Clinical Trial Details (PDF Generation Date :- Tue, 19 Apr 2022 08:22:41 GMT)

CTRI Number	CTRI/2022/04/041936 [Registered on: 19/04/2022] - **Trial Registered Prospectively**
Last Modified On	13/04/2022
Post Graduate Thesis	No
Type of Trial	Observational
Type of Study	Cohort Study
Study Design	Other
Public Title of Study	A study to evaluate the unexpected medical problems occurring during insertion and removal of tube in the windpipe of patients for artificial ventilation
Scientific Title of Study	aDverse EvenTs duRing artIficial airway ManagemENT in Indian ICUs (DETRIMENT): A prospective multicentre cohort study

Secondary IDs if Any

Secondary ID	Identifier
3922_Protocol version 2.0 dated 03.02.22	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Atul Kulkarni
Designation	Professor and Head, Division of Critical Care
Affiliation	Tata Memorial Hospital
Address	Dept. of Anaesthesia, Critical Care and Pain, Second floor, Main Building, Dr. E Borges Road, Tata Memorial Hospital, Parel, Mumbai Mumbai MAHARASHTRA 400012 India
Phone	9869077526
Fax	
Email	kaivalyaak@yahoo.co.in

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr Atul Kulkarni
Designation	Professor and Head, Division of Critical Care
Affiliation	Tata Memorial Hospital
Address	Dept. of Anaesthesia, Critical Care and Pain, Second floor, Main Building, Dr. E Borges Road, Tata Memorial Hospital, Parel, Mumbai MAHARASHTRA 400012 India
Phone	9869077526
Fax	
Email	kaivalyaak@yahoo.co.in

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr Atul Kulkarni
Designation	Professor and Head, Division of Critical Care
Affiliation	Tata Memorial Hospital
Address	Dept. of Anaesthesia, Critical Care and Pain, Second floor, Main Building, Dr. E Borges Road, Tata Memorial Hospital, Parel, Mumbai MAHARASHTRA 400012 India

Phone	9869077526
Fax	
Email	kaivalyaak@yahoo.co.in

Source of Monetary or Material Support

Source of Monetary or Material Support
> Airway Management in Indian iCU Study (AMICUS) group, Tata Memorial Hospital, Dr. E Borges Road, Parel, Mumbai 400012

Primary Sponsor

Primary Sponsor Details	
Name	Tata Memorial Hospital
Address	Dept of Anaesthesia, Critical care and Pain, Dr. E Borges Road, Parel, Mumbai
Type of Sponsor	Research institution and hospital

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Atul Kulkarni	Tata Memorial Hospital	Department of Anesthesia Critical care and Pain Second floor, Main Building, Tata Memorial Centre Dr E Borges Road Parel Mumbai MAHARASHTRA	9869077526 kaivalyaak@yahoo.co.in

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethics Committee I	Approved	04/04/2022	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Other Procedures

Intervention / Comparator Agent

Type	Name	Details
Intervention	Nil	NA
Comparator Agent	Nil	NA

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	90.00 Year(s)
Gender	Both
Details	1. All consecutive adult critically ill patients (age > 18 years) having endotracheal or tracheostomy tube in situ, unless they meet exclusion criteria

Exclusion Criteria

Exclusion Criteria	
Details	1. Patients 2. Pregnant patients

Method of Generating Random Sequence	Not Applicable
Method of	Not Applicable

Concealment	
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
Incidence of unplanned extubation in critically ill adults	At the time of extubation

Secondary Outcome

Outcome	Timepoints
1. Incidence of blocked endotracheal/tracheostomy tubes 2. Incidence of malpositioned ETT 3. No. of patients requiring re-intubation (after accidental extubation) 4. ICU outcomes at discharge or at 30 days (whichever is earlier) 5. Hospital outcomes at discharge or at 30 days (whichever is earlier)	1. At the time of extubation 2. At 60 min post extubation 3. At 30 days

Target Sample Size	**Total Sample Size=**3500 **Sample Size from India=**3500 **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	N/A
Date of First Enrollment (India)	22/04/2022
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	Nil

Brief Summary

Introduction

Invasive Mechanical ventilation is one of the mainstays of organ support in the critically ill patients. Tracheal intubation or tracheostomy is commonly performed therefore in these patients. Tracheal intubation and tracheostomy are associated with myriad major and minor complications, which can be classified as be immediate, early or late.[1,2] Tracheal intubation may lead to complications related to the ETT or TT being situ for many days, and complications may occur during the ensuing days to weeks of ICU admission. The longer a tube stays in-situ, the greater the chances are of unplanned or self extubation, blocked tube and kinking, which may be life-threatening. However, most of these complications are preventable.

The rates of unplanned extubations from the 1970s to the 1990s were variable and relatively high, ranging from 3% to 16%.[3,4] The incidence of

self-extubation can be reduced to a mere 0.5% with appropriate precautions.[5] Large studies analyzing the epidemiologic pattern of all airway accidents in an ICU is scarce.[6-8] Preventive interventions such as managing nurse patient ratio, standardization of procedures for securing the ETT, protocolized sedation and the use of physical restraints have been reported to be useful in reducing the incidence of self-extubation, de Groot et al, reported that protocolised sedation (using Ramsay Sedation Scale) and the use of midazolam for sedation were independently associated with unplanned extubation.[9] Detecting short displacements, correcting orotracheal tube position at the teeth at least once per shift, and keeping patients' hands more than 20 cm away from the endotracheal tube, have been shown to be useful in decreasing incidence of unplanned extubation.[5] Although unplanned extubation has been not associated with an increase in mortality of ICU patients compared to matched controls, patients with unplanned extubation had a significantly longer duration of MV (19 versus 11 days, $p < 0.01$), longer stay in the ICU (21 versus 14 days, $p < 0.05$), and longer hospital stay (30 versus 21 days, $p < 0.01$), and survivors were more likely to require chronic care (64% versus 24%, $p < 0.001$)[10].

The sedation practices have changed with improved understanding about delirium in the critically ill, and analgesia first approach has been increasingly adopted in most ICUs around the world. The publication of PAD guidelines by SCCM has also influenced sedation practices.[11]

The data related to the mishaps related to tracheal intubation and tracheostomy is old and mostly from small no. of intensive care units in India. We therefore aimed to conduct this observational study to determine the incidence, complications, risk factors and outcomes complications of prolonged artificial airway management in ICU, such as unplanned extubation, blocked and misplaced endotracheal/tracheostomy tubes.

Aims

Primary outcome:

1. Incidence of unplanned extubation in critically ill adults

Secondary outcomes:

1. Incidence of blocked endotracheal/tracheostomy tubes
2. Incidence of malpositioned ETT

o Endobronchial intubation (EBI) occurring while the ETT/TT is in place (not at the time of intubation)

o Displaced ETT with air leak from the larynx while the ETT/TT is in place (not at the time of intubation)

o Complications secondary to the airway mishaps while the ETT/TTis in place (not at the time of intubation)

3. No. of patients requiring re-intubation (after accidental extubation)

4. ICU outcomes at discharge or at 30 days (whichever is earlier)

5. Hospital outcomes at discharge or at 30 days (whichever is earlier)

Study Design: Prospective observational study

Patients

Inclusion Criteria

1. All consecutive adult critically ill patients (age > 18 years) having endotracheal or tracheostomy tube in situ, unless they meet exclusion criteria.

Exclusion Criteria

1. Patients < 18 years of age

2. Pregnant patients

Method

Data will be collected using web-based Clinical Record Form, for all consecutive adult patients intubated in the ICU of all the participating centres (this means all patients recruited in the IMPACT study). This will be used as the denominator i.e. total no of intubations. The data for adverse events as defined will be collected for the following variables. The Nurse Patient Ratio and the Residents in each shift will be noted by the investigator present on duty and this will be verified from the duty roster. Presence of Doctor/Nurse during the event will be noted in the CRF.

Variables

The data of following variable will be collected

1. Age
2. Sex
3. Weight
4. Height
5. SOFA score on the day of the event
6. Technique of ETT fixation
7. Distance (from upper incisors) at which ETT was fixed
8. Cuff pressure before the incidence (last cuff pressure available)
9. Whether the patient needed reintubation, if yes, reason for reintubation
10. Sedative and analgesic drugs (and their doses) being given at the time of airway mishap
11. RASS score at the time of the event
12. CAM-ICU score at the time of the event
13. Whether physical restraints being used at the time of the mishap
14. Was the patient being weaned from ventilation at the time of mishap
15. If patient was not reintubated, type of oxygen support required

a. NIV
b. HFNC
c. Oxygen by Mask
d. Oxygen by NRBM

16. Interval between intubation / Tracheostomy and the event (days)
17. Time of occurrence of airway mishap

18. Nurse: patient ratio at the time of airway mishap

19. Resident: patient ratio at the time of airway mishap

20. Was a doctor present near patient the time of airway mishap

21. Was a nurse present near patient the time of airway mishap

22. Complications of airway mishap

a. Hemodynamic instability defined as

i. Severe hypotension: Mean arterial pressure < 65 mmHg recorded at least one time and/or < Systolic blood pressure < 90 mmHg lasting > 5 mins, despite fluid loading and/or requiring introduction or increase in dose of vasopressor),

ii. Severe hypoxia (SpO_2 < 80%), or

iii. Cardiac arrest.

b. Aspiration of gastric contents

c. Need for reintubation

d. Need for tracheostomy

23. Severity of the airway accident

a. Mild: Little or no physiological consequence/ managed by resident on call.

b. Moderate: Cardio respiratory decompensation/ senior or experienced person required to manage the problem.

c. Major: Near or actual Cardio respiratory arrest/death

24. ICU outcomes at discharge or at 30 days (if still in ICU)

25. Hospital outcomes at discharge or at 30 days (if still in hospital)

The airway accident rate will be calculated in terms of

1. No. of accidents per patient

2. No. of accidents/intubation days for each patient

3. Incidence of airway mishaps: No of patients with airway accidents/total no. of patients intubated.

4. Total tube days (TD): period from the date of intubation or tracheostomy until extubation/removal of the tracheostomy tube/ death.

Tube will be considered to be blocked if there is inability to ventilate the patient or resistance is felt on passing a suction catheter down the tube, or if the lumen is found narrowed at extubation.

Statistics

Sample size calculation: Patients will be recruited for a period of 3 months in all ICUs, after IEC approval. We will include all the patients (3500) that are recruited in the "**A**Irway **M**a**N**agement **P**rActices and **C** omplications of in**T**ubation in Indian ICUs (IMPACT): A prospective multicenter cohort study in Indian ICUs" study.

Statistical analysis plan: For descriptive analysis, categorical variables will be presented as counts and percentages. Continuous variables will be reported as mean and standard deviation if normally distributed (using Kolmogorov–Smirnov test) or as median and interquartile range (IQR) if non-normally distributed. For normally distributed data, we will use student T-test. Kruskal Wallis test will be used for reporting non-normal distributed data such as medians and IQRs. Categorical variables will be analysed using Pearson's chi^2 test or Fisher exact test where appropriate. We will carry out a univariate analysis for identifying variables associated with the composite end point, i.e. major complications of intubation, and the variables found to be significant will be entered into multivariable logistic regression analysis to identify independent. predictors of major complications of intubation. A two-sided p-value < 0.05 will be considered as being statistically significant.