

## **AIrway MaNagement PrActices and Complications of InTubation in Indian ICUs (IMPACT): A prospective multicenter cohort study in Indian ICUs.**

### **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 for intubation to the patient and accessing the head end may often be difficult.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup> The NAP4 audit found 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%).<sup>4,5</sup> A multicenter study describing immediate complications of tracheal intubation in the ICU found that major complications occurred in 28% of patients.<sup>6</sup> A secondary analysis of this study published later revealed a nearly 30% incidence of severe cardiovascular collapse.<sup>7</sup> A recent study found a much higher (45.2%) incidence of major complication in critically ill patients undergoing tracheal intubation.<sup>8</sup>

There is no data about intubation practices from India. There is scarce data from Indian ICUs, barring a few single center studies. A study evaluating intubation bundle compliance and complications found that major complications occurred in 47.5% patients.<sup>9</sup> Incidence of major complications during tracheal intubation in pediatric population was found to be 31%.<sup>10</sup> 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<sub>2</sub> < 80%), or
  - c. Cardiac arrest.

#### Secondary outcomes:

1. No. of attempts for successful intubation
2. Difficult intubation i.e. >2 attempts at laryngoscopy;
3. Esophageal intubation;
4. Aspiration of gastric contents (visible gastric contents in airways during intubation or in endotracheal tube suctioning post intubation)
5. Cardiac arrhythmias (except for ventricular fibrillation, ventricular tachycardia, and asystole)
6. Dangerous agitation (Richmond Agitation Sedation Scale, RASS > 3)
7. Dental injuries.
8. Other injuries to lips and/or structures oral cavity such as tonsillar pillars
9. Risk factors predicting complications of tracheal intubation
10. ICU outcome at 30 days
11. Hospital outcome at 30 days

**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 3 or 4 months) Assuming an incidence of 48-50% severe complications (with a precision of 5%), this should give > 80% power to the study.

#### 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's chi2 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.

### **Inclusion criteria:**

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

### **Exclusion criteria:**

1. Patients < 18 years of age
2. Pregnant patients
3. Patients intubated for resuscitation due to cardiac arrest
4. Patients with known difficult airway (ventilation/laryngoscopy/intubation)
5. Patients with anterior mediastinal mass
6. 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 be verified from the duty roster. Presence of Doctor/Nurse at the during the event will be noted in the CRF.

The following data will be collected using web-based Clinical 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 30 days
25. Hospital outcome at 30 days

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