

Tracheostomy in Patients Who Need Mechanical Ventilation: Early or Late? Surgical or Percutaneous? A Prospective Study in Iran

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Abstract Tracheostomy can be performed surgically or by percutaneous (percutaneous dilatory tracheostomy, PDT) methods, and it may be used early or late. In a 3-month follow-up, all patients who underwent tracheostomy in Semnan in 2013 were evaluated for complications of tracheostomy considering the method used and the timing of operation. A total of 55 patients underwent tracheostomy (26 cases surgery, 29 cases PDT, 30 cases early, and 25 cases late based on 14 days reference). The mean durations of operation were 19.19 ± 5.78 min in the surgery method and 4.7 ± 2.42 min in the PDT method ($P < 0.001$). The mean durations of the need for ventilator after the tracheostomy were 10.7 ± 9.25 and 18.6 ± 14.39 days in early and late tracheostomy, respectively ($P = 0.024$). The mean intensive care unit (ICU) stay were 12.70 ± 10.24 and 23.44 ± 18.49 days ($P = 0.014$) and the mean hospital stay were 16.04 ± 10.88 and 23.48 ± 18.47 days, respectively ($P = 0.100$). Short-term complications were observed in six cases (10.09 %) in the surgery group, including emphysema (two), bleeding (two), wound infection (one), and clot formation inside the tube (one). Only one complication (bleeding) occurred in one case in the PDT group. After 3 months, 21 patients survived. Compared with surgery, the most important advantage of the PDT method was its shorter duration

of surgery. Nearly half of the patients underwent tracheostomy late, while the majority of the patients in the late group were referred from internal ICU. No major and minor complications were noted during the procedure, as well as no tracheostomy-related deaths were observed. Early tracheostomy was shown to be superior to late, reducing the time of mechanical ventilation and ICU or hospital stay.

Keywords Tracheostomy · Percutaneous tracheostomy · Complications · Long-term intubation

Introduction

Tracheostomy is performed for 24 % of patients undergoing mechanical ventilation [1, 2]. Some studies suggest that patients who have undergone tracheostomy not only had better results in the hospital but their 1-year survival also improved [3].

Tracheostomy is used for at least four reasons: relieving upper airway obstruction, preventing damage to the throat and upper airway by prolonged translaryngeal intubation, providing easy access to the lower airways, and providing a stable airway in patients who require prolonged mechanical ventilation [4]. However, it has some complications, which are categorized into: intraoperative (hypoxia, hypertension, bleeding, and pneumothorax); early (bleeding, decannulation, infection, neck hematoma, cardiopulmonary arrest, subcutaneous emphysema, pneumothorax, injury to the lining of the trachea or esophagus, and trachea ring fractures); and late complications (stenosis of the trachea, windpipe fistula to the innominate artery, tracheal fistula to the esophagus, permanent openings of trachea, and tracheomalacia) [2, 4, 5].

There is no consensus about the timing of tracheostomy partly due to the difficulty in the prediction of the exact time needed for mechanical ventilation [6]. Some studies showed

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that the application of tracheostomy during the first 7 days reduced the time of mechanical ventilation and both intensive care unit (ICU) and hospital stay. However, some other studies showed that the timing of tracheostomy did not significantly change the clinical outcomes of critically ill patients [2, 7–9]. The decision about the timing of tracheostomy should be made based on a comparison of the advantages and disadvantages of the method for each person individually. However, it has been said that patients requiring long-term intubation benefit from early tracheostomy [10–13].

There are many ways to do tracheostomy, which are generally classified into two methods including open surgery (OS) and percutaneous dilatory tracheostomy (PDT) [4]. Compared to OS, PDT can be done on the patient's bed, which avoids the risk of moving the patient and being delayed by the waiting lists. In addition, the use of this method required smaller incision as well as shorter time than the surgery. On the other hand, it is more appropriate for patients with neck trauma [1, 2, 8].

The present study aimed to evaluate the causes, effects, methods, timing, and outcomes of tracheostomy at the main hospital in Semnan, a city in Iran, regarding the method used (OS vs. PDT) and timing of operation (early vs. late).

Patients and Methods

The study was conducted on all patients who underwent tracheostomy in Semnan in 2013. All patients had been intubated prior to the tracheostomy. Data on participants' demographics were recorded, as well as other information including the reason, method (OS vs. PDT), and time taken for the procedure (from incision to the end of the tracheostomy insertion), timing of procedure (early vs. late) based on the duration of intubation, time required for mechanical ventilation before and after tracheostomy, ICU and hospital stay, blood pressure, heart rate, and arterial oxygen saturation, and its complications. The median observed time was taken as the criterion for early and late tracheostomy in our study. Since PDT was a new procedure in the hospital and the staff were less familiar with it, all PDTs were performed in the operating room without bronchoscopic guide. Concerning intraoperative bleeding, bleeding of more than 15 ml was considered positive, and it was equivalent with soaking more than three gauze pieces or with the presence of blood throughout the suction tube or the presence of blood in the suction bottle [8]. To detect pneumothorax, mediastinal, or subcutaneous emphysema and the location of the tracheostomy tube, postoperative chest radiograph was performed. Patients were evaluated every day for the prevalence of side effects during hospitalization. The early complications emerge in the first week and late side effects are observed after the first week. All patients were followed up via telephone interview. Accordingly, patients with significant symptoms were referred to visit the determined physician.

Results of the visits were also recorded. At the end of the third month after the tracheostomy, all patients were evaluated for complications.

Results

A total of 55 patients were followed up in the study. The major indication for tracheostomy in patients was long-term intubation (98.2 %). The mean (\pm standard deviation) duration of intubation in patients was 17.6 ± 10.7 days. The mean ages were 69.38 ± 19.83 in the OS group and 49.37 ± 20.44 in the PDT group ($P < 0.001$; Table 1).

Thirty participants (54.5 %) had an underlying medical condition, of whom 21 (80.8 %) were in the surgery group and nine (31 %) were in the PDT group. Of these patients, 24 were from the late group and six were from the early group. There was a significant relationship between the method and timing of tracheostomy and the presence of underlying disease ($P < 0.001$).

According to Table 2, the mean duration of intubation was 8.63 ± 2.07 in the early tracheostomy group (during 2 weeks) and 28.36 ± 5.70 in the late tracheostomy group (performed after 2 weeks). The OS group underwent tracheostomy significantly later than patients in the PDT group.

Duration of tracheostomy via the PDT method was significantly shorter than in the OS ($P < 0.001$). A statistically significant difference was observed in two early and late groups in terms of the time required for the ventilation and length of ICU stay ($P = 0.014$ and $P = 0.024$, respectively). However, there was no significant difference between the other variables in terms of time and method of tracheostomy.

During 1 week, six cases (10.09 %) had some early complications (Table 3). No significant difference was observed between subgroups (by the method and timing) in terms of complications.

Seven patients (12.7 %) died during hospitalization, all due to disease progression. Of the discharged patients, 13 (23.6 %) were decannulated before discharge, of whom one patient was in the OS (3.8 %) and 12 patients were in the PDT group (41.4 %). Moreover, all the 13 patients were among those who had undergone early tracheostomy (43.3 %). In other cases, because of the need for T-Piece, decannulation was not performed. After discharge, patients were followed up monthly by telephone. No patient reported severe respiratory symptoms such as dyspnea, stridor, and severe and permanent voice changes, but symptoms such as mild dysphagia, sporadic aspiration, and respiratory symptoms like cough and sputum were reported.

Finally, 21 patients (38.2 %) were alive at the end of the third month, of which six were from the symptomatic group (Table 4). All 21 patients were evaluated for asymptomatic complications, of whom two were from the OS and 19 were

Table 1 Characteristics of participants

Characteristics		Method			Time (based on 14 days reference)		
		OS (<i>n</i> = 26)	PDT (<i>n</i> = 29)	<i>P</i>	Early (<i>n</i> = 30)	Late (<i>n</i> = 25)	<i>P</i>
Age (mean ± SD)		19.83 ± 69.38	20.44 ± 49.37	<0.001	22.02 ± 47.07	14.09 ± 72.2	<0.001
Sex	Male	10	18	0.08	18	10	0.14
	Female	16	11		12	15	
Underlying medical condition	Yes	21	9	<0.001	6	24	<0.001
	No	5	20		24	1	

from the PDT group. Only one patient from the late tracheostomy group was still alive at the end of the third month.

Discussion

Tracheostomy can be performed via OS or PTD methods, and it may be used early or late [10–13]. The present study showed that nearly half of the patients underwent tracheostomy late. It is clear that the rate of complications in patients increased with the increase in the duration of intubation [6, 14, 15]. In this study, the mean duration of intubation was 17.6 ± 10.7 days. In the study of Kiakjori et al., the mean duration of intubation was 20.1 ± 8.2 days [16]. In another study, the duration of intubation ranged between 6 and 21 days, with a mean of 12.3 days [17], and in the study by Carrer et al., the mean duration was 8.1 ± 4.5 days [12].

Of all patients, the majority (92 %) of the late group were referred from internal ICU. As a result, it can be concluded that there is a difference in the attitude of the staff working in the two internal and surgical wards toward the timing of tracheostomy.

The OS group significantly underwent tracheostomy later than the PDT group (22.88 ± 9.8 vs. 12.86 ± 9.32 days, *P* < 0.001). In the study by Liao et al., the mean time to perform tracheostomy in the PDT group was 7.4 days while in the OS group was 14 days [13]. In a study by Beltrame et al., OS was conducted later than PDT (12.4 ± 6 vs. 8.7 ± 8.5 days) [15]. In Friedman's study, the durations of intubation were 17.2 days in the PDT method and 21.3 days in the OS method (*P* = 0.44). In

Porter's study, the durations were 9.8 days in PDT and 12.4 days in the OS method (*P* = 0.21). Moreover, in the study of Farhanchi et al., the durations of intubation were 19.1 days in the PDT method and 23.6 days in the OS method (*P* = 0.21) [8].

The mean durations of tracheostomy were 19.19 ± 5.78 min in OS and 4.7 ± 2.42 min in the PDT method (*P* < 0.001). This finding was in line with other studies [8, 15, 18]. However, it was not consistent with the study by Youssef et al. which reported that the mean times of tracheostomy in both methods were statistically similar (21.1 vs. 19.3 min) [17].

This study showed that early tracheostomy in patients, sooner than 14 days, was associated with better outcomes in terms of the need for mechanical ventilation and the duration of stay of patients in intensive care units; this finding was in line with other studies.

In this study, no major and minor complications were noted during the procedure, including persistent fistula of trachea, as well as no tracheostomy-related deaths were observed, and for none of the patients was the method changed. In Carrer's study, the prevalence of intraoperative complications was 9.9 %, and the most common complication was accidental decannulation. In the study by Gambale et al., it was reported in 4.9 % of patients, and the most common complication was minor bleeding during OS (6.6 %) [19]. In the Norwood et al. study, the prevalence of complications during OS was 3.38 %, and the most common complication was minor bleeding (only in 1.2 %) [14]. In the study by Youssef et al., the prevalence of intraoperative complications was 37.5 %, [17]. In the study by Melloni et al., the prevalence of intraoperative complications

Table 2 Duration of intubation, time required for ventilator after tracheostomy, and length of hospital and ICU stay in patients

Variable	Method			Time (based on 14 days reference)		
	Surgery (<i>n</i> = 26)	PDT (<i>n</i> = 29)	<i>P</i>	Early (<i>n</i> = 30)	Late (<i>n</i> = 25)	<i>P</i>
Duration of intubation (days)	22.88 ± 9.8	12.86 ± 9.32	<0.001	8.36 ± 2.07	28.36 ± 5.70	<0.001
Time required for ventilator after tracheostomy (days)	16.76 ± 12.31	10.06 ± 10.48	0.16	10.7 ± 9.52	18.6 ± 14.39	0.024
Length of ICU stay after tracheostomy (days)	20.03 ± 17.16	12.37 ± 10.57	0.274	12.70 ± 10.24	23.44 ± 18.49	0.014
Length of hospital stay after tracheostomy (days)	20.84 ± 16.87	16.51 ± 11.51	0.578	16.04 ± 10.88	23.48 ± 18.47	0.100
Duration of operation (min)	19.19 ± 5.78	4.7 ± 2.42	<0.001			

Table 3 Early and late complications

Complications	Method			Time (based on 14 days reference)		
	Surgery (n = 26)	PDT (n = 29)	P	Early (n = 30)	Late (n = 25)	P
Early ^a	Bleeding	1	0.09	1	1	0.165
	Emphysema	2		0	2	
	Wound infection	1		0	1	
	Tube blockage	1		0	0	
Late ^b	Tube blockage	1	0.437	1	0	0.357
	Tracheal Stenosis	0		0	0	

^a During 1 week

^b After 1 week up to 3 months

was 4 %. No complication was observed in patients undergoing OS; however, in the PDT method, only minor bleeding was observed in two patients [18]. In Farhanchi’s study, the prevalence of intraoperative complications was 16.6 %. The most common complication was bleeding in a volume more than 15 cc, which was observed in one patient in the PDT group and in five patients in the OS group (the number of patients in each group was 18) [8]. In the Zheng et al. study, the overall prevalence of intraoperative complications was 13.4 %, and no significant difference was observed between the OS and PDT methods ($P=0.71$); the most common complication was intraoperative hypoxia [20].

Based on the abovementioned studies, the prevalence of intraoperative complications, regardless of the tracheostomy method, ranged from 3.3 to 37.5 %. The results of the aforementioned studies have reported no significant association between the tracheostomy method and intraoperative complications. Our study is overall not consistent with them.

In this study, although patients in the early group were discharged from the hospital earlier than the other group, the difference was not statistically significant. In the Saboori et al. study, the mean lengths of patient hospitalization in the early and late groups were 30.25 and 36.55 days, respectively ($P=0.042$) [21].

In the present study, 10.09 % of patients were affected by early onset of complications, and the frequency of these complications was as follows: three cases of bleeding (two cases in the surgical site and one case of bleeding together with clot formation in the tracheostomy tube), two cases of emphysema, and one case of wound infection. In the study by Carrer, the prevalence of early complications was 6.6 %; minor bleeding was observed in four patients (2.2 %) and wound infection in the first week after OS was observed in eight patients (4.4 %) [12]. In Mofateh and Golboei-Mosavi’s study, 39 patients (22.1 %) had complications, and the most common complication was bleeding after OS, which was observed in nine patients (5.1 %) [22]. In the Totonchi et al. study, 114 patients (54.3 %) had complications; 8.6 % of patients had early complications in the first hours after OS, which included 15 cases of bleeding and three cases of pneumothorax and pneumomediastinum. Moreover, in the first week, 47.8 % were affected by the early complications, and, again, the most common complication was bleeding, which was observed in 39 patients [23]. In the study of Gambale et al., ten complications (5.5 %) were observed during the stay in ICU, and the most common complication was wound infection, which was observed in eight patients (6.6 %) [19]. In the Kiakjori et al. study, from 96 subjects, early complications were observed in

Table 4 Three-month telephone follow-ups

Symptoms	Method				Time (based on 14 days reference)			
	Surgery		PDT		Early		Late	
	Count	%	Count	%	Count	%	Count	%
Death ^a	24	92.3	10	34.4	10	33.3	24	96
Mild dysphasia	1	3.8	3	10.3	4	13.3	0	0
Occasional aspiration	0	0	1	1.8	1	3.3	0	0
Cough and sputum	0	0	1	1.8	1	3.3	0	0
No complaints	1	3.8	14	48.2	14	46.6	1	4

^a Seven patients died during hospitalization and others died after discharge. The cause of death for all patients was their underlying disease

15, which include infection in seven, bleeding in three, air leak in three, and inflammation in two [16].

Concerning the prevalence of side effects, according to the abovementioned studies, it seems that the rate of early complications in this study was more than the prevalence of complications in Carrer's and Gambale's studies (3.3 and 4.5 %, respectively), but in comparison with similar studies in Iran, the prevalence observed in our study was lower. This may indicate that better care is provided during and after tracheostomy in other countries. On the other hand, the lower prevalence of complications in this study, compared with other studies conducted in the country, might be due to the differences in the studied population and variations in the skills of the OS and therapy teams in the studied center. The most common complication in this study was bleeding (5.4 %), which was more prevalent compared with the studies by Carrer, Gambale, and Mofateh; however, its prevalence was much lower than that in the studies by Totonchi and Kiakojouri. Therefore, it is necessary to pay more attention to the operation techniques and postoperative care to reduce the incidence of complications.

In this study, six early complications were observed: there was only one complication in the PDT method (3.4 %); the other five complications were found in the surgical procedure (19.23 %). Despite the observed numerical differences, no significant relationship was observed between the tracheostomy methods and early complications. In the study by Beltrame et al., the prevalence of early complications was 31 cases (19.2 %) in the OS method vs. 31 cases (19.2 %) in the PDT method, which was not statistically significant. The most common early complication observed in the OS method was bleeding, while in PDT method was rupture in the trachea ring (35 cases) [15]. In the study of Melloni et al., nine early complications occurred after the operation, which includes one case of minor bleeding, seven cases of wound infection in the tracheostomy opening, and one case of random decannulation. In the PDT method, there was only one case of early postoperative complication (minor bleeding). The prevalence of early postoperative complication in the OS method of 36 % and in the PDT method of 4 % confirms that PDT has a lower rate of early postoperative complications [18]. In the Farhanchi et al. study, only two patients in the PDT group (5.6 %) developed subcutaneous emphysema and damage to the posterior wall of the trachea, which was not statistically significant [8].

In the abovementioned studies, except for Farhanchi's, similar to this study, the prevalence of early complications in the PDT method was lower than in the OS method. But in Farhanchi's study, the observed early complications in the PDT method were more than in the OS method. Furthermore, in the abovementioned studies, similar to this study, there was no significant relationship between the tracheostomy methods and early complications. In Farhanchi's study, according to the researcher's conclusion, the higher number of complications in the PDT method was due to the lack of basic skills and knowledge

of possible side effects; as a result, the two observed side effects occurred in the second and third cases of PDT and then no complication occurred. Therefore, in general, it can be concluded that the OS and PDT methods were similar in terms of morbidity and that the PDT method had no additional complications than does the surgical treatment. Therefore, it is a reliable method for opening the airway in patients who need long-term ventilation.

In the Carrer et al. study, patients underwent bronchoscopy 3, 6, and 12 months after discharge, and all long-term complications were identified in the first round (2.1 %); in one case (0.7 %), tracheal stenosis required stenting. Recurrent granulation of the wound occurred in two patients (1.4 %) [12]. In the study by Totonchi et al., 37.1 % of patients showed long-term complications, including three cases of persistent fistula of trachea to skin, 21 cases of tracheal stenosis, 12 cases of granulation formation, three cases of tracheomalacia, six cases of tracheoesophageal fistula, and nine cases of scar at the tracheostomy site [23]. In the Gambale et al. study, symptomatic patients were evaluated 8 months after discharge, and the results showed that the prevalence of tracheal stenosis in that study was 1.2 % [19]. In Norwood's study, the assessments were performed 30 ± 25 months after PDT. Twenty-seven (27 %) patients reported voice changes and two (2 %) reported persistent severe hoarseness. Vocal cord abnormalities occurred in 4 of 38 (11 %) patients, laryngeal granuloma in one (3 %) patient, focal tracheal mucosal erythema in two (5 %) patients, and severe tracheomalacia/stenosis in one (2.6 %) patient. Long-term follow-up of critically ill patients identified symptomatic stenosis manifested by subjective respiratory symptoms after decannulation was found in 3 of 48 (6 %) patients. However, in this study, there was no association between the duration of intubation and tracheal stenosis ($P=0.69$) [14]. In the study by Beltrame et al., 267 of the patients were followed up after 10 months; the results showed that the prevalence of long-term complications was 4.9 % in the OS method vs. 2.18 % in the PDT method, which was not statistically significant. Of five patients, two using the PDT method and three undergoing OS were affected by tracheal stenosis [15]. In the study of Melloni et al., no long-term complication in the trachea in OS was observed; however, two cases of long-term complications were observed in patients undergoing PDT (one segmental malacia and one stenosis at the level of the stoma), although they were not statistically significant [18]. Hazard also reported less long-term complications in the PDT group compared with the OS group [23, 24]. It should be noted that, after tracheostomy, tracheal stenosis would not become symptomatic until when the stenosis covers more than 75 % of the tracheal diameter or when the actual diameter of the trachea reduces to less than 5 mm [14].

The major limitation of our study, which should be considered in conclusion, is the fact that patients who underwent OS had an underlying medical condition and were therefore in the

ICU longer and 92 % died. There was therefore hardly any follow-up.

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Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflicts of interest.

Ethical Considerations The study proposal was approved by the research council affiliated to Semnan University of Medical Sciences. The study was approved by the Committee of Graduate Education and the Research Ethics (decree no. AEF1/0/81.2). The research was conducted at selected hospitals after making application to the relevant authorities and obtaining authorized written permissions. The aim and the study method were described to all participants. Participants were assured that their responses would remain confidential and anonymous, and if willing, they would be notified about the research results. They were also assured that withdrawal from the study process would not have any impact on the patient's care and treatment plan. Those who willingly agreed to participate in the study signed the informed consent form.

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