Effect of Early vs Late Tracheostomy Placement on Survival in Patients Receiving Mechanical Ventilation
The TracMan Randomized Trial

Duncan Young, DM
David A. Harrison, PhD
Brian H. Cuthbertson, MD
Kathy Rowan, DPhil
for the TracMan Collaborators

A tracheostomy is commonly performed when clinicians predict a patient will need prolonged mechanical ventilation. The use of this procedure has increased, especially following the introduction of a practical bedside percutaneous tracheostomy technique in 1985,1 such that up to one-third of patients requiring prolonged mechanical ventilation now receive a tracheostomy.2,3 The perceived advantages of a tracheostomy over prolonged translaryngeal endotracheal intubation include improved patient comfort and reduced sedative drug use, faster weaning from mechanical ventilation, a reduced incidence of nosocomial pneumonia, and shorter hospitalization.4 These beneficial effects might be maximized if tracheostomies were performed early in a patient’s illness.

The United Kingdom has a very limited intensive care provision, with about one-seventh of the intensive care beds per 10 000 population provided in the United States and a third of those provided in France.5 As a result, patients treated in UK intensive care units (ICUs) tend to be more severely ill, with more than two-thirds mechanically ventilated on admission compared with less than one-fifth of other countries such as the United States.6 The low provi- sion of, and hence increased pressure on, intensive care beds in the United

Importance Tracheostomy is a widely used intervention in adult critical care units. There is little evidence to guide clinicians regarding the optimal timing for this procedure.

Objective To test whether early vs late tracheostomy would be associated with lower mortality in adult patients requiring mechanical ventilation in critical care units.

Design and Setting An open multicentered randomized clinical trial conducted between 2004 and 2011 involving 70 adult general and 2 cardiothoracic critical care units in 13 university and 59 nonuniversity hospitals in the United Kingdom.

Participants Of 1032 eligible patients, 909 adult patients breathing with the aid of mechanical ventilation for less than 4 days and identified by the treating physician as likely to require at least 7 more days of mechanical ventilation.

Interventions Patients were randomized 1:1 to early tracheostomy (within 4 days) or late tracheostomy (after 10 days if still indicated).

Main Outcomes and Measures The primary outcome measure was 30-day mortality and the analysis was by intention to treat.

Results Of the 455 patients assigned to early tracheostomy, 91.9% (95% CI, 89.0%-94.1%) received a tracheostomy and of 454 assigned to late tracheostomy, 44.9% (95% CI, 40.4%-49.5%) received a tracheostomy. All-cause mortality 30 days after randomization was 30.8% (95% CI, 26.7%-35.2%) in the early and 31.5% (95% CI, 27.3%-35.9%) in the late group (absolute risk reduction for early vs late, 0.7%; 95% CI, 5.4% to 6.7%). Two-year mortality was 51.0% (95% CI, 46.4%-55.6%) in the early and 53.7% (95% CI, 49.1%-58.3%) in the late group (P= .74). Median critical care unit length of stay in survivors was 13.0 days in the early and 13.1 days in the late group (P=.74). Tracheostomy-related complications were reported for 6.3% (95% CI, 4.6%-8.5%) of patients (5.5% in the early group, 7.8% in the late group).

Conclusions and Relevance For patients breathing with the aid of mechanical ventilation treated in adult critical care units in the United Kingdom, tracheostomy within 4 days of critical care admission was not associated with an improvement in 30-day mortality or other important secondary outcomes. The ability of clinicians to predict which patients required extended ventilatory support was limited.

Trial Registration isrctn.org Identifier: ISRCTN28588190

JAMA. 2013;309(20):2121-2129 www.jama.com

©2013 American Medical Association. All rights reserved.
Kingdom means that techniques that may reduce the duration of mechanical ventilation, ICU stay, or both generate considerable interest. This low-intensive care bed provision and increased severity of illness on admission to intensive care means that interventions such as tracheostomy are often considered early in a patient’s ICU stay.

A clinical research priority-setting exercise among the 2200 members of the UK Intensive Care Society in 2004 gave the highest priority to studies investigating the timing of tracheostomy in patients mechanically ventilated. A subsequent systematic review of the literature and meta-analysis suggested that early tracheostomy placement reduced the duration of mechanical ventilation and hospital stay. In the largest of the reviewed studies, a considerable reduction in hospital mortality was also identified.

There are probably large numbers of tracheostomies being performed on patients mechanically ventilated each year. Based on a prestudy survey of 37 of the 252 ICUs in the United Kingdom, we estimated there were up to 15000 tracheostomies annually. Audit data from Scottish ICUs and a systematic review of all the published case series of tracheostomy use revealed that the median time to insertion of a tracheostomy was 10 to 11 days after the start of admission to a critical care unit, but up to 13% of tracheostomies were placed within 2 days of admission. Another survey reflecting UK practice in 2005 suggested that half of all tracheostomies were placed within a week of critical care admission, and a subsequent survey suggested 21% of tracheostomies were placed within 5 days of admission.

With the suggestion from the meta-analysis that early tracheostomy might reduce the duration of mechanical ventilation, data from a single-center study suggesting that early tracheostomy might confer a survival advantage, and evidence that early tracheostomy placement was already occurring, the TracMan (Tracheostomy Management) study was commenced. The hypothesis tested was that tracheostomy as early as practicable (early) vs deferred placement until after 10 days and then only if required (late) would be associated with a lower mortality in adult patients requiring mechanical ventilation in critical care units.

**METHODS**

**Patients**

TracMan enrolled mechanically ventilated patients in adult critical care units, who were identified by the treating clinician in the first 4 days after admission as likely to require at least 7 more days of ventilatory support. We excluded patients requiring an immediate, life-saving tracheostomy; those in whom a tracheostomy was contraindicated for anatomical or other reasons; and those with respiratory failure due to chronic neurological disease because our study centers indicated these patients usually receive early tracheostomies.

Written, informed consent or signed agreement from the patients’ legal representative/welfare guardian was obtained. The study was approved by a multicenter research ethics committee and each hospital’s local research ethics committee.

**Randomization and Blinding**

Randomization was conducted using an automated 24-hour telephone service using an algorithm that minimized the imbalance between groups of the study by allocating each patient, with 80% probability, to the group which minimized the imbalance in the following covariates: center, age, sex, and 7 major diagnostic groups (intracranial pathology, altered consciousness due to drug or metabolic causes, acute peripheral nerve or muscle disorder, pulmonary pathology, burns, heart failure, and other).

Preparation assignment could not be blinded to the caring team nor to the analysis team because it was apparent from the data to which group a patient had been assigned. Patients were randomly assigned in a 1:1 ratio, either to early tracheostomy or to late tracheostomy (FIGURE 1).

**Procedures**

As a condition of participation, all senior physicians in participating units agreed to include all eligible patients and to abide by randomization to reduce both inclusion bias and crossovers between the groups. All participating units maintained a screening log of eligible patients not enrolled.

By protocol the early tracheostomies were to be placed within 4 days of critical care unit admission and the late tracheostomies were to be placed on day 10 or later and then only if the treating clinician deemed the procedure still clinically indicated. Tracheostomies were performed according to each critical care unit’s local practice (percutaneous or surgical tracheostomy). All other care was at the discretion of the treating clinicians.

**Data**

During the first 24 hours in the critical care unit, clinicians recorded data for the acute physiology, age, and chronic health evaluation II (APACHE II) severity scoring system. In both groups of the study, details of the tracheostomy procedure were collected including timing, location, type (percutaneous or open surgical), immediate complications, and the seniority of the individual performing the procedure. From randomization, daily information on respiratory support was recorded using the Critical Care Minimum Data Set definitions of organ failure used routinely in all UK critical care units. Antimicrobial and sedative drug use was recorded for the duration of care on the critical care unit.

Patients’ vital status was determined for 2 years following randomization from the UK Office for National Statistics (ONS) and the NHS Strategic Tracing Service (NHSSTC), both of which hold registers of all deaths in the United Kingdom.

The primary outcome measure was all-cause mortality 30 days from randomization. Secondary outcome measures were mortality at critical unit and hospital discharge and at 1 and 2 years, length of stay in the critical care unit.
and in an acute hospital, days in critical care up to 30 days from randomization when intravenous sedatives were administered, and antimicrobial-free days in critical care up to 30 days from randomization (as a proxy for hospital acquired infections).

**Statistical Analysis**

The critical care unit mortality of patients receiving a tracheostomy in 35 UK critical care units was obtained by survey to estimate the sample size. The original planned sample size was for 1208 patients to give 80% power to detect a 7.5% absolute reduction (based on our original effect-size estimate from a meta-analysis of studies of early tracheostomy) in critical care unit mortality (surrogate for 30-day mortality) from 30% to 22.5%, based on a 5% level of significance and to allow for a 4% combined withdrawal and loss to follow-up. The planned sample size was subsequently increased to 1692 patients to detect a 6.3% absolute (21% relative) reduction in mortality based on a more accurate estimate of the likely effect size published in a systematic review when the UK Medical Research Council funded the second phase of the study in 2006, with other assumptions as above. However, due to study fatigue indicated by a decreasing average per center recruitment rate in spite of considerable help and encouragement and exhaustion of funding, the planned sample size was not achieved. The final sample of 899 patients available for analysis of the primary outcome had the power to detect an 8.3% absolute change in 30-day mortality from the “late” group value of 31.5% with 80% power and a 5% level of significance.

All the main analyses were by intention-to-treat and followed an a priori statistical analysis plan. The number of deaths in each group was compared with the Fisher exact test and survival times with Kaplan-Meier curves and a log-rank test. Length of stay and duration of therapy were compared with the Wilcoxon rank sum test, stratified by survival status.

An independent Data Monitoring and Ethics Committee designed the monitoring schedule and reviewed unblinded data from 4 interim analyses using a Peto-Haybittle stopping rule (the study would continue unless the primary outcome was different between the groups at \( P < .001 \) at interim analysis) to recommend early termination of the study due to either benefit or harm. Statistical significance for the final analysis was therefore based on \( P < .049 \). The committee did not specify a futility boundary. All statistical comparisons were 2 sided. SPSS version 20 (IBM Corp) and Stata version 10 (StataCorp) were used for statistical analysis.

The full protocol for the study can be found at [http://www.tracman.org.uk](http://www.tracman.org.uk).

**RESULTS**

Between November 2004 and November 2008, 70 adult, general critical care units and 2 cardiothoracic surgical critical care units (from 13 university and 59 nonuniversity hospitals) recruited patients. Final 2-year follow-up was completed in January 2011. In all, 909 patients were randomly assigned (Figure 1). Of these, 455 were allocated to receive early tracheostomy and 454 to receive late tracheostomy. The TracMan Study Flow Diagram is shown in Figure 1. The TracMan Study Flow Diagram

©2013 American Medical Association. All rights reserved.
cated to early and 454 were allocated to the late tracheostomy group. Excluding duplicate randomization and withdrawals (despite measures in place to minimize both of these), 451 (99.1%) patients in the early and 448 (98.7%) in the late groups were available for the primary analysis. Table 1 shows the baseline characteristics, which were similar between the groups.

Of those randomized to the early tracheostomy group, the procedure was performed within 4 days of admission to the critical care unit for 385 patients (84.6%; 95% CI, 81.0%-87.7%). Despite meeting study eligibility criteria at randomization, 66 patients (14.5%) did not receive an early tracheostomy (95% CI, 11.6%-18.1%), 31 of whom (6.8) never received a tracheostomy (95% CI, 4.8%-9.5%) and 35 patients (7.7%) received it late (95% CI, 5.6-10.5). Of those who did not receive a tracheostomy, 4 (0.9%) died (95% CI, 0.3%-2.3%), 11 (2.4%) recovered and did not need one (95% CI, 1.3%-4.3%), and 16 (3.5%) remained too unstable for the procedure (95% CI, 2.1%-5.7%). Of those who received a tracheostomy after the time allowed by the protocol, 19 (4.2%) were too unstable during the time window (95% CI, 2.6% to 6.5%), 6 (1.3%) had unavailable facilities or operators (95% CI, 0.5%-2.9%), 4 (0.9%) initially improved (95% CI, 0.3%-2.3%), 2 (0.4%) were because of investigator errors (95% CI, 0.0%-1.7%) investigator errors, and 4 (0.9%) were for unknown reasons (95% CI, 0.3-2.3). The details of the tracheostomies performed are in Table 2. The distributions of the tracheostomy timing for both groups of the study are shown in Figure 2.

Of the 454 randomized to late tracheostomy, the procedure was conducted as per protocol either on or after day 10 or never, as no longer clinically indicated for 425 patients (93.6%; 95% CI, 91.0%-95.6%). Of the 244 patients (53.7%) for whom tracheostomy was never performed (95% CI, 49.2%-58.3%), 89 (19.6%) had been discharged alive from the critical care unit by day 10 (95% CI, 16.2%-23.5), 78 (17.2%) remained in the critical care unit but no longer required ventilatory support (95% CI, 14.0%-20.9%), 54 (11.9%) died (95% CI, 9.2%-15.2%), 11 (2.4%) remained too unstable (95% CI, 1.3%-4.3%), 2 (0.4%) had treatment withdrawn (95% CI, 0.0-1.7), and 10 (2.2%) had no recorded reason (95% CI, 1.2%-4.1%).

Tracheostomy was performed for 33 patients (7.3%) in the late group before day 10 (95% CI, 5.2%-10.1%): 21 (4.6%) received tracheostomy because of clinical decision (95% CI, 3.0-7.0), 4 (0.9%) because their relatives insisted on the procedure (95% CI, 0.3%-2.3%), and 4 (0.9%) because of investigator error (95% CI, 0.3%-2.3%), and for 4 patients (0.9%) the reason was not recorded (95% CI, 0.3%-2.3%).

For the 622 patients receiving tracheostomies, procedure-related complications were reported for a total of 39 patients (6.3%; 95% CI, 4.6%-8.5%): twenty-three (5.5%) of 418 patients in the early group (95% CI, 3.7%-8.2%) and 16 (7.8%) of 204 patients in the late group (95% CI, 4.8%-12.4%). The most frequent complication was bleeding sufficient to require intravenous fluids or another intervention, which occurred in 19 (3.1%) of the 622 patients (95% CI, 2.6%-4.1%).
CI, 1.9%-4.8%); 11 patients (2.6%) in the early group (95% CI, 1.4%-4.7%) and 8 (3.9%) in the late group (95% CI, 1.9%-7.7%).

The patients received a mean (SD) of 13.6 (12.0) total days of respiratory support (positive pressure ventilation or continuous positive airway pressure [CPAP] for any period in a day) in the early group and 15.2 (14.4) days in the late group (mean difference, 1.7 days, 95% CI, 3.4 to 0.1 days; \( P = .06 \)).

Patients received respiratory support through a tracheostomy in the early group for a mean (SD) of 12.9 (11.8) days (417 patients) and 16.1 (14.7) days (200 patients) in the late group.

The primary outcome, all-cause mortality 30 days from randomization, was not statistically different in the 2 groups—early 139 patients (30.8%) in the early group (95% CI, 26.7%-35.2%) and 141 patients (31.5%) in the late group (95% CI, 27.3%-35.9%; Table 3).

Table 2. Details of the Tracheostomies Performed

<table>
<thead>
<tr>
<th>Grade of clinician performing tracheostomy</th>
<th>Early (n = 418)</th>
<th>Late (n = 204)</th>
<th>Total (n = 622)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attending/specialist physician</td>
<td>222 (53.1)</td>
<td>116 (56.9)</td>
<td>338 (54.3)</td>
</tr>
<tr>
<td>Resident</td>
<td>133 (31.8)</td>
<td>47 (23.0)</td>
<td>180 (28.9)</td>
</tr>
<tr>
<td>House officer/junior resident</td>
<td>46 (11.0)</td>
<td>27 (13.2)</td>
<td>73 (11.7)</td>
</tr>
<tr>
<td>Staff grade/associate specialist/fellow</td>
<td>16 (3.8)</td>
<td>11 (5.4)</td>
<td>27 (4.3)</td>
</tr>
</tbody>
</table>

Grade of most senior clinician actively involved in, or directly supervising the tracheostomy procedure:

| Attending/specialist physician             | 387 (92.6)     | 179 (89.1)    | 566 (91.4)      |
| Resident                                   | 27 (6.5)       | 19 (9.5)      | 46 (7.4)        |
| House officer/junior resident              | 2 (0.5)        | 1 (0.5)       | 3 (0.5)         |
| Staff grade/associate specialist/fellow    | 2 (0.5)        | 2 (1.0)       | 4 (0.6)         |

Table 3.

<table>
<thead>
<tr>
<th>Type of procedure</th>
<th>Early (n = 418)</th>
<th>Late (n = 204)</th>
<th>Total (n = 622)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operating theater</td>
<td>37 (8.9)</td>
<td>25 (12.3)</td>
<td>62 (10.0)</td>
</tr>
<tr>
<td>Bedside</td>
<td>3 (0.7)</td>
<td>2 (1.0)</td>
<td>5 (0.8)</td>
</tr>
<tr>
<td>Percutaneous</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operating theater</td>
<td>1 (0.2)</td>
<td>2 (1.0)</td>
<td>3 (0.5)</td>
</tr>
<tr>
<td>Bedside</td>
<td>377 (90.2)</td>
<td>174 (85.7)</td>
<td>551 (88.7)</td>
</tr>
</tbody>
</table>

Duration of procedure, median (IQR), min:

| All procedures | 30 (20-45) | 30 (20-45) | 30 (20-45) |
| Surgical       | 49 (30-74) | 45 (37-73) | 45 (31-73) |
| Percutaneous   | 30 (20-40) | 30 (20-40) | 30 (20-40) |

Abbreviation: IQR, interquartile range.

There were 622 tracheostomies performed. ICU indicates intensive care unit.

©2013 American Medical Association. All rights reserved.
care admission was 13.0 (interquartile range [IQR], 8.2-19.1) days in the early group and 13.1 (IQR, 7.4-23.6) days in the late group (P = .74). For 133 patients who died in the early group and the 132 who died in the late group while in the critical care unit the median survival was 9.3 (IQR, 4.2-16.0) days for the early group and 10.4 (IQR, 6.0-19.7) days for the late group (P = .16).

Median total hospital stay in those surviving to discharge (256 both groups) was 33 (IQR, 19-55) days in the early group and 34 (IQR, 20-56) days in the late group (P = .68) and for those not surviving to discharge (168 early, 180 late) was 11 (IQR, 6-24) days in the early group and 14 (7-30) days in the late group (P = .13).

Antibiotic use to 30 days after randomization was the same in both groups. For the 304 in the early group those surviving to 30 days and 300 in the late group, antibiotics were not given on a median of 5 (IQR, 1-8) days in the early group and 5 (IQR, 1-8) days in the late group (P = .95). Patients not surviving to 30 days (139 early, 140 late) had a median of 1 (IQR, 0-4) days alive and free of antibiotics in the early group and 2 (IQR, 0-5) days in the late group (P = .14).

**DISCUSSION**

**Principal Findings**

These results suggest that early tracheostomy (within 4 days of admission)
has no effect on mortality in mechanically ventilated patients identified by the treating clinician in the first 4 days following admission as likely to require at least an additional 7 days of ventilatory support compared with waiting 10 or more days before placing a tracheostomy if still indicated. For those allocated to the late tracheostomy group, only 45% of patients had a tracheostomy performed. In more than two-thirds of the rest, a tracheostomy was not required by day 10 either because they had recovered; they were alive but no longer being ventilated or they had already been discharged alive from the critical care unit.

The patients meeting the inclusion criteria for this study represent a very high-risk cohort, with an overall 41% mortality at discharge, 47% at year 1, and 53% at year 2. This presumably reflects the severity of the underlying disease leading to the need for mechanical ventilation, which in 69% was pulmonary pathology.

Most of the 622 tracheostomies performed during the study used percutaneous, dilator-based techniques undertaken at the bedside. There were no deaths attributed to the procedure. The overall complication rate was 6.3%, most of these were bleeding requiring intravenous fluids. In another study of the timing of tracheostomy on nosocomial pneumonia, the complication rates were similar at 8.3%. One patient experienced an esophageal perforation. This study was not resourced to follow the patients to see if they developed late complications of tracheostomy such as tracheal stenosis.

The main justifications used for early tracheostomy placement is that the tracheostomy is far better tolerated than endotracheal intubation. Placing the tracheostomy might therefore allow a reduction in sedative use, which in turn might result in early extubation. The results for 30-day mortality concur with the 2 other multicenter randomized studies on early vs late tracheostomy published since this study started. Blot and colleagues and Terragni and colleagues found no difference in 28-day mortality in 123 and 419 patient randomized controlled studies, respectively. Two single center studies by Koch and colleagues and Zheng and colleagues also did not show a mortality benefit for early tracheostomy. In a multicenter nonrandomized, propensity matched comparison, Clech and colleagues found no difference in critical care unit mortality. A further study by Scales et al performed a stratified propensity score analysis from a provincial database and suggested a small increase in long-term mortality with later tracheostomy, but the increase was of questionable clinical significance. Blot and colleagues did not demonstrate any difference in duration of mechanical ventilation, critical care unit length of stay, or respiratory infection, which is consistent with the findings reported herein, although Terragni et al, Koch et al, and Zheng et al demonstrated a reduced duration of critical care and hospital stay. The proportion of patients not requiring a tracheostomy in the late group fell midway between that reported in the other 2 multicenter studies (43% and 74%).

Results in the Context of Others

The results for 30-day mortality concur with the 2 other multicenter randomized studies on early vs late tracheostomy published since this study started. Blot and colleagues and Terragni and colleagues found no difference in 28-day mortality in 123 and 419 patient randomized controlled studies, respectively. Two single center studies by Koch and colleagues and Zheng and colleagues also did not show a mortality benefit for early tracheostomy. In a multicenter nonrandomized, propensity matched comparison, Clech and colleagues found no difference in critical care unit mortality. A further study by Scales et al performed a stratified propensity score analysis from a provincial database and suggested a small increase in long-term mortality with later tracheostomy, but the increase was of questionable clinical significance. Blot and colleagues did not demonstrate any difference in duration of mechanical ventilation, critical care unit length of stay, or respiratory infection, which is consistent with the findings reported herein, although Terragni et al, Koch et al, and Zheng et al demonstrated a reduced duration of critical care and hospital stay. The proportion of patients not requiring a tracheostomy in the late group fell midway between that reported in the other 2 multicenter studies (43% and 74%).

Strengths and Weaknesses

The strengths of this study lie in the open invitation for all UK critical care units to participate, the large numbers of units participating and the representativeness of the types of hospitals in which the units were located. Due to recruitment occurring in a broad range of clinical units, the broad inclusion criteria and the limited exclusion criteria, and the completeness of follow-up, we believe the study has reasonably high external validity. The study succeeded in ensuring a reasonable separation with regards to the timing of the intervention between the early and late tracheostomy groups.

The study did not recruit its intended sample size despite every effort to do so. The main reason was recruitment fatigue although exhaustion of funding was also a factor. The study design included a pilot period with a
EARLY VS LATE TRACHEOSTOMY PLACEMENT

small number of critical care units followed by a staggered increase to full participation of many more units. This strategy allows for piloting of study methodology and reduces the risks to the funders but extends the recruitment period and potentially fuels recruitment fatigue. The decision to stop the study was made by the trial steering committee on practical rather than for statistical reasons. The study rarely met monthly recruitment targets, in spite of strenuous efforts to increase recruitment by a number of techniques including raising awareness, increasing the number of study centers, and increasing the financial support available to centers to cover costs. Two formal recruitment reviews took place, during which the investigators at the sites were interviewed and the “not in trial” logs examined to identify impediments to recruitment. The committee met when an application for extension funding would have to be made. At this point, recruitment was static in spite of an increasing number of sites, representing a falling per-site recruitment rate, so prediction of the likely time required to reach full recruitment was difficult. The trial steering committee, which contained a funder’s representative, stopped the study because further funding would not be made available in these circumstances and because the study had reached the end of its allocated funds. Not reaching the intended sample size affected the final precision of the study. The final 899-patient study had the power to detect an 8.3% absolute change in 30-day mortality from the late group value of 31.5% with 80% power and a 5% level of significance. Not reaching the intended sample size also informed our decision to wait and report the longer-intended sample size also informed our decision to wait and report the longer-term data. Among mechanically ventilated critically ill patients in the United Kingdom, early tracheostomy (within the first 4 days after admission) was not associated with an improvement in 30-day mortality or other important secondary outcomes. Early tracheostomy should therefore be avoided unless tools to accurately predict the duration of mechanical ventilation on individual patients can be developed and validated.

CONCLUSIONS

Among mechanically ventilated critically ill patients in adult, general critical care units in the United Kingdom, early tracheostomy (within the first 4 days after admission) was not associated with an improvement in 30-day mortality or other important secondary outcomes. Early tracheostomy should therefore be avoided unless tools to accurately predict the duration of mechanical ventilation on individual patients can be developed and validated.

Author Affiliations: Adult Intensive Care Unit, John Radcliffe Hospital, Oxford (Dr Young); National Audit and Research Centre (ICNARC), Napier House, London (Dr Harrison and Rowan); England; Department of Critical Care Medicine, Sunnybrook Health Sciences Centre (Dr Cuthbertson); and Department of Anesthesia, University of Toronto (Dr Cuthbertson), Toronto, Ontario, Canada.

Author Contributions: Dr Young had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: All authors.

Acquisition of data: Young, Cuthbertson.

Analysis and interpretation of data: All authors.

Drafting of the manuscript: All authors.

Critical revision of the manuscript for important intellectual content: All authors.

Statistical analysis: Harrison.

Obtained funding: Young, Cuthbertson.

Administrative, technical, or material support: Young, Rowan.

Study supervision: Young.

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

Hospitals and Principal Investigators: Aberdeen Royal Infirmary (Dr Brian H. Cuthbertson); Alexandra Hospital (Dr Tracey Leach); Barnet Hospital (Dr Andy Cohen); Barnsley District General Hospital

Implications

The implications for clinical practice and for patients, from this study are found from the results in the late group. Not only were there no statistically significant difference in mortality between the 2 groups but, through waiting, an invasive procedure was avoided in a third of patients. Avoiding this significant proportion of tracheostomies, a procedure associated with a 6.3% acute complication rate in this study (and 38%-39% overall complication rates in the other recent multicenter studies), did not appear to be associated with any significant increase in health care resource use, as measured by critical care unit or hospital stay. It would appear that delaying a tracheostomy until at least day 10 of a patient’s critical care unit stay is the best policy. As noted, only 45% of the late group had a tracheostomy performed mainly due to tracheal extubation and subsequent discharge from the critical care unit. This raises questions about clinicians’ abilities to predict the requirement for a additional 7 days of ventilation early in a patient’s critical care unit stay and the wisdom of basing any treatments, including tracheostomy, on this prediction.

Study concept and design: All authors.

Acquisition of data: Young, Cuthbertson.

Analysis and interpretation of data: All authors.

Drafting of the manuscript: All authors.

Critical revision of the manuscript for important intellectual content: All authors.

Statistical analysis: Harrison.

Obtained funding: Young, Cuthbertson.

Administrative, technical, or material support: Young, Rowan.

Study supervision: Young.

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

Hospitals and Principal Investigators: Aberdeen Royal Infirmary (Dr Brian H. Cuthbertson); Alexandra Hospital (Dr Tracey Leach); Barnet Hospital (Dr Andy Cohen); Barnsley District General Hospital

Implications

The implications for clinical practice and for patients, from this study are found from the results in the late group. Not only were there no statistically significant difference in mortality between the 2 groups but, through waiting, an invasive procedure was avoided in a third of patients. Avoiding this significant proportion of tracheostomies, a procedure associated with a 6.3% acute complication rate in this study (and 38%-39% overall complication rates in the other recent multicenter studies), did not appear to be associated with any significant increase in health care resource use, as measured by critical care unit or hospital stay. It would appear that delaying a tracheostomy until at least day 10 of a patient’s critical care unit stay is the best policy. As noted, only 45% of the late group had a tracheostomy performed mainly due to tracheal extubation and subsequent discharge from the critical care unit. This raises questions about clinicians’ abilities to predict the requirement for a additional 7 days of ventilation early in a patient’s critical care unit stay and the wisdom of basing any treatments, including tracheostomy, on this prediction.

CONCLUSIONS

Among mechanically ventilated critically ill patients in adult, general critical care units in the United Kingdom, early tracheostomy (within the first 4 days after admission) was not associated with an improvement in 30-day mortality or other important secondary outcomes. Early tracheostomy should therefore be avoided unless tools to accurately predict the duration of mechanical ventilation on individual patients can be developed and validated.

Author Affiliations: Adult Intensive Care Unit, John Radcliffe Hospital, Oxford (Dr Young); and Intensive Care National Audit and Research Centre (ICNARC), Napier House, London (Dr Harrison and Rowan), England; Department of Critical Care Medicine, Sunnybrook Health Sciences Centre (Dr Cuthbertson); and Department of Anesthesia, University of Toronto (Dr Cuthbertson), Toronto, Ontario, Canada.

Author Contributions: Dr Young had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: All authors.

Acquisition of data: Young, Cuthbertson.

Analysis and interpretation of data: All authors.

Drafting of the manuscript: All authors.

Critical revision of the manuscript for important intellectual content: All authors.

Statistical analysis: Harrison.

Obtained funding: Young, Cuthbertson.

Administrative, technical, or material support: Young, Rowan.

Study supervision: Young.

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

Hospitals and Principal Investigators: Aberdeen Royal Infirmary (Dr Brian H. Cuthbertson); Alexandra Hospital (Dr Tracey Leach); Barnet Hospital (Dr Andy Cohen); Barnsley District General Hospital
EARLY VS LATE TRACHEOSTOMY PLACEMENT

(De Ye Myint); Bedford Hospital (Dr Jane Hurst); Castle Hill Hospital (Dr Sean Bennett); Causeway Hospital (Dr Chris Watters); Cheorley Hospital (Dr Segun Akinkelu); City General Hospital Stoke on Trent (Dr Nick Coleman); City Hospital Birmingham (Dr John Beaustdale); Derriford Hospital (Dr Peter Macnaghton); Dumfries & Galloway Royal Infirmary (Dr Wayne Wrathall); Eastbourne District General Hospital (Dr Ian Andrews and John Cook); Freeman Hospital (Dr Andrew Klier); Glas Cwmd District General Hospital (Dr Brian Tahan); Glenfield Hospital (Dr Sanjay Agrawal); Hammers Hospital (Dr David Allen); Huddersfield Royal Infirmary (Dr Peter Hall); James Cook University Hospital (Dr Judith Wright and Fiona Clark); James Paget Hospital (Dr Andreas Brodbbeck); John Radcliffe Hospital (Dr Duncan Young); King’s College Hospital (Dr Georg Auzinger); King George Hospital (Dr Tomas Jovaisa); Kings Mill Hospital (Dr Sandeep Dhill); Kingston Hospital (Dr Kaggere Plowright); Leeds General Infirmary (Dr Andy Bodenham); Leicester Royal Infirmary (Dr William Russell and Jonathan Greiff); Luton & Dunstable Hospital (Dr Mark Patten); Manchester Royal Infirmary (Dr Niall O’Keeffe and Jane Eddlestone); Medway Maritime Hospital (Mrs Catharine Pownght); Newcastle General Hospital (Dr Angus Vincent); New Cross Hospital (Dr Jaggatt Poon); Ninewells Hospital (Dr Stephen Cole); North Middlesex Hospital (Dr Ah-Fee Chan); Peterborough District Hospital (Dr Tuba Hussain); Princess Alexandra Hospital (Dr Dev Dutta and Ms Lindsay Spalding); Queen Alexandra Hospital (Dr David Pogson); Rochdale Infirmary (Dr Anil Gupta); Royal Alexandra Hospital (Dr Tom Ireland and H. Striton); Royal Berkshire Hospital (Dr Atul Kapila); Royal Bournemouth Hospital (Dr Rob McCormick); Royal Cornwall Hospital (Dr Jonathan Paddle); Royal Devon & Exeter Hospital (Dr Chris Day); Royal Hampshire County Hospital (Dr Geoff Wat- son and Satish Kumar); Royal Infirmary of Edinburgh (Dr Tim Walsh, David Hope, and Caroline Macleland); Royal Surrey County Hospital (Dr Maha Zuleika); Rus- sell Hall Hospital (Dr Julian Sonkton); Scunthorpe Hospital (Dr Ka Raafat Shariawi); Southampton General Hos- pital (Dr Tom Woodcock); Southend Hospital (Dr David Higgins); St Sistine District General Hospital (Dr Christoph Muench); St Richard’s Hospital (Dr Michael Margason); St Thomas’ Hospital (Dr Duncan Wyn- colli); Staffordshire General Hospital (Dr John Hawkins); Sunderland Royal Hospital (Dr Mark Carpenter); Taunton & Somerset Hospital (Dr Andy Daykin); Tor- bay Hospital (Dr Jonathan Ingham); University Hos- pital Lewisham (Dr Martin Mostert); University Col- lege Hospital (Dr Geoff Bellingan); Weston General Hospital (Dr Ioannis Tsagurnin and Libby Cauldwell and Ms Belinda Williams); Whiston Hospital (Dr Robin Macmillan and David Comyn); Whittington Hospital (Dr Sarah Gillis); Worthing Hospital (Dr Richard Venn); Wythenshawe Hospital (Dr Phil Haji-Michael); Yeovil District Hospital (Dr Rob Daum and Lisa Martin); and York Hospital (Dr Henry Paw).

Study Management: L. Morgan, F. Greenland, V. Bar- ber (study coordinators), L. Bowler, K. Coleman, J. Quinton (recruitment facilitating nurses). D. New- man, C. Bouse (administration), J. Griffiths (clinical fel- low), and D. Young (chief investigator).


Data Monitoring and Ethics Committee: P. Sander- cock (chair), M. Mythen, and S. Richards.

Funding/Support: The UK Intensive Care Society funded the research prioritization work that led to this study. The study was funded by the UK Intensive Care Society and the Medical Research Council.

Role of the Sponsor: The University of Oxford acted as the sponsor. The funders and sponsor had no in- fluence on the design and conduct of the study; the collection, management, analysis, and interpretation of the data; or the preparation, review, or approval of the manuscript. The randomization service was pro- vided by the Health Services Research Unit in the Uni- versity of Aberdeen.

REFERENCES