Observational iNternational study of TRACHeostomy practice in adult intensive care units - ON TRACH

Summary

Steering Committee

Michelle Smyth
Dr Aisling McMahon
Prof Ger Curley
Prof John Laffey
Dr James O Rourke
Dr Vincenzo Russotto
Dr Massimo Muraccini
Dr Lise Piquilloud Imboden
Dr Maria Vargas
Dr Denise Battaglini
Assoc Prof Michael Brenner
Dr Brendan Mc Grath
Assistant Prof Elisabeth Riviello
Prof Shiela Myatra
Prof Andrew Udy

National Coordinators

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List of Abbreviations

ANP: Advanced Nurse Practitioner

ARDS: Acute respiratory distress syndrome

CPAP: Continuous Positive Airway Pressure

eCRF: electronic Case Report Form

ENT: Ear, Nose, and Throat

EPAP: Expiratory Positive Airway Pressure

FEES: Fiberoptic Endoscopic Evaluation of Swallowing

FiO2: Fraction of Inspired Oxygen

FOIS: Functional Oral Intake Scale

GCS: Glascow Coma Scale

GDPR: General Data Protection Regulation (GDPR)

GTC: Global Tracheostomy Collaborative

HAP: Hospital-Acquired Pneumonia

ICU: Intensive Care Unit

IMS: ICU mobility scale

IMV: Intermittent Mandatory Ventilation

IPAP: Inspiratory Positive Airway Pressure

MAP: Mean Airway Pressure

MDT: Multidisciplinary Team

NIV: Non-Invasive Ventilation

NTSP: National Tracheostomy Safety Project

OWV: One-Way Valve

PCV: Pressure-Controlled Ventilation

PEEP: Positive End-Expiratory Pressure

PF ratio: PaO2/FiO2 ratio

PT: Physiotherapist

Ppeak: Peak Inspiratory Pressure

PPlat: Plateau Pressure

PS: Pressure Support

RR: Respiratory Rate

SIMV: Synchronized Intermittent Mandatory Ventilation

SLT: Speech and language therapist

TV: Tidal Volume

VAP: Ventilator-Associated Pneumonia

VCV: Volume controlled ventilation

XLT: Extended-Length Tracheostomy

Study Synopsis

Introduction

Background

Care of the patient with a tracheostomy is a core element of critical care practice, with up to 20% of patients admitted to an intensive care unit (ICU) undergoing tracheostomy insertion during their admission(1, 2). By nature of their illness, these are often patients with prolonged mechanical ventilation, a protracted ICU length of stay, ICU acquired weakness, prolonged rehabilitation needs, and high mortality. This population also includes patients undergoing tracheostomy for reasons such as reduced consciousness, with impaired cough or swallowing reflexes, or compromised airway patency requiring protection and prolonged ventilatory support. (3-5) Although there is no definitive mortality benefit associated with tracheostomy or with early versus late tracheostomy insertion, there are other advantages potential including reduced work of breathing, decreased use of sedation, facilitation of weaning from the ventilator, earlier restoration of vocal communications, oral intake, mobilisation and potentially a lower incidence of pulmonary infections.(6-18)
Beyond the acute phase, tracheostomy has a major impact on the patient's recovery trajectory, influencing weaning duration, rehabilitation potential, and long-term functional outcomes. However, post-tracheostomy follow-up remains heterogeneous, and non-standardized outcome measures—such as time to decannulation, communication and swallowing recovery, or quality of life—are often under-reported despite their relevance to patients and caregivers.(19-23)

Previous studies have highlighted that considerable practice variation remains surrounding treatment of these patients. Variation exists not only because of patient characteristics, but also from an organisational perspective with diversity in hospital settings, system demands and governance structures. These inconsistencies lead to deficiencies in care and avoidable harm, increased morbidity and mortality.(24, 25)

In an effort to improve standards of care and patient safety, the Global Tracheostomy Collaborative (GTC) and the UK National Tracheostomy Safety Project (NTSP) were established. These initiatives focus on quality improvement. Their establishment has enabled patient level data collection on outcomes, quality, safety and organisational efficiencies in participating centres in Australia, the UK and USA.(24, 25) Armed with this knowledge, the GTC and NTSP have been able to identify the presence of variation in practice and show that guided implementation of a quality improvement programme in the UK is feasible and associated with better outcomes and has been replicated in other jurisdictions.(26) (27, 28)

Despite these initiatives considerable variation in practice continues to exist and many questions with regards to tracheostomy timing, insertion, management and longer-term outcomes remain.(29-31) There is comprehensive data coming from the USA, UK and

Australia but data internationally is lacking with the last survey of practice 10 years ago and more recent incites in ARDS patients from a secondary analysis of LUNG-SAFE.(1, 32). A recent scoping review has highlighted the unique challenges of tracheostomy care faced by low- and middle-income countries. (33)

To address this knowledge gap, we plan to conduct an international multicentre prospective observational study to comprehensively characterise current tracheostomy practice. The study aims to describe the indications, timing, techniques, and management of tracheostomy insertion and care; to evaluate patient-centred outcomes and procedure-related adverse events; and to explore the organisational structures and models of care supporting tracheostomised patients in the ICU and beyond. This will allow us to identify variation in care, it's origin, drive improvement and enhance safety and outcomes for patients with a tracheostomy in the future.

Rationale

Aim

The aim of this study is to evaluate the timing and practice of tracheostomy insertion, management, weaning and longer-term outcomes of these patients, in intensive care units internationally.

Objectives

- To describe the practice of tracheostomy insertion including indication, timing and insertion technique
- To describe the demographics, reason for ICU admission and severity of illness of patients requiring tracheostomy.
- To describe the care of patients with a tracheostomy in relation to ventilation, sedation, method of weaning from mechanical ventilation and decannulation
- To determine outcomes of patients with a tracheostomy including return to vocalisation, oral intake, mobilisation, length of stay, and mortality at hospital discharge.
- To assess the incidence and nature of adverse events experienced by patients with a tracheostomy
- To assess long-term functional and neuropsychological outcomes of patients with a tracheostomy at 6 and 12 months.
- To evaluate organisational aspects of tracheostomy care internationally including multidisciplinary care, standardised protocols and equipment, staff training and education at ICU and ward level, including discharge location following ICU and management of weaning from this point.

Prespecified Subgroup Analysis:

- Subgroup analysis of patients with an acute neurological condition as the indication for tracheostomy insertion.

- Subgroup analysis exploring the impact of organisational structure of care and geographic location (categorised by world bank income group into high, upper and lower middle-income and low-income countries) for patients with a tracheostomy.
- Subgroup analysis exploring outcomes based on timing of tracheostomy insertion with time treated as a continuous variable.

Methods

This is an international, multicentre, prospective observational study. ICU's internationally will be invited to participate and recruit patients over a 12-week period while the study is ongoing. We aim to recruit a convenience sample of ICU's which will be broadly representative of international practice. Sites from middle- and lower-income countries will be actively invited to participate to ensure broad representation from all geographic location.

Participants

We aim to include all consecutive adult patients (≥ 18 years of age) who were admitted to ICU and subsequently required tracheostomy insertion as part of their critical care admission.

Screening:

- All patients aged >18 admitted in the ICU after commencement of the enrolment period, and that are in receipt of invasive ventilator support, will be screened daily until ICU discharge or death.

Inclusion

- ≥ 18 years of age
- Admitted to ICU (Intensive Care Unit)
- Underwent tracheostomy insertion as part of critical care admission

Exclusion

- Long-term tracheostomy pre ICU admission
- Elective tracheostomy insertion for head and neck pathology
- Tracheostomy insertion for emergency surgical management of airway obstruction
- Mini tracheostomy insertion only
- Patients admitted to ICU with tracheostomy following a transfer from another hospital/ICU

Outcomes

Primary Outcome

- Successful decannulation from time of tracheostomy insertion censored at 90 days.

Secondary Outcomes

- Mortality at 90 days
- Return to vocalisation, oral intake and mobilisation
- Hospital utilization metrics (mechanical ventilation duration, tracheostomy duration,
- ICU and hospital length of stay)Tracheostomy related adverse events
- Proportion of sites with standardised care in place
- Variation in practice and outcomes between high, upper and lower middle income, and low income countries
- Patient disposition and quality of life at 6 and 12 months

Data Management and Analysis

Data Sources

Data pertaining to study outcomes will be collected from ICU healthcare records and participant's medical chart where applicable and questionnaire for the optional long-term follow up study.

Data Protection

Data collected as part of this study will be coded/pseudonymised. No identifying personal data will be entered on to the database. Data collected as part of this study will be retained by the coordinating centre for 15 years. Once all data have been entered into the CRF and checked for accuracy, the key to reidentify individuals and each site will be destroyed, rendering the data anonymous. Retained data will be anonymous. The study will comply with GDPR and relevant national data protection regulations.

Data Collection

Data pertaining to this study will be collected by multi professional team members i.e. intensive care doctors in training, intensive care specialists, nurses, critical care health and social care professionals. Data will be entered into an electronic case report form (eCRF), RedCAP, managed by Royal College of Surgeon's, Dublin, Ireland.
Access to the data entry system will be protected by username and password. Username and password will be assigned during the registration process for team members collecting data. Users will only have access to data for their site.

For each participating site we will collect site data as per the 'Site Survey Form'. Data will be recorded regarding number of beds, hospital and intensive care type, as well as organisational aspects of care for patients with a tracheostomy. .

All ventilated patients be screened on a daily basis to determine the proportion of patients undergoing tracheostomy insertion in the ICU. All participating centres will contribute to a core dataset. Data collection must be done **at a fixed time for that particular ICU, which can be between 6 and 10am** each day.

Participant demographic and clinical characteristics

Individual data will consist of:

- Demographic characteristics – age, sex and BMI
- Indication for ICU admission and severity of illness
- Patient co-morbidities and baseline frailty

- Data on:
    - Indication for tracheostomy
    - Time from intubation to tracheostomy
    - Insertion technique
    - Method of weaning
    - One way valve use and vocalisation
    - Resumption of oral intake measured using a FOIS of 3
    - Return to mobilisation measured using an ICU mobility scale of 4
    - Decannulation of tracheostomy
    - Tracheostomy related complications
    - Discharge destination
    - Patient outcomes – ICU and hospital length of stay, ICU, acute hospital and 90 day mortality
    - Patient disposition at 6 and 12 months
    - Quality of life at 6 and 12 months assessed with the EQ-5D-5L and Clinical Frailty Scale

Individual sites will have the option to opt into an enhanced datasets including:

- An enriched physiological dataset with comprehensive daily recording of ventilator mode, settings and weaning technique.
- A long-term follow up substudy, capturing information on patient survival, location, frailty and quality of life (EQ-5D-5L) at day 90,6 and 12 months after tracheostomy insertion.

Statistical Analysis

Analysis of data will be performed by the lead coordinator and the steering committee using a statistical software programme and assisted by expert statisticians when necessary.

Sample size calculation

We plan to recruit a convenience sample of over 2,500 patients. Based on WEAN SAFE data, approximately six patients undergoing tracheostomy are expected to be enrolled per ICU over a 12-week period, requiring participation from 500 ICUs, allowing for a 10% dropout.

Data analysis

Data will be summarised using descriptive statistics. Group comparisons will use parametric or non-parametric tests as appropriate, with adjustment for multiple testing. Associations between successful decannulation and clinical factors will be examined using competing-risk survival analysis (Fine–Gray model), with death treated as a competing event. Multilevel regression models will assess associations between clinical and sociodemographic characteristics and outcomes, accounting for clustering of patients within ICUs and ICUs within countries. For outcomes measured at two time points, models will include a patient-level random intercept and time as a fixed effect to account for within-patient correlation. Country will be included as a random effect to quantify between-country variation, and country income group (high/middle/lower) as a fixed effect to assess differences in practices and outcomes across income settings. Statistical significance will be set at $p \leq 0.05$. Missing data will be handled using multiple imputation. Analyses will be performed using Stata SE v19.0.

Participating Centres

Ethics

The study will be conducted in accordance with the principles of the Declaration of Helsinki and the Guidelines for Good Clinical Practice. It is the responsibility of participating centres to ensure ethical approval has been sought and granted through their sites to participate. The study protocol will be submitted to the Research Ethics Committee of the participating institutions. A copy of hospital approval will be forward to study coordinator. Participating sites are required to follow local requirements for the approval.

Consent

Due to the nature of their critical illness, a significant proportion of patients will lack the capacity to grant informed consent. Attempts to gain consent from all participants could affect the scientific validity of the study as the sample population would not be truly representative. Each country must comply with local/national consent procedures. Given the low-risk nature of this study (observational with no intervention), some countries will not require formal consent while others will require consent/proxy assent from the patient/patient representative, and others will allow deferred consent (survivors after discharge). Consent and/or patient representative assent will be sought from patients or their representatives for future related research and participation in the long-term follow up cohort of this study.

Publication Rules

Steering committee members and national coordinators for countries that have enrolled more than 100 participants will be part of the writing committee and listed as authors of the final manuscript. All participating centres will have collaborators listed in supplementary material based on number of participants enrolled. Number of collaborators to be listed per site will be a maximum of 3.

Expected results

This study will explore current practice around tracheostomy insertion in intensive care units. It is expected results from this study will provide opportunities for quality improvement initiatives and inform potential future research.

References

1. Abe T, Madotto F, Pham T, Nagata I, Uchida M, Tamiya N, et al. Epidemiology and patterns of tracheostomy practice in patients with acute respiratory distress syndrome in ICUs across 50 countries. Crit Care. 2018;22(1):195.
2. Pham T, Heunks L, Bellani G, Madotto F, Aragao I, Beduneau G, et al. Weaning from mechanical ventilation in intensive care units across 50 countries (WEAN SAFE): a multicentre, prospective, observational cohort study. Lancet Respir Med. 2023;11(5):465-76.
3. Premraj L, Camarda C, White N, Godoy DA, Cuthbertson BH, Rocco PRM, et al. Tracheostomy timing and outcome in critically ill patients with stroke: a meta-analysis and meta-regression. Crit Care. 2023;27(1):132.
4. Camarda C, Premraj L, Pelosi P, Cho SM, Battaglini D. The stroke care puzzle: Does tracheostomy timing fit? Crit Care. 2023;27(1):216.
5. Terragni PP, Antonelli M, Fumagalli R, Faggiano C, Berardino M, Pallavicini FB, et al. Early vs late tracheotomy for prevention of pneumonia in mechanically ventilated adult ICU patients: a randomized controlled trial. JAMA. 2010;303(15):1483-9.
6. Young D, Harrison DA, Cuthbertson BH, Rowan K, Collaborators T. Effect of early vs late tracheostomy placement on survival in patients receiving mechanical ventilation: the TracMan randomized trial. JAMA. 2013;309(20):2121-9.
7. Diehl JL, El Atrous S, Touchard D, Lemaire F, Brochard L. Changes in the work of breathing induced by tracheotomy in ventilator-dependent patients. Am J Respir Crit Care Med. 1999;159(2):383-8.
8. Lais G, Piquilloud L. Tracheostomy: update on why, when and how. Curr Opin Crit Care. 2025;31(1):101-7.
9. Cagino LM, Kercheval JB, Kenes MT, McSparron JI, Blank R, Chinn SB, et al. Association of Tracheostomy with Changes in Sedation during COVID-19: A Quality Improvement Evaluation at the University of Michigan. Ann Am Thorac Soc. 2021;18(5):907-9.
10. Merola R, Iacovazzo C, Troise S, Marra A, Formichella A, Servillo G, et al. Timing of Tracheostomy in ICU Patients: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Life (Basel). 2024;14(9).
11. Siempos II, Ntaidou TK, Filippidis FT, Choi AMK. Effect of early versus late or no tracheostomy on mortality and pneumonia of critically ill patients receiving mechanical ventilation: a systematic review and meta-analysis. Lancet Respir Med. 2015;3(2):150-8.
12. Chorath K, Hoang A, Rajasekaran K, Moreira A. Association of Early vs Late Tracheostomy Placement With Pneumonia and Ventilator Days in Critically Ill Patients: A Meta-analysis. JAMA Otolaryngol Head Neck Surg. 2021;147(5):450-9.
13. Arabi Y, Haddad S, Shirawi N, Al Shimemeri A. Early tracheostomy in intensive care trauma patients improves resource utilization: a cohort study and literature review. Crit Care. 2004;8(5):R347-52.
14. Cinotti R, Voicu S, Jaber S, Chousterman B, Paugam-Burtz C, Oueslati H, et al. Tracheostomy and long-term mortality in ICU patients undergoing prolonged mechanical ventilation. PLoS One. 2019;14(10):e0220399.
15. Deng H, Fang Q, Chen K, Zhang X. Early versus late tracheotomy in ICU patients: A meta-analysis of randomized controlled trials. Medicine (Baltimore). 2021;100(3):e24329.

16. Quinn L, Veenith T, Bion J, Hemming K, Whitehouse T, Lilford R. Bayesian analysis of a systematic review of early versus late tracheostomy in ICU patients. Br J Anaesth. 2022;129(5):693-702.
17. Sutt AL, Tronstad O, Barnett AG, Kitchenman S, Fraser JF. Earlier tracheostomy is associated with an earlier return to walking, talking, and eating. Aust Crit Care. 2020;33(3):213-8.
18. Villemure-Poliquin N, Lessard Bonaventure P, Costerousse O, Rouleau-Bonenfant T, Zarychanski R, Lauzier F, et al. Impact of Early Tracheostomy Versus Late or No Tracheostomy in Nonneurologically Injured Adult Patients: A Systematic Review and Meta-Analysis. Crit Care Med. 2023;51(2):310-8.
19. Mc Mahon A, Griffin S, Gorman E, Lennon A, Kielthy S, Flannery A, et al. Patient-Centred Outcomes Following Tracheostomy in Critical Care. J Intensive Care Med. 2023;38(8):727-36.
20. Vargas M, Battaglini D, Antonelli M, Corso R, Frova G, Merli G, et al. Follow-up short and long-term mortalities of tracheostomized critically ill patients in an Italian multi-center observational study. Sci Rep. 2024;14(1):2319.
21. Dempsey GA, Morton B, Hammell C, Williams LT, Tudur Smith C, Jones T. Long-Term Outcome Following Tracheostomy in Critical Care: A Systematic Review. Crit Care Med. 2016;44(3):617-28.
22. Damuth E, Mitchell JA, Bartock JL, Roberts BW, Trzeciak S. Long-term survival of critically ill patients treated with prolonged mechanical ventilation: a systematic review and meta-analysis. Lancet Respir Med. 2015;3(7):544-53.
23. Gentile MN, Irvine AD, King AM, Hembrom AS, Guruswamy KS, Palivela NE, et al. Enhancing Communication in Critically Ill Patients with a Tracheostomy: A Systematic Review of Evidence-Based Interventions and Outcomes. Tracheostomy. 2024;1(1):26-41.
24. Brenner MJ, Pandian V, Milliren CE, Graham DA, Zaga C, Morris LL, et al. Global Tracheostomy Collaborative: data-driven improvements in patient safety through multidisciplinary teamwork, standardisation, education, and patient partnership. Br J Anaesth. 2020;125(1):e104-e18.
25. Brenner MJ, Davies EA, McGrath BA. Reducing variation in tracheostomy care can improve outcomes. Br J Anaesth. 2022;128(4):e282-e4.
26. McGrath BA, Wallace S, Lynch J, Bonvento B, Coe B, Owen A, et al. Improving tracheostomy care in the United Kingdom: results of a guided quality improvement programme in 20 diverse hospitals. Br J Anaesth. 2020;125(1):e119-e29.
27. Mikhaeil M, Bernard M, Currie J, Bolduc C, Radke J, Kranjc S, et al. Improving weaning and liberation from mechanical ventilation for tracheostomy patients: a quality improvement initiative. BMJ Qual Saf. 2025;34(7):480-8.
28. Carton E, Fitzgerald E, Elebert R, Malone C, O'Brien S, Dunne A, et al. Changes in Multidisciplinary Tracheostomy Team Practice Over Time. Ir Med J. 2021;114(8):433.
29. Zaga CJ, Milliren CE, McGrath BA, Yang CJ, Schiff BA, Warrillow SJ, et al. Predictors of Decannulation Success in Tracheostomy: A 10-Year Analysis of the Global Tracheostomy Collaborative Database. Otolaryngol Head Neck Surg. 2025;173(5):1138-48.
30. Polok K, Fronczek J, van Heerden PV, Flaatten H, Guidet B, De Lange DW, et al. Association between tracheostomy timing and outcomes for older critically ill COVID-19 patients: prospective observational study in European intensive care units. Br J Anaesth. 2022;128(3):482-90.
31. Merola R, Vargas M, Sanfilippo F, Vergano M, Mistraletti G, Vetrugno L, et al. Tracheostomy Practice in the Italian Intensive Care Units: A Point-Prevalence Survey. Medicina (Kaunas). 2025;61(1).

32. Vargas M, Sutherasan Y, Antonelli M, Brunetti I, Corcione A, Laffey JG, et al. Tracheostomy procedures in the intensive care unit: an international survey. Crit Care. 2015;19(1):291.
33. Selekwa M, Maina I, Yeh T, Nkya A, Ncogoza I, Nuss RC, et al. Tracheostomy care quality improvement in low- and middle-income countries: A scoping review. PLOS Glob Public Health. 2023;3(11):e0002294.