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At Higher Risk of Difficulty Is Not True Difficulty: The Challenge of Device Performance Assessment in the Difficult Airway

To the Editor:

I read with interest the article by Aziz *et al.* on the comparative effectiveness of the C-MAC® video laryngoscope *versus* direct laryngoscope in the setting of the predicted difficult airway.[1] I congratulate them on a well designed and executed prospective comparison study, providing more information to clinicians regarding the performance of this device.

Aziz *et al.* examined the clinical entity of patients who are best described as being at increased risk of difficulty during laryngoscopy because of abnormal preoperative airway testing, but not truly difficult at laryngoscopy. By examining their figure 2, it can be seen that the majority of the study population had an easy view at laryngoscopy (Cormack–Lehane view grades I or II) irrespective of whether the C-MAC® (Karl Storz, Tuttlingen, Germany) or standard direct laryngoscopy was used.

Unfortunately, their findings are incorrectly extended to conclude a performance benefit when using the C-MAC® in true difficult airways compared with standard direct laryngoscopy. The low incidence of true difficulty at intubation in their study population is unsurprising given the weakness of our current preoperative airway tests to predict true difficulty at laryngoscopy.[2] Prediction is further weakened by the accepted definition of true difficulty at laryngoscopy (Cormack–Lehane view grades III or IV during direct laryngoscopy), as in clinical practice many patients with a grade III view are relatively easily intubated with or without the use of a bougie. The use of a bougie during standard direct laryngoscopy was not considered in their study design, limiting its overall clinical relevance.

Success at first laryngoscopic attempt was chosen to be the outcome of interest. The authors reasoned that this was because of safety concerns regarding multiple intubation attempts in patients with true difficult airways. As previously discussed, the great majority of their study population consisted of easy laryngoscopy, making the point less valid. This outcome of first-attempt success is particularly affected by unblinding, because the clinician randomized to the direct laryngoscopy group may be inclined to abandon the direct laryngoscopy attempt early and move on to another device managing these patients thought to be at risk of laryngoscopic difficulty. In contrast, the unblinded providers may have been more inclined to persevere with the C-MAC®, with the idea that this device has particular utility in the difficult airway. After examining their figure 1, it can be seen that the actual overall success rate for C-MAC® *versus* direct laryngoscopy use was 96% *versus* 92%, respectively. This difference is not statistically significant. The emphasis on first-attempt success is certainly of interest, but does reduce the clinical relevance of their findings. The term "overall success rate" is used misleadingly throughout the manuscript when describing the first-attempt success rate.

The efficacy of a new laryngoscopic device in patients with a known difficult airway is very hard to study. The use of such a device in an anesthetized, paralyzed patient with a known difficult airway is ethically dubious given the accepted guidance that a technique that retains spontaneous ventilation should be considered when difficulty is anticipated at laryngoscopy.[3] The most common method used by North American anesthesiologists in this situation is awake fiberoptic intubation.[4] For this reason, prospective studies of novel airway devices in elective intubations, where laryngoscopy is known to be truly difficult, are rare and likely unethical. The use of good retrospective data to study such a rare occurrence should not be discounted, particularly when ethics, blinding, and the requirement of adequate statistical power preclude a prospective study design.

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In Reply:

We thank Xue *et al.* as well as Healy for their interest in our work and for the excellent questions regarding our randomized controlled study, "Comparative effectiveness of the C-MAC video laryngoscope *versus* direct laryngoscopy in the setting of the predicted difficult airway."[1]

Xue *et al.* raised concerns regarding the training level that the providers had with the two devices tested. All providers were proficient in direct laryngoscopy and had exposure to the tested video laryngoscope before the commencement of the randomized controlled study. We agree that it would be also reasonable to design a study that exactly quantifies the prestudy experience with a device. Our study design aimed at comparing the clinical effectiveness of the two different airway management tools in a defined clinical challenge ("predicted difficult airway"). It is very well possible that with more clinical experience using the video laryngoscope, the performance with the device could have been optimized further. Therefore, we find it remarkable that despite less clinical experience as compared with direct laryngoscopy, the intubation success on first attempt was better with the new video laryngoscope. The data of this study suggest that the learning curve for video laryngoscopy is steep and the implementation of the new technology will offer immediate measurable benefit for the provider.

Xue *et al.* raise concerns about the sample size. The study design was based on a careful power analysis regarding the primary outcome. We reported all secondary outcomes in order to provide the reader and potential researchers in the field with additional information about the study population and clinical environment. Accordingly, we did not explore conclusions around the relative performance of resident anesthesiologists, attending anesthesiologists, or certified nurse anesthetists.

Xue *et al.* raise concerns that intubation failure in the video laryngoscopy group occurred secondary to an omission of a stylet from the endotracheal tube while approaching intubation. Although not explicitly mentioned in the method section of the publication, providers were guided to use a styleted endotracheal tube for the initial attempt, and asked to remove it if a gum–elastic bougie was used. We expected that intubation failure would occur with the use of the video laryngoscope despite an optimized laryngeal view, because it has been described in the literature before.[2,3] Although this is likely a multifactorial problem and for some providers may be related to the level of experience with the technique, the failure in this study was not because of lack of stylet use. Future research is poised to determine the nature of video laryngoscopy failure in the setting of an adequate laryngeal view.

Healy expresses concerns about the definition of "difficult airway" in our study. He points to the heart of the problem when he calls the clinical practice of airway assessment at the bedside before anesthesia of limited predictive value. Yentis has contributed an outstanding dissection of the dilemma that our field is facing in this regard.[4] Although bedside tests may have a reasonable negative predictive value, providers have few tools to guide their care when these predictors do exist. For the most concerning airways, preserving spontaneous ventilation is appropriate, and we encourage the practitioners to maintain appropriate equipment and skills available for this very vulnerable patient population, as Healy suggests.

Healy also suggests that clinical research that aims at identifying the role of particular airway management solutions should take into consideration the outcome of multiple intubation attempts. The design of our study was guided by the goal to determine which of the two tested devices provides the best first-attempt success and therefore can be suggested to the practitioner as the most effective first choice to successfully intubate a patient with a suspected difficult airway according to the preanesthesia assessment. The result of the study now suggests using video laryngoscopy as the best first choice in such situations, and thereby has important clinical implications for the day-to-day practice in anesthesiology.

Healy also raised concerns that the study was not blinded for the providers. We see no alternative to this study design, as in other research that involves manual techniques. We determined objective criteria that demonstrated that the gum–elastic bougie and external laryngeal manipulation were less frequently applied when the case was randomized to the video laryngoscope system. A gum–elastic bougie facilitated eight endotracheal intubations in the video laryngoscopy group and 14 in the direct laryngoscopy group. We conclude from this data that the video laryngoscope requires less frequent use of airway adjuncts likely related to the improved laryngeal view achieved as demonstrated in our study.

Healy suggests studying the known difficult airway separately. We agree that more evidence would help to determine the optimal techniques for managing the known difficult airway. Although we support conducting randomized clini-