Fiberoptic *versus* Videolaryngoscopic Management of the Difficult Airway: Problems with Postrandomization Patient Exclusion

To the Editor:

We read with interest the recent article by Rosenstock *et al.*[1] comparing the success of fiberoptic *versus* videolaryngoscopic intubation in patients with difficult airways. In that study, the authors conclude that there are no important differences between the two techniques. However, we are concerned by the postrandomization exclusion of a large number of patients from the analysis (9 of 93). In addition, there was a striking imbalance between the groups in the number of excluded patients (2 of 45 from the fiberoptic group and 7 of 48 from the videolaryngoscopy group). These exclusions have the potential for biasing or distorting the conclusions of the study.

It is unclear why a number of these patients (*i.e.*, the seven in whom a transtracheal injection was impossible) were enrolled in the study. It presumably would have been possible, based on a physical examination, to identify these patients before the randomization. In addition, the authors do not provide any *a priori* criteria for postrandomization exclusion, leaving open the possibility that the decision to exclude was left in the hands of the study providers at the time of the case—a potentially serious cause of exclusion bias. However, regardless of these issues, intention-to-treat rules demand that, because these nine patients were enrolled, randomized, and studied, they must somehow be included in the analyses; they cannot simply be discarded.

We appreciate the problems of analyzing data when the experiment was difficult or impossible to complete as planned. There is, however, an established literature on dealing with missing data,[2–4] and there are many different approaches depending on the nature of the data and the situation. The authors' primary outcome was time to successful placement of the endotracheal tube. They might assign the shortest observed intubation time (which, from table 3, seems to be 20 s) to all nine excluded patients and rerun the analysis. Alternatively (and perhaps preferably), they might assign the longest possible intubation time (678 s) to all of the excluded patients. For an "extreme case analysis," they could assign the shortest time to the excluded patients in one group and the longest time to the excluded patients in the other (and *vice versa*). Adding two patients with an intubation time of 20 s to the fiberoptic group and seven patients with an intubation time of 678 s to the laryngoscopy group would almost certainly result in a "significant difference" between groups. We agree that this may be too extreme given the large amount of missing data,[5] but it points out the possibility that simply excluding patients from the analysis can confound the results. Conversely, if these various analyses result in a conclusion similar to the original (*i.e.*, that there are no significant differences), then we can be reasonably comfortable that the missing data have not biased the results.

The authors should also include these patients in their secondary outcome analyses, for example, number of attempts. In the authors' table 3, they report the distribution of the number of attempts to secure the airway (one, two, or three attempts). They report a *P* value of 0.64 and conclude that there were no differences. However, this does not include the nine excluded patients. It would be reasonable to classify these as "failures" and add them to the analysis: two failures in the fiberoptic group and seven failures in the laryngoscopy group. When this is done, the *P* value (Fisher exact test) for the comparison decreases to 0.34. If one models a study with twice as many patients (assuming the same distribution of numbers of attempts and the same fraction of failures), the *P* values approach to 0.05—suggesting the possibility that the study was simply underpowered to detect an important difference between the two techniques.

We do not wish to imply that these issues invalidate the authors' work. But at the least, the possible impact of postrandomization exclusions should be discussed as an important limitation of the study and its potential influence on the outcome acknowledged. In addition, it reinforces the absolute necessity of abiding to intention-to-treat rules.

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