Ο R I G I N A L   A R T I C L E

Early versus Late Tracheostomy Promotes Weaning in Intensive Care Unit Patients

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Abstract. *Background and aim of the study:* The time interval between the patients' intubation and the performance of a tracheostomy has been considered as critical for the disease prognosis and outcome. The aim of the present study was to compare and contrast the outcomes of early vs late tracheostomy with regard to intensive care unit (ICU) patients' weaning from respiratory support. *Methods:* This retrospective observational study, involved patients who were hospitalized in two general and one Covid-19 ICUs of two tertiary hospitals in Athens and were subjected to tracheostomy. Data were collected from the patients' medical records in order to estimate the duration of patient weaning and the number of days from the patients' intubation until the time of tracheostomy. In the present study the term *early* tracheostomy denotes tracheostomy performed within 14 days from patient intubation and *late* tracheostomy defines the tracheostomy carried out after 14 days. For Covid-19 patients, guidelines suggested that tracheostomies should be performed 21 days following intubation, due to the high risk of virus transmission. *Results:* One hundred and thirty-one patients who underwent tracheostomy participated in the study. Most tracheostomies were performed using the percutaneous technique. The group of patients tracheostomized within 14 days after their admission in ICU weaned faster from respiratory support compared to ones who were tracheostomized after 14 days. *Conclusions:* The most common distinction between early and late tracheostomy is 14 days, with early tracheostomy being more beneficial in terms of patients' outcomes, and specifically ICU patients' weaning. (www.actabiomedica.it)

Key words: tracheostomy, Intensive Care Units, mechanical ventilator, ventilator weaning, respiratory support, Covid-19, critical care nursing

Introduction

Tracheostomy is a common procedure performed in the Intensive Care Unit (ICU). It is a bedside technique carried out by a surgeon or an intensivist (1). There are various indications for tracheostomy, which are rather uncertain, since each hospital follows its own policy on this issue. There is no doubt, however, that tracheostomy can be conducive to the weaning of patients with prolonged mechanical ventilation and therefore contribute to the reduction of complications and decrease patient's length of stay (LOS) in the ICU.

Furthermore, depending on the time interval between the patient's intubation and the performance of a tracheostomy, the procedure is described as early or late. The intensivists have repeatedly examined the question of the optimal timing for the performance of a tracheostomy but no consensus has been reached. It appears though, that prolonged intubation is related to the occurrence of several complications and poor

patients' outcomes such as ventilator-associated pneumonia (VAP) and tracheal lesions (2).

In addition, a tracheostomy can be performed by using two different techniques, the surgical tracheostomy (ST) or the percutaneous dilational tracheostomy (PDT). The latter method has gained wide acceptance in clinical practice due to quicker operative time and less postoperative bleeding (3).

Finally, the benefits of tracheostomy and especially of PDT have been extensively valued as it enhances patient's communication and allows his earlier mobilization. In addition, tracheostomy facilitates oral feeding and enable the patient to breathe spontaneously many hours per day (4).

Aims

The aim of the present study was to compare and contrast the outcomes of early vs late tracheostomy with regard to ICU patients' weaning from respiratory support. Furthermore, the type of tracheostomy (ST/PDT) performed in general ICUs, was documented and assessed.

Materials and Methods

This is a retrospective observational study. This study was carried out in three ICUs in Athens, Greece, whom voluntarily took part in the project. Patients' clinical records of those who were hospitalized in two general and one Covid-19 ICUs of two tertiary hospitals and who were subjected to tracheostomy from the 9th of August, 2019 to the 23rd of August, 2021, participated in the study. The sample consisted of patients who were tracheostomized in non-Covid ICUs, as well as patients who had been diagnosed with Covid-19 in Covid ICUs. The decision to proceed to tracheostomy was made by the patients' attending physicians.

For the purpose of data recording, a specific documentation form was used. This form was developed by the researchers, in accordance with relevant literature [4]. Data collected comprised of social and demographic patient information, such as age, gender, nationality, profession. In addition to those, reason for admission to ICU, chronic conditions, and prior hospitalizations were

also recorded. Information such as, date of admission to ICU, date of performing the tracheostomy, type of technique performed, date of tracheostomy stoma closure (in case of success), number of efforts to achieve a closure, success or failure of closure, date of patient discharge from the ICU and reasons for closure failure (in the cases where closure was not achieved), were recorded. Finally, patient duration of weaning (successful weaning meant no need for mechanical ventilation for more than 48 hours at any moment after the performance of a tracheostomy) and the time interval (in days) between the intubation of the patient and the performance of a tracheostomy, were assessed. Data were collected from patients' admission to patients' discharge from ICU. Early tracheostomy was defined as the one performed within 14 days from the time of intubation and late tracheostomy as that performed after a period of 14 days (3).

Data Analysis

The Statistical Package for Social Sciences (SPSS) ver.24 was used for recording, processing and, analyzing the study results. Initially, descriptive statistics was used and quantitative variables were described as a mean (M) and Standard Deviation (SD), while the qualitative variables were described as absolute (n) and relative frequencies (%). The Kolmogorov-Smirnov normality test was used to confirm data normality. The comparison between the two groups was made with the use of the Student's t-test and the Mann-Whitney U test. In addition, the Pearson's statistical test was used. In the cases where the requirements for the application were not met the tests of Fisher and Monte Carlo were used. The level of statistical significance set for all tests was $p \leq 0,05$.

Ethical Consideration

Prior to the commencement of the study, ethical approval was gained by the Hospitals' Scientific Advisory Boards (Ref No 5844/29-3-2018 and 24845/3-5-2020). Ethical principles such as data protection, anonymity and confidentiality were fully preserved throughout this study. All procedures performed during the research process were in accordance with the ethical standards set

by the institutional research committee and by the 1964 Helsinki declaration and its latest amendments.

Results

The study included 131 patients who had undergone tracheostomy. The mean age of the patients was 58,8 (SD=16,96) years and 85 of them (64,9%) were male. Eighty-six patients (65,6%) were subjected to tracheostomy within 14 days from the time of their intubation. Demographic characteristics of the study participants are presented in Table 1.

Out of the 131 patients, 43 (32,8%) were diagnosed upon hospital admission with neurological problems, 29 (22,1%) with head injuries, 20 (15,3%) with respiratory problems, 18 (13,7%) with Covid-19, 8 (6,1%) with sepsis-septic shock, 4 (3,1%) with cardiovascular problems and 3 (2,3%) with post-surgical complications. There was no statistically significant relationship between the diagnosis upon admission, patients' chronic conditions and the two groups of tracheostomies (early – late) (p-value>0,05). It is worth noting that none of the COVID-19 patients who were involved in the present study were subjected to tracheostomy after the 21st day of ICU admission (Table 2).

Most tracheostomies were performed using the PDT [n=116, (88,5%)] and there was no statistically

significant difference between the two tracheostomy groups (p-value=0,505). 72,5% of the tracheostomies carried out had a successful closure; the mean duration of closure from the day of tracheostomy was 24,42 (SD=10,78) days and the mean duration of closure from the day of admission was 34,64 (SD=11,60) days. The highest incidence of closure failure was due to neurological causes [n=16 (12,2%)] followed by respiratory causes [n=9 (6,9%)], neurological/respiratory causes [n=5 (3,8%)], neurosurgical causes [n=4 (3,1%)] and neurological/neurosurgical causes [n=2 (1,5%)]. The mean of efforts for closure for the 131 patients was 3,85 (SD=2,27) times and there was no statistically significant difference between the two groups of tracheostomies (p-value=0,344). The duration of weaning for all patients was 40,14 (SD=14,23) days and a statistically significant difference was found between the two groups of tracheostomies (p-value=0,004) (Table 3).

Discussion

The present study was carried out in three ICUs of two general hospitals of Athens and comprised of 131 patients with various reasons for admission, including Covid-19. Tracheostomies performed within 14 days from admission were categorized as early, while those performed after 14 days, as late. The patients of the early

Table 1. Demographic characteristics of the patients

*p- value < 0,05

	Total (n=131)	Early tracheotomy (n=86)	Late tracheotomy (n=45)	p-value
Gender				
Men	85 (64,9%)	53 (61,6%)	32 (71,1%)	0,280
Women	46 (35,1%)	33 (38,4%)	13 (28,9%)	
Age in years	58,8 (16,96)	56,8 (17,60)	62,7 (15,08)	0,061
Nationality				
Greek	115 (87,8%)	72 (83,7%)	43 (95,6%)	0,049
Other	16 (12,2%)	14 (16,3%)	2 (4,4%)	
Occupation				0,019
Public Sector employee	13 (9,9%)	10 (11,6%)	3 (6,7%)	
Private Sector employee	31 (23,7%)	25 (29,1%)	6 (13,3%)	
Free-lancer	24 (18,3%)	10 (11,6%)	14 (31,1%)	
Other	63 (48,1%)	41 (47,7%)	22 (48,9%)	

Table 2: Clinical characteristics of the patients

*p- value < 0,05

	Total (n=131)	Early tracheotomy (n=86)	Late tracheotomy (n=45)	p-value
Diagnosis upon admission				
Neurological problems	43 (32,8%)	30 (34,9%)	13 (28,9%)	0,488
Cardiovascular problems	4 (3,1%)	3 (3,5%)	1 (2,2%)	1,000
Respiratory problems	20 (15,3%)	10 (11,6%)	10 (22,2%)	0,109
Head injuries	29 (22,1%)	20 (23,3%)	9 (20,0%)	0,670
Covid-19	18 (13,7%)	13 (15,1%)	5 (11,1%)	0,527
Post-surgical complications	3 (2,3%)	1 (1,2%)	2 (4,4%)	0,233
Sepsis- septic shock	8 (6,1%)	4 (4,7%)	4 (8,9%)	0,445
Other	6 (4,6%)	5 (5,8%)	1 (2,2%)	0,431
Chronic conditions				
Respiratory	33 (25,2%)	19 (22,1%)	14 (31,1%)	0,259
Cardiovascular	63 (48,1%)	38 (44,2%)	25 (55,6%)	0,216
Neurological	29 (22,1%)	15 (17,4%)	14 (31,1%)	0,074
Urological	17 (13%)	12 (14%)	5 (11,1%)	0,646
Haematological	5 (3,8%)	3 (3,5%)	2 (4,4%)	1,000
Musculoskeletal	11 (8,4%)	4 (4,7%)	7 (15,6%)	0,046
Reproductive	8 (6,1%)	3 (3,5%)	5 (11,1%)	0,123
Diabetes Melitus	31 (23,7%)	21 (24,4%)	10 (22,2%)	0,779
Autoimmune diseases	6 (4,6%)	6 (7%)	0 (0,0%)	0,093
Other medical conditions	2 (1,5%)	0 (0,0%)	2 (4,4%)	0,116
Prior hospitalisations	73 (55,7%)	44 (51,2%)	29 (64,4%)	0,146

Table 3: Clinical and procedural outcomes of tracheostomy

*p- value < 0,05

	Total (n=131)	Early tracheotomy (n=86)	Late tracheotomy (n=45)	p-value
Type of procedure				0,505
Surgical	15 (11,5%)	11 (12,8%)	4 (8,9%)	
Percutaneous	116 (88,5%)	75 (87,2%)	41 (91,1%)	
Success of closure	95 (72,5%)	64 (74,4%)	31 (68,9%)	0,501
Causes for closure failure				0,705
Neurological cause	16 (12,2%)	8 (36,4%)	8 (57,1%)	
Neurosurgical cause	4 (3,1%)	3 (13,6%)	1 (7,1%)	
Respiratory cause	9 (6,9%)	6 (27,3%)	3 (21,4%)	
Neurological cause /Respiratory cause	5 (3,8%)	3 (13,6%)	2 (14,3%)	
Neurological cause/Neurosurgical cause	2 (1,5%)	2 (9,1%)	0 (0,0%)	
Number of efforts for closure	3,85 (2,27)	4,03 (2,48)	3,51 (1,78)	0,344
Time from intubation to tracheostomy (in days)	13,08 (4,87)	10,64 (3,69)	17,73 (3,17)	<0,001
Duration of weaning	40,14 (14,23)	37,41 (12,39)	45,36 (16,09)	0,004

tracheostomy group weaned faster from respiratory support than the patients of the late tracheostomy one.

Similar results were observed in a retrospective study conducted in the USA for Covid -19 patients. Early tracheostomy was associated with earlier weaning, decreased duration of mechanical ventilation and reduced LOS in ICU. Furthermore, patients having PDT had better outcomes to those having an ST, such as low incidence of ventilator associated pneumonia, faster weaning from respiratory support and reduced LOS in ICU (5).

The distinction between early and late tracheostomy was made according to the policy followed by each particular hospital participating in the study. Relevant literature does not provide any evidence regarding the cut-off point between early and late tracheostomies. Although this has been an issue of debate among the members of the scientific society, the existing data have not enabled them to reach a consensus on the time interval between the patients' intubation and the performance of a tracheostomy and thus define the exact time for performing a tracheostomy after intubation (2).

Similarly, to the present study, Lely et al., in their study, distinguished between early and late tracheostomy on the basis of 14 days. According to the results weaning from mechanical ventilation varied between the two subgroups with an average time of 5 days for all patients (4).

Moreover, Tang et al., compared the outcomes between early and late tracheostomy at a sample of Covid- 19 ICU patients. The results showed that the tracheostomies performed late (after 14 days), were associated with an increased mortality rate compared to those performed early (before 14 days) (6).

In the study by Robba et al., which involved patients with brain injuries, tracheostomy was defined as early (≤ 7 days upon admission) or late (> 7 days upon admission), due to the fact that tracheostomy is a standard procedure for patients with severe neurological injury. The results of this study shown that early tracheostomy is associated with a better neurological outcome and reduced LOS (2).

The New York and Neck Society provided guidelines on the performance of tracheostomies during the SARS-CoV-2 pandemic. They recommend that the procedure of tracheostomy should be delayed up to 21 days from the onset of symptoms, in Covid- 19 patients, if such a choice is feasible. The reason for this, is to protect healthcare professionals from exposure to increased risk of contamination. However, this recommendation does not apply when the patient's life is at risk or when a patient's prognosis is expected to be improved significantly by performing the tracheostomy earlier (7).

Likewise, the University of Pennsylvania in the USA and the University of California recommend that tracheostomy should not be performed as a standard procedure before the 21st day for Covid-19 patients, due to the high risk of transmitting the virus and the poor prognosis of such intubated patients. In this regard, ST is also recommended instead of the PDT for minimizing the risk of virus transmission (8, 9). Furthermore, research findings indicate that tracheostomy for Covid-19 patients is not performed unless at least 14 days have elapsed since the day of endotracheal intubation (10).

Finally, the present study did not reveal any statistically significant difference between ST and PDT procedures. Research evidence indicated that these two techniques are almost equivalent, with PDT slightly outperforming than ST (11). When tracheostomy is performed following the appropriate Covid-19 guidelines, the procedure can be safely carried out either with the surgical or with the percutaneous technique (12). It is worth pointing out that PDT prevails and, on many occasions, constitutes the predominant method used due to its ease of performance, quicker operative time and less postoperative bleeding compared to ST (13).

Conclusions

The scientific community is yet to accurately identify a gold standard in terms of optimal time interval between intubation and tracheostomy performance. Therefore, each hospital follows its own policy on it. The findings of the present study, similarly to others, support that the most common distinction between early and late tracheostomy is 14 days, with early tracheostomy being more beneficial in terms of patients' outcomes, and specifically ICU patients' weaning from respiratory support. Early tracheostomy appeared to be beneficial for Covid-19 patients, even though guidelines and research evidence recommend that tracheostomy should be performed 21 days following patient intubation because of the high risk of virus transmission. PDT prevailed on

ST and in many cases - excepting the Covid-I9 patients - constitutes the predominant method used due to its ease of performance and efficiency.

However, the findings of the present study should be viewed in the light of the following limitations. The patients involved were hospitalised in two general and one Covid-19 ICUs of two tertiary public hospitals located in Athens. A larger sample size including patients hospitalised in public and private general hospitals ICUs located in different geographical areas might provide a better understanding for the topic under investigation and a generalizability of results. The same principle applies to Covid-19 patients, for whom data collection may continue in the light of the ongoing pandemic (14). Furthermore, limited availability of medical records did not allow a more detailed documentation of clinical and procedural outcomes (15).

Further research is needed to explore long-term outcomes for ICU early tracheostomized patients and promote best clinical practice in this field.

Conflict of Interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article.

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