BJA Advance Access published December 22, 2014

British Journal of Anaesthesia Page 1 of 10
doi:10.1093/bja/aeu440

BJA

Effect of early tracheostomy on resource utilization and clinical outcomes in critically ill patients: meta-analysis of randomized controlled trials

T. Szakmany[1,2]*, P. Russell[1], A. R. Wilkes[1] and J. E. Hall[1]

[1] Cardiff Institute of Infection and Immunity, Cardiff University, UHW Main Building, Heath Park, Cardiff CF14 4XN, UK
[2] Cwm Taf UHB, Royal Glamorgan Hospital, Llantrisant, UK

* Corresponding author. E-mail: szakmanyt1@cardiff.ac.uk

Editor's key points

- It is unclear whether early tracheostomy in acutely ill, ventilator-dependent patients reduces costs and complications.
- Small trials are unlikely to reliably estimate relative benefits and risks of tracheostomy.
- This study identifies a clear benefit of reduced duration of sedation.
- A policy of early tracheostomy will however increase the number of procedures being undertaken.

Background. Early tracheostomy may decrease the duration of mechanical ventilation, sedation exposure, and intensive care stay, possibly resulting in improved clinical outcomes, but the evidence is conflicting.

Methods. Systematic review and meta-analysis of randomized trials in patients allocated to tracheostomy within 10 days of start of mechanical ventilation was compared with placement of tracheostomy after 10 days if still required. Medline, EMBASE, the Cochrane Controlled Clinical Trials Register, and Google Scholar were searched for eligible trials. The co-primary outcomes were mortality within 60 days, and duration of mechanical ventilation, sedation, and intensive care unit stay. Secondary outcomes were the number of tracheostomy procedures performed, and incidence of ventilator-associated pneumonia (VAP). Outcomes are described as relative risk or weighted mean difference with 95% confidence intervals.

Results. Of note, 4482 publications were identified and 14 trials enrolling 2406 patients were included. Tracheostomy within 10 days was not associated with any difference in mortality [risk ratio (RR): 0.93 (0.83–1.05)]. There were no differences in duration of mechanical ventilation [−0.19 days (−1.13–0.75)], intensive care stay [−0.83 days (−2.05–0.40)], or incidence of VAP. However, duration of sedation was reduced in the early tracheostomy groups [−2.78 days (−3.68 to −1.88)]. More tracheostomies were performed in patients randomly assigned to receive early tracheostomy [RR: 2.53 (1.18–5.40)].

Conclusion. We found no evidence that early (within 10 days) tracheostomy reduced mortality, duration of mechanical ventilation, intensive care stay, or VAP. Early tracheostomy leads to more procedures and a shorter duration of sedation.

Keywords: complications; early medical intervention; survival; tracheostomy; ventilator-associated pneumonia

Accepted for publication: 29 September 2014

Tracheostomy is commonly performed in critically ill patients with the objective of increasing comfort and shortening the duration of sedation, mechanical ventilation, and intensive care stay.[1] However, the evidence to confirm this benefit is unclear.[2]

The alternative is prolonged tracheal intubation which carries the risk of respiratory tract injury and other complications including ventilator-associated pneumonia (VAP) and sinusitis.[3 4] Tracheostomy is associated with procedure-related complications, including bleeding, hypoxia, oesophageal rupture, tracheal stenosis, tracheal granulomas, and death.[2 5–8] There has been a significant increase in the utilization of tracheostomies especially since the introduction of bedside percutaneous tracheostomy in the mid-1980s.[9–11] It has been estimated that up to one-third of patients who undergo mechanical ventilation in the intensive care unit (ICU) will undergo tracheostomy.[10 11] As the percutaneous technique has become widely available, the earlier use of tracheostomy has become commonplace.[10 11]

Consequently, there is ongoing debate about the benefits of early tracheostomy. The objective of this study was to summarize the available evidence through a systematic review and meta-analysis. Specifically, we wished to confirm the effects of tracheostomy within 10 days on critical care resource utilization and short-term mortality compared with late tracheostomy or prolonged intubation.

Methods

Search strategy

We followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses recommendations for this meta-analysis.

Two authors (P.R. and T.S.) independently performed the electronic searches.

We searched the following databases: Cochrane Central Register of Clinical Trials (CENTRAL) (The Cochrane Library 2013, Issue 13); MEDLINE (January 1950 to February 2014); EMBASE (January 1980 to February 2014); CINAHL (1982 to February 2014); the NHS Trusts Clinical Trials Register and Current Controlled Trials (www.controlled-trials.com); LILACS; KoreaMED; MEDCARIB; INDMED; PANTELEIMON; Ingenta; ISI Web of Knowledge and the National Trials Register to identify all relevant randomized controlled trials available for review using the strategy detailed in Supplementary material, Appendix S1. We searched the bibliographies of reports of randomized trials and any identified reviews. Ongoing clinical trials were identified from the clinicaltrials.gov website, and additional studies of interest were found through Internet searches on Google Scholar and hand searches of bibliographies. We identified relevant studies initially by title then by abstract and finally by full text. All studies in human beings that were published in full text, abstract, or poster form were eligible for inclusion, with no restrictions on publication date, language, or status. The authors resolved any discrepancies by discussion, if necessary.

Selection criteria

We included randomized clinical trials conducted in adult critically ill patients expected to require prolonged mechanical ventilation of between 24 h and 21 consecutive days, for more than 6 h per day. We included trials where one of the groups received early tracheostomy, this must be carried out within 10 days of mechanical ventilation; the alternative is prolonged tracheal intubation with the potential for a tracheostomy to be placed after 10 days.

Unmasked quality assessment on the selected published studies (not abstract reports) was carried out by two investigators, (T.S., P.R.) on composite aspects of study quality. To draw conclusions about the overall risk of bias for an outcome it was necessary to evaluate the trials for major sources of bias, also defined as domains (random sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting, and other sources of bias).

Data extraction

Data extracted for each eligible study included: author; year of publication; number of subjects; timing of tracheostomy; number of procedures performed in each group; primary and other study outcomes; commercial support; mortality within 60 days; mortality at the longest reported follow-up, incidence of VAP; incidence of complications of procedure (where reported).

If sufficient studies were identified we constructed funnel plots (trial effect *vs* standard error) to assess for possible publication bias, expressed by asymmetry.[12] In the case of asymmetry we chose to apply the Arcsine–Thompson test, as proposed by Rücker and colleagues.[12] In case of publication bias, we have repeated the analysis by removing the affected trial from the analysis.

Data collection and evaluation

Two authors (P.R., T.S.) independently extracted data (as far as possible) on the basis of an intention-to-treat analysis and entered all data independently into Review Manager (RevMan 5.3.1.) after checking for differences.

We used the Mantel–Haenszel model to calculate pooled risk ratios (RRs) and 95% confidence intervals (CIs) with random effects model or fixed-effect model depending on the presence or absence of statistical heterogeneity, respectively. Heterogeneity across studies was measured by I^2 statistics examining the percentage of heterogeneity because of variation between studies (0% suggest no heterogeneity; a value between 0 and 25% suggests very low heterogeneity; a value between 25 and 50% suggests low heterogeneity; a value between 50 and 75% suggests moderate heterogeneity; a value of >75% suggests high heterogeneity). When I^2 was >50% we applied the random effects model as described before. The mean difference for continuous data was analysed using the inverse variance method.

Outcome measures

The co-primary outcomes were short-term mortality within 60 days, duration of mechanical ventilation, duration of sedation, and duration of intensive care stay. Secondary outcomes were the number of tracheostomy procedures performed, ventilator-associated pneumonia and mortality at longest follow-up.

Results

We identified 4482 potential studies in the initial electronic search. No additional studies were identified after screening of reference lists of potentially eligible studies and previously published systematic reviews (Fig. 1). We included 14 published trials conducted between 1976 and 2011 and including 2406 patients.[13–26] A detailed description of each trial included can be found in Table 1. Combining the data from the studies showed no significant difference in the relative risk of short-term (up to 60-days) mortality between the groups: 356/1180 (30.2%) deaths in the early tracheostomy *vs* 391/1226 (31.9%) deaths in the prolonged intubation group, RR: 0.93 (95% CI 0.83, 1.05; I^2=12%) (Fig. 2).

Early tracheostomy was not associated with any significant difference in duration of intensive care stay, duration of mechanical ventilation or incidence of VAP (Figs 3–5). We found that the duration of sedation was significantly shorter in the early tracheostomy group (5 studies, 1425 patients, −2.78 days 95% CI: −3.68, −1.88) (Fig. 6).

There was no difference in the long-term outcome, which was assessed at the longest reported time by the studies (14 studies, 2281 patients RR: 0.95 95% CI: 0.87, 1.03 I^2=0%) (Fig. 7). Where data were available, we analysed the number of those patients randomized to an early tracheostomy treatment arm and those who received this allocated treatment. The tracheostomy utilization was significantly higher in the