

Tracheostomy in Adult Intensive Care Unit: An ISCCM Expert Panel Practice Recommendations

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ABSTRACT

Background and Aim: Critically ill patients on mechanical ventilation undergo tracheostomy to facilitate weaning. The practice in India may be different from the rest of the world and therefore, in order to understand this, ISCCM conducted a multicentric observational study “Dilatational percutaneous vs Surgical tracheostomy in intensive Care unit: A practice pattern observational multicenter study (DISSECT Study)” followed by an ISCCM Expert Panel committee meeting to formulate Practice recommendations pertinent to Indian ICUs.

Materials and methods: All existing International guidelines on the topic, various randomized controlled trials, meta-analysis, systematic reviews, retrospective studies were taken into account to formulate the guidelines. Wherever Indian data was not available, international data was analysed. A modified Grade system was followed for grading the recommendation.

Results: After analyzing the entire available data, the recommendations were made by the grading system agreed by the Expert Panel. The recommendations took into account the indications and contraindications of tracheostomy; effect of timing of tracheostomy on incidence of ventilator associated pneumonia, ICU length of stay, ventilator free days & Mortality; comparison of surgical and percutaneous dilatational tracheostomy (PDT) in terms of incidence of complications and cost to the patient; Comparison of various techniques of PDT; Use of fiberoptic bronchoscope and ultrasound in PDT; experience of the operator and qualification; certain special conditions like coagulopathy and morbid obesity.

Conclusion: This document presents the first Indian recommendations on tracheostomy in adult critically ill patients based on the practices of the country. These guidelines are expected to improve the safety and extend the indications of tracheostomy in critically ill patients.

Keywords: Coagulopathy, Obesity, Percutaneous dilatational, Recommendations, Tracheostomy, Ultrasound.

Indian Journal of Critical Care Medicine (2020); 10.5005/jp-journals-10071-G23184

INTRODUCTION

Although tracheostomy is one of the most commonly performed procedure in Intensive care unit (ICU),¹ it is also one of the most diverse with respect to the choice of technique (surgical vs percutaneous). Similarly, there are lot of controversies regarding the indications, contraindications and timing of tracheostomy and these add to the complexity of decision making when faced with a mechanically ventilated patients requiring tracheostomy.²

The purpose of this document is to produce practice based recommendations which are relevant in the Indian ICUs based on the available scientific evidence from within the country and also from international literature. The compilation of the recommendation was done at the consensus meeting of a group of expert intensivists from across the country and also based on the information obtained from the multicentric observational study: DISSECT study³ (Dilatational percutaneous vs Surgical tracheostomy in intensive Care unit: A Practice Pattern Observational Multicenter Study). The recommendations of this document are applicable only to individuals who are above 18 years of age.

DEFINITIONS

Tracheostomy means creating an opening in the trachea for the passage of the tube through which patients can be ventilated or the patient can breathe spontaneously.

Surgical Tracheostomy (ST) involves placement of a tracheostomy tube in the trachea after performing dissection of

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How to cite this article: Gupta S, Dixit S, Choudhry D, Govil D, Mishra RC, Samavedam S, Tracheostomy in Adult Intensive Care Unit: An ISCCM Expert Panel Practice Recommendations. *Indian J Crit Care Med* 2020;24(Suppl 1):S31–S42.

Source of support: Nil

Conflict of interest: None

pre-tracheal fascia and creating an opening in the trachea under direct vision. It can be performed both in ICU or operation theatre (OT).

Percutaneous Dilatational Tracheostomy (PDT) is mostly performed as a bedside procedure where tracheostomy tube is placed in the trachea after creating an opening in the trachea by blunt dissection of pre-tracheal soft tissue with the help of Seldinger technique.

METHODS

The Expert Panel

The guidelines were developed by an Expert Panel of Members of Indian Society of Critical Care Medicine (ISCCM) under the chairmanship of the President of ISCCM. The panel comprised of senior intensivists, experts in the field and five principal

investigators who contributed maximally to the DISSECT study. The results of DISSECT study were taken as a reflection of the tracheostomy practices in India and the guidelines were formulated keeping in mind the available resources and the practice trends.

Literature Search and Review

A PUBMED search was performed with various keywords like "tracheostomy", "tracheotomy", "percutaneous", "surgical", "open tracheostomy", "indications", "complications", "mortality", "length of stay", "bronchoscopy", "ultrasound", "cost", "obese", "morbidly obese", "coagulopathy" which were relevant to various questions framed for the guideline. None of the studies or case reports or meta-analysis were rejected but they were graded as per the strength of the article. Cross references from the relevant articles and all guidelines on the topic were also reviewed.

Literature Grading and Recommendations

We used the modified grade system to classify the quality of evidence and the strength of recommendations (Table 1). The draft document that was formulated was reviewed by the expert panel and all suggestions were incorporated in the final draft after approval through consensus. The questions developed for the guidelines used the acronym PICO:⁴ P, patients; I, intervention; C, comparison; and O, outcome.

Scope of Guidelines

The scope of this document includes the indications of tracheostomy in ICU, the choice between surgical versus percutaneous tracheostomy, guidance used during tracheostomy, the immediate complications of tracheostomy, the weaning time frame after tracheostomy and the average cost of this procedure in India. They also cover tracheostomy in special situations like morbidly obese and coagulopathic patients. These guidelines are only for adult patients (>18 years).

TRACHEOSTOMY – INDICATIONS AND CONTRAINDICATIONS

Are there any Absolute Contraindications to Tracheostomy?

Traditionally, certain contraindications for performing tracheostomy have been described in the literature and they were more pertinent to PDT. But the literature also emphasizes that as the experience of the user with the technique increases,⁵ these contraindications become relative and hence, the risk associated with these conditions also decreases.⁶

Morbid obesity was earlier considered as a contraindication for performing PDT due to difficult anatomy. However, recent studies have shown that PDT is equally safe as compared to ST in this subset of patients.⁷

Coagulopathy was also considered as a contraindication for performing tracheostomy and its prior correction was deemed necessary before the procedure. Although now there is ample literature demonstrating that with increased skill of the operator, coagulopathy is a relative contraindication and the procedure can be performed safely.^{8,9} A recent observational study involving data of tracheostomy in 652 patients with and without coagulopathy

Table 1: Modified grade system

<i>Quality of Evidence</i>	<i>Level</i>
Evidence from ≥ 1 good quality and well-constructed randomized control trial(s) or meta-analysis of RCT's	1
Evidence from at least 1 RCT of moderate quality, or well-designed clinical trial without randomization; or from cohort or case-controlled studies.	2
Evidence from descriptive studies, or reports of expert committees, or opinion or respected authorities based on clinical experience	3
Not backed by sufficient evidence; however, a consensus reached by the working group, based on clinical experience and expertise	Useful Practice Point (UPP)
<i>Strength of Recommendations</i>	<i>Grade</i>
Strong Recommendations to do (or not to do) where the benefits clearly outweigh the risk (or vice versa) for most, if not all patients	A
Weak Recommendations, where benefits and risk are more closely balanced or are more uncertain	B

concluded that PDT can be safely performed in patients with altered coagulation status with no increase in complications.¹⁰

In the recent DISSECT study,³ the most common reason for performing a surgical tracheostomy was altered neck anatomy like short neck or thick neck or obese patients. Other reasons were coagulopathy and in few cases, the admitting physician was not confident on performing PDT.

The common indications¹¹ of tracheostomy in ICU are:

- Prolonged ventilation
- Weaning from ventilator support
- Tracheobronchial toileting and secretion management
- Upper airway obstruction
- Permanent airway control in malignancies or trauma or neurological conditions

The contraindications for tracheostomy are:

Absolute

- Informed consent not available
- Infection at the site of tracheostomy

Relative

- Coagulopathy
- Altered neck anatomy like thyroid mass/swelling
- Unstable cervical spine
- Morbidly obesity
- Patients on ventilator support with high PEEP

Recommendation

There are no absolute contraindications to tracheostomy except refusal of consent and infections at the site of planned procedure (3B)

TIMING OF TRACHEOSTOMY

For the purpose of the document, ISCCM Expert Panel has decided to define Early Tracheostomy as within or equal to 7 days of ventilation and late tracheostomy as any tracheostomy performed beyond 7 days.

Does early tracheostomy reduce the incidence of ventilator associated pneumonia (VAP) as compared to late tracheostomy?

Intubated patients are at an increased risk of VAP due to micro-aspiration of oropharyngeal secretions. The question that whether early tracheostomy (ET) confers advantage in prevention of VAP is controversial. First the definition of ET has been different in various RCTs ranging from day 1 to day 4, to upto day 10. Most of the literature takes ET as the procedure performed upto day 7 of intubation.

A meta-analysis¹² involving four RCTs¹³⁻¹⁶ in 2005 found no difference in hospital-acquired pneumonia in both the groups (relative risk 0.90, 95% CI 0.66–1.21). A large RCT¹⁷ conducted in Italian ICU in 2010 involving almost 600 patients also did not find any statistically significant difference in VAP incidence in early vs late tracheostomy (14% vs 21%, $p = 0.07$). Another meta-analysis¹⁶ involving 7 RCTs^{13-16, 19-21} conducted in 2011 involving 1044 patients did not find any difference in VAP rates in critically ill patients undergoing early tracheostomy (relative risk 0.94, 95% CI 0.77–1.15). The limitation of all these RCTs included in meta-analysis was the heterogeneity of the definition of VAP. Some studies followed the CPIS (Clinical Pulmonary Infection Score) scoring system whereas others measured VAP as per the definition of patients on ventilator for > 48 hours.

In the RCT²⁰ carried out in a mixed medical surgical ICU, it was found that the ICU-acquired pneumonia curves did not differ between the groups [$P = 0.94$; HR = 0.98 (95%CI: 0.60–1.62)].

In a recent meta-analysis²² of six observational studies involving 2037 patients, it was found that there was no statistically significant difference in the VAP prevalence rates between early and the late tracheostomy groups (11.6% vs 11%, odds ratio 0.71, 95% CI 0.48-1.04, $p = 0.08$).²³⁻²⁵ In the recently concluded DISSECT study, the prevalence of early tracheostomy was much higher than late tracheostomy (73.7% vs 26.3%, $p < 0.05$).

Recommendation

- The incidence of VAP does not change with early (within 7 days of ventilation) or late tracheostomy (1 A)
- Early Tracheostomy should not be used as a strategy to reduce the incidence of VAP (1 A)

Does early tracheostomy reduce the ICU length of stay (LOS) as compared to late tracheostomy?

In the meta-analysis conducted in 2005¹² involving around 226 patients from two RCTs^{13,14} concluded that early tracheostomy reduces the ICU length of stay (–15.3 days, –24.6 days to –6.1 days, $P = 0.001$). They also pointed out that there is lot of heterogeneity in various RCTs regarding the ICU LOS. In the meta-analysis published by Wang et al¹⁸ in 2011 which included 1044 patients from seven RCTs, there was a trend towards reduced ICU LOS but it did not meet statistical significance (Weighted Mean Difference, –6.93 days; 95% CI, –16.50-2.63; $P = .16$). In a recent meta-analysis of 2016,²⁶ nine studies comprising of 2040 patients were enrolled out of which 5 studies discussed the relationship of early tracheostomy with ICU LOS and they concluded that ICU LOS does not reduce with early tracheostomy, although the trend was towards reducing the LOS but not meeting statistical significance (WMD = –7.57 days; 95% CI = –15.42 to 0.29 days; $P = 0.06$). The studies were heterogenous in nature and not high quality studies.

Apart from these, there are various RCTs conducted in various subsets of patients which have concluded that early tracheostomy leads to reduced ICU LOS. In the RCT by Tong et al,²⁵ it was found that early tracheostomy reduced ICU LOS by 33%. Similarly, in the RCT conducted by Mohamed et al,²⁷ the ICU LOS was shorter in the early PDT group as compared to late PDT group (32.2 ± 10.5) vs (20.6 ± 13 days; $p = 0.004$). In the RCT conducted by Terragni et al,¹⁷ the ICU free days were significantly higher in the early tracheostomy group as compared to the late group.

In the retrospective study by Zirpe et al²⁸ conducted in neurointensive care unit, it was found that early tracheostomy results in shorter stay in ICU (mean, 28.8 vs. 34.37 days, $P = 0.019$).

Recommendation

Early tracheostomy may result in reduction of ICU length of stay as compared to late tracheostomy (1A)

Does early tracheostomy increase the ventilator free days (VFD) as compared to late tracheostomy?

There are many RCTs and meta-analysis supporting the practice of early tracheostomy to increase the ventilator free days (VFD) as compared to late tracheostomy group. In a retrospective analysis of surgical ICU patients,²³ the authors found that early tracheostomy (<7 days of ventilation) increases the VFD (12.2 ± 0.9 vs 21.9 ± 1.3 days). In the TracMan trial²⁹ 909 patients were enrolled and divided into early and late tracheostomy groups. The patients in the early tracheostomy group had reduced need of respiratory support as compared to late tracheostomy group, although it did not meet statistical significance (mean 13.6 days vs 15.2 days, $p = 0.06$). Devarajan et al³⁰ in their retrospective review of patients who underwent tracheostomy after cardiac surgery showed that early tracheostomy group (within 10 days of ventilation) had shorter intubation time by 5.5 days as compared to late tracheostomy group ($p = 0.011$). In a meta-analysis²⁰ of four observational trials,^{23,24,25,31} the early tracheostomy group had shorter duration of mechanical ventilation as compared to delayed tracheostomy group (mean difference – 10.04 d, 95% CI – 15.15 to – 4.92, $p = 0.001$).

In a systematic review by Koji et al,³² five RCTs^{17,19,21,33,34} were studied for VFD and it was greater with early tracheostomy group (WMD 2.10, 0.44, $p < 0.01$). Contrary to the available literature, a meta-analysis³⁶ which included nine studies^{15,16,19,20,21,29,34,36,37} (1623 patients) studying the relationship of duration of mechanical ventilation and timing of tracheostomy could not establish a statistical significance and concluded that early tracheostomy did not increase VFD [- 0.19 days (-1.13–0.75)]. A meta-analysis¹² conducted in 2005 included 406 patients from 5 RCTs¹³⁻¹⁶ concluded that early tracheostomy significantly reduces the duration of mechanical ventilation (WMD 8.5 days). Similarly, the Cochrane review³⁸ conducted in 2015 included various studies^{13,17,21,34,37} of varying heterogeneity and on individual evaluation of these studies, the results were different in all studies although most studies pointing towards early tracheostomy reducing the duration of mechanical ventilation and increasing VFD.

The effect of early tracheostomy on VFD has been studied in neurointensive care in various RCTs and has shown that it significantly reduces the need for mechanical ventilation in patients with stroke or who have undergone decompressive craniectomy.^{39,40} The average reduction has ranged from 10-16 days. In two retrospective cohort studies^{41,42} one in Japan and the other in Taiwan, looked at VFD and early tracheostomy. It was found

that early tracheostomy had a median of 10 days more ventilation free days as compared to late tracheostomy (CI = 1.06-2.38, $p = 0.027$) in the Japan study whereas the MV duration was shorter in the other study (35.2 ± 21.4 vs 46.6 ± 18.8 days, $P = .001$). A small RCT conducted⁴³ on 67 adult ICU patients concluded that early tracheostomy reduced MV days significantly (7.91 ± 4.937 SD vs 15.32 ± 7.472 SD, $p = 0.001$)

Recommendation:

Early Tracheostomy may reduce the duration of mechanical ventilation and may result in more ventilator free days in critically ill patients (2 B)

Does early tracheostomy reduce the mortality in critically ill patients as compared to late tracheostomy?

There have been many RCTs and meta-analysis which has evaluated the relationship of timing of tracheostomy and mortality in critically ill patients. In the RCT by Blot et al,²⁰ they found that mortality at day 28 was similar in early tracheostomy vs prolonged intubation (20%; 95%CI: 11-31 vs 24%; CI:15-36) and also at day 60 (27%; 95% CI:17-39 vs 24%; 95% CI: 15-36). In another Italian RCT,¹⁷ the survival at 1 year was compared and in the early group, 72 patients (50%; 95% CI, 41%-61%) survived to 1 year compared with 63 patients (43%; 95% CI, 34%-52%) in the late group ($P = .25$). In the TracMan trial,²⁹ 909 patients were enrolled and mortality data was looked at 30 days and at 2 years. The all-cause mortality at 30 days in the early vs late tracheostomy was 30.8% (95% CI, 26.7%-35.2%) vs 31.5% (95% CI, 27.3%-35.9%) and absolute risk reduction was 0.7% (95% CI, 5.4% to 6.7%). The two-year mortality was 51.0% (95% CI, 46.4%-55.6%) in the early and 53.7% (95% CI, 49.1%-58.3%) in the late group. In few other single centre RCTs,^{33,34,44,45} mortality at different time frames was compared with timing of tracheostomy and it was found that mortality at 60 days ($p = 0.949$), 90 days (25.7% vs 29.9%), 1 year (CI 95% 0.7 [0.5-1.001], $p = 0.051$) and at hospital discharge (20% vs 22%) had no difference. Similarly, a RCT³¹ in trauma patients revealed that early tracheostomy did not improve ICU and hospital mortality ($p = 0.66$).

The RCTs conducted in neurocritical care units had varying results. In patients with severe head injury,¹⁶ early tracheostomy did not change the mortality rates (38.7% vs 22.5%, $p = 0.27$). In stroke patients,³⁷ early tracheostomy decreased the ICU mortality (10% vs 47%, $p < 0.01$) as well as 6-month mortality (27% vs 60%, $p = 0.02$). Patients undergoing early tracheostomy after decompressive craniectomy³⁹ had decreased hospital mortality ($p = 0.013$). Tracheostomy in cardiac surgical patients^{21,46} have not shown any benefit in terms of mortality at varying time frames whereas a retrospective review of prospective data conducted by Devarajan et al³⁰ concluded that early tracheostomy is associated with reduced in hospital mortality (21.1% vs 40.4%, $p = 0.002$)

There have been atleast seven meta-analysis studying the relationship of timing of tracheostomy and mortality. Wang et al¹⁸ showed that early tracheostomy did not reduce the short term mortality (RR, 0.86; 95% CI, 0.65-1.13; $P = 0.28$) as shown by seven trials ($N = 1044$)^{13,15-17,19-21} as well as long term mortality (RR, 0.86; 95% CI, 0.65-1.13; $P = 0.28$) as shown by two trials ($N = 443$).^{17,21} In another meta-analysis conducted by Meng et al,²⁶ nine studies^{13,15,17,19-21,27,29,34} were included and the result was that

early tracheostomy did not reduce the mortality [relative risk (RR) = 0.88; 95% CI = 0.76-1.00; $P = 0.06$]. Szakmany et al³⁵ conducted the meta-analysis by including 14 studies^{13,15-17,19-21,29,34,36,38,47,48} and found no difference in short term mortality (upto 60 days) between early and late tracheostomy (356/ 1180 [30.2%] vs 391/1226 [31.9%], RR: 0.93 [95% CI 0.83, 1.05]). In the meta-analysis by Siempos et al⁴⁹ enrolling 13 trials ($N = 2434$)^{13-17,19-21,29,34,37,45,47} concluded that the all-cause mortality was not lower in early tracheostomy as compared to late or no tracheostomy group (303 vs 345 deaths; OR 0.80, 95% CI 0.59-1.09; $p = 0.16$). Another meta-analysis by Liu et al⁵⁰ concluded that there was no significant difference in hospital mortality (relative risk, 0.84; 95% CI, 0.67 to 1.04; $P = .11$), data was from 11 studies.^{13-15,17,19,29,34,48} The Cochrane database³⁸ which included seven studies^{13,17,19,21,29,34,37} concluded that early tracheostomy reduced mortality as compared to delayed tracheostomy although the quality of evidence is moderate (47.1%; 448/ 950 vs 53.2%; 507/953, RR 0.83; 95% CI 0.70 to 0.98; $p = 0.03$). Another meta-analysis³² which enrolled 11 studies^{13,15,17,19-21,29,33,34,37,45} also concluded that short term mortality is not affected by timing of tracheostomy.

The various retrospective studies^{25,28,42,43,51,52} conducted in different patient subsets also confirmed that the timing of tracheostomy does not reduce in hospital mortality.

Recommendation

- There is no difference in short term and long term mortality between early and late tracheostomy (1 A).
- Patients with stroke and those undergoing decompressive craniectomy may have reduced short term mortality with early tracheostomy (3 B).

PDT vs ST

Does ST results in lower complications as compared to PDT in critically ill patients?

The complications studied have been either divided into immediate and late complications or into serious, intermediate and minor complications. In the various RCTs, there was no difference in intermediate (desaturation, hypotension, posterior tracheal wall lesion, canula misplacement, switch to surgical technique) or serious (death, pneumothorax, pneumomediastinum) complications between ST & PDT. Minor complications like hemorrhage, difficult tube placement was more in PDT group ($p = 0.024$).⁵³ The other minor complications like cosmetic sequelae and postoperative infections have been higher with ST ($p = 0.044$).⁵⁴ The skin incision size was smaller with PDT ($p < 0.0001$).⁵⁵

The meta-analysis by Higgins et al⁵⁶ which included 15 studies ($N = 973$),^{55,57-70} showed no statistical significance for major complications between ST and PDT but the overall pattern of complications favored PDT (0.75, 0.56-1.00, $p = 0.05$) in regards to incision scarring, wound infection and shortened procedure time. In another meta-analysis⁷¹ enrolling 14 studies,^{57,58,61,63,64,66,68,70,72-77} it was found that PDT causes less wound infection (pooled OR 0.20 [0.11 to 0.35]; $P < 0.0001$). The same meta-analysis looked at data from 11 studies^{59,61-63,68-70,60,72,78,74} and found that PDT decreases the procedure time (pooled OR 21.7 [22.7 to 0.7]; $P = 0.001$). The meta-analysis by Delaney et al⁸¹ which included 15 studies^{55,57-63,65-70,80} concluded that the pooled odds ratio (OR)

for wound infection was 0.28 (95% confidence interval (CI), 0.16 to 0.49, $p < 0.0005$), indicating a significant reduction with PDT compared to ST. Rest of the complications like bleeding and long-term complications including death were similar between PDT and ST. The meta-analysis performed by Putensen et al⁸¹ which included 9 RCTs^{58,55,60,61,63,65,66,70,74} also concluded that stomal infection was lower with PDT (odds ratio, 0.22 (95% CI, 0.11 to 0.41 ($P < 0.00001$)) and rest of the other complications did not meet statistical significance.

As per the retrospective analysis of the studies,^{82,83,84,85,86} all concluded that PDT and ST are equally safe without any difference in the rate of major complications. PDT had higher peri-procedural complications like false passage whereas ST had higher stomal infection.

As per the DISSECT study,³ PDT had marginally higher incidence of intra-procedural minor bleeding and desaturation but ST had higher incidence of major complications like major bleeding, hypotension, need for bronchoalveolar lavage (BAL) and even death.

Recommendation

The incidence of complications is similar between ST and PDT except for a higher incidence of stomal infection and a bigger scar with ST (I B)

Does ST results in cost reduction for ICU patients as compared to PDT?

The data on this topic is only available from international studies and is presented only in US dollars. In the RCT by Freeman et al,⁵⁹ PDT had less equipment charges (PDT, \$688 ± 103 vs. ST, \$1,526 ± 87, $p < 0.0001$) and professional charges as compared to ST (PDT, \$880 ± 54 vs. ST, \$1,647 ± 50; $p < 0.0001$) and hence overall PDT was cheaper than ST (PDT, \$1,569 ± \$157 vs. ST, \$3,172 ± \$114). Similar findings were present in the RCT by Heikkinen et al⁶² and they concluded that PDT was having a cost beneficial advantage over ST (PDT mean cost \$161 [SD, 10.4; range, \$159–\$219], ST mean cost \$357 [SD, \$74; range, \$239–\$599], $p < 0.001$). Contrary to the literature available, the RCT by Massick et al⁶⁴ revealed that cost of bedside ST was less than PDT by roughly \$436. This inference was probably due to the procedure being conducted at bedside rather than operation theatre.

A meta-analysis⁵⁶ involving four studies^{59,62,64,70} favored PDT over ST as the cost efficient technique without any increased risk of complications (\$456.61 USD less with PDT).

The retrospective data analysis⁸² in cardiac surgery patients who underwent tracheostomy, PDT was found to have significant cost saving potential in terms of decreased ICU days and decrease resource utilization. In another retrospective study,⁸⁶ PDT was found to have significant cost saving potential specifically in resource constraint conditions ($p < 0.0001$).

As per the DISSECT study,³ cost of PDT is much lower than ST in India with an average cost difference of Rs 13104 between the two procedures ($p < 0.05$).

Recommendation

PDT is more cost effective as compared to ST performed in operation theatre in critically ill patients (2 A)

PDT TECHNIQUE

Does any technique of PDT results in lower complications in critically ill patients?

RCT by Kost et al⁸⁷ and Johnson et al⁸⁸ compared Ciaglia percutaneous tracheostomy multiple dilator vs Ciaglia Blue Rhino Single dilator kit. There were no major differences in complications between the two techniques except the association found between the experience and the chances of complication. It was more with multiple dilator technique ($p < 0.0001$). The other observation was that single dilator technique was faster (6:01 ± 3:03 mins vs 10:01 ± 4:26 mins, $p < 0.0006$).

In a cohort study⁸⁹ with long term follow up of Griggs technique, it was found that one third of the patients had tracheal dilatation even after decannulation which was not present after Ciaglia technique in other studies. In another RCT comparing Ciaglia single dilator with Griggs technique, it was found that major complication rate was 4.4 times higher with Griggs technique. Similarly, postoperative complications were less with Ciaglia technique (2% vs 25%, $p = 0.023$)⁹⁰ and there was a risk of over dilatation with Griggs technique.⁹¹ In a biomechanical animal study⁹² comparing Ciaglia and Griggs technique, it was concluded that Ciaglia technique required almost 50% more energy to perform a PDT ($p < 0.0001$).

The systematic review in 2014⁹³ compared various techniques of PDT. The techniques compared were Ciaglia Multiple dilator vs Ciaglia Blue Rhino,^{88,94} Ciaglia Blue Rhino vs Ciaglia Balloon Dilator,⁹⁵ Ciaglia Blue Rhino vs Griggs Dilating forceps,^{91,96-98} Ciaglia Multiple Dilator vs PercuTwist,⁹⁹ Ciaglia Blue Rhino vs PercuTwist,¹⁰⁰ Ciaglia Multiple Dilator vs Griggs,^{90,101,103} Ciaglia Multiple Dilator vs PercuTwist vs Griggs,¹⁰² Griggs vs Fantoni,¹⁰⁴ Griggs vs PercuTwist.¹⁰⁵ Among all the techniques, it is impossible to decide which is better but Blue Rhino method is less difficult and preferred by physicians.⁹³

In DISSECT Study,³ single dilator technique was the most preferred technique followed by Griggs technique and then multiple dilator (60.4% vs 28.7% vs 11% respectively)

Recommendation

- All the techniques of PDT do not differ in the incidence of complication rates (2 B)
- The single dilator technique may be used by less experienced operators (UPP)

Does the use of Fiberoptic Bronchoscope (FOB) while performing PDT reduces the complication rate?

There have been very few RCTs studying the direct relationship of bronchoscopy guided PDT and the incidence of complications. In the earlier studies^{78,87,106} it was found that bronchoscopic guidance reduces the risk of complications and is safe and cost effective but the recent studies^{107,108} have demonstrated that PDT can be safely performed even without bronchoscopic guidance and avoid delays due to non-availability of bronchoscope. The most common complication mentioned in all the studies was desaturation during the procedure.

Most of the data available is from retrospective studies. The studies¹⁰⁹⁻¹¹⁵ compared PDT with and without bronchoscopy in various clinical subset and all of them concluded that PDT can be safely performed even without the aid of bronchoscope

without any increase in complications and it is not mandatory to do bronchoscopy guided PDT. The complications studied were bleeding, desaturation and false passage. Similarly, in the meta-analysis by Putensen et al,⁸¹ there was no difference in procedural bleeding with or without bronchoscope. In DISSECT study, 28.1% PDT were done with the guidance of FOB.

Recommendation

Fiberoptic bronchoscope may be used, whenever available to aid PDT although it does not reduce the rate of complications. (UPP)

Does the use of real-time ultrasound (US) of neck while performing PDT reduces the complication rate?

Yavuz et al¹¹⁶ compared US guided neck anatomy evaluation vs clinical judgement and found that perioperative complication was lower with US group although not statistically significant (7.8% vs 15%). The puncture attempts were also lower with US group (3.9% vs 13.6%, $p = 0.003$). In another RCT,¹¹⁷ Fiberoptic bronchoscopy guided PDT was compared with US guided PDT. The mean hemorrhage ratio and the procedure time was lower with US PDT ($p < 0.05$). Similarly, the Trachus trial¹¹⁸ compared US PDT vs FOB PDT and found no difference in complication rate. Mahmoud et al,¹¹⁹ compared US with FOB with no guidance. The landmark technique was associated with higher complications as compared to the guidance methods. Comparing US with FOB, did not result in any major statistically significant difference. In another RCT¹²⁰ comparing landmark technique with US PDT, first pass puncture success rate was higher with US PDT (87% vs 58%, CI 1.03 to 2.17, $p = 0.028$). The procedural complication rate was not statistically significant (22% vs 37%, CI 0.23 to 1.47, $p = 0.24$).

In the two retrospective studies,^{121,122} it was found that real time US guided PDT was not associated with any complications and reduced the number of puncture attempts as compared to the landmark technique. In another retrospective comparative analysis¹²¹ between real time US PDT and FOB PDT in obese patients, US group had short operating time (mean \pm SD, 12.8 \pm 4.8 vs 16.2 \pm 4.4 minutes; $P = 0.026$), fewer punctures ($P = 0.011$) and less hemorrhagic complications (2.1 \pm 4.6 versus 16.8 \pm 4.3 mL; $P = 0.009$).

In the review on US PDT,¹²⁴ the studies included revealed that US helps in defining the landmarks for tracheostomy,^{125,126} in identifying vulnerable structures like blood vessels and thyroid gland¹²⁶⁻¹²⁸ choosing an appropriate location for puncture.¹²⁹⁻¹³⁴ In one of the study in neurocritical care over a 8-year period, it was found that the odds of having an adverse outcome was significantly low with US group (odds ratio = 0.08; 95% confidence interval, 0.009 to 0.811; $P = 0.032$).¹³⁵

As per the data from DISSECT study,³ US was used in 38.6% cases of PDT for evaluation of neck anatomy and to identify the puncture point.

Recommendation

- Use of real-time ultrasound could identify correct position of puncture, decrease the number of puncture attempts and intraprocedural hemorrhage. (2 B)
- Whenever available, ultrasound should be used to scan the neck to identify the anatomy prior to needle puncture (UPP)
- PDT should be performed under real-time ultrasound guidance whenever expertise is available (UPP)

EXPERIENCE

Is there any minimum number of tracheostomies required to safely and independently perform the procedure?

Although no major trials are available which have concluded on how many tracheostomies will give sufficient experience to perform the procedure safely but still few observational and prospective analysis have provided some insights. In 2000, Massick et al,¹³⁶ tried to study the learning curve for PDT and the incidence of complications. He concluded that perioperative and late complications were higher in first 20 PDTs, more so in patients with altered or difficult anatomy. They proposed that early experience should be gained in a controlled environment. In the RCT by Nates et al,⁹⁰ they compared two techniques of PDT. They defined senior operator as one who has done > 6 tracheostomies. They could not find any major difference in complication rates of experienced or inexperienced operators but they concluded that their study was not meant to define the minimum number of tracheostomies required to become a senior operator. ERS/ATS¹³⁷ recommends that the trainee should perform atleast 5-10 PDTs under supervision before performing the procedure independently. They also recommended that the operator should continue to perform atleast 10 PDT /year to maintain the expertise. Similarly, as per the American College of Chest Physicians,¹³⁸ the minimum number of tracheostomies under supervision should be atleast 20 and thereafter the operator should continue doing atleast 10 tracheostomies/year to maintain expertise.

In the DISSECT Study,³ most of the tracheostomies were performed by experienced operators having done more than 25 tracheostomies (87.4%).

Recommendation

The minimum number of supervised PDT may be atleast 10 to do the procedure independently (UPP)

Is there an appropriate specialist required to perform tracheostomy?

In 2006,¹³⁹ a questionnaire-based survey was carried out to study the practices of medical intensivists regarding tracheostomy in India. It was found that 57.4% were anesthesiologist, 7.4% were pulmonologist and 35.2% were from medicine background. Almost 90% tracheostomies performed were PDT. The surgical tracheostomies were performed by ENT specialist. There was no difference in complication rates.

All other data on this topic is retrospective in nature. Klein et al⁴ and Seder et al¹⁴⁰ compared PDT performed by ENT surgeon and intensivist. They concluded that PDT performed by intensivist was equally safe and also reduced delay by avoiding OT waiting time. A similar kind of retrospective analysis was done by Yarmus et al¹⁴¹ where they compared PDT being done by the surgical team vs interventional pulmonologist. They found no difference in complications in either group except a decrease in delay from the decision of doing the tracheostomy to performing the procedure in the pulmonologist group. In an another retrospective data analysis¹⁴² on physician intensivist performing tracheostomy, it was found that trained physicians working as intensivist can safely perform PDT without an increased incidence of complications.

As per the data from DISSECT study,³ most of the tracheostomies were performed by the intensivist (53.8%), followed by surgeons (17%), followed by trainees who were mainly anesthesiologist posted in ICU (13.8%) and then interventional pulmonologist (0.8%).

Recommendation

Any intensivist, proficient in airway management can perform PDT (UPP)

SPECIAL CONDITIONS

Can PDT be safely performed in Coagulopathic patients?

In the prospective data collection by Beiderlinden et al.,¹⁴³ 137 patients out of 415 had coagulopathy like platelet count < 50,000/L, aPTT > 50s or PT > 50% normal values. They found no difference in bleeding episodes between coagulopathy and non-coagulopathic patients. Auzinger et al.¹⁴⁴ prospectively collected data of PDT in liver ICU and did not find any increased incidence of bleeding related complications. An abstract by Patel et al.¹⁴⁵ also concluded that there was no significant increase in respiratory and hemodynamic complications in patients with coagulopathy. In the retrospective single center cohort study,¹⁴⁶ patients who underwent PDT were divided into high risk and low risk based on coagulation parameters. There was no change in bleeding complications between the two groups, although the mortality was more in high risk group but unrelated to tracheostomy. Pasin et al.¹⁴⁷ and Luserbrink et al.¹⁴⁸ found no increase in bleeding complications in patients on anticoagulants and antiplatelets while undergoing PDT. Whereas Huang et al.¹⁴⁹ concluded that antiplatelets and anticoagulants increases the risk of bleeding.

Recommendation

- PDT can be safely performed in coagulopathic patients after appropriate correction of deranged coagulation (UPP)
- Use of FOB &/or real-time ultrasound can reduce complications in coagulopathic patients (UPP)
- Newer Oral anticoagulants (NOACs) and antiplatelets agents may be stopped, if feasible, before performing tracheostomy (UPP)

Can PDT be safely performed in Morbidly Obese patients?

Alhajhusain⁵² et al conducted a retrospective analysis of morbidly obese patients who had undergone PDT and could not find any increase in incidence of complications. In the prospective study by Aldawood et al,¹⁵⁰ 50 PDT were performed in obese patients out of total of 227 PDT. There was no difference in incidence of minor complications except in 3 patients where procedure had to be abandoned but none of the complications resulted in death. The use of FOB was higher in obese patients. Guinot et al¹⁵¹ conducted PDT under ultrasound guidance and found no difference in incidence of complications in obese and non-obese population (35% vs 33%, $p = 0.92$). They concluded that obesity may not constitute a contraindication for US guided PDT. Similarly, in two other studies^{152,153} comparing PDT in obese with non-obese, it was found that incidence of complications was similar in both groups ($p = 0.343$) and PDT can be safely performed in obese patients.

Recommendation

Use of real-time ultrasound can increase the safety of performing PDT in obese patients (UPP)

CONCLUSION

The scope of this document is for intensivist and medical practitioners dealing with critically ill patients. PDT is the most preferred technique of performing tracheostomy in critically ill patients and single dilator technique is the one with maximum experience. The timing of tracheostomy does not affect incidence of VAP or mortality but increases VFD and leads to cost saving. Both bronchoscopy and/or ultrasound guidance can be used to perform PDT but the preference now is tilting towards US due to non-inferiority to FOB and cost effectiveness. PDT has a learning curve and atleast 10 assisted PDT must be done under supervision before performing the procedure independently. These recommendations have taken into account certain points mentioned in other international guidelines available on the tracheostomy.¹⁵⁴⁻¹⁵⁷

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