ORIGINAL RESEARCH

# Tracheostomy without mechanical ventilation in patients with traumatic brain injury at a tertiary referral hospital in Malawi: a cross sectional study

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## Abstract

### Background

Tracheostomy alone, without mechanical ventilation, has been advocated to maintain a free airway in patients with traumatic brain injury in low-income settings with minimal critical care capacity. However, no reports exist on the outcomes of this strategy. We examine the results of this practice at a central hospital in Malawi.

### Methods

This is a retrospective review of medical records and prospectively gathered trauma surveillance data of patients admitted to Kamuzu Central Hospital, with traumatic brain injury from January 2010 to December 2015. In-hospital mortality rates were examined according to registered traumatic brain injury severity and airway management.

### Results

In our analysis, 1875 of 2051 registered traumatic brain injury patients were included; 83.3% were male, mean age 32.6 (SD 12.9) years. 14.2% (n=267) of the patients had invasive airway management (endotracheal tube or tracheostomy) with or without mechanical ventilation. Mortality in severe traumatic brain injury treated with tracheostomy without mechanical ventilation was 42% (10/24) compared to 21% (14/68) in patients treated without intubation or tracheostomy (p= 0.043). Tracheostomies had an overall complication rate of 11%.

### Conclusion

Tracheostomy without mechanical ventilation in severe traumatic brain injury did not improve survival outcomes in our setting. Tracheostomy for severe traumatic brain injury cannot be recommended when mechanical ventilation is not available unless there are sufficient specialized human resources for follow up in the ward. Efforts to improve critical care facilities and human resource capacity to allow proper use of mechanical ventilation in severe traumatic brain injury should be a high priority in low-income countries where the burden of trauma is high.

**Keywords:** tracheostomy, mechanical ventilation, traumatic brain injury, airway management, critical care, in-hospital mortality

## Introduction

Tracheostomy is a common surgical procedure performed in patients with severe traumatic brain injury (TBI) to facilitate prolonged airway and ventilatory support[1]. Early establishment and maintenance of airway is critical as mortality increases in those patients who suffer from hypoxia[2]. In patients on mechanical ventilation, tracheostomy may facilitate weaning from the ventilator, decrease length of intensive care unit (ICU) or hospital stay, and improve pulmonary toilet[3,4]. Many studies have confirmed that tracheostomy is a safe, effective method of airway management for patients with severe head, facial and multisystem organ trauma[5]. If performed appropriately in a setting with adequate resources, it is associated with a low complication rate[6]. Haspel et al have recorded an overall complication rate of 2.7% in their study among patients with oral and maxillofacial conditions[7]. Reported complications include bleeding, pneumothorax, pneumomediastinum, subcutaneous emphysema, oesophageal injury and tracheostomy tube occlusion among many[8].

Due to the inadequate number of mechanical ventilators and trained ICU staff in many under-resourced hospitals in LMICs, definitive airway management with tracheostomy alone has been advocated by some surgeons in patients with severe TBI when a mechanical ventilator is unavailable in ICU[9,10]. However, our search of the literature turned up few reports describing the use of tracheostomy without mechanical ventilation in severe TBI. We found only one study from India reporting better results in TBI patients that received tracheostomy and ward care due to lack of intensive care unit capacity, but this hospital had a fairly good patient to nurse ratio, some of the most severe cases did receive mechanical ventilation in the wards, some were ventilated with Ambu-bags, and close specialized follow up of the patients was available[10].

Kamuzu Central Hospital (KCH) is a public tertiary referral and teaching hospital in Lilongwe, Malawi, and serves a population of about 8 million Malawians from the central



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and northern regions of the country[11,12]. The TBI prevalence rate at KCH has been reported to be as high as 19% of all trauma patients in 2013[13]. Treatment of TBI patients at KCH requiring critical care is hampered by inadequate trauma and intensive care unit (ICU) resources. Like in many developing countries, care of the critically ill in Malawi is poorly developed. Intensive care, as recognized in developed countries, is simply not possible in this part of the world due to limited human and equipment resources[14]. For example, at KCH, the 1000 bed central hospital in the capital city of Malawi, the newly built ICU and Surgical High Dependency Unit (SHDU) can only accommodate a maximum of 6 patients each at a time.

At KCH this practice of definitive airway management by tracheostomy when a ventilator is not available was introduced in an attempt to improve the survival of severe TBI patients in a setting where the surgical wards have a nurse to patient ratio of around 1:40, sometimes even less. The impact of this practice has not been evaluated before in our severely resource constrained setting. In this study, we aimed to evaluate the outcomes of TBI patients treated with tracheostomy without mechanical ventilatory support at KCH.

## Ethical approval

Approval to conduct the study was obtained from the Malawi National Health Science Research Committee (NHSRC) with approval number NHSRC# 16/4/1575 and the KCH administration on 05 July 2016.

## Methods

### *Sample population and size*

We used a total sampling approach. All patients with a history of an altered level of consciousness following head trauma admitted at KCH from January 2010 to December 2015 were eligible for inclusion in our study.

### *Study design and data collection*

We carried out a retrospective cross-sectional review of data recorded in the KCH electronic trauma registry and actual patient files obtained from the hospital's surgery ward records and medical records office at KCH. Data extracted from these records included demographic and clinical information for all admissions of TBI patients. These were age, sex, district of origin and clinical data; date and time of admission, Glasgow coma scale (GCS) at time of admission, airway management, complications associated with tracheostomy, neurosurgical intervention (e.g. burr hole), length of hospital stay and discharge destination (discharged home or died in hospital). We excluded patients that died in the casualty department.

### *Data Analysis*

Data were entered on research record sheets and later transferred into a Microsoft Access 2013 database, imported into and analyzed using Stata/IC 12.0 (StataCorp, College Station, Texas, USA). We set Alpha at 0.05 for this study. Descriptive statistics were used to determine the proportions of some variables particularly basic patient characteristics, airway management categories and complications associated with tracheostomy. Central tendency was described with means and standard deviations (SD) for normally distributed variables. For non-normally distributed variables medians and interquartile ranges (IQR) were used. Pearson Chi-square and Student T-test were used to determine any association between categorical variables and compare means respectively.

TBI patients requiring definitive airway management i.e. endotracheal intubation or tracheostomy were compared with respect to the main outcome variable; mortality/survival. Patients were categorized into four groups; ETT group (who received endotracheal intubation plus mechanical ventilation), TMV group (who received tracheostomy plus mechanical ventilation), TwMV group (who received tracheostomy only) and no ETT/Tracheostomy group (who received neither tracheostomy nor endotracheal intubation and were not placed on a mechanical ventilator). In an attempt to determine if tracheostomy without mechanical ventilation improved outcomes in patients with GCS ≤8 who did not receive mechanical ventilation, this group was compared to patients with the same TBI severity that did not receive any definitive airway management (ETT or Tracheostomy). Logistic regression modelling was used to determine Odds ratios, confidence intervals and adjusted odds ratios for airway management and outcome.

This work has been reported in line with the STROCSS criteria [15]

## Results

A total of 2051 patients were registered with TBI in the KCH trauma database from 1st January 2010 to 31st December 2015. Of these, the patient file was available for 1480 patients. For the remaining 571 patients only the electronic data from the trauma database was reviewed. Patients that did not have initial GCS, airway management or survival outcome recorded in their records were excluded from the study leaving 1875 patients meeting the study criteria (Figure 1).

**Table 1. Baseline patient characteristics**

| | N (%) |
|---|---|
| Gender | |
| Male | 1562 (83.3) |
| Female | 313 (16.7) |
| Mean age (SD) years | 32.6 (± 12.9) |
| Traumatic Brain Injury Severity (GCS) | |
| Severe (3-8) | 260 (13.9) |
| Moderate (9-12) | 225 (12.0) |
| Mild (13-15) | 1390 (74.1) |
| Admission ward | |
| ICU | 190(10.1) |
| SHDU | 77(4.1) |
| General surgical ward | 1608(85.8) |
| Patient Outcome | |
| Discharged | 1664 (88.7) |
| Dead | 211(11.3) |

**Table 2: Airway management in TBI patients**

| Airway management | TBI severity (GCS) | | | Total(n) |
|---|---|---|---|---|
| | Severe (3-8) | Moderate (9-12) | Mild (13-15) | |
| Endotracheal intubation | 90 | 16 | 12 | 118 |
| Tracheostomy | 102 | 30 | 17 | 149 |
| None | 68 | 179 | 1361 | 1608 |
| Total (n) | 260 | 225 | 1390 | 1875 |

**Table 3: Crude analyses of mortality for patients with severe TBI**

| | | N | Discharged (%) | Dead (%) | P-value |
|---|---|---|---|---|---|
| Gender | Male | 221 | 114 (48.4) | 107 (48.4) | 0.58* |
| | Female | 39 | 22 (56.4) | 17 (43.6) | |
| Mean Age (±SD) | | 260 | 30.5 (±12.9) | 34.2(±15.4) | 0.04 |
| Associated Injury | YES | 81 | 40 (49.4) | 41 (50.6) | 0.53 |
| | NO | 179 | 96 (53.6) | 84 (46.4) | |

**Table 4: Odds ratios among the airway treatment groups with reference to no ETT/tracheostomy group**

| Treatment category | Odds ratio | 95% confidence interval |
|---|---|---|
| Endotracheal tube with mechanical ventilation | 3.64 | 1.11-11.90 |
| Tracheostomy and mechanical ventilation | 0.78 | 0.25-2.45 |
| Tracheostomy without mechanical ventilation | 2.62 | 0.74-9.32 |

**Table 5. Complications associated with tracheostomy**

| Complication | TMV(n=99) | TwMV(n=50) | DEATHS (N) | P-value |
|---|---|---|---|---|
| Tracheostomy tube occlusion | 3 | 1 | 1 | 0.17* |
| Surgical site bleeding | 4 | 2 | 2 | |
| Surgical site infection | 5 | 1 | 5 | |
| Other (unspecified) | 0 | 1 | 1 | |
| None | 87 | 45 | 47 | |

Patients who were admitted to ICU had a median GCS of 6 (IQR 5-8) and those admitted to SHDU and general wards had median GCSs of 10 (IQR 6-13) and 15 (14-15) respectively. The overall mortality rate for patients with TBI was 11.3 % (n=211) (Table 1).

Patients in the TwMV group represented 0.03% of the TBI patients included in the study. Their median age was 30 (IQR 24-36) years. There were more males (n=47, 94%) than females (n=3, 6%). In this group, 24 (48%) patients had severe TBI, 12 (24%) patients had moderate TBI and 14 (28%) patients had mild TBI. These patients were admitted in general wards (n=37, 74%) and SHDU (n=13, 26%). Fifteen of these patients (30%) died in hospital.

There were 99 (5.3%) patients in the TMV group. Thirty (30.3%) patients died in ICU. Among the patients who were discharged from ICU (n=69) to SHDU and general wards, 11(15.9%) died. Seventeen patients with mild TBI received tracheostomy either with or without mechanical ventilation due to associated facial and chest injuries.

The ETT group had 118 (6.2%) patients and all were admitted to the ICU. Patients were discharged from ICU after endotracheal tube removal with or without tracheostomy. The overall mortality in this group was 72.0%; Most patients died in the ICU (n=76) and others after discharge to SHDU and general wards (n=9).

The patients in the no ETT/Tracheostomy group (n=1608) were all admitted to the general wards. The overall mortality in this group was 4.5% (n=72).

## *Does tracheostomy without mechanical ventilation improve survival in severe TBI?*

Among the patients with severe TBI (n=260), 34.6% (n=90) had ETT, 30.0 %( n=78) received TMV, 9.2% (n=24) received TwMV and 26.2% (n= 68) did not have a definitive airway treatment (i.e. ETT or tracheostomy), table 2. Among the mechanically ventilated patients, mortality was 73.3% (n=66) in ETT group and 43.6 %( n=34) in TMV, ($p<0.001$). Mortality in TwMV was 41.7% (n=10) and 20.6% (n=14) in the patients with no ETT/tracheostomy ($p= 0.043$). The mean GCS was 6.1 in the TwMV group and 6.8 in the no ETT/tracheostomy group ($p=0.032$). In the ETT and TMV

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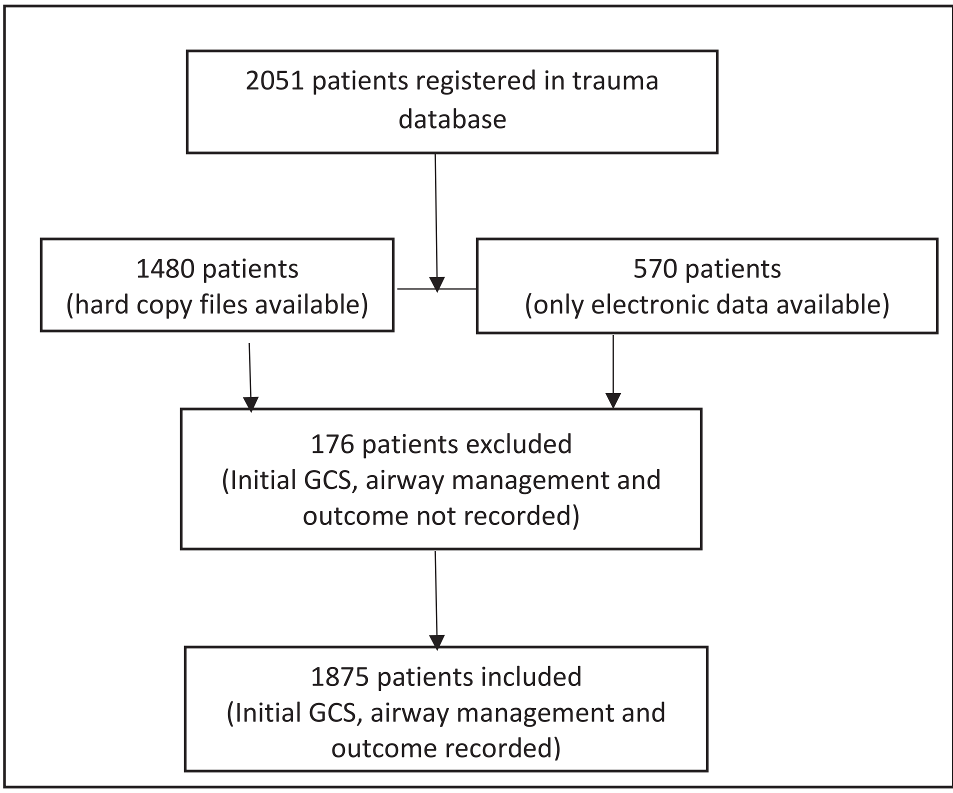


**Figure 1: Flow diagram illustrating patient inclusion for analysis**

groups, the mean GCS was the same, 5.6. Five patients (n=3, TwMV group, n=2, no ETT/Tracheostomy group) were later admitted in the ICU for mechanical ventilation but did not survive.

Following a bivariate analysis (Table 3), age, neurosurgical intervention and admission ward were statistically significant variables included in the logistic regression model to determine the odds of mortality among ETT, TMV and TwMV patients. With reference to the no ETT/tracheostomy group, the adjusted odds of mortality was higher in the ETT and TwMV groups and was lower in the TMV group (Table 4).

### *Complications of tracheostomy*

The common complications associated with tracheostomy irrespective of type of ventilation were bleeding, infection and tracheostomy tube occlusion (Table 5). The overall complication rate was 11.4%, 12.1% (n=12) in TMV patients and 10.0% (n=5) TwMV patients (p=0.60).

## Discussion

The main findings of this study were that patients with severe TBI who received tracheostomy without mechanical ventilation had a higher mortality rate than patients with no ETT or tracheostomy. Tracheostomy with mechanical ventilation had a lower mortality rate than endotracheal intubation with mechanical ventilation. In addition, the Odds of mortality in TMV patients was lower than in no ETT/tracheostomy. Irrespective of mode of ventilation our overall tracheostomy complication rate was 11.4%.

In Austria, it has been reported, despite the greater severity of traumatic brain injury, patients with isolated TBI who underwent tracheostomy with mechanical ventilation had a lower risk-adjusted mortality than patients who remained intubated[16]. Similar results were observed in our patients. In the literature, several other studies with similar observations have therefore recommended early tracheostomy, to improve clinical outcome in this group of patients[17,18].

In our experience, tracheostomy without mechanical ventilation in TBI is not uncommon in developing countries where the intensive care facilities are scarce even at tertiary referral centres. Many critical patients have to be managed in high dependency cubicles in the ward, often with inadequately trained clinical and nursing staff and equipment to monitor the patient, and a lack of medical follow-up once the patient is discharged from specialized areas like ICUs[19]. Our results show a higher mortality in the patients who received a tracheostomy without mechanical ventilation compared to those who neither had a tracheostomy or endotracheal intubation (p= 0.043). There was a slightly higher mean GCS in the no ETT or tracheostomy group (6.8 vs 6.1, p=0.032), suggesting the possibility for some selection bias. However, considering the complication rate for tracheostomy in our setting and the lack of ward personnel to provide tracheostomy care at KCH this finding cannot be ignored.

A higher Odds Ratio of mortality among ETT patients compared to no ETT/tracheostomy group may further emphasize challenges encountered in our critical care practice which include inadequate equipment, well trained staff and expertise.

Although tracheostomy is an increasingly used procedure, it may be associated with complications including stomal infection, stomal haemorrhage, major vascular injury, pneumothorax, subglottic stenosis, and tracheoesophageal fistulae, therefore, a decision to perform the procedure should not be taken lightly[20]. We observed tracheostomy tube occlusion, surgical site bleeding and surgical site infection to be the most common complications in our patients with an overall tracheostomy complication rate of 11.3%. In other studies, an overall inpatient tracheostomy complication rates as high as 47% have been reported[21]. Our complication rate may be lower than these previously reported high rates due to reporting bias.

The tracheostomy rate in the total population of TBI patients at KCH was 8%. The percentage of trauma patients requiring tracheostomy varies considerably in reports and ranges from 14% to 48%[22]. In Austria, Baron et al have reported a 25.6% tracheostomy rate among patients with moderate to severe TBI admitted to ICU16. Even though, in our study, the overall tracheostomy rate was lower than reported in these studies, higher proportions of tracheostomy were observed among severe (68%) and moderate (20.7%) TBIs. This is probably due to the fact that if definitive airway management is indicated, tracheostomy was performed during admission regardless of availability of a mechanical ventilator, while endotracheal intubation was performed only after ensuring the availability of a mechanical ventilator and an ICU bed. The rate limiting step to more conventional critical care management practice in our setting are ICU bed space and ventilator availability[23,24]. Our TBI patient population was young with an average age of 32.6 ± 12.9 years. The finding of a young population of patients in our study is not surprising as traumatic brain injuries in the young population are steadily increasing and are a major cause of mortality and morbidity, leading to the loss of life and productivity in developing countries [9]. This is especially evident in Africa, and we have seen a rapidly growing burden of Road Traffic Injuries at KCH from 2009 to 2015[25].

The limitations of this study were those inherent to any study with a retrospective methodology. In our setting, record keeping is not ideal and hence missing data resulted in excluding some patients in our analysis. There could have been a selection bias of patients that ultimately received a tracheostomy, as they could have been perceived as palliative particularly in the absence of available mechanical ventilators. This is further suggested by the finding of a 0.7 higher GCS score in the control group compared to the TwMV group as reported above. Performing a random controlled trial (RCT) to study the effectiveness of TwMV would be preferable but poses an ethical challenge. The high mortality rate in the ETT group could also suggest that this airway management strategy may have been reserved for patients with the most severe prognosis. On the other hand, the level of care received by patients inside the ICU compared to those outside the ICU was very different, and this is more likely to have accounted for some of the differences seen. In addition, we did not adjust for GCS score and other risk factors for mortality such as anaemia and active haemorrhage on admission in our analysis and that may indicate some bias in our study. Injury severity score (ISS) or abbreviated injury scale (AIS) data was not available in our records therefore associated injuries were not adjusted for these scores. However, the large number of patients included in this study adds to its strength.

## Conclusion

Tracheostomy without mechanical ventilation in severe TBI did not improve survival outcomes in our setting. We recommend that this practice is discontinued where resources are too limited to provide close observation and care of the patients. If a mechanical ventilator and ICU bed-space are available, tracheostomy prior to mechanical ventilation should be considered.

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