

A CLINICAL STUDY ON BEDSIDE ELECTIVE OPEN TRACHEOSTOMY IN ICU OF A TERTIARY HOSPITAL IN KERALASunil Kumar K. P¹, Divya G. M², Vijeyta Dahiya³, S. Muneeruddin Ahmed⁴**HOW TO CITE THIS ARTICLE:**

Sunil Kumar K. P, Divya G. M. Vijeyta Dahiya, S. Muneeruddin Ahmed. "A Clinical Study on Bedside Elective Open Tracheostomy in ICU of a Tertiary Hospital in Kerala". Journal of Evolution of Medical and Dental Sciences 2015; Vol. 4, Issue 37, May 07; Page: 6495-6504, DOI: 10.14260/jemds/2015/942

ABSTRACT: INTRODUCTION: Tracheostomy is a common procedure performed in critically ill ventilator-dependent patients to provide long-term airway access. About 10% of the ICU patients require prolonged mechanical ventilation and hence a tracheostomy is needed. Early bedside tracheostomy in such patients reduces the length of stay in ICU and number of days on ventilator by facilitating weaning. **AIMS AND OBJECTIVES:** This prospective clinical study aims to study the results of early versus late Tracheostomy in critically ill patients of ICU and other Emergency wards. This study also aims to observe and analyze the outcomes of bedside open tracheostomy, in relation to its safety, complications, and duration of hospital stay; mortality and problems of decannulations. **MATERIALS AND METHODS:** This is a prospective study done in Govt. Medical College, Calicut from Jan 2013 to June 2014 and includes all the patients in ICU's and wards who underwent bedside tracheostomy by open surgical method during the study period. Results: The study sample consisted of 60 patients in the age group of 15-75 years. 41(68%) males and 19(32%) females. The main indication for tracheostomy is prolonged ventilation (90%). Patients with head Injury fared better than with neurological diseases in our study, with a statistical significance. (P value-0.02).Mortality is 53.33%. One patient died directly as a result of the procedure. Remaining patients recovered from primary disease and decannulated. There was significant relationship between early tracheostomy with early weaning, early decannulations and shorter ICU and overall hospital stay (P value <0.05). All complications were managed conservatively without any sequelae. **CONCLUSION:** Operative complications of bedside tracheostomy are less. Most of these develop in the first week and can be managed without morbidity. Majority of deaths in our study are related to the primary disease rather than the procedure. There was no significant relationship between timing of tracheostomy with laryngotracheal stenosis and overall mortality.

KEYWORDS: Bedside Tracheostomy; Ventilator, Decannulations, PEEP, Tracheal stenosis.

INTRODUCTION: Emergency tracheostomy is a common procedure creating an airway in patients with airway obstruction or to remove anatomical dead space.¹Tracheostomy is defined as a surgical procedure creating a stoma in the trachea, communicating to outside with a conduit.² First known reference of Tracheostomy can be found in Rig Veda, the Hindu scripture dating back to 2000BC. In recent years, there has been a considerable shift in emphasis regarding the indications of tracheostomy with recognition of the more physiologic and functional indications in addition to those of a strictly obstructive nature. Historically, the complication rate was high which led some authors to suggest that a tracheostomy should be done only in operating room. Concerns regarding the hazards of transporting critically ill patients to Operation Theatre led to the concept of BEDSIDE TRACHEOSTOMY. Bedside tracheostomy in ICU's and wards has been shown to be safe, but this concept has not been widely accepted.

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Tracheostomy is probably the most common surgical procedure performed in critically ill patients. About 10% of mechanically ventilated critically ill patients secure a tracheostomy to facilitate prolonged airway and ventilator support³. Most of the cases of brain injury patients require prolonged ventilator support to protect their airway from aspiration, reduce anatomical dead space and to treat pulmonary complications. Extubation is delayed in these patients due to their impaired level of consciousness.⁴ Early tracheostomy in such patients reduces length of stay in ICU, number of days on ventilator and incidence of Ventilator Associated Pneumonia.⁵ Main critical issue is to identify those patients who will more often require long term ventilator support and determine the timing for tracheostomy.

Such patients should meet the Standard weaning criterion also. Major and coworkers⁶ suggested the utility of daily assessment of objective scores such as Glasgow Coma Scale (GCS) and Simplified Acute Physiology Score; scores on these scales of below 7 and greater than 15, respectively, on day 4 had a high positive predictive value for identifying those head-injured patients who required tracheostomy for prolonged airway protection. Although the need for and optimal timing of tracheostomy for brain-injured patients is a common clinical problem. No large randomized trials have unequivocally clarified whether this intervention improves outcome. The present study is an attempt to focus on the aspects of bedside tracheostomy, performed in ICU's and wards without the standard OT setup. The aim is to present analysis of the timings and outcomes of such bedside tracheostomy.

AIMS AND OBJECTIVES: Aims of the study are to determine the outcomes of bedside tracheostomies done in ICU's and wards, including short term and long term complications, weaning from the ventilator, changeover to metallic tube and finally the decannulations. This will guide to analyze the requirement of early tracheostomy instead of prolonged endotracheal intubation. It will also guide to know the average time of decannulations.

MATERIALS AND METHODS: STUDY DESIGN: The present study is a prospective clinical study of patients undergoing bedside Open tracheostomy in ICU's and wards, admitted in Government Medical College Calicut during the period from January 2013 to June 2014.

Inclusion Criteria: 1. Patients of all ages and sex undergoing bedside open tracheostomy.

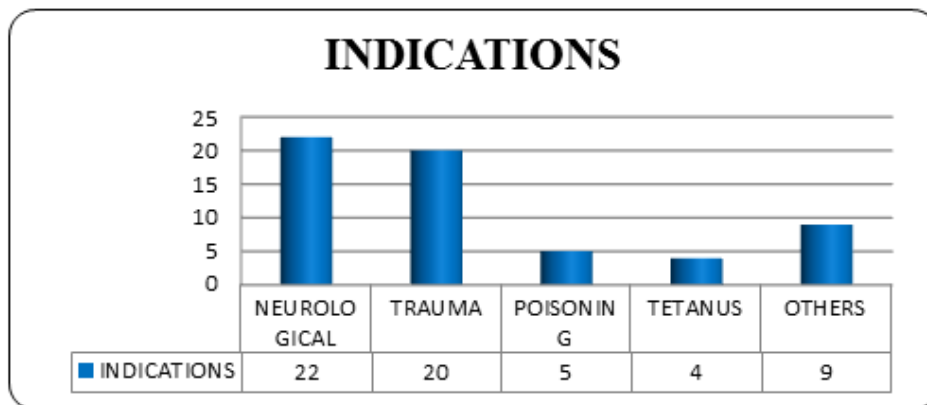
Exclusion Criteria: 1. Patients with airway obstruction due to malignancies of Head and Neck. 2. Patients below 12 years. The demographic data of the patients is collected. A clinical proforma is prepared to record the data in relation to the indication for tracheostomy, time lapse between endotracheal intubation and tracheostomy, duration of stay in ICU/ emergency ward on ventilation, time taken for weaning timing of tracheostomy. The proforma also records the immediate, intermediate and late complications and their management. Problems during decannulations, incidence of tracheal stenosis and mortality rates were studied. Outcome is assessed post operatively and followed up for a minimum period of 4 weeks after decannulations.

Ethical Concerns: Written and valid consent from the patient's attendants or authorized person is obtained.

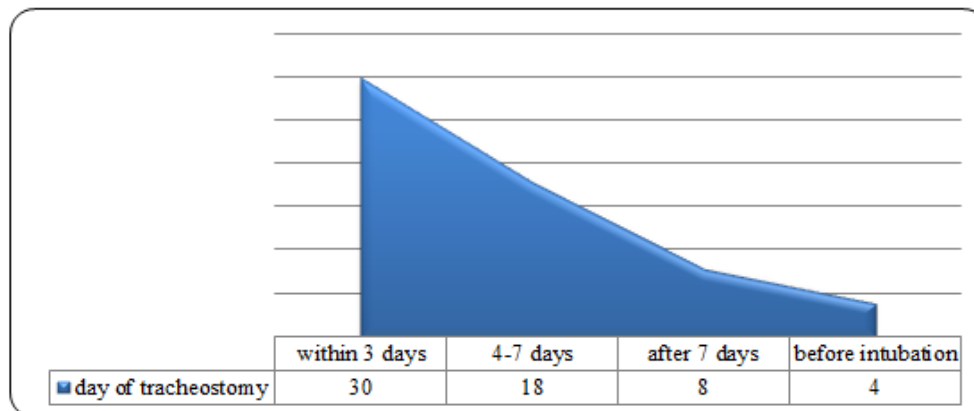
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Analysis: Statistical analysis was done using SPSS version 16.0. Results were expressed as mean and standard deviation. Chi square test and t-test were used for comparison and P value less than 0.05 were taken as significant.

OBSERVATIONS: 60 patients in the age group of 15-75 years who underwent bedside open tracheostomy in the ICU/emergency wards are included in the present study. 41(68%) of them are males and 19(32%) are females. 20(33.33%) patients belonged to the age group of 45-59 years. The indication in 54 (90%) of the patients was requiring prolonged ventilation. In four (6.66%) patients the indication is difficulty intubation and in two (3.33%) patients the indication is tracheo bronchial secretions. Indications for endo tracheal intubation and ventilation included neurological disease in 22(36.66%), followed by Head Injury (trauma) patients 20(33.33%). Five patients with poisoning (8.33%) and four with tetanus (6.66%) are operated upon.



Based on Glasgow coma scale the patients are categorized into two groups. The patients showing score more than 7 are 42(70%) and patients with less than score 7 are 18(30%). In 56 (93.33%) patient's bedside tracheostomy is done with endo tracheal tube in situ. Four Patients having tetanus (4) required emergency tracheostomy to secure airway. Bed side tracheostomy is done within three days in 30 (50%) patients, within 4 to 7 days in 18(30%) and in 8(3.33%) of them after 7 days. In four patients tracheostomy is done before endo tracheal intubation.



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Following observations are made in relation to the complications:

Intra operative complications:

1. Repeated fall in O₂ saturations 3: (11.6%)
2. Cardiac arrest (Eisenmenger syndrome) 1: (1.66%)
3. Bleeding. (Patients on aspirin) 2: (15%)

Immediate Complications:

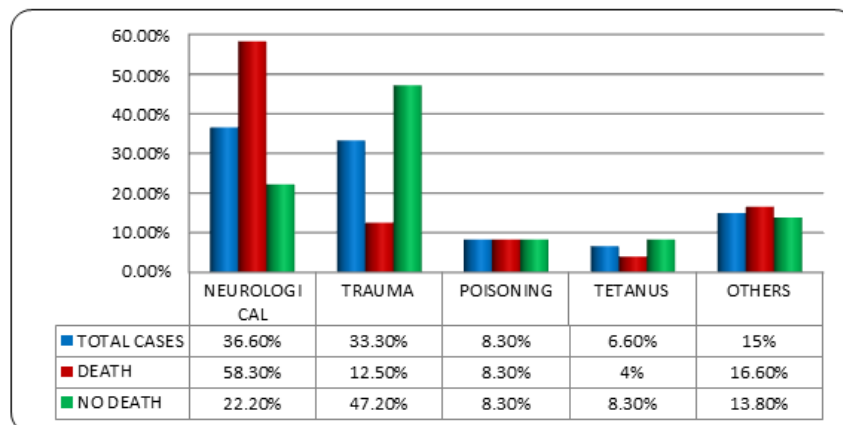
1. Recurrent Crusting 2: (16.66%)
2. Accidental Extubation 2: (8.33%)
3. Infection of the wound 2: (18.33%)
4. Skin excoriation 1(1.66%)

Late Complications:

1. Difficulty in weaning 1(1.66%)
2. Difficulty in Extubation 2
3. Tracheal stenosis. 4(6.66%)

20(33.33%) patients showed complications which are managed according to the situation. Among these 20 patients with complications 8(40%) belonged to the age group of 15-29. There are more complications in the patients with neurological diseases than others but the difference was not statistically significant. Out of total 20 patients with complications, 18 developed in patients with GCS 3-6(85.7%). This was statistically significant with P value of 0.046. The statistical significance of incidence of complications in the present study is P value 0.571. (Expected P value is <0.05). If the incidence of complications are related to the sex of the patient 11(26.82%) out of 41 males showed complications and 10(52.63%) out of 19 females showed complications. 24 patients who did not survive, one patient died during the procedure, and could not be revived. In 23(38.33%) patients, it is assumed that the death is related to the primary disease because the tracheostomy was patent.

Twenty (55.8%) patients were weaned from ventilator in first week. Decannulation was done successfully in thirty six patients. Laryngotracheal stenosis was seen in 4(6.66%) patients out of 36 patients. The stenosed segment was upper trachea in all these patients. 45(75%) of the patients stayed in ICU and ward up to 14 days. 42 patients (70%) are discharged within one month of tracheostomy. Mortality was more in age group of 45 years and above; 58.2%. 29 48.33% of the Trauma patients survived when compared to 13(21.66%) of the patients with Neurological diseases. This observation is statistically significant with P value 0.02.



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All the patients with GCS above 6 were successfully weaned within 3 days while only 12 patients out of total 26(46%) were weaned who had GCS 3-6. This was statistically significant with P value of 0.028.

In the 30 patients undergoing tracheostomy within 3 days, decannulations are done successfully after weaning. Successful decannulations done in them are 18(60%). 12 deaths occurred in this group (40%). It was statistically significant with P value of 0.027. The complication rate in patients undergoing tracheostomy within 3 days is less compared with those undergoing after 3 days. But there is no statistical significance. There is statistically significant relation between timing of tracheostomy and weaning from ventilator. Out of the total weaned patients, 77% of cases were those who underwent tracheostomy within 7 days of intubation with P value < 0.001. Early tracheostomy is associated with lesser number of days in ICU's.

Out of 27 patients who underwent tracheostomy within 7 days of intubation, 11(41%) recovered from their primary illness, to be shifted to the ward. In those patients undergoing tracheostomy after 1 week of intubation no recovery from primary illness is found. The result was statistically significant with P value 0.043. 69.2% of those who underwent tracheostomy within one week are discharged within one month compared to 57% of discharge in late tracheostomy group.

This is also statistically significant with P Value of 0.042. Overall mortality is more in those with early tracheostomy, but it may be due to the primary disease. Out of 48 patients (80% of total) who underwent early tracheostomy, 22(45.8%) expired. But this is not statistically significant. This can be attributed to the severity of the underlying illness and not to the procedure.

DISCUSSION:⁽⁷⁾ Bed side Open tracheostomy is one of the most commonly performed procedures in India and elsewhere among the ICU/ Emergency wards of a Hospital.⁽⁸⁾ At least 10% of these patients requiring more than 3 days of ventilator support undergo tracheostomy.⁽⁹⁾ Evolution of lesser invasive procedures performed on bed side to avoid difficulty in weaning of endotracheal tubes is becoming popular.⁽¹⁰⁾ Recently, prevention and better clinical management of Pneumonia with early tracheostomy is evaluated.⁽¹⁰⁾ Tracheostomy is generally indicated for respiratory failure requiring prolonged mechanical ventilation. Airway protection in disease states leaving patients unable to protect the airway, such as severe traumatic brain injury, and for bypass of airway obstruction owing to cancer or trauma or surgery or other diseases are other indications. Despite its broad range of indications, the data on exactly who should get a tracheostomy, and more importantly when, are still debated and no clear answer exists.⁽¹¹⁾

A recent review of more than 1000 consecutive tracheostomies found that 76% were performed to facilitate mechanical ventilation. In our study which included only bedside tracheostomy, the main indication for doing the procedure is prolonged mechanical ventilation. Tracheostomy is a common procedure performed in critically ill ventilator-dependent patients to provide long-term airway access. Indications for intubation and ventilator support are diverse. In the present study 22 patients (37%) cases are intubated because of neurological illnesses followed by trauma cases (33%). Despite the risks, there are populations who clearly benefit from tracheostomy. In evaluating the literature on the need for tracheostomy, it becomes obvious that defining criteria for that should get a tracheostomy is complicated. One population extensively studied is the trauma population.⁽¹²⁾ Barquist and colleagues studied non-brain-injured or mildly brain-injured trauma patients and attempted to randomize patients to early (8 days) versus late (28 days) tracheostomy.

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This study was stopped early after interim analysis determined there was no difference in outcomes. Despite the lack of difference between early and late tracheostomy, a large percentage of patients in this study clearly required a tracheostomy.⁽¹³⁾

NehadShirawi et al in their study concluded that tracheostomy should be considered early in critically ill trauma patients should be strongly considered if the patient requires intubation for more than 7 days.⁽¹⁴⁾ In another study of a state wide trauma registry, it was found that in patients with a low probability for survival, early tracheostomy was associated with increased mortality. They attributed this mortality effect to the disease process, however, and not the tracheostomy.

This underscores the difficulty of predicting that will require tracheostomy, as this patient population is profoundly ill and predicting survivors is an inexact science. For those patients who lived for greater than 4 days, there were improved outcomes in terms of total ventilator days and ICU length of stay if a tracheostomy was performed between days 4 and 7 compared with those whose tracheostomy was delayed for greater than 8 days. In our study, females had more chance of developing complications than males and it is statistically significant also with P value 0.049. Out of 41 males, 13 expired (31.7% of males) whereas out of 19 females only 8 survived and rest 11 expired (57.8%).

This is also statistically significant with P value less than 0.05. So both complications and mortality is more in females as compared to males. We didn't find any study in literature comparing mortality and complications in different sexes. In our study, the end results of trauma patients are far better than those with neurological diseases with more patients of trauma group who survived. It was statistically significant with P value of 0.02. Mortality in patients with neurological disease group was 58.3% of total mortality while in trauma groups it is 12.5%. Complication rates of the procedure are also more in cases with neurological illnesses than trauma group (42.8% compared to 28.5%).

Francesco Imperatore et al observed in their study the incidence of total complications was 5.71%; hemorrhage in 2.14%, infection in 2.85% and tracheal stenosis in 0.71%. Mortality rate was 43.57% though not technically related to tracheostomy. This study is similar to our study. Total of 53% cases among trauma group were successfully weaned from ventilator whereas only 23.5% of neurologic illness group could be weaned.⁽¹⁵⁾ Tracheostomy may be beneficial in patients with a low Glasgow Coma Score, both from trauma and non-trauma etiologies.^{(16),(17)}

In another study, nearly 16% of more than 20,000 patients who presented to the hospital with a GCS less than 8 and evidence of a head injury required tracheostomy. In our study, there is statistically significant relationship between Glasgow coma score with complications and weaning from ventilator. Out of total 21 complications, 18 developed in patients with GCS 3-6 (85.7%). This is statistically significant with P value of 0.046. Mortality is also more in patients with low score which is attributable to the disease severity. All the patients with GCS above 6 were successfully weaned within 3 days while only 12 patients out of total 26 (46%) are weaned who had GCS 3-6. This was statistically significant with P value of 0.028. Hence even though the complications are more in younger age group overall mortality is more among elderly. But the results are not statistically significant with P value 0.19. So females had more chance of developing complications than males and it is statistically significant also with P value 0.049.

Out of 41 males, 13 expired (31.7% of males) whereas out of 19 females only 8 survived and rest 11 expired (57.8%). This is also statistically significant. 49.2% of patients underwent tracheostomy in first three days of intubation, 29.5% patients it is between 3-7 days and in 13% after

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7 days of intubation. So in total about 80% it is performed within 7 days of intubation. This is still the area of debate in literature where many studies have supported the need for early tracheostomy. In our study, there is statistically significant relationship between timing of tracheostomy and weaning from ventilator and successful decannulations. Out of the total weaned patients, 77% of cases are those who underwent tracheostomy within 7 days of intubation. Out of these patients in whom tracheostomy is done early within three days of intubation, there are 18(54.5%) successful decannulations and 12 deaths (54.5%).

It was statistically significant with P value of 0.027. Hence it is assumed that early tracheostomy is associated with early decannulations in this study. Also in our study, early tracheostomy was associated with lesser number of days in ICU's compared with late tracheostomy.

Out of 27 patients who underwent tracheostomy within 7 days of intubation, 11(41%) are transferred to ward within one week unlike in patients in whom the procedure was done after one week. The result was statistically significant with P Value of 0.043. Similarly early tracheostomy is associated with early discharge from hospital. 69.2% of those who underwent tracheostomy within one week were discharged within one month compared to 57% of discharge within one month in late tracheostomy group. This is also statistically significant with P Value of 0.042. This is in accordance with what has been described in the literature. ^(18,19)

Three meta-analyses have been published regarding the effect of the timing of tracheostomy on the prognosis of prolonged mechanically ventilated patients. Of these studies, two studies defined early tracheostomy as a tracheotomy conducted up to 7 days and one study up to 10 days after the initiation of translaryngeal intubation; these studies assessed the influence of tracheostomy early or late on the incidence of mortality, the duration of mechanical ventilation (MV) and ICU stay and other important clinical outcomes in critically ill adult patients. However, inconclusive results were presented concerning several outcomes among the three meta-analyses. Early tracheostomy was associated with early discharge from hospital. ⁽²⁰⁾Blot and colleagues attempted to prospectively study the effect of early tracheostomy. One hundred twenty-three patients expected to require mechanical ventilation for more than 7 days were randomized to either early tracheostomy or prolonged intubation. There was no difference between groups in terms of mortality or rate of pneumonia, but subjectively comfort was improved in the tracheostomy group. In the largest randomized study. ⁽²¹⁾

Terragni and colleagues randomized 419 patients (of 600 enrolled) to either early tracheostomy (6-8 days) or delayed tracheostomy (13-15 days). There were no differences in 28-day mortality, but ICU days and ability to wean from mechanical ventilation were improved in the early tracheostomy group. Unfortunately the lack of ability to predict who will be ill enough to require prolonged intubation, yet well enough to live long enough to benefit from early tracheostomy makes studying this procedure quite difficult. This only underscores the need to take an individual approach in deciding who needs a tracheostomy and when it should be performed until more evidence becomes available. The intra operative complications occurred in 5 patients in the form of saturation fall in 3 and excessive bleeding in one patient. One patient with congenital heart disease and Eisenmenger syndrome expired at the time of doing the procedure.

In rest of four patients the condition was stable after the procedure. Early complications are noted in 17 patients (47.2%) out of 36 who survived. These included tracheostomy tube block in seven patients, tracheostomy site infection, the wound healed without any sequelae. In two patients

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there is cuff leak and aspiration which was managed by tube change. Another two patients developed bleeding from tracheostomy site which is managed conservatively. Tube dislodgement occurred in two patients which are corrected immediately. Late complication in the form of stenosis developed in four patients. In all four it was the stenosis of upper trachea. These patients developed breathing difficulty after decannulation and tracheostomy tube has to be reinserted. X-ray neck lateral view revealed stenosis in these patients. In all patients serial dilations with progressively larger tubes was done. The need for surgical correction didn't arise in any patient.

In our study, the complication rate in those who are tracheostomy nearly within 7 days is less compared with those after 7 days. But again the results are not statistically significant with P value 0.09. In a recent study on tracheostomy complications,⁽²²⁾ Halum et al compared the complication rates for tracheostomy performed in the operating room with those at the bedside and concluded that surgical location did not correlate with complication rates. However, their study was a multi-institutional analysis, used data from 1,175 patients, and included percutaneous tracheostomies, although open tracheostomies were 8 times more common than percutaneous tracheostomies.

In a study by,⁽²³⁾ Delaney A, Bagshaw SM, they found that there is no difference between Percutaneous tracheostomy and bedside tracheostomy in relation to bleeding during the procedure, morbidity and mortality. Outcomes in short, out of 60 patients, twenty three expired due to primary disease, only one patient died directly as a result of the procedure. Rest 36 patients were successfully decannulated and discharged within one month. All complications were managed conservatively without any sequel.

CONCLUSION: Open bedside tracheostomy is a common, simple procedure in experienced hands, if the selection criteria are within permissible limits. Common indication in ICU is necessity of prolonged intubation. Peri operative outcome in trauma patients is showing statistical significance. Glasgow coma score can predict the survival, chance of developing complications and weaning of these intubated patients. There is a statistical significance and good correlation between early tracheostomy and safe weaning and decannulations leading to short hospital stay.

There is no correlation between timing of tracheostomy and mortality and tracheal stenosis.

The mortality and post-operative complications are more common in females than in males. The cause of mortality is usually the underlying primary disease rather than tracheostomy in majority of patients. Hence the benefit of bedside open tracheostomy outweighs its major risks. Significantly more research is needed to determine early whether an ICU patient will require prolonged intubation so that tracheostomy can be planned more effectively.

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