An End-user Assessment of the Novel i-view Video Laryngoscope After a Clinical Trial

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ABSTRACT

Introduction: Airway obstruction is a leading cause of potentially survivable death on the battlefield. Intubation remains the most frequently performed prehospital airway intervention. Unfortunately, survival is lower after prehospital intubation compared to the emergency department. After-action review data suggest that forward-staged technology is lacking. Additionally, video laryngoscopy (VL) is superior to direct laryngoscopy, especially in the hands of novice intubators. The i-view is a novel, inexpensive, handheld VL device that showed promise in far-forward areas. However, our clinical study demonstrated inferior clinical performance of the i-view compared to our current standard devices in first-pass success. This study used feedback from intubating operators to identify potential causes of this substandard performance. **Methods:** We conducted a prospective survey of intubating operators using the novel video device as part of a clinical trial. We sought their feedback using a Likert scale survey and free text feedback. The study team reviewed the free text feedback using a thematic analysis method. **Results:** We surveyed 31 emergency physicians who had used the device (30 fully completed surveys and one partially completed). The lowest-scoring areas were screen brightness, with a median score of 2 (IQR 2–4), and screen resolution, with a median score of 2 (1–4), indicating that these were the major performance challenges. Thematic analysis suggested that the i-view's primary challenges were screen brightness, resolution, visibility through bodily fluids, and fogging. **Conclusions:** Our survey highlighted multiple issues with i-view's use. Our findings will inform device development and modification for prehospital deployed use.

KEYWORDS: *airway; i-view; video; laryngoscopy; laryngoscope; military; trauma; intubation*

Introduction

Video laryngoscopy (VL) has changed intubation methodology, especially in the emergency setting. Current data suggest that VL is superior to direct laryngoscopy (DL), especially in the hands of novice intubators.[1–7] Current VL technology is cost-prohibitive for dispersion around the battlespace, yet many of the intubators in far-forward areas are relatively novice.[8–10] Previous after-action review data suggest that much of the challenges surrounding intubation in locations such as the battalion aid station are related to training and lack of technology, including video technology.[11–13] As a point of reference, the U.S. Military previously fielded the GlideScope at a cost of $12,292.67 for each (National Supply Number 6515-01-572-7262). The currently fielded GlideScope device is no longer being manufactured, and the military needs a replacement device for fielding.

The i-view (Figure 1) is a novel single-use VL device produced by Intersurgical (Wokingham, United Kingdom) that costs approximately US$100–200 each. This device is handheld with a built-in screen and a blade that generally mirrors a standard geometry blade. This technology is potentially advantageous to the U.S. Military as it does not require ongoing maintenance and is cost-friendly for wide dispersion.[14] Thus, it may fill the gap in needed technology in these forward-staged areas. The low cost makes it an attractive tool for the civilian prehospital setting, where it would not be cost-effective to place many VL systems in each EMS vehicle.[15,16]

Given these findings, we conducted a prospective, quasi-experimental clinical trial in the emergency department (ED) at two level I trauma centers to assess whether this device has adequate clinical performance characteristics. We initially performed simulation testing prior to the clinical trial, which was promising.[17] However, during a clinical trial in which patients were prospectively assigned devices for intubation in the ED, we found inferior first-pass success with the i-view device.[18] We performed an unplanned interim analysis after receiving negative feedback from the end-users and stopped the clinical trial early due to the futility of reaching our noninferiority endpoint. Given the informal feedback received, we sought to perform a prospective follow-on study formally assessing operator feedback to inform technology development for the Role 1 deployed setting.

Methods

Participants and Setting

We conducted our study in parallel at two sites—the Brooke Army Medical Center (BAMC) and the Colorado University

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FIGURE 1 *i-view device.*

(CU) Anschutz Medical Campus.[7,19] Both facilities are level 1 trauma centers and tertiary care hospitals in urban settings. We conducted our study through parallel but independent protocols at each site. The BAMC site operated under U.S. Army Institute of Surgical Research protocol H-21-022x. The CU Anschutz site operated under Colorado Multiple Institutional Review Board protocol 20-2040. Both sites requested and were granted a waiver of informed consent.

Study Preparation

Prior to the study, we simulated use to help integrate the new device into departmental practices. This simulation included intubations with and without fluid in the airway using a SynDaver (Tampa, FL) simulation model.[20] These occurred during education periods and while on shift. The potential operators were allowed unlimited use of the device during simulations. We also performed a run-in period during which the devices were available for clinical use within the department at operator discretion.

Survey

Upon early termination of the study, since our study was supported by a Defense Health Program Office (DHP) 6.7 grant, we opted to perform a survey of end-users to gather technology development data. DHP 6.7 focuses on (1) modifications to existing marketed products or (2) secondary uses of existing marketed products for use in the deployed combat environment. During the clinical trial, the intubating operator would complete the data collection form. We used the data collection forms to identify the intubating operators to perform the survey. Clinical investigators created and revised the survey, and different investigators reviewed it for face validity. We prospectively offered them a voluntary survey (Table 1). They also provided free text feedback, which the clinical investigators analyzed using a thematic analysis method.

TABLE 1 *End-user i-view Device Feedback*

Question	Median Likert scale score (IQR)
I prefer having a disposable device available in the hospital	4 (3–4)
I would prefer a disposable device available when I am deployed (BAMC only)	4 (0–5)
I prefer the weight of the i-view	3 (2–4)
I prefer the color of the i-view	3 (2–3)
I prefer the location of the screen	4 (2–4)
I prefer the angle of the screen	3 (2–4)
The screen had sufficient brightness	2 (2–4)
The i-view had sufficient battery life	4 (3–5)
The screen had sufficient resolution	2 (1–4)
The screen size was adequate	4 (3–4)
I prefer the location of the on/off button	3 (3–4)
I prefer the way this device felt in my hand	3 (3–4)
I prefer a standard geometry blade shape	4 (3–5)
I would prefer a hyperangulated blade shape	3 (2–4)
I like having the option of direct laryngoscopy	4 (4–5)
I found the packaging easy to open	4 (4–5)
I was typically able to get a sufficient laryngeal view while intubating	4 (2–5)
I had challenges with secretions or vomit affecting the view	3 (2–4)

1=Strongly disagree; 2=Disagree; 3=Neutral; 4=Agree; 5=Strongly disagree.
BAMC = Brooke Army Medical Center; IQR = interquartile range.

Statistical Analysis

We performed all statistical analysis using Excel version 365 (Microsoft, Redmond, Washington, USA) and JMP Statistical Discovery version 16 (SAS, Cary, NC, USA). We used descriptive statistics to analyze and present the data.

Results

We surveyed 31 emergency physicians after they had used the device. In total, 189 patients were enrolled, with 81 in the i-view group and 108 in the standard device group in the original intent-to-treat analysis. The 31 physicians completed all 189 intubations.

All operators at BAMC (n=16) completed the survey. At CU, 15 operators began surveys, of which 14 were completed. The median scores for all questions asked ranged from 2–4. The lowest scoring areas were screen brightness, with a median score of 2 (IQR 2–4), and screen resolution, with a median score of 2 (1–4), suggesting that these were the major performance challenges. Thematic analysis suggested that the primary challenges associated with this device related to view, including screen brightness, resolution, ability to see through bodily fluids, and fogging (Tables 2 and 3).

Discussion

Airway management on the battlefield is critical to optimize the survival of combat casualties, but airway intervention is

TABLE 2 *Select Quotes Lifted from the End-User Feedback Assessments in Favor of the Device*

… Exchangeable blade would be the absolute game changer here. Being able to switch out standard for hyperangulated blade, different sizes would make me prefer this device over others…
… Geometry closer to a standard Mac blade…
… portability, ease of set up, packaging was good
would want this rather than nothing in deployed setting/ environment setting
Portability, Weight, Ease of opening and use
Portability, Simplicity of machine, Common sense-nature of use

TABLE 3 *Select Quotes Lifted from the End-user Feedback Assessments Not in Favor of the Device*

It is fine as a device, but I prefer the glide scope geometry and video screen, c-mac would be my second choice and i-view last choice.
The resolution is not as good as the C MAC The brightness is not as good as the C MAC. The size of the screen is different and could be a bit bigger.
It feels slightly more difficult to perform DL with the i-view. A less angulated blade may help in those situations where video is difficult secondary to blood or copious secretions. A slightly larger screen couldn't hurt, but the current size is adequate. Exchangeable blade would be the absolute game changer here. Being able to switch out standard for hyperangulated blade, different sizes would make me prefer this device over others.
Issues with fogging of camera, better screen resolution, brighter screen
Thickness/strength of blade (too thick), Angulation, thickness affected back up use of direct laryngoscope, screen resolution
Video is either crappy resolution, or too small. I honestly couldn't tell. I never accidently hit the power button, but it needs to be in a less accident prone area.
Resolution is poor especially once device enters mouth/moist environment. Not bright enough once in mouth. I wish the video box angle was adjustable left, right, up, and down.

associated with significant morbidity and mortality.[21] The risk of adverse outcomes rises with the number of attempts required to cannulate the airway successfully.[22] Consequently, first-pass success has become a surrogate measure for effective airway management.[23–27] Our clinical study of the i-view demonstrated inferior first-pass success compared to standard video laryngoscopy.[18] This study employed qualitative research methods to elucidate the reasons behind this finding.

In this study, we surveyed 100% of the emergency physicians who used the i-view device during our clinical trial. The lowest-scoring areas related to the device focused on screen resolution and brightness. Upon further investigation with the thematic analysis, this appears to be related to the inability to see the video clearly (especially once the camera is device to secretions and vomit) and issues with angulation, resulting in a lower first-pass success.

The follow-on survey aimed to inform device selection for deployed use and potentially modify currently marketed device for the deployed setting. This survey study highlighted the limitations in conducting a clinical trial to find the best device, as repetitive clinical trials become expensive, whereas surveys are much less expensive. Through the combination of these studies (survey and clinical trial), we found that a device that showed promise during simulation testing did not translate to success in the clinical setting.[17,28,29] The reason for this is likely multifactorial. First, in the simulation setting, we are unable to reproduce the anxiety that occurs when performing the procedure clinically, where time is a major limiting factor due to desaturation. Second, we are unable to replicate the secretions and bodily fluids in the airway that we will experience clinically compared to the simulation setting.

Based on these two studies, we believe that an optimal device selection process may occur in reverse—with robust surveys and qualitative feedback on all potentially feasible devices, followed by a clinical study validating the use of the device. We recently completed an unrelated airway study, employing qualitative methods (including thematic analysis and surveys) to down-select supraglottic airway devices for medics to carry in their aid bags.[30] We believe that this method can be applied to selecting the optimal VL device for the military to field in the deployed setting. Furthermore, some of the newer devices use smartphone technology, including device connections to the phone, which may further enhance screen resolution while reducing costs. However, these devices may not be compatible with the security requirements of future conflicts given the electromagnetic signal they emit.[31]

Our study has several limitations to highlight. First, the survey participants knew we had to stop the clinical trial early due to the i-view's poor clinical performance; this may have biased their answers. Second, survey administration occurred after the study's completion, and therefore, there may be recall bias. Third, our survey only underwent face validation. Serial iterations of the survey may have elucidated further detail. Fourth, only one of our two clinical sites included military physicians; thus, we have limited feedback from military personnel best suited to assess the suitability of the technology for use in a deployed setting. Lastly, all of the intubations were performed by physician trainees, so the application to physician assistants and nurse practitioners may be limited.

Conclusion

Our survey highlighted multiple issues with the i-view device in clinical settings. Our findings will inform device development and modification for prehospital deployed use.

Author Contribtions

SGS, JKM, MDA, and VSB were involved in the grant application. SGS, AAA, BJL, WTD, JKM, MDA, AAG, and VSB developed and obtained regulatory approvals. SGS and DRA served as the primary site investigators. JM was the primary research coordinator involved in prospective data collection, regulatory management, and data verification. AAA was the study statistician. SGS drafted the manuscript, with all other authors providing critical revisions. All authors contributed substantially to the research study. SGS is the study and grant principal investigator and accepts responsibility for all aspects of the study.

Disclosures

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Disclaimer

The views expressed in this article are those of the authors and do not reflect the official policy or position of the U.S. Army

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