Systematic review and meta-analysis of studies of the timing of tracheostomy in adult patients undergoing artificial ventilation

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Abstract

Objective To compare outcomes in critically ill patients undergoing artificial ventilation who received a tracheostomy early or late in their treatment.

Data sources The Cochrane Central Register of Clinical Trials, Medline, Embase, CINAHL, the National Research Register, the NHS Trusts Clinical Trials Register, the Medical Research Council UK database, the NHS Research and Development Health Technology Assessment Programme, the British Heart Foundation database, citation review of relevant primary and review articles, and expert informants.

Study selection Randomised and quasi-randomised controlled studies that compared early tracheostomy with either late tracheostomy or prolonged endotracheal intubation. From 15 950 articles screened, 12 were identified as “randomised or quasi-randomised” controlled trials, and five were included for data extraction.

Data extraction Five studies with 406 participants were analysed. Descriptive and outcome data were extracted. The main outcome measure was mortality in hospital. The incidence of hospital acquired pneumonia, length of stay in a critical care unit, and duration of artificial ventilation were also recorded. Random effects meta-analyses were performed.

Results Early tracheostomy did not significantly alter mortality (relative risk 0.79, 95% confidence interval 0.45 to 1.39). The risk of pneumonia was also unaltered by the timing of tracheostomy (0.90, 0.66 to 1.21). Early tracheostomy significantly reduced duration of artificial ventilation (weighted mean difference −8.5 days, 95% confidence interval −15.3 to −1.7) and length of stay in intensive care (−15.3 days, −24.6 to −6.1).

Conclusions In critically ill adult patients who require prolonged mechanical ventilation, performing a tracheostomy at an earlier stage than is currently practised may shorten the duration of artificial ventilation and length of stay in intensive care.

Methods

We defined a randomised trial as one in which patients were assigned prospectively to either early tracheostomy or late (or no) tracheostomy by random allocation at time of enrolment. We defined early tracheostomy as a tracheostomy conducted up to seven days after admission to the intensive care unit, initiation of translaryngeal intubation, and mechanical ventilation. Late tracheostomy was any time thereafter.

We used several techniques to identify published and ongoing studies for this review. We searched Medline, CINAHL, Embase, the Cochrane Central Register of Clinical Trials, the National Research Register, the NHS Trusts Clinical Trials Register, the Medical Research Council UK database, the NHS Research and Development Health Technology Assessment Programme, and the British Heart Foundation database in January, May, and November 2004. The search strategies for Medline were based on the terms recommended by the Cochrane Collaboration to identify randomised trials coupled with the term "tracheo*" to identify tracheostomies. We identified relevant studies initially by title, then by abstract, and finally by full text. Initially two authors did the electronic searches in duplicate and then repeated them independently. We also searched the
bibliographies of reports of randomised trials and any identified reviews. Finally we contacted UK experts in the subject.

**Study selection and data extraction**

We selected studies for inclusion in the analysis if they were randomised or quasi-randomised clinical trials including adult patients requiring artificial ventilation. The intervention was early tracheostomy, compared with either continued translaryngeal intubation or continued translaryngeal intubation followed by late tracheostomy. The primary outcome measure in the review was mortality; secondary outcomes were length of stay in the critical care unit, duration of artificial ventilation, and incidence of ventilator associated pneumonia. We combined hospital and 30 day mortality in the analysis, and if the point at which mortality was assessed was not given we assumed it to be hospital mortality. Not all studies included all outcome measures.

**Statistics and analysis**

We recorded mortality and the presence of hospital acquired pneumonia at any time in the study period as binary variables and length of stay in the critical care unit and duration of artificial ventilation as continuous variables. We used a random effects meta-analysis with RevMan 4.1 software (Cochrane Collaboration, Oxford) to analyse the data. We considered $I^2 > 50\%$ to indicate significant heterogeneity between the trials.

**Results**

The initial searches identified 15 950 unique titles. After initial screening by title and then abstract, we identified 12 randomised clinical trials from manuscript review. We excluded studies without either an English title or abstract. We also identified one study from a published conference abstract.24 We did not find any further relevant publications by reviewing the bibliography of the selected studies and review articles.

We then excluded two of the randomised studies because the timing of early and late tracheostomy were separated only by a 24 hour period,25 26 another because the timing of the early tracheostomy was after seven days (a criterion of this review),27 and a further two because the articles did not contain any data on the outcome measures on which this review is based.28 29 We excluded another study because of unclear evidence of bias either in the selection of patients or their exclusion after randomisation, as a 1:1 randomisation schedule resulted in an approximately 5:1 final distribution of patients between study arms.30 Finally we excluded another study as it described only the study design.31 Figure 1 shows the search process.

Overall, only five trials with a combined study population of 406 patients were original, randomised or quasi-randomised, methodologically sound clinical trials of the timing of tracheostomy in the management of artificially ventilated, critically ill adults. These studies spanned a 20 year period between 1984 and 2004. One of the studies compared tracheostomy only with continuing translaryngeal intubation,25

Table 1 summarises the study characteristics. The two oldest studies25 26 were quasi-randomised, using randomisation techniques that allowed the assignment of the patient to be determined before enrolment, thereby producing a potential for bias. The studies by Saffle et al and Rumbak et al were appropriately randomised.6 17 The most recent study was described as randomised but did not define its randomisation strategy.18 24

Each of the studies examined different populations of critically ill patients, in critical care units for surgical, trauma, and burns patients and one multicentre study in three medical critical care units. All studies came from the United States, with the exception of the Moroccan study of Bouderka et al.

**Mortality**

Information on hospital mortality was available for four of the five studies (332 patients). Figure 2 shows the random effects meta-analysis of relative risk of hospital mortality for early compared with late tracheostomy. The timing of tracheostomy did not alter mortality significantly (relative risk 0.79, 95% confidence interval 0.45 to 1.39, P = 0.42).

**Risk of hospital acquired pneumonia**

Information on the number of patients developing hospital acquired pneumonia while in the intensive care unit was available for all five studies. Figure 3 shows the random effects meta-analysis of relative risk of hospital acquired pneumonia for early versus late tracheostomy. The risk of developing hospital acquired pneumonia was unchanged by tracheostomy timing (0.90, 0.60 to 1.21, P = 0.48).

**Duration of artificial ventilation**

Information on the duration of artificial ventilation was available for four of the five studies (332 patients). Figure 4 shows the forest plot. The combined results showed duration of artificial ventilation to be significantly lower in the early tracheostomy group (weighted mean difference − 8.5 days, 95% confidence interval − 13.3 days to − 1.7 days, P = 0.03).

**Length of stay in the critical care unit**

Information on the length of stay in a critical care unit was available for two of the five studies (226 patients). Figure 5 shows the forest plot. Overall the length of stay in the critical care unit was significantly lower in the early tracheostomy group (− 15.3 days, − 24.6 days to − 6.1 days, P = 0.001).

**Discussion**

Early tracheostomy placement may lead to a markedly reduced duration of ventilation and shorter stays in critical care units in artificially ventilated, critically ill adult patients. However, the limited numbers of studies and patients available for analysis leave some doubt as to the accuracy of the result.
Possible limitations

It is possible that we did not identify all available published research, but by performing a comprehensive and repeated literature search we minimised this risk. In spite of this extensive searching, we identified only five original, randomised or quasi-randomised clinical trials of the timing of tracheostomy in the

<table>
<thead>
<tr>
<th>Study</th>
<th>No of patients</th>
<th>Timing of tracheostomy</th>
<th>Intensive care setting</th>
<th>Randomisation</th>
<th>Mortality expressed on intention to treat basis</th>
<th>Duration of ventilation and critical care stay expressed on intention to treat basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bouderka et al 2004&lt;sup&gt;24&lt;/sup&gt;</td>
<td>62</td>
<td>5-6 days after admission</td>
<td>Prolonged endotracheal intubation</td>
<td>Unit for patients with head injuries</td>
<td>Randomised; method not stated</td>
<td>Implied</td>
</tr>
<tr>
<td>Dunham et al 1984&lt;sup&gt;25&lt;/sup&gt;</td>
<td>74</td>
<td>3-4 days after initiation of translaryngeal intubation</td>
<td>14 days after initiation of translaryngeal intubation</td>
<td>Trauma unit</td>
<td>Quasi-randomised</td>
<td>Mortality not recorded Pneumonia analysed by intention to treat</td>
</tr>
<tr>
<td>Rodriguez et al 1990&lt;sup&gt;26&lt;/sup&gt;</td>
<td>106</td>
<td>1-7 days after admission to intensive care unit</td>
<td>8 or more days after admission to intensive care unit</td>
<td>Surgical unit</td>
<td>Quasi-randomised</td>
<td>Implied</td>
</tr>
<tr>
<td>Rumbak et al 2004&lt;sup&gt;27&lt;/sup&gt;</td>
<td>120</td>
<td>0-2 days after initiation of mechanical ventilation</td>
<td>14-16 days after initiation of mechanical ventilation</td>
<td>Three medical units</td>
<td>True randomisation</td>
<td>Implied</td>
</tr>
<tr>
<td>Saffle et al 2002&lt;sup&gt;16&lt;/sup&gt;</td>
<td>44</td>
<td>Next available operative day</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Fig 2 Random effects meta-analysis of relative risk (95% confidence interval) of mortality with early compared with late tracheostomy

Fig 3 Random effects meta-analysis of relative risk (95% confidence interval) of hospital acquired pneumonia with early compared with late tracheostomy

Fig 4 Random effects meta-analysis of weighted mean difference (95% confidence interval) of duration of ventilation in days
management of artificially ventilated, critically ill adults. The trials all had relatively small study populations, giving a total combined population of only 406 patients.

**Heterogeneity between studies**

Heterogeneity between the studies included in this review arises because the exclusion and inclusion criteria differed across the trials and because each trial used a different definition of what constituted an “early” or “late” tracheostomy (table 1). The critical care populations studied also differed because the trials were undertaken in different specialist rather than general critical care units. Some heterogeneity existed in the way some outcomes were defined. The diagnostic criteria for hospital acquired pneumonia varied between studies (table 2), leading to large differences in the proportion of patients reported as developing infections.

If an early tracheostomy strategy were adopted widely many mechanically ventilated patients could have a tracheostomy placed earlier in their stay, a procedure they would not receive when a more conservative, late approach is used. However, in the randomised controlled trial by Rumbak et al, eight patients (35%) were defined as survivors in the late tracheostomy arm no longer had a clinically significant complication in the same treatment arm of different studies.

**Random effects meta-analysis of weighted mean difference (95% confidence interval) of length of stay in the critical care unit in days**

![Fig 5](https://example.com/fig5.png)

Table 2 Criteria used to diagnose hospital acquired pneumonia

<table>
<thead>
<tr>
<th>Study</th>
<th>Early tracheostomy</th>
<th>Late tracheostomy</th>
<th>Weighted mean difference (random) (%)</th>
<th>Weighted mean difference (random) 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rodriguez et al 199024</td>
<td>18 (7.14)</td>
<td>19 (7.46)</td>
<td>-1.00 (-2.78 to 0.78)</td>
<td>-2.41 (-5.24 to 0.42)</td>
</tr>
<tr>
<td>Rumbak et al 200417</td>
<td>60 (2.43)</td>
<td>70 (2.47)</td>
<td>-0.00 (-0.60 to 0.60)</td>
<td>-0.60 (-1.20 to 0.00)</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>111</td>
<td>115</td>
<td>-0.00 (-0.60 to 0.60)</td>
<td>-0.60 (-1.20 to 0.00)</td>
</tr>
</tbody>
</table>

Although this review would support a limited benefit—that is, a shorter stay in the intensive care unit and duration of ventilation—premature or ill advised placement of a tracheostomy may not represent an appropriate balance of risk.

To avoid this problem, attempts have been made to develop formulas to predict the probability of a patient requiring prolonged ventilation, allowing better selection of patients likely to benefit from early tracheostomy. However, to date no validated specific and sensitive test or scoring system is available that predicts the need for prolonged ventilation in general populations in critical care, and so the selection of patients for tracheostomy remains a subjective decision.

**Conclusion**

Current practice for definitive airway management in critically ill adults uses translaryngeal intubation in the early stages. Tracheostomy is subsequently performed if the attending doctor estimates that the patient will require an extended period of artificial ventilation. However, if the results from our meta-analysis can be generalised, in spite of the small numbers of trials and patients, it may be advisable to place a tracheostomy earlier on in the proceedings. The UK critical care community has recently highlighted this specific clinical question in a priority setting exercise. The first, large scale study in UK intensive care units of the effect of the timing of tracheostomy powered on mortality has now started recruitment.

**What is already known on this topic**

Tracheostomy is considered to be the standard care in patients requiring long term ventilation

Many trials have reported the use of tracheostomy in adult patients, but most involved small numbers of participants with specific conditions

Previous reviews have reached different conclusions about the timing of tracheostomy in adult patients

**What this study adds**

Earlier placement of a tracheostomy in critically ill patients may shorten duration of artificial ventilation and length of stay in intensive care
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Adult Intensive Care Unit, John Radcliffe Hospital, Oxford OX3 9DU
John Griffiths specialist registrar
J Duncan Young consultant
Nuffield Department of Anaesthetics, University of Oxford, John Radcliffe Hospital
Vicki S Barber trial coordinator
Lesley Morgan trial coordinator
Correspondence to: J Duncan Young, duncan.young@nda.ox.ac.uk