**Declaration of interest**

None declared.

N. Smith1*
C. Ashes2
1Wollongong, Australia
2Toronto, Canada
*E-mail: natasmith@hotmail.com

doi:10.1093/bja/aeu044

**Anticipation of the difficult airway**

Editor—We have with great interest read the article by Cattano and colleagues1 on anticipation of the difficult airway (DA). We would like to thank the authors for addressing this pivotal area of our profession. However, we have some major concerns regarding the used study methodology. We find the trial at risk of (1) systematic errors (bias), (2) random errors, and (3) other design errors.

(1) The study is presented as an individually patient-randomized trial, but is in fact randomized in clusters, each population managed by a resident being a cluster. As the study is conducted on one department, how did the authors control for a potential spillover effect from the experimental to the control group? Residents constituting the control group must inevitably have gained information about trial intervention in the experimental group thus influencing their performance. It opens up for huge bias in comparison of the two groups of patients (should have been analysed in clusters).

(2) The reader is not presented with a sample size or a power estimation, which should have been based on a clearly stated outcome measure and adjusted for intra-cluster correlation because of cluster randomization. The number of patients needed in a cluster-randomization is highly dependent on both intra- and inter-cluster correlation and may exceed the number of patients needed for an individual randomization substantially.2 This may induce huge risks of random errors.

(3) We would like to suggest an alternative primary outcome measure as the difference in correct prediction rate of DA between the two groups, hypothesizing superior prediction accuracy using the ASA guideline. It is unclear whether the authors employed intention to treat- or per protocol analyses. The flow diagram (Fig. 2) and the numbers in the text are inconsistent. Also, we find the definition ‘Accuracy of DA prediction’ (Table 2) somewhat misleading. The presented figures are the number of preoperative airway assessments that are in agreement with the actual airway management. Fortunately, DA is a rare situation, also documented by the authors’ result of 11.97% DA corresponding...
to a rate of 88% non-DA. The presented percentages of 71.2 and 69.1%, respectively, are comprised by true positives and true negatives—a vast majority of these being true negatives, that is correctly identified non-DAs. The trial report therefore does not give a clear picture of the prognostic accuracy (‘accuracy rate’) with which the DA is predicted. Further, the level of agreement between preoperative airway assessment and the subsequent actual airway management cannot be assessed by evaluating only true positives and true negatives as random agreement is not taken into consideration this way. Thus, ‘Accuracy of DA prediction’ would be better presented by sensitivity; specificity; positive and negative predictive values, and likelihood ratios. Figures and measurements appear inconsistent and incorrectly calculated in some cases. We find a concerning discrepancy between the study reporting and the recommendation in the consolidated standards of reporting trials (CONSORT) statement— with which clinical trials published in British Journal of Anaesthesia ought to comply. Further, we would like to ask the authors whether a protocol was published or the trial was registered in a trial registry at the beginning of randomization?

Finally, we agree with the authors that a multi-centre trial is needed in order to promote understanding of the optimal use of tools for prediction of DA management. This should be a large trial designed with low risk of bias in agreement with the standard protocol items: recommendations for interventional trials (SPIRIT) and CONSORT statements.

Declaration of interest

None declared.

A. K. Nørskov*  
L. H. Lundstrøm  
J. Wetterslev  
C. V. Rosenstock  
Copenhagen, Denmark  
*E-mail: anderskehlet@hotmail.com


doi:10.1093/bja/aeu041

Reply from the authors

Editor—We thank Nørskov and colleagues for their interest in our prospective, observational study on airway management and resident education. The trial was initiated as a resident education project, continued as a quality improvement project (2005–6), and then supported as a clinical–educational trial by FAER (2007) to assess the efficacy of a comprehensive airway assessment that included all recommendations of the 2003 ASA Difficult Airway Management Guidelines, and a previous pilot study. Nørskov found our study important because it addressed a pivotal clinical issue in our profession but voiced concern regarding the methodology utilized, claiming the trial was at risk of systematic errors, random errors, and other design errors. We concur with Nørskov that the majority of the points raised are not only valid and legitimate, but offer a point of scientific discussion that otherwise would have been neglected, for the sake of brevity and editing necessities in our original work.

We would like to point out that, in general, any study is at risk for such errors, and that proper design tends to mitigate the occurrence of errors. Technically, there is no such thing as a perfect study. The first criticized point of our investigation was the randomization: this occurred based on the resident year, on a 1:1 allocation, and it assumed an equal distribution in terms of experience, skills, and standard training. However, our study did not evaluate education matters only, but and before all, airway management based on patients features and modalities. Our assumptions were similar training between and within the residents, and also a large sample size. Nørskov’s concern that our study was presented as a patient randomized trial but should have been randomized as subjects in clusters: this could have been an option. A cluster randomized trial is a randomized trial in which patients are not allocated to treatments independently, but randomized to different treatment groups at a ‘group’ level. Therefore, the patients in one cluster may behave similarly to members in the same cluster. In general, analysis of cluster trials needs to take into account the clustered nature of the data, otherwise the risk of a type I error rate inflates. Intra-class correlation coefficient is a statistical measure of the dependence within a cluster. Owing to this intra-class correlation, the sample size needed to achieve a specified power is larger than the individual randomized controlled trials. Ignoring this correlation and assuming the subjects of the investigation are independent will mislead the results and overestimate the treatment effect (narrow confidence interval and small P-values). A limitation that is worth mentioning, but also another reason for deciding not to use a cluster analysis, was the preoperative evaluation was not necessarily performed by the same resident who performed the airway management.

Avoiding a ‘spill of effect’ was in our specific study impractical and not possible. Risk for knowledge contamination, data manipulation (from the experimental resident group), and Hawthorne effect needs to be taken into account. Indeed, certain precautions and study control checkpoints were