Medicine®

CLINICAL TRIAL/EXPERIMENTAL STUDY

OPEN

A Prospective Randomized Study Comparing Mini-surgical Percutaneous Dilatational Tracheostomy With Surgical and Classical Percutaneous Tracheostomy

A New Method Beyond Contraindications

Seyed Mohammad-Reza Hashemian, MD, FCCM and Hadi Digaleh, MD, the Massih Daneshvari Hospital Group

Abstract: Although percutaneous dilatational tracheostomy (PDT) is more accessible and less time-demanding compared with surgical tracheostomy (ST), it has its own limitations. We introduced a modified PDT technique and brought some surgical knowledge to the bedside to overcome some standard percutaneous dilatational tracheostomy relative contraindications. PDT uses a blind route of tracheal access that usually requires perioperational imaging guidance to protect accidental injuries. Moreover, there are contraindications in certain cases, limiting widespread PDT application. Different PDT modifications and devices have been represented to address the problem; however, these approaches are not generally popular among professionals due to limited accessibility and/or other reasons.

We prospectively analyzed the double-blinded trial, patient and nurse head evaluating the complications, and collected data from 360 patients who underwent PDT, ST, or our modified mini-surgical PDT (msPDT, Hashemian method). These patients were divided into 2 groups—contraindicated to PDT—and randomization was done for msPDT or PDT in PDT-indicated group and msPDT or ST for PDT-contraindicated patients. The cases were compared in terms of pre and postoperational complications.

Data analysis demonstrated that the mean value of procedural time was significantly lower in the msPDT group, either compared with the standard PDT or the ST group. Paratracheal insertion, intraprocedural hypoxemia, and bleeding were also significantly lower in the msPDT group compared with the standard PDT group. Other complications were not significantly different between msPDT and ST patients.

The introduced msPDT represented a semiopen incision, other than blinded PDT route of tracheal access that allowed proceduralist to withdraw bronchoscopy and reduced the total time of procedure. Interestingly, the most important improvement was performing msPDT on PDT-contraindicated patients with the complication rate comparable to surgical procedure. Supplements citation missing in the text. Please check supplements video in original manuscript.

(*Medicine* 94(47):e2015)

Abbreviations: ARDS = acute respiratory distress syndrome, BDT = balloon dilation technique, FiO_2 = fraction of inspired oxygen, GWDF = guidewire dilating forceps, ICU = intensive care unit, INR = international normalized ratio of prothrombin time, IPF = idiopathic pulmonary fibrosis, MAP = mean arterial pressure, MDT = multiple dilator technique, msPDT = mini-surgical PDT, PDT = percutaneous dilatational tracheostomy, PEEP = positive end-expiratory pressure, PTT = partial thromboplastin time, RDT = rotational dilation technique, SaO_2 = arterial O_2 saturation, SSDT = ingle-step dilatation technique, ST = surgical tracheostomy.

INTRODUCTION

Percutaneous (dilatational) tracheostomy (PDT) was first introduced by Sheldon in 1957[1] and decades later gained acceptance as an alternative to surgical tracheostomy (ST) in intensive care units (ICUs). Nonstop advancement of PDT techniques, with widespread access to its instruments and the application of bronchoscopy in the procedures, moved PDT progressively forward to become a golden standard over surgical procedure.[2] This was because of bedside operation with minimal resources and less time-demanding nature, still preserving the safety and efficacy of ST. As recently reviewed by Putensen et al,[3] multiple dilator technique (MDT) and single-step dilatation technique (SSDT) take the round from guidewire dilating forceps (GWDFs) due to lower traumatizing dilation and minor bleeding, although they are associated with more risk of intraprocedural technical difficulties. Later, modified techniques, rotational dilation technique (RDT), and balloon dilation technique (BDT) became less popular because of higher failure rates and/or complications.[4]

Considering studies on PDT growth, specifically those comparing PDT with ST, it became more apparent that PDT is associated with the high risk of morbidity and mortality in certain patients, assuming as relative contraindication to PDT. These contraindications include high positive end-expiratory pressure (PEEP) or fraction of inspired oxygen (FiO_2) requirement, difficult anatomy (eg, marked obesity, thick short neck, and tracheal deviation), coagulopathy, emergency procedures,

Editor: Mohan Gurjar.
Received: July 15, 2015; revised: October 11, 2015; accepted: October 18, 2015.
From the Chronic Respiratory Diseases Research Center, National Research Institute of Tuberculosis and Lung Diseases, Shahid Beheshti University of Medical Sciences, Tehran, Iran.
Correspondence: Seyed Mohammad-Reza Hashemian, Chronic Respiratory Diseases Research Center, National Research Institute of Tuberculosis and Lung Diseases, Shahid Beheshti University of Medical Sciences, Tehran, Iran (e-mail: iran.criticalcare@yahoo.com, smrhashemian@sbmu.ac.ir).
Massih Daneshvari Hospital Group consists of (1) Critical Care Group—Hamidreza Jamaati, Majid Malik-Mohammad, Behrooz Farzanegan, Mehdi Ghahramani, Shahab Kalantar, Omid Mirhoseini, Seyed Pouzhia Shojaee, Maryam Movaffaghi, Seyed Amir Mohajerani; (2) Surgical Group—Ghasem Abolghasem Daneshvar Kakhaki, Seyed Reza Saghebi, Seyed Ali Safavi Naeeni; and (3) Department of Statistics—Batoul Khoundabi.
The authors declare no conflicts of interest.
Copyright © 2015 Wolters Kluwer Health, Inc. All rights reserved.
This is an open access article distributed under the Creative Commons Attribution-NoDerivatives License 4.0, which allows for redistribution, commercial and non-commercial, as long as it is passed along unchanged and in whole, with credit to the author.
ISSN: 0025-7974
DOI: 10.1097/MD.0000000000002015

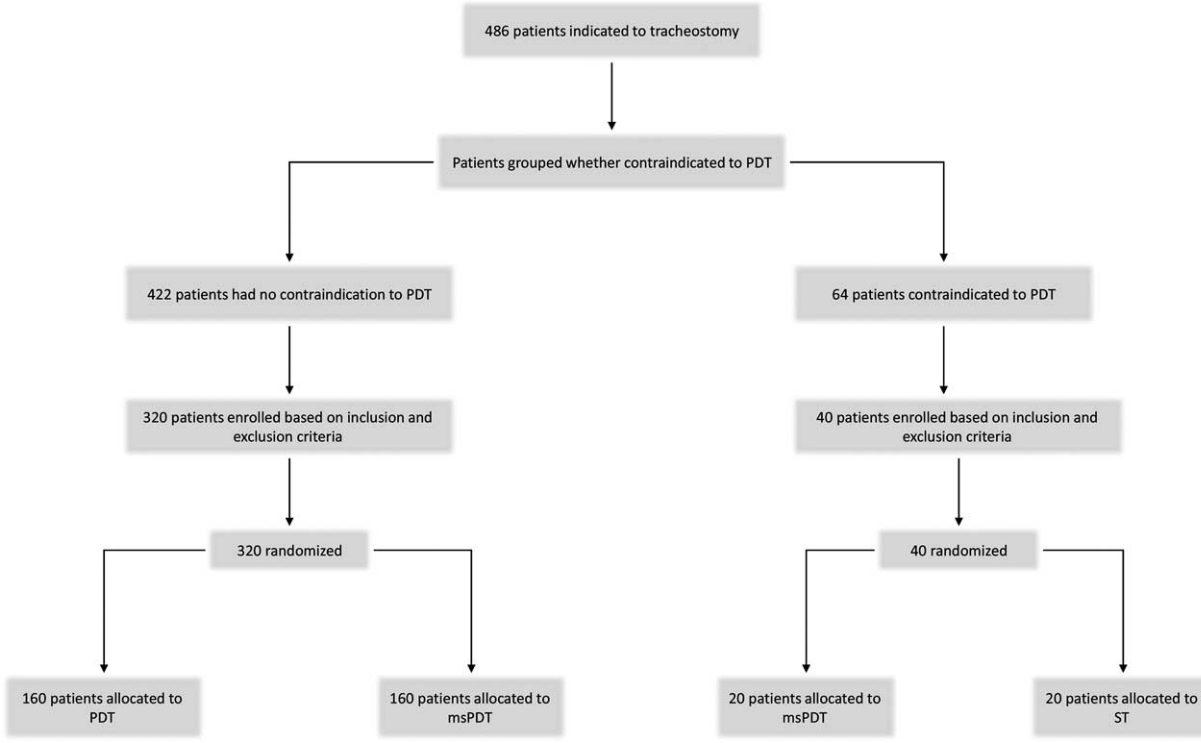

FIGURE 1. Flow diagram.

and hemodynamic instability.[5] The need for better visualization of local neck anatomy and more control of oxygenic/hemodynamic stability made ST as the safest method in some critical situations. Interestingly, experience, technical improvement, and newly designed devices allowed some experts to cross the limitations and perform PDT on complicated cases, beyond contraindications.[6,7] These studies, however, relied on highly experienced hands or complex/costly instruments, which are not well examined, and also the fundamental risks which still exist and are not resolved. Here, we introduce our modified mini-surgical technique (msPDT, Hashemian method), incorporating bedside and surgical experiences, to overcome common PDT limitations. Our purpose was to compare a number of preoperational and short-term postoperational complications of msPDT with well known methods of ST and Ciaglia PDT.

MATERIALS AND METHODS

Patients

Having obtained the approval from the University of Shahid Beheshti review board and the research ethics committee of Massih Daneshvari Hospital, we prospectively analyzed the data from 360 patients who underwent tracheostomy during a 5-year period (April 2009 to June 2014, registered with ID number IRCT2015040120592N3 in *www.irct.ir*). All available 486 patients were from ICU unit at Massih Daneshvari Hospital, an educational and university affiliated hospital. According to msPDT application on previous patients who either underwent ST or percutaneous tracheostomy, we decided to compare msPDT with both ST and PDT in 2 independent groups. Three hundred and sixty patients selected, based on inclusion and exclusion criteria, were grouped in PDT/msPDT group as PDT-indicated patients and in ST/msPDT group as PDT-contraindicated patients (Fig. 1). The inclusion criterion in PDT-indicated group was traditional indication to tracheostomy, along with having none of absolute or relative contraindications to PDT. In this group, both PDT and msPDT, after randomization, were conducted by a single attending physician (Seyed Mohammad-Reza Hashemian) with the aid of an intensive care fellow for PDT. Inclusion criterion in the PDT-contraindicated group was also indication to tracheostomy and concomitant with relative contraindication to PDT (coagulopathy, high PEEP or FiO_2 requirement, difficult anatomy, and hemodynamic instability). In PDT-contraindicated patients, after randomization, msPDT was conducted by the same team in the PDT-indicated group and ST was performed by an independent surgical team. Although there was no exclusion for the ST, our exclusion criteria in both groups were the patients $\leq$18 years of age, those on whom a nonstandard Ciaglia Tracoe Percutan single dilator kit was used, absolute contraindications to PDT (those performed emergently, having previous tracheostomy scar, severe infection at the puncture site, or cervical spinal injury that had not been internally fixed), and whom sufficient medical records could not be obtained from.

Since the department performed almost all tracheostomies by means of PDT (except absolute PDT contraindications) since 2013, almost all randomizations were done before this time, and, accordingly, the earlier open surgical and classical PDT groups were considered historical controls. As the timeline shows (Fig. 2), all analyses on PDT-indicated patients were obtained before 2010, due to retraction of classical PDT by institution after this time. Data from PDT-contraindicated patients were from the analysis period (2009–2014); however, lower numbers of patients were randomized for ST or msPDT after 2013, because of msPDT admission and application to

Copyright © 2015 Wolters Kluwer Health, Inc. All rights reserved.

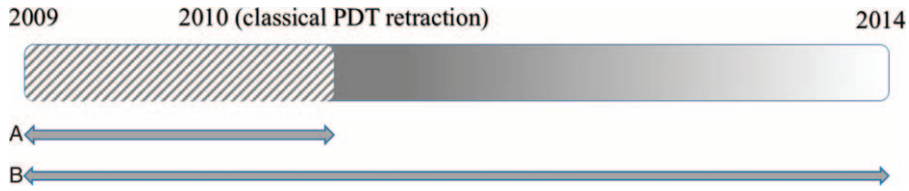

FIGURE 2. Selected patients in specific period of time were grouped in (A) indicated to PDT and (B) contraindicated to PDT. Following cases were randomized for msPDT or PDT procedure in group A and msPDT or ST in group B. msPDT = mini-surgical percutaneous dilatational tracheostomy, ST = surgical tracheostomy.

almost all nonabsolute PDT-contraindicated patients before 2013. Randomization was done for the selected patients to undergo msPDT or PDT in PDT-indicated group and msPDT or ST in PDT-contraindicated group. Considering the route of selecting contraindicated patients and randomization for surgical or msPDT, it lasted 5 years to roll up patients matching to the mentioned criteria. We stopped collecting data as the number of patients in PDT-contraindicated group reached a satisfactory number for analyzing the new modified PDT method done on PDT-contraindicated patients.

Randomization

In this study, the statistical analyzer generated random allocation sequence. The nurse head in ICU was responsible for enrolling and assigning, although she/he did not take part in the study and was blinded to none of the surgical operations, analyses, variables measurement, or patient care steps. Some part of data that could be collected blinded to the operation, including intraoperative/postoperative bleeding (by gauze weight quantification method), hypotension, and hypoxia (assessed by postoperative recheck of monitoring devices), were collected by a nurse, assigned by the nurse head and blinded to the operation. The remaining collected data (such as cuff leak) could not be blinded by the collector. Patients and operators were not blinded to the route of tracheostomies. Nevertheless, as the whole complication assessed was perioperative and objective, we proposed that patient blinding was not necessary in the study. In this regard, the data collector and analyst were the only individuals blinded in the trial (double-blinded trial).

Block randomization was used for achieving equal sample sizes in each group. For example, in ST/msPDT comparison, the process involved recruiting participants in short blocks and ensuring that half of the participants within each block were allocated to the "ST" group and the other half to the "msPDT" group. Within each block, however, the order of patients was random. We considered size 4 blocks. If ST/msPDT is represented by S/M methods, there would be 6 different ways in which 4 patients can be split evenly between 2 methods: SSMM, SMSM, SMMS, MSSM, MSMS, and MMSS. Selecting the numbers' sequence "5251646463" via random permutation table, 40 patients were allocated to methods equally in this order: MSMS, SMSM, MSMS, SSMM, MMSS, MSSM, MMSS, MSSM, MMSS, and SMMS. A similar approach was applied in PDT/msPDT comparison.

Tracheostomy Procedure

All PDTs were performed in the ICU using the technique described by Ciaglia et al. The bronchoscopy was not performed during the operation. However, in certain cases suspected to paratracheal insertion or tracheal injury, a confirmation bronchoscopy was done right after the procedure. We considered absolute and relative contraindications in the PDT group, including uncontrolled coagulopathy (platelet count $\leq$50,000, international normalized ratio of prothrombin time [INR] $\geq$1.5, and/or partial thromboplastin time [PTT] $\geq$50 s), high PEEP or FiO_2 requirement (PEEP $\geq$10 mbar), difficult anatomy (eg, morbid obesity, short thick neck, and excessive goiter), and hemodynamic instability (being on vasopressor before the procedure). All STs were performed in the operative suite using standard techniques described elsewhere. The surgical procedure was conducted by an attending physician, resident assistant, and standard operating room staff.

Our modified PDT technique, msPDT, utilized a Tracoe experc dilatation set and was performed by a team including single attending physician (SMRH) with the assistance of an intensive care fellow and nurses in ICU. All anticoagulants were discontinued at least 12 hours before the procedure or after the indication of coagulopathy correction. Analgesia (fentanyl 50–70 μg), sedation (midazolam 2–5 mg), and relaxation (atracurium 0.5 mg/kg) were prescribed, and the neck was hyperextended (unless there was severe cervical spine injuries or other precautions). At least 5 minutes before incision, lidocaine 2% (Xylocaine) with epinephrine 1:100,000 (3–5 mL) was used for local analgesia and to minimize bleeding during the procedure. The patient lied supinely on the bed; after prepping and draping, the cricoid was palpated, and a 2-cm vertical skin incision was made 1 cm below the cricoid cartilage. The attending physician stood at the head part of the bed and the assistant fellow stood at the right side of the patient. Separation of subcutaneous tissue through 2 curved hemostats in different sizes (8 and 5 inches) was performed at vertical and horizontal directions by incision. Retraction was done step by step and progressively deep in subcutaneous tissue so that the fibromuscular tissue, overlaying the tracheal ring, was seen (Fig. 3). Depending on the case, in

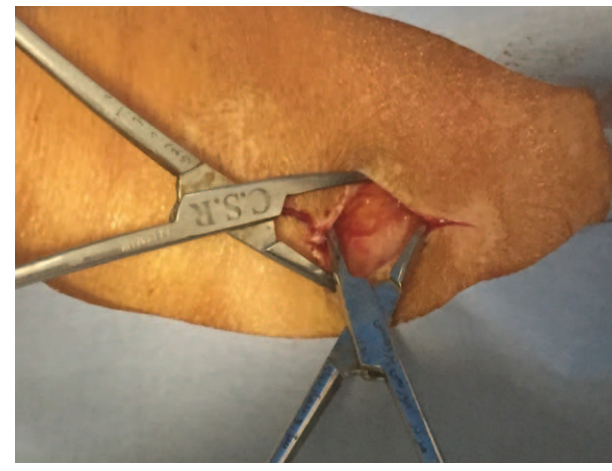

FIGURE 3. Step by step tissue retraction in msPDT procedure. msPDT = mini-surgical percutaneous dilatational tracheostomy.

Copyright © 2015 Wolters Kluwer Health, Inc. All rights reserved.

obese patients, more steps were required to visualize paratracheal fascia. In patients with difficult anatomy, the size of the first dissection increased, and the gentle tissue retraction contributed to visualizing of anatomical and vasculature variation. Lateral retraction proceeded to the deeper tissue in a slight and progressive manner, preventing a blunt needle insertion, and after dilation in which arteries or veins may be dissected accidentally, it was retracted by a surgical retractor. Here, the endotracheal tube cuff deflated and was withdrawn approximately 6 cm (an average depth of 16 cm in females and 17 cm in males at the teeth) until it passed the cricoid. The trachea was then manually palpated by the left index finger and a large-bore catheter introducer needle connected to a 5 cc syringe filled with 3 cc of saline, injected between the second and third tracheal rings (depending on the neck thickness and presumed downward transposition of trachea, the needle was injected between the first and second tracheal rings, instead) with a 45° oblique angle to prevent posterior wall injury. Aspiration of bubbles and mucus suggested appropriate tracheal puncture that lead guidewire insertion followed by needle removal. A short, small-diameter dilator was passed over the wire to initially dilate the tracheal opening. A single curved dilator was then inserted in an arc-like motion to perform the progressive dilation in 1 step until tracheostomy tube was placed over the guidewire. Intratracheal placement of the tracheostomy tube was confirmed immediately by the end-tidal CO_2 trace along with suction of tracheal mucus by the tracheostomy tube.

Data Scaling

Since it has been proved that physicians, especially the surgeons, underestimate the amount of blood loss during invasive procedures, we applied the gauze weight quantification method to calculate the actual blood loss during the procedures.[8,9] Mild ($\leq$2 cc), moderate (2–5 cc), and severe ($\geq$5 cc) bleeding was also defined. Hypoxemia was considered as arterial O_2 saturation (SaO_2) $\leq$90% in patients who were not on hypoxemic state before the procedures. In idiopathic pulmonary fibrosis (IPF) and other pulmonary diseases that affect baseline SaO_2, our cut-off for hypoxemia definition was 5% lower than baseline SaO_2. As such, hypotension was considered as mean arterial pressure (MAP) $\leq$65 mm Hg. We included coagulopathy, high PEEP or FiO2 requirement, difficult anatomies, and hemodynamic instability as relative contraindications to PDT that were not considered in ST and msPDT techniques.

Data Analysis

The data were analyzed using the statistical package IBM SPSS version 22.0 and descriptive statistics (Statistical Package for the Social Sciences, Chicago, IL). The categorical variables are expressed as proportions and frequencies. The continuous variables are summarized as means. The data scatter is quantified using standard deviation. To explore the independent nature of some variables and the time length of the procedure, chi-square and *t* tests were used for independent samples, categorical, and continuous variables, respectively. *P* values less than 0.05 were considered significant.

RESULTS

Patient Profiles

During the study, 360 patients were selected concerning all tracheostomy procedures as they completely matched the inclusion and the exclusion criteria. Considering the fact that classical PDT was retracted by attending Massih Daneshvari Hospital ICU, almost 1 year after the msPDT introduction in 2009, we compared the indicated patients to PDT between 2009 and 2010. ST procedure was also significantly limited by applying msPDT procedure to PDT-contraindicated patients. However, it remains for rare patients absolutely contraindicated to PDT, and more important, it was done as a part of educational program. The patients were randomized to PDT/msPDT and ST/msPDT after the adjustment by indication and contraindication to PDT, respectively. Demographic data for 320 patients indicated to PDT are displayed in Table 1. Table 2 provides demographic data for contraindicated patients, either submitted to ST or msPDT. Patients presenting acute exacerbation of chronic pulmonary diseases were more likely to undergo tracheostomy.

msPDT Versus PDT

Cumulating number of studies has compared various PDT techniques in terms of pre, post, and intraprocedural complications. A review by Cools-Lartigue et al,[10] analyzing current employed PDT techniques, indicated important weak points.

TABLE 1. Demographic Data (PDT-indicated Patients)

Variables	Standard PDT (n = 160)	Mini-surgical (n = 160)	*P* value
Age (y, mean [SD])	50.5 (13.4)	53.0 (14.8)	0.11
Sex (male, number [%])	98 (61)	109 (68)	0.19
Diagnosis on admission			
Sepsis (number [%])	35 (21.9)	40 (25.0)	0.51
COPD (number [%])	48 (30.0)	50 (31.3)	0.81
ARDS (number [%])	28 (17.5)	24 (15.0)	0.54
IPF (number [%])	19 (11.9)	16 (10.0)	0.59
Bronchiectasis (number [%])	12 (7.5)	14 (8.8)	0.68
Other (number [%])	18 (11.3)	16 (10.0)	0.72
Duration of ICU stay (d, mean [SD])	10.6 (5.4)	9.5 (4.7)	0.06
Duration of MV (d, mean [SD])	6.5 [4.9]	5.6 [5.5]	0.12
Difficult to wean (number [%])	41 (25.7)	42 (26.5)	0.89
APACHE II score (mean [SD])	20.9 (7.4)	21.7 (8.0)	0.35

APACHE II = Acute Physiology and Chronic Health Evaluation II, ARDS = acute respiratory distress syndrome, COPD = chronic obstructive pulmonary disease, ICU = intensive care unit, IPF = idiopathic pulmonary fibrosis, MV = mechanical ventilation, PDT = percutaneous dilatational tracheostomy, SD = standard deviation.

Copyright © 2015 Wolters Kluwer Health, Inc. All rights reserved.

TABLE 2. Demographic Data (PDT-contraindicated Patients)

Variables	ST (n = 20)	Mini-surgical (n = 20)	*P* value
Age (y, mean [SD])	50.5 (13.4)	53.0 (14.8)	0.11
Sex (male, number [%])	98 (61)	109 (68)	0.19
Diagnosis on admission			
Sepsis (number [%])	35 (21.9)	40 (25.0)	0.51
COPD (number [%])	48 (30.0)	50 (31.3)	0.81
ARDS (number [%])	28 (17.5)	24 (15.0)	0.54
IPF (number [%])	19 (11.9)	16 (10.0)	0.59
Bronchiectasis (number [%])	12 (7.5)	14 (8.8)	0.68
Other (number [%])	18 (11.3)	16 (10.0)	0.72
PDT contraindication			
Coagulopathy (number [%])	2 (10.0)	5 (25.0)	0.21
High PEEP or FiO_2 requirement (number [%])	6 (30.0)	7 (35.0)	0.72
Difficult anatomy (number [%])	7 (35.0)	5 (25.0)	0.49
Hemodynamic instability (number [%])	5 (25.0)	6 (30.0)	0.73
Duration of ICU stay (d, mean [SD])	13.3 (9.9)	13.8 (10.4)	0.87
Duration of MV (d, mean, [SD])	7.6 (5.0)	6.9 (4.9)	0.65
Difficult to wean (number [%])	9 (45.0)	7 (35.0)	0.52
APACHE II score (mean [SD])	22.2 (8.1)	24.4 (9.6)	0.48

APACHE II = Acute Physiology and Chronic Health Evaluation II, ARDS = acute respiratory distress syndrome, COPD = chronic obstructive pulmonary disease, FiO_2 = fraction of inspired oxygen, IPF = idiopathic pulmonary fibrosis, MV = mechanical ventilation, PDT = percutaneous dilatational tracheostomy, PEEP = positive end-expiratory pressure, SD = standard deviation, ST = surgical tracheostomy.

The procedural time, and the duration between the first skin incision and tracheostomy tube placement were recorded. The number of minor procedural complications including cuff leak, posterior wall injury, difficult dilatation, intraprocedural hypoxia, hypotension and bleeding, postprocedural bleeding, several attempts at insertion, paratracheal insertion, and reintubation were compared. The number of major complications pneumomediastinum, pneumothorax, and subcutaneous emphysema were also compared.

Data analysis demonstrated that the mean procedural time for the patients who underwent msPDT (2 min; SD = 0.7) was significantly lower ($P < 0.001$) than patients who underwent PDT (7.5 min; SD = 3.3). None of the patients in the msPDT group was complicated with intraoperative hypoxemia and paratracheal insertion, indicating a significant ($P < 0.001$) difference compared with the PDT group (6 patients; SD = 3.8 for both hypoxemia and paratracheal insertions). Two patients in the msPDT group were suspected to paratracheal insertion; hence; we conducted confirmation bronchoscopy right after the tracheostomy tube insertion. Although there was no significant difference in mild and moderate bleeding between the 2 groups of patients, only 2 patients (SD = 1.3) who underwent msPDT showed severe bleeding. The difference was statistically significant ($P < 0.001$) in comparison to 6 patients (SD = 6.9) among the patients who underwent PDT. One of the patients experiencing severe bleeding in the msPDT group was thrombocytopenic (plt <10000), and the platelet was transfused before the procedure. The other rate of complications did not display a significant difference between PDT and msPDT techniques (Table 3). Our data suggested a significant improvement in intraoperative vital sign management and procedural comfort by application of msPDT in ICU patients.

msPDT Versus ST

Surgical approach is always considered as the gold standard, even after PDT introduction. This is due to the lower reliability of PDT in certain situations. It is worth noting that noticeable and bold efforts in performing PDT on hard patients display the contrary.[6,7] As would be expected for the patients contraindicated to PDT, the mean procedure time for the patients underwent msPDT (5 min; SD = 2.3) was 3 minutes more than the indicated patients. Still, msPDT was much quicker than the surgical procedure (35 min; SD = 12.1), which ordinarily requires more steps and considerations. We selected intraoperative bleeding, paratracheal insertion, and intraprocedural hypotension and hypoxemia to measure msPDT with ST in terms of complications. This decision was primarily due to the importance of these complications in contraindicated patients to PDT. Intraoperative hypotension is the common cause of surgical referring of patients on vasopressors. On the contrary, the need of bronchoscopy is the main cause of PDT contraindication in patients who are dependent on high PEEP. Paratracheal insertion is an indicator of a variety of complications related to difficult anatomy as another PDT contraindication. Coagulopathic patients are more suspected to complication with severe bleeding during invasive procedures. Considering these, the current analysis indicated a meaningful analogy between the 2 groups, with no significant difference in the number of complications (Table 4).

DISCUSSION

There is an ongoing debate on the safety of PDT in relatively contraindicated patients. In complicated patients, indicated for tracheostomy, the cautious hands almost always have chosen ST over bedside percutaneous procedure. Our prospective analysis of 360 patients, undergone PDT, ST, and our modified msPDT technique, was able to detect comparable differences between PDT and msPDT in measuring the procedure time and perioperative complications. More significantly, we matched msPDT with ST procedural time and complications in patients contraindicated to PDT. Surprisingly,

Copyright © 2015 Wolters Kluwer Health, Inc. All rights reserved.

TABLE 3. Compared Complications of Classical PDT Versus msPDT

Variables	Standard PDT (n = 160)	Mini-surgical (n = 160)	*P* value
Time (min, mean [SD])**	7.5 (3.3)	2 (0.7)	<0.001**
Minor complications			
Cuff leak (number [%])	5 (3.1)	5 (3.1)	1.00
Posterior wall injury (number [%])	1 (0.6)	0 (0.0)	0.32
Difficult dilatation (number [%])	3 (1.9)	3 (1.9)	1.00
Hypotension (number [%])	37 (23.1)	32 (20.0)	0.50
Hypoxemia (number [%])	6 (3.8)	0 (0.0)	0.01**
Intraoperative bleeding (number [%])			
Mild (<2 cc)	120 (75.0)	112 (70.0)	0.32
Moderate (2–5 cc)	12 (7.5)	6 (3.8)	0.14
Severe (>5 cc)	11 (6.9)	2 (1.3)	0.01**
Loss of airway (number [%])	3 (1.9)	2 (1.3)	0.65
Postoperative bleeding (number [%])	2 (1.3)	1 (0.6)	0.56
Multiple attempts at insertion (number [%])	6 (3.8)	5 (3.1)	0.75
Paratracheal insertion (number [%])	6 (3.8)	0 (0.0)	0.01**
Reintubation (number [%])	3 (1.9)	1 (0.6)	0.31
Major complications			
Pneumomediastinum (number [%])	0 (0.0)	1 (0.6)	0.32
Pneumothorax (number [%])	3 (1.9)	2 (1.3)	0.65
Subcutaneus emphysema (number [%])	3 (1.9)	2 (1.3)	0.65

msPDT = mini-surgical percutaneous dilatational tracheostomy, SD = standard deviation.
** Significance of the effect at significance level of 5%. Values are mean (SD) or number (percentage).

statistical analysis showed almost parallel outcome, still rendering msPDT 7 times faster than ST.

Compared with open surgical procedure, PDT has always challenged technical difficulties and blunt dissection matters when coming across variation in vasculature and other important anatomical components in the neck.[11] Experiencing dreadful complications, such as pneumothorax, airway obstruction, and decannulation, is possible during routine PDT and may convert it to a surgery. Accordingly, Barba et al[12] introduced bronchoscopy in the PDT program to help selecting the puncture site and guide the real-time entrance of the needle into the trachea, which reduces posterior wall lesions. Although this approach has helped PDT, it has also caused bronchoscopy-induced complications such as reduced gas exchange, resulting in carbon dioxide retaining followed by increased intracranial pressure.[13,14] Moreover, bronchoscopy makes it impossible to perform PDT in high-PEEP required patients such as those with acute respiratory distress syndrome (ARDS). Nevertheless, intubated IPF patients are very sensitive to hypoxia, and bronchoscopy is a high-risk procedure to be developed right after heart failure.[15] Taking into account these observations, some experts have tried to revise the bronchoscopy necessity in distinct PDT trials. In this regard, Calvache et al[16] studied 80 ICU patients undergoing PDT and showed that there was little difference in the incidence of overall early complications without the use of the bronchoscope. This idea has been also reviewed prospectively and retrospectively in other earlier studies.[17,18] On the basis of these findings and our almost open technique, we conducted msPDT without the bronchoscopy guidance, leading to elimination of hypoxemic attacks in the msPDT group, significantly reduced compared with classical PDT. Nevertheless, in 10 patients with the suspicion of paratracheal and/or posterior wall injury, we investigated postprocedural bronchoscopy to rule out this possibility. Another invasive cure for blunt dissection was introduced by Griggs et al in 1990.[19] GWDF allows cannula placement in a direct

TABLE 4. Compared complications of ST Versus msPDT

Variables	ST (n = 20)	Mini-surgical (n = 20)	*P* value
Time (minute, mean [SD])**	35 (12.1)	5 (2.3)	<0.001**
Intraoperative bleeding (number [%])			
Mild (<2 cc)	18 (90)	15 (75)	0.21
Moderate (2–5 cc)	3 (15)	2 (10)	0.63
Severe (>5 cc)	1 (5)	2 (10)	0.55
Hypotension (number [%])	6 (30)	4 (20)	0.46
Hypoxemia (number [%])	1 (5)	1 (5)	1.00
Paratracheal insertion (number [%])	0 (0)	1 (5)	0.31

PDT = percutaneous dilatational tracheostomy, SD = standard deviation, ST = surgical tracheostomy.
** Significance of the effect at significance level of 5%. Values are mean (SD) or number (percentage).

Copyright © 2015 Wolters Kluwer Health, Inc. All rights reserved.

vision; however, due to a recent meta-analysis, major intraprocedural bleeding of skin and intercartilagineous tissue were experienced, retracting many physicians from this technique.[3] Also, postoperative tracheal stenosis has been reported by GWDF.[20] Conversely, we gently retracted the subcutaneous tissue step by step, letting us visualize the local anatomy and preventing accidental large vessel dissection. Not only this approach provided a surgical view that significantly hindered paratracheal insertions, but also reduced severe bleeding, which is largely due to blunt artery dissection. One of the 2 patients with severe bleeding can be attributed to less experience in earlier msPDTs. We did not have any surgical conversion in the msPDT group, although in case of the mentioned patients with severe bleeding, we called for surgeon consult.

Considering relative contraindications led us to investigate msPDT in some complicated patients including those with high PEEP or FiO_2 requirement, difficult neck anatomy, coagulopathy, and hemodynamic instability (requiring vasopressor before operation). Four patients with difficult neck anatomy, 1 with severe thrombocytopenia, and a hypoxemic IPF patient had surgical refusal due to the high risk of difficulties and mishaps associated with transport to and from the operation room and the risks of undergoing general anesthesia. In fact, there is a lack of efficient ventilation support in transporting to operation room that withdraws PEEP and has high portability of ventilator-induced lung injury development.[21] Lagoo et al[22] believed that the benefit of doing PDT in some contraindicated patients is sufficient, mainly by means of increasing training and experience in recent years, and rapid operation which minimizes the exposure time to any risk. In terms of patients requiring high PEEP, a RCT by Beiderlinden et al[23] revealed that the level of PEEP, procedure duration, and PDT technique are not accompanied by a significant deterioration in gas exchange. However, they concluded that the experience of physicians is a cornerstone, which significantly affects the result. A recent common approach to sustain the mechanical ventilation during PDT is the application of double lumen endotracheal tubes (DLETs) for airway management.[7,24] DLETs have an independent channel, dedicated to the patient's ventilation, and one devoted to flexible fiberoptic bronchoscope. In addition to the cost-effectiveness issue that may intervene with convenient application of PDT in ICUs, there have been few trials evidencing the safety and complication rate of DLETs in PDT. Widely reported complications of DLETs are intubation failure, tracheal injury, and airway edema, which are not uncommon and often require further surgery to be corrected.[25,26] The present study recorded no significant difference in hypoxemic gaps (oxygen saturation $\leq$90% in nonhypoxemia patients) between msPDT and ST in contraindicated patients. Even in patients on high PEEP, supported mechanical ventilation allowed the proceduralist to have complete control over ventilation indices. Nonetheless, new approaches have been introduced targeting high PEEP-required patients. As an example, Fan et al[27] proposed applying PDT kit under surgical circumstances in operation room.

Morbid obesity has been challenged as a relative contraindication to PDT.[28] In obese patients (body mass index $\geq$30), trachea is oriented obliquely and posteriorly within the thorax. Along with large thick neck, it totally makes it difficult to identify the landmarks by physical examination and easy tracheal access. On the contrary, bronchoscopic translumination is almost helpless through thickened neck commonly used to indicate the puncture site and confirm the needle position. Under these circumstances, previously published trials have indicated paratracheal insertion, oxygen desaturation, and accidental decannulation as the common complications seen in morbidly obese cases.[28,29] Despite these points, several prospective randomized clinical trials have performed PDT on obese patients with the complication rate equal to ST.[30,31] In fact, the difficulty in identifying anatomical landmarks is associated with the occurrence of complications. The ability of a proceduralist to touch anatomical markers by the finger tip or often observation by direct vision in msPDT may explain the low incidence of paratracheal insertion in contraindicated patients. Once the soft tissue of neck is retracted by 2 curved hemostats, tracheal anatomy and the location can be identified nearly in all obese patients. Here, ultrasonography (US)-guided PDT, reviewed by Guinot et al, is another alternative for better anatomical assessment.[6] This approach, however, requires 3 operators, accessible device, and absolutely highly skilled physicians in US operating, still challenging the poor view in some morbid obese patients.

Patients who are on vasopressor and/or with coagulopathy are another concern in percutaneous tracheostomy. ICU patients may be hemodynamically unstable and coagulopathic because of illness and/or because of the need for anticoagulation or antiplatelet therapy. When otherwise indicated, we performed msPDT on these complicated patients, as the overall procedural time was significantly less than the surgically operated patients, reducing the risk of major bleeding and hypotensive period. Apart from this, our experience on indicated patients suggests obviously lower rates of hypotension and bleeding in msPDT. As the data indicate, severe intraoperative bleeding rate was notably low in both ST and msPDT procedures, and the number of patients suffered intraprocedural hypotension (MAP $\leq$65) was acceptable. Recently, Takahashi et al[32] safely performed PDT on 149 cardiac surgical patients who suffered sustained coagulopathy, not corrected before the procedure. Al-Ansari and Hijazi[33] also discussed PDT studies attempted to overpass PDT-relative contraindications, including coagulopathic cases.

CONCLUSIONS

Few institutions have established a multidisciplinary procedural tracheostomy program. Since we lunched msPDT in Masih ICUs, the rate of STs gradually declined over time, and now, they are almost limited to educational purposes. We believe that the main concerns on percutaneous tracheostomy to become an accepted gold standard include the majority of indicated patients and exclude less little dependency on imaging devices during the procedure, rare requirement to convert surgical procedure, and being handled by medium-experienced proceduralist.

Here are some superiorities of the presented modified technique, msPDT over PDT:

(1) The most outstanding advantage of msPDT is its applicability for cases relatively contraindicated to PDT, which have to undergo surgical procedure.
(2) MsPDT is performed at bedside in ICU for PDT-contraindicated cases (instead of an operating room); however, msPDT is 7 times faster than ST in the aforementioned cases.
(3) In PDT-indicated patients, msPDT significantly displayed lower rate of paratracheal insertion and less bleeding and hypoxemia along with faster tracheal tube insertion.

There are few limitations. Only a small number of complications were considered in comparing msPDT with ST procedure. On the contrary, long-term and postprocedural

Copyright © 2015 Wolters Kluwer Health, Inc. All rights reserved.

complications were not intended in the study. Future researches may include prospective studies evaluating delayed and late complications.

REFERENCES

1. Sheldon CH, Pudenz RH, Tichy FY. Percutaneous tracheostomy. *JAMA.* 1957;165:2068–2070.
2. Kornblith LZ, Burlew CC, Moore EE, et al. One thousand bedside percutaneous tracheostomies in the surgical intensive care unit: time to change the gold standard. *J Am Coll Surg.* 2011;212: 163–170.
3. Putensen C, Theuerkauf N, Guenther U, et al. Percutaneous and surgical tracheostomy in critically ill adult patients: a meta-analysis. *Crit Care.* 2014;18:544.
4. Cabrini L, Monti G, Landoni G, et al. Percutaneous tracheostomy: a systematic review. *Acta Anaesthesiol Scand.* 2012;56:270–281.
5. Huang CS, Chen PT, Cheng SH, et al. Relative contraindications for percutaneous tracheostomy: from the surgeons' perspective. *Surg Today.* 2014;44:107–114.
6. Guinot PG, Zogheib E, Petiot S, et al. Ultrasound-guided percutaneous tracheostomy in critically ill obese patients. *Crit Care.* 2012;16:R40.
7. Vargas M, Servillo G, Tessitore G, et al. Double lumen endotracheal tube for percutaneous tracheostomy. *Respir Care.* 2014;59:1652–1659.
8. Awobusuyi JO, Mapayi FA, Adedolapo A. Blood loss during vascular access cannulation: quantification using the weighed gauze and drape method. *Hemodial Int.* 2008;12:90–93.
9. Ram GG, Suresh P, Vijayaraghavan PV. Surgeons often underestimate the amount of blood loss in replacement surgeries. *Chin J Traumatol.* 2014;17:225–228.
10. Cools-Lartigue J1, Aboalsaud A, Gill H, et al. Evolution of percutaneous dilatational tracheostomy–a review of current techniques and their pitfalls. *World J Surg.* 2013;37:1633–1646.
11. Gilbey P. Fatal complications of percutaneous dilatational tracheostomy. *Am J Otolaryngol.* 2012;33:770–773.
12. Barba CA, Angood PB, Kauder DR, et al. Bronchoscopic guidance makes percutaneous tracheostomy a safe, cost-effective, and easy-to-teach procedure. *Surgery.* 1995;118:879–883.
13. Reilly PM, Sing RF, Giberson FA, et al. Hypercarbia during tracheostomy: a comparison of percutaneous endoscopic, percutaneous Doppler, and standard surgical tracheostomy. *Intensive Care Med.* 1997;23:859–864.
14. Reilly PM, Anderson HL3rd, Sing RF, et al. Occult hypercarbia. An unrecognized phenomenon during percutaneous endoscopic tracheostomy. *Chest.* 1995;107:1760–1763.
15. Weng T, Poth JM, Karmouty-Quintana H, et al. Hypoxia-induced deoxycytidine kinase contributes to epithelial proliferation in pulmonary fibrosis. *Am J Respir Crit Care Med.* 2014;190: 1402–1412.
16. Yuca K, Kati I, Tekin M, et al. Fibre-optic bronchoscopy-assisted percutaneous dilatational tracheostomy by guidewire dilating forceps in intensive care unit patients. *J Otolaryngol Head Neck Surg.* 2008;37:76–80.
17. Jackson LS, Davis JW, Kaups KL, et al. Percutaneous tracheostomy: to bronch or not to bronch: that is the question. *J Trauma.* 2011;71:1553–1556.
18. Paran H, Butnaru G, Hass I, et al. Evaluation of a modified percutaneous tracheostomy technique without bronchoscopic guidance. *Chest.* 2004;126:868–871.
19. Griggs WM, Worthley LI, Gilligan JE, et al. A simple percutaneous tracheostomy technique. *Surg Gynecol Obstet.* 1990;170:543–545.
20. Dollner R1, Verch M, Schweiger P, et al. Long-term outcome after Griggs tracheostomy. *J Otolaryngol.* 2002;31:386–389.
21. Hashemian SM, Mohajerani SA, Jamaati HR, et al. Ventilator-induced lung injury. *N Engl J Med.* 2014;370:979–980.
22. Lagoo JY, D'Souza MC, Appanervanda KM. Percutaneous tracheostomy by Griggs technique: a retrospective analysis. *Int J Res Med Sci.* 2015;3:738–742.
23. Beiderlinden M, Groeben H, Peters J, et al. Safety of percutaneous dilational tracheostomy in patients ventilated with high positive end-expiratory pressure (PEEP). *Intensive Care Med.* 2003;29:944–948.
24. Vargas M, Pelosi P, Tessitore G, et al. Percutaneous dilatational tracheostomy with a double-lumen endotracheal tube: a comparison of feasibility, gas exchange, and airway pressures. *Chest.* 2015;147:1267–1274.
25. Fitzmaurice BG, Brodsky JB. Airway rupture from double-lumen tubes. *J Cardiothorac Vasc Anesth.* 1999;13:322–329.
26. Taguchi H, Yamada K, Matsumoto H, et al. Airway troubles related to the double-lumen endobronchial tube in thoracic surgery. *J Anesth.* 1997;3:173–178.
27. Fan Y, Cai J, Yan C. Technical Improvements of difficult tracheotomy. *Indian J Surg.* 2014:1–5.
28. Byhahn C, Lischke V, Meininger D, et al. Peri-operative complications during percutaneous tracheostomy in obese patients. *Anaesthesia.* 2005;60:12–15.
29. El Solh AA. Airway management in the obese patient. *Clin Chest Med.* 2009;30:555–568.
30. Romero CM, Cornejo RA, Ruiz MH, et al. Fiberoptic bronchoscopy-assisted percutaneous tracheostomy is safe in obese critically ill patients: a prospective and comparative study. *J Crit Care.* 2009;24:494–500.
31. Heyrosa MG, Melniczek DM, Rovito P, et al. Percutaneous tracheostomy: a safe procedure in the morbidly obese. *J Am Coll Surg.* 2006;202:618–622.
32. Takahashi M, Itagaki S, Laskaris J, et al. Percutaneous tracheostomy can be safely performed in patients with uncorrected coagulopathy after cardiothoracic surgery. *Innovations (Phila).* 2014;9:22–26.
33. Al-Ansari MA, Hijazi MH, et al. Clinical review: percutaneous dilatational tracheostomy. *Crit Care.* 2006;10:202.

Copyright © 2015 Wolters Kluwer Health, Inc. All rights reserved.