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Ultrasound-guided percutaneous dilatational tracheostomy (PDT) versus fiber- optic bronchoscopy-guided (PDT) in critically ill patients.

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Abstract

Percutaneous dilatational tracheostomy (PDT) is routinely performed by bronchoscopy guided technique in the intensive care unit. Recently, ultrasound has become a potentially useful tool for PDT to reduce procedure-related complications. The aim of this study is to evaluate the safety and the efficacy of real time ultrasound guided PDT compared to bronchoscopy-guided PDT in critically ill patients.

Methods: Randomized controlled trial, done from March 2017 to March 2019 .30 patients were eligible;15 were assigned to bronchoscopy guided PDT and the other 15 were assigned to ultrasound (us) guided PDT.

Conclusion: Ultrasound guided PDT can be used to decrease complications during the procedure with comparable results with bronchoscope.

Keywords

Ultrasound, Tracheostomy, Bronchoscopy

Trial registration:"PanAfrican Clinical Trial Registration(PACTR),201801002947288"

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1) Introduction

Tracheostomy has become common in the ICU. Its importance is increasing in patients with prolonged ventilation who require long term airway maintenance. ICU patients are unstable most of times ,so the bedside PDT is suitable for them as it does not necessitate to transfer patients to the operating theatres [1]**.** There are many ways to perform the PDT .First ,the land mark technique ,however it has complications such as bleeding or misdirection .Bronchoscopy guided PDT provides many advantages such as accurate puncture site detection ,better visualization to the guide wire and the successive dilators and suctioning of any secretions have been found [2]**.**Ultrasound become a potentially safe noninvasive useful tool ;it can identify aberrant vessels in the front of the neck to be avoided during the procedure and abnormal anatomical structures [3] to identify the puncture site and to guide the proceeding needle [4]**.**

2. Patients and Methods

2.1. Type and time of study:

Randomized controlled trial was conducted from March 2017 and March 2019.

2.2. Study Settings and data collection tool:

This study was conducted in critical care department, faculty of medicine; Beni-Suef University. Including all patients above 18 years who were intubated for long time(>10 days) and in need for tracheostomy to secure their airways.

Excluded from the study, patients who had abnormal anatomy (i.e., short neck, thyroid gland enlargement, tracheal deviation, cervical anatomical anomaly, previous cervical surgery,). Patients who were unable to perform neck extension (Known to have cervical trauma, cervical tumors, disc prolapse and progressive cervical rheumatoid arthritis), patients who were hemodynamically unstable patients who had bleeding tendency (PC<50% and/or PLT count <80.000), Patients who couldn't be intubated with an ET size >7.5 F. Patients who refused the procedure (or next of kin/guardian).Patients were divided into two groups ; Group (I); in whom ultrasound guided PDT was done. Group (II); in whom fiber -optic bronchoscopy guided PDT was done.

Ultrasound guided PDT technique: Percutaneous tracheostomy technique in the ultrasound guided group was done using Ciaglia Blue Rhino®Percutanous Dilatation Tracheostomy and Edan DUS 60 Digital Ultrasound with the insertion of a suitable sized tracheostomy tube.

Bronchoscopy guided PDT techniques: It was done using Ciaglia Blue Rhino Percutaneous Dilatation Tracheostomy, by the help of the flexible fiberoptic bronchoscope (Olympus BF type 1 T40).

2.3. Statistical analysis:

Data was summarized by descriptive statistics using mean, standard deviation, median, minimum, and maximum in quantitative data and using frequency (count) and relative frequency (percentage) for categorical data. Mean values and standard deviation were compared using simple t-test (for two variables). For comparing categorical data, Chi square test was performed. Correlation between quantitative variables were done using spearman correlation coefficient. Data were coded and entered using the statistical package SPSS (statistical package for social sciences) version 25.A P-value <0.05 was considered statistically significant

2.4. Ethical Considerations and Review:

Study protocol was approved by Faculty of Medicine, Beni-Suef University, Research Ethics Committee. FWA (federal wide assurance): FWA00015574.

3) Results

Table (1): patient's characteristics

	Bronchoscopy guided PDT (N=15)	Ultrasound guided PDT (N=15)
Male:N(%) Female:N(%)	6(40%) 9(60%)	 11(73.3%) 4(26.7%)
Age in years (mean±SD)	56.87 ±20.90	59.33 ±20.33
Main causes of ICU admission (%): Non hemorrhagic stroke Hemorrhagic stroke Respiratory failure Brain tumor Others	 7(46.7%) ——— 4(26.7%) 2(13.3%) 2(13.3%)	 6(40.0%) 4(26.7%) 2(13.3%) 2(13.3%) 1(6.7%)
APACHE II on admission(mean±SD)	15.20 ±9.60	18.33 ±9.10
Days before tracheostomy from day of admission (mean±SD)	16.27 ±11.14	17.87 ±6.51
Ventilator days before tracheostomy	14.87 ±9.89	16.47 ±6.89

3.1. Study patients :Between March 2017 and March 2019, a total of 30 patient were assessed to be eligible for the study .15 patients were randomly assigned for real time ultrasound guided PDT

and another 15 patients were assigned for bronchoscopy guided PDT. Baseline characteristics were well balanced between the study groups.

3.2 Procedure

In bronchoscopy group, the mean procedure time was 35.27 ±26.69 min while in the US group was 29.53 ±11.60 min, with no statistically significant difference between both groups with a p=0.45. In the bronchoscopy guided group, patients who had one needle attempt were 53.3% while others who had more than one attempt were 46.7%. In the ultrasound guided group, patients who had one needle attempt were 26.7% while others who had more than one attempt were 73.3% (p= 0.14). In the bronchoscopy guided patients who had median needle insertion were 66.7% while others who had paramedian insertion were 33.3% while in US guided group were patients who had median needle insertion were 53.3% while others who had paramedian insertion were 46.7% (p=0.46)

4.Outcome

Table(2):outcome measures

	Bronchoscopy guided PDT (N=15)	Ultrasound guided PDT (N=15)	P value
procedure time:min(mean±SD)	35.27 ±26.69	29.53 ±11.60	0.45
Site of entry: Median:N(%) Paramedian:N(%)	 10(66.7%) 5(33.3%)	 8(53.3%) 7(46.7%)	 0.46
Number of puncture attempts: One attempt: More than one attempt	 8(53.3%) 7(46.7%)	 4(26.7%) 11(73.3%)	0.14
Complications during the procedure: Hypoxia:N(%) Minor bleeding stopped by compression: N (%) Mal directed wire led to difficult wire extraction: N (%) Pneumothorax: N (%) Orotracheal cuff rupture: N (%) Difficult dilatation: N (%)	 10(66.7%) 12(80%) ——— ——— ——— ———	 3(20%) 5(33.3%) 1(6.7%) 1(6.7%) 1(6.7%) 1(6.7%)	 0.010* 0.010* 0.30 0.30 0.30 0.30
Ventilator days after tracheostomy (mean±SD)	20.80 ±25.84	14.67 ±10.81	0.40

Length of ICU stay after the procedure in days (Mean ±SD)	21.43±14.06	15±6.12	0.5
Final hospital outcome Survivors:N(%) Non survivors:N(%)	 2(13.3%) 13(86.7%)	 3(20.0%) 12(80.0%)	 0.62

4.1. Primary outcomes

In the bronchoscopy guided group, patients suffered from hypoxia during the procedure were 10 (66.7%), patients who had minor bleeding stopped by compression were 12(80%). In the ultrasound guided group, patients suffered hypoxia were 20%, patients had difficult dilatation were 6.7%, patients had difficult wire extraction were 6.7%, patients had cuff rupture by needle were 6.7% and patients had pneumothorax were 6.7%. There was highly statistically significant difference between both groups as regarding minor bleeding and hypoxia as a complication during the procedure with a p-value 0.010 for both (more in the bronchoscopy guided group) while other complications had no statistically significant difference between both groups.

Mean ventilator days after the procedure was 20.80 ±25.84 days in bronchoscopy guided group while in the US guided group was 14.67 ±10.81 days (p=0.40).

Length of ICU stay was 37.73 (±25.20) days in bronchoscopy group, while in US group was 32.87 ±12.63 days (p=0.40)

4.2. Secondary outcomes

In the bronchoscopy guided group, survivors were 2 patients (13.3%), while non survivors were13 patients (86.7%). In the ultrasound guided group, survivors were 3 patients (20%) while non survivors were 12 patients (80%) (p=0.62).

5.Discussion

In this study ,changing site of insertion (other than median) was higher in the ultrasound guided group than in the bronchoscopy guided group (46.7% versus 33.3% respectively) but there was no statistical significance (p=0.46).These findings was in agreement with , V. Rajajee**,**et al who included obese patients with previous tracheostomy and had spinal injury ,changing site of the puncture was due to presence of midline pre tracheal veins presumed to be inferior thyroid veins[5] .

Moreover; E. Kollig, et al had similar findings in 17 patients (23.6%) the place of planned puncture was changed according to prior ultrasound evaluation to avoid complications caused by lesions of subcutaneous vessels[7] . Our study showed faster procedure related to US guided group .Mean time was 29.53 min in the US guided group while 35.27 min in the bronchoscopy guided group but was not significantly different (p=0.45).This was agreed with A. L. N. Gobatto *et al.*, **i**n their randomized non inferiority controlled trial where the median procedure time was 11 in the US guided group while 13 min in the bronchoscopy guided group ,but without statistically significant difference (p=0.468) [8].On the contrary ,there were shorter procedure time in the US guided group when compared to the bronchoscopy guided group with statistically significant difference in the studies done by J. Chacko, et al , (13.9 vs 10.7 min, $p < 0.0001$) [9]**.**

In our study, multiple puncture attempts were more in the US guided group 73.3% than the bronchoscopy guided group 46.7%, however this was not statistically significant (p=0.14). These findings agreed with Albardan Ahmed et al, 2018 who found that there was one puncture in 19 cases (95%) in bronchoscopy guided group, while one puncture in 17 cases (85%) in the US guided group with no statistically significant difference [15].

However, compared to this study, we have more percentage of patient population categorized to be difficult in visualization by US which may impact the statistical findings.

In the current study minor bleeding was 33.3% in the US guided group versus 80% in the bronchoscopy group with a significant P value (p=0.01).This agreed with P.-G. Guinot *et al* who reported no major bleeding and less incidence of minor bleeding after using US prior to percutaneous tracheostomy however patients with platelets count <80.000 or INR >1.2 were excluded in this study which may impact the results[6] .

However our findings disagreed with A. L. N. Gobatto *et al* who reported 4 cases with minor bleeding in the US guided group ,5 cases in the bronchoscopy guided group without statistically significant difference [8].In our study it was found that more procedure related hypoxia was in the bronchoscopy guided group 66.7% while 20% in the US guided group (p=0.010).These findings agreed with P. R. Ravi and M. N. Vijay who studied seventy four consecutive patients who were included in a prospective study and randomly divided into US guided percutaneous tracheostomy and Bronchoscopy guided percutaneous tracheostomy[10]. They noticed that

desaturation for less than 5 min in four patients (11.11%) in the bronchoscopy guided group in comparison to ultrasound guided group which had no incidence of hypoxia ($p < 0.05$) [10]. This disagreed with A. L. N. Gobatto *et al.*, who reported minor hypoxemia in the ultrasound guided group[8] .They justified this due to higher SAPS3 score in the US guided group or less team experience with the new method[8] .In the current study an endotracheal tube cuff puncture happened in one case in the US guided group while no cases were reported in the bronchoscopy guided group, however this was not statistically significant p=0.30.This agreed with A. L. N. Gobatto *et al.*, who reported 3 cases in the US guided group and only 1 case in the bronchoscopy guided group, this was not statistically significant p=0.619 **.**

In the current study, there was only one case of the guide wire maldirection and difficult in extraction in the US guided group (p=0.3) while nil in the bronchoscopy guided group. This was in agreement with J. Chacko who reported guide wire maldirection cranially in US guided case which was seen and corrected by bronchoscope[11] . In this study, only one case was complicated with pneumothorax during US guided PDT (p=0.30) while no such complication were in the bronchoscopy guided group. Albardan Ahmed et al,2018 had similar findings with one case of pneumothorax in the US guided group 5% which was not statistically significant difference between groups [15]. In the contrary, J. Chacko had no pneumothorax in both groups [11].This study showed that there was no significant difference between both groups regarding MV days (p=0.4), mean ventilator days after the procedure (p= 0.40), length of ICU stay (p=0.5) length of hospital stay (p=0.5) or hospital mortality (0.6).This agreed with A. L. N. Gobatto *et al.*, who found no statistically significant difference between both groups regarding MV (p=0.699), Length of ICU stay (p=0.8),length of hospital stay (p=0.27),hospital mortality(p=0.864) [8].

6. Conclusion

Bedside dilatational tracheostomy is a very important procedures in ICU patients for maintaining airway especially in patients with prolonged ventilation. Bronchoscopy has been used to decrease complications during the procedure. Ultrasound has been used recently to improve accuracy and avoid vessel injury during the procedure with comparable results.

8. Study limitations :

Lack of experience of the operator has been incriminated in prolonging time of the procedure. Continuous CO2 measurement during the procedure was necessary to detect transient hypercapnia that can occur during the procedure. Small sample size of the study

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10.No conflict of interests to the manuscript authers .

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