Clinical Trial Details (PDF Generation Date :- Tue, 19 Apr 2022 08:21:34 GMT)

CTRI Number	CTRI/2022/04/041935 [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 practices and complications of intubation (the insertion of a tube into the windpipe of a patient for an artificial ventilation)
Scientific Title of Study	AIrway MaNagement PrActices and Complications of InTubation in Indian ICUs (IMPACT): A prospective multicenter cohort study in Indian ICUs

Secondary IDs if Any

Secondary ID	Identifier
3923_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
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Details Contact Person (Scientific Query)

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Name	Dr Atul Kulkarni
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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	05/04/2022	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) requiring endotracheal intubation, unless they meet exclusion criteria

Exclusion Criteria

Exclusion Criteria	
Details	1. Pregnant patients 2. Patients intubated for resuscitation due to cardiac arrest 3. Patients with known difficult airway (ventilation/laryngoscopy/intubation)

	4. Patients with anterior mediastinal mass 5. Patients with SVC syndrome

Method of Generating Random Sequence	Not Applicable
Method of Concealment	Not Applicable
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
Composite end point comprising of one of the following, within 45 min of endotracheal intubation: a. 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), b. Severe hypoxia (SpO2 80%), or c. Cardiac arrest.	Within 45 min of intubation

Secondary Outcome

Outcome	Timepoints
1. Airway assessment method 2. Experience of person performing intubation 3. Preoxygenation method 4. Drugs administered for intubation 5. Whether Rapid Sequence intubation or Delayed Sequence Intubation 6. Cricoid pressure applied or not 7. Type of laryngoscope used 8. Whether external manipulation required for intubation 9. Adjuncts used for achieving intubation 10. Number of attempts required for successful intubation 11. Method of confirmation of successful intubation 12. No. of attempts for successful intubation 13. Difficult intubation i.e., 2 attempts at laryngoscopy; 14. Esophageal intubation; 15. Aspiration of gastric contents 16. Cardiac arrhythmias 17. Dangerous agitation 18. Dental injuries 19. Other injuries to lips and/or structures oral cavity such as tonsillar pillars 20. Risk factors predicting complications of tracheal intubation 21. ICU outcome at discharge or 28 days 22. Hospital outcome at discharge or 28 days	1. At 45 min of intubation 2. At 28 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

Intubation in critically ill patients is different from that performed in patients undergoing elective surgeries. Many factors contribute to these differences. Inexperienced non-anaesthetist personnel, without supervision, often carry out intubations in ICU. Not being in OT, capnography an essential tool, and difficult intubation equipment may also not be available. Giving appropriate position forintubation to the patient and accessing the head end may often be difficult.[1] The ICU patients may be at risk of aspiration of gastric content, due to having full stomach and effects of opiates. Apart from the usual chance of having anatomically difficult airway;critically ill patients have a physiologically difficult airway, manifesting as hypoxia, low blood pressure, metabolic acidosis, and right ventricular failure.[2] This decreases their cardiorespiratory reserve and makes them vulnerable to likelihood of serious complications.

Complications are more common therefore, in non-OT locations such as ICU and Emergency Departments. Simpson et al reported that hypotension (22%) and hypoxia (20%) were the commonest complications during intubation in ICU.[3] The NAP4 auditfound that the incidence of airway complications was 3 fold higher in ICU and ED as compared to OT. More worrying were the outcomes of these patients, a large no. of whom either died (50%) or had permanent brain damage (25%). [4,5]A multicenter studydescribing immediate complications of tracheal intubation in the ICU found that majorcomplications occurred in 28% of patients.[6] A secondary analysis of this study published later revealed a nearly 30% incidence of severe cardiovascular collapse.[7]
A recent study found a much higher (45.2%) incidence of major complication in criticallyill patients undergoing tracheal intubation.[8]

There is scarce data from IndianICUs about intubation practices and immediate complications, barring a few single center studies. A study evaluating intubation bundlecompliance and complications found that major complications occurred in 47.5% patients.[9] Incidence of major complications during tracheal intubation in pediatric population was found to be 31%.[10] We therefore decided to conduct this multicenter prospective study with the aim to describe intubation practices and immediate complications of tracheal intubation.

Outcomes:

1. Primary outcome: Composite end point comprising of one of the following, within 45 min of endotracheal intubation:

a. 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),

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

c. Cardiac arrest.

Secondary outcomes:

1. Airway assessment method
2. Experience of person performing intubation
3. Preoxygenation method
4. Drugs administered for intubation

- Sedatives
- Hypnotics
- Analgesics
- Muscle relaxant

5. Whether Rapid Sequence intubation or Delayed Sequence Intubation
6. Cricoid pressure applied or not
7. Type of laryngoscope used
8. Whether external manipulation required for intubation
9. Adjuncts used for achieving intubation
10. Number of attempts required for successful intubation
11. Method of confirmation of successful intubation

12. No. of attempts for successful intubation
13. Difficult intubation i.e., >2 attempts at laryngoscopy;
14. Esophageal intubation;
15. Aspiration of gastric contents (visible gastric contents in airways during intubation or in endotracheal tube suctioning post intubation)
16. Cardiac arrhythmias (except for ventricular fibrillation, ventricular tachycardia, and asystole)
17. Dangerous agitation (Richmond Agitation Sedation Scale, RASS > 3)
18. Dental injuries.
19. Other injuries to lips and/or structures
oral cavity such as tonsillar pillars
20. Risk factors predicting complications of tracheal intubation
21. ICU outcome at discharge or 28 days (whichever is earlier)
22. Hospital outcome at discharge or 28 days (whichever is earlier)

Sample size calculation: We will collect data of consecutive intubations carried out in each ICU, after IEC approval, at least 3500 patients (or for a period of 4 months) Assuming an incidence of 48-50% overall complications (with a precision of 5%), this should give > 80% power to the study.[9]

Statistical analysis

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'schi2 test or Fisher exact test where appropriate. We will carry out a univariate analysisfor 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.

Inclusion criteria:

1. All consecutive adult critically ill patients (age > 18 years) requiring endotracheal intubation, unless they meet exclusion criteria.

Exclusion criteria:

1. Pregnant patients
2. Patients intubated for resuscitation due to cardiac arrest
3. Patients with known difficult airway (ventilation/laryngoscopy/intubation)
4. Patients with anterior mediastinal mass
5. Patients with SVC syndrome

Methods

All consecutive adult patients (>18 years) requiring tracheal intubation in all participating centers will be included in the study. The Nurse Patient Ratio and the Residents in each shift will be noted by the investigator present on duty and this will beverified from the duty roster. Presence of Doctor/Nurse at the during the event will benoted in the CRF.

The following data will be collected by the investigators and filled in the using web-based Case Record Form.

Variables

The data for following variables will be collected:

1. Age
2. Sex
3. Weight
4. Height

5. APACHE II score on the day of intubation

6. SOFA score on the day of intubation

7. Indication for intubation

8. Whether this was reintubation, if yes, reason for reintubation

9. Hemodynamic parameters before, during and up to one hour after intubation

10. Oxygenation parameters before, during and up to one hour after intubation

11. Airway assessment method

12. Experience of person performing intubation

13. Preoxygenation method

14. Drugs administered for intubation

a. Sedatives

b. Hypnotics

c. Analgesics

d. Muscle relaxant

15. Whether Rapid Sequence intubation or Delayed Sequence Intubation

16. Cricoid pressure applied or not

17. Type of laryngoscope used

18. Whether external manipulation required for intubation

19. Adjuncts used for achieving intubation

20. Number of attempts required for successful intubation

21. Method of confirmation of successful intubation

22. Complications of intubation

23. Need for fluid boluses or vasopressors before and after intubation

24. ICU outcome at discharge or 28 days (whichever is earlier)

25. Hospital outcome at discharge or 28 days (whichever is earlier)