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Original Article

Direct endotracheal intubation using a novel detachable optic probe (Sunscope) by emergency medical technicians with various training backgrounds

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ABSTRACT

Objective: Effective airway management requires both proper technique and the appropriate devices. With the widespread implementation of advanced life-support techniques in emergency medical services (EMS), orotracheal intubation is now performed not only by professional practitioners but, in many occasions, nonprofessionals. With extensively diversified skill equipped, we tested whether the Sunscope, a patented tracheal intubation device with a digital display, is able to facilitate tracheal intubation by naïve EMS personnel with various training backgrounds.
Methods: We conducted a study to determine rate of success and time required to insert an orotracheal tube into a mannequin using Sunscope. The participants were placed into the professional group (i.e., anesthesiologists and emergency medical paramedics; EMT-P) or the nonprofessional group (i.e., emergency medical technicians; EMT). Intubation required three steps: equipment preparation, vocal cord exposure, and tube insertion. The time required for each step was recorded by a senior staff member, and the data were analyzed by nonparametric statistics.
Results: Each consecutive step in the operating procedure was significantly shorter for the professional group in comparison with the nonprofessional group during the first trial: equipment preparation, 10.5 ± 2.1 vs. 11.9 ± 4.1 seconds; vocal cord exposure, 7.4 ± 7.7 vs. 12.2 ± 7.7 seconds; tube insertion, 8.8 ± 4.8 vs. 17.6 ± 9.4 seconds; and total time required for intubation, 26.7 ± 8.8 vs. 35.8 ± 19.6 seconds. The professional practitioners showed no significant improvement, in terms of time reduction, on the following three trials. On the other hand, the nonprofessional practitioners showed no significant differences, in terms of time required to expose the vocal cords and total operation time, following the third trial in comparison with the professional practitioners.
Conclusion: Our research demonstrates that professional practitioners are able to use the Sunscope on their first attempt. Despite a lack of training in conventional endotracheal intubation, emergency medical technicians (EMT-I and -II) were able to complete intubation on their first attempt; a significant reduction in the time required to intubate was noted after repeated practice. All levels of naïve EMTs were able to readily visualize the vocal cords through Sunscope and, thereby, reliably insert the endotracheal tube in less than 1 minute, regardless of their skills before testing.

1. Introduction

It is often challenging for emergency medical service (EMS) practitioners to establish a secure airway for endotracheal intubation. In addition to the relative level of inexperience and work setting, conventional direct laryngoscopy is regarded as the most difficult procedure for EMS practitioners with insufficient training to perform. Inadequate training and poor equipment not only lead to malpositioning of the placed endotracheal tube but unnecessary

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trauma.[1] The major obstacle of direct laryngoscopy is failure to visualize the larynx because of anatomical variation and/or manipulation errors.[2,3] In contrast, illumination on the tip of the tracheal tube with a lighted stylet (e.g., Lightwand) demonstrates a high rate of successful intubation (97.9–100%).[4,5] However, poor illumination in association with obesity, skin pigmentation, and resistance to the advancement of the endotracheal tube all lead to intubation failure. Accordingly, a video-guided intubation system with a lighted stylet could facilitate endotracheal intubation and avoid many of the mishaps of "blind" intubation.[6]

In addition to difficulty of intubation, the operator (and/or the supervisor) is subject to unnecessary contamination when he must position his eyes close to the patient's mouth in order to obtain an optimized view of the vocal cords. This can result in the transmission of infections, including tuberculosis, severe acute respiratory syndrome (SARS), hepatitis, and HIV, through contact with contagious respiratory secretions or droplets.[7] Because of this concern, the manipulators should keep themselves as far away as possible from the mouths of their patients.[8,9]

In an earlier study, we found that a visual module that is integrated with Light-Emitting Diode (LED) lights, a lens, and a Complementary Metal-Oxide-Semiconductor (CMOS) sensor could meet the crucial demands of both the operator and patient.[10] Sunscope, which features a detachable image probe, is an anesthesiologist-initiated innovative device invented to meet the scrutinizing demands of clinical anesthesiologists in terms of protection against infection, portability, detachability, and affordability.[11] The prototype has been successfully tested on an endotracheal intubation model and in animal trials, and it has proven its clinical capabilities for use in anesthetic practice. In this study, we went on to investigate how EMS practitioners with diverse training backgrounds performed endotracheal intubation on mannequins using Sunscope.

2. Material and methods

2.1. Study population

The 13 participants who enrolled in this study were divided into two groups. One group consisted of seven professional practitioners, including physicians, nurse specialists, and emergency medical paramedics (EMT-P) who had performed over 1280 hours of training, who could perform some invasive medical procedures such as endotracheal intubation and administer drugs for resuscitation. The other group consisted of six nonprofessional practitioners, specifically emergency medical technicians (EMT) who lacked endotracheal intubation training and could only perform noninvasive airway establishment such as placing nasopharyngeal and oropharyngeal airways and laryngeal mask airways (LMA). The purpose of this study was to compare the times required to perform endotracheal intubation between these two groups.

Before administering the test, instruction on how to properly use the Sunscope to perform intubation was provided, including a demonstration of the airway anatomy, step-by-step operation, and practice on a mannequin. Because the anatomic structure of a mannequin is fixed, there are some differences between the model and a real human body. Furthermore, repeated practice on a mannequin will certainly improve the success rate of intubation as familiarity with its structure increases, but not necessarily when performed on a real human. Based on the above considerations, this test was performed as follows: each participant performed the intubation procedure three times on a mannequin (for 5 minutes) after the airway anatomy tutorials and operational training sessions had been provided, and each time was recorded. The time expenditure on first trial was considered the first successful intubation and procedure record, and the other trials were considered improvement records. Based on the training backgrounds of the participants, only the professional practitioners had ever performed a laryngoscopy before, and the others had only inserted oral, nasal, or laryngeal mask airways.

2.2. Device settings

Sunscope is a video-assisted intubation endoscope. With the tracheal tube mounting on the Sunscope, the user can bend the distal end of the scope by 90–120°, depending on the curvature of the patient's oral cavity, and gently slide it into the mouth via the lateral side. As the scope reaches the posterior pharynx (behind the base of the tongue), it can be rotated 90° to make the camera tip toward the trachea in order to target it and visualize the epiglottis, arytenoids, and vocal cords (Fig. 1).

In order to quickly familiarize the participants with this device, this study established a standard operating procedure (SOP) for Sunscope. There are eight major steps to SOP:

Step 1. Mount the endotracheal tube onto the visual tube by locking the console-side tenon.
Step 2. Appropriately curve the visual tube and endotracheal tube to an angle of 90–120°. It is necessary to adjust the tube angle to fit the patient's oral cavity and the estimated location of the tip at the trachea.
Step 3. Slide the scope and the endotracheal tube into the oral cavity through the lateral side of the mouth.
Step 4. Rotate the endotracheal tube 90° perpendicular to the visual tube towards the vocal cords.
Step 5. Once the vocal cords are visualized, advance slightly and point the visual tube toward the tip of the trachea.
Step 6. Using the left hand to fix the tracheal tube and the right hand to hold the console, disconnect the tracheal tube from the visual tube.
Step 7. Advance the endotracheal tube down into the trachea to an adequate depth.
Step 8. Pull out the visual tube and connect the bag valve to the tracheal tube. Ventilate and confirm the position of the tracheal tube. The successful criterion of this operation is the proper inflation of the mannequin's lungs during ventilation.

All of the participators operated this device by following this SOP, and the procedure time was considered the total time required to perform steps 1–8.

2.3. Data collection

We attempted to simulate the intubation conditions of an out-of-hospital cardiac arrest (OHCA), a common EMS situation. The intubation procedure was carried out by the practitioners in the kneeling position, and we divided the intubation time into three parts. During the first part, the equipment preparation stage (steps 1–2), the sham patient received cardiopulmonary resuscitation (CPR) by the rescuers in order provide the brain with a low, but steady, perfusion of oxygen. The second part, vocal cord exposure (steps 3–5), requires the interruption of CPR in order to start endotracheal intubation. During the third part, tube insertion (steps 6–8), the endotracheal tube is placed and CPR can be reintroduced. Endotracheal intubation was divided into parts 2 and 3 following research and discussion with senior anesthesiologists. The major reason for the lengthy intubation time is to allow visualization of vocal cords; therefore, part 2 is needed as the confirmation step.

During the test, not only was the process time recorded, but the success rate of endotracheal intubation was determined by senior anesthesiologists. Once the data were collected, the success and

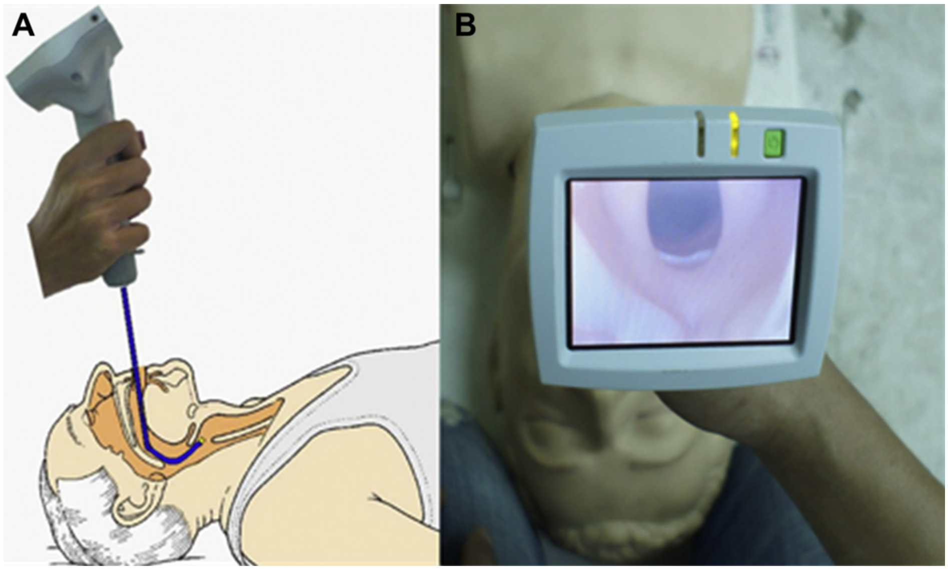

Fig. 1. (A) Anatomical positioning. (B) Image of the mannequin's glottic structure.

failure rates of each participant were analyzed. Moreover, the success rate of endotracheal intubation and the procedure time of each group was examined and discussed. This experiment was designed to determine if Sunscope decreases the operating time and increases the success rate of endotracheal intubation among nonprofessional practitioners.

2.4. Data processing and statistics

The data obtained from these three parts were recorded by the simulator, processed, and analyzed using SPSS for Windows (release 16.0; SPSS Inc. Chicago, IL, USA). Variables were expressed as the means ± standard deviations (SD). The Mann-Whitney U-test and Kruskal-Wallis H-test for nonparametric statistics were used to determine the association the between professional and nonprofessional practitioners. All tests were two-tailed. A *p*-value of <0.05 was considered significant.

3. Results

Thirteen participants were recruited to participate in this trial, seven of whom were classified as professional practitioners, including three anesthesiologists from the Department of Anesthesiology of the National Taiwan University College of Medicine and four EMT-P from the Fire Bureau of New Taipei City, Taiwan. The other six nonprofessional practitioners included two basic-level (EMT-I) and four intermediate-level EMT-II.

3.1. First trial

The first test comparing the actions of these two groups is shown in Fig. 2. The mean equipment preparation time of the professional group versus the nonprofessional group was 10.5 ± 2.1 versus 10.1 ± 4.1 seconds. The nonprofessional group was faster than the professional group; however, the results showed no significant difference between these two groups according to the Mann-Whitney U-test. The procedure time for vocal cord exposure was 7.4 ± 7.7 and 10.6 ± 10.2 seconds respectively. The professional group was significantly faster than the nonprofessional group according to the Mann-Whitney U-test ($p < 0.05$). In addition, the professional group required 8.8 ± 4.8 seconds and the nonprofessional group required 11.7 ± 10.5 seconds. The procedure time required for tube insertion by the professional group was significantly less than the nonprofessional group according to the Mann-Whitney U-test ($p < 0.05$).

3.2. Third trial

There were no significant differences between the three trials of the professional group according to the Mann-Whitney U-test. The total operation time of each respective test was 26.8 ± 7.3, 27.7 ± 7.4, and 25.6 ± 12.1 seconds, respectively. The time required to perform the second step, vocal cord exposure, was 15.7 ± 7.7, 17.0 ± 7.0, and 15.8 ± 13.1, respectively.

To determine the amount of improvement that resulted from practice in the nonprofessional group by the third trial, we compared the different components of the third trial between the nonprofessional and professional groups. The procedure time required to perform the vocal cord exposure step was 10.3 ± 4.6 and 6.3 ± 3.6 seconds, respectively. There was no significant difference between the two groups according to the Mann-Whitney U-test. The total time required to complete intubation was 35.3 ± 8.5 and 26.8 ± 7.3 seconds, respectively. There was no significant difference between the two groups according to the Mann-Whitney U-test. Following three practice sessions, we found

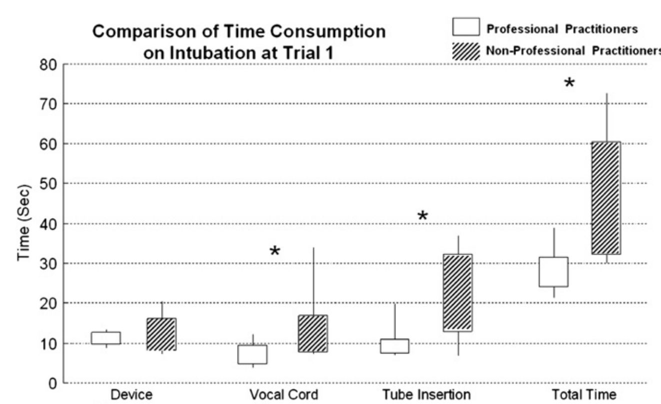

Fig. 2. Comparison of times recorded for the professional group and nonprofessional group during the first trial (see the box plot for the data; asterisks indicate significant difference of $p < 0.05$ according to the Mann-Whitney U-test).

that the nonprofessional practitioners were not inferior to the professional group in terms of the total time required to perform intubation by the third trial (Fig. 3).

4. Discussion

In this study, we demonstrated that professional practitioners and all levels of naïve EMT were able to accurately perform the SOP for Sunscope on simulation tests after a brief training course. Inexperienced EMS practitioners (EMT-I and -II) were able to perform the intubation process on their first attempt and demonstrated further improvement, including a reduction in the overall intubation time, with repeated practice.

4.1. Equipment preparation

According to the test data, there was no obvious difference between the professional group and the nonprofessional group in terms of equipment preparation. The preparation time required to use Sunscope was only 8–10 seconds, but properly bending the stylet can be time consuming and affect how the vocal cords are exposed. This means that an adequately bent stylet helps to rapidly and properly complete vocal cord exposure step. Although the use of a readily bent stylet could sufficiently reduce the equipment preparation time, in theory, it might fail to reduce the equipment preparation time due to unanticipated difficult airways and individual variations in each person's anatomical structure, which are related to age, height, and weight. Accordingly, it is impossible to accurately predict the length of the respiratory tract using only a few parameters, and a readily bent stylet would not guarantee successful endotracheal intubation.[12]

4.2. Vocal cord exposure

Although all of the participants completed the intubation process using Sunscope after a brief training session, the experienced participants required less total operation time to complete the intubation procedure than participants who do not possess related skills. The major reason for this is that the operator only receives information on the patient's oral condition via the imaging monitor of the Sunscope during the vocal cord exposure step. Therefore, those who know more about the anatomy of the oral cavity will certainly be able to quickly identify the relationship between the front end of the visual tube and the larynx.

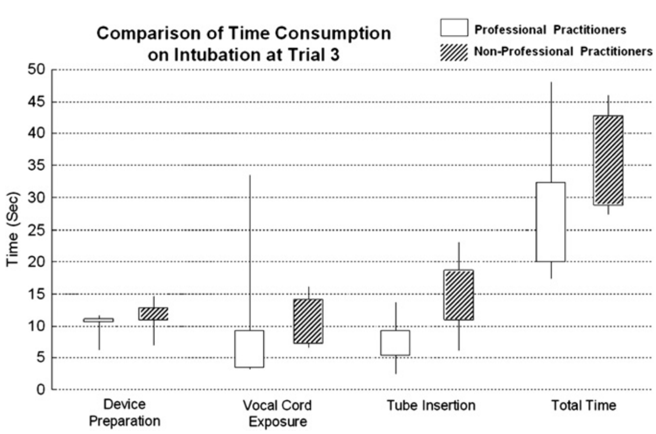

Fig. 3. Comparison of times recorded for the professional group and nonprofessional group during the third trial (see the box plot for the data; there was no significant differences between the two groups according to the Mann-Whitney U-test).

On the other hand, the inexperienced participants who do not immediately recognize the corresponding position of the camera were still able to finish the intubation process in a short period of time. If provided with the proper intubation equipment and more practice, these individuals could perform endotracheal intubation as well as experienced practitioners.

4.3. Tube insertion

This study demonstrates that there was significant difference between the professional group and the nonprofessional group when performing the tube insertion step. The major reason for this difference is that when the endotracheal tube is placed into patient's airway, the participant has to use his left hand to fix the endotracheal tube and his right hand to pull the Sunscope out. Although the front end of the visual tube is composed of a soft complex compound, it still needs to be pulled out with an appropriate force, some inappropriate bent angle on visual tube would increase the resistance between the visual tube and endotracheal tube.

Due to the fact that the professional group knew how to intubate using a stylet, they were able to pull the stylet out more smoothly and steadily maintain the endotracheal tube much better in comparison with the nonprofessional group. The nonprofessional group was new to the removal procedure and had to learn by a trial-and-error method that inevitably required more time. Be that as it may, the time required by the nonprofessional group decreased and achieved the level as the professional group with repeated training.

4.4. Airway management by EMS in New Taipei City

In New Taipei City, noninvasive (oral or nasal) airway and LMA insertion can be performed by EMT ($n = 1{,}400$) while endotracheal tube (ETT) intubation can be only performed by EMT-P ($n = 75$). All cases of OHCA in New Taipei City were identified from our database between January 1–June 30, 2010 ($n = 481$). Those patients who underwent defibrillation with automated external defibrillator (AED) and those who received resuscitation drugs (e.g., epinephrine and amiodarone) during CPR were excluded. A total of 325 patients were divided into two groups: LMA ($n = 294$) and ETT ($n = 31$). The primary endpoints were "survival rate of OHCA 2 hours after hospital admission" and "time consumption during emergency treatment." Of the 294 patients who received LMA, 77 survived (26.2%) and 14 (45.1%) received ETT intubation 2 hours after hospital admission. Odds ratio of the survival rate for the two groups was 2.31 (ETT/LMA). The statistical number determined by the Chi-square test was $\chi2 = 5.00$, $p < 0.05$. The operation time was 13.04 ± 6.19 minutes for LMA and 15.61 ± 6.21 minutes for ETT intubation, with a mean difference of 2.57 minutes between the two groups (paired t-test, $p < 0.05$).

Another retrospective study[13] demonstrates that OHCA patients who underwent endotracheal tube intubation had a superior survival rate at 2 hours after hospital admission in comparison with those who received LMA despite requiring an extended operation time during emergency treatment. By quantifying the ETT intubation and shortening the intubation time by adequate initial training and frequent practice, we may improve the survival outcome after OHCA. We recommend EMS administration to facilitate ETT intubation by promoting the use of new technology and frequent retraining.

4.5. Endotracheal intubation in emergency circumstances

EMS practitioners usually know little about the injury mechanism and should not rashly move the patient. It is difficult to perform endotracheal intubation because the standard "sniffing position" is usually hard to achieve due to immobilization of the neck. In such doubtful circumstances, it is possible to cause devastating spinal injuries by performing laryngoscopy, and the lengthy intubation time required due to poor visualization of the vocal cords leads to hypoxic insults. Gastric regurgitation and the resulting chemical aspiration may occur during this procedure. Thus, tracheal intubation under direct laryngoscopy usually fails.[14]

Compared with the direct laryngoscope, Sunscope is a video-assisted endoscope that is composed of a digital visual stylet that acts as a guide for introducing the tracheal tube. It can reach the trachea and complete intubation without lifting up the glossoepiglottic folds. It can also be used to examine the patient's oral cavity to determine if any foreign body is present in the airway during intubation.

The Sunscope consists of a console, viewer, visual probe, and air/water channel. The operator can use a new probe in the same platform when examining a new patient, thus reducing cross-contamination, the time required for disinfection, and the use of costly heat- and chemical-resistant coatings. The viewer can watch the real-time image at an unlimited viewing angle, while the console is equipped with light-adjusting functions and an independent power supply. The visual module also has image-sharing abilities, so multiple users can share the real-time image stream using a 3.5 G communication protocol to connect with a remote medical center for consultation and further image processing. Thus, the Sunscope acts as the perfect EMS airway-management tool.

5. Research limitations

There are a number of limitations to the study. Despite the high success rate of intubation in the mannequin during all three tests, there are numerous unpredictable anatomic variations in actual human airways. In addition, there is a sharp learning curve during mannequin tests, and clinical trials are still necessary to demonstrate the efficacy of Sunscope. When facing an anticipated or unexpected difficult airway, the employment of Sunscope should still follow the current difficult airway-management algorithm.[15] In addition, the real human oral cavity is filled with saliva, copious secretion, translucent tissues, and water vapors, and may be obstructed by dropped the tongue or relaxed mandible. Although the effects of water vapor, oral temperature, and illumination could be overcome in animal trials, what will happen to the nonprofessional practitioners when they meet these issues remains unclear. Therefore, further clinical studies are needed.

In conclusion, this study shows that professional users, such as anesthesiologists and EMT-P, are able to quickly learn how to intubate using the Sunscope without any obstacles. Nonprofessional practitioners, such as EMT-I and EMT-II, who do not know how to perform endotracheal intubation, are able to not only accomplish the procedure within 1 minute, which meets the clinical requirements, but even achieve the skill level of the professional group after repeated practice. This study reveals the potential Sunscope has to improve the quality of EMS airway management and possibly enhance the survival rate of advanced life support. Further studies are warranted to evaluate the effectiveness of Sunscope in prehospital medical services.

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