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Why Shouldn't *A Priori* Analysis Plans Be Publicly Available for All Observational Studies?

To the Editor:

We read with interest the recent editorial by Eisenach *et al.*¹ on the importance of reporting the *a priori* analysis plan of observational research. In a similar vein, clinical trialists are already very familiar with the need for prospectively registering randomized controlled trials (RCTs); indeed, if you have not registered the RCT, no major anesthesia journal is likely to publish the results. A key aspect of registration is its public accessibility that allows both the reviewer and reader to detect selective reporting, outcome switching, and data dredging. Some trial registries also have the capacity for researchers to upload the entire protocols and analysis plans, which further allows the reader to evaluate the veracity of the published work. Indeed, increasingly, RCT protocols are being published in dedicated journals well in advance of the eventual trial completion.

However, the standards for *a priori* reporting of protocols and analysis plans for observational studies have lagged those for RCTs. Eisenach *et al.*¹ point out that some researchers do register their observational studies in trial registries, even though they are not RCTs *per se*; however, this is a relatively small proportion of observational studies. The change in policy of *ANESTHESIOLOGY* outlined in the editorial now asks authors to indicate if they had an *a priori* analysis plan at all.

ANESTHESIOLOGY also strongly encourages researchers to develop a robust analytical plan and present it to a peer-review forum; however, these forums may not necessarily be public. While this is a step toward better reporting, and hopefully all anesthesia journals will follow their lead, it does ask the question as to why we should not expect the full analysis plans, or at the very least a summary, to be placed in a truly publicly accessible registry before analysis? This is not difficult to do with currently available registries (*i.e.*, clinicaltrials.gov), and it is possible that doing so further increases the veracity of the results.

Competing Interests

Dr. Davidson is Editor-in-Chief for *Pediatric Anesthesia*, and Dr. Grocott is Editor-in-Chief for *Canadian Journal of Anesthesia*.

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Reference

1. Eisenach JC, Kheterpal S, Houle TT: Reporting of observational research in *ANESTHESIOLOGY*: The importance of the Analysis Plan. *ANESTHESIOLOGY* 2016; 124:998–1000

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In Reply:

This editorial policy¹ was formulated after discussion with key researchers in observational study design and implementation, including discussion at panels of meetings of the Multicenter Perioperative Outcomes Group in 2013 and 2015. There are two reasons why we chose not to require prior public registration of observational studies as we do for randomized clinical trials. First, many observational studies utilize publicly available data, and there was concern that publication of a study, analysis plan, and identification of the database could result in others with more resources taking these ideas, performing the analysis, and publishing the results before the original investigator. This is less of a concern with clinical trials, which often require many months to even initiate. Second, clinical trial registration was formed in large part to avoid underreporting of negative results, especially trials supported by industry. Multicenter Perioperative Outcomes Group investigators and editors of the Journal felt that underreporting of negative results in observational studies was likely a minor problem. Rather, lack of *a priori* definition of an analysis plan would more likely yield positive results due to the multiplicity of analyses that could be performed.

Competing Interests

Dr. Eisenach has received consultant fees from Teva Pharmaceuticals and Adynxx and has received salary support

from the American Society of Anesthesiologists as Editor-in-Chief of ANESTHESIOLOGY.

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1. Eisenach JC, Kheterpal S, Houle TT: Reporting of observational research in ANESTHESIOLOGY: The importance of the analysis plan. ANESTHESIOLOGY 2016; 124:998–1000

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Is Tapered-cuff Shape a Risk Factor for Overinflation of Tracheal Cuff?

To the Editor:

We read with interest the study by Monsel *et al.*¹ on the relationship between tapered-cuff tracheal tube and early postoperative pneumonia. The authors should be congratulated for the excellent work they did.

They found no significant difference in the postoperative pneumonia rate or in the microaspiration of gastric contents and oropharyngeal secretions between patients intubated with tapered tracheal tubes and those intubated with standard tracheal tubes. They recorded cuff pressure (P_{cuff}) for 5 h and reported that the percentage of time spent with overinflation of tracheal cuff (P_{cuff} more than 30 cm H_2O) was significantly higher in the tapered compared with the standard groups. They suggested that the higher variations in P_{cuff} might have been related to the tapered-cuff shape and could explain the negative results of their study. However, in our opinion, the cause-to-effect relationship between the tapered-cuff shape and overinflation of the tracheal cuff is unlikely. First, the percentage of time spent with underinflation was low and not significantly different between the two groups, which is against this hypothesis. Second, P_{cuff} is tightly correlated to airway pressure (P_{aw}). Therefore, no valuable conclusion could be drawn without information on P_{aw} in the two study groups. The significantly higher positive end-expiratory pressure reported in the tapered compared with the standard groups suggests that P_{aw} might have been also higher in the intervention group. Have the authors recorded P_{aw} during P_{cuff} recording? If not, could they at least provide the data usually recorded by nurses every 2 to 4 h regarding P_{aw} ?

Two previous prospective studies including a large number of patients in which P_{cuff} and P_{aw} were continuously recorded for 24 h did not find any impact of tapered-cuff shape on time spent with overinflation, underinflation, or P_{cuff} variations.^{2,3}

The authors concluded that tapered shape had no significant impact on microaspiration of gastric contents or

oropharyngeal secretions. However, pepsin and α -amylase were only measured at two time points (once per day, during two consecutive days). It is well known that microaspiration is not a constant phenomenon, and to evaluate it accurately, one must measure it in consecutive tracheal aspirates during at least 24 to 48 h.⁴ Measuring these markers at several time points allows identification of those patients with abundant microaspiration, *i.e.*, the presence of pepsin or α -amylase at significant concentrations in more than 30% of tracheal aspirates, and a higher risk of ventilator-associated pneumonia. Microaspiration is very common in intubated critically ill patients, but only a few patients develop subsequent ventilator-associated pneumonia. Previous animal studies clearly showed that a higher concentration of bacteria in the lower respiratory tract was associated with an increased risk of pneumonia.⁵ One could argue that microaspiration could not be completely prevented in intubated patients but only reduced using different preventive measures. Therefore, accurate quantification of microaspiration in intubated critically ill patients is a key point in evaluating the efficiency of preventive measures aiming at reducing microaspiration.⁶

Our group performed a large randomized controlled multicenter study to evaluate the impact of tapered-cuff shape on microaspiration of gastric content.⁷ Pepsin and α -amylase were quantitatively measured in all tracheal aspirates during 48 h. The results of the BestCuff study will be helpful to determine the efficiency of tapered-cuff shape in reducing microaspiration.

Competing Interests

Dr. Nseir received funding (lecture) from Medtronic (Dublin, Ireland). The other authors declare no competing interests.

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