

Early vs late tracheostomy in critical care

This article reviews the current literature and practice of tracheostomy with consideration of timing and the benefits of early tracheostomy, taking account of the results from the recent TracMan study.

Ventilation and tracheal cannulation are synonymous with the modern perception of intensive care medicine, and the origins of the specialty and the practice lie closely entwined.

Records of tracheal cannulation pre-date modern medicine and the first surgical tracheostomy in modern history was used in the early 1900s to treat upper airway obstruction as a consequence of diphtheria and laryngeal tumour (Borman and Davidson, 1963). In the 1950s with the advent of positive pressure ventilation for the treatment of the poliomyelitis epidemic, the development of the technique of tracheal cannulation accelerated and expanded to use in the broader setting of respiratory failure (Lassen, 1953).

Audit results from Scottish and English intensive care units have identified that between 8 and 16% of all UK intensive care unit admissions require a tracheostomy with placement occurring at about 10 days (Scottish Intensive Care Society Audit Group, 2002; TracMan, 2007).

The question that has been raised, and remains disputed, is whether patients requiring potentially prolonged mechanical ventilation would benefit from earlier siting of a tracheostomy than at day ten. This review looks at the potential benefit and harm of early *vs* late tracheostomy.

Tracheostomy vs translaryngeal intubation

The practice of conversion from translaryngeal intubation to tracheostomy in long-term ventilated patients has become standard practice in western medicine. The current practice of performing tracheostomy at 10 days was established following an American consensus published in 1989. The consensus recommended tracheostomy placement in long-term ventilated patients at between 10 and 21 days (Plummer and Gracey, 1989). The recommendations were based largely on anecdotal evidence and expert opinion as there were no control trial data at the time comparing long-term translaryngeal intubation with tracheostomy.

The 1989 consensus recommended further research to compare translaryngeal ventilation with tracheostomy. However, clinicians have been reluctant to become involved in clinical trials that would prohibit tracheo-

stomy in one arm of the trial. A French group attempted to complete a randomized trial addressing this question, but the study was prematurely closed because of difficulties with recruitment (Blot et al, 2008). This group set a primary end point of 28-day mortality in a heterogeneous patient population assigned to either prolonged translaryngeal intubation or tracheostomy within 4 days. The power analysis determined that a sample size of 470 would be required to identify a significant reduction in 28-day mortality. However, the study was only able to recruit 123 patients and was unable to identify any significant differences between the groups when comparing the primary outcome or any of the secondary outcomes (intensive care unit-acquired pneumonia, intensive care unit length of stay and duration of ventilation). However, despite the lack of evidence clinicians appear satisfied that long-term translaryngeal intubation is not a suitable management option in long-term artificial ventilation.

Benefits of tracheostomy

Placement of tracheostomy can be a considerable turning point during a patient's intensive care unit course. It facilitates improved nursing care, nutrition and physiotherapy as well as reducing sedation requirements and allowing greater mobility. The potential improvement in mortality figures relating to tracheostomy are likely to be multi-factorial in origin and not exclusive to the elimination of a single risk associated with translaryngeal intubation.

Physiologically, it has been argued that tracheostomy reduces both the potential dead space and improves the work of breathing. However, the reductions in dead space are minimal. The upper airway in the average adult has a volume of approximately 150 ml. This compares with 5 ml in a tracheostomy cannula and 20 ml in an endotracheal tube and these minor differences have been confirmed to be of negligible clinical relevance (Mohr et al, 2001).

However, work of breathing, which is a function of airway resistance, is significantly improved with tracheostomy compared with translaryngeal intubation (Davis et al, 1999). This reduced work of breathing was demonstrated in a group of chronic obstructive pulmonary disease patients who had previously failed weaning. Placement of a tracheostomy in these patients resulted in a clinically significant decrease in the observed intrinsic positive end expiratory pressure and the work of breathing (Diehl et al, 1999).

The placement of a tracheostomy reduces sedation requirements and reduction in sedation has been shown to be beneficial (Kress et al, 2000; Girard et al, 2008).

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Girard et al (2008) studied 336 mechanically ventilated patients. The intervention arm, who were randomized to a protocol driven spontaneous waking ($n=168$), had significant improvements in time spent on intensive care unit (9.1 days *vs* 12.9 days, $P=0.01$), hospital length of stay (14.9 days *vs* 19.2 days, $P=0.04$) and a reduced duration of mechanical ventilation ($P=0.02$). Kress et al (2003) studied 128 patients randomized to a daily wake protocol or clinician lead sedation weaning. Daily waking reduced duration of mechanical ventilation ($P=0.004$) and duration of intensive care unit stay ($P=0.02$). There was also an association with reduced psychological impact of intensive care unit admissions.

Percutaneous vs surgical

The development of percutaneous techniques allowed tracheostomies to be readily sited in the intensive care unit without the need for surgical or theatre time. The first report of the technique appeared in 1957 and the dilatational technique, variations of which are in common use today, dates from 1985 when Ciaglia demonstrated the rapidity, simplicity and safety of the procedure (Ciaglia et al, 1985).

Studies that have compared percutaneous and surgical techniques, and the subsequent meta-analysis, have shown no clear distinction between them when considering overall risks (Dulguerov et al, 1999; Freeman et al, 2000). Freeman et al looked at five studies with a total of 236 patients finding no difference with respect to overall complication rates. It was noted that percutaneous techniques incurred lower rates of perioperative bleeding (odds ratio = 0.14, 95% confidence interval = 0.02–0.39) and stomal infections (odds ratio = 0.02, 95% confidence interval = 0.01–0.07) relative to surgical techniques. However, these data are pooled from relatively small studies and although the techniques and practices are safe there remains a need to complete larger appropriately powered studies with less heterogeneity within the populations. The need for further investigation is highlighted by Dulguerov et al (1999) who collated data from a population of 3512 patients between 1985 and 1996. Although incidences of complications with percutaneous techniques were lower the severity of complications was greater with a higher incidence of postoperative death (0.44% *vs* 0.03%).

Beltrame et al (2008) considered the practical and logistical issues, comparing the different techniques. This study compared a population of 367 patients receiving percutaneous tracheostomy with a heterogeneous historical cohort of surgical tracheostomies ($n=161$). There were no significant differences in long-term morbidity or mortality between the populations. However, there were significant differences in the timing of tracheostomy and length of procedure. On average the percutaneous tracheostomy was placed 4 days earlier and procedure time was 15 minutes quicker. These results reflect the difficulty in arranging the theatre time for

surgical tracheostomies and the ease and speed with which the percutaneous technique can be completed.

Timing of tracheostomy

A number of studies and meta-analyses have tried to address the issue of the timing of tracheostomy (Griffiths et al, 2005). Conclusions have been limited by the small population sizes and the heterogeneity of patients included. Currently tracheostomies are sited after approximately 10 days of mechanical ventilation (based on the consensus recommendations), but there has been an increasing school of thought that earlier tracheostomy may offer benefits.

A retrospective cohort analysis reviewed the outcomes from tracheostomies placed before and after 10 days in acute care hospitals in Ontario, Canada (Scales et al, 2008). Although this was a retrospective study the sample size was large with 3758 in the early group and 7169 patients in the late group. The results demonstrated a lower mortality rate in the early group and that each additional delay of 1 day beyond 10 days increased mortality. However, the number needed to treat was high at 71 patients to save one life per week delay. This study, although not controlled, suggests delay of tracheostomy beyond 10 days may be harmful.

A randomized prospective trial assessed early *vs* late tracheostomy in 120 patients admitted to a medical intensive care unit (Rumbak et al, 2004). Early tracheostomies were placed within 2 days of mechanical ventilation and late occurred between 14 and 16 days. This trial identified lower mortality (31.7% *vs* 61.7%, $P<0.005$) and morbidity in the early group. The early group also spent less time mechanically ventilated (7.6 *vs* 17.4 days, $P<0.001$) and less time in intensive care (4.8 *vs* 16.2 days, $P<0.001$).

A smaller study of 44 burns patients were randomized to early tracheostomy on average 4 days post burn or late, at more than 14 days post burn (Saffle et al, 2002). The study identified no significant difference between groups with regard to mortality, duration of ventilation (31.4 *vs* 35.5 days) or hospital stay (57.3 *vs* 58.4 days). However, they did note a significant improvement in the ratio of arterial partial oxygen tension (PaO_2) to the fraction of inspired oxygen (FiO_2).

A meta-analysis of the timing of tracheostomy identified five studies as either randomized or quasi randomized, with a total sample size of 406 patients (Griffiths et al, 2005). The results demonstrated that early placement of tracheostomy reduced duration of mechanical ventilation (mean 8.5 days, $P=0.03$) and reduced the length of intensive care unit stay (mean 15.1 days, $P=0.001$), but there was no significant improvement in mortality (relative risk 0.79, $P=0.42$), morbidity or incidence of hospital-acquired pneumonia (relative risk 0.9, $P=0.48$).

The Intensive Care Society of UK have now completed a large multi-centre, prospective, randomized

trial, the TracMan trial, to attempt to establish a stronger evidence base in this area. The trial was conducted after a priori poll of the UK critical care community, which identified that the issue of early *vs* late tracheostomy remained unresolved and was a high priority. The TracMan protocol allowed percutaneous or surgical techniques. The trial arms were based on the number of days post admission to intensive care. During days one to four of admission patients were assessed as to whether mechanical ventilation would be required for 7 days or more. Patients were then randomly assigned to the early or late group. The early group received placement of tracheostomy within 4 days of admission, with the late group having placement 10 days or more after admission. The primary outcome measure was 30-day mortality with secondary outcomes of intensive care unit and hospital length of stay (TracMan, 2007).

The full TracMan results await publication but provisional results have been presented in abstract form and are discussed with permission. The trial closed after recruiting over 900 patients. The study showed no difference in mortality at either 30 days or hospital discharge. There was no distinction in intensive care unit or hospital length of stay. The only difference was a moderate reduction in sedation requirements in the early tracheostomy group. Importantly, within the late group approximately 45% of patients improved to the extent that they did not require tracheostomy.

These results also concur with a study by Ranieri et al that was also presented in abstract form at the International Symposium of Intensive Care and Emergency Medicine 2009. In a similar protocol to TracMan, 200 patients were randomized to early (day three to five) or late (day 10 to 12) tracheostomy. Early tracheostomy was not associated with any beneficial effect on the development of ventilator-associated pneumonia or mortality. However, Ranieri and colleagues did note higher incidence of successful weaning, reduced intensive care unit stay and reduced sedative require-

ments in the early group. One limitation of this study was the large portion of neurological case load (45%).

These results, including TracMan, which is the largest randomized prospective trial in the subject area, raise a number of questions with regard to practical recommendations. Not only does it question the risk/benefit profile of early tracheostomy but it also questions the thoroughness of methods used to predict ventilator requirements.

Targeted patient selection for early tracheostomy

It has previously been noted that the heterogeneity in the populations included in the tracheostomy trials contributes significantly towards the variability in findings and conclusions (Griffiths et al, 2005). A major intention of the TracMan study was to standardize the research protocol and attain suitable study numbers to reduce the potential of heterogenic influence. Unfortunately despite this a definitive conclusion on the use of early tracheostomy remains elusive.

It seems likely that primary pathology should influence the tracheostomy strategy. The positive results in the population of primary respiratory complaints (Rumbak et al, 2004) suggest that early tracheostomy may benefit this group.

When considering the global population of intubated critical care patients a major problem is the ability to identify early which patients will require prolonged mechanical ventilation. This problem is highlighted by the significant number of patients in both the TracMan (45%) and Rumbak (35%) trials who improved within the late arms of the trial to the extent that tracheostomy was not required between 10–14 days (Rumbak et al, 2004; TracMan, 2007).

The first step towards resolving this issue will be to produce a sensitive and validated formula to identify who will require long-term ventilation. There have been attempts to produce a formula to help identify which burns patients will require long-term ventilation (Sellers et al, 1997). However, to date a similar formula for the general population has yet to be produced and validated.

Conclusions

Considering the current available evidence this review is unable to recommend the early placement of tracheostomy before day seven in the general critical care population. However, there is no evidence of harm from early tracheostomy and it should be remembered that tracheostomy does incur considerable benefits for the patient with regard to reduced sedation and reduced duration of ventilation. It appears that delay of tracheostomy beyond 10–14 days is likely to be detrimental. However, beyond this, until a validated scoring tools exists to identify patients who will benefit from early tracheostomy, recommendations cannot be made about the timing of tracheostomy. **BJHM**

KEY POINTS

- Tracheostomy remains a mainstay of ventilatory care in the critical care environment.
- Percutaneous and surgical techniques share a similar risk profile.
- Tracheostomy assists the multidisciplinary team care for critical care patients by reducing sedative requirements and improving ventilation.
- Delay of tracheostomy beyond 10 days may be detrimental.
- Despite the potential advantage of placing tracheostomy early with regard to improved care large randomized control trials have shown no long-term survival benefit.
- Future tracheostomy management strategies will be improved by the development of scoring systems that identify patients in need of long-term mechanical ventilation.

Conflict of interest: none.

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