whereas the part 2 cohort (*group 2*) comprised exclusively paramedic-level providers. **Results.** In group 1, 51 (98%) of the subjects were able to successfully place the SALT and ventilate the cadaver (BLS phase), with 48 (92.3%) subjects successfully placing it on the first attempt. In group 2, 21 (96%) of the subjects were able to successfully place the SALT, with 19 (86%) placing the SALT on the first attempt. Successful blind placement of an ET through the SALT (ALS phase) by group 1 was 48.1% (95% confidence interval [CI]: 34–62), with 37% (95% CI: 24–51) placing the ET on the first attempt. In group 2, 20 subjects (91% [95% CI: 71–99]) were able to successfully place an ET through the SALT, with 13 (59% [95% CI: 36–79]) doing so on the first attempt. **Conclusions.** Emergency medical services providers of varying levels can successfully and rapidly place the SALT and ventilate a cadaver specimen. The success rate for blind placement of an ET through the SALT was suboptimal. **Key words:** airway; extraglottic airway; emergency medical services; paramedic; EMT

PREHOSPITAL EMERGENCY CARE 2011;15:359–365

Introduction

Effective airway management is an essential skill for prehospital providers. While endotracheal intubation (ETI) via direct laryngoscopy has been the preferred practice, research in the last several years has questioned the widespread use of the procedure in the out-of-hospital setting.[1,2] Because of this, several alternative airway devices have been introduced into prehospital care.[3] Many of these devices have proven satisfactory in prehospital care.[4–9] However, the question that remains is whether these alternate airways satisfactorily replace ETI in the prehospital setting.[10,11]

Numerous alternative airways have been developed for use by prehospital providers.[7] Among these is the Supraglottic Airway Laryngopharyngeal Tube (SALT) (Microtek Medical, Inc., Columbus, MS). The device was designed to serve as a basic life support (BLS) mechanical airway device but also as an endotracheal tube (ET) introducer for use by advanced life support (ALS) providers for blind ET insertion in situations where direct laryngoscopy is unavailable or difficult. It is shorter and less pliable than traditional supraglottic airways and more closely resembles an oropharyngeal airway. The SALT received Food and Drug Administration (FDA) approval as a Class I medical device on May 31, 2005, and was later introduced to the prehospital market.

The purpose of this study was to address two questions: First, could a sample of prehospital providers place the SALT and ventilate a cadaver specimen? Second, could a sample of prehospital providers blindly insert an ET through the SALT and ventilate a cadaver specimen?

Methods

Study Design

This was a two-phase, two-group nonblinded, prospective time trial using a convenience cohort of prehospital providers. The methods and study

Received September 20, 2010, from the Department of Emergency Medicine, University of Nevada School of Medicine (BEB, DES, RL), Las Vegas, Nevada; University Medical Center of Southern Nevada (WF), Las Vegas Nevada; MedicWest Ambulance (LJ), Las Vegas, Nevada; and the University of Nevada at Las Vegas (GR), Las Vegas, Nevada. Revision received December 30, 2010; accepted for publication January 15, 2011.

Supported by Microtek Medical—a wholly owned subsidiary of Ecolab. Funding was limited to laboratory costs.

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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doi: 10.3109/10903127.2011.561410

FIGURE 1. Prototype of the Supraglottic Airway Laryngopharyngeal Tube (SALT) airway used in part 1 of the study.

FIGURE 2. Revised version of the Supraglottic Airway Laryngopharyngeal Tube (SALT) airway used in part 2 of the study. The distal angle of the airway was reduced, a stabilization collar was added, and the central axis of the airway was marked on the proximal opening of the device.

protocol were reviewed and approved by the University Medical Center of Southern Nevada Institutional Review Board. First, we sought to prospectively assess whether a sample of prehospital providers could insert the SALT and ventilate a cadaver specimen (*BLS phase*). Second, we sought to determine whether a sample of prehospital providers could blindly insert an ET into the trachea using the SALT as an adjunct (*ALS phase*). Our study's specific aims were 1) to assess the rate of successful placement of the SALT in a human cadaver by emergency medical services (EMS) providers with differing levels of certification; 2) to evaluate the time required to successfully place and ventilate a human cadaver using the SALT; and 3) to determine whether prehospital personnel could successfully place an ET using the SALT.

STUDY SETTING AND PARTICIPANTS

Part 1 (SALT Prototype)

A convenience sample of 53 prehospital providers (*group 1*) participated in part 1 of this study. They were volunteer subjects from EMS education programs and EMS agencies in Clark County, Nevada. They represented the complete spectrum of prehospital providers. During part 1, a preproduction prototype of the SALT device was used (Fig. 1).

Part 2 (Modified SALT Device)

During part 2, an updated version of the SALT device was used (a later preproduction prototype). Several developmental changes were made in the device when compared with the version used in part 1. These changes were based on provider and researcher feedback and included the addition of a mark on the top of the airway indicating the central axis of the device, the addition of a collar to secure the airway with a strap, and a slight increase in the acuity of the angle of the distal aspect of the device (Fig. 2). Twenty-two prehospital providers participated in part 2. This sample (*group 2*) was exclusively paramedics (only because of subject availability) (Table 1).

STUDY PROTOCOL

Both groups of study participants attended a SALT educational session provided by a representative of the manufacturer. The session included a lecture and practice on various airway manikins. The goal of the educational session was to instruct the participants in placement of the SALT and in blind insertion of an ET into the trachea using the SALT as an adjunct. Prior to advancing to the prospective, cadaveric trial, the participants had to demonstrate manikin competency for insertion, ventilation, and ET placement

TABLE 1. Demographics of the Subjects Participating in Part 1 (Group 1) and Part 2 (Group 2) of the Study

Group	*n*	Provider Level		Gender		Mean Age (Range)
1	53	EMT-B	19 (36%)	Male	39 (74%)	31.6 yr (19–67)
		EMT-I	18 (34%)	Female	14 (74%)	
		EMT-P	16 (34%)			
2	22	EMT-B	0 (0%)	Male	17 (77%)	35.1 yr (23–53)
		EMT-I	0 (0%)	Female	5 (23%)	
		EMT-P	22 (100%)			

EMT-B=emergency medical technician–basic; EMT-I = emergency medical technician–intermediate; EMT-P = emergency medical technician–paramedic.

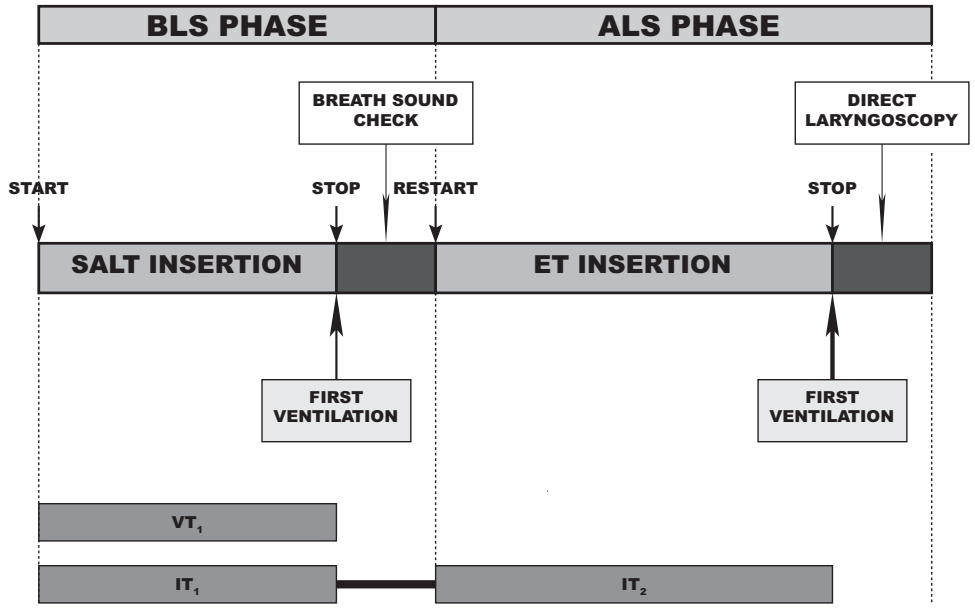

FIGURE 3. The experimental definitions and measurements for the two phases of the study. VT_1 = time interval for placement of the Supraglottic Airway Laryngopharyngeal Tube (SALT) and subsequent effective ventilation (basic life support [BLS] phase); IT_1 = time interval for placement of the SALT and subsequent effective ventilation (advanced life support [ALS] phase); IT_2 = time interval for placement of the endotracheal tube (ET) through the SALT and subsequent effective ventilation (ALS phase).

using the SALT. The participants then moved to a commercial surgical training facility (MedCure Surgical Training Center, Henderson, NV). Four unembalmed human cadavers were used (two separate cadavers for each of the two groups). These had been frozen immediately after death and were thawed to room temperature prior to the study. All had been previously tested and found to be free of infectious diseases. The cadavers were placed on standard operating room tables positioned approximately 1 meter above the floor.

BLS Phase

The participants were asked to ventilate the cadavers with a bag–valve–mask (BVM) unit. Then, the BVM was removed, the SALT was inserted, and ventilations were resumed. Proper SALT placement was determined by observing the rise and fall of the chest and the presence of bilateral breath sounds upon auscultation. The time to place the SALT was the interval from removal of the BVM to the onset of ventilation following SALT placement (Fig. 3).

ALS Phase

Following successful SALT placement, the cadaver was ventilated using the SALT, the BVM was removed, and a 7.0-mm ET was inserted through the SALT. The mask was removed from the BVM, the BVM was attached to the ET, and ventilations were resumed (Figs. 4 and 5). Proper ET placement was confirmed by one of the investigators using direct laryngoscopy. The investigators also recorded the rise and fall of the chest, the presence of breath sounds upon auscultation in the midaxillary lines bilaterally, and the absence of sounds over the epigastrium. The time to first ventilation and the time to ET insertion were recorded. The number of attempts at ET insertion was limited to three, with

FIGURE 4. Blind insertion of an endotracheal tube through the Supraglottic Airway Laryngopharyngeal Tube (SALT) airway.

FIGURE 5. Close-up of the Supraglottic Airway Laryngopharyngeal Tube (SALT) airway showing insertion of an endotracheal tube (ET). A small port in the distal part of the airway remains closed until opened by insertion of the ET.

a maximum time of 30 seconds per attempt. All times were measured with a stopwatch and adjudicated with video. Immediately upon completion of their intubation attempts, the subjects confidentially recorded their perceived ease of use using a 10-cm visual analog scale (VAS) (with 0 = easy and 10 = difficult).

Performance Measures

The primary performance measure for the BLS phase was ventilation success proportion, defined as the proportion of subjects who were able to successfully insert the SALT and ventilate the cadaver using a BVM. The secondary performance measure for the BLS phase was time to first ventilation (VT_1) (Fig. 3).

The primary performance measure for the ALS phase was first-pass success proportion; the secondary performance measures were time to successful tracheal intubation and number of attempts to achieve success. Data were recorded using a standardized data-collection tool, entered into a database (Microsoft Access, Microsoft Corp., Redmond, WA), and analyzed using NCSS Statistical Software (NCSS version 7.1.8, Kaysville, UT).

RESULTS

Part 1 (SALT Prototype)

In group 1, 51 (98%) of the subjects were able to successfully place the SALT and ventilate the cadaver. Of these, 48 (92.3%) were able to place the SALT and ventilate the cadaver on the first attempt. The median time for successful SALT placement by the group 1 subjects was 14 seconds (interquartile range [IQR] = 12–16). There was no difference in the proportions of successful SALT airway placement as the providers' level of EMS certification increased.

In group 1, 25 of the subjects (48.1% [95% confidence interval [CI]: 34–62]) were able to successfully insert an ET via the SALT. Of these, 19 subjects (37% [95% CI: 24–51]) were able to place the ET and ventilate the cadaver on the first attempt. The median time to ET placement was 30 seconds (IQR = 29–31). Although there was a trend toward an increase in the rate of successful ET placement using the SALT as the level of provider certification increased, this did not reach statistical significance for any of the provider-level groups. The overall ease of SALT use perceived by the subjects in part 1 was 6.2 (standard error of the mean [SEM] = 1.8 [95% CI: 2.5–9.9]).

Part 2 (Modified SALT Device)

Twenty-one (96%) of the subjects in group 2 were able to successfully place the SALT and ventilate the cadaver. Of these, 19 subjects (86%) were able to place the SALT on the first attempt. The median (IQR) time for successful SALT placement for the BLS phase by the subjects in group 2 was 12 (10–14) seconds.

In group 2, 20 subjects (91% [95% CI: 71–99) were able to successfully place an ET through the SALT. Of these, 13 (59% [95% CI: 36–79]) were able to successfully intubate the trachea on the first attempt. The median (IQR) time to ET placement was 14 (12–24) seconds. The average overall perceived ease of SALT use by the subjects in group 2 was 1.84 (SEM = 0.43 [95% CI: 0.93–2.74]).

DISCUSSION

While ET intubation remains the mainstay of prehospital airway management by paramedics, problems with the procedure have resulted in the research and development of alternate airway devices.[6] We found that EMS personnel of all levels of certification were highly successful in insertion of the SALT and using the SALT as a basic airway adjunct in a human cadaver model (BLS phase). SALT airway placement was quick and had a high rate of first-placement success (Fig. 6).

The rate of successful blind insertion of the ET though the SALT was suboptimal for both groups, but improved with group 2 (exclusively paramedics). This improvement in success proportions may be related to prior operator experience and/or modification of the device. There appeared to be a relationship between successful ET placement through the SALT and prior

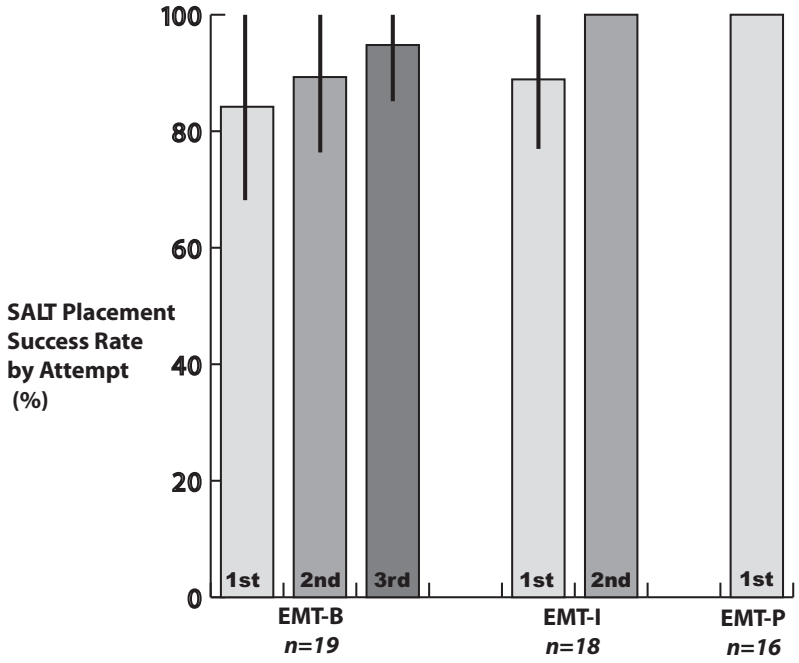

FIGURE 6. Successful Supraglottic Airway Laryngopharyngeal Tube (SALT) placement by level of emergency medical services provider (with 95% confidence intervals). EMT-B = emergency medical technician–basic; EMT-I = emergency medical technician–intermediate; EMT-P = emergency medical technician–paramedic.

experience with standard ET placement using direct laryngoscopy (Figs. 7 and 8).

The rates of successful placement of the ET through the SALT were similar to reported placement success rates of other alternative airway devices following limited educational sessions.[12] In a cadaveric study of insertion of two types of the laryngeal mask airway (LMA) by naïve operators, researchers found that 92% (60 of 75) of subjects were able to place the intubating laryngeal mask airway (ILMA) and ventilate the

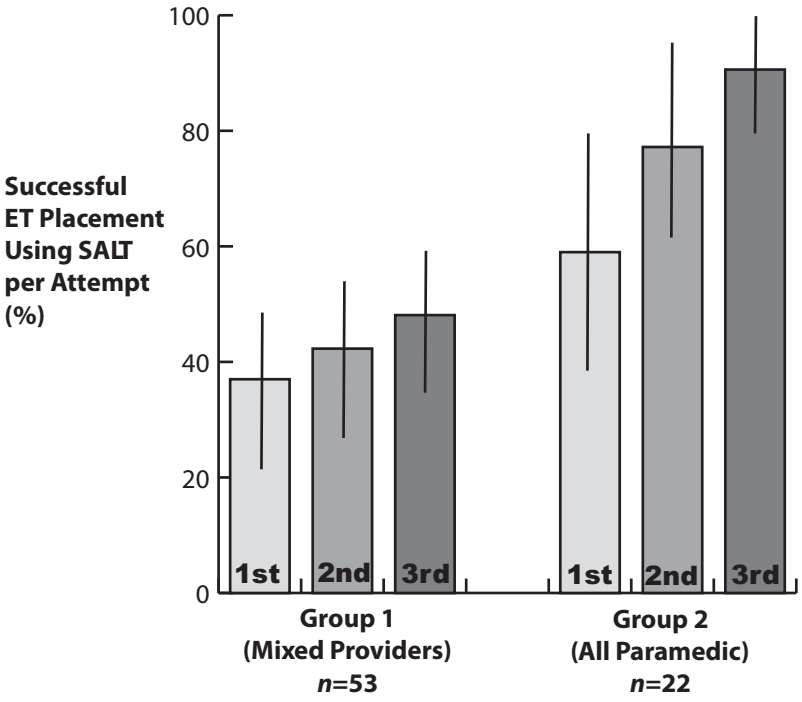

FIGURE 7. Successful insertion of an endotracheal tube (ET) through the Supraglottic Airway Laryngopharyngeal Tube (SALT) by study group (with 95% confidence intervals).

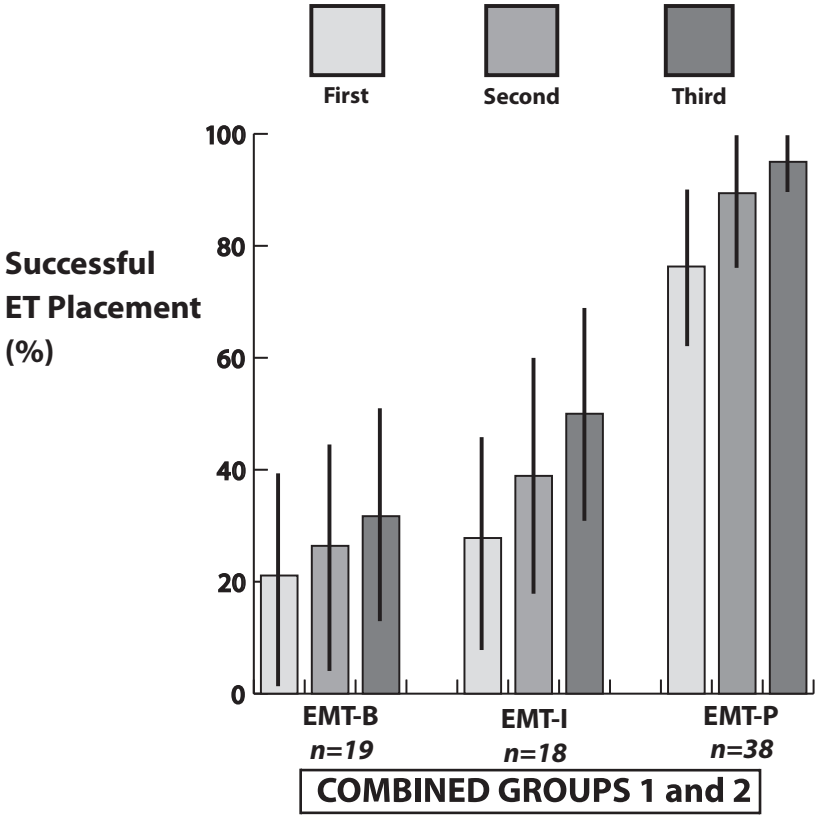

FIGURE 8. Successful insertion of an endotracheal tube (ET) through the Supraglottic Airway Laryngopharyngeal Tube (SALT) by provider level (with 95% confidence intervals). EMT-B = emergency medical technician–basic; EMT-I = emergency medical technician–intermediate; EMT-P = emergency medical technician–paramedic.

cadaver on the first attempt, compared with 76% (57 of 75) of subjects being able to place the standard LMA and ventilate on the first attempt. When asked to place an ET through the ILMA, only 67% (52 of 75) of subjects were successful.[13] These rates are similar to the rates of successful SALT placement and ET introduction through the SALT that we found in our study, although our subjects had lower first-attempt success rates. We did see improvement in ET placement through the SALT with developmental changes in the device. Additional improvements may improve the successful ET placement rate.

This study adds to a growing body of evidence that naïve EMS providers with limited education in ETI cannot effectively place an ET with direct laryngoscopy or alternative devices (e.g., SALT, ILMA).[14,15] There is a clear association between provider experience at ETI and success rates.[16] We feel that some of this relates to providers' having a better knowledge of airway anatomy and prior experience physically manipulating the ET. The amount of education in airway placement remains problematic in EMS. Experience with ETI clearly illustrates that increased education and practice correlate with improved rates of successful ETI.[17,18] It would seem intuitive that increased education and practice in inserting an ET through the SALT might also increase the success proportions. Additional studies are warranted.

LIMITATIONS AND FUTURE RESEARCH

There were several limitations to our study. First, the study was nonblinded and nonrandomized and used a convenience sample. Second, there were anatomic variations between the cadavers, and distortion and damage of the cadaver occurred following repeated use. Interestingly, many of the subjects in our cohort had never seen or practiced on human cadavers. Design changes and improvements in the SALT between part 1 and part 2 of our study could have accounted for improved placement rates by the group 2 subjects. The SALT devices used in the study were preproduction prototypes and may not reflect the final version of the device. The same airway was used repeatedly by the subjects and may have impacted performance. The educational sessions differed between the two groups, as different instructors were used. Also, during the group 2 education, the participants received practice on a cadaver before entering the study. Additional studies are needed to compare SALT airway performance with other airway management methods.

Conclusions

Our study shows that EMS providers of varying levels can successfully and rapidly place the SALT and ventilate a cadaver specimen. However, the success rate of blind placement of an ET through the SALT was suboptimal, but success rates increased with the providers' level of EMS certification.

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