Percutaneous Tracheostomy under Real-time Ultrasound Guidance in Coagulopathic Patients: A Single-center Experience

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Abstract

Objective: To examine the safety and complications associated with percutaneous tracheostomy (PT) in critically ill coagulopathic patients under real-time ultrasound guidance.

Materials and methods: Coagulopathy was defined as international normalized ratio (INR) > 1.5 or thrombocytopenia (platelet count ≤ 50,000/mm3). Neck anatomy was assessed for all patients before the procedure and was characterized as excellent, good, satisfactory, and unsatisfactory based on the number of vessels in the path of needle. Percutaneous tracheostomy was performed under real-time ultrasound (USG) guidance, with certain modifications to the technique, and patients in both groups were assessed for immediate complications including bleeding.

Results: Six hundred and fifty-two patients underwent USG-guided PT. Three hundred and forty-five (52.9%) were coagulopathic before the procedure. Ninety-nine patients (15.2%) had an excellent neck anatomy on USG scan, and 112 patients (62 in coagulopathy group vs 50 in noncoagulopathy group, p value 0.386) had an unsatisfactory neck anatomy for tracheostomy. A total of 42 events of immediate complications were noted in 37 patients (5.7%). No difference was seen in the rate of immediate complications in both groups (5.8% in coagulopathy group vs 5.9% in noncoagulopathy group, p value 0.886). The incidence of minor bleeding in coagulopathic patients was 14 patients (4.1%) and 7 (2.3%) in those without coagulopathy, and this difference was not statistically different (p value—0.199). In the subgroup analysis of patients with significant coagulopathy and unsatisfactory anatomy, no difference was observed in the incidence of immediate complications.

Conclusion: This study shows the efficacy and safety of real-time ultrasound-guided PT, even in patients with coagulopathy.

Keywords: Airway, Coagulopathy, Percutaneous tracheostomy, Ultrasound.

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Introduction

Tracheostomy is performed in about a quarter of intensive care unit (ICU) patients in whom prolonged mechanical ventilation is anticipated, weaning from assisted ventilation has been difficult or failed or there is a need for airway suction and airway protection on a long-term basis.1 Tracheostomy improves patient comfort compared with the standard intubation. However, despite the advantages, tracheostomy performed early upon ICU admission has not shown any survival benefits. Increasingly bedside percutaneous tracheostomy (PT) has become the procedure of choice in critically ill patients requiring long-term mechanical ventilation and it continues to replace conventional surgical (open) tracheostomy (ST).2,3 Percutaneous tracheostomy was introduced in the mid-1950s. Over the past 50 years, the technique has evolved from a challenging procedure to a safe method of securing a definitive airway.4,5 In recent years, the placement of a tracheostomy tube has gained popularity to facilitate the weaning of patients from mechanical ventilation, as it reduces pulmonary dead space and provides access for the clearing of pulmonary secretions under various pathologic conditions.6

Percutaneous tracheostomy may offer several advantages over conventional ST. Percutaneous tracheostomy is performed at the bedside, thus avoiding the scheduling, time commitment, and cost associated with surgical operating facilities and also eliminating the risks of patient transport.2,4

Despite its technical simplicity and safety, a number of contraindications to PT are recognized, and presence of coagulopathy and thrombocytopenia are some of the relative contraindications to PT.7,8

Coagulopathy is a common problem in ICU and is usually associated with many disorders such as sepsis, liver disease, hematological disorder, and anticoagulation treatment. Thrombocytopenia occurs frequently in critically ill patients. It is reported in 23–27% of ICU patients9,10 and is considered a reflection of the severity and progression of an underlying disease.
Development of thrombocytopenia leads to an increased risk of iatrogenic and unprovoked bleeding and is also associated with increased mortality.\textsuperscript{9,11} The use of real-time ultrasound during PT in such patients may increase the safety and decrease the unnecessary use of blood products and their related side effects.

**Objective of the Study**

The objective of our study was to examine the safety and complications associated with PT in critically ill coagulopathic patients under real-time ultrasound guidance.

**Materials and Methods**

An observational study was conducted in gastroenterology and liver transplant ICU at a tertiary care hospital in India.

After obtaining approval from Institutional Review Board, all consecutive adult patients who underwent PT under ultrasound guidance were included.

Consent for tracheostomy was obtained as a standard practice. The exclusion criteria were patients with unstable cervical spine, patient or attendant refusal for PT and infection at incision site.

Coagulopathy was defined as INR \(\geq\) 1.5 or thrombocytopenia (platelet count \(\leq\) 50,000/mm\(^3\)). Correction of coagulopathy by fresh frozen plasma (FFP) and/or platelet transfusion was done at the discretion of the treating physician. The INR and platelet count were not checked again after transfusion.

In all cases, data were collected on patient age, sex, the duration of mechanical ventilation prior to the tracheostomy, and the coagulation profile on the day of the procedure (including platelet count and INR).

The site of PT was screened prior to the procedure with ultrasound, and the neck vascular anatomy was classified on the basis of ultrasound findings as unsatisfactory, satisfactory, good, or excellent. The neck vascular anatomy was classified as unsatisfactory if there were more than three blood vessels in the track of the needle, satisfactory if there was up to three blood vessels, good if there was up to two blood vessel around the needle track, and excellent when the surgical field was absolutely clear of vessels.

Any complications that occurred during the procedure were recorded (see below for details). All patients were followed until ICU discharge or death, whichever was earlier.

**Percutaneous Tracheostomy Procedure**

Two physicians performed all PT procedures at the bedside, one of them was a critical care consultant (who performed 25 or more USG-guided PTs) and the other was a consultant, critical care fellow or ICU rotating resident. Ultrasound was the preferred technique of choice over bronchoscopy, as assessment of neck anatomy and identification of vessels in the tract of tracheostomy was possible by USG, thereby avoiding injury to the blood vessels and decreasing the incidence of bleeding.

Before starting the procedure, sedation and muscle relaxation were achieved through the use of intravenous agents (fentanyl, propofol, and atracurium) at the discretion of the treating intensivist.

The patient’s neck was extended using a towel roll placed beneath the shoulder blades. The neck was scanned using a linear high-frequency ultrasound (Sonosite™, FujiFilm) probe to determine the anatomy of the trachea, possible deviations, subcutaneous vessels, thyroid gland, other anomalies overlying the site of puncture; and the neck anatomy was classified as unsatisfactory, satisfactory, good, or excellent based on the definition provided previously.

All PTs were performed per “single-step dilation” technique using the Portex\textsuperscript{\textregistered} ultraPERC\textsuperscript{\textregistered} tracheostomy kit. A thorough oral and nasogastric suction was done followed by cleaning of the oral cavity with chlorhexidine mouthwash. The tip of the endotracheal tube was withdrawn under laryngoscopy guidance.

Once the neck was cleaned and draped, under all aseptic precautions, a 14-gauge needle and cannula was introduced through the middle anterior tracheal membrane between the best visible tracheal rings under real-time ultrasound guidance, avoiding the first and second tracheal rings. Free aspiration of air and bubbling of fluid placed over the hub of the cannula during ventilation confirmed correct intratracheal placement. A guidewire was then placed through the cannula.

As an innovation to normal procedure, we used the introducer of the guidewire (the plastic introducer that keeps the J tip of the guidewire straight) for blunt dilation of the skin and subcutaneous tissues (Fig. 1A). Since most patients were coagulopathic and no correction of coagulation profile or platelets was done in most patients, all efforts were made not to give any incision over the skin or subcutaneous tissues. The trachea was then punctured with 5Fr tracheal dilator over the guidewire and then a tapering dilator was introduced over the guidewire until the stoma was dilated. In patients with difficult dilatation, stab incision of 1 mm was made along the dilator over the skin to aid in dilatation (Fig. 1B). The stoma was not dilated to the designated black mark on the dilator, instead the dilatation was performed only till 38Fr mark point on the dilator (this corresponds to 8.5 mm of the tracheostomy tube), in order to avoid overdilation of track and chances of bleeding (Fig. 1C). The dilator was withdrawn and the tracheostomy tube was inserted.

Accurate tracheostomy position was confirmed by auscultation, end tidal carbon-di-oxide (ETCO\(_2\)), and USG. Chest X-ray was obtained after the procedure.

**Complications**

The following complications were looked for during and after the procedure: bleeding, aborting the procedure, accidental extubation, conversion to surgical PT, paratracheal tube placement, subcutaneous emphysema, transient hypotension, the development of pneumothorax, or death.

Bleeding was subdivided into major (requiring blood product transfusion or surgical intervention) and minor bleeding (requiring pressure dressing or suturing).

**Statistical Analysis**

The analysis included profiling of patients on different demographic and clinical parameters. Categorical data were expressed as absolute number and percentage. The Chi square test (or Fisher exact test when appropriate) was used to test the association between categorical variables. The \(p\) value <0.05 was considered statistically significant. All analyses were done using SPSS software, version 24.0.

**Results**

A total of 652 patients underwent ultrasound-guided PT. Of the 652 patients, 345 (52.9%) were coagulopathic (INR \(\geq\) 1.5 or...
thrombocytopenia–platelet count <50,000/mm³). The median BMI was 28.4 kg/m² (95% central range: 19.3–62.5 kg/m²). Three hundred and forty-seven patients (53.22%) were admitted for medical illness and 295 patients (45.24%) were admitted in ICU after a surgical illness. A total of 520 patients (79.8%) were on mechanical ventilation before PT (Table 1). Sonographic delineation of anatomy was done in all enrolled patients. Ninety-nine patients (15.2%) had an excellent neck anatomy on USG scan and 112 patients (62 in coagulopathy group vs 50 in noncoagulopathy group, p value 0.386) had an unsatisfactory neck anatomy for tracheostomy (Table 2 and Fig. 2).

**Table 1: Patient characteristics**

| Coagulopathy | Present (n = 345) (%) | Absent (n = 307) (%) | Total (n = 652) (%) |
|--------------|----------------------|---------------------|-------------------|
| Intubated and ventilated | 286 (82.9) | 234 (76.2) | 520 (79.8) |
| Nonintubated | 59 (17.1) | 73 (23.8) | 132 (20.2) |
| Coagulopathy corrected | 111 (32.2) | 9 (2.9) | 120 (18.4) |

**Table 2: Ultrasound of peritracheal vascular anatomy**

| Ultrasound assessment | Coagulopathy | Present (n = 345) (%) | Absent (n = 307) (%) | Total (n = 652) (%) |
|----------------------|--------------|----------------------|---------------------|-------------------|
| Excellent            | Coagulopathy-excellent | 59 (17.1) | 40 (13) | 99 (15.2) |
| Good                 | Coagulopathy-present | 215 (62.3) | 210 (68.4) | 425 (65.2) |
| Satisfactory         | Coagulopathy | 9 (2.6) | 7 (2.3) | 16 (2.5) |
| Unsatisfactory       | Coagulopathy | 62 (18) | 50 (16.3) | 112 (17.2) |

**Coagulopathy and Complications**

Among all patients with deranged coagulation, only 111 patients (32.2%) received blood products (FFPs or platelets) to correct coagulopathy prior to the procedure and 234 (67.8%) coagulopathic patients underwent tracheostomy without correction of coagulopathy. Nine patients who did not have coagulopathy received blood products for reasons other than the procedure (gastrointestinal and intracranial bleed) and since blood products were administered before the procedure, they were included in coagulopathy-corrected group for analysis. Of the 652 patients, 581 (89.1%) underwent tracheostomy in a single attempt. This number was similar in both groups (90.7% in coagulopathy group vs 87.3% in noncoagulopathy group, p value 0.348). The procedure was successfully completed in all patients and no patient required
In the subgroup analysis of patients with significant coagulopathy, no difference was observed in the incidence of immediate complications (7.8% in significant coagulopathy group vs 4.2% in patients with coagulopathy, p value of 0.338) and bleeding (5.9% vs 2.6%, p value of 0.10).

**Coagulopathy with Difficult Anatomy**

One hundred and twelve patients (62 in coagulopathy group vs 50 in noncoagulopathy group, p value 0.386) had an unsatisfactory neck vascular anatomy for tracheostomy. The number of attempts taken to complete the procedure and incidence of immediate complications, including bleeding (8.1%) in patients with unsatisfactory neck vascular anatomy with coagulopathy vs 4% in patients with satisfactory, good or excellent neck vascular anatomy with coagulopathy, p value 0.377 was comparable in both groups. Twenty-eight patients (25%) with unsatisfactory neck anatomy also had significant coagulopathy. In the subgroup analysis of patients with significant coagulopathy and unsatisfactory anatomy, no difference was observed in the incidence of immediate complications. Two patients with unsatisfactory neck vascular anatomy and significant coagulopathy developed bleeding and the incidence was comparable with patients with no coagulopathy with favorable anatomy.

**Discussion**

The perioperative complications of PT include bleeding (2.5–4.4% of all cases), pneumothorax, hypoxia, hypotension, and loss of airway.\(^ {10–14} \) The presence of anatomic vascular variations, tracheal aberrations, or accompanying cervical disease or disorder can lead to increased complication rates.\(^ {15} \)

In our study, we have studied 652 patients, of which 345 (52.9%) were coagulopathic, and coagulopathy correction was attempted in only 111 (32.2%) of them. Effectively 234 patients (67.8%) were coagulopathic during the procedure. No difference was observed in the incidence of immediate complications between the groups (5.8% in coagulopathy group vs 5.5% in noncoagulopathy group, p value 0.886). One hundred and fifty-three patients in the coagulopathy group had a significant coagulopathy before the procedure. The incidence of bleeding between patients with significant coagulopathy and other group was comparable (5.9% vs 2.3%, p 0.10). Sixty-two patients in coagulopathy group had an unsatisfactory neck vascular anatomy during the procedure. No difference was observed in the incidence of immediate complications and bleeding even in patients with unsatisfactory neck anatomy.

Al Dawood et al. did prospective study on 190 patients with coagulopathy and or thrombocytopenia undergoing PT and demonstrated a low incidence of bleeding in 4 (12%) patients.\(^ {16} \)

Pandian et al. conducted a retrospective analysis of the records of 483 patients who had undergone percutaneous dilatational tracheostomy (PDT) to investigate the safety of PDT in those who were coagulopathic. In their study, 32 patients (6.6%) were coagulopathic. The bleeding complication was 1.11% in the noncoagulopathic groups, whereas no patients in the coagulopathic group had bleeding complication.\(^ {17} \)

In a more recent study by Takahashi et al.\(^ {18} \) of 149 post cardiothoracic surgery patients of which 75 patients (49%) were coagulopathic (platelets ≤50,000, INR of prothrombin time ≥1.5, and/or partial thromboplastin time, ≥50). In their study, no

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**Table 3: Number of attempts and complications**

| Coagulopathy | Present (n = 345) (%) | Absent (n = 307) (%) | Total (n = 652) (%) | p value |
|--------------|-----------------------|---------------------|-------------------|--------|
| No. of attempts |                       |                     |                   |        |
| Single       | 313 (90.7)            | 268 (87.3)          | 581 (89.1)        | 0.348  |
| Double       | 26 (7.5)              | 33 (10.7)           | 59 (9)            |        |
| Triple       | 6 (1.7)               | 6 (2)               | 12 (1.8)          |        |
| Immediate complications | 20 (5.8) | 17 (5.5) | 37 (5.7) | 0.886 |
| Pneumothorax | 1 (0.3)               | 2 (0.7)             | 3 (0.5)           | 0.496  |
| Bleeding     | 14 (4.1)              | 7 (2.3)             | 21 (3.2)          | 0.199  |
| False tract  | 4 (1.2)               | 5 (1.6)             | 9 (1.4)           | 0.608  |
| Desaturation | 0 (0)                 | 3 (1)               | 3 (0.5)           | 0.066  |
| New ventilator requirement | 2 (0.6) | 4 (1.3) | 6 (0.9) | 0.334 |

* p value < 0.05—statistically significant

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**Fig. 3:** Comparison of the number of attempts and complications in both groups
patients had overt bleeding. One coagulopathic patient (1.3%) had clinical oozing treated with packing, as opposed to zero in the noncoagulopathic patients (p = 1.00). Post tracheostomy mediastinitis or late tracheal stenosis was not reported in any patients. They concluded that uncorrected coagulopathy and therapeutic anticoagulation did not increase the bleeding risk of PT in cardiothoracic surgical patients.

A few studies have demonstrated an increased safety and efficacy of ultrasound-guided PT. Rajjee et al.19 retrospectively studied the impact of real-time ultrasound guidance on the complications of PDT. In this study, a total of 200 patients underwent PDT, and among them 107 received real-time ultrasound guidance. Among the 26 patients (13%) with coagulopathy, 4/12 (33%) who underwent conventional PT vs 0/14 who underwent real-time ultrasound-guided PT suffered bleeding requiring intervention (p = 0.033). In this study, none of the patient with coagulopathy received preprocedural blood products to correct coagulopathy. Real-time ultrasound guidance can provide valuable information on preprocedural airway assessment and planning and guide needle placement and also assist in screening for complications. Ultrasound has been shown to be useful in defining the pre- and paratracheal airway anatomy, especially in cases where distortion or obesity obscured normal palpation, and has been associated with improved speed and success of cannula placement and reduced number of attempts required.20–22

A prospective, single-center randomized control trial study of 74 consecutive patients done by Ravi et al.23 evaluated the efficacy of ultrasound-guided PT (USPT) and bronchoscopic-guided percutaneous tracheostomy (BPT) and the incidence of complications. Twelve cases (32.22%) of minor (<5 mL) bleeding and four cases (11.11%) of major bleed (<50 mL) were reported in the BPT group, which was statistically significant in comparison to those in the USPT (p < 0.05). Study also demonstrated low incidence (statistically significant) of cuff puncture, multiple punctures, and desaturation in USPT group compared to those in the BPT group.

Similar randomized prospective study was carried out in 80 patients by Saritas and Kurnaz24 who randomly divided the patients into fiber optic bronchoscopy-guided PDT (FOB-PDT) and ultrasound-guided PDT (US-PDT) groups. The mean hemorrhage ratio of the FOB-PDT group was significantly higher than that of the US-PDT group (p < 0.05). Hemorrhage was observed in one (2.5%) patient in the US-PDT group and in eight (20%) patients in the FOB-PDT group. Study results showed that real-time US-DT has the advantages of a low complication rate and short duration of procedure, being informative with regard to neck anatomy, facilitating the prevention of vascular puncture.

Our study is the largest series till date regarding the use of real-time ultrasound assistance for percutaneous tracheotomy in patients with coagulopathy, evaluating 652 patients, of which 345 (52.9%) patients had coagulopathy, and among the coagulopathy group 153 patients had significant coagulopathy and 62 had unsatisfactory neck anatomy for tracheostomy. The use of real-time USG for PT, avoidance of vessels in the tract of tracheostomy, technique modification (use of introducer for blunt dilatation and terminating dilatation before the designated mark and avoiding the use of skin and soft tissue incisions with a blade incision during the procedure) should have contributed to the overall reduced incidence of complications and bleeding, even in patients with significant coagulopathy.

The drawbacks of our study were that it was an observational study and coagulopathy correction was not standardized and instead left to the discretion of the treating physician. Blood parameters were not repeated before the procedure, so actual correction of coagulopathy could not be determined. In our observation study, we noticed that the rate of clinical significant procedure-related complications, specifically bleeding, is low in patients despite a high incidence of uncorrected and significant coagulopathy. Our study demonstrates the improved safety and efficacy of PT using real-time ultrasound guidance and has shown that PT can safely be done on patients with unsatisfactory neck anatomy and coagulopathy without preprocedure cover of plasma/platelets transfusion, by a simple modification of the technique.

Conclusion

In conclusion, this observational study shows the efficacy and safety of real-time USPT, even in patients with coagulopathy by simple modifications of the technique described.

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