Capability and Effectiveness the TCI,™ a Dynamically Controllable Introducer, in the Context of Rescue after Failed Video Laryngoscopy and Direct Laryngoscopy.

Evaluation of a single hospital system's experience.

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ABSTRACT:

Multiple intubation attempts are associated with increased morbidity and mortality. In the face of failed attempts with video laryngoscopy and/or direct laryngoscopy, the ability to quickly and effectively rescue an intubation using alternative advanced intubation techniques is important to limit the number of total attempts and reduce the risk of harm to patients. The effectiveness of other common advanced intubation techniques in the context of rescue has been studied. Nothing is known about the effectiveness of the Total Control Introducer™ (TCI™) in the context of rescue after failed video and/or direct laryngoscopy. A large, single hospital system, airway management database was studied to understand the capabilities and effectiveness of the TCI™ articulating introducer as a rescue technique.

METHODS:

A database containing five years of consecutive anesthesia cases was analyzed for cases in which the TCI™ articulating introducer was used as a rescue technique after failed laryngoscopy. The primary outcome was the success rate for tracheal intubation after failed video and/or direct laryngoscopy using a TCI.™

RESULTS:

A total of **34** cases were identified in which the TCI™ articulating introducer was used after failed video laryngoscopy, direct laryngoscopy, and even after a failed fiberoptic bronchoscope. The overall success rate was **33/34 (97%)**. Of these successes, **32/33 (97%)** were successful on the first pass, and **1(3%)** was successful on the second pass. Importantly, rescue with the TCI™ articulating introducer was successful in **12/12 (100%)** of the subset of cases in which both video and direct laryngoscopy had failed.

CONCLUSION:

In this single-center study, the TCI™ articulating introducer in combination with a video laryngoscope was found to be capable of rescue after failed direct laryngoscopy, failed video laryngoscopy, and even failed fiberoptic intubation. Most importantly, the TCI™ articulating introducer was able to rescue **100%** of the cases where both video and direct laryngoscopy failed. The rescue intubation success rate of video laryngoscopy combined with the TCI™ articulating introducer found in this study, is superior to published rescue success rates of fiberoptic intubation, intubating supraglottic airway, lighted stylet, and optical stylet. It is similar to the published success rate of combined techniques utilizing laryngoscopes with fiberoptic bronchoscopes.

INTRODUCTION:

Direct laryngoscopy **(DL)** and video laryngoscopy **(VL)** are the most common primary techniques used to perform tracheal intubation. Both techniques can fail, either individually or in sequence, signaling that the patient has a difficult airway. There is a clear correlation between the number of intubation attempts and morbidity and mortality.[1 2] The ability to predict difficult intubations is poor.[3] It is therefore essential to have plan B, or even plan C, advanced airway techniques readily available in the event of DL and/or VL failure. Understanding the capability and effectiveness of advanced airway techniques in the context of 'rescue after failed laryngoscopy' is important.

Common advanced airway techniques include intubating supraglottic airways (**iSGA**), flexible fiberoptic bronchoscopes (**FOB**), lighted stylets, optical stylets, and combined technique (**VL+FOB or DL+FOB**). A recent large, retrospective, multicentered study demonstrated rescue success rates after failed laryngoscopy to be iSGA (**78%**), FOB (**77%**), lighted stylet (**77%**) and optical stylet (**66%**).[3] Such high rates of failure to rescue is alarming as each attempt is one more step towards the danger zone of "cannot intubate and cannot ventilate".[4]

An advanced intubation technique with a perfect success rate, short learning curve, and single-operator execution is considered the 'Holy Grail' of airway management.[5] This technique has yet to be found and proven. One candidate for the 'Holy Grail' is combined VL+FOB in which the visualization capabilities of a VL are complimented with the flexible shaft and dynamic tip control of a FOB.

In an intriguing study by Lenhardt et al. (**2014**), subgroup analysis found that this combination of VL+FOB was able to intubate **20/20** with cervical spine pathology with limited neck mobility; known risk factors for difficult intubations with VL.[6] This subgroup was too small of a group to be statistically definitive. It is, nonetheless, an intriguing glimpse into 'what might be'.

Another study by Sgalambro et al. (**2013**), demonstrated perfect rescue success using a combination of DL+FOB in **253** unexpected difficult intubations.[7]

The Total Control Introducer™ (**TCI™; Through The Cords, LLC; Salt Lake City, UT**) is an articulating introducer designed to mimic the flexible shaft and articulating tip of a FOB without any optical capabilities. (*See figure 1.*)

The TCI™ is used in combination with a VL. VL provides a glottic view and the TCI™ provides easy access to the trachea via its flexible shaft and fully articulating tip. (**See supplemental video 1**)

It is known that VL provides a consistently better view of the glottis than DL.[8,9] FOB is the gold standard difficult airway management devices due to its combination of precision maneuverability and internal optical capabilities.[5]

In theory, VL's superior view combined with the dynamically controllable tip and flexible shaft of the TCI™ can allow both major problems of intubation, visualization of the glottis and tracheal access to be solved at once. This may lead to success rates comparable to classic combined techniques using VL+FOB when managing difficult intubations.

Nothing is known about the TCI's™ ability to rescue after failed laryngoscopy. The TCI™ has been in use at the University of Utah for **1.5 year**s. We set out to investigate the rescue performance of the TCI™ after failed laryngoscopy.

METHODOLOGY:

This study design is a retrospective, single hospital system, consecutive case, chart review.

Approval for this study was granted by the University of Utah Health Sciences Institutional Review Board. 'Anesthesia Perioperative Analytics as the University of Utah Covered Entity' **IRB#0096411**.

A continuously collecting database was set up five years ago to archive all consecutive airways managed in the course of the provision of an anesthetic by the University of Utah Department of Anesthesiology in all operating rooms, including both in-patient and outpatient sites.

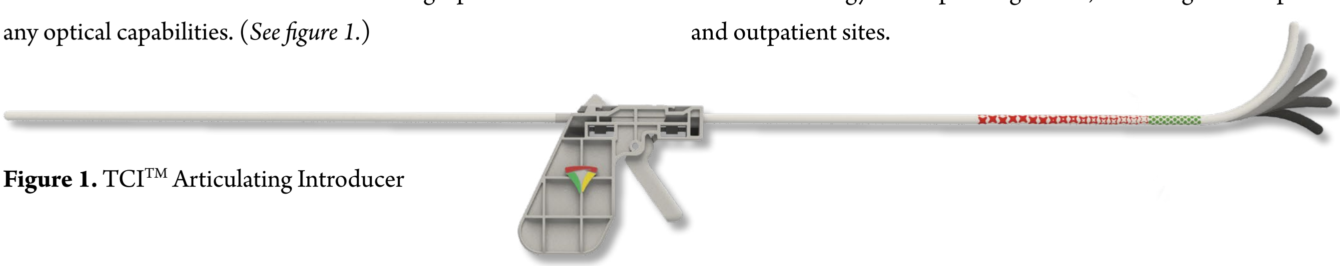

Figure 1. TCI™ Articulating Introducer

In total, **138,387** consecutive individual cases were logged into the University electronic medical record (**EPIC**®) and collected into a database from **5/12/2015** through **8/20/2020**. This database was methodically searched for the use of a TCI™ articulating introducer. These cases were then evaluated for cases in which the TCI™ use as a rescue technique after failed attempts with any other intubation technique.

These TCI™ rescue cases were then evaluated for antecedent failed techniques, the number of attempts with the TCI™ to intubate, and the success or failure of the TCI™ to intubate.

Data fields include: intubation devices used, the free text airway procedure note detailing specifics of airway management, the date of case, the in-room time stamp, induction time stamp, and intubated time stamp. Data is archived on an excel spread sheet.

A retrospective data pull of all anesthesia airway notes was performed from the **5/12/2015** through **8/20/2020**. These included all operating room sites in our system.

A total of **138,387** airway notes were found. These were then searched for those cases in which a TCI™ use was documented in the airway note.

A total of 167 cases were identified in which the TCI™ was used. **('Any TCI™ used' subset.)**

The subset of 'any TCI™ used' was then searched for those cases in which a TCI™ was used after failed attempts with other intubation techniques. **('TCI™ rescues' subset.)**

A total of **34** cases were found in which the TCI™ was used for rescue.

This subgroup of 'TCI™ rescues' cases was then evaluated to determine these endpoints:

1) What preceding technique or techniques had failed.

2) The number of cases in which TCI™ rescue was successful overall.

3) The number of cases in which the TCI™ was successful on the first rescue attempt.

4) The number of cases in which the TCI™ was successful after multiple attempts.

5) The number of cases in which the TCI™ failed to rescue.

RESULTS:

A total of **34** cases were identified in which the TCI™ was used as a rescue technique. The rescue was successful in 33/34 using the TCI™ for an overall success rate of **97%**. Of these successes, **32/33** were on the first pass and one on the second pass. (*See Table 1. for results*).

In the sub-group analysis of antecedent technique failures rescued with a TCI™, the rescue was successful after eight failed DLs, after **14** failed VLs, and **12** cases where both DL and VL failed (*See Table 2. for results*).

DISCUSSION:

An easy to learn, single operator, capable and effective advanced intubation technique is the 'Holy Grail' of airway management.[5] It has yet to be found and proven.

Table 1. Successful rescues after any failed intubation attempt

The Overall number of cases with a TCI™ rescue attempted	Overall VL+TCI™ rescue attempt success	First Pass VL+TCI™ rescue attempt success	Second Pass VL+TCI™ rescue attempt success	VL+TCI™ failure to rescue
34	33/34 (97%)	32/34 (94%)	1 (3%)	1 (3%)

Table 2. Successful rescue after various failed intubation attempts subgroup analysis.

Proceeding failed techniques	The Overall VL+TCI™ rescue attempt success	First Pass VL+TCI™ rescue attempt success	Second Pass VL+TCI™ rescue attempt success	VL+TCI™ failure to rescue
After Failed DL and VL	12/12 (100%)	12	0	0
After Failed DL only	7/7 (100%)	7	0	0
After Failed VL only	13/14 (93%)	12	1	1/14 (7%)
After failed DL and VL and FOB	1/1 (100%)	1	0	0

The wide variety of skills, settings, and individual patient anatomic and physiologic characteristics means that primary intubation techniques such as DL and VL can fail. In these cases, it is critical to have advanced intubation techniques readily available to rescue the intubation. Therefore, it is essential to understand how different advanced techniques perform in the context of rescue.

Successful intubation involves two steps: **1)** visualization of glottis and **2)** accessing the trachea with the endotracheal tube (**ETT**). More than three intubation attempts or blind insertion of ETT can increase the risk of 'cannot intubate-cannot ventilate' by causing complications such as bleeding or tissue edema [1]

Understanding why VL and DL fail is useful. In the case of DL, most failures take place due to the inability to visualize the glottis. VL improves the glottic view by allowing providers to 'look around the corner'; however, this comes at the cost of creating two directionally opposed curves in the upper airway with an inflection point at the glottis. This serpentine pathway through the upper airway to the glottis and then into the mid-trachea can make accessing the trachea difficult.[10] Failure to successfully navigate this serpentine pathway accounts for up to half of intubation failures with VL.[11] This is the paradox of VL; the superior view comes at the cost of challenging tracheal access.

As VL and DL tend to fail for opposite reasons (**DL because of visualization and VL because of access**), each can serve as a rescue technique for the other.[3] Failure of both DL and VL is alarming as it signals a truly difficult intubation. In these cases, capable and effective advanced airway techniques become critical to protect the patient from harm.

Common advanced rescue techniques include FOB, iSGA (**with or without FOB**), and combinations of VL or DL laryngoscopes and FOB.[7] Each has advantages and disadvantages. None are perfect, and success rates in the context of rescue are disturbingly low save for combined techniques.

The most promising advanced technique is the combination of VL+FOB. This combination harnesses the easy to obtain, superior and panoramic view of the glottis provided by VL with the superior tracheal access capabilities provided by the dynamically articulating tip and flexible shaft of the FOB.

VL was introduced into practice over a decade ago with the focus on solving the visualization problem. Interestingly, few introducers have been designed explicitly for VL.[12, 13, 14] The capability of dynamic tip articulation while in the upper airway to ease navigation of the serpentine pathway into the trachea seems a major gap in intubation technology. This 'tracheal access gap' may be a real limit to the overall performance of video laryngoscopes. Current 'combined techniques' depend on cross-purposing a FOB for dynamic navigation. Using a FOB to fill this gap comes with drawbacks of cost, immediate availability and the need for two skilled operators in order to execute.

Lenhart et al. studied VL+FOB demonstrating the ability to rescue after failed VL using a standard rigid, pre-curved stylet.[6]

In addition **20/20** patients with cervical spine pathology and limited neck range of motion were successfully intubated using VL+FOB. Interestingly, in this study, it is not clear whether the FOB was used at all for visualization, or only for its navigational capabilities.

Sgalambro et al. studied a combined technique utilizing DL+FOB in unexpected difficult airways. All **253** patients with unexpected difficult intubations were successfully intubated using DL+FOB.[15] They also found that the learning curve was only ten intubations.

Mazzinari et al. studied the combination of VL+FOB with the FOB was used only as a dynamically shapable stylet in predicted difficult airways. This study found that a dynamically shapable stylet resulted in a significantly higher first pass rate, a significantly lower injury rate, and a significantly lower intubation time when compared to the standard rigid pre-curved stylet.[16]

The main limitations to the widespread dissemination of these highly effective combined techniques are cost, immediate availability, and the need for two operators for execution. These limitations are mainly associated with the FOB.[17]

Our study found that the modified combined technique using VL+TCI™ was capable of rescue after failed VL and DL, and in one case, failed FOB with a success rate similar to other classic combined techniques.

Most importantly, in all cases where both VL and DL failed, the combination of VL+TCI™ was able to rescue on the first attempt. This is important, as failure of both VL and DL techniques signals a truly anatomically difficult airway and a growing risk of harm to the patient. In these cases, it is critical that the patient's intubation be solved with as few further attempts as possible.

Advantages of the modified combined technique utilizing VL+TCI™ over combined techniques utilizing a FOB are; lower costs, immediate availability, and single-operator execution.

The capability and effectiveness of the TCI™ in combination with VL found in this study support the need for further investigation to gain a greater understanding of the capabilities and effectiveness of VL+TCI™ as an advanced airway management tool in a wider variety of settings. This study includes only operating room intubations performed by anesthesia providers. Further studies are needed to understand if the capabilities and high rate of success observed in this study are similar in other settings.

The next step is to perform a retrospective case-controlled study comparing VL+TCI™ with other common advanced airway techniques to understand other important factors such as learning curve, time to intubation, and rescue success rates.

CONCLUSION:

In this study, the modified, combined technique using VL+TCI™ was shown capable of rescuing after failed DL, failed VL, and even failed FOB. Most importantly, VL+TCI™ was able to rescue **100%** of the cases where both VL and DL failed. The success rate of VL+TCI™ rate found in this study is superior to published success rates of FOB, iSGA, lighted stylet, and optical stylets. The success rate of VL+TCI™ found in this study is similar to published success rates of classic combined techniques utilizing VL or DL+FOB.

Further studies are needed to fully understand the value of VL+TCI™ as an advanced airway management tool.

CONFLICT OF INTEREST:

Sean Runnels MD is the inventor of the TCI™ and holds shares in Through The Cords, LLC. He was involved in study design and manuscript writing. He was not involved in any data collection or evaluation. No other authors reported any conflicts of interest.

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