A comparison of percutaneous tracheostomy and of surgical tracheostomy in patients in the Neurosurgical ICU at Charlotte Maxeke Johannesburg Academic Hospital

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the Degree of Master of Medicine.

Johannesburg, 2023.

I, Ruan Marais declare that this Research Report is my own work. It is being submitted for the degree of Master of Medicine at the University of the Witwatersrand, Johannesburg. It has not been submitted previously for any degree or examination at any other University.

(Signature of candidate)

6th day of June 2023 in Johannesburg

I dedicate this to my parents for all their love and support

Pieter Johannes Marais

Johanna Christella Marais

Abstract

Introduction

A tracheostomy is a surgically created opening in the anterior wall of the trachea through which a tube can be inserted. Egyptian hieroglyphic paintings that depict a tracheostomy procedure can be dated back to 3100 BC.[1] Tracheostomy is a procedure that is commonly performed on Intensive Care Unit (ICU) patients and, with an increasing need for intensive care services, the number of patient referrals for tracheostomy will likely increase as well.

Aim

The purpose of this study was to compare various clinical characteristics of patients who received either a percutaneous tracheostomy (PT) or a surgical tracheostomy (ST) during their stay in the Neurosurgical Intensive Care Unit (NSICU) at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH).

Method

A retrospective study of the records of all patients who underwent a tracheostomy procedure during their stay in NSICU at CMJAH between 1st January 2017 and 31st December 2020 was undertaken. Clinical information collected for all patients included age, gender, Glasgow Coma Score (GCS), Simplified Acute Physiology Score (SAPS II), duration of stay in NSICU before and after tracheostomy, duration of mechanical ventilation pre- and post-tracheostomy and in-NSICU actual mortality. Predicted mortality percentage for each patient was calculated from SAPS II. A Glasgow Outcome Score (GOS) was assigned to each patient on discharge from NSICU. Patients were allocated to one of two groups. Those who received PT were allocated to GroupPT while those who received ST were allocated to GroupST. The percentage case fatality risk for each tracheostomy group was calculated.

Results

Of the 66 patients who underwent a tracheostomy procedure during the study period, 19 patients (28.8%) fell into GroupPT. The remaining 47 patients (71.2%) fell into GroupST. The median age of GroupPT was 28 years with lower and upper inter-quartile range (IQR) of 25 and 32 years, respectively. The median age of GroupST was 40 years (IQR 31, 54). This difference was statistically significant ($p < 0.05$). The median SAPS II score for Group PT was 41 (IQR 29, 47) and that of Group ST was

44 (IQR 30, 50). This difference was not significant. There were no differences in GCS, duration of stay in NSICU, number of days of mechanical ventilation pre- or post-tracheostomy procedure, actual mortality or GOS between the two groups.

Conclusion

In this group of 66 patients ST was the commoner of the two procedures performed. Even so, the findings of this study suggest that PT is a suitable procedure that may be performed safely on patients in the NSICU.

Acknowledgements

I wish to express my gratitude to my supervisors: Dr. C.W. Clinton, Consultant Anaesthesiologist, Department of Anaesthesia, CMJAH and Prof. J.R. Ouma, Chief Neurosurgeon and Head of Division of Neurosurgery, Department of Surgery, CMJAH and University of the Witwatersrand for support and guidance during the research and their mentorship of my academic training.

I am grateful to Dr. M.Z. Zvifadzo, Department of Statistics, University of the Witwatersrand for guidance with the data analysis.

Sincere appreciation is extended to those administrative officers of the University of Witwatersrand and the CMJAH who made it possible for me to carry out the research.

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Nomenclature

AD	Anno Domini
BC	Before Christ
CMJAH	Charlotte Maxeke Johannesburg Academic Hospital
CEO	Chief Executive Officer
ET	Early tracheostomy
GCS	Glasgow Coma Score
GOS	Glasgow Outcome Score
GroupPT	Percutaneous tracheostomy group
GroupST	Surgical tracheostomy group
ICU / ICUs	Intensive Care Unit / Intensive Care Units
IQR	Inter-quartile Range
LT	Late tracheostomy
M:F ratio	Male: female ratio
N	number
ns	not significant
NSICU	Neurosurgical Intensive Care Unit
PT	Percutaneous Tracheostomy
SAPS II	Simplified Acute Physiology Scoring System
ST	Surgical Tracheostomy
TLI	Trans-laryngeal intubation
e.g.	exempli gratia
%	Percentage

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1. INTRODUCTION

A tracheostomy is a surgically created opening in the anterior wall of the trachea through which a tube can be inserted. The tracheostomy procedure can be dated back at least to 3100 BC when the ancient Egyptians created hieroglyphic paintings depicting tracheostomy.[1,2] The tracheostomy is referenced in the sacred book of Hindu medicine, the Rig Veda (dating between 2000-1000 BC), and in Eber's Papyrus (1550 BC) - two of oldest known medical works.[2,3] It is also recorded that in the fourth century BC, Alexander the Great saved a soldier from choking on a bone lodged in his throat by puncturing his trachea with the point of his sword.[2,4] Though the tracheostomy can be regarded as one of the oldest surgical procedures, the procedure is still an important intervention for any surgeon, anaesthesiologist, ICU specialist or treating physician to have in his or her armamentarium when treating patients in an ICU setting. Tracheostomy is now one of the more common procedures performed on ICU patients and, due to the growing need for intensive care services, it is likely to become an even more frequent procedure.

Trauma is a burden for the South African population - traumatic brain injury in Johannesburg has an incidence of 316 per 100 000 according to a study undertaken by Nell and Brown in 1991.[5] Patients with traumatic brain injuries often have a prolonged ICU stay and often require mechanical ventilation. These factors ultimately lead to requests from ICU clinicians for tracheostomy procedures in such patients in order to reduce laryngeal and vocal cord trauma, improve patient comfort and facilitate liberation from mechanical ventilation.

Numerous studies and meta-analyses comparing the safety of surgical tracheostomy (ST) with percutaneous tracheostomy (PT) have been undertaken.[6,7] Most studies have concluded that PT is a safe procedure which can be performed in an ICU.[6,8] Many of the studies have been conducted on patients in multi-disciplinary ICUs. Consequently the patient mix included a diverse range of primary illness. The purpose of this dissertation was to compare clinical characteristics of patients with only central nervous system pathology who received either PT or ST during ICU admission to the NSICU at CMJAH.

2. LITERATURE REVIEW

2.1 The Tracheostomy Procedure

The word tracheostomy originates from two Greek words meaning "I cut the trachea".[3] The first elective tracheostomy procedure is said to have been performed by Asclepiades of Bythinien in 100 BC.[2,3] During the 5th to 15th centuries AD the tracheostomy procedure was considered to be dangerous and have a high risk for wound infection. Thus, the procedure fell into disrepute and disuse.[2,3] A historical review of the tracheostomy procedure[3] states that in 1546 AD a successful tracheostomy was performed by and described by the Italian physician, Antonio Musa Brasavola. Although the initial purpose of a tracheostomy was to relieve airway obstruction, Galloway[9] expanded the use of tracheostomy to treatment of patients with paralysis requiring artificial ventilation. In 1965, the tracheostomy procedure was defined in terms of complications, indications and its interrelation with endotracheal intubation.[10] These refinements established tracheostomy as an airway management option for the ICU patient and currently tracheostomy is a procedure regularly performed in the ICU. Between 2% and 11% of ICU patients, requiring mechanical ventilation, will undergo a tracheostomy procedure during their hospitalisation.[11]

ST has undergone little change since a description in the early 1900's by Chevalier Jackson.[12] Performance of ST requires transport of the patient to the operating theatre where, under general and/ or local anaesthesia, the surgical team dissect the pre-tracheal tissues, open the trachea and insert a tracheostomy tube into the trachea under direct vision.[13] Transport of any critically ill patient carries a degree of risk for that patient. Kilic et al [14] concluded that the elimination of patient transportation and reduction in operating theatre usage were two major advantages of the PT procedure.

PT was introduced by Shelden et al in 1957.[15] This technique only gained popularity in 1985 when the Seldinger-based insertion method was developed by Ciaglia et al.[16] In 1990 Schachner et al [17] described a technique using a device that slid over a metal guide wire into the trachea and, when opened, would result in dilatation of inter-cartilaginous spaces and facilitate placement of a tracheostomy tube. Griggs and co-workers [18] modified the Howard Kelly forceps so that the forceps could pass over a

guide wire into the trachea and be used as a blunt dilator for creating a tracheal stoma through which the tracheostomy tube could then be inserted.

There are five commercially available tracheostomy insertion kits: Ciaglia multiple dilators, Blue Rhino, Griggs forceps, Fantoni's translaryngeal insertion device and the Screw-in Dilator Device. The latter device has been described by Frova and Quintel.[19] The development and introduction of the PT kit has simplified the procedure to the extent that treating physicians, surgeons of respective disciplines, anaesthesiologists and ICU specialists can reliably perform the procedure after a short period of instruction.

There are many articles that compare and contrast the various tracheostomy procedures. McWhorter[7] reviewed various articles on PT and ST and concluded that there were conflicting opinions: some articles suggested that PT was superior to ST while others held an opposite view. Although there is agreement that PT is a safe and efficient alternative to ST[8] definitive indications for PT are not yet established. For example, a study by Yang et al[20] conducted in New York State, United States of America, concluded that ST was performed more often than PT and older, low-income, sicker patients were more likely to receive a PT. However, this article does not clarify whether the PT procedures were undertaken in an ICU setting or an operating room setting. Older patients may have been chosen for a PT because the procedure is less invasive and usually associated with a shorter duration of anaesthesia. For safety reasons, the procedure may have been carried out in an operating room environment.

Tracheostomy in an ICU patient is said to have the following advantages over prolonged translaryngeal intubation(TLI): improved patient comfort, more effective airway secretion clearance, decreased airway resistance, reduction in duration of mechanical ventilation, enhanced patient mobility, increased opportunity for articulated speech, ability to eat orally, and improved airway security.[11, 21]

2.2 The Simplified Acute Physiology Score (SAPS II)

SAPS II is a severity of illness and mortality estimation tool developed by Le Gall and co-workers.[22] The scoring system consists of 12 physiological variables and 3 disease-

related variables (see Appendix 1). Each variable is assigned a score that increases as the variable deviates from the normal range. The points obtained by each variable during the first 24 hours following admission to ICU are then summed to provide a grand total. The predicted hospital mortality is calculated as a percentage, using the total point score, from a mathematical equation devised by those who developed SAPS II.[22]

SAPS II is routinely calculated for all patients admitted to NSICU at CMJAH. Thus the predicted hospital mortality would be available to any researcher conducting a chart review.

2.3 Glasgow Coma Scale

This scale is an accepted clinical scale providing means of quantifying central nervous system depression. It is based on patient responses in terms of eye opening, motor response and verbal response. Each response receives a numerical point score based on deviation from normal function (See Appendix 2). Points are then summed to produce the Glasgow Coma Score (GCS) which ranges from 3 to 15 points with 3 points indicating the worst possible situation and 15 points the best.[23]

2.4 Glasgow Outcome Scale

The Glasgow Outcome Scale is an arbitrary numerical description of a patient's recovery or dependence (se Appendix 3). The Scale ranges from 1 point (indicating death) to 5 points (indicating a good, but not necessarily complete, recovery).[24] The assigned numerical value constitutes the patient's Glasgow Outcome Score (GOS).

2.5 Description of the Neurosurgical ICU

CMJAH has an eight bed NSICU that serves the central, northern, eastern and southern environs of Johannesburg. The Unit admits elective and emergency patients. The admission rate is approximately 300 patients per year.

2.6 Decision making with regard to Tracheostomy Procedure

The academic medical literature does not provide precise indications regarding appropriate timing for a tracheostomy nor for the precise tracheostomy procedure. Deciding on the need for a tracheostomy in a neurosurgical patient is a team decision in the NSICU at CMJAH. Factors that influence a proposal for tracheostomy include:

- Likelihood of prolonged mechanical ventilation,
- Current duration of mechanical ventilation is in excess of 14 days,
- Current GCS of 7 or less.
- The presence of a neurological condition that prevents a patient from maintaining a patent airway (e.g. Bulbar palsy).
- Likelihood of prolonged duration of coma (± greater than 3 months).

The choice as to which tracheostomy procedure is undertaken is not random. It depends on the availability of theatre time, availability of surgical and anaesthesia staff, and the patient's physiological condition.

The need for tracheostomy is regularly considered in the management strategies applied to all patients. Performing a tracheostomy at an appropriate time in a patient who is likely to have prolonged intubation not only enhances that individual's respiratory care but also facilitates his or her liberation from mechanical ventilation.

3. MOTIVATION FOR THE STUDY

Most research on the topic of tracheostomy in the ICU patient has focused on patients in multi-disciplinary ICUs. Thus the patient groups often have diverse clinical conditions.

There is limited conclusive research comparing PT to ST in a group of patients who have only central nervous system pathology. Determination of the role and feasibility of PT and ST in a cohort of patients with a specific pathology – namely central nervous system disease or injury – might provide useful information.

4. AIM OF THE RESEARCH

The aim of the study is:

> To compare the various clinical characteristics and the outcomes of patients who received either PT or ST in the NSICU at CMJAH during the time period 1st January 2017 to 31st December 2020.

5. STUDY OBJECTIVES

The objectives of the study are:

- To describe the demographic information: age and gender, of patients who received either a PT or a ST in the NSICU.
- To compare:
    a) GCS on admission to NSICU, SAPS II score on admission and duration of stay in ICU pre- and post-tracheostomy of patients who received either PT or ST in the NSICU.
    b) On-admission to NSICU predicted mortality (obtained from SAPS II) with the actual mortality of patients who received either a PT or a ST in the NSICU.
    c) GOS of patients who received either PT or ST in the NSICU.

6. ETHICS APPROVAL

The study received approval from the Ethics Committee for Research on Human Subjects of the University of the Witwatersrand prior to commencement. (Reference No. M210656, See Appendix 4)

7. METHOD

7.1 Study Design

- Retrospective study of patient records

7.2 Inclusion Criteria

- Patients older than 18 years.
- Patients who were being cared for in the NSICU at CMJAH when the tracheostomy was performed.
- Patients who underwent surgery for a tracheostomy while being cared for in NSICU during the period 1st January 2017 to 31st December 2020.

7.3 Exclusion Criteria

- Patient records missing essential information for the study

7.4 Definitions

For the purposes of this review a tracheostomy, regardless of the procedure type, was classified as either an Early Tracheostomy (ET) or a Late Tracheostomy (LT). ET was defined as a tracheostomy performed up to and including the 7th day of mechanical ventilation. LT was defined as a tracheostomy performed on the 8th day of mechanical ventilation or later.

7.5 Data collection and handling

A retrospective review of patient records commenced once permission for the study was granted by the Ethics Committee for Research on Human Subjects of the University of the Witwatersrand and the Chief Executive Officer (CEO) of Charlotte Maxeke Johannesburg Academic Hospital.

A Tracking Number was allocated per patient (instead of using a patient's hhospital number) in order to ensure patient confidentiality.

Historical patient chart information recorded on a data sheet included:

- Date of admission to NSICU,
- Age, gender and co-morbid conditions,
- Reason for NSICU admission: Elective or emergency admission, pathology (infection, neoplasia, vascular origin, traumatic or non-traumatic),
- GCS,
- SAPS II,
- Date of tracheostomy,
- Tracheostomy technique (PT or ST),

- Location of procedure (ICU or operating theatre),
- Duration of mechanical ventilation before and after tracheostomy,
- Duration of stay in NSICU before and after tracheostomy.
- GOS on discharge from ICU

The information was obtained from patient records and recorded on data sheets. Data were entered into an Excel spreadsheet. Patient confidentiality was secured as the hospital number was only used for reference purposes and did not form part of the analysis data of the study.

7.6 Statistical Analysis

There were two groups of patients – patients who underwent PT (Group PT) were compared to those who underwent ST (Group ST).

A statistician was consulted regarding the appropriate statistical analysis of data. The following aspects of the two groups of patients were considered be suitable for statistical comparison:

- Age of patients,
- Male : Female distribution
- GCS,
- SAPS II,
- Durations of stay in ICU pre and post tracheostomy,
- Duration of mechanical ventilation pre and post tracheostomy,
- Predicted mortality percentage (calculated from SAPS II),
- Actual in-ICU mortality (number of patients in each group who die in the ICU),
- Percentage case fatality risk for each group.
- GOS (Glasgow outcome score).

Data Analysis:

- To describe demographic factors, frequency and percentage have been used to report categorical variables. Continuous variables have been reported as median and inter-quartile range (IQR). Comparison of categorical variables of GroupPT and GroupST was achieved using a Chi-square test or Fisher's exact

test while a Mann Whitney U test was used to compare continuous variables of the two groups.

- GCS, SAPS II score and duration of stay in NSICU pre- and post-tracheostomy have been compared using the Mann Whitney U test. The results are reported as median and inter-quartile ranges (IQR).
- For each group the percentage predicted mortality at admission has been reported as median and IQR while the actual mortality has been recorded as both a percentage and a whole number.
- GOS of each group was compared using the Mann Whitney U test.
- Statistical significance was set at 5% and the statistical software used was TIBCO Statistica®, version 14 (TIBCO Software Inc., United States of America).

8. RESULTS

A total of 1304 patients were admitted to the NSICU between 1st January 2017 and 31st December 2020. Of this number, 66 patients were referred for tracheostomy. Prior to the tracheostomy procedure each of the 66 patients was reviewed by a neurosurgeon and an anaesthesiologist. Anaesthesia decisions were based on the patient's American Society of Anaesthesiologists (ASA) physical status classification, presence or absence of comorbidity and current use of inotropic support. Surgical considerations included visibility of the anatomical landmarks of the thyroid cartilage and cricoid cartilage and the length of trachea palpable above sternal notch. On the basis of anaesthesia-related principles and surgical considerations 19 patients (28.8%) were deemed suitable for PT performed under total intravenous anaesthesia in the NSICU. The remaining 47 patients (71.2%) were considered suitable only for ST in an operating theatre. Thus the patients were not allocated to different groups on a randomised basis but rather on the basis of anaesthesia-related and surgical suitability.

Table 1 illustrates the demographic data of the patients involved in the study. The median age of patients in GroupPT was 28 years (IQR 25, 32) while in GroupST the median age was 40 years (IQR 31, 54). This difference was statistically significant ($p < 0.01$) and might well be due to the anaesthesia-related selection process.

The number of male and female patients in GroupPT was 19 and 0, respectively. In Group ST there were 39 males and 8 females. This difference did not reach statistical significance. However there is a clinical interest here in that the male population comprised a total of 58 out of the 66 study patients - equivalent to a male: female ratio of 7.25:1.

Table 1: Demographic Data for GroupPT and GroupST.

Variable	GroupPT	GroupST	Total
Number of patients. n. (%)	19 (28.8)	47 (71.2)	66 (100)
Age in years. median (IQR)	28 (25, 32)*	40 (31, 54)	35 (28, 50)
Number of male patients. n.	19	39	58
Number of female patients. n.	0	8	8

*$p < 0.01$ compared to GroupST.

Table 2 identifies various comorbid conditions found in the study patients and shows the distribution within each group. Comorbidity was found only in GroupST patients. While there was no statistically significant difference between the two groups, the fact that comorbidity existed only in GroupST suggests that patients with a comorbid condition were more likely to be selected for ST.

Table 2: Distribution of patient comorbidity between GroupPT and GroupST.

Comorbidity	GroupPT. n.	GroupST. n.	Total. n.
Hypertension.	0	6	6
Hypertension and Diabetes Mellitus.	0	1	1
Epilepsy.	0	1	1
None.	19	39	58
Total.	19	47	66

Table 3 summarises the reasons for admission to NSICU. Traumatic brain injury was the leading cause in both patient groups and accounted for 74.24% of all patients. No statistically significant difference for any admission reason existed between the two groups. Again, of clinical interest is the fact that of the 49 patients with traumatic brain injury, 45 were of male gender. This translates into a male: female ratio of 11.25: 1 for this subset of the study patients and indicates the preponderance of traumatic brain injury among the male members of the study population.

Table 3: Reason for admission to NSICU for GroupPT and GroupST.

Reason for admission	GroupPT	GroupST	Total
Cranial/ Intracranial Trauma. n. (%)	16 (24.24%)	33 (50%)	49 (74.24%)
Intracranial infection. n. (%)	1 (1.52%)	1 (1.52%)	2 (3.03%)
Intracranial vascular pathology. n. (%).	2 (3.03%)	6 (9.09%)	8 (12.12%)
Intracranial neoplasia. n. (%)	0 (0%)	6 (9.09%)	6 (9.09%)
Spinal degenerative disease. n. (%)	0 (0%)	1 (1.52%)	1 (1.52%)
Total. n.	19	47	66

Table 4 illustrates various aspects of the two study groups. There was no statistically significant difference between the two study groups with regard to their GCS and SAPS II score on admission. There was no statistically significant difference between the two groups with regard to the number of ventilation days pre-tracheostomy. There was no difference in the number of pre-tracheostomy days spent in NSICU. No difference was found, neither in the number of ventilation days post-tracheostomy, nor in the number of days spent in NSICU post-tracheostomy. Median predicted mortality for the two groups was not significantly different. Closer examination of the mortality figures reveals that the percentage actual mortality for each study group falls between the lower inter-quartile value and the median value of the percentage predicted mortality. Since predicted mortality is calculated at the time of admission these observations indicate that creating a tracheostomy in a study patient did not result in a mortality rate in excess of the predicted mortality. The median GOS was exactly the same for each group.

Table 4: Study related results for GroupPT and GroupST.

	GroupPT	**GroupST**	**p-value**
Admission GCS. median (IQR).	6 (4, 7)	6 (5, 7)	p = 0.46
Admission SAPS II score. median (IQR).	41 (29, 47)	44 (30, 50)	P = 0.51
Ventilation Days pre-tracheostomy. median (IQR).	20 (14, 27)	21 (14, 32)	p = 0.51
Ventilation Days post-tracheostomy. median (IQR).	9 (4, 18)	10 (4, 23)	p = 0.91
Days Stayed in NSICU pre-tracheostomy. median (IQR).	20 (14, 27)	21 (14,32)	p = 0.51
Days Stayed in NSICU post-tracheostomy. median (IQR).	12 (5, 18)	11 (4, 25)	p = 1.00
Percentage Predicted mortality. median (IQR).	26.6 (9.7, 39.2)	32.6 (10.6, 46.1)	p = 0.51
Percentage Actual Mortality.	15.7	19.1	p = 0.52
GOS on discharge. median (IQR).	3 (2, 4)	3 (2, 4)	p = 0.76

A comparison of Group PT with Group ST has shown that there was no statistical difference in the number of days of mechanical ventilation post tracheostomy between the two groups (see Table 4). However, actual number of days for this variable ranged widely, from 1 to 29 days for GroupPT and from 1 – 66 days for GroupST. The possibility that the wide range in post-tracheostomy mechanical ventilation days could be related to the timing of the tracheostomy procedures was examined. Table 5 illustrates the number of ET (early tracheostomy) and LT (late tracheostomy) procedures performed in GroupPT and GroupST. (see Section 7.4 for definition of early and late tracheostomy timing).

Table 5: Number of Early and Late Tracheostomy procedures in GroupPT and GroupST.

	GroupPT	**Group ST**
ET procedures. n.	0	2
LT procedures. n.	19	45
Total. n.	19	47

From Table 5 it can be seen that 64 of the 66 patients (96.9%) involved in the study underwent a LT procedure. Despite the preponderance of LT in the review, 10 patients in GroupPT were liberated from mechanical ventilation in less than 10 days from the time of tracheostomy. The corresponding number for GroupST was 23 patients.

Figure 1 is a scatter diagram of individual patient data points. It shows the number of post-tracheostomy mechanical ventilation days versus the number of pre-tracheostomy mechanical ventilation days for the 19 patients in GroupPT who underwent LT. The correlation coefficient of minus 0.08 indicates that there is no association between the two variables in this patient group.

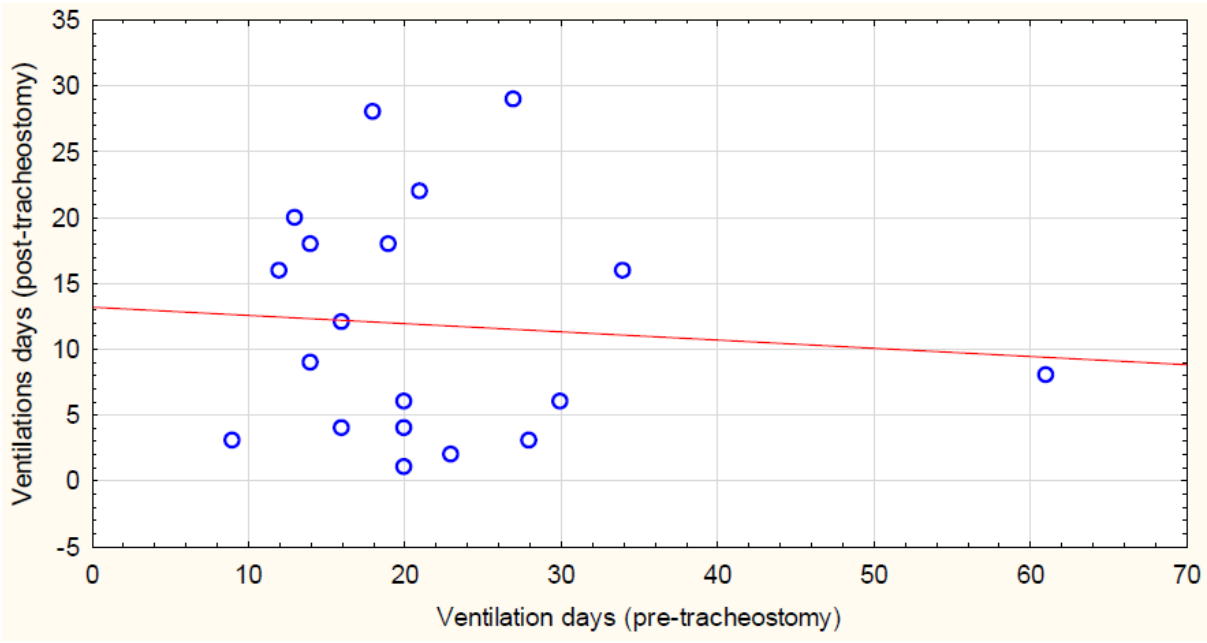

Figure 1: Ventilation days (post-tracheostomy) versus Ventilation days (pre-tracheostomy) for 19 patients in GroupPT. (Individual data points are denoted by open circles. The solid line represents the linear regression line.)

Figure 2 is a scatter diagram of individual patient data points. It shows the number of post-tracheostomy mechanical ventilation days versus the number of pre-tracheostomy mechanical ventilation days for the 45 patients in GroupST who underwent LT. The correlation coefficient of 0.01 indicates that there is no association between the two variables in this patient group.

This information provides evidence that, in this study, LT could be associated with either a short or a long duration of post-tracheostomy mechanical ventilation days.

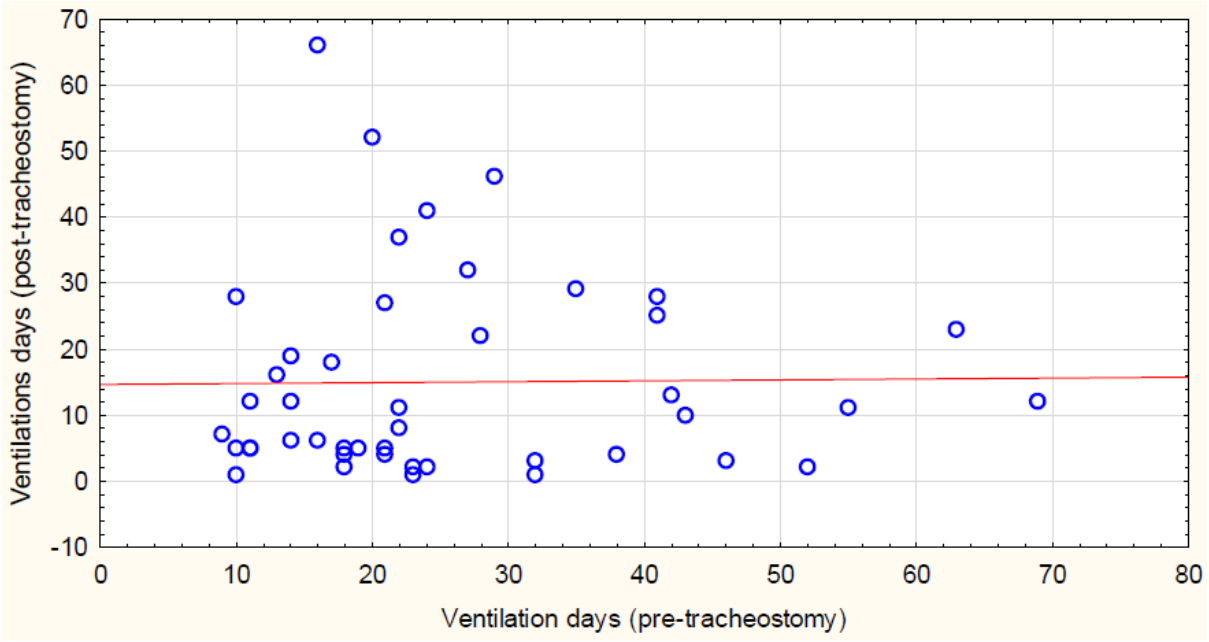

Figure 2: Ventilation days (post-tracheostomy) versus Ventilation days (pre-tracheostomy) for 45 out of 47 patients in GroupST. (Individual data points are denoted by open circles. The solid line represents the linear regression line.)

Table 6 is a summary of the actual mortality and the predicted mortality of the two study groups expressed in whole numbers. The actual mortality for each group is presented as a real number. The median and IQR values for predicted mortality of each group (see Table 4) have been converted from percentages to real numbers (rounded up or

down to the nearest whole number). As noted in Table 4, the actual mortality value of each study group falls between the lower inter-quartile value and median value of predicted mortality.

Table 6: Mortality outcome expressed in whole numbers for GroupPT and GroupST.

	GroupPT.	**Group ST.**
Actual mortality. n.	3	9
Predicted mortality. n. (IQR)	5 (2, 7)	15 (5, 22)

Table 7 shows the numerical distribution of GroupPT and GroupST patients within the various categories of the Glasgow Outcome Scale.

Table 7: Distribution of GroupPT and GroupST patients within each category of the Glasgow Outcome Scale.

GOS.	**GroupPT. n.**	**GroupST. n.**	**Total. n.**
1	3	9	12
2	4	10	14
3	5	12	17
4	7	16	23
5	0	0	0
Total.	19	47	66

9. DISCUSSION

CMJAH is a hospital located in central Johannesburg, South Africa. The hospital renders services to the northern, central, eastern and southern parts of Johannesburg. The hospital is the major referral centre for traumatic brain injuries and central nervous system pathology in the area. The catchment area falls mostly within the geographical areas known as the Ekurhuleni Municipality and Johannesburg Municipality. The precise population of the catchment area is not known, however the population of the Ekurhuleni Municipality according to Stats SA website[25] is 3.17 million people as per the 2011 census. The male: female distribution in the area as per the 2011 census was 48.9% and 51.1% respectively.[25] Thus, the male: female ratio (M:F ratio) in the geographical area is close to 1: 1.

In 1991, Nell and Brown[5] studied the incidence of traumatic brain injury in the Johannesburg area. They concluded that the incidence was 316 per 100 000, with a male to female ratio of 4.8:1. The same authors also noted that 7.9% of their study population sustained moderate traumatic brain injuries (GCS 7-12) and 4.6% severe traumatic brain injuries (GCS 3-6).[5]

Some findings of the research presented in this dissertation report (hereafter referred to as “the current study”) can be interpreted in light of the information published by Stats SA[25] and Nell and Brown.[5] In the current study of 66 patients with central nervous system pathology undergoing tracheostomy there were 58 male patients and 8 female patients – a M:F ratio of 7.25:1. Furthermore, 49 patients (74.2%) had sustained a traumatic brain injury and of these 49 patients 45 were male – a M:F ratio of 11.25:1. This ratio is higher than the figure of 4.8: 1 quoted in the 1991 study of Nell and Brown.[5] The figures highlight the fact that, even in the second decade of the 21st century, traumatic brain injury remains a major burden on the Johannesburg metropole’s health system and that male gender constitutes the majority of that burden.

Patients with severe traumatic brain injuries frequently require intubation and mechanical ventilation primarily because they have depressed airway reflexes and/ or an abnormal breathing pattern that predisposes them to hypoxaemia and

hypercarbia.[11,27] Once a decision to provide mechanical ventilation to a patient is made the patient must undergo tracheal intubation. Unless contraindicated, the oro-translaryngeal-tracheal route is usually the procedure of choice. Once tracheal intubation has taken place the question of long-term airway management will arise because there are a number of complications related to translaryngeal intubation (TLI). Some of the complications are related to the intubation process itself, others are related to the presence of the endotracheal tube. Complications related to the endotracheal tube become more frequent as the duration of TLI increases.

Tracheal intubation via a tracheostomy is an alternative to TLI. Although tracheostomy has complications of its own the reasons for performing the procedure centre around the observations that tracheostomy is associated with a decrease in laryngeal trauma, improved patient comfort, reduced need for patient sedation and analgesic drug use and better access to the mouth for oral hygiene, to name a few. In some patients, performing a tracheostomy procedure assists in liberation from mechanical ventilation support and thus facilitates discharge from ICU.[26] On balance, the benefits of tracheostomy usually outweigh the combined complications of tracheostomy and long-term tracheal intubation.

Tracheostomy is performed more frequently on traumatic brain injured patients in the ICU compared to the incidence in a general ICU population (31.8% versus 10.0%), findings demonstrated by the study published by Robba et al.[27] As a result of an increased demand for tracheostomy procedures, PT has become an attractive alternative to ST because it is a procedure that can be performed in the ICU environment.[6] Apart from PT being a safe and cost effective alternative; it is an important technique for Intensive care physicians to have in their armamentarium. In the current study the majority of the patients received ST in an operating theatre which echoes the study findings of Yang et al[20]. This probably reflects the selection process used to identify suitable candidates for PT in ICU. The anaesthesia considerations probably played the main role in the selection process. Another factor contributing to the majority of patients receiving ST is the availability of an experienced team that can perform PT in the ICU. Although the skills required to perform a PT procedure can be acquired reasonable quickly, the operator must still be able call on expert assistance

to perform a ST should the PT fail. Thus, PT should only be undertaken by a non-surgical operator during time periods when expert surgical assistance is close at hand.

Tracheostomy in the ICU is usually divided into “early” and “late”. There is, however, no standard definition of those terms. In a review by Marra et al[26] of 9 studies on the timing of tracheostomy all 9 studies used a different definition for the term “early”. However, there are suggestions that a tracheostomy performed by the 7th day of mechanical ventilation should be classified as “early” and those performed after the 7th day should be classified as “late”. There is no evidence to suggest whether ET or LT is the definitive option. In the current study, although the earliest tracheostomy was performed on day 4, there were only 2 ET procedures in total. Thus, the current study does not provide any information on whether ET or LT is the better of the two options.

There is published opinion stating that ET leads to early liberation from mechanical ventilation compared to LT.[26] The Brain Trauma Foundation Guidelines of 2007 recommend that patients with severe traumatic brain injuries should receive a tracheostomy early in the course of their illness in order to help reduce the amount of mechanical ventilation days.[28] However, in the United Kingdom, the “Tracman” randomized clinical trial comparing ET with LT did not find a reduction in the number of mechanical ventilation days in patients who received ET compared to those who received LT .[21] In a similar vein, the current study was associated with both early and late liberation from mechanical ventilation following LT. In some instances patients were liberated from mechanical ventilation within 1 day of a late procedure. In fact, the current study could not demonstrate any correlation between the timing of an LT procedure and the subsequent duration of post-tracheostomy mechanical ventilation, regardless of the type of tracheostomy procedure performed. Perhaps the explanation for conflicting results among various studies lies in the fact that there are different clinical circumstances for which patients may be intubated and receive mechanical ventilation. It is possible that certain pathological conditions are associated with a long recovery period from mechanical ventilation and this association cannot be altered by the timing of an intercurrent tracheostomy procedure. It has been pointed out by Hansson et al[29] that patients selected for LT may have a clinical dysfunction that prevents selection for ET. A non-random allocation to LT could result in an apparent

relationship between LT procedures and increased duration of mechanical ventilation post-tracheostomy when there is actually no relationship.

10. CONCLUSION

In conclusion the current study demonstrates that ST was the commoner of the two tracheostomy procedures performed on NSICU at CMJAH during the study period. Older patients were more likely to receive surgical tracheostomies. With no statistically significant differences in post-tracheostomy mechanical ventilation days, length of stay in ICU, patient mortality or patient outcome between the PT and ST groups, this study suggests PT is an acceptable procedure to be performed in NSICU.

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APPENDICES

Appendix 1

How the SAPS II score is calculated

1.	Age (years)	<40	40-59	60-69	70-74	75-79	≥ 80
		0 pts	7 pts	12 pts	15 pts	16 pts	18 pts
2.	Heart rate	70-119	40-69	120-159	≥ 160	<40	
		0 pts	2 pts	4 pts	7 pts	11 pts	
3.	Systolic BP (mmHg)	100-199	≥200	70-99	<70		
		0 pts	2 pts	5 pts	13 pts		
4.	Temperature (ºCelcius)	<39	≥39				
		0 pts	3 pts				
5.	If on mech. vent. PaO_2 ($mmHg/FiO_2$)		≥200	100-199	<100		
			6 pts	9 pts	11 pts		
6.	Urine Output (L/day)	≥ 1	0.5 -0.9	<0.5			
		0 pts	4 pts	11 pts			
7.	Urea (mmol/L)	<10	10-29.9	≥ 30			
		0 pts	6 pts	10 pts			
8.	White blood cells (x 10^9/L)	1-19.9	≥ 20	< 1.0			
		0 pts	3 pts	12 pts			
9.	Potassium (mmol/L)	3-4.9	< 3 or ≥ 5				
		0 pts	3 pts				
10.	Sodium (mmol/L)	125-144	≥ 145	< 125			
		0 pts	1 pts	5 pts			
11.	Bicarbonate (mmol/L)	≥ 20	15-19	< 15			
		0 pts	3 pts	6 pts			
12.	Bilirubin (*u*mol/L)	<68.4	68.4 – 102.5	≥ 102.6			
		0 pts	4 pts	9 pts			
13.	Glasgow Coma Scale	14 -15	11-13	9-10	6-8	<6	
		0 pts	5 pts	7 pts	13 pts	26 pts	
14.	Chronic disease		Metastatic CA	Haematological malignancy	AIDS		
			9 pts	10 pts	17 pts		
15.	Type of admission	Scheduled surgery	Medical	Unscheduled surgery			
		0 pts	6 pts	8 pts			

pts = points. mech vent = mechanical ventilation. mmol/L = millimole/ litre.

umol/L = micromole/ litre. mmHg = millimetres mercury. BP = blood pressure.

FiO_2 = fractional inspired oxygen concentration.

Appendix 2

Glasgow Coma Scale.

Variable:	Point Score:
<u>Eye Opening:</u>	
Spontaneous	4
To speech	3
To pain stimulus	2
None	1
<u>Best Motor Response:</u>	
Obeys commands	6
Localises to stimulus	5
Normal Flexion	4
Abnormal Flexion	3
Extension to stimulus	2
None	1
<u>Verbal Response:</u>	
Orientated	5
Confused	4
Inappropriate words	3
Sounds	2
None	1

The Glasgow Coma Score is the summation of the individual points obtained for each Variable. Minimum score is 3 points. Maximum score is 15 points.

Appendix 3

Glasgow Outcome Scale.

Score.	Description.
1	Death
2	Persistent Vegetative State
3	Severe Disability
4	Moderate Disability
5	Good, but not necessarily complete, recovery.

Appendix 4

Ethics Approval

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG	HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

Office of the Deputy Vice-Chancellor (Research and Innovation)

TO:	Dr R Marais School of Clinical Medicine Department of Surgery Division of Neurosurgery Medical School University E-mail: ruan.marais7@gmail.com
CC:	Supervisor: Dr C Clinton and Professor J Ouma <cclinton@doctors.org.uk> and <HREC-Medical Research Office@wits.ac.za>
FROM:	Mr Iain Burns Human Research Ethics Committee (Medical) Tel: 011 717 1252 E-mail: Iain.Burns@wits.ac.za
DATE:	2022/04/14
REF:	R14/49
PROTOCOL NO:	**M210656** (This is your ethics application reference number. Please quote it in all enquiries, oral or written, relating to this study.)
PROJECT TITLE:	*A comparison of percutaneous tracheostomy and of surgical tracheostomy in patients in the neurosurgical ICU at Charlotte Maxeke Johannesburg Academic Hospital*

Please find attached the Clearance Certificate for the above project. I hope it goes well and that an article in a recognized publication comes out of it. This will reflect well on your professional standing and contribute to Government funding of the University.

MSWorks2000/Iain0007/Clearscan.wps

UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

R49 Dr R Marais

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M210656

NAME: **(Principal Investigator)**	Dr R Marais
DEPARTMENT:	School of Clinical Medicine Department of Surgery Division of Neurosurgery Medical School University
PROJECT TITLE:	*A comparison of percutaneous tracheostomy and of surgical tracheostomy in patients in the neurosurgical ICU at Charlotte Maxeke Johannesburg Academic Hospital*
DATE CONSIDERED:	2021/06/25
DECISION:	Approved unconditionally
CONDITIONS:	
NOTE:	If contact information regarding student study participants is required, please contact the Registrar's office - <Nicoleen.Potgieter@wits.ac.za>
SUPERVISOR:	Dr C Clinton and Professor J Ouma
APPROVED BY:	CB Penny Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	2022/04/14

This Clearance Certificate is valid for 5 years from the date of approval. An extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office secretariat on the 3rd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated from the research protocol as approved, I/we undertake to submit details to the Committee. **I agree to submit a yearly progress report**. When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in **June** and therefore reports and re-certification will be due in the month of **June** each year. Unreported changes to the study may invalidate the clearance given by the HREC (Medical).

Signature of Principal Investigator _____ Date _____