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COVIDTrach; a UK national service evaluation of mechanically ventilated COVID-19 patients undergoing tracheostomy

Introduction

COVID-19 can lead to a severe respiratory illness with 5-12% requiring mechanical ventilation.[1,2] Standard UK intensive care practice is to consider a tracheostomy after 7-10 days of mechanical ventilation in order to facilitate weaning. This is based on evidence demonstrating that tracheostomy reduces duration of mechanical ventilation, shortens intensive care stay and reduces complications relating to prolonged presence of an endotracheal tube.[3-6] The question is whether these results can be translated to patients diagnosed with COVID-19 infection and undergoing mechanical ventilation.

There are also unique considerations regarding health care professional (HCP) safety when performing tracheostomy in COVID-19 patients due to the potential of aerosol generation and transmission of the infection.[7] ENT UK has issued guidance regarding surgical tracheostomy in terms of timing, environment, technique and level of personal protective equipment (PPE).[8] The ability of hospital departments to follow this guidance and the effectiveness of these measures is unknown.

This UK national service evaluation aims to assess the effects of tracheostomy in patients diagnosed with COVID-19 and mechanically ventilated on weaning, time with mechanical ventilation and ITU stay, clinical outcomes and mortality. Data will be related to UK intensive care data of all mechanically ventilated patients diagnosed with COVID-19 collated through the UK Intensive Care National Audit and Research Centre.[9]

In parallel we will collect data on the tracheostomy procedure and compare these to ENT UK/ ICS/ BAOMS/ DAS guidance on tracheostomy in patients diagnosed with COVID-19, as well as on COVID-19 infections in the surgical and medical teams involved in the care of these patients.

Aim

To establish the clinical outcome of patients in UK NHS hospitals diagnosed with COVID-19 and mechanically ventilated who undergo tracheostomy to expedite ventilator weaning.

Objectives

I. To establish the clinical outcome of mechanically ventilated COVID-19 patients undergoing tracheostomy in terms of:

   a. Tracheostomy related complications (bleeding, displaced tube, blocked tube, other) and timing of these complications (during tracheostomy, between tracheostomy and successful weaning from mechanical ventilation, between successful weaning and tracheostomy decannulation);

   b. Number of attempts to wean from mechanical ventilation, time from tracheostomy to successfully weaned from mechanical ventilation (in days), time from successfully weaned to decannulation of the tracheostomy tube (in days);

c. Length of stay at intensive care and total length of stay in hospital;

d. Mortality including timing and cause of death;

II. To establish whether surgical tracheostomies in COVID-19 patients follow ENT UK guidance in terms of:

a. Indication: including timing from start of mechanical ventilation and ventilation parameters;

b. Surgical team: consultant vs trainee led and number of surgeons;

c. PPE of the surgical and anaesthetic team;

d. Location of tracheostomy procedure: ICU, operating room, negative pressure;

e. Procedure: percutaneous vs open vs hybrid;

f. Type of tracheostomy tube: size, cuffed vs uncuffed, fenestrated vs unfenestrated.

III. To establish infection from COVID-19 positive patients to members of the HCP involved in the tracheostomy procedure and care.

Methods

Design

National multicentre service evaluation

Setting

UK NHS hospitals that perform tracheostomy. Each department is to nominate a site lead (consultant) and key contributors (middle grades) who will be responsible for collecting data and local governance.

Patient population

Inclusion criteria: any patient diagnosed with COVID-19 and mechanically ventilated undergoing elective surgical or percutaneous tracheostomy; of any age and any gender.

Exclusion criteria: COVID-19 patients undergoing an emergency tracheostomy.

Outcome measures

Primary:

Clinical outcome of patient diagnosed with COVID-19 and mechanically ventilated undergoing tracheostomy in terms of time from tracheostomy to successful weaning from mechanical ventilation.

Secondary:

I. Clinical outcome of patient diagnosed with COVID-19 and mechanically ventilated undergoing tracheostomy in terms of:

a. Other weaning related outcomes and time to tracheostomy decannulation;

b. Tracheostomy related complications;

c. Length of stay at intensive care and total length of stay in hospital;

d. Patient mortality during or following tracheostomy and cause of death

II. Adherence of tracheostomy procedure to national guidance;

III. Symptomatic or test positive COVID-19 infection in associated HCPs acquired after exposure to these tracheostomised patients.

Comparator

I. National data of all COVID 19 patients undergoing mechanical ventilation derived from the UK Intensive Care National Audit and Research Centre (ICNARC). At a later date, data will be compared to ICNARC data in patients with COVID-19 who did not undergo tracheostomy and patients without COVID-19 who underwent tracheostomy.

II. National guidance on surgical tracheostomy in patients diagnosed with COVID-19.[8]

Data collection

Data will be collected on:

- Trust and person entering data including email address.
- Patient demographic and disease specific characteristics: age, gender, weight, height, BMI, co-morbidities, smoking history, ICU/Health score, anticoagulation or antiplatelet medication, inflammatory markers, timing of pyrexia, neck factors affecting tracheostomy, outcomes of COVID-19 test;
- Ventilation: How many days between admission and intubation, period of non-invasive ventilation, number of failed extubations;
- Ventilation at the time of tracheostomy: Number of days of ventilation before tracheostomy? Details on mechanical ventilation (FiO2, pO2, PEEP setting), cuff leak test;
- Tracheostomy procedure: operating team (level of seniority, number of operators), location (ITU, operating room, negative pressure environment), surgical technique (surgical open, percutaneous, hybrid), type of tracheostomy tube (cuffed, uncuffed, fenestrated, unfenestrated), brand of tube, size of tube, adjustable flange tube, PPE used (double gloves, face visor, surgical gown, apron, FFP3, FFP2, surgical mask, PAPR hood, disposable hood);
- Complications at surgery: during tracheostomy (problematic bleeding, cuff tear, displaced tube, false passage, hypoxia, blood pressure changes, cardiac arrhythmias, other), between tracheostomy and successful weaning from mechanical ventilation (problematic bleeding, cuff tear, displaced tube, blocked tube, other), between successful weaning and tracheostomy decannulation (problematic bleeding, cuff tear, displaced tube, blocked tube, other);
- Weaning from mechanical ventilation and tracheostomy decannulation: number of days from tracheostomy to first wean, number of days from tracheostomy to successful wean,

number of wean attempts, number of days from tracheostomy to tracheostomy decannulation;

- Length of stay at intensive care and total length of stay in hospital;
- Mortality: timing (during tracheostomy, between tracheostomy and successful weaning from mechanical ventilation, between successful weaning and tracheostomy decannulation) and cause of death (COVID-19 related, tracheostomy related, other).
- Symptomatic or test positive COVID-19 infections in HCPs involved in the care of these patients acquired after exposure to these tracheostomised patients (developing COVID-19 symptoms and/or positive COVID-19 swab).

Consent

There will be no deviation from the usual standard of care for any patient, and routinely collected patient data will be anonymised before sharing; therefore, consent is not required.

Confidentiality and information governance

Non-patient identifiable information will be uploaded onto REDCap, a secure online data collection platform via the weblink https://redcap.slms.ucl.ac.uk/surveys/?s=74AEDN4JC4. All data will be transferred and stored in accordance with data governance regulations (Data Protection Act 2018). It will only be accessed by members of the project team and will be encrypted and archived or deleted before sharing data for analysis. No patient identifier other than gender will be collected and no dates relating to the hospital admission or treatment will be recorded. Locally stored identifiers will be deleted in the long-term.

Local Approvals

CovidTrach is a multi-centre service evaluation. Each named lead within a trust is responsible for obtaining local approval relating to the collecting of data at the local site. Data should not be uploaded onto the REDCap database until local approval is confirmed.

Statistical analysis

To follow

Authorship

COVIDTrach is a collaborative national project and site leads and key contributors from each department within contributing NHS hospitals will be recognised on future publications as co-authors using a corporate authorship model providing data sets are returned.

References

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