Impact of Early Versus Late Tracheostomy on Patients Outcomes (Length of Stay, Ventilation associated Pneumonia and Mortality) at Qena University Hospital

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Abstract: This study examined the potential effects of time of tracheostomy on mechanical ventilation duration, intensive care unit (ICU) and hospital length of stay (LOS), ICU ventilation associated pneumonia (VAP) and Intensive Care Unit (ICU) and hospital mortality. The data were obtained from prospective Intensive care unit database information on all patients who were admitted and underwent tracheostomy over 2-years period: demography, Acute Physiology and Chronic Health Evaluation II score, Simplified Acute Physiology Score II, Glasgow Coma Scale score, ICU ventilation associated pneumonia, ICU and hospital length of stay and mortality. The type of tracheostomy procedure is surgical. Tracheostomy was considered early if it was performed before or on day 7 of mechanical ventilation. Of 353 ICU patients, 75 (21.2%) required tracheostomies, 18 of whom were early and 57 were late. Age, sex, Acute Physiology and Chronic Health Evaluation (APACHE) II score, and Simplified Acute Physiology Score (SAPS) II were not different between the two groups. Duration of mechanical ventilation was significantly shorter with early tracheostomy (mean ± standard error: 9.6 ± 1.2 days versus 18.7 ± 1.3 days; with significant P value < 0.0001). Similarly, ICU LOS was significantly shorter with early tracheostomy (10.9 ± 1.2 days versus 21.0 ± 1.3 days; with significant P < 0.0001). ICU ventilation associated pneumonia cases were less in early tracheostomy than the late one (2 cases versus 21 cases, with significant P value = 0.039). ICU mortality rates were similar for the 2 groups. In this study we found that time of tracheostomy is a predictor of mechanical ventilation duration, also using multivariate analysis late tracheostomy was an independent predictor of prolonged ICU stay (>14 days). So; early tracheostomy might lead to significant resources saving without negatively affecting survival.


Keywords: Tracheostomy, Intensive Care Unit (ICU), Mechanical Ventilation (MV), Length of stay (LOS), Ventilation associated Pneumonia (VAP).

1. Introduction:

Tracheostomy is one of the most common surgical procedures performed on critically ill patients (Bardell and Drover, 2005). Studies reported that prevalence around the world varies between 10% and 20% (Flaatten et al, 2006; Esteban et al, 2008). Tracheostomy is performed in 11% of mechanically ventilated patients and 6% of intensive care unit (ICU) patients in general (Frutos-Vivar et al, 2005; Freeman et al, 2005).

Tracheostomy has been shown to reduce total mechanical ventilation time, shorten period of Intensive Care Unit “ICU” and hospital stays (Arabi et al, 2004). Decrease the occurrence of pneumonia (Kanna et al, 2005; Schneider et al, 2009). Reduce hospital mortality (Yavas et al, 2009) and improve hospital resources use (Brook et al, 2000). Tracheostomy may increase patient comfort (Blot et al, 2008), increase tolerance of mechanical ventilation and facilitate nursing care (Nieszkowska et al, 2005). It can improve communication (Heffner, 2005) and oral hygiene and makes mobilization more possible. It decreases the number of self extubations and extubation-reintubation cycles and decreases the requirement for sedation (Nieszkowska et al, 2005). Tracheostomy may also reduce upper airway injury including vocal cord ulceration (Barquist et al, 2006), decrease dead space ventilation and airway resistance and optimize the work of breathing; therefore facilitating separation from ventilator support and allowing for earlier transfer out of the ICU (Diehl et al, 1999). Several studies have demonstrated that early tracheotomies associated with decreased time of liberation from mechanical ventilation and decreased ICU length of stay “LOS” (Bouderka et al, 2004, Griffeths et al, 2005); however, there is still lack of consensus on what constitutes early versus late tracheostomy.

The decision to proceed to tracheostomy is often made only if the patient could not be reintubated within 10–14 days or more (Lesnik et al, 1992). For those; with anticipated need for artificial airway for more than 21 days, tracheostomy was recommended.
For all other patients, the decision regarding the timing of tracheostomy was left to daily assessment and physician preference. The aim of the present study is to examine the impact of early tracheostomy on outcomes and resources utilization in ICU patients.

**Research Questions:**

Patients with acute severe trauma or head injury anticipated to require prolonged endotracheal intubation and mechanical ventilation have always been the subject of debate between physicians whether to go for early versus late tracheostomy with variable evidence on the outcome of both approaches. Another point of debate was the definition of early and late tracheostomy.

**Objective:**

In our study, we are aiming to detect any difference between the two group’s assigned to early versus late tracheostomy as regards the ICU and hospital length of stay (LOS), time of weaning from mechanical ventilation, cases with ventilation associated pneumonia (VAP), rate of patient discharge from ICU and ICU and hospital mortality rate. We are conducting this study to help to clarify the effect of outcome and prognosis of early and late tracheostomy in such two groups of patients.

**2. Subjects and Methods:**

The study was performed at Qena University Hospital ICU. From the 400- hospital beds there were 18-beds ICU staffed by full-time staffs, on-site intensive care for the 24 hours per day and 7 days per week. The department has five consultants’ intensive care specialists, all of whom are certified in critical care. Medical care in the ICU is provided by the ICU specialists.

The decision to perform tracheostomy and when to perform the procedure was at the discretion of the treating intensive care specialist and was typically based on clinical assessment, including the failure to wean, the inability to “protect the airway,” and the inability to cough spontaneously. Tracheostomy was performed in certain patients without an attempt to extubate if the intensive care specialist judged that the chance for successful extubation was low. In other patients, tracheostomy was performed after one or more failed attempts to extubate.

**Data collection**

We have maintained prospective database including all ICU consecutive patients admitted to the ICU over a 2-year period (August 2011 to August 2013) who underwent tracheostomy during their ICU stay. Patients were included in the study if they were aged 18 years or older and had tracheostomy performed during their ICU stay. Patients were excluded from the study if they were (a) readmitted to ICU within their current hospital stay, (b) referred from another institution and/or (c) admitted for burn management. The following data were extracted: age, sex and admission severity of illness estimated by using the Acute Physiology and Chronic Health Evaluation (APACHE) II (Knaus et al, 1985), Simplified Acute Physiology Score II (Le Gall et al, 1993) and Glasgow Coma Scale of 6 or lesser assessed in non-sedated or pre-sedated condition or based on the best clinical judgment that reflects the true neurologic status rather than the effect of sedatives. The main diagnostic categories for ICU admission were derived from the APACHE II system and were divided into the following groups: respiratory, cardiovascular, neurologic, trauma, postoperative non trauma and other medical diseases (Knaus et al, 1985).

We documented whether an extubation trial was given before tracheostomy, the number of days from initiation of ventilation to tracheostomy, from admission to tracheostomy, from tracheostomy to weaning, from tracheostomy to discharge from ICU, the duration of mechanical ventilation and ICU length of stay (LOS) were all calculated. All these durations were calculated as the number of calendar days, with the day of admission being considered day zero “0”. Ventilation associated pneumonia cases (VAP) and ICU and hospital mortality rates were also documented.

We divided patients into two groups: the early tracheostomy group; in which tracheostomy was performed within the first 7 days of initiation of mechanical ventilation and the late tracheostomy group; in which tracheostomy was performed after 7 days. Prolonged ICU stay was defined as ICU stay in excess of 14 days. Both groups of patients assigned to early and late tracheostomy were compared as regards demographic data, acute physiology and chronic health evaluation (APACHE II) score, Glasgow coma score (GCS), being weaned from mechanical ventilation on day 3 post-tracheostomy, ICU LOS, discharge from ICU and mortality rate.

**Statistical analysis**

The statistical analysis was performed using the Sigma Stat program, version 2.0, SPSS Inc. version 17, Chicago, IL, USA. Continuous variables are expressed as means ± standard error of the mean, and were compared using t-tests. Categorical variables are expressed by numbers and percent and were compared using chi square ($\chi^2$) test. Linear correlation was performed to test for associations between timing of tracheostomy and duration from initiation of mechanical ventilation to tracheostomy and ICU LOS. To assess further the impact of delayed tracheostomy on ICU LOS, univariate and multivariate analyses were performed to examine
whether delayed tracheostomy is an independent predictor of prolonged ICU stay. Results of prediction are expressed as odds ratios (ORs) at 95% confidence intervals (CIs). P ≤ 0.05 and/or <0.001 were considered statistically significant.

3. Results:
Table 1 summarizes the patients' characteristics at baseline. During the period of study there were 353 patients admitted to the ICU. The number of patients who required tracheostomy was 75 (21.2%); 18 patients had tracheostomy within 7 days of mechanical ventilation and the remaining 57 underwent tracheostomy after 7 days. Comparison of demographic data between the two groups revealed no significant differences regard the age and sex, APACHE II score and Simplified Acute Physiology Score II. But there were significant differences between the two groups in Glasgow Coma Scale (p = 0.04).

There was no significant difference in the presence of respiratory, cardiovascular, neurological or other medical diseases between the two groups. Early tracheostomy were more common in traumatic patients (44.4% versus 19.3%; P = 0.03) with significance difference (P<0.05), whereas non traumatic postoperative patient were less common (5.5% versus 17.5%; P = 0.21 non-significant).

Table 2 shows tracheostomy timing data and main outcomes. Extubation trials were performed in 24.6% of patients with late tracheostomy as compared with 5.5% of those with early tracheostomy (P = 0.019). After placement of the tracheostomy, both groups were weaned off from mechanical ventilation and discharged from the ICU after similar periods. Early tracheostomy was associated with a significantly shorter duration of mechanical ventilation (9.6 ± 1.2 days versus 18.7 ± 1.3 days; P < 0.001) and shorter ICU LOS (10.9 ± 1.2 days versus 21.0 ± 1.3 days; P < 0.001) and significant reduction of ventilation associated pneumonia VAP ( 2 cases versus 21 cases; P value = 0.039 ). ICU and hospital mortalities were not different between the two groups.

<table>
<thead>
<tr>
<th>Items</th>
<th>Tracheostomy ≤ 7 days</th>
<th>Tracheostomy &gt;7 days</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>18</td>
<td>57</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>35 ± 3</td>
<td>30 ± 1</td>
<td>0.5</td>
</tr>
<tr>
<td>Male sex (%)</td>
<td>16 (88.9%)</td>
<td>52 (91.2%)</td>
<td>0.75</td>
</tr>
<tr>
<td>APACHE II score</td>
<td>20 ± 1</td>
<td>19 ± 1</td>
<td>0.35</td>
</tr>
<tr>
<td>SAPS II score</td>
<td>42 ± 2</td>
<td>39 ± 1</td>
<td>0.36</td>
</tr>
<tr>
<td>GCS score</td>
<td>5.2 ± 0.5</td>
<td>6.5 ± 0.4</td>
<td>*0.04</td>
</tr>
<tr>
<td>Main reason for ICU admission (n[%])</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory</td>
<td>11 (61.1%)</td>
<td>35 (61.4%)</td>
<td>0.98</td>
</tr>
<tr>
<td>Trauma</td>
<td>8 (44.4%)</td>
<td>11 (19.3%)</td>
<td>*0.03</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>7 (38.9%)</td>
<td>25 (43.8%)</td>
<td>0.71</td>
</tr>
<tr>
<td>Neurological</td>
<td>2 (11.1%)</td>
<td>11 (19.3%)</td>
<td>0.42</td>
</tr>
<tr>
<td>Non-traumatic postoperative</td>
<td>1 (5.5%)</td>
<td>10 (17.5%)</td>
<td>0.21</td>
</tr>
<tr>
<td>Other medical diseases</td>
<td>6 (33.3%)</td>
<td>21 (36.8%)</td>
<td>0.89</td>
</tr>
</tbody>
</table>

Values are expressed as mean ± standard error of the mean. APACHE: Acute Physiology and Chronic Health Evaluation; GCS: Glasgow Coma Scale; SAPS: Simplified Acute Physiology Score. *P value=significant

<table>
<thead>
<tr>
<th>Items</th>
<th>Tracheostomy ≤ 7 days</th>
<th>Tracheostomy &gt;7 days</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ventilation days before tracheostomy</td>
<td>4.6 ± 0.5 (6, 2.5–7)</td>
<td>13.9 ± 0.5 (13, 10–16)</td>
<td>**&lt;0.001</td>
</tr>
<tr>
<td>Days from ICU admission to tracheostomy</td>
<td>4.6 ± 0.5 (6, 2.5–7)</td>
<td>14.1 ± 0.5 (13, 11–17)</td>
<td>**&lt;0.001</td>
</tr>
<tr>
<td>Number (%) of patients with extubation trials</td>
<td>1 (5.5%)</td>
<td>14 (24.6%)</td>
<td>*0.019</td>
</tr>
<tr>
<td>Days from tracheostomy to weaning</td>
<td>4.9 ± 1.2 (2, 1–7)</td>
<td>4.9 ± 1.1 (1, 1–4)</td>
<td>1.0</td>
</tr>
<tr>
<td>Days from tracheostomy to ICU discharge</td>
<td>6.3 ± 1.3 (4, 2–8.5)</td>
<td>6.9 ± 1.1 (3, 2–7)</td>
<td>0.72</td>
</tr>
<tr>
<td>Duration of mechanical ventilation (days)</td>
<td>9.6 ± 1.2 (8, 6–13)</td>
<td>18.7 ± 1.3 (15, 12–20)</td>
<td>**&lt;0.001</td>
</tr>
<tr>
<td>ICU LOS (days)</td>
<td>10.9 ± 1.2 (10, 7–14)</td>
<td>21.0 ± 1.3 (17, 14–23)</td>
<td>**&lt;0.001</td>
</tr>
<tr>
<td>Hospital LOS (days)</td>
<td>101 ± 19 (68, 33–139)</td>
<td>105 ± 7 (83, 54–136)</td>
<td>0.84</td>
</tr>
<tr>
<td>ICU infection pneumonia (VAP)</td>
<td>2 (11.1%)</td>
<td>21 (36.8%)</td>
<td>*0.039</td>
</tr>
<tr>
<td>ICU mortality (n [ ])</td>
<td>1 (5.5%)</td>
<td>1 (1.7%)</td>
<td>0.38</td>
</tr>
<tr>
<td>Hospital mortality (n [%])</td>
<td>1 (5.5%)</td>
<td>5 (27.8%)</td>
<td>0.09</td>
</tr>
</tbody>
</table>

**P value= highly significant (<0.001)  *P value=significant (<0.05)
Figure 1 shows the distribution of patients by timing of tracheostomy and the mean ICU LOS for patients, stratified by timing of tracheostomy.

Both Figures 2 and 3 showed that the duration of mechanical ventilation and ICU LOS were significantly shorter in the early tracheostomy group (log rank P value < 0.001 for both).

Figure 1 Patients distribution by timing of tracheostomy and mean ICU LOS for patients, stratified by timing of tracheostomy. There is direct correlation between the timing of tracheostomy and mean ICU LOS ($r = 0.91; P < 0.001$).

Figure 2 Kaplan–Meier curves for duration of mechanical ventilation in early and late tracheostomy groups. Early tracheostomy was associated with a significantly shorter duration of mechanical ventilation (log rank P value < 0.001).

Figure 3 Kaplan–Meier curves of intensive care unit (ICU) length of stay (LOS) in early and late tracheostomy groups. Early tracheostomy was associated with a significantly shorter ICU LOS (log rank P value < 0.001).
4. Discussion:

The timing of tracheostomy remains a matter of controversy and the recommendations are still based on the experience of specialists rather than on scientific evidence. Prolonged tracheostomy is known to be associated with many problems that can dramatically affect the course of patient recovery, including higher risk of infections including ventilator associated pneumonia (VAP), higher doses of sedation and difficulty of weaning from mechanical ventilation, while early tracheostomy (less than 2 postoperative days) for respiratory failure after surgery was associated with reduced morbidities and in hospital mortality and ICU and total hospital length of stay "LOS" (Combes et al, 2007).

In our study we found that early tracheostomy before day 7 of mechanical ventilation in ICU patients associated with a significant reduction in the duration of mechanical ventilation and ICU LOS without affecting patient outcome. It demonstrates that the relationship between time of tracheostomy and ICU LOS and mechanical ventilation duration follows a continuum rather than a dichotomous model, the later the tracheostomy, the longer ICU LOS and mechanical ventilation duration. We also found that late tracheostomy was an independent predictor of prolonged ICU stay more than 14 days. Patients with early tracheostomy had lower GCS, reflecting the common practice of performing tracheostomies earlier in patients with low GCS; while delaying tracheostomy in patients with higher GCS in case extubation becomes possible.

Rumbak et al, 2004 conducted a study where they randomized 120 ICU patients to either early tracheostomy (within 48 hours) or delayed tracheostomy (at days 15-16). They found that the early tracheostomy group had shorter mechanical ventilation duration (7.6±2.0 versus 17.4±5.3 days) and ICU LOS (4.8±1.4 versus 16.2±3.8 days) as well as less mortality (31.7% versus 61.7%). Armstrong et al, 1998 performed a retrospective chart review of 157 patients with blunt trauma and found that early tracheostomy (<6 days of intubation) was associated with a decrease in the ICU and hospital LOS. Rodriguez et al, 1990 randomized 51 patients to early tracheostomy (within 7 days of intubation) and 55 patients to late tracheostomy (after 7 days) and found that early tracheostomy was associated with a decrease in mechanical ventilation duration, ICU LOS and hospital LOS. D'Amello et al, 1994 studied 45 patients with trauma retrospectively, 31 of whom underwent tracheostomy. Patients who had tracheostomy done within the first 7 days of intubation had shorter mechanical ventilation duration as well as ICU and hospital LOS. In a study from tertiary care teaching center Riyadh, Saudi Arabia; Yassen et al, 2009 examined the impact of early versus late tracheostomy on the outcome of 136 patients with trauma who underwent tracheostomy, 29 of whom had early tracheostomy (<7 days of mechanical ventilation). They found that the duration of mechanical ventilation and ICU LOS was significantly shorter in the early tracheostomy group, but mortality rate were similar.

Maziak et al, 1998 performed a systematic review for 5 studies on the effect of time of tracheostomy. The authors found that there was insufficient evidence support that early tracheostomy could result in shorter mechanical ventilation duration in critically ill patients. However, there were limitations to this systematic review including the retrospective nature of 2 of the studies and the significant limitations of the included randomized controlled trials. Surgerman et al, 1997 conducted a prospective randomized multicenter study of 157 patients, 18 of whom were patients with trauma. Patients were randomized on days 3 to 5 to receive tracheostomy or to continue with translaryngeal intubation. Patients who remained intubated were randomized again on days 10 to 14. They found that ICU LOS was not different between the 2 groups. However, of the 5 participating centers only one center complete the study and of 157 enrolled patients only 112 complete the study. Also; Trouillet and coauthors, 2011 in a prospective randomized trial compared outcomes in adult cardiac surgery patients who underwent early percutaneous bedside tracheostomy (on postoperative day 4) with those who had prolonged intubation and tracheostomy 15 days after randomization. They reported no difference between the 2 groups in ventilator free day, mortality and ICU or hospital LOS, this assumed because prolonged intubation group had a greater use of noninvasive ventilation. Patel and Kress, 2011 point out several limitations in Trouillet investigations including the high number of ventilator free days in the late tracheostomy resulted in the investigation being underpowered for the primary outcome. Patient selection for randomization was to a certain degree subjective and selection criteria were not well defined. Only 27% of the patients in late group ultimately required tracheostomy. It is difficult in predicting on postoperative day 4 which patients will require tracheostomy. It is therefore conceivable that some patients who didn’t require tracheostomy had it and vice versa. Including and excluding this misclassified patients in analysis is problematic.

Our study shows significant reduction of Ventilation Associated Pneumonia in early tracheostomy in comparison with the late one with P value < 0.05 (0.039). Therefore, in patients who are
likely deemed to require tracheostomy, it might be preferred to perform tracheostomy earlier than later. These results suggest the need for a prospective protocol strategy to identify the patients who are likely to require tracheostomy, so it can be performed earlier than later (Freeman et al, 2008). It's found that prevention of ventilation associated pneumonia “VAP” had inverse relationship with inadequacy of nursing care and care of health care workers to the patients (receiving mechanical ventilation and/or with tracheostomy) and with prolonged ICU patients stay (Marc et al, 2004). Clinicians and nursing care for patients at risk for VAP at ICU should promote the development and application of local programs encompassing interventions based on local resources availability, one of these interventions is quality of nursing care at ICU and nursing care to tracheostomy tube to prevent occurrence of VAP (Kollef and Marin, 2004). Nursing care of tracheostomy patients includes the following: keep appropriate equipment at the patient's bedside for immediate use in an emergency, consult the physician about first-aid measures for tracheostomy patient if an emergency occur; follow the facility's policy regarding procedure if a tracheostomy tube is expelled or if the outer cannula becomes blocked or if the patient's breathing is obstructed for example; when the tube is blocked with mucus that can't be removed by suctioning or by withdrawing the inner cannula provide manual resuscitation with a handheld resuscitation bag or reconnect the patient to the ventilator, refrain from changing tracheostomy ties unnecessarily during the immediate postoperative period before the hole is well formed (usually 4 days) to avoid accidental dislodgment and expulsion of the tube; unless secretions or drainage is a problem; ties can be changed once per day, if the patient's neck or the hole is excoriated or infected; apply a water-soluble lubricant or topical antibiotic cream as ordered; never to use a powder or an oil-based substance on or around the hole because aspiration can cause infection and abscess and replace all equipment, including solutions, regularly according to the policy to reduce the risk of nosocomial infections (Elizabeth, 2004).

There was no significance difference in ICU or hospital number of mortalities or mortality percentages (case fatality rate) between early and late tracheostomy. This is in line with a study in Saudi Arabia shows that time of tracheostomy was not associated with ICU or hospital mortality (Yassen et al, 2009). In another study early tracheostomy was associated with decreased in-hospital mortality (21.1% versus 40.4%, P = 0.002), decreased cardiac morbidity (14% versus 33.3%, P < 0.001) and reduce occurrence of sternal wound infection 6% versus 19.5%, P = 0.009 (Jagan et al, 2012). The very low mortality seen in the patients we studied may be explained by selection of proper candidates for tracheostomy, excluding those patients who were unlikely to survive. Our results are consistent with theory proposed by Waltz and colleagues, 2006 that events occurring between the interval of admission to the ICU and tracheostomy and the patient condition are the primary determining variables associated with long term outcomes (Waltz et al, 2006; Murthy et al, 2007). In addition; Jagan and coauthors, 2012 reported that severity of illness, real or perceived, presumably affects tracheostomy timing and outcomes. For example; the decision to perform tracheostomy might be delayed in severely ill patients because of increased risk; similarly, tracheostomy might be delayed in patients who thought to be improved.

The results of our study should be interpreted in light of its strengths and limitations. Strengths included the large number of patients and the prospective data collection. Limitations included the fact that it was conducted in a single center and was generated from a general ICU database. These findings need to be validated in a properly powered intention-to-treat multicenter randomized controlled trial.

Conclusions:
Based on our study, early tracheostomy is expected to have a better outcome in patients with acute severe injury as head injury. We found that early tracheostomy in trauma ICU patients was associated with a significant reduction in the duration of mechanical ventilation, ICU LOS and ICU ventilation associated pneumonia (VAP) without affecting patient mortality. This study suggests that in patients who appear likely to require tracheostomy, early tracheostomy might lead to significant resources saving without negatively affecting survival.

Recommendations:
1. Protocol to identify the patients who are likely to require tracheostomy and define early versus late tracheostomy.
2. When patients require tracheostomy, early tracheostomy is preferred as it lead to better outcomes (decrease ICU and hospital LOS), decrease number of ventilation associated pneumonia cases and significant resources saving without negatively affecting survival.
3. Quality of nursing care and health care workers care is crucial in prevention of ICU ventilation associated pneumonia.
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References

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