Original Article

Percutaneous dilatational versus conventional surgical tracheostomy in intensive care patients

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Abstract

Background: Tracheostomy is usually performed in patients with difficult weaning from mechanical ventilation or some catastrophic neurologic insult. Conventional tracheostomy involves dissection of the pretracheal tissues and insertion of the tracheostomy tube into the trachea under direct vision**.** Percutaneous dilatational tracheostomy is increasingly popular and has gained widespread acceptance in many intensive care unit and trauma centers. **Aim:** Aim of the study was to compare percutaneous dilatational tracheostomy versus conventional tracheostomy in intensive care patients. **Patients and Methods:** 64 critically ill patients admitted to intensive care unit subjected to tracheostomy and randomly divided into two groups; percutaneous dilatational tracheostomy and conventional tracheostomy. **Results:** Mean duration of the procedure was similar between the two procedures while the mean size of tracheostomy tube was smaller in percutaneous technique. In addition, the Lowest SpO_2 during procedure, $PaCO_2$ after operation and intra-operative bleeding for both groups were nearly similar without any statistically difference. Postoperative infection after 7 days seen to be statistically lowered and the length of scar tend to be smaller among PDT patients. **Conclusion:** PDT technique is effective and safe as CST with low incidence of post operative complication.

Keywords: Tracheostomy, intensive care, air way.

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Introduction

Tracheostomy is usually performed in patients with difficult weaning from mechanical ventilation or some catastrophic neurologic insult. Also many infectious and neoplastic laryngeal processes may require a surgical airway [1]. No absolute contraindications exist to tracheostomy but a strong relative contraindication to discrete surgical access to the airway is the anticipation that the blockage is a laryngeal carcinoma [2].

Conventional surgical tracheostomy involves a full dissection of the pretracheal tissues and insertion of the tracheostomy tube into the trachea under direct vision [3]. However, the postoperative complications such as bleeding, cellulites-infection of the stoma and bad cosmetic results still exist and relatively frequent [4]. In addition, critically ill patients require transport from the intensive care unit (ICU) to the operating theatre [5].

Although surgical cricothyroidotomy performed in intensive care units is rapid and simple procedure [6], but most otolaryngologists disagree with its elective use due to complications such as subglottic stenosis, vocal cord paralysis and recommend the procedure for emergency situations only [7, 8]. Ciaglia et al introduced the percutaneous dilatational tracheostomy (PDT) which become increasingly popular and has gained widespread acceptance in many ICU and trauma centers as a viable alternative approach [4]

This study aimed to compare between the percutaneous dilatational tracheostomy (PDT) versus conventional surgical tracheostomy (CST) in intensive care patients requiring tracheostomy regarding the operative parameters and post operative complications in both techniques.

Patients and Methods

Patients

64 critically ill patients admitted to intensive care unit from February 2007 to August 2010 subjected to the present study either for prolonged intubation, airway protection or pulmonary hygiene. Patients with distorted anatomy, history of previous surgery at the neck, bleeding disorder, goiter, neck masses, unstable general condition or cervical spine trauma were excluded. Patients were divided randomly into two equal groups; first group (32 patients) subjected to percutaneous dilatational tracheostomy (PDT group) while the other group (32 patients) subjected to conventional surgical tracheostomy (CST group).

Randomization

Randomization was performed prior to study commencement as follows: Opaque envelopes were numbered sequentially from 1 to 64. A computer-generated table of random numbers was used for group assignment; if the last digit of the random number was from 0 to 4, assignment was to Group A (PDT), and if the last digit was from 5 to 9, assignment was to Group B (CST). As eligible participants were entered into the trial, these envelopes were opened in sequential order to give each patient his or her random group assignment. The envelopes were opened by the operating surgeon after patient consent and just prior to the surgery.

Sample size

The overall complications of open tracheostomy in previous studies [P^1] is about 36-41% and those of percutaneous dilatational tracheostomy [P^2] is about 6-12 % [9, 10]. Calculation of the sample size included the number of participants using the two mathematical equation [11, 12] .Using the first equation [11], the number, N = ~ 31 patients for each group, as given by:

$$\frac{2 \times [Z(1-\acute{\alpha}/2) + Z(1-\beta)]^2}{\Delta^2}$$

where z (1-a/2) and z (1-β) represent percentage points of the normal distribution for statistical significance level (ά) at 0.05 value is 1.96 and power (1-β) with accepted 95 % positive rate is 1.6449, where β, the false-negative rate. **Δ** represents the standardized difference (i.e. the treatment difference divided by its standard deviation.

$$\text{Standardized difference } \Delta = \frac{P^1 - P^2}{\sqrt{\Sigma \times (1 - \Sigma)}}$$

$$\text{Where } \Sigma = \frac{P^1 - P^2}{2}$$

The sample size was calculated according to the second equation [12].

$$N = \frac{K\,(p1q1+p2q2)}{d^2}$$

$$= 32 \text{ patients}$$

Where: q1 = (1-p1), q2 = (1-p2), and d = (p1-p2).
K = constant, which depends on: alpha and beta levels, where alpha =0.05 and beta =0.1. Then K =8.6.

Methods

All patients were subjected to general anesthesia and orotracheal intubation with continuous monitoring arterial blood gasses, blood pressure, electrocardiography, pulse oximetry, intra operative blood loss and record to tracheostomy tube size. PDT patients groups procedure done using the Griggs' guide wire dilating forceps technique (through trans cervical insertion and the trachea cannulated with 14-G cannula between the second, or the second and third tracheal rings and J guide wire inserted followed by blunt dilation) [4]. This procedure was successful in all patients. CST patients group subjected to horizontal skin incision midway between the sternal notch and cricoid cartilage, revealing the thyroid isthmus and then the cricoid cartilage identified, cricoid hook used to pull the trachea superiorly finally insert suitable tracheostomy tube [8].

End points

Primary parameters were the mean operative time, intra operative arterial blood gasses, intra operative blood loss and trachestomy tube size and secondary parameters were post operative complications in both techniques.

All patients were subjected to strict observation in first 24 hours then daily for one week and each other day for cleaning the tube with suction for one month. Then after that, patients were educated to have self tube cleaning with regular home suction and finally were followed up weekly for one year at least. Infection was identified post operatively by symptoms such as cough, excessive sputum formation with change in characters as odour, colour, viscosity, also other manifestation such as chest tightness, dysphagia, and chest pain with systemic symptoms as fever, body aches. Signs were pus in trachestomy site, character of aspirated sputum, chest examination if there is wheeze or creptiation, finally blood investigation as culture and sensitivity test from sputum, and chest X ray.

Statistical analysis

Data collected processed using SPSS version 15 (SPSS Inc., Chicago, IL, USA). Quantitative data expressed as means ± SD while qualitative data expressed as numbers and percentages (%). Student *t* test used to test significance of difference for quantitative variables that follow normal distribution.

Ethical consideration

Written consents were obtained from all patients or first degree relatives before the study. The steps of both operative interferences were explained to all patients. The

local ethics committee had approved all operative procedures.

B-Results

There was no statistical difference between the two groups regarding age and sex as shown in Table 1. In both groups, 22 patients were admitted to the intensive care unit due to neurological disease, 20 patients had respiratory disease, 18 patients with cardiovascular disease and 4 patients due to head trauma. Duration of endotracheal intubation ranged from 6 - 21 days with mean 12.3 days.

There was no mortality related to both tracheostomy techniques. A total of 18 of 64 patients died because of progression of their underlying diseases while the tracheostomy was functioning well. Of the survived patients, 36 needed decannulation, the time from institution of tracheostomy to decannulation ranged from 14 to 22 days with a mean of 16.3 days. The other 10 patients survived with their tracheostomies and probably will never be decannulated due to primary diseases.

Acute Physiology and Chronic Health Evaluation (APACHE) II score for PDT patients group ranged from 15 to 26 with mean 19.1 while ranged from 17 to 25 with mean 18.4 in CST patients group with no statistically significance difference between both groups.

Laboratory parameters among both groups were within normal values as PT-INR Mean 1.1, APTT Mean 30.2, Platelet count ($\times 10^3$**)** Mean 295.5 and Hb (g/dl) Mean 11.6 with no statistical significant difference between both groups.

Mean duration of the procedure was nearly similar between both groups (20.1 versus 19.3 minutes, respectively) with no statistical difference between them. Mean size of tracheostomy tube used in the procedures was smaller in case of PDT group compared with CST group (7.9 ± 0.3 and 8.9 ± 0.2, respectively) with statistically significant difference for small tube in PDT group.

In addition, the lowest SpO2 during procedure, PaCO2 after operation and intra-operative bleeding for both groups were nearly similar with no statistical difference as seen in Table 1.

Pneumothorax occurred in one patient in PDT group and in two patients in CST group with no statistical significant difference, none had surgical emphysema in PDT groups but only one in CST group who needed closed observation with complete resolution after 3 days while accidental decannulation and postoperative bleeding didn't occurred in both groups.

14 patients in PDT group developed cough which subjected to anti cough therapy (bromhexine hydroxide 8 mg/kg/day) and 12 patients in CST also need the same treatment with regular tracheal suction and improved from 7 to 14 days post operative without any statistically significance difference between both groups.

Infection after 7 days was seen to be statistically lowered in PDT group compared with CST group as seen in Table 2 that needed continuous local skin care, local antibiotics and anti septic with complete recovery after a period ranged from 6 to 10 days. Both groups were subjected to closed observation, systemic antibiotics (amoxicilline-clavunate 40 mg/kg for 7 days post operative for all patients in both groups), regular wound cleaning and regular suction from trachea and X ray chest to rule out any complications. Finally the length of scar tended to be smaller among PDT patients group as seen in Table 3 with statistically significance difference.

Table 1 Demographic characteristics among studied patients in the two studied groups

Characteristic			PDT group (n=32)	CST group (n=32)	*P* value
Age (ys)	Mean ± SD		43.12 ±15.3	41.58±18.6	0.8 (NS)
	Range		34 – 67	32 - 60	
Sex	Male	N(%)	18 (56%)	16 (50%)	0.9 (NS)
	Female	N(%)	14 (44%)	16 (50%)	

NS: No statistically significant difference

Table 2 Preoperative and intra-operative characteristics among both groups

Characteristic		PDT group (n=32)	CST group (n=32)	*P* value
Lowest SpO_2 during procedure (%)	Mean±SD	99.4±0.6	99±0.5	NS
	Range	98-100	98-100	
$PaCO_2$ after operation	Mean±SD	31.3±4.3	31.4±4.1	NS
	Range	27 – 35	26 –36	
Intra-operative bleeding	Minimal	21	22	NS
	Moderate	11	10	
	Severe	0	0	

NS: No statistically significant difference

Table 3 Postoperative characteristics among both groups

Characteristic		PDT group (n=32)	CST group (n=32)	*P* value
Postoperative infection after 7 days	Zero	28	10	0.01*
	Mild	2	9	
	Moderate	2	8	
	Severe	0	5	
Length of scar (cm)	< 1 cm	8	2	0.002*
	1 – 2 cm	23	9	
	> 2 cm	1	21	

*Statistically significant difference (*P* value < 0.05)

Discussion

Surgical tracheostomies are often performed in critically ill patients who need prolonged respiratory care. Despite the long experience with ST, the technique still has many complications, with an overall incidence of 6%-66%, including pneumothorax or subcutaneous emphysema

(4%-17%), tube dislodgement (0%-7%), bleeding (3%-37%), stomal infection (17%-36%) and a mortality rate of 0%-5.3% [8, 13].

PDT has a number of important advantages over performing a ST in critically ill patients who require an elective tracheostomy. First, PDT was associated with a reduction in the incidence of clinically important wound infections compared with traditional ST, secondly and importantly, there was no evidence that PDT resulted in an increased incidence of clinically significant bleeding, major peri-procedural or long term complications [8, 13, 14]. In agreement with these studies, we found that the mean duration of the procedure, lowest SpO_2 during procedure, $PaCO_2$ after operation and intra-operative bleeding , post operative complications and cough were all nearly similar between the two groups with no statistically difference between. Also in his series, Türkmen et al mentioned that the PDT was not associated with clinically important hemorrhage , purulent infection at the stoma, or any lethal complication [8]. Griggs et al found that the PDT technique was associated with a shorter procedure time and a significantly fewer morbidity, in comparison to the standard ST technique and this is due to the good experience in their technique [7].

While the mean size of tracheostomy tube used, postoperative infection after 7 days and mean length of scar tend to be less in PDT group compared with CST group with statistically significance difference between two groups. Delaney mentioned that it is not surprising to find reduced incidence of wound infection with the PDT technique and stated that minimally invasive surgical techniques is a factor for reduction in the rates of surgical site infections [14, 15]. In addition, the minimization of the local tissue damage with a dilatational technique and the relative preservation of immune functions when minimally invasive techniques are used may be a factor for such reduction [16].

A meta-analysis of studies comparing PDT versus ST has been published in which PDT was found to be associated with an increased incidence of per operative complications.[17, 18] and the risk of subsequent stenosis [19]. However, the strength and experience of the operator may also influence the formation of tracheal stoma [8]. Despite this meta-analysis, many studies stated that the per operative complications are few and minor PDTs, however, have significant advantages when compared with the standard techniques of tracheostomy [19-21]. Delaney et al reported that there was no evidence that PDT was associated with an overall increase in the rate of bleeding, other major complications or long-term complications, compared to ST but he mentioned that the PDT technique is the choice for critically ill patients who require a tracheostomy [14]. Leinhardt et al recommended to keep this technique in the domain of surgery, and also pointed out that some doctors in non-surgical specialties, such as intensive care and anesthesia, have already been skilled in vascular access using the Seldinger technique, they could also be trained to perform percutaneous tracheostomy [22].

A meta-Analysis for percutaneous versus surgical tracheotomy stated that although significantly faster than ST, PDT has more early complications compared with open tracheotomy in the operating room or at the bedside. The long-term complications of the two techniques appear comparable but have not been thoroughly investigated. These findings suggest that a team approach between surgeons and critical care specialists is essential to select the appropriate tracheotomy technique for a given patient [23].

Conclusion

PDT technique is similarly effective and safe as CST with low incidence of post operative complication. PDT reduces the overall incidence of wound infection and may further reduce clinical relevant bleeding and mortality when compared with ST. PDT may be considered the procedure of choice for performing elective tracheostomies in critically ill adult patients.

(Trial registration number: ACTRN12611000342910).

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