Author's response to reviews

Title: Percutaneous versus surgical strategy for tracheostomy: Protocol for a systematic review and meta-analysis of perioperative and postoperative complications

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Author's response to reviews: see over
Dear Mr Sanabria,

Thank you very much for your helpful and thorough revisions to our protocol with the title: “Percutaneous versus surgical strategy for tracheostomy: Protocol for a systematic review and meta-analysis of perioperative and postoperative complications”. Below you will find our answers and comments.

Major Compulsory Revisions

1. Due to the expected low number of events, I suggest to use absolute differences instead of OR.
   We will implement your good proposal and use absolute differences instead of odds ratio.

2. It should be clarified that if clinical or statistical heterogeneity is found, meta-analysis will not be done.
   Thank you for this precious comment. We will be very careful with performing meta-analysis in case of clinical, statistical or methodological heterogeneity. “Meta-analyses will only be performed where this is meaningful i.e. if the treatments, participants, and the underlying clinical question are similar enough to justify pooling.” Furthermore, “the decision to conduct quantitative synthesis with these data will be based upon individual decision for each outcome.” “If substantial heterogeneity (>75%) is identified, this will be explored by pre-specified subgroup analyses.”

3. How will the authors combine outcomes to make a combined endpoint? Adding all outcomes? A yes/no alternative?
   “The combined primary endpoint will be the risk of potentially life-threatening events including loss of airway, false route, tracheal/esophageal injury, major bleeding, gastric aspiration, pneumothorax/-mediastinum, subcutaneous emphysema, difficult tube change, and other potentially life-threatening events.”
   The following sentences were amended in the protocol: “All potentially life-threatening events will be added to calculate the combined endpoint. For each procedure not more than one potentially life-threatening event will be counted to estimate the combined primary endpoint.”

4. There are planned comparisons without RCTs? How do authors planned to deal with this?
   Only RCTs will be assessed in this systematic review, other data such as clinical compared trials without randomization will not be included.

5. How are you going to test publication bias?
   To explore possible publication bias a funnel plot will be created and examined for asymmetry.

Minor Compulsory Revisions

6. LILACS database should be included in the searching obeying to the lack of language restriction paragraph.
   Thank you for this valuable hint. LILACS database was included in the search to prevent unintentional language restriction.

7. Statistical analysis could be explained better (model, for example, was not specified)
   The following phrases were added to the protocol: Whenever sufficient data for a specific outcome are provided, meta-analysis will be performed by use of a random-effects model (DerSimonian 1986). If substantial heterogeneity (>75%) is identified, this will be explored by pre-specified subgroup analyses.
Thank you for giving us the opportunity to resubmit the paper. We would be very pleased if you accepted it for publication.

With kind regards,

Phillip Knebel, MD