

## A Review of Tracheostomy Practices in an Intensive Care Unit amongst Patients Requiring Invasive Ventilation who have Failed Endotracheal Extubation

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### Abstract

**Background and Aim:** Tracheostomy is an invasive procedure performed in cases of emergency upper airway obstruction and elective or semi-electively in patients needing long-term invasive ventilatory support due to neurological insults or prolonged weaning on Intensive care units. Any patient requiring re-intubation within seventy-two hours was included in the study. Extubation failures are associated with higher costs, morbidity and mortality amongst mechanically ventilated patients. The aim of this study was to provide an overview of trends associated with tracheostomy practice amongst patients who have failed extubation following prolonged respiratory weaning on an intensive care unit in a busy district general hospital.

**Methods:** A review of patient data from Electronic medical records of all cases of tracheostomy on the critical care unit between 2010 - 2017 was undertaken. A comparative analysis using statistically analysis-using SPSS. Outcome data from the Intensive Care National Audit and Research Centre (ICNARC) datasets was also included.

**Results:** Two hundred and sixty seven tracheostomies procedures were carried out on the unit between January 2010 and July 2017. Two hundred and two patients were excluded, as they did not fit the eligibility criteria. Over the period of review, the overall number of tracheostomies decreased (60 in 2010 vs 8 in 2017). Sixty-six patients met the inclusion criteria, 70.8% were male and the mean age was 62.71 years (standard deviation (SD) 16.5)/median age 67 years (interquartile range (IQR) 28). Female patients in this cohort were younger than male patients. The APACHE II scores were 26 (IQR = 5.9) and 23 (IQR = 10) amongst males and females respectively. Elective tracheostomy performed for patients requiring prolonged weaning from invasive ventilation had significantly decreased over last few years (p value = 0.004). This was associated with a significant shift in our use of sedative agents including significant reduction in use of clonidine (p = 0.04). Sedation bundle and achievement of appropriate sedation scores resulted in significant decrease in tracheostomy despite higher APACHE II admissions to unit. We had introduced tracheostomy passports on the unit to improve safety and mitigate clinical risk management.

In the last few years, the numbers of tracheostomies performed have significantly decreased on our unit, even amongst those with higher APACHEII scores.

**Conclusion:** An integrated sedation bundle and tracheostomy practices ingrained into daily critical care practices has significantly decreased the use of haloperidol and midazolam (p value = 0.005) amongst patients requiring advanced ventilatory days. Even amongst the cohort of patients with higher APACHEII scores needing prolonged invasive ventilation, tracheostomies performed had significantly decreased (p value = 0.005), as target ideal plain of sedations were achieved in the last few years. The number of visits to the CT scanner for brain CT imaging in this cohort and subsequent clinical risk associated during these transfers has significantly decreased. Dedicated training and teaching amongst junior doctors, nursing and all allied health care staff enable delivery of sedation practices (RASS scores -1 to +1) successfully on the Intensive care unit.

**Keywords:** Tracheostomy; Intensive Care Unit; Invasive Ventilation; Endotracheal Extubation

## Introduction

In the UK, approximately 15,000 tracheostomies are inserted per annum [1], with an estimated 8,400 undertaken in adult critical care units [1]. This procedure is not a new invention; references to tracheostomies have been found throughout history, from 1550 BC, ancient medical texts of the Hindus and Egyptians respectively to records of the treatment of gladiators in the second century by Claudius Galenus [2,3].

Tracheostomy insertion is performed in clinical practice either by surgical or percutaneous approach. The surgical technique was first described in 1909 by Chevalier Jackson [3,4] and remained the mainstay of treatment until the development of the percutaneous technique by Ciaglia, *et al.* in 1985 [5]. Percutaneous tracheostomies tend to be the preferred method of insertion on the critical care units in modern times due to benefits such as improved cosmetic outcomes, higher safety profile and the ability to perform the procedure at the ICU bedside [6-9]. However, it should be noted that there is no difference in the overall ICU mortality rates associated with the use of either method [10]. The surgical approach is still commonly used in-patient with difficult airways and neck anatomy.

Tracheostomies are most commonly an elective procedure, indicated in cases of upper airway obstruction, long term mechanical ventilation or respiratory support, they are additionally used when weaning from invasive ventilation has proven to be difficult [11-13]. Long term use of endotracheal tube is associated with laryngeal and tracheal injury due to tube pressure and the risk of scarring and stenosis to the surrounding anatomical structures [14,15]. In order to tolerate the ETT, patients commonly require sedation, introducing the risk of further complications associated with over sedation such as delirium and dependency on mechanical ventilation for an increased period of time [16,17]. Tracheostomies are associated with an improved long-term laryngeal function [18] and a reduced need for sedation, with further benefits such as improved clearance of airway secretions and a reduction in mechanical ventilation time [19-21].

In cases of prolonged respiratory weaning from mechanical ventilation, tracheostomies are thought to aid the weaning process through reduced sedation requirements and a decreased dead space [22]. A recent prospective observational study noted that tracheostomy in difficult to wean patients compared with endotracheal intubation was associated with an increased tidal volume ( $\Delta = 33.7$  ml, 95% CI, 9.0 to 58.5,  $P < 0.008$ ), whilst the airway resistance ( $\Delta = -4.9$ , 95% CI, -5.8 to -4.0,  $P < 0.001$ ) and rapid shallow breathing index ( $\Delta = -14.6$ , 95% CI, -25.4 to -3.7,  $P < 0.009$ ) decreased [23].

The Intensive Care Society provides standards as guidance to the principles for insertion technique and care of tracheostomies [1]. The timing of tracheostomies is largely based on clinical judgment. However, the TracMan study [24], the first multi-centre randomised control trial to assess mortality associated with tracheostomy timing, found early tracheostomy (within 4 days of mechanical ventilation) showed no benefit over later tracheostomies (after 10 days of mechanical ventilation). Mortality at 30 days was 30.8% (95% CI 26.7%-35.2%) in the early group compared to 31.5% (95% CI 27.3%-35.9%) in the late group [24].

Interestingly, our Critical care unit had developed experience in the use of the more recent sedative agents including remifentanyl, dexmedetomidine as a part of our integrated care bundle for management of sedation and ICU delirium amongst critically ill patients needing prolonged invasive ventilatory support. Doctors and nursing staff adopted a dedicated sedation care bundle as a part of daily ICU clinical practice in last few years.

## Aim of the Study

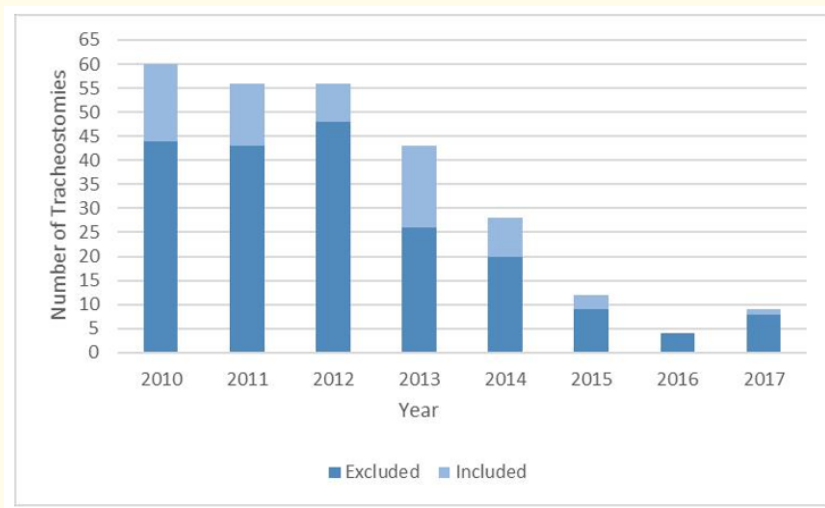
The aim of this study is to provide an overview of trends associated with tracheostomy practice for prolonged respiratory weaning on the critical care unit in a busy district general hospital.

## Methods

All patients who had a tracheostomy on the critical care unit between January 2010 and July 2017 were reviewed. Structured Query Language (SQL) was used to retrieve electronic patient data from in house records. Patients whom had tracheostomies performed for prolonged respiratory wean alone were included in the study. Whilst patient who had tracheostomies due to neurological insults or airway emergencies such as anaphylaxis, stridor or airway obstruction were excluded. Electronic medical records of all patients, recorded prospectively by junior doctors, nursing staff and intensive care consultants were collected; and the ICIP electronic medical records of all patients identified were reviewed, through detailed review of full medical record during intensive care stay. Data collected included patient demographics -gender, age, Acute Physiology and Chronic Health Evaluation II (APACHE II score), past medical history, admission details; dates of hospital admission, ICU admission, discharge, length of stay; and tracheostomy details (procedure type, time between admission and insertion, complications, time on invasive ventilation), sedation scores and agents used, agitation and ICU delirium. Data from these patients was compared with Intensive Care National Audit and Research Centre (ICNARC) quarterly data submitted to ICNARC case mix programme database. SQL, Microsoft excels spreadsheet and IBM Statistics SPSS 22 was used for data analysis.

## Results

Two hundred and sixty seven tracheostomies were identified as being carried out at the unit between January 2010 and July 2017. Two hundred and two patients did not fit the eligibility criteria and were therefore excluded (Figure 1 and 2). Over time, the overall number of tracheostomies decreased (60 in 2010 vs 8 in 2017). Sixty-six patients met the inclusion criteria, 70.8% were male, the mean age was 64.3 years (standard deviation (SD) = 16.6 years) and median age 72 years (interquartile range (IQR) = 29 years). Females comprised 29.2% of the cohort, with a mean and median age of 58.8 (SD = 15.6) and 58.0 (IQR = 21.3) years respectively. There were nine octogenarians in this cohort of patients (13.6%). The age of the patients who had tracheostomy performed showed a bimodal distribution between 2010 and 2015. In the last 3 years, significantly, older patients were considered for tracheostomy with a mean age of 67.3 vs. 61.6 years prior to 2014; this data has not been included in table 1 due to the small number of patients in the last 24 months. The median APACHE II scores of the patients admitted to unit requiring invasive ventilation were 26 (IQR = 5.9) and 23 (IQR = 10) amongst males and females respectively. However, the mean APACHE II score in the tracheostomy cohort was consistently higher than the overall mean score for the patients admitted intensive care unit (Figure 3). The table 1 represents the demographic characteristics and admission details.



**Figure 1:** Number of tracheostomies at the unit per year.

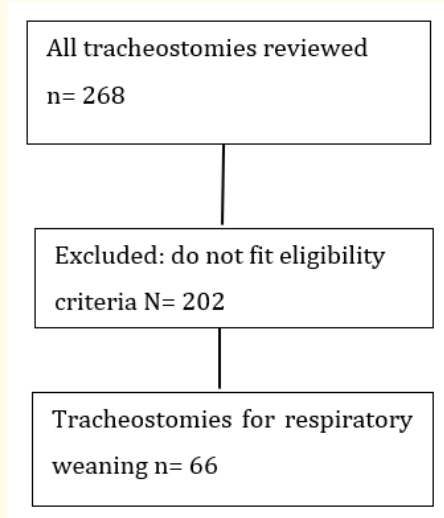


Figure 2: Consort diagram.

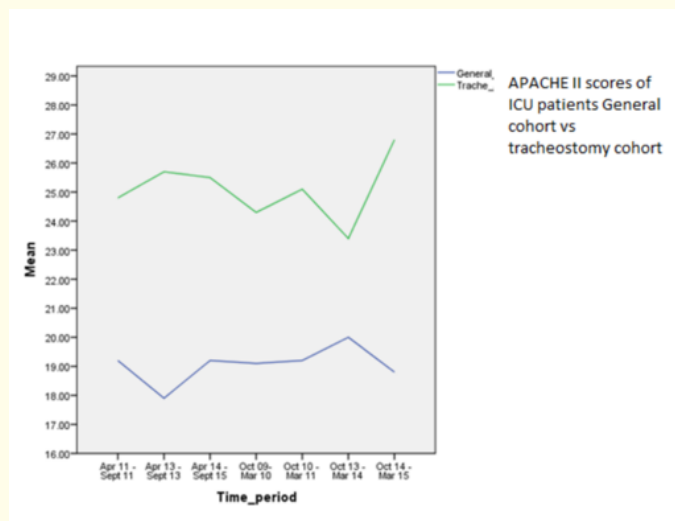


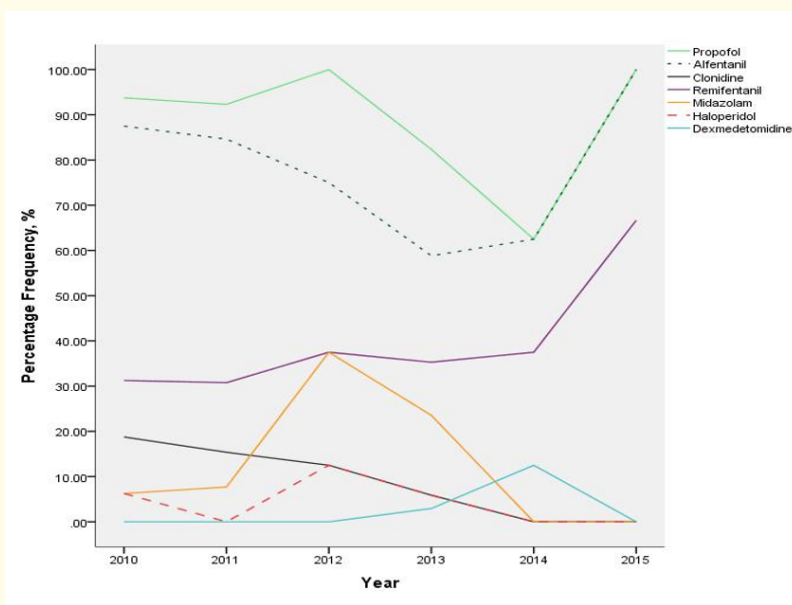
Figure 3: Comparison of APACHE II scores between all ICU admissions and patients with tracheostomies for prolonged respiratory weaning.

Time Period	Gender, Male Female	Method of insertion, % percutaneous	Mean Age (SD)	Median ICU stay, days (IQR)	Median APPACHE II score (IQR)	Median time on invasive ventilation prior to tracheostomy, days (IQR)	Median time on invasive ventilation after tracheostomy, days (IQR)	Median time before tracheostomy considered, days (IQR)
Jan10- Mar10	1.33:1	85.7	53 (22.9)	19 (14)	24 (9)	7 (2)	11 (10)	6 (3)
Apr10 - Sept10	2.5:1	71.4	66.9 (12.0)	21 (7)	26 (11)	7 (5)	8 (8)	6 (5)
Oct 10- Mar11	3:1	87.5	70.5 (13.4)	25 (13.5)	26 (8.75)	8 (8.75)	10 (8.25)	5.5 (8.25)
Apr11 - Sept11	1:1	100	76.8 (7.7)	17 (21.25)	23 (8.75)	3.5 (6.5)	8 (13.25)	3 (4.75)
Oct 11- Mar12	4:1	100	62.8 (15.2)	22 (29)	20 (10.5)	5 (17)	11 (11)	4 (17)
Apr12 - Sept12	1:0	80.0	61.8 (15.5)	19 (16.5)	29 (12)	9 (6)	7 (10.5)	8 (4.5)
Oct 12 - Mar 13	1.5:1	60	52.5 (14.4)	25 (24)	22 (12.5)	13 (4.5)	10 (25)	7 (7)
Apr 13 - Sept 13	3.5:1	88.9	55.3 (19.6)	17 (11)	26 (5.5)	6 (5.5)	6 (6.5)	5 (2)
Oct 13 - Mar 14	1.5:1	80	55 (17.4)	16 (10)	26 (15.5)	8 (7)	5 (2)	6 (6)
Apr 14 - Sept 14	3:1	100	74.5 (11.1)	18 (10)	27 (7.25)	6 (7.25)	15 (11.75)	4.5 (8.25)
Oct 14 - Mar 15	2:1	50	68.2 (10.7)	22 (17.75)	28 (7.75)	12 (9.25)	6 (5.25)	10.5 (12)

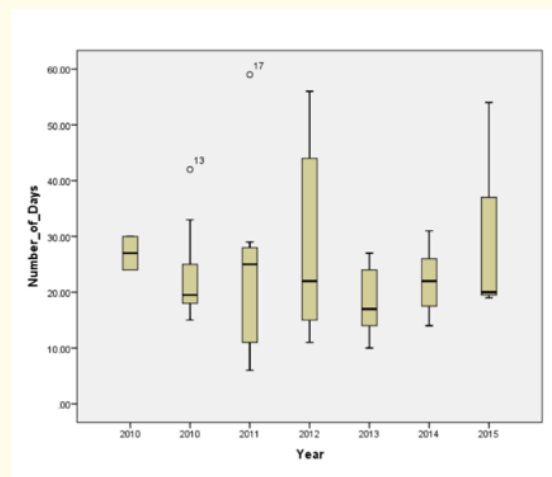
Table 1: Demographics and admission details of patients with tracheostomy for respiratory weaning.

The last twenty-two months (2016 - 2017), only one tracheostomy was performed, in a case of severe intraabdominal sepsis that developed critical illness myopathy. Despite the sedation bundle, patient was complaining of fatigue and weakness, any spontaneous breathing trails were futile. Henceforth, elective tracheostomy performed.

Length of ICU stay from 2010 revealed a bimodal distribution with peaks during winters followed by a trough during summer and autumn except for summer of 2010. It could be the aftermath of 2009 pandemic H1N1 virus, which resulted in Health protection agency modelling predicting more than 100,000 cases per week (Figure 4). However, yearly comparison revealed no significant difference in the median number of days spent on ICU by patients with a tracheostomy for respiratory weaning (Figure 5). From 2010 to 2015, the number of days on mechanical ventilation prior to tracheostomy increased (Figure 6). Patient remained ventilated longer prior to tracheostomy towards the end of 2014 and first quarter of 2015 (p value = 0.15) (Figure 6). There was similar trend noted in median time before ICU physician considered tracheostomy in these patients (2010 6 days, IQR = 3.75 vs. 2015 12 days, IQR = 4.6 p value = 0.05). However, there was no significant change in the number of invasive ventilatory days following tracheostomy insertion over the observed time (Figure 7).



**Figure 4:** Graph below representing percentage use of various sedative agents over the period of 2010-2015 on ICU unit. (A significant decline in use of haloperidol, midazolam and clonidine in the tracheostomy patients).



**Figure 5:** Graph to show the median number of days spent on ICU.

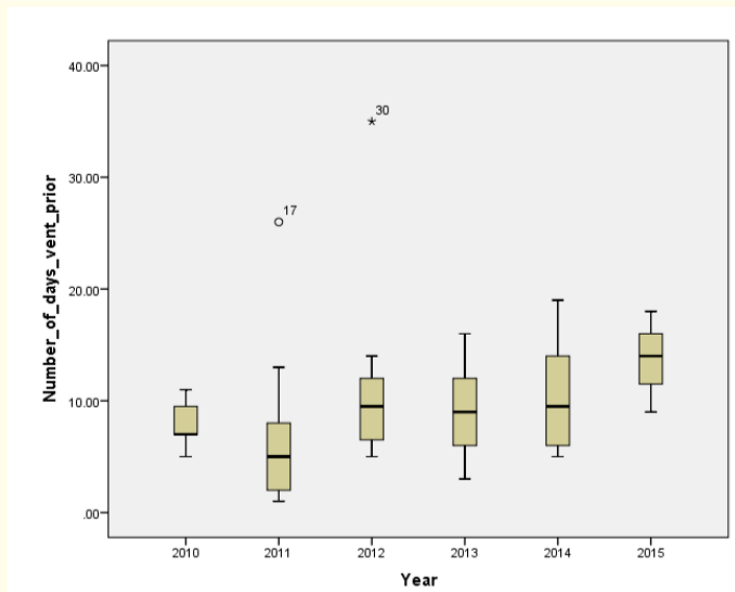


Figure 6: Median number of days on mechanical ventilation prior to tracheostomy.

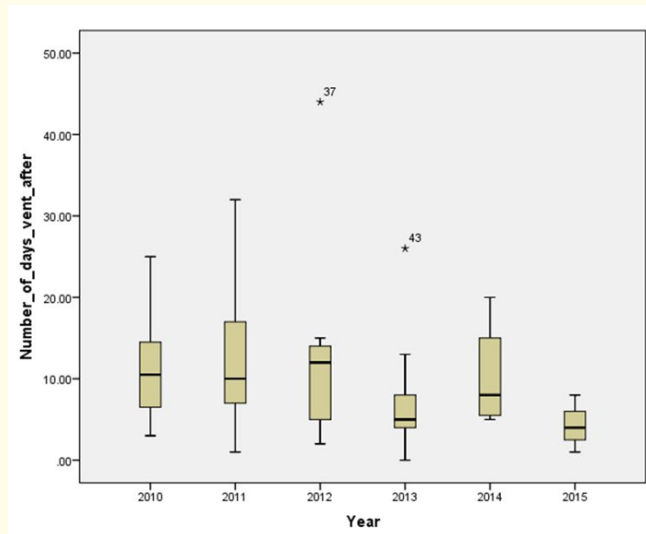


Figure 7: Median number of days on mechanical ventilation post tracheostomy.

Notably, the number of advanced respiratory support days decreased significantly amongst sicker patients with higher APACHEII scores after tracheostomy in 2015. Overall, the mean length of stay on ICU amongst the study cohort was consistently higher than that of all other invasively ventilated patients on the unit (22.1 days, SD = 11.1 vs. 6 days, SD = 8.1). A comparison of outcomes between the tracheostomy for prolonged wean group and the unit averages is presented in table 2.

Time Period	Unit mortality at discharge, %	Unit mortality for ventilated patients, %	Patients with tracheostomy for respiratory weaning mortality, %	Unit mean APPACHE II score (SD)	Mean APPACHE II score for patients with tracheostomy for respiratory weaning	Mean length of stay on unit for ventilated patients, days (SD)	Mean length of stay on unit for patients with tracheostomy for respiratory weaning, days (SD)
Oct 09 - Mar 10	24	31.8	14.3	19.1 (6.4)	24.3 (4.5)	6.7 (8.8)	22.1 (7.1)
Apr 10 - Sept 10	15.3	19.4	0	*	24.4 (5.8)	8.2 (12.6)	23.1 (8.9)
Oct 10 - Mar 11	22.2	29.2	0	19.2 (7.5)	25.1 (5.3)	7.2 (10.9)	26 (14.8)
Apr 11 - Sept 11	18.2	36.2	0	19.2 (7.8)	24.8 (5.0)	4.7 (6.6)	17.3 (11.4)
Oct 11 - Mar 12	*	*	0	*	21.8 (7.1)	*	25.2 (18.5)
Apr 12 - Sept 12	*	*	20	*	25.8 (8.5)	*	19.2 (9.1)
Oct 12 - Mar 13	*	*	20	*	21.8 (6.6)	*	28.2 (15.8)
Apr 13 - Sept 13	18.3	26	22.2	17.9 (6.4)	25.7 (4.3)	4.1 (5.8)	18 (5.6)
Oct 13 - Mar 14	32.3	47.2	20	20 (7.6)	23.4 (9.4)	6.2 (6.8)	16.8 (5.9)
Apr 14 - Sept 15	26.1	31.3	50	19.2 (6.9)	25.5 (10.0)	6 (7.9)	19 (5.3)
Oct 14 - Mar 15	18.4	25.5	16.7	18.8 (7.3)	26.8 (4.8)	6.1 (7.7)	27.8 (13.6)

**Table 2:** Comparison of outcomes between patients with tracheostomy for respiratory wean and the unit average. \*: Data unavailable. \*: ICNARC data reporting had changed in the period October 2011-March 2013: resulting in few data of the general statistics and demographic of the ICU unit admissions.

### Sedation

There was a significant increase in the median number of days patients remained sedated for advanced respiratory support prior to consideration of tracheostomy (Figure 8). During the last three years, there was a significant impetus given to target the correct sedation plain for these patients. Nursing staff and junior doctors were regularly taught about the importance of documentation and adjusting sedation to achieve ideal RASS score (-one to 1) during daily ward rounds and this was reiterated repeatedly. This reflected in the general trend of sedation scores, prior to tracheostomy, towards zero (Figure 9). There was no variation in trends of RASS sedation score post tracheostomy.

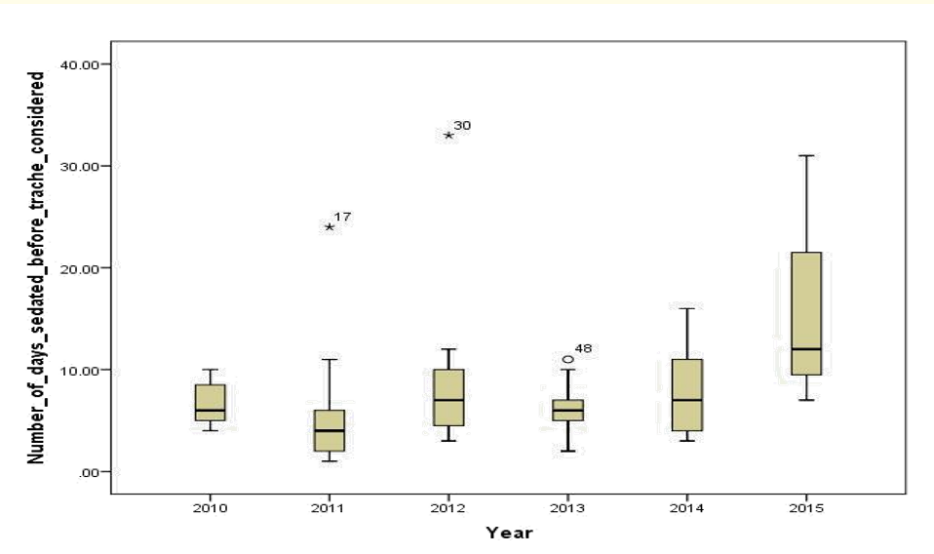


Figure 8: Median number of invasive ventilation days (sedated) before tracheostomy was considered. {Y axis: No: of day's vs x axis: years}.

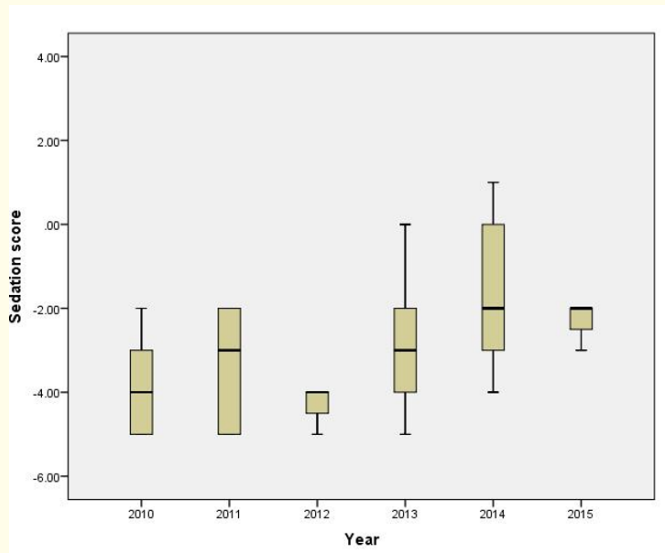


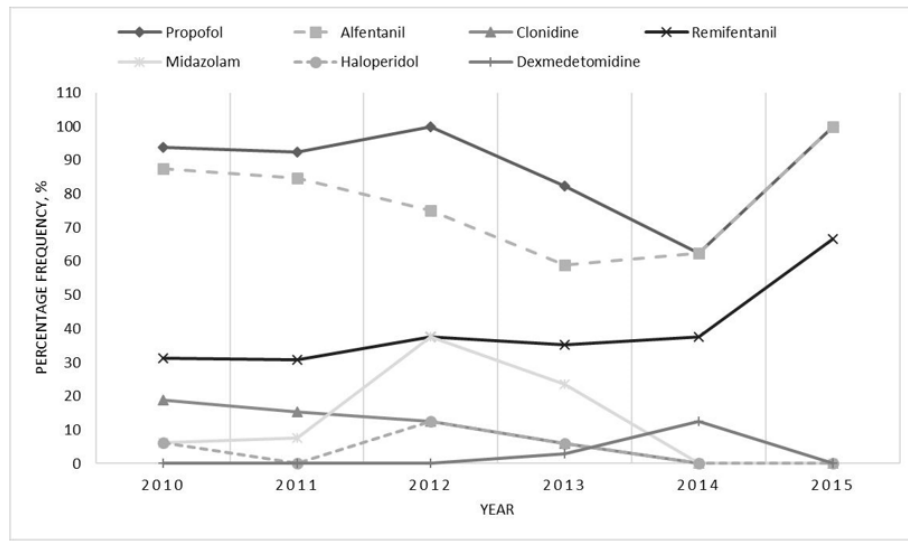
Figure 8: RASS sedation score 24 hour prior to tracheostomy.

A graph above representing a steady improvement of ideal RAAS scores: reflective of steady improvement in awareness and compliance with sedation bundles (Sedation scores on Y axis: -6 to +4; X axis years 2010 -2015).

Trends of use of demedetomidine remained largely static except for a small blip in 2014, which implies rigorous daily ward round screening of ICU delirium and targeted sedation scores were effective in early identification and management of delirium despite de-



crease in use of haloperidol and clonidine. A significant decrease in the use of clonidine in the tracheostomy cohort was noted ( $p = 0.04$ ). However, there was a general shift away from use of a number of sedative agents including midazolam ( $p = 0.96$ ) and haloperidol ( $p = 0.1$ ). A combination of propofol and alfentanil remained the sedative used most frequently across the studies time period, whilst an increase in the use of remifentanyl was noted ( $p = 0.01$ ) substituting alfentanil during last five years (Figure 10).



**Figure 10:** (Below) Sedative agents used in patient prior to consideration of tracheostomy.

Sedation Bundle	2010	Current
Sedative agents	Propofol + Alfentanil	Propofol+ Alfentanil
Post tracheostomy sedative agent	Remifentanyl +/-	Remifentanyl +++++
Sedation break during daily ICU Ward round	+	+++
RASS scores	-2 to 2	-1 to 1
Simulation Training	+/-	++++
Tracheostomy Passport	0	++++
Bedside tracheostomy kit	0	+++
Dexmedetomidine	+	+
Haloperidol	++	+
Midazolam	++	+
Clonidine	++++	0

**Table 3:** Introduction of Integrated Sedation care bundle: Reflective Change in Clinical practice depicted in the table below.

Use of the sedative Drugs and Intervention Bundles: += The use of pharmacological agent or intervention of the Bundle

+/-: Not Consistent use.

Zero = Not in Use or Not existed before in clinical practice (Intervention/pharmacological agent).

### Discussion

Use of integrated sedation bundle during the daily ICU ward rounds had a significant change in the attitude of nursing staff and doctors, ensuring patients maintained in an ideal plain of sedation. Sedation breaks during daily ICU consultant ward reviews lead to regular assessment of patient neurology. This ensured that neuroimaging events of these patients remarkably reduced. Thereby, minimising clinical risk associated with the intra-hospital patient transfers in this cohort of patients.

A tracheostomy passport was introduced for all patients with tracheostomy and dedicated tracheostomy kit was made available by the patient's bedside. A dedicated difficult airway ICU consultant undertook simulation training for nursing staff and junior doctors. As a part of mandatory training, dedicated sessions for tracheostomy care & implementation of sedation care bundles were conducted regularly.

Thus, ICU doctors and nursing staff became adept at the implementation of sedation care bundles. This was reflective in sedation scores achieved by nursing staff before and after tracheostomy in this cohort of patients trending to a RASS score of zero.

ICU physicians had used remifentanyl in the last two years of the study more frequently as compared to Alfentanil. However, as the patients undergoing tracheostomies were small, we could not demonstrate any significant correlation between tracheostomy days and remifentanyl use.

Interestingly, post Tracman study, patient undergoing a tracheostomy procedure remained ventilated longer prior to considering a tracheostomy.

We acknowledge, due to limitations of data available from ICNARC datasets, mean values were used instead of median. Standard deviation of mean was used to address this limitation.

### Conclusion

Our review concluded that there was a significant decrease in the tracheostomies performed amongst patients requiring Invasive Ventilation who have failed endotracheal extubation. These patients were waiting longer before tracheostomy was considered (as guided by Tracman study), from 2013 - 2015 Sedation score trend signified a shift of sedation scores towards zero. There was decrease in the use of clonidine and midazolam infusions.

There was an increased used of remifentanyl infusion, however we cannot demonstrate it to be statistically significant. We are aware of the limitations of data.

An integrated sedation and tracheostomy bundle do make a significant change to clinical practice. They can decrease accessory airway device significantly (tracheostomies). We recommend further multicentre clinical studies to investigated role of intervention care bundles in this challenging cohort of population.

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