

# THE SAFETY OF PERCUTANEOUS TRACHEOSTOMY IN PATIENTS WITH COAGULOPATHY OR THROMBOCYTOPENIA

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## Abstract

The safety and complications of percutaneous tracheostomy (PT) without bronchoscopic guidance in a group of ICU patients with thrombocytopenia (platelet count of  $\leq 60,000/\text{mm}^3$ ) or coagulopathy (INR  $\geq 1.5$  or systemic heparinization), was studied.

During the study period (May 2004-June 2005), 190 percutaneous tracheostomies were performed. Of these there were 11 (6%) patients with prolonged INR, 7 (4%) patients with thrombocytopenia and 14 (7%) patients on systemic heparin. There was no evidence of bleeding in patients with prolonged INR. A minor bleeding developed in only one patient with thrombocytopenia, and in two patients receiving systemic heparin. The PT was aborted for one patient with thrombocytopenia and slight increase of INR (1.3) due to major bleeding in spite of transfusion

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of both platelets and FFP. Our data suggest the incidence of bleeding is low in patients with coagulopathy and or thrombocytopenia-undergoing PT without bronchoscopic guidance.

**Keywords:** percutaneous tracheostomy, coagulopathy, thrombocytopenia, complications, Saudi Arabia.

## **Introduction**

Percutaneous tracheostomy (PT) is one of the most commonly performed procedures in critically ill patients requiring long-term mechanical ventilation and it continues to replace conventional surgical tracheostomy (ST) as the procedure of choice in intubated patients<sup>1,2</sup>. PT 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 an adequate airway<sup>3,4</sup>. 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<sup>5</sup>.

PT may offer several advantages over conventional surgical tracheotomy. PT can be 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<sup>1,3</sup>.

Despite its technical simplicity and safety, there are a number of recognized contraindications to PT including coagulopathy and thrombocytopenia<sup>6,7</sup>. Coagulopathy is common problem in ICU, and is usually associated with many disorders such as sepsis, liver disease, hematological disorder and anticoagulation treatment. Thrombocytopenia is reported in 23-27% of ICU patients<sup>8,9</sup>. It occurs frequently in critically ill patients and probably reflects the severity and progression of an underlying disease. Thrombocytopenia is associated with increased mortality and higher incidence of bleeding<sup>8,10</sup>. Few studies<sup>3,7</sup> have evaluated the safety of PT in obese patients and in most of these studies

bronchoscopy is used.

The routine use of bronchoscopy has been advocated as an adjunct to PT<sup>11,12</sup>. However bronchoscopy has risks as well, including decreased oxygenation and ventilation, particularly in patients with severe respiratory failure; loss of the airway has also been described<sup>13,15</sup>. There is a growing body of data supporting that PT can be safely performed without bronchoscopic guidance<sup>16-18</sup>.

The objective of our study was to examine the safety and complications of PT without bronchoscopic guidance in a group of ICU patients with coagulopathy or thrombocytopenia.

## Methods and Materials

This prospective study was conducted in a 21 beds, medical and surgical ICU in a 800-bed tertiary care teaching hospital in Riyadh, Saudi Arabia. This ICU is closed unit, run by in-house full-time board-certified intensivists, with more than a thousand admission per year.

All consecutive patients who underwent PT between May 2004 – June 2005 were included.

Consent for tracheostomy was obtained as a standard practice, the study was approved by Institutional Board Review.

Contraindication to bedside PT included visible blood vessels in the operative field, unstable cervical spine, active cutaneous infection and age less than 16 years.

Patients were prospectively identified as being coagulopathic (INR  $\geq 1.5$  or systemic heparinization) or thrombocytopenic (platelet count  $\leq 60.000/\text{mm}^3$ ).

Patients with a high INR or thrombocytopenia received fresh frozen plasma FFP or platelet transfusion respectively at the discretion of the treating physician. In both cases, prophylactic or therapeutic unfractionated heparin was held 6 hours before the procedure, data were collected on patient age, sex.

Acute Physiology and Chronic Health Evaluation III (APACHE III) score<sup>19</sup>, the duration of mechanical ventilation prior to the tracheostomy, the coagulation profile on the day of the procedure (including platelet count, International Normalized Ratio (INR) and the use of bronchoscopic guidance were documented. Complications of PT in both groups were monitored as listed under complications. All patients were followed until ICU discharge or death.

### **The PT Procedure**

The PT procedures were routinely performed without bronchoscopic guidance. In selected cases, bronchoscopy was used upon the discretion of the treating intensivist.

Two physicians performed all PT procedures at the bedside, one of them was a critical care consultant and the other was a consultant, critical care fellow or ICU rotating resident. Before starting the procedure, sedation and muscle relaxation were achieved through the use of intravenous agents (midazolam, fentanyl, propofol and cisatracurium) at the discretion of treating intensivist.

#### *The technique of the Ciaglia “Single-Step Dilation” Tracheostomy*

The tip of the endotracheal tube was withdrawn into larynx. A 14-gauge angiocatheter was introduced through the middle anterior tracheal wall between tracheal rings 2 and 3 or rings 3 and 4. Free aspiration of air and bubbling of fluid placed over the hub of the cannula during ventilation confirmed correct placement. A guide-wire was placed through the angiocatheter. Transverse skin incision was made 1 cm across the guide-wire then trachea was punctured with small dilator over guide wire, and then a tapering dilator was introduced over the guide wire until the stoma was dilated to an aperture of 36 F. The dilator was withdrawn, and the tracheostomy tube was inserted. Accurate tracheostomy position was confirmed by auscultation, capnography and by exhaled tidal volume. Chest X-ray was obtained after procedure.

## Complications

Complications included the following: bleeding, aborting the procedure, accidental extubation, conversion to surgical PT, paratracheal placement transient hypoxia (an increase in  $\text{FiO}_2$  of  $> 10\%$  to achieve the pre-procedure oxygen saturation), subcutaneous emphysema and transient hypotension, and the development of pneumothorax or death. Bleeding was subdivided into major and minor, major bleeding (requiring blood product transfusion or surgical intervention), minor bleeding (requiring pressure dressing or suturing).

## Statistical Analysis

Statistical analysis was performed using Minitab for windows. Release 12.1 (State college, PA, USA), Continuous data was presented as means and standard deviations (SD). Normality of distribution was tested using Kolmogorov-Smirnov Normality test. (Categorical data was presented as proportions with 95% confidence intervals [CIs].

## Results

During the study period, 190 PT were performed. Of these 11 (6%) patients with prolonged INR, 7 (4%) patients with thrombocytopenia and 14 (7%) patients on systemic heparin for pulmonary embolism or renal replacement therapy. Only one patient had both coagulopathy and thrombocytopenia. All patients who had coagulopathy or thrombocytopenia underwent PT without bronchoscopic guidance.

The mean  $\pm$  standard deviation (SD) age of patients with prolonged INR and thrombocytopenia were  $62 \pm 18$  and  $61 \pm 16$  years, respectively. The mean  $\pm$  SD of INR and thrombocytopenia were  $1.57 \pm 0.08$  and  $50.000/\text{mm}^3 \pm 1200$  respectively (Table 1).

Table 1  
Demographics data

Characteristics	High INR	Thrombocytopenia
Number of Patients	11	7
INR*	1.57 ± 0.08	1.18 ± 0.21
Platelets count* (mm <sup>3</sup> )	214000 ± 125000	50.000 ± 12000
Age* (Y)	62 ± 17	61 ± 17
Male <sup>†</sup>	8 (72%) [39-94]	4 (57%) [18-90]
APACHE III	82 ± 36	111 ± 37
Duration on MV prior to tracheostomy (D)*	12 ± 7	11 ± 9
Number of patients attempted to be extubated <sup>†</sup>	4 (36%) [11-69]	2 (28%) [4-71]
GCS on the day of tracheostomy*	8 ± 3	7 ± 3

\* Mean ± standard deviation, <sup>†</sup> N (%) [Confidence interval CI], INR: international normalized ratio, APACHE III: Acute physiology and chronic health evaluation III, MV: mechanical ventilation, GCS: Glasgow Coma Score

High INR (INR ≥ 1.5); Thrombocytopenia (platelet ≤ 60.000/mm<sup>3</sup>).

The Glasgow Coma Score of patients with either high INR or thrombocytopenia on the day of tracheostomy was 8 ± 3 and 7 ± 3, respectively. Only four patients (36%) with high INR received FFP, three patients received 4 units of FFP and the fourth one received 6 units of FFP. Three patients (43%) with thrombocytopenia received platelets (two of them received 6 units and the third received 12 units platelets). The majority of the patients were medical (Table 2).

Table 2  
Underlying disease of patients with coagulopathy

Disease	High INR group	Thrombocytopenia
Liver failure	4 (36%) [11-69]	3 (42%) [10-82]
Pneumonia	3 (27%) [6-61]	1 (14%) [0.4-58]
CVA	3 (27%) [6-61]	
Sepsis	1 (9%) [0.3-41]	2 (28%) [4-71]

N (%) [Confidence interval CI], INR: international normalized ratio, CVA: Cerebral vascular accident.

Despite the coagulation and platelet abnormalities in our patients, the number of bleeding complications was minimal (Table 3). There was no evidence of bleeding in patients with prolonged INR. A minor bleed developed in only one patient with thrombocytopenia, and in two patients receiving systemic heparin, which was controlled by a pressure dressing in spite of holding the heparin 6 hours before the procedure. The PT was aborted for one patient with thrombocytopenia and slight increase of INR (1.3) due to major bleeding in spite of transfusion of both platelets and FFP.

Beyond the above noted bleeding episodes. No other complications were noted.

*Table 3*  
*The bleeding complications*

Characteristics	High INR	Thrombocytopenia	Systemic heparin
No of patients	11	7	14
Major bleed*	0 [0-25]	1 (14%) [.04-58]	0 [0-23]
Minor bleed*	0 [0-25]	1 (14%) [.04-58]	2 (14%) [2-43]
FFP transfused	1.6 ± 2.3		
Platelets transfused		3.4 ± 4.7	

N (%), [Confidence interval CI], INR: International Normalized Ratio, FFP: Fresh Frozen Plasma.

None of these patients with coagulopathy or thrombocytopenia required bronchoscopic guidance during or post the procedure.

## Discussion

Our study demonstrates a low incidence of bleeding that occurred in only 4 (12%) patients with coagulopathy and or thrombocytopenia-undergoing PT without bronchoscopic guidance and in overall demonstrates a low complication rate.

Bleeding complication rates associated with PT vary, with a reported incidence from 0 to 12%<sup>1,20</sup>. In our study, the risk of bleeding was

minimal, minor bleeding occurred in only 3 patients (9%) and major bleeding in only one patient (3%) (Table 3). To our knowledge this is the first study conducted to evaluate the complication rates in patients with coagulopathy and thrombocytopenia undergoing PT without bronchoscopic guidance.

Few studies in the literature focused on patients with coagulopathy and thrombocytopenia requiring tracheostomy. The most recent and relevant study by Kluge et al<sup>8</sup> reviewed 42 patients with thrombocytopenia (platelets less than 50,000/mm<sup>2</sup>) who underwent PT using Griggs method with bronchoscopic guidance. These investigators reported that this approach is safe in this group of patients. Patients received an average 6 units of platelets before the procedure and heparin infusion was temporally interrupted during the procedure. This study reported major bleeding requiring suturing in 2 patients (5%) and minor bleeding in 3 patients (7%). The majority of these patients were suffering from acute respiratory insufficiency after bone marrow transplantation (BMT) or hematological malignancies.

Blankenship et al<sup>3</sup> studied 54 patients who underwent PT using bronchoscopic guidance. Patients were prospectively identified as being high risk if they were coagulopathic (INR > 1.5, heparin infusion or platelets count less than 20,000/mm<sup>3</sup>) or morbidly obese; all other patients were considered low risk. The high-risk group had a mean estimated blood loss of 7.8 ml; whereas the mean estimated blood loss in the low risk group was only 5 ml (P = 0.22 for the difference). There was no major bleeding that required intervention or conversion to surgical tracheostomy. Information about number of units of FFP transfusions were lacking in this study.

Few studies have discussed patients with coagulopathy undergoing PT but with lacking data about bleeding complications. Beiderlinden et al<sup>13</sup> studied the complications of PT in 133 patients. Fifty-five patients had thrombocytopenia (platelets less than 60,000/mm<sup>3</sup>). This study did not provide the incidence of bleeding in this subgroup. Another study<sup>21</sup> reported 55 patients out of 203 with thrombocytopenia (platelets less than 60,000), again without providing the incidence of bleeding, transfusion

requirements or general complications in this subgroup. In two case reports<sup>22,23</sup>, the safety of PT in patients with thrombocytopenia and coagulopathy was demonstrated (Table 4).

*Table 4*  
*Studies describing bleeding complications in patients with coagulopathy undergoing percutaneous tracheostomy.*

Study	Type of study	Number of patients	Type of coagulopathy	Bronchoscopic guidance use	Major bleed	Minor bleed	Comment
Blankenship et al <sup>3</sup> 2005	Prospective	9	INR > 10.5, platelets < 20000/mm <sup>3</sup> or systemic heparin	Yes			No blood loss difference between two groups (high vs, lower risk)
Kluge et al <sup>8</sup> 2004	Retrospective	42	INR > 1.5, platelets < 50000/mm <sup>3</sup>	Yes	5%	7%	Majority of patients post BMT or hematological malignancy
Byhan et al <sup>6</sup> 200	Case report	2	Hemophilia A patients	Yes		100%	Case report of patients with hemophilia A
Maxwell et al <sup>22</sup> 1996	Case report	1	Platelets count 14000/mm <sup>3</sup>	Yes			Case report of a patient with bone marrow transplant
Aldwood et al 2006	Prospective	32	INR ≥ 1.5, platelets ≤ 60000/mm <sup>3</sup> or systemic heparin	NO	3%	9%	Study conducted in mixed ICU

INR: International normalized ratio, BMT: bone marrow transplantation, ICU: Intensive Care Unit.

Controversy overshadows the use of routine bronchoscopic guidance during PT. Bronchoscopy, as an adjunct to PT was not used until 1989. Since that time, many studies have advocated its use citing a decreased rate of operative complications<sup>11</sup>. Bronchoscopy has been advocated to enhance safety and avoid injury to adjacent structures including great vessels of the neck as well as paratracheal insertions and also to confirm the right positioning of the guide wire and the tube<sup>2,16</sup>.

However, use of bronchoscopy may impair ventilation and can result in hypercarbia, respiratory acidosis and hence increased intracranial

pressure<sup>13-15</sup>. Reilly and coworkers<sup>14</sup> conducted a prospective clinical trial to characterize and quantify the occurrence of hypercarbia and respiratory acidosis during PT with or without bronchoscopic guidance on twenty patients. They found increase in PaCO<sub>2</sub> in PT with and without bronchoscopic guidance by  $24 \pm 3$ ,  $8 \pm 2$  mmHg,  $P < 0.05$  respectively. Reilly and coworkers<sup>15</sup> described a case series of 3 patients underwent PT with bronchoscopic guidance with monitoring PaCO<sub>2</sub>, pH and intracranial pressure (ICP). They found marked elevations in PaCO<sub>2</sub> during the procedure and also elevation of ICP on a patient with ICP monitor. All these changes were transient and well tolerated by the patients. In addition, it has been suggested that bronchoscopic guidance might not be necessary and that its use may contribute to increased cost and delay<sup>18</sup>. On the other hand many studies<sup>16-18</sup> have demonstrated the safety of PT without bronchoscopic guidance. Paran et al<sup>16</sup> conducted an observational clinical study of modified PT, in which limited blunt dissection of the subcutaneous tissues is performed before the puncture is done without bronchoscopic guidance. Over 30 months, 61 procedures were attempted. Three procedures (4.9%) were deferred due to anatomic problems. They found that the PT is simple, safe and relatively easy to learn. PT saved costs, operating room burden, and carried low morbidity rates. Of note, the operators in this study were trained surgeons.

Mallick et al<sup>17</sup> conducted a randomized trial in which 55 patients were allocated to either bronchoscopy or capnography for confirmation of needle insertion, with comparable results in each group. Similar findings were shown previously by Maddali and co workers<sup>18</sup> who conducted a retrospective analysis of 78 patients who underwent PT without bronchoscopic guidance. These investigators showed it can be performed safely and speedily if simple precautions like ensuring free aspiration of air on needle insertion into trachea, bubbling of fluid placed over the hub of the cannula during ventilation and free mobility of guide wire at each step of the procedure. None of the foregoing studies commented on bleeding complication rates.

It is important to note the effect of learning curve on PT in high-risk patients. Massick and coworkers<sup>24</sup> examined the complication in the first

100 PT procedures. They found that these patients had significantly higher perioperative complication and post complication rates, but these complications occurred during the first 20 cases of PT performed in local community hospital. The authors concluded that the complications were related to the learning curve. This factor is important to keep in mind in all studies examining the safety of PT. In our ICU, the PT is performed routinely for > 10 years with a large yearly volume. Nearly 15% of the 1000 patients admitted yearly require tracheostomy, 85% of which are performed percutaneously. Therefore, all operators have acquired large cumulative experience with bedside PT.

Our study demonstrates that in the majority of patients with coagulopathy or thrombocytopenia, PT can be performed safely without bronchoscopic guidance. Whether bronchoscopy adds a significant advantage needs further evidence. Most recommendations are based on observational studies and expert opinions. Up to date, there is no multicenter randomized controlled trial comparing the safety bronchoscopic and non bronchoscopic-guided PT in high-risk patients such as patients with coagulopathy or thrombocytopenia.

Our study has several strengths. Our data were collected prospectively. This ICU is run under a closed system and is staffed mainly by Critical Care Board certified intensivists, which increases the homogeneity of clinical management. The ICU has a long-standing history of performing PT. On the other hand our study has some limitations. The study was conducted in only single center and the sample size is small. The coagulation profile and platelets count were not available after transfusion.

In summary, we found that PT without bronchoscopic guidance appears to be safe. The complication rates were low in patients with coagulopathy and thrombocytopenia when performed by ICU physicians.

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