Turk J Intensive Care
DOI: 10.4274/tybd.galenos.2022.38268

ORIGINAL RESEARCH / *ÖZGÜN ARAŞTIRMA*

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The Impact of the COVID-19 Pandemic on Tracheostomy Applications in the COVID and Non-COVID Intensive Care Units: A Single-center Experience

COVID-19 Pandemisinin COVID ve COVID Dışı Yoğun Bakımlarda Trakesotomi Uygulamalarına Etkisi: Tek Merkez Deneyimi

Received/Geliş Tarihi : 08.09.2022
Accepted/Kabul Tarihi : 28.09.2022

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ABSTRACT *Objective:* There was an initial reluctance to perform tracheostomy in COVID-19 patients due to early reports of high mortality rates and concerns about the transmission of infection. We reported the clinical characteristics and outcomes of patients who underwent an electivetracheostomy during the pandemic.
Materials and Methods: The data from patients who underwent the elective tracheostomy between March 20, 2020, and January 01, 2021, were evaluated retrospectively. Medical records were analyzed for age, gender, comorbidities, complications, and outcomes. The duration from intubation to tracheostomy and the length of ICU and hospital stay were calculated. The data of COVID-19 patients (Group I) and non-COVID-19 patients (Group II) were compared. Additionally, early tracheostomy (≤14 days) and late tracheostomy (>14 days) groups were compared in terms of clinical outcomes.
Results: A total of 144 patients, 70 of whom were diagnosed with COVID-19, were included. Tracheostomy was performed on the median 19th day in both groups (p =0.85). Percutaneous tracheostomy (68.6%) was performed more frequently in COVID-19 patients. The time of tracheostomy application had no positive effect on mortality in either groups. Bleeding occurred less frequently in Group I.
Conclusion: Percutaneous tracheostomy was performed more frequently and earlier in COVID-19 patients. Percutaneous tracheostomy is feasible to be conducted by the ICU team at the bedside with few complications.
Keywords: Intensive care unit, tracheostomy, invasive mechanical ventilation, COVID-19

ÖZ *Amaç:* COVID-19 hastalarında, yüksek ölüm oranlarına ilişkin raporlar ve enfeksiyon bulaşmasıyla ilgili endişeler nedeniyle trakeostomi uygulanması konusunda pandeminin erken dönemlerinde tereddütler mevcuttu. Çalışmamızda, pandemi döneminde elektif trakeostomi uygulanan hastaların klinik özelliklerini ve sonuçlarını sunmayı amaçladık.
Gereç ve Yöntem: 20 Mart 2020 - 01 Ocak 2021 tarihleri arasında elektif trakeostomi uygulanan hastaların verileri geriye dönük olarak değerlendirildi. Tıbbi kayıtlar yaş, cinsiyet, komorbiditeler, komplikasyonlar ve sonuçlar açısından analiz edildi. Entübasyondan trakeostomiye kadar geçen süre, yoğun bakım ve hastanede kalış süreleri hesaplandı. COVID-19 (Grup I) ve COVID-19 tanılı olmayan (Grup II) hastaların verileri karşılaştırıldı. Ayrıca, erken trakeostomi (≤14 gün) ve geç trakeostomi (>14 gün) grupları klinik sonuçlar açısından karşılaştırıldı.
*Bulgular:*Çalışmaya 70'i COVID-19 tanılı toplam 144 hasta dahil edildi. Her iki grupta da ortanca 19. günde trakeostomi açılmıştı (p=0.85). COVID-19 hastalarında perkütan trakeostomi (%68,6) daha sıktı. Her iki grupta da trakeostomi uygulama süresinin mortalite üzerine olumlu etkisi tespit edilmedi. Kanama Grup I'de daha az meydana gelmişti.
Sonuç: COVID-19 hastalarında perkütan trakeostomi daha sık ve daha erken uygulanmıştı. Perkütan trakeostomi, YBÜ ekibi tarafından yatak başı düşük komplikasyon riski ile uygulanabilir.
Anahtar Kelimeler: Yoğun bakım ünitesi, trakeostomi, inavaziv mekanik ventilasyon, COVID-19

Introduction

During the coronavirus disease-2019 (COVID-19) pandemic, the increasing number of patients caused difficulty on the intensive care unit (ICU) processes (1). COVID-19 can induce severe respiratory problems that require invasive mechanical ventilation (IMV) hence tracheostomy opening due to prolonged IMV (2).

Tracheostomy is one of the commonly performed procedures during prolonged IMV in critically ill patients. Traditionally, tracheostomy is performed to ease weaning from ventilator support, clearance of secretions, improve patient comfort and mobility (3). Besides, some studies have shown an association between early tracheostomy and a shorter duration of mechanical ventilation and ICU stay (4). However, tracheostomy carries risk of complications, which are bleeding, infection of the stoma, pneumothorax or pneumomediastinum, or even death (5-7). Therefore, the decision to perform a tracheostomy and if decided, the procedure must be based on a balance between risks and benefits (2). In addition, there was an initial reluctance to perform tracheostomy in COVID-19 patients due to early reports of high mortality rates and concerns about the transmission of infection to healthcare workers (5,6-8). In the face of uncertainty, several consensus reports have been published about the tracheostomy in the COVID-19 patients (4,6-9). Although timing recommendations for tracheostomy varied, the most common recommendation was that mechanical ventilation should be delayed until at least day 14 (5-7). On the other hand, the optimal tracheostomy technique (surgical versus percutaneous) in the COVID-19 patients is unclear (5,6). A high level of consensus has been achieved in guidelines on safety standards such as the use of personal protective equipment (PPE) (hair cover, N95 mask, surgical mask, face shield, gown and gloves) and an apneic approach during tracheostomy (10-12). Despite many of the guidelines on tracheostomy practice, there is limited experience and data on tracheostomy performance (5,6,13,14).

Due to the rapid increase in the number of patients with pneumonia who required intensive care treatment during the pandemic in Turkey, existing intensive care beds and even some operating rooms have been converted to ICUs for the treatment of COVID-19 patients. In addition, while anesthesiologists and intensive care specialists were mostly responsible for COVID-19 ICUs, other physicians were assigned to non-COVID-19 ICUs. All these nonroutine practices are also likely to cause differences in standard intensive care procedures.

This study had two aims: to compare the clinical features and outcomes of patients with and without COVID-19 who underwent elective tracheostomy; and to evaluate whether the COVID-19 pandemic changed the approach of intensive care specialists to the practice of tracheostomy, which is frequently applied in ICU.

Materials and Methods

Study Design and Patients

This retrospective, observational study was conducted in COVID-19 and non-COVID-19 ICUs. The data from patients treated between March 20, 2020, to January 01, 2021, were evaluated. Adult patients (>18 years) who underwent elective tracheostomy were included. COVID-19 was diagnosed according to the World Health Organization interim guidance (15).

Data Collection

The demographic and clinical data were obtained from the electronic medical records. Medical records were analyzed for age, gender, comorbidities, laboratory tests, acute physiology and chronic health evaluation (APACHE) II scores, complications due to tracheostomy, and outcomes. The numbers of days from initiation of invasive mechanicalventilation to tracheostomy, from tracheostomy to weaning, from tracheostomy to discharge from ICU, ICU length of stay (LOS), and hospital LOS were all calculated. Moreover, the type of tracheostomy technique (surgical versus percutaneous), and transmission to staff were recorded.

Outcomes

The primary outcome was the 28-day survival (from the date of ICU admission). We also determined the 60-day mortality. The secondary outcome measures were tracheostomy technique, ICU stay, discharge from ICU, tracheostomy decannulation rate, and complications.

Exploratory Analyses

We divided the patients who underwent elective tracheostomy into two groups: patients diagnosed with COVID-19 (Group I) and those who were not diagnosed with COVID-19 (Group II). These groups were compared in terms of demographic, clinical, and outcome data.

Additionally, both groups were divided into two subgroups according to the timing of tracheostomy. There was no

difference between the groups in terms of age, gender, APACHE II values and indication. The early tracheostomy group, in which tracheostomy was performed within the first 14 days of the initiation of invasive mechanical ventilation; and the late tracheostomy group, in which tracheostomy was performed after 14 days of mechanical ventilation. Laboratory data at the time of admission to ICU for patients with a diagnosis of COVID-19 were compared for the early and late tracheostomy groups.

Tracheostomy Technique and Procedure

The decision of tracheostomy was made by the treating clinicians. In our hospital, all percutaneous tracheostomies were performed at the bedside by the ICU team. Our intensive care unit is in the form of single rooms, and the number of personnel inside was limited to three during the procedure. Percutaneous tracheostomy was performed using Griggs percutaneous technique, known as the guidewire dilating forceps technique (16). All surgical tracheostomies were performed by an otolaryngologist and because of viral load and risk to the healthcare team, it was decided to perform a tracheostomy for all patients, specifically after at least 21 days of ventilation and at least one negative RT-PCR test. There was a minimum of five personnel in the negative pressure operating room during the procedure. The surgical technique was performed with a horizontal incision between the 2nd and 3rd rings of the trachea (16). All patients were completely parlayed by a muscle relaxant. In both techniques, all personnel wore full PPE, and all patients received volume/pressure-controlled ventilation of the lungs with a fraction of inspired oxygen (FiO2) of 100% during the procedure. The ventilator was paused while the tracheostomy cannula was inserted.

Statistical Analysis

The data were analyzed with the statistical software IBM SPSS Statistics for Windows version 20.0 (IBM Corp., Armonk, New York, USA). The descriptive statistics were presented as number (n), percentage (%), mean ± standard deviation (mean ± SD), median, and interquartile range (IQR) values. The normal distribution of the data of the numerical variables was evaluated using the Shapiro-Wilk normality test. Comparisons between groups were performed using Student's t-test for variables with normal distribution and Mann-Whitney U-test for variables not showing normal distribution. The relationship between categorical data was evaluated using chi-square test statistics. A p-value of <0.05 was considered statistically significant.

Results

During the study period, a total of 144 patients, 70 of whom were diagnosed with COVID-19, were included in our study. The mean age of patients diagnosed with COVID-19 (Group I) was 68.4 years; 71.4% were male. In Group II, the mean age of patients was 67.8 years, and 56.8% were male. Although the groups did not differ significantly by gender and age, the APACHE II score was significantly higher in Group I (p=0.019). Hypertension (44.3%) was the most common comorbidity in Group I, while it was cerebrovascular disease (54.1%) in Group II. There was no significant difference between the two groups regarding the ICU LOS and duration from tracheostomy to ICU discharge. However, the hospital LOS was significantly shorter in Group I (Table 1,2).

The indication for tracheostomy in all patients was prolonged IMV. The cause of prolonged IMV in Group I was pulmonary dysfunction, while it was neuromuscular dysfunction in Group II. The median timing of tracheostomy was 19 days after intubation in both groups (range: 1-44 and 1-69 days, respectively). While percutaneous tracheostomy

Table 1. Baseline characteristics of patients

	Group I (n=70)	Group II (n=77)	p-value
Age, years, mean ± SD	68.4±12.8	67.8±13.7	0.88
Gender, male-n (%)	50(71.4)	42(56.8)	0.06
APACHE II score, median (IQR)	23(11)	20(9)	0.019
Chronic medical illness*- n (%)			
Hypertension	31(44.3)	32(43.2)	0.9
COPD	7(10)	5(6.5)	0.48
Cerebrovascular disease	16 (22.9)	40 (54.1)	<0.001
Diabetes	27 (38.6)	14 (18.9)	0.009
Coronary heart disease	11(15.7)	18(24.3)	0.19
Asthma	4(5.7)	0	0.053
Length of ICU stay, median (IQR) days	38(23)	42(28)	0.39
Length of hospital stay, median (IQR) days	38(20)	44(27)	0.04
Mortality – n (%) 28th day 60th day	13(18.6) 42(60)	8(10.8) 32(43.2)	0.23 0.04

APACHE: Acute Physiology and Chronic Health Evaluation, COPD: *Chronic Obstructive Pulmonary Disease,* ICU: Intensive Care Unit, *One patient had more than one chronic disease

(68.6%) was performed more frequently in Group I, surgical tracheostomy (71.6%) was performed more frequently in Group II (p < 0.001). Early and late tracheostomy rates were similar in the two groups. Early tracheostomy was performed in 17 patients in both groups (p=0.85). The most frequent perioperative complication was bleeding in Group II patients as opposed to Group I (1.4 vs. 9.5%; p = 0.06) (Table 2).

Both groups were divided into two subgroups according to the timing of tracheostomy. There was no difference between the groups in terms of age, gender, APACHE II values and indication. (Table 3) Diabetes mellitus and hypertension were higher in Group I patients who underwent early tracheostomy. The median time between intubation and tracheostomy was significantly shorter in the early tracheostomy patients for both groups (for both of them p <0.001). In Group I, percutaneous tracheostomy was performed more frequently in the early tracheostomy patients (88.2%, p=0.07). The hospital and ICU LOS was shorter in the early tracheostomy group in COVID-19 patients (p=0.008 for both). There was no difference between the 28th or 60th-day mortality in the groups who underwent early and late tracheostomy patients (Table 3).

Two patients in Group I and five patients in Group II were decannulated. The discharge data of the patients from the ICU are presented in Table 4.

Table 2. Tracheostomy procedural and technical considerations

	Group I (n=70)	Group II (n=74)	p-value
Indications for tracheostomy, n (%)			
Prolonged IMV, n (%)			
Pulmonary dysfunction	52 (74.3)	15 (20.3)	<0.001
Neuromusculer dysfunction	17 (24.3)	56 (75.7)	<0.001
Airway obstruction - n (%)			
Laryngomalacia	1 (1.4)	3 (4.1)	-
Duration from intubation to tracheostomy, days, median (IQR)	19 (9)	19 (13)	0.85
Duration from tracheostomy to ICU discharge, days, median (IQR)	18 (18)	19 (24)	0.73
Tracheostomy technique, n (%)			
Percutaneous	48 (68.6)	21 (28.4)	<0.001
Open	22 (31.4)	53 (71.6)	<0.001
Tracheostomy Time - n (%)			
Early (≤14 days)	17 (24.3)	17 (23)	0.85
Late (>14 days)	53 (75.7)	57 (77)	0.85
Complications - n (%)			
Tracheostoma bleeding	1 (1.4)	7 (9.5)	0.06
Tracheostomy tube malposition	1 (1.4)	0	0.3
Pneumothorax	1 (1.4)	0	0.3
Tracheostoma infection	0	1 (1.4)	0.3

IMV: Invasive Mechanical Ventilation, ICU: Intensive Care Unit

Discussion

The COVID-19 pandemic caused an unprecedented increase in the number of critically ill patients. Hospitals are overwhelmed, and medical professionals had to make difficult decisions regarding the care of these patients. The potential risk of viral transmission and the high mortality reported in COVID-19 patients raised questions that needed to be answered for more informed decisions about tracheostomy. There is no clear timing for tracheostomy in COVID-19 patients. In addition, it is unknown whether percutaneous or surgical tracheostomy is superior to each other or if it is different in terms of the risk of transmission (13,14,16,17).

Different from other studies, we evaluated tracheostomy applications in critically ill patients with COVID-19 and without COVID-19 (5,13,14). The most common indication for tracheostomy in non-COVID-19 patients was neuromuscular dysfunction, while pulmonary dysfunction in COVID-19 patients. Tracheostomy was performed on the median 19th day in both groups. Considering that the tracheostomy was performed mostly due to neuromuscular dysfunction in the non-COVID-19 patients, the average time from intubation to tracheostomy would be expected to be shorter. We think that this situation is caused by the fact that physicians other than the ICU specialist and anesthesiologist were responsible for non-COVID ICUs during the pandemic and that tracheostomy was performed at least on the 21st day after intubation with one negative RT-PCR test result. Insufficient data on the clinical course, the risk of viral transmission in the early stages of the pandemic, and the presence of asymptomatic carriers were also influential in this decision taken by otolaryngologists. Routine negative RT-PCR test before the procedure was not decided by the ICU team in the COVID

ICU. Delaying tracheostomy to achieve negative tests is likely to prolong endotracheal ventilation and thus alter the potential benefits of tracheostomy while increasing the risk of complications related to endotracheal intubation. Critical ill patients can continue testing positive for several weeks after the onset of symptoms, and whether the detection of viral RNA by PCR predicts the risk of infectivity to surgeons and other healthcare professionals is uncertain (18,19).

Although the effects of tracheostomy are mostly revealed by retrospective observational studies, the data on the timing in patients with COVID-19 are even more limited (14,20-22). Glibbery et al. have shown that the time from intubation to tracheostomy was strongly positively correlated with the duration of IMV, time from intubation to decannulation, and time from intubation to ICU discharge (22). In a multicenter study including 153 patients, it was shown that early tracheostomy application (<15 days) was associated with shorter ICU stay, although no difference was found in terms of mortality (23). Especially during the pandemic, shortening the duration of intensive care and hospital stay is critical for managing the patient population that complicates the hospital operation. Although the ICU stay was short in the early tracheostomy group in our study, mortality was very high in this group.

Tracheostomy is a procedure that can be performed with surgical or percutaneous techniques. With the increasing

Table 3. Baseline characteristics and outcomes of patients receiving early and late tracheostomies

	Group I (n=70)			Group II (n=74)		
	Early (n=17) (<14 days)	Late (n=53) (>14 days)	p-value	Early (n=17) (<14 days)	Late (n=57) (>14 days)	p-value
Age, years- mean ± SD	66.7±12.2	68.9±13.1	0.47	65.8±18.3	68.4±12.1	0.87
Gender, male - n (%)	12 (70.6)	38 (71.7)	1.00	9 (52.9)	23 (40.4)	0.41
APACHE II score, median (IQR)	22 (12)	23(10)	0.52	18 (12)	21 (10)	0.30
Chronic medical illness*, n (%)						
Hypertension	8 (47.1)	23 (43.4)	1.00	7 (41.2)	25 (43.9)	1.00
COPD	2 (11.8)	5 (9.4)	1.00	0	5 (8.8)	0.33
Cerebrovascular disease	2 (11.8)	14 (26.4)	0.32	10 (58.8)	32 (52.6)	0.78
Diabetes	10 (58.8)	17 (32.1)	0.08	3 (17.6)	11 (19.3)	1.00
Coronary heart disease	3 (17.6)	8 (15.1)	1.00	4 (23.5)	14 (24.6)	1.00
Asthma	2 (11.8)	2 (3.8)	0.24	0	0	-
Duration from intubation to tracheostomy, days, median (IQR)	11 (4)	21 (7)	<0.001	10 (6)	24 (12)	<0.001
Duration from tracheostomy to ICU discharge, days, median (IQR)	17 (14)	18 (21)	0.73	17 (17)	19 (26)	0.71
Indications for tracheostomy, n (%)	0.20			0.008		
Pulmonary dysfunction	11 (64.7)	41 (77.4)		4 (23.5)	11 (19.3)	
Neuromuscular dysfunction	5 (29.4)	12 (22.6)		10 (58.8)	46 (80.7)	
Laryngomalacia	1 (5.9)	0		3 (17.6)		
Tracheostomy technique, n (%)	0.07			0.22		
Percutaneous	15 (88.2)	33 (62.3)		7 (41.2)	17 (24.1)	
Open	2 (11.8)	20 (37.7)		10 (58.8)	43 (75.4)	
Length of ICU stay, days, median (IQR)	28 (15)	42 (20)	0.008	34 (31)	43 (28)	1.00
Length of hospital stay, days, median (IQR)	31 (13)	42(20)	0.008	45 (30)	51 (27)	0.67
28th day mortality, n (%) 60th day mortality, n (%)	6 (35.3) 12 (70.6)	7 (13.2) 30 (56.6)	0.06 0.39	1(5.9) 6 (35.3)	7 (12.3) 26 (45.6)	0.67 0.58

APACHE: Acute Physiology and Chronic Health Evaluation, ICU: Intensive Care Unit, *One patient had more than one chronic disease

Table 4. Outcome of patients discharged alive		
	Group I (n=17)	Group II (n=25)
Decannulated, n (%)	2 (11.8)	5 (20)
Oxygen via tracheostomy, n (%)	1 (5.9)	10 (40)
Completely ventilator dependent, n (%)	14 (82.3)	10 (40)

experience over the years, the number of patients who have undergone percutaneous tracheostomy has increased. However, the pandemic has led to debates on the efficacy and safety of percutaneous and surgical tracheostomy techniques (24-26). Bassi et al. reported that if the suggested precautions are strictly followed, percutaneous tracheostomy could be performed with minimal aerosol spread as well as surgical tracheostomy (27). In a multicenter prospective observational study that included 1890 COVID-19 patients, Martin-Villares et al. reported that most of the procedures were performed at the bedside in ICU and used the surgical technique (28). It was reported that there were no cases of COVID-19 related to the procedures among healthcare workers in the study. In our study, most of the tracheostomy applications in COVID-19 patients were performed by ICU physicians using the percutaneous technique at the bedside. The implementation of bedside percutaneous tracheostomy has prevented the unnecessary transport of ventilated patients and the repeated disconnection and reconnection of ventilator circuits during transport. In addition, the number of personnel could be kept more limited with the percutaneous tracheostomy compared to the surgical tracheostomy (three versus a minimum of five staff, respectively). Unlike the period before the pandemic, in both percutaneous and open techniques, ventilation was stopped from the time of opening the trachea to placing the tracheostomy tube and inflating the cuff, and the whole team used the appropriate PPE. Although we did not have a strict protocol on the timing or method for tracheostomy, we had a standard approach, and all precautions were consistently taken to minimize risks to clinicians. No transmissions to healthcare workers occurred during any procedure.

The most frequently reported complication associated with a tracheostomy procedure is minor bleeding (28). The most common complication in our study was also bleeding. Surgical tracheostomy was performed in five of the eight patients who developed bleeding (one patient in Group I, four patients in Group II). None of the patients required blood transfusion or surgical procedures related to tracheostomy bleeding. It has been reported that the use of a smaller incision and blunt dissection are associated with less bleeding in percutaneous tracheostomy. Also, the stoma fits tightly around the tracheostomy tube and is effective in reducing bleeding with its compression effect. (24-26).

This study is one of the first and largest series to describe early outcomes of COVID-19 patients undergoing tracheostomy in Turkey. In addition, according to our research, it is the first study in the literature to compare tracheostomy applications in COVID-19 and non-COVID-19 patients during the pandemic period. However, our study has several limitations. This is a retrospective cohort study with a relatively small number of patients and short-term mortality. Therefore, the power to detect mortality differences may be inadequate. The analysis of long-term outcomes, long-term disability, and chronic care were also lacking. Comparing patients according to the diagnosis of COVID-19 is one of the strengths of our study.

The role of tracheostomy in COVID-19-associated pneumonia is unknown. Currently, there is no clear indication of the timing of tracheostomy in these patients. There is no evidence that tracheostomy improves the COVID-19 patient's clinical course. There is a need for studies that will guide the timing of tracheostomy and the effect of tracheostomy techniques on morbidity and mortality in critically ill, mechanically ventilated COVID-19 patients.

This study shows that percutaneous tracheostomy can be performed by the ICU physician at the bedside with few complications. Since percutaneous tracheostomy can be applied safely at the bedside, it seems more advantageous than surgical tracheostomy, as there is no need for patient transport, and the number of personnel can be kept more limited during the procedure. However, the timing and type of tracheostomy did not affect survival.

Ethics

Ethics Committee Approval: Ethics approval was received from the University of Health Sciences Turkey, Bursa City Hospital Clinical Research Ethics Committee on January 6, 2021, with the project number (decision no: 2021-1/17).

Informed Consent: Retrospective study

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: G.Ç., S.T., P.K.K., G.T., Concept: G.Ç., P.K.K., E.U., N.K.G., Design: G.Ç., S.T., G.T.,

N.K.G., Data Collection and Process: S.T., P.K.K., G.T., E.U., Analysis or Interpretation: G.Ç., P.K.K., N.K.G., Literature Search: S.T., G.T., E.U., Writing: G.Ç., N.K.G.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declared that this study received no financial support.

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