## **Original Research Article**

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# A clinical study on the outcomes of tracheostomy in a tertiary care center: a prospective observational study

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#### **ABSTRACT**

**Background:** Tracheostomy is most commonly performed in patients who have difficulty in weaning off a ventilator. This surgical procedure is associated with complications. The present study was aimed to evaluate the outcomes of tracheostomy with primary and secondary objectives.

**Methods:** This study was done in department of ENT, KIMS Health, Trivandrum, Kerala. Based on the inclusion and exclusion criteria 81 patients were included in the study. Study procedure was explained and informed consent was obtained from close relatives or kin of patients. Demographic, clinical and complication data was collected from the patients and analysed with Statistical Package for Social Sciences (20.0 version) software. Correlation was done between complications and period of decanulation.

**Results:** The study was done in 81 patients under gone tracheostomy. Maximum number of patients had age between 61-80 years. Males were more number than females. Portex type of tube used in maximum patients. 70 patients underwent elective and 11 underwent emergency tracheostomy. 74 patients underwent surgery in operation theatre and 5 in an ICU. Prolonged ventilation is the major indication for tracheostomy. Out of 81 patients 55 did not show any complications. 9 patients developed granulations. Significant correlation was observed between complications with period of decanulation.

**Conclusions:** Postoperative care, regular follow up and proper nursing home care is essential for the patients who require prolonged tracheostomy and also to prevent complications with speedy recovery.

**Keywords:** Decanulation, Haemmorhage, Intubation, Trachoestomy, Postoperative care, Ventilation

## **INTRODUCTION**

Tracheostomy is an operative procedure that creates a surgical airway in the cervical trachea. It is most often performed in patients who have had difficulty weaning off a ventilator, followed by those who have suffered trauma or a catastrophic neurologic insult. Tracheostomy is a utilitarian surgical procedure of access; therefore, it should be discussed in light of the problem it addresses: access to the tracheobronchial tree. The trachea is a conduit between the upper airway and the lungs that delivers moist warm air and expels exhaled air and sputum. Failure or blockage at any point along that

conduit can be most readily corrected with the provision of access for mechanical ventilators and suction equipment. In the case of upper airway obstruction, tracheostomy provides a path of low resistance for air exchange. It is one of the earliest surgical procedures. The procedure consists of making an opening in the anterior wall of trachea and converting it into a stoma on the skin surface. Sir Chevalier Jackson's work in Philadelphia helped to standardize techniques for performing tracheotomy and establish protocols for the care of these patients. Even though there are other different techniques available to address airway obstruction, it still remains a time tested lifesaving

procedure. Now the most common indication for tracheostomy is prolonged mechanical ventilation and it is also used as the most definitive management of upper airway obstruction.<sup>4,5</sup> Mortality rate from procedure complications is approximately 0.60%. related Complications have been reported to be higher in patients with upper airway infections, obesity, cerebrovascular accident and congestive cardiac failure. Mortality was also higher in patients with cardiac conditions (>25.0%) than in patients with trauma (6.0% to 11.50%) or pulmonary infection (5.70%).<sup>6</sup> Otolaryngologists are continuously developing and refining the surgical techniques of tracheostomy so that there is significant reduction in the number of complications and death following tracheostomy. Tracheostomy is possibly the commonest emergency procedures done in the department of otorhinolaryngology and it is currently one of the most commonly performed operations in the critically ill patients.<sup>7,8</sup> The use of multidisciplinary teams and protocols for tracheostomy can result in earlier decannulation and generally improve the quality of life of tracheostomised patients. By anticipating the various complications and performing early interventions the morbidity and mortality following tracheostomy can be reduced. The timing of tracheostomy is very important. If the tracheostomy can be performed before severe anoxia and irreversible lung damage have set in, it greatly simplifies the post-operative care and helps to reduce the forthcoming complications: in fact, the best time to do tracheostomy is when the attending physician first thinks about it in a particular case (Moser's dictum). Elective tracheostomy is much more favourable than waiting for the situation to become emergency. Tracheostomy being a commonly performed procedure in a tertiary care centre, it is worthy to study in detail about the procedure and its outcomes. The indications, ideal timings and selection of critically ill patients for tracheostomy have been topics of considerable debate. The Council on Critical Care of the American College of Chest Physicians recommends to perform tracheostomy in patients who are expected to require mechanical ventilation for longer than 7 days. The final decision of timing is made on an individual basis based on comorbidities and the patient's current condition. The present study aimed to evaluate the outcomes of tracheostomy in patients admitted in tertiary care hospital in South India.

## **METHODS**

#### Study design

This was a randomized prospective observational study.

#### Study settings

The study was conducted in the Department of ENT, KIMS Health, Trivandrum, Kerala.

#### Study period

The study was done for a duration from November 2020-June 2021.

#### Inclusion criteria

Patients of both genders; and those who underwent tracheostomy were included.

#### Exclusion criteria

Those who were not willing to sign informed consent form; and those with genetic disorders were excluded.

#### Procedure

The study was initiated after obtaining Institutional Human Ethical Committee clearance. tracheostomised patients admitted in various deparements of KIMS Health, Trivandrum and willing to sign on informed consent were included in the study. The history of patient was taken in detail and all patients were subjected to routine physical and ENT examinations and relevant investigations and endoscopic examination of larynx. Details of procedure like surgical steps, the intraoperative and postoperative parameters were collected from hospital records. Parameters included primary bleeding, prolonged surgery, post-operative infection, bleeding or any other complications. As per the hospital protocols patients and bystanders were explained in detail about the expected outcomes. They were encouraged to clarify their doubts regarding the procedure and post procedure care and taught about the need for a capable bystander to assist the patient in her/his daily activity till the patient becomes acclimatized to tracheostomy tube. Frequent review of patient was done till discharge from hospital or till decannulation to observe for remote complications as well as to document outcomes like improvement in GCS, weaning from ventilator, duration of first tube change, duration for decannulation. Follow up was done after 1 week and 1 month for patients discharged with tracheostomy tube in situ. Collected data was entered into the structured proforma and analysed as per the appropriate statistical methods. The primary outcomes of the study were most common complication and period of decannulation and the secondary outcome was common indication for tracheostomy.

#### Statistical analysis

The data was expressed in number and percentage. Statistical Package for Social Sciences (20.0) version used for analysis. Descriptive statistics are used to summarize the distributions and were examined using histograms. A p value less than 0.05 was considered statistically significant.

#### **RESULTS**

The study was conducted in 81 patients. Maximum number of patients (n=30) had age between 61-80 years followed by 27 had 41-60 years. 1 was aged above 80 years and 4 were less than 20 years old. In this study 58 are males and 23 females (Table 1). Portex type of tracheostomy tube is used in 78 patients and Bivona in 3 patients. Elective tracheostomy was done in 70 patients. Most of the patients (n=74) underwent tracheostomy in operation theatre and 5 in ICU (Table 2). 58 patients had less than 7 days and 23 had more than 7 days between intubation and tracheostomy (Figure 1). Prolonged ventilation is the indication for tracheostomy in 44 patients. Other indications are surgical access (8.64%), failed extubation (11.10%), spinal surgery (1.20%), impending airway obstruction (13.60%), protection of airway (9.90%) and laryngectomy (1.20%) (Table 3). 52 patients had less than 5 days and 29 had more than 5 days for weaning period from ventilator (Figure 2). Maximum number of patients (n=55) did not show any complications. Granulation was developed in 9 patients, 5 had delayed haemorrhage, 5 showed peristomal widening, 5 had intra operative haemorrhage and 4 showed peristomal infection (Table 4). More number of patients (n=40) had less than 2 weeks of decannulation and 26 had more than 2 weeks. In 15 patients decanulation was not yet done (Figure 3). In this study significant (p<0.0001) correlation was observed between complications with period of decanulation (Table 5).

Table 1: Distribution of patients based on demographic data.

Demographic data	Number (n=81)	Percentage		
Age (years)				
<20	4	4.90		
21-40	19	23.50		
41-60	27	33.30		
61-80	30	37.00		
>80	1	1.20		
Gender		-		
Male	58	71.60		
Female	23	28.40		

Table 2: Distribution of patients based on clinical observations.

Clinical observations	Number (n=81)	Percentage				
Type of tracheostomy tube						
Portex	78	96.30 3.70				
Bivona	3	3.70				
Type of tracheostomy						
Elective	70	86.40				
Emergency	11	13.60				
Site of tracheostomy						
Operation theatre	74	91.40				
ICU	5	6.20				
Other hospital	2	2.50				

Table 3: Distribution of patients based on the indications for tracheostomy.

Indications for tracheostomy	Number	r Percentage		
Surgical access	7	8.64		
Failed extubation	9	11.10		
Spinal surgery	1	1.20		
Impending airway	11	13.60		
Prolonged ventilation	44	54.30		
Protection of airway	8	9.90		
Laryngectomy	1	1.20		

Table 4: Distribution of patients based on the complications.

Complications	Number	Percentage		
No complication	55	67.90		
Delayed haemorrhage	5	6.20		
Granulation	9	11.10		
Peristomal widening	3	3.70		
Intraop haemorrhage	5	6.20		
Peristomal infection	4	4.90		

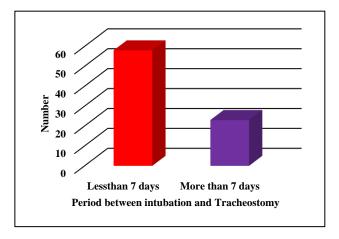


Figure 1: Distribution of patients based on the period between intubation and tracheostomy.

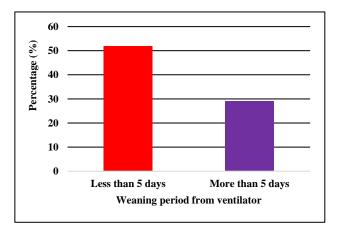


Figure 2: Distribution of patients based on weaning period from ventilator.

Complications	Period	Period of decanulation							
	Lees than equal to 14 days		More than 14 days		Not done		Total		P value
	N	%	N	%	N	%	N	%	
No complications	35	87.50	15	57.70	5	33.30	55	67.90	
Delayed haemorrhage	0	0.00	4	15.40	1	6.70	5	6.20	
Granulation	2	5.00	5	19.20	2	13.30	9	11.10	0.0001
Peristomal widening	0	0.00	2	7.70	1	6.70	3	3.70	_
Intraop haemmorhage	1	2.50	0	0.00	4	26.70	5	6.20	
Peristomal infection	2	5.00	0	0.00	2	13.30	4	4.90	_

**Table 5: Correlation of decannulation period with complications.** 

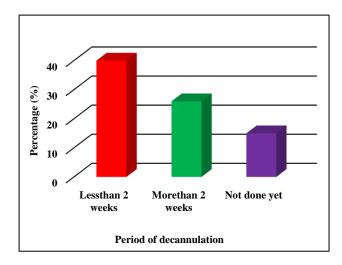


Figure 3: Distribution of patients based on period of decannulation.

## **DISCUSSION**

Total 81 patients who had undergone tracheostomy in this tertiary care centre, 58 patients were male (72%) and 23 patients were females (29%). This was in accordance with the similar study conducted by Kawale et al. The most common age group for tracheostomy found was 40-80 years of age i.e., 57 cases (70.3%), but only 4 (4.9%) patients belonged to younger age group (0-20 years) and only 1 patient (1.2%) belonged to older age groups (more than 80 years). Age of the patient ranged from 1 year to 84 years. Here the age group range had increased by a decade compared to Kawale et al study. This could be because of the advancement and improvement in the management of critically ill patients compared to previous era, in which young age group shows more response and speedy recovery. The most common indication for tracheostomy in this study was prolonged ventilation (54.0%), secondary to traumatic brain injury and acute stroke, which was in agreement with the study conducted by Goldenberg et al who had reported the commonest indication of tracheostomy as prolonged mechanical ventilation.<sup>5</sup> The second most common indication was impending airway (13.0%) mostly due to malignancy of upper aero digestive tract followed by failed extubation (11.0%). Other indications for tracheostomy observed were for protection of airway, as a part of maxillofacial as well as other oncological surgeries. Other studies reported upper airway obstruction due to malignancy or trauma as the most common indications of tracheostomy followed by prolonged ventilation. These variations between studies might be due to different patient population and also due to changing trends of indication. Among the 81 patients, 70 subjects (86.4%) underwent elective tracheostomy and remaining 11 patients underwent emergency tracheostomy. The prevalence of emergency and elective tracheostomy was in accordance with the study conducted by Kawale et al.9

The need for emergency tracheostomy had come down drastically over the last few decades. Now days, it's very rare to be presented with an airway emergency, in whom endotracheal intubation was not at all possible, except in some cases of severe trauma with faciomaxillary injuries in cases with advanced aerodigestive tract malignancies. 74 subjects (91.4%) had undergone tracheostomy in an operation theatre, while 5 patients had undergone the procedure in ICU.<sup>10-13</sup> In former group, due to ease of attaining adequate position, proper visualization and procedure was possible. All adult tracheostomies used cuffed Portex tracheostomy tube while paediatric tracheostomies used Bivona tubes. 64.2% among the group presented with an already done procedure from other hospital. The procedure done in a well-equipped operation theatre was found to be associated with less complication and patients could be effectively weaned off from ventilator within 5 days of tracheostomy while the rest took more than 5 days. 14 The weaning period ranged from 0 days to 21 days with a mean duration of 5 days. Among the 81 study subjects, 66 patients (81.5%) were successfully decannulated within the study period. 15-18 40 patients among those 66 could be decannulated within 14 days of tracheostomy. 15 subjects could not be decannulated within the study period due to various reasons such as general condition of the patient, worsening of primary pathology. 67.9% of the study subjects didn't have any intraoperative or postoperative complication.<sup>19</sup> The incidence of complications was almost in accordance with the study conducted by Gilyoma et al during 2011.20 Presence of granulation at the tracheostomy site was the most commonly observed complication which comes around 11.1% (n=9). It was mostly seen in patients who were on tracheostomy tube for more than 14 days (n=5). Delayed haemorrhage was seen in 5 patients, of which all of them were on tracheostomy for more than 2 weeks. 5 subjects also had intraoperative haemorrhage which was managed effectively on table. Other minor complications include peristomal widening and peristomal infection. Early diagnosis of complications and initiation of treatment can prevent the mortality rate in patients who underwent tracheostomy.

#### Limitations of the study

There were some limitations in the study performed. Some patients lost follow up. Intraoperative complications of patients who underwent tracheostomy from outside hospital could not be assessed.

#### **CONCLUSION**

Adequate postoperative care and daily regular follow up on immediate post-operative days could easily pick up early tracheostomy complications and thus can be managed effectively. Proper nursing care by care giver at home and frequent follow up is essential for the patients who require prolonged tracheostomy.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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