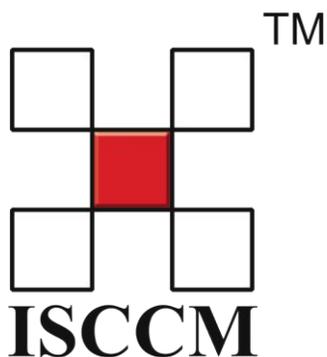


STUDY PROTOCOL

Dilatational percutaneous vs Surgical tracheoStomy in intEnsive Care uniT: A Practice Pattern Observational Multicenter Study (DISSECT study)

An ISCCM Research Project



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INTRODUCTION

Tracheostomy means creating a hole in the trachea for the passage of a tube through which the patient can be ventilated or the patient can breathe spontaneously. It is one of the most commonly performed procedures in the intensive care unit (ICU) nowadays¹. It is commonly done for patients who require long term ventilator support. Long term airway protection as in patients with neurological disorders, emergent airway as in upper airway obstruction are other indications. The advantage of tracheostomy is that it reduces dead space, helps in bronchopulmonary toileting, prevents aspiration and can help the patients retain their voice with the help of speaking valve.

Percutaneous Dilatational Tracheostomy (PDT) is becoming the preferred technique of choice in last 50 years². There have been various studies comparing the surgical tracheostomy (ST) with PDT but till date no evidence of the technique of choice^{3,4,5,6}. The blinding of the studies is not possible as both the procedures are technically different and even the scarring in the follow up period is different. The surgical technique is generally done in operation theatre by the surgeons either under local or general anaesthesia. It is very rarely performed at bedside. The PDT is a bedside procedure performed under local anaesthesia or mild analgesia and sedation. There are various percutaneous tracheostomy techniques, the earliest was mentioned by Ciaglia et al⁷ where they performed PDT with serial dilators. Later on the procedure was simplified by introducing a single dilator technique. The Griggs guidewire dilating forceps technique is another technique to perform PDT but it has been associated with more incidence of complications like overdilatation of trachea and more intraprocedural bleeding episodes⁸.

The PDT can be performed either by clinically palpating the tracheal ring or under bronchoscopic guidance where the puncture by the introducer needle in the anterior tracheal wall is visualized by bronchoscope⁹. This technique is one of the most widely practiced but also has been associated with complications like puncture of the bronchoscope by the needle, increased

need of oxygen due to loss of PEEP. The other technique to perform PDT is under real time ultrasound guidance where the track of needle puncture is visualized¹⁰.

Despite various small studies comparing PDT with ST, there has been no consensus regarding the ideal technique for tracheostomy in critically ill patients. We would like to collect data prospectively from various ICUs across the country regarding the practice of tracheostomy in adult patients and various techniques used in a 90 -day study period. We would like to compare PDT with ST on various intra-procedural and post procedural variables in an attempt to define the ideal choice of tracheostomy for various indications in critically ill patients.

OBJECTIVES:

- To capture data on the practice pattern of performing tracheostomy in critically ill patient
- To identify the indications which determines the technique of tracheostomy
- To compare PDT and ST on various intra-procedural complications and post-procedural outcomes

METHODS:

Study design:

- Prospective Observational Multi-Centre National Cohort Study

Patient enrollment:

The study would invite all ICUs across the country to participate in the study. The invites will be sent at frequent intervals till 15th October by the Research Committee. Hospitals with more than one ICU can enroll each ICU separately. Each ICU can contribute as much data as possible during the study period belonging to any arm of the study. Each ICU will designate one PI and one co-PI for the study who will be responsible for ethical committee clearance, data collection and study co-ordination in their ICU. Each ICU will collect data from 1st September to 30th November. The study would end on 30th November.

Each centre can start recording the data in paper CRF till they get an Ethics approval and later on can fill the data online.

Study timelines:

Email invitation to proposed ICU: **20th August 2019**

Start of data collection: **1st September 2019**

Last date of data collection: **30th November 2019**

Data cleaning and analysis: **December 2019**

Presentation to ISCCM research committee: **January 2020**

Presentation in CRITICARE 2020: **February 2020**

Publication: **2020**

Inclusion Criteria:

- All adult patients (> 18 years old) admitted to ICU undergoing tracheostomy – either surgical or percutaneous

Exclusion Criteria:

- Any patient shifted to ICU from OT with tracheostomy done intra-operatively as part of surgical plan

Data Collection:

There will be no direct patient contact or change in intervention. The procedure will be performed as per the prevailing practice of the ICU. The data will be collected prospectively and filled in the Case Record Form (CRF) after the completion of the procedure.

The following data will be collected:

- ***Patient demographic data*** – age, gender, co-morbidities, clinical parameters
- ***Procedure related data*** – type of tracheostomy decided, indication, timing of tracheostomy (early vs late), days on ventilator support, place of procedure (ICU or OT), technique of PDT (if used), reason for surgical tracheostomy, neck anatomy evaluation, guidance used during PDT, number of attempts, sedation paralysis used during procedure
- ***Operator related data*** – Tracheostomy performed by, experience details of the performer
- ***Complications related data*** – minor complications, major complications
- ***Outcome related data*** – duration of procedure, outcome of the procedure, time to wean the ventilator post tracheostomy, total time duration of ventilator in 7 day follow-up and cost of the procedure.

Primary Outcome:

- Comparison of PDT with ST in terms of safety
- Ventilator free days

Secondary outcome:

- Time lag from decision to actual procedure
- Cost effectiveness

Sample Size:

The plan is to enroll as many ICUs in the country as possible. Each centre will collect data from all consecutive patients undergoing tracheostomy. An acceptable sample size would be atleast a total of 100 tracheostomies in each group collectively from all centres.

STUDY REGISTRATION:

The Principal Investigator (PI) will register the study on clinical trials.gov on behalf of all the investigators and the registration number would be provided to them once available.

INSTITUTIONAL ETHICS COMMITTEE APPROVAL

All the local PI and Co-PI should ensure that they obtain the necessary Ethics Committee approval for the study, if deemed necessary by the institute. As this is an observational data collection with no intervention, the study can also be approved by the Head of the institute or Medical Superintendent if there is no Ethics Committee in the institute. As per the latest ICMR guidelines, this study falls in minor risk category where it is eligible for ethics exemption or an expedited review by ethics committee.

CONSENT FOR DATA COLLECTION:

This being an observational data collection with no change in the local practice of the institute, the consent is not required from the patient or their legally accepted representative. But if still the institute demands consent, then sample consent forms in Hindi and English will be provided.

STUDY FUNDING:

This is an ISCCM funded study. The ISCCM will fund the PI of the study for the expenses incurred related to software development, secretarial assistance, data analysis and other miscellaneous expenses against actual bills. No funding will be given to other investigators from other centres for contributing the data.

DATA OWNERSHIP:

As this is an ISCCM initiated project, the entire ownership of the data will be with the ISCCM.

PUBLICATION AND AUTHORSHIP POLICY:

The main results of the study will be published in a peer-reviewed medical journal.

The Authorship policy will follow the recommendations laid down by International Committee of Medical Journal Editors (ICMJE). The authorship would be decided on the basis of the contribution in study design, protocol writing, data interpretation and cleaning, data analysis and writing the final manuscript.

Steering Committee: Members would include 2 members from the PIs centre, ISCCM President 2019-20, ISCCM President Elect 2019-20, ISCCM Research Committee Chairman, 2 members from Research Committee, 3 National experts and PIs from top 2 centres contributing maximum data. The name of the Steering Committee members will be in the main author list.

The PI and Co PI of all the contributing centres will be included in the list of study collaborators and will be indexed in PubMed.

REFERENCES:

1. G. M. Koxsal, N. C. Sayilgan, and H. Oz, “Percutaneous dilatational tracheostomy,” *Middle East Journal of Anesthesiology*, vol.18, no. 5, pp. 903–910, 2006.
2. Cooper RM. Use and safety of percutaneous tracheostomy in intensive care. Report of a postal survey of ICU practice. *Anaesthesia*. 1998;53(12):1209–12
3. Susanto I. Comparing percutaneous tracheostomy with open surgical tracheostomy. *BMJ*. 2002;324(7328):3–4.
4. Dulguerov P, Gysin C, Perneger TV, Chevrolet JC. Percutaneous or surgical tracheostomy: a meta-analysis. *Crit Care Med* 1999; 27:1617–1625.
5. Allam MG, Eldeek AM. Comparative study between percutaneous dilatation tracheostomy and surgical tracheostomy. *Ain-Shams J Anaesthesiol* 2015;8:505-10
6. Freeman BD, Isabella K, Lin N, Buchman TG. A meta-analysis of prospective trials comparing percutaneous and surgical tracheostomy in critically ill patients. *Chest* 2000;118:1412-8.

7. Ciaglia P, Firshing R, Syniec C. Elective percutaneous dilatational tracheostomy: a new simple bedside procedure. *Chest* 1985;87:715-9.
8. Ambesh SP, Pandey CK, Srivastava S, Agarwal A, Singh DK: Percutaneous tracheostomy with single dilatation technique: a prospective, randomized comparison of Ciaglia Blue Rhino versus Griggs' guidewire dilating forceps. *Anesth Analg* 2002, 95:1739–1745
9. Kollig E, Heydenreich U, Roetman B, Hopf F, Muhr G. Ultrasound and bronchoscopic controlled percutaneous tracheostomy on trauma ICU. *Injury* 2000;31:663–668
10. Rajajee V, Fletcher JJ, Rochlen LR, Jacobs TL (2011) Real-time ultrasound guided percutaneous dilatational tracheostomy: a feasibility study. *Crit Care* 15:R67