Pre-Procedural Ultrasonography for Tracheostomy in Critically Ill Patients: A Prospective Study

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ABSTRACT: **Background:** Percutaneous dilatational tracheostomy (PDT) has become a standard technique for critically ill patients who require long-term ventilation. The most common early postoperative complication is bleeding related to anatomical variation in vasculature. The procedure is performed at the patient's bedside unless this is deemed unsafe and then the accepted alternative is open tracheostomy in the operating room.

Objectives: To evaluate the use of pre-procedural ultrasound to aid in the decision of whether PDT in critical care patients should be performed at the patient's bedside or by open surgical tracheostomy.

Methods: Patients were jointly evaluated by a critical care physician and a head and neck surgeon. Based on this evaluation, the method of tracheostomy was determined. Subsequently, pre-procedural ultrasound examination of the anterior neck was performed. The final decision whether to perform PDT or open surgical tracheostomy was based on the ultrasound findings. Changes in management decisions following ultrasound were recorded.

Results: We included 36 patients in this prospective study. Following ultrasound examination, the management decision was changed in nine patients (25%).

Conclusions: Pre-procedural ultrasound for critically ill patients undergoing tracheostomy can influence management decisions regarding the performance of tracheostomy.

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KEY WORDS: percutaneous dilatational tracheostomy (PDT), ultrasound, post-operative complication, open tracheostomy, critical care

Tracheostomy is a commonly performed procedure in critically ill patients who require long-term ventilation. Percutaneous dilatational tracheostomy (PDT) was first described by Ciaglia et al. in 1985 [1]. It has since become a standard technique [2,3] and now supersedes open surgical tracheostomy for all but the most complicated cases. It is considered to be a minimally invasive procedure that is performed at the patient's bedside in the intensive care unit [4]. The time required to perform bedside PDT is considerably shorter than that required for performing an open tracheostomy [5]. Bedside PDT prevents the need to schedule an operating room and anesthesiology team and also avoids the hazards of transportating of critically ill patients. The cost of open surgical tracheostomy is approximately double the cost of PDT [2].

Although overall complication rates are low, PDT remains one of the few procedures routinely undertaken in intensive care units where serious adverse events, including death, are still reported [4,6]. The blind technique of the procedure and restricted possibilities in diagnosis of anatomic variations may lead to significant complications. In an autopsy study, Sustic et al. [7] found a 33% rate of tube misplacement in patients with favorable cervical anatomy.

The most common early postoperative complication is bleeding [8]. Most serious bleeding complications relate to unrecognized and unanticipated anatomical variation in vasculature [9,10] or to tracheal tube erosion into adjacent vasculature in the case of late bleeding complications, which are thought to be related to initial tracheal tube malposition [2,11]. The procedure-related death rate for PDT has been estimated to be 0.6% [12,13].

Various techniques have been explored to enhance precision and safety of PDT. Bronchoscopic guidance during the procedure has been widely used as an additional safety adjunct to confirm intra-tracheal placement of the guide wire before the tract is dilated [14]. This technique, however, provides little additional assistance in appropriately positioning the initial puncture site or avoiding aberrant vessels [6]. Pre-procedural and real-time intra-procedural ultrasound guidance have been advocated as potential tools to further improve the safety of the procedure [12,15,16]. Several studies have demonstrated the value of ultrasound mapping of the neck region prior to PDT [15,17,18]. Ultrasound examination often modifies the puncture site with respect to that chosen solely on the basis of anatomical palpation data [6,19,20]. Traditionally, the procedure is performed at the patient's bedside in the intensive care unit, and if this is deemed unsafe, the accepted alternative is open tracheostomy in the operating room. The objective of this study was to evaluate the use of pre-procedural ultrasound to aid in the decision whether tracheostomy in critical care

patients should be performed by PDT at the patient's bedside or by open surgical tracheostomy in the operating room. We hypothesized that ultrasound imaging would change the above decision in a significant number of cases.

PATIENTS AND METHODS

A prospective study was carried out in accordance with the code of ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans and was approved by the Human Experimentation Ethics Committee of the Ziv Medical Center.

Patients were recruited through the intensive care unit at Ziv Medical Center. All patients or legal guardians were given a full explanation of the study by an experienced member of the research team before recruitment. Informed consent was obtained from the patients who participated in the investigation or from their legal guardians. Adults aged 18 years or older undergoing tracheostomy were included in the study. Exclusion criteria included age younger than 18 years, lack of consent, coagulopathies that could potentially cause intra-procedural or post-procedural bleeding, and cervical spine precautions. After the decision to perform tracheostomy, the patients were jointly evaluated by an experienced critical care physician and a head and neck surgeon. Based on these evaluations, the method of tracheostomy (PDT or open surgical tracheostomy) was determined. Subsequently, pre-procedural ultrasound examination of the anterior neck was performed by an experienced head and neck surgeon, trained in cervical ultrasonography (EE). A SonoSite Titan™ portable ultrasound machine (Sonosite Inc, Bothell, WA, USA) with a 5–8 MHz microconvex transducer was used. Doppler ultrasound imaging was performed on patients with aberrant vascularity to determine arterial or venous origin. The final decision whether to perform PDT or open surgical tracheostomy in the operating room was based on the ultrasound findings. Changes in management decisions following ultrasound were recorded. PDT was performed using a standard tapered dilator technique (Portex Ultraperc, Smiths Medical, Kent, UK). Neither bronchoscopic nor intra-procedural ultrasound guidance was used. All adverse events and perioperative complications were recorded. Demographic data were also collected.

STATISTICAL METHODS

For categorical variables a summary is provided giving sample size and relative frequencies. The Pearson chi-square test was applied for testing the correlations between the study groups for the categorical parameters. Table 1 shows demographic data of study participants, grouped by management decision. Mann–Whitney non-parametric tests were applied for testing differences in the study groups for quantitative parameters. *P* values of 5% or less were considered statistically significant. The data were analyzed using the SPSS software, version 20 (SPSS Inc. Chicago, IL, USA).

Table 1. Demographic data of study participants, grouped by participants with and without a change in management decision

	All patients (n=36)		No change in management decision (n=27)		Change in management decision (n=9)		
	Mean	SD	Mean	SD	Mean	SD	*P*
Gender, male	20	55.6	17	63.0	3	33.3	0.245*
Age (year)	70.7	14.9	71.1	15.8	69.4	12.4	0.661**
Hospitalization (days)	13.7	5.6	13.7	5.8	13.6	5.3	0.998**
Mechanical ventilation (days)	11.6	5.0	11.9	5.3	10.8	4.1	0.620**
Waiting for tracheostomy (days)	1.7	1.8	1.7	1.9	1.7	1.3	0.748**

*chi-square

**Mann–Whitney non-parametric test

SD = standard deviation

RESULTS

Our study population was a convenience sample, as participants were only recruited when the prime investigator was physically present at the hospital. Between May 2014 and November 2015, 48 critical care patients were deemed suitable for participation in the study. Twelve patients met exclusion criteria and 36 were included in this prospective study. Demographic data, grouped by management decision, are presented in Table 1. There were no significant demographic differences between patients with and without a change in management decision. The results of the physical examination and the ultrasound examination are detailed in Table 2. According to preoperative physical examination, 25 patients (69.4%) were allocated for PDT and 11 patients (30.6%) were allocated for open surgical tracheostomy. Following ultrasound examination, the management decision was changed in nine patients (25%). Five patients (13.9%) who were originally scheduled to undergo open surgical tracheostomy successfully underwent bedside PDT with no complications. In four patients (11.1%), the original decision to perform PDT was changed to open surgical tracheostomy. Complications, which occurred in four patients (11.1%), included delayed minor bleeding 3 days following surgery in two patients from the PDT group, mild subcutaneous emphysema 2 hours after surgery in one patient from the PDT group and a tracheostomy site infection in one patient from the open tracheostomy group. None of these complications necessitated any additional surgery. The mean age of patients suffering complications was 77.5 years. None of the four patients with complications had a management decision change following ultrasound.

DISCUSSION

In a survey of the membership of the American Academy of Otolaryngology–Head and Neck Surgery [21], 55% of respondents reported caring for at least one patient with a catastrophic event related to a tracheostomy. Of these, 34.3% involved accidental de-cannulation and 31.6% involved bleeding. Minor bleeding during the performance of PDT has been reported to occur in less than 20% of cases. Major bleeding occurred in less than 5% of cases and was usually venous [10]. Catastrophic hemorrhage is rare, usually delayed and in most cases is the result of a tracheo-innominate artery fistula [22]. Fatal intra-operative complications of PDT are extremely uncommon and almost all result from vascular injury [4]. Several studies have emphasized the value of pre-PDT ultrasound examination of the neck region to reduce the incidence of complications [12,15,17,18]. Ultrasound can provide information about variations in neck anatomy, measure the distance from skin to trachea and identify bleeding structures such as the thyroid isthmus, anterior jugular and inferior thyroid vessels [16]. Case selection for PDT or open surgical tracheostomy is of great importance. PDT, even if performed correctly, involves temporary loss of a secure airway. If a difficult intubation or a difficult procedure are anticipated, it may be preferable not to attempt PDT, but rather to perform open surgical tracheostomy without first attempting PDT [4].

The purpose of this study was to evaluate the use of pre-procedural ultrasound for examination of the anterior neck prior to PDT. Our results indicate that ultrasound can change the decision of how and where to perform tracheostomy in critical care patients. Yavuz et al. [23] found that pre-incisional ultrasound led to the reconsideration of the puncture site in 23.8% of cases and to a conversion from PDT to open tracheostomy or vice versa in 9% of cases, with revision from open surgical tracheostomy to ultrasound-guided PDT after ultrasound examination in 6 of 166 patients (3.6%) and revision from ultrasound-guided PDT to surgical tracheostomy after ultrasound examination in 9 of 166 patients (5.4%). The perioperative complication rates were slightly lower in the ultrasound group, although not significantly so. These results differ from our 25% rate of change in management decision following ultrasound. The reasons for this difference are not clear. The ultrasound was performed by a radiologist and not a head and neck surgeon or critical care physician, which meant the involvement of another member of staff from a different department. Our study involved ultrasound performed by a clinician directly involved in the patient's care, thereby simplifying the process and minimizing logistic difficulties.

In the same study by Yavuz and colleagues [23], two patients were initially allocated to PDT, but the procedure could not be successfully completed after multiple puncture attempts. These patients were referred for open surgical tracheostomy. In our study, 11 patients (30.5%) were transferred to the operating room for open surgical tracheostomy. No emergency transfers of patients to the operating room were required. A possible limitation of this study is the small sample size, which did not enable accurate evaluation of intra- and postoperative complication rates compared to a control group or to a historic control.

Table 2. Study results grouped by participants with and without a change in management decision

	All patients (n=36)		No change in management decision (n=27)		Change in management decision (n=9)		
	N	%	N	%	N	%	*P**
Procedure performed							
PDT	25	69.4	21	77.8	4	44.4	0.060
OST	11	30.5	6	22.2	5	55.6	
Neck extension	17	47.2	13	48.1	4	44.4	0.577
Good	19	52.8	14	51.9	5	55.6	
Limited							
Cervical scars	29	80.6	23	85.2	6	66.7	0.333
Absent	7	19.4	4	14.8	3	33.3	
Present							
Cervical subcutaneous fat							
None	23	63.9	17	63.0	6	66.7	0.555
Small amount	9	25.0	6	22.2	3	33.3	
Large amount	4	11.1	4	14.8	0	0	
Skin to trachea distance by ultrasound							
‹ 1 cm	14	40.0	11	40.8	3	33.3	0.892
1–2 cm	12	34.3	9	33.3	3	33.3	
› 2 cm	9	25.7	7	25.9	3	33.3	
Palpable pulsating cervical blood vessels							
Absent	32	88.9	24	88.9	8	88.9	0.745
Present	4	11.1	3	11.1	1	11.1	
Cervical midline blood vessels by ultrasound							
None	26	74.3	21	80.8	5	55.6	0.114
Vein	7	20.0	3	11.5	4	44.4	
Artery	2	5.7	2	7.7	0	0	
Enlarged thyroid gland by physical examination	33	91.7	25	92.6	8	88.9	0.590
Enlarged thyroid gland by ultrasound	31	88.6	23	88.5	8	88.9	0.732
Trachea by physical examination							
Midline	35	97.2	27	100	8	88.9	0.250
Deviated	1	2.8	0	0	1	12.5	
Trachea by ultrasound							
Midline	33	94.3	25	96.2	8	88.9	
Deviated	2	5.7	1	3.8	1	11.1	0.454
Cricoid to supra-sternal notch distance by physical examination							
› 2 cm	14	38.9	10	37.0	4	44.4	0.698
1–2 cm	13	36.1	11	40.1	2	22.3	
0 cm	9	25.0	6	22.2	3	33.3	
Cricoid to second tracheal ring distance by ultrasound							
‹ 1 cm	15	44.1	12	48.0	3	33.3	0.018
1–2 cm	14	41.2	12	48.0	2	22.3	
› 2 cm	5	14.7	1	4.0	4	44.4	

*chi-square

PDT = percutaneous dilatational tracheostomy, OST = open surgical tracheostomy

CONCLUSIONS

Pre-procedural ultrasound for critically ill patients undergoing tracheostomy can influence the decision whether to perform bedside PDT or open surgical tracheostomy in the operating room. This choice could lead to increased safety in the performance of PDT, lessen the need for the transfer of critically ill patients to the operating room and prevent emergency transfer of patients with failed PDT from the intensive care unit to the operating room.

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Capsule

Long-term survival in glioblastoma with cytomegalovirus pp65-targeted vaccination

Patients with glioblastoma have a median survival rate of less than 15 months despite surgical resection, high-dose radiation, and chemotherapy with temozolomide. Previous studies demonstrated that targeting cytomegalovirus pp65 using dendritic cells (DC) can extend survival and, in a separate study, that dose-intensified temozolomide (DI-TMZ) and adjuvant granulocyte macrophage colony-stimulating factor (GM-CSF) potentiate tumor-specific immune responses in patients with glioblastoma. Now Batich et al. have evaluated pp65-specific cellular responses following DI-TMZ with pp65-DCs and determined the effects on long-term progression-free survival and overall survival. Following standard-of-care procedures, 11 patients with newly diagnosed glioblastoma received DI-TMZ (100 mg/m^2/d × 21 days per cycle) with at least three vaccines of pp65 lysosome-associated membrane glycoprotein mRNA-pulsed DCs admixed with GM-CSF on day 23 ± 1 of each cycle. Thereafter, monthly DI-TMZ cycles and pp65-DCs were continued if patients had not progressed. Following DI-TMZ cycle 1 and three doses of pp65-DCs, pp65 cellular responses significantly increased. After DI-TMZ, both the proportion and proliferation of regulatory T cells (Tregs) increased and remained elevated with serial DI-TMZ cycles. Median progression-free survival and overall survival were 25.3 months and 41.1 months exceeding survival using recursive partitioning analysis and matched historical controls. Four patients remained progression-free at 59 to 64 months from diagnosis. No known prognostic factors (age, Karnofsky performance status, *IDH*-1/2 mutation, and *MGMT* promoter methylation) predicted more favorable outcomes for the patients in this cohort. The authors conclude that despite increased Treg proportions following DI-TMZ, patients receiving pp65-DCs showed long-term progression-free survival and overall survival, confirming prior studies targeting cytomegalovirus in glioblastoma.

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