

# **A RETROSPECTIVE OBSERVATIONAL CASE STUDY TO ASSESS THE SAFETY AND FEASIBILITY OF PERCUTANEOUS DILATATIONAL TRACHEOSTOMY PERFORMED BY TRAINEES.**

## **ABSTRACT**

Percutaneous dilatational tracheostomy is a procedure commonly performed in patients requiring prolonged ventilatory care in intensive care unit. In this procedure, a tracheal tube is inserted in the anterior tracheal wall between the second and third tracheal rings using seldinger's approach. There have been many studies that proved the efficiency and associated complications of PDT, but not many have compared the safety and feasibility of PDT performed by trainees and intensivist. The aim of this study is to assess the safety and feasibility of PDT by trainees. The primary objective is to compare the duration of performing PDT by trainees and intensivists and complications associated with it. This is a retrospective observational study done on patients who underwent PDT between January 2020 till June 2020 in our institute. The data collected retrospectively were categorized into two groups. One group consisted of PDT done by trainees and the other group where PDT was performed by intensivists. On analysis, the results showed a significant difference, in the duration of performing PDT between trainees and intensivist, with  $p = 0.001$ . However, there weren't any differences in other study parameters like demographics and complication rate. It is thus, concluded that PDT performed by trainees although, a little time consuming than those performed by intensivists, was evaluated to be safe and feasible without any complications.

## **INTRODUCTION**

Percutaneous dilatational tracheostomy is a credible procedure performed in critically ill patients requiring prolonged ventilatory care and is currently becoming popular. Many studies support the efficacy, safety and cost effectiveness of this procedure [1]. This technique involves placement of a tracheal tube in the anterior tracheal wall between the second and third tracheal rings. With the help of seldinger and serial dilator approach, the airway is secured precisely using a tracheal tube. It has now been recognized as an effective and safe alternative to surgical tracheostomy in patients (2,3,4). Although multiple studies scrutinized the effectiveness of PDT, there is limited data on analysing the safety and feasibility of PDT performed by trainees. Therefore, this study is aimed at studying the safety and feasibility of PDTs done by trainees who were in final year anaesthesiology training program and compared it to those done by intensivists.

**AIM:**

To assess the safety and feasibility of percutaneous dilatational tracheostomy done by anaesthesiology trainees during critical care rotation, in terms of duration and complications developed during the procedure, when compared to intensivists led procedures.

#### OBJECTIVES :

Primary objective is to compare Percutaneous dilatational tracheostomy performed by trainees and intensivists with respect to:

- 1.) Time taken (duration) to perform PDT.
- 2.) Complications including bleeding, desaturation, etc associated with the procedure.

#### MATERIALS AND METHODS:

This is a Retrospective, observational, cross-sectional, non-randomized, non-blinded and open study conducted on all patients on whom PDT was performed between January 2020 to June 2020 in our institute. Over the study period, all patients who underwent PDT in ICU were retrospectively analysed and registered. These patients were then categorized into two groups on the basis of performer. Group 1 includes PDT performed by trainees and Group 2 consisted of PDT done by intensivists. These two groups were then compared with respect to different study parameters like demographics, duration and complications. The following information was collected on each registered patient: Name, age, sex, height, weight, BMI, diagnosis, days on endotracheal tube, reason for tracheostomy, duration of the procedure and complications developed during the procedure.

The procedure time was defined as time from incision to insertion of tracheostomy tube.

Bleeding was classified as minor and major. Minor bleeding is defined as one from the incision site requiring frequent dressing and major bleeding as one that requires blood transfusion or surgical assistance.

False passage, cuff perforation and accidental extubation were all procedure related complications.

Hypoxemia was referred to an episode of pulse oximetry reading less than 90% during procedure.

Pneumothorax, pneumomediastinum, subcutaneous emphysema were confirmed when the chest Xray taken after 6hours showed evidence of relevant pathology.

#### PROCEDURE:

In this study, all PDTs were performed in the same manner. As described by Ciaglia et al[2], all patients were kept in supine position with hyperextension of the neck. Local anaesthesia was administered with 2% lignocaine and sedation and analgesia was used as needed. All patients were mechanically ventilated with 100% oxygen during the procedure. A 1-1.5cm vertical incision was made at the inferior edge of cricoid cartilage. The pretracheal soft tissue was bluntly dissected using a mosquito clamp and trachea is then punctured with a 14G needle and guidewire inserted. A guide sheath is then placed to prevent wire bending and trachea was serially dilated using appropriate sized dilators and tracheostomy tube was then passed over a dilator into the trachea. In all these cases Cooks percutaneous tracheostomy set was used.

In this study, two intensivists have been performing the procedure since 1998 in our hospital. The trainees who performed the procedures were first required to assist in two or more procedures and then perform two or more procedures under their supervision before undertaking the procedures by themselves.

#### STATISTICS:

Sample size for our analysis was calculated using a reference article. Based on the study, "Safety and feasibility of Percutaneous Dilatational Tracheostomy performed by Intensive Care Trainees" by Daesang Lee et al[3], the sample size for our evaluation was measured.

#### SAMPLE SIZE:

A power analysis indicated that a sample size group1&2(35 +35 = 70) was sufficient to detect a significant statistical difference with  $\alpha = 0.05$  and power  $1-\beta = 0.8$ . (Using a software- epiInfo). We, therefore chose 100 patients for both group.

#### Sample size calculation

Proportion 1	68
Proportion 2	32
Confidence level	95
Power	80
Ratio of sample sizes (n2/n1)	1
Tails	2

### Sample size required

	Sample size
Sample size 1 (n1):	35
Sample size 2 (n2):	35
Total sample size (both groups):	70

### STATISTICAL ANALYSIS

Statistical Analysis was done by using SPSS Version 26. All values were expressed as mean (SD) for continuous variables and number (percentages) for discrete variables. Chi- square test and fisher's exact test will be used to find out association between the categorical variables. Independent 't'-test will be used to find the significance difference between groups.  $P < 0.05$  will be considered as statistically significant.

### RESULTS :

Table-1 AGE DISTRIBUTION

PERFORMER		MEAN	SD	P-VALUE
AGE	INTENSIVIST	47.85	16.195	0.220 NS
	TRAINEE	43.87	15.298	

Fig 1

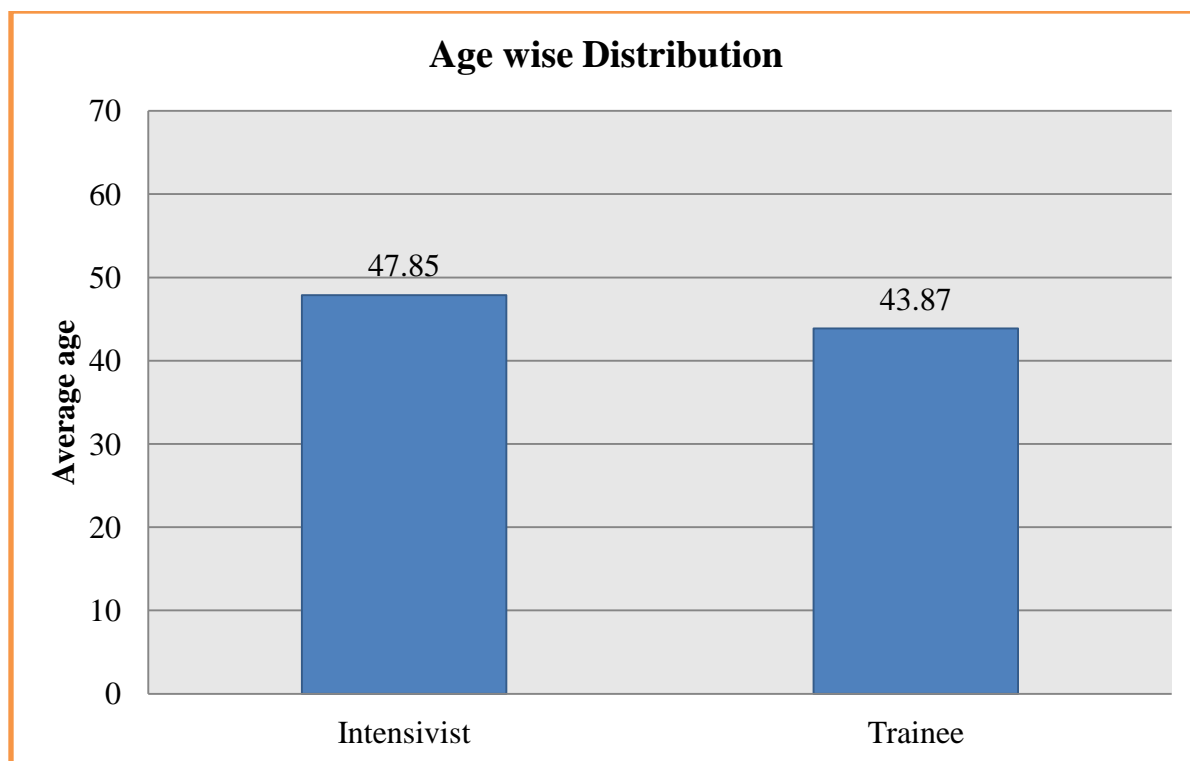


Table-2 GENDER DISTRIBUTION

VARIABLE		PERFORMER		P-VALUE
		INTENSIVIST	TRAINEE	
SEX	MALE	31	50	0.628 NS
		79.5%	83.3%	
	FEMALE	8	10	
		20.5%	16.7%	

Fig - 2

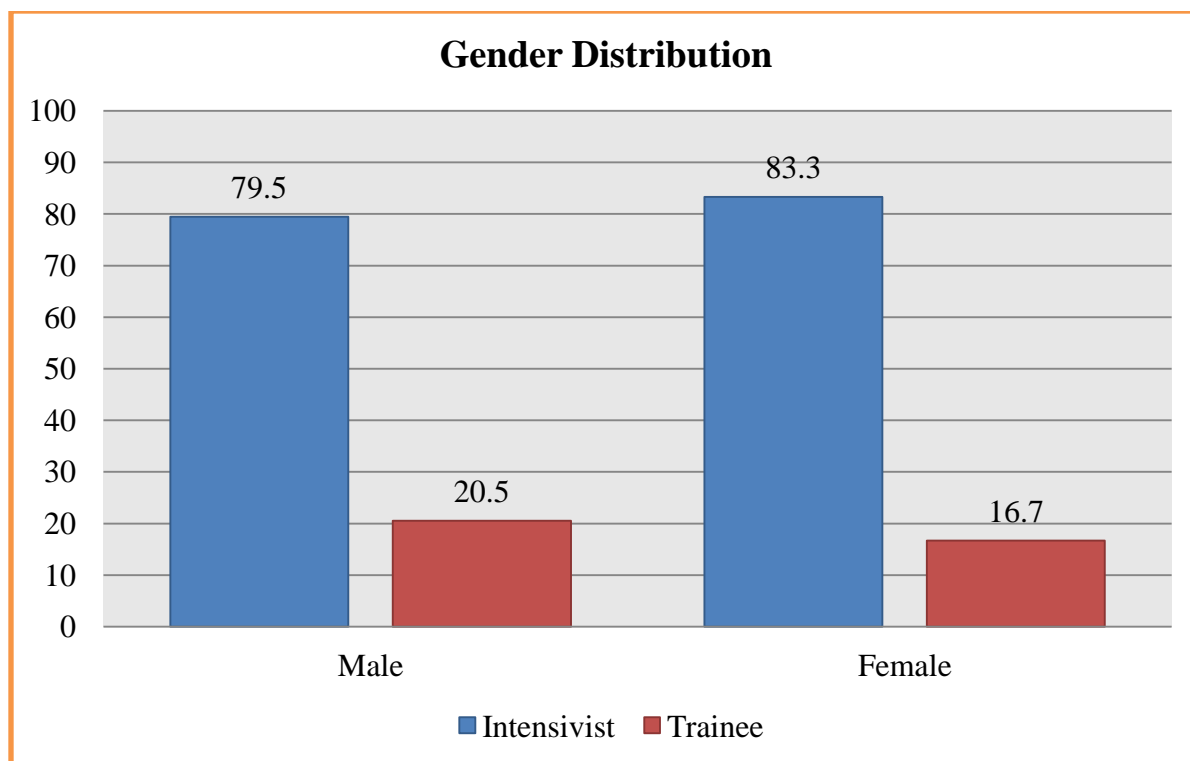


Table-3

VARIABLE	VALUES IN		‘P’ VALUE
	TRAINEES	INTENSIVIST	
HEIGHT (CMS)	165.0 $\pm$ 7.0	165.6 $\pm$ 7.3	0.75 NS
WEIGHT (KGS)	70.9 $\pm$ 10.0	72.8 $\pm$ 9.4	0.427 NS
BODY MASS INDEX	26.0 $\pm$ 3.1	26.6 $\pm$ 3.4	0.471 NS

Fig-3

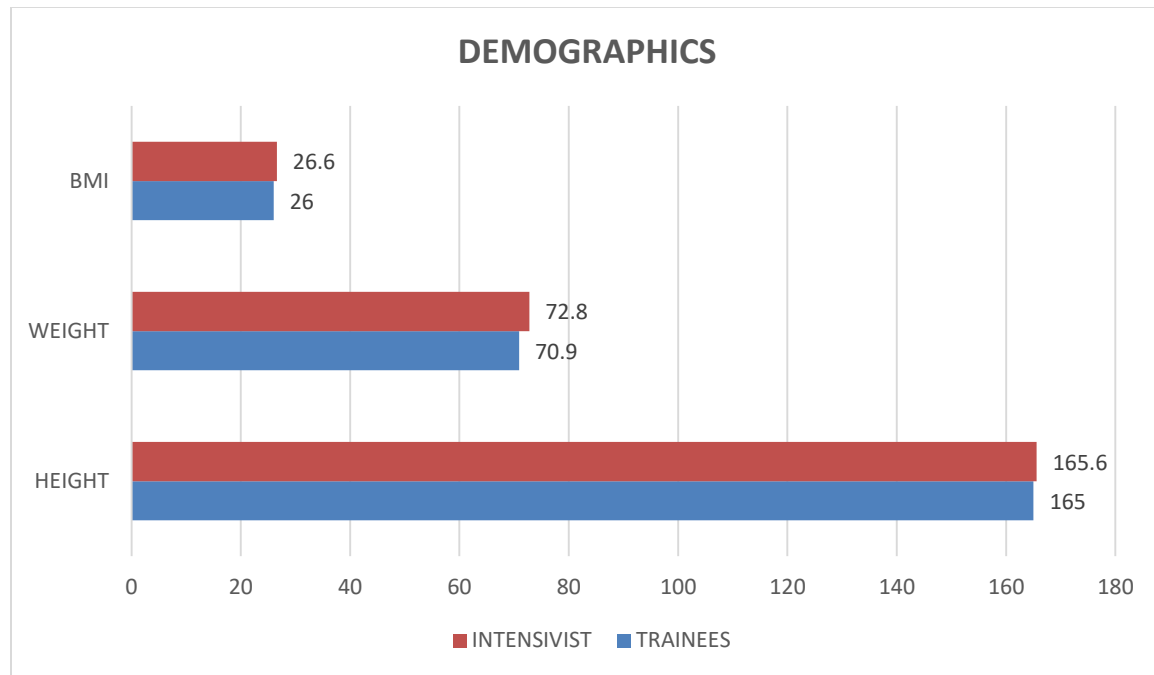


Table-4

PERFORMER		MEAN	SD	P-VALUE
DAYS ON ETT	INTENSIVIST	8.72	5.140	0.352 NS
	TRAINEE	9.73	5.361	
DURATION	INTENSIVIST	10.92	5.896	<b>0.001 SIG</b>
	TRAINEE	19.47	7.886	

Fig-4

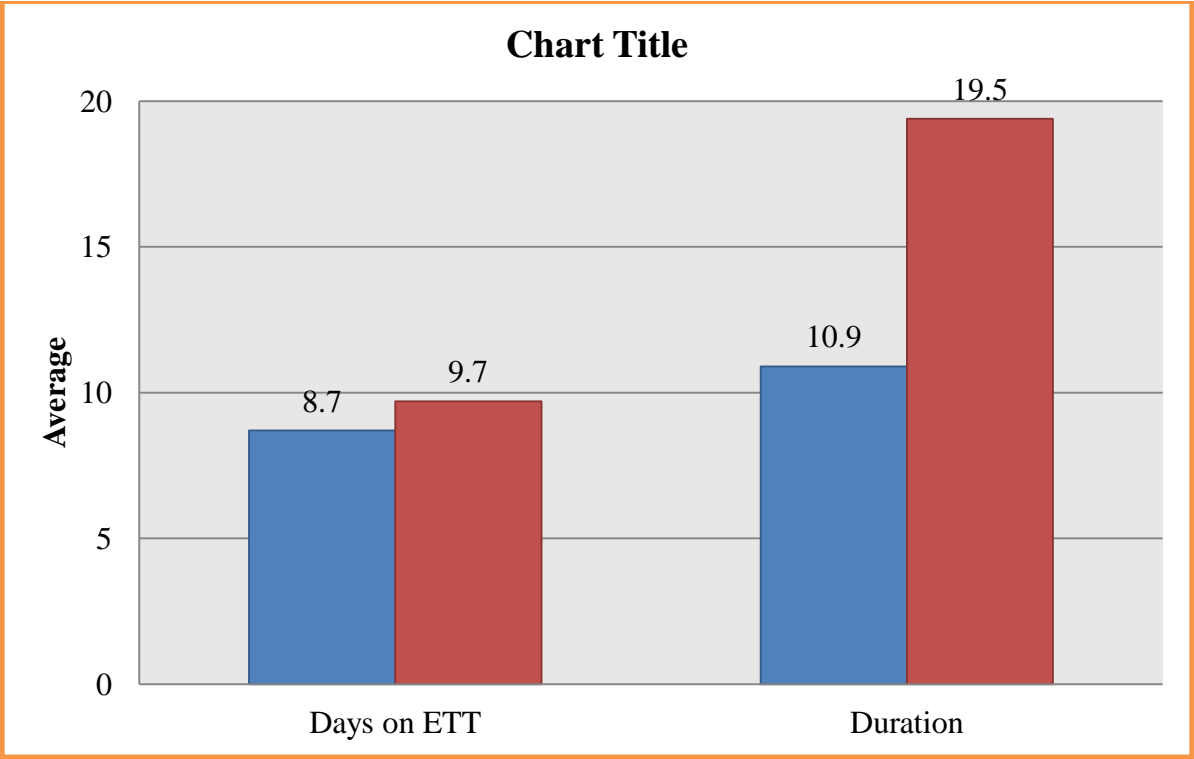


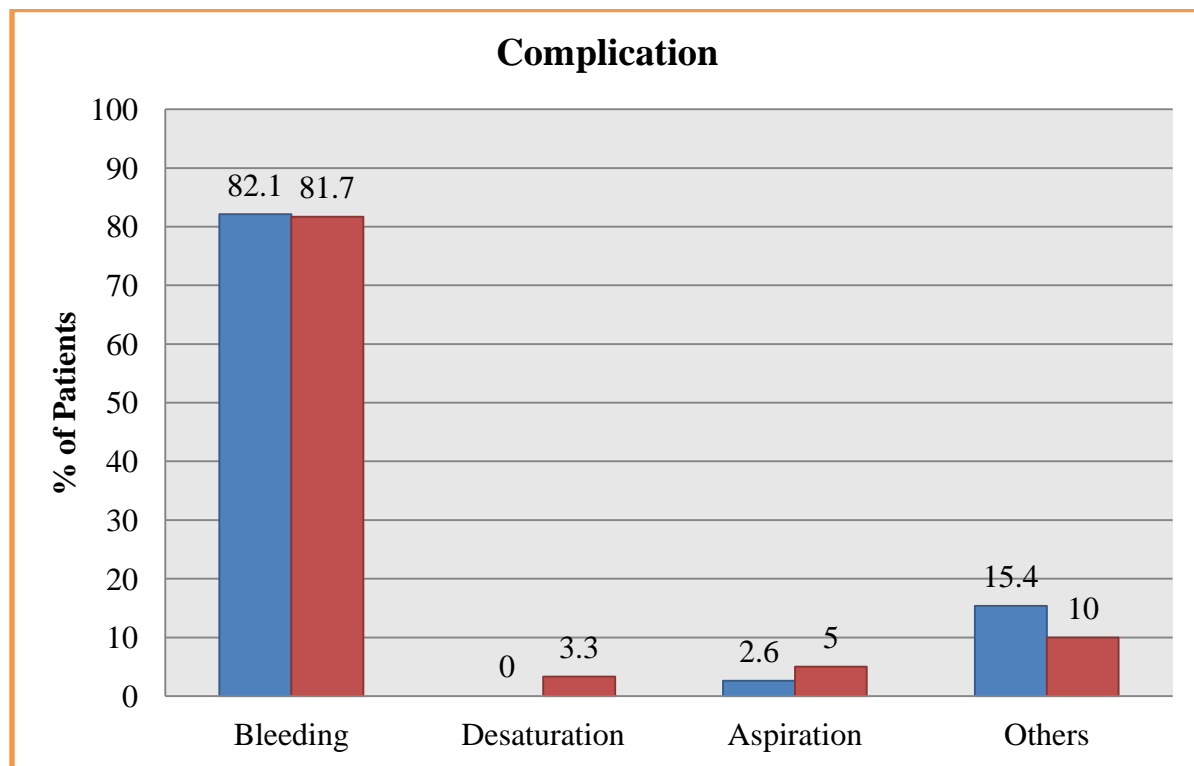
Table-5

VARIABLE		PERFORMER		P-VALUE
		INTENSIVIST	TRAINEE	
COMPLICATIONS	BLEEDING	32	49	0.529 NS
		82.1%	81.7%	
	DESATURATION	0	2	
		0.0%	3.3%	



	ASPIRATION	1	3	
		2.6%	5.0%	
	OTHERS	6	6	
		15.4%	10.0%	

Fig-5



In our study period of six months, 99 patients underwent percutaneous dilatational tracheostomy in our ICU. 60(60.1%) by Trainees and 39(39.4%) by Intensivists. There were no statistically significant differences in clinical characteristics including demographics (Age, sex, height, weight) and days on endotracheal tube. The body mass index is considered to be an important criteria while performing percutaneous tracheostomy, as obese patients with short neck will pose a threat to the procedure and are considered to have comparatively more complications than those with normal BMI. But in our retrospective analysis, we were not able to identify any significant difference in complication rate among overweight population within the study group and also, there were comparable results between the trainee group and the intensivist group with

respect to the BMI of the patients in the study. The p value with respect to the height, weight and BMI of the study group were more than 0.05 and concluded to have insignificant differences between the two groups in the study.

The mean duration of the procedure was 19.47 with SD of 7.886 minutes in Trainee led procedures whereas it was 10.92 with SD of 5.896 minutes in intensivist led procedures. The p value is 0.001 which is statistically significant.

Saturation of oxygen were monitored in patients throughout the procedure and there were no significant drop in saturation in either groups. Only 3.3% of patients in the trainee led group desaturated during the procedure and hence the final results were comparable and insignificant with  $p=0.529$ . The majority of the complication which developed during the procedure was bleeding which was only minor (50% in each group) and it is statistically insignificant and comparable between the two groups.

## DISCUSSION:

The purpose of this study was to evaluate safety and feasibility of PDT performed by trainees by comparing clinical outcomes and complications between trainee-led PDT and intensivist-led PDT. PDT had been compared to conventional surgical technique in many previous studies and proved to be better, quicker and safer [6,7,8].

There were no significant results on comparing the demographic data between the two groups in our study. The factors including age, gender and weight of the patients did not have significant differences in complication and duration between our study groups. However, it is proved in studies that  $BMI > 27.5$ , and obese patients carried a 4.9 fold increased risk of complications during tracheostomy (9,10). Also, in few other studies (10,11), obesity was proved to be an independent risk factor for tracheostomy related complications with odds ratio of 4.4.

On the other hand, certain studies showed the safety of PDT in obese patients without higher complication rate (12,13). A retrospective study on 143 patients with  $BMI > 35$  showed no significant difference in complication rates including malpositioning of tracheostomy tube, loss of airway, or bleeding.

Oxygen saturation was monitored throughout the procedure in all the patients in both groups and it was identified that there were no notable drop in oxygen saturation from the beginning to the end of procedure. On evaluation of data, the mean drop in oxygen saturation between the two groups was calculated to be statistically insignificant and they were comparable at all study

points throughout the procedure. These results are similar to a reference study (14), which analysed the immediate and late outcomes of tracheostomy and concluded that there were no hypoxic episodes indicating desaturation during the procedure.

However, we had identified a significant difference in duration of performing the procedure between trainees and intensivists with a p value of 0.001. The average time taken by a trainee in our study for performing the procedure was around 19.466 min with SD of 7.886 and that of an intensivist was around 10.92 min with SD of 5.896. These values are similar to a previous study(20), where the average time taken for performing a PDT was around 12 to 18 min. This goes in par with our analysis with regards to the mean time taken to perform PDT. Still, in some studies [ 5,15] although the mean procedure time were similar to our study, the comparison of duration of performing PDT between trainees led group and intensivists led group were insignificant and were analogous. This could be due to the fact that the study included trainees who were subspecializing in intensive care and they could have more years of experience and practice compared to final year trainees specializing in anesthesia who were considered as a part of our study.

There were no significant procedure related complications in both the groups. Most frequent complication identified in both groups was minor bleeding and its was comparable between them. These were fairly similar with the results of previous studies [16,17,18]. In another study which compared the PDT with and without bronchoscopy also concluded that there were no complications in either groups and tracheostomy even without aid of bronchoscopy proved to be safe (19,20). Percutaneous tracheostomy can be safely performed at the bedside in patients with a prolonged need for mechanical ventilation (21).

## CONCLUSION:

From this study, it is concluded that percutaneous dilatational tracheostomy performed by trainees is safe and feasible. Use of bronchoscopy or ultrasound, appropriate sized tracheostomy tube, proper timing of the procedure and appropriate post tracheostomy care could further enhance its safety profile.

## LIMITATIONS:

The study is retrospective in nature and has a small sample size.

Only early complications were analysed and late complications were not taken into account.

Bronchoscopy provides real-time visual guidance during PDT, and in our study it was not used.

No potential conflict of interest reported.

## **Ethical Approval:**

Institutional ethical committee permission was obtained

## **Consent**

As per international standard or university standard, patients' written consent has been collected and preserved by the author(s).

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