

Fiberoptic Bronchoscope-guided vs Mini-surgical Technique of Percutaneous Dilatational Tracheostomy in Intensive Care Units: A Comment

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We read with avid interest the article published by authors Kumar et al. titled "Fiber-optic Bronchoscope-guided vs Mini-surgical Technique of Percutaneous Dilatational Tracheostomy in Intensive Care Units," and we appreciate the author's work toward an area that needs to be explored further.¹ Despite its strengths, a few comments pertaining to the methodology need to be addressed. The authors cited a previous prospective randomized study by Hashemian et al. for sample size calculation. The incidence of complications has been considered the primary objective.² With 90% power and an alpha error of 5% the calculated sample size was 120 patients. However, it is unclear as to how much decrease in the incidence of complications in the mini-surgical group as compared to the percutaneous dilatational tracheostomy (PDT) group authors expect. The treatment effect difference between the two groups is one of the most important parameters in sample size calculation and therefore warrants a detailed description by the authors. As per the methodology laid down in the summary available from the Clinical Trial Registry of India (CTRI) (CTRI/2018/04/013191), the primary outcome was mean procedural time and the calculated sample size was 20 patients in each group. We feel that a comment is needed to address why the primary outcome was changed and whether this change was made after the completion of patient recruitment and analysis. Any disagreement between the published and registered outcome usually implies selective outcome reporting based upon significant *p* values. This practice undermines the validity of a clinical trial and may mislead clinicians and policymakers.³ Hence, the finding that mini-surgical tracheostomy is a faster alternative to PDT with the same complication rates, cannot be concluded firmly, until the aforementioned methodological inconsistencies are addressed.

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