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Tracheotomy During Pandemic COVID-19 Outbreak. Experience At University Clinical Center Tuzla

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ABSTRACT

Objective: The aim of the study was to present experience of performed tracheotomies during the Covid19 pandemic and to outline the adjustments made to the procedure for security reasons.
Materials and Methods: In the retrospective study for the period March 2020 to April 2022 we analyzed the disease history data and surgical findings from all patients in UCC Tuzla who underwent surgical tracheotomy during the COVID-19 pandemic.
Results: 52 patients who underwent open surgical tracheotomy after an invasive mechanical ventilation were analyzed in our study. Group A were 32 COVID-19 consecutive patients (22 male, mean age±13.54 years, range 23-76). The tracheotomy was performed approximately on day 12.4 of the intubation (range 4-28). Group B consisted of 22 patients who had not suffered from COVID-19, and their PCR test was negative for SARS-Cov-2 (12 male, mean age 59.4±20.40 years, range 19-87). The tracheotomy was performed approximately on day 10.1 of the intubation (range 2-20). There was a statistically significant difference in mortalities when both groups were compared. The most common complication was diffuse bleeding from soft tissue of the neck in the early post tracheotomy period and local infection in the later period. The most common comorbidities were arterial hypertension and diabetes mellitus.
Conclusion: According to our study results, COVID-19 elderly patients who are on Invasive Mechanical Ventilation (IMV) have an uncertain prognosis. Correct timing of the tracheotomy is necessary so as not to further traumatize the patients.

Keywords: Tracheotomy, COVID-19, Complications, Comorbidity

INTRODUCTION

Tracheotomy is the oldest and most common surgical procedure performed on patients in an intensive care unit (ICU), and it is conducted on between 10% and 24% of patients on invasive mechanical ventilation (IMV) (1). The novel coronavirus (COVID-19) global pandemic was characterized by rapid respiratory decompensation and subsequent need for endotracheal intubation and mechanical ventilation in severe cases. Approximately 3% to 17% of hospitalized patients required invasive mechanical ventilation (2-8), and a tracheotomy was chosen due to the need for prolonged mechanical ventilation. Therefore, tracheotomy was the most common surgical intervention that was performed during the period of the SARS-CoV-2 pandemic (9). Tracheotomy is an aerosol-generating procedure (10), and it is high risk due to possible infection transmission on healthcare workers.

At the beginning of the COVID-19 pandemic, physicians in intensive care units faced some dilemmas concerning

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tracheotomies. The questions asked were: "Why perform tracheotomies? When and by which method should tracheotomies be performed? Where should tracheotomies be carried out? What is the preferred method of tracheal incision?

The recommendations in the beginning were based on the experiences of the SARS-CoV-1 epidemic and Middle East respiratory syndrome which had a higher rate of infection transmission, and they relied on the expert opinion of surgeons and epidemiologists (11). A greater understanding of the virus developed with continuous research effort. The new literature has helped us to understand different aspects of COVID-19, including the patients' outcomes and risks to healthcare workers.

There were a few protocols issued for the tracheotomy, tracheobronchoscopy, and laryngoscopy management, representing a modification of standard procedure, and the aim was to decrease intraoperative exposure to aerosols and to protect the healthcare workers (12-15). The protocols refer to the methodology of procedure, the minimization of the staff and instrument presence during the procedure, the recommendation for Personal Protective Equipment (PPE) and for the covering of the patient, and providing for the removal of aerosols during the procedure.

Aims of the study: To show the complications, comorbidities, tracheostoma and tracheal aspirate swab microbiological samples, to present the outcome of open surgical tracheotomy on COVID-19 and "non COVID-19" patients, and to outline the methodology of performing tracheotomy under COVID-19 conditions at UCC Tuzla.

MATERIALS AND METHODS

A retrospective study on 52 patients was conducted at the ENT Clinic and Clinic for anesthesiology, UCC Tuzla, Bosnia and Hercegovina, from March 2020 to April 2022. The patients were divided into two groups. Group A consisted of 32 COVID-19 consecutive patients which were tracheotomized after prolonged intubation on IMV. All of them had pneumonia leading to acute respiratory distress syndrome. Group B consisted of 22 patients who had not suffered from COVID-19 and whose PCR test had been SARS-Cov-2 negative, but who underwent surgical tracheotomy for prolonged intubation. The medical charts of the patients and surgeon's reports were analyzed in patients which were tracheotomized after prolonged intubation on IMV. The patients who had been exposed to radiation in the neck region or who underwent neck region surgeries were not included in the study.

In group A all tracheotomies were performed at the bedside (without negative pressure rooms). Preoperative antibiotic prophylaxis and low molecular weight heparin (LMWH) was administered in all cases. The surgical team always included one surgeon (ENT) and one nurse. The whole staff wore protective clothing "PPE": water-resistant disposable gown, cap, shoe covers, double gloves, mask (FFP3/FFP2-N95), goggles and face mask. After pre-oxygenation with 100% oxygen for 3 minutes, apnea was allowed to reduce aerosol generation during the tracheal incision and tracheostomy tube insertion. The trachea was then incised between rings II-III according to Bjork (16), and the orotracheal tube was removed after which a tracheal cannula was inserted leading to ventilation. We modified the Bjork flap procedure. Unlike the tracheotomy procedure described by Bjork, a vertical incision on skin was made, and after the trachea incision, the tracheal ring and the "flap" were additionally sutured laterally in order to prevent bleeding because all the patients were on high LMWH doses.

The tracheotomies on group B patients were in most cases performed using the identical procedure as the tracheotomies for group A patients. The difference in tracheotomy methodology in both groups was in the type of protective clothes for the staff.

Statistical analysis

Categorical variables were presented as percentages. Continuous variables were summarized as mean±standard deviation or mean and range. Comparisons between the groups were performed by Pearson's chi-squared test or Fischer's exact test for categorical variables.

The Point-biserial correlation coefficient was calculated to determine the relationship between the categorical and the continuous variable. Statistical significance was presented as *p*-value, with observed differences considered statistically significant at a $p \leq 0.05$.

This study was approved by the institutional ethics committee 17.11.2021. No.: 02-09/2-83-2/21.

RESULTS

The research included 52 patients who underwent a tracheotomy. There were 33 (63.5%) male, and 19 (36.5%) female patients. The youngest patient was 19, and the oldest was 87 years old. The average age of the subjects was 59.8±16.5. The demographic characteristics of the patients and the comorbidities are presented in Table 1. After the statistical analysis, there were no significant differences in variables between the two subject groups determined.

After the analysis of tracheostoma or aspirate swab samples from trachea, it was determined that bacteria were present in 37.5% of the patients in group A, and the most common was Klebsiella pneumoniae (in 12.5% of the patients). In group B, the bacteria were isolated in 55% of the patients, and the most common was Acinetobacter species (in 35.0% of the patients). χ^2 test did not determine a statistically significant difference in the number of infected patients between the two groups of patients on the level of statistical importance $p<0.05$ (Table 2).

Table 3 presents the complications in tracheotomy that occurred during the surgery, both in the early (up to 24 hours) and late postoperative period.

Table 1: Demographic characteristics and comorbidity of patients

Clinical summary	All pts (52)	Group A (32)	Group B (22)	p value
Demographics				
Age (mean, range)	59.8 (19-87)	60.0 (23-76)	59.4 (19-87)	0.91*
Sex (male/female ratio)	1.7	1.9	1.5	0.91**
Comorbidity (%)				
Arterial hypertension	51.9	62.5	35.0	0.10**
Diabetes mellitus	17.3	15.6	20.0	0.72***
Obesity BMI > 25	11.5	18.8	0.0	-
Other	32.7	31.3	35.0	0.97**
With comorbidity	75.0	81.3	65.0	0.32**
Without comorbidity	25.0	18.7	35.0	
Comorbidity=1	48.1	75.6	61.1	0.73***
Comorbidity≥2	26.9	24.4	38.9	

*Mann-Whitney U test. **Pearson χ2 test; ***Fisher exact test

Table 2: Pathogens identified from peristomal swabs or tracheal aspiration

Pathogens	All patients	Group A	Group B
Candida al.	1/52 (1.9)	1/32 (3.2)	0/20 (0.0)
Stenotrophomonas mal.	1/52 (1.9)	1/32 (3.2)	0/20 (0.0)
Acinetobacter bau,	3/52 (5.8)	3/32 (9.4)	0/20 (0.0)
Klebsiella pn.	6/52 (11.5)	4/32 (12.5)	2/20 (10.0)
Proteus mir.	3/52 (5.8)	3/32 (9.4)	0/20 (0.0)
Pseudomonas ae.	4/52 (7.7)	3/32 (9.4)	1/20 (5.0)
Staphylococcus au.	1/52 (1.9)	1/32 (3.2)	0/20 (0.0)
Acinetobacter sp.	7/52 (13.5)	0/32 (0.0)	7/20 (35.0)
Providentiaa sp.	1/52 (1.9)	0/32 (0.0)	1/20 (5.0)
Identified with pathogens	23/52 (44.2)	12/32 (37.5)	11/20 (55.0)
Without infection by pathogens	29/52 (55.8)	20/32 (62.5)	9/20 (45.0)
p=0.34*			

Values are: number of patients (percentage). *Pearson χ^2 test

Table 3: Postoperative complications

	Group A (32) n (%)	Group B (20) n (%)	All patients (52) n (%)	p
Complications				
Tracheostomal Infection	8 (25.0)	3 (15.0)	11 (21.2)	0.50***
Hemorrhage	7 (21.9)	2 (10.0)	9 (17.3)	0.45***
Subcutaneous emphysema	2 (3.9)	0 (0.0)	2 (3.9)	-
Death	26 (81.3)	10 (50.0)	36 (69.3)	0.04**
Day of death after tracheotomy (mean, range)	8.1 (0-46)	5.0 (0-14)	6.9 (0-46)	0.52*
The duration of intubation before tracheotomy (mean, range)	12.4 (4-28)	8.1 (0-46)	11.5 (4-28)	0.08*

*Mann-Whitney U test. **Pearson χ^2 test; ***Fisher exact test

There was a significant death prevalence in group A (81.25%) compared to group B (50%). χ^2 test showed that there was a significant difference in the distribution of data on death prevalence of patients in group A compared to group B *(χ^2=4.07; df=1;* p=0.04). Fi correlation coefficient showed that, according to Koen criterium, it was a moderate correlation (p=0.33).

Table 3 represents the basic statistical parameters and testing results for the differences in data for the variables of intubation duration both before tracheotomy and on the day of death after the tracheotomy. The average value was higher in group A patients for both variables. Mann-Witney U test did not identify statistically significant differences in the results on the level of statistical difference p<0.05.

DISCUSSION

In our study, we analyzed the data from 52 performed elective surgical tracheotomies at UCC Tuzla during the COVID-19 pandemic The patients were divided into two groups depending on their COVID-19 status. The indications for the procedure were the prolonged intubations in the patients on invasive mechanical ventilations. During the COVID-19 pandemic, each of the performed tracheotomies presented a new cognition and experience to make the procedure easier and more secure. The decision to conduct the tracheotomy procedure was made after consultation with the anesthesiologist and ear, nose and throat specialist, on the basis of the clinical status of the patient and the need to improve the tracheobronchial toilet and oxygenation of the patient as well. The surgical team consisted of one ENT doctor and one nurse. An anesthesiologist and respiratory nurse were also present during the procedure. After the incision of the trachea between rings II-III on our patients, we formed the tracheostoma according to Bjork (16). The procedure of Bjork flap forming was modified, such that tracheal ring and “flap” were additionally sutured on the skin in order to prevent bleeding in the tracheostoma area (because all patients were on high doses LMWH). A Bjork flap can prevent post-tracheostomy tracheal stenosis in patients undergoing elective tracheostomy. A Bjork flap is recommended to avoid false passage in the event of accidental decannulation. Shifrer et al. (17) recommend forming an opening in the trachea in the shape of a Middle Ages shield, with the removal of a part of the tracheal wall. All tracheotomies in our patients were performed at the bedside, in an intensive care unit (ICU). In the available guidelines it was suggested that ICU and surgical teams check the optimum location for tracheotomy. Special attention was paid to the use of diametric, due to the high oxygen concentration in the infirmaries and the possibility of causing explosion and fire. In the period between May 2020 and May 2021, there were 38 non-surgical oxygen-related fires on the premises where COVID-19 patients were being treated with numerous victims noted (as reported or suspected) as found in media reports, scientific articles and other publications. A catastrophic fire in an Iraqi hospital took the lives of 82 people. Since the outbreak of the pandemic in March 2020, the incidents of hospital fire related to oxygen in different countries around the world caused more than 200 deaths, of which most of them were critical COVID-19 patients (18, 19).

It is recommended that tracheotomy on non - COVID-19 patients in intensive care units is performed up to seven days after intubation. The advantages of tracheotomy within the seven day period include a shorter stay in the intensive care unit, shorter time on mechanical ventilation, lower risk from subglottic stenosis development and the improvement of tracheobronchial toilet (20-23).

In group A, the average day on which a tracheotomy was performed was 12.4 of endotracheal intubation (range 4-28), while in group B it was on day 10.1 of intubation (range 2-20). The most controversial decision is to determine the term for tracheotomy in COVID-19 patients. In numerous publications the determination of the term for tracheotomy is based on the duration of SARS CoV-2 positivity or the duration of endotracheal intubation. At the beginning of the COVID-19 pandemic, before the vaccination had been initiated, the duration of prolonged intubation for tracheotomy had been longer compared to the period when the healthcare workers had received immunization. McGrath et al. (18). suggest postponing the tracheotomy at least up to 10 days of mechanical ventilation and it should be taken into consideration only when the patients show signs of clinical improvement. Van Kampen et al. (24) suggest that the best time to perform tracheotomy in COVID-19 patients is on the 21st day from the beginning of Sars Cov-2 positivity. This term for tracheotomy is safe from two aspects. First, the patient is not contagious anymore, and the second, the possibility for laryngotracheal stenosis up to 14 days of prolonged intubation is small, if the cuff is not overblown. Tiffany et al. (25) suggest that a tracheotomy can be taken into consideration with prolonged periods of intubation, defined as longer than 21 days, and that such cases do not have significant comorbidities, the expectation being that they will have a good prognosis if recovery is achieved. Tracheotomy should not be performed before 21 days in COVID-19 patients since the existing literature shows that there is a high risk of transmission and a bad prognosis for patients who need intubation and ventilation . If the patient is COVID-19 positive and fewer than 20 days have passed since the first symptoms occurred or the first positive RT-PCR was determined, we recommend that tracheotomy should not be performed in this group of patients who are potentially still infected (26-30), except if it is urgent due to inadequate airways.

In our study there was a dominance of males (63.5%), which is in keeping with the published data in numerous studies where it is within the range 51-82% (31-34).

We analyzed the bleeding, an occurrence of subcutaneous emphysema and infection in patients after tracheotomy. In our study there was no statistically significant difference in variables of complications between the subject groups. There was a significantly important correlation of the presence of pathogenic microorganisms and tracheostoma infection (p=0.00) determined for the whole sample, and after a

subsequent testing, it was determined that this correlation results from statistically significant correlation of the presence of pathogenic microorganisms and the infection of tracheostoma only in group A patients. The rate of individual complications in our study was between 3.9% to 25% which does not differ significantly from the published figures in the literature ranging from 5.6% to 27.2% (35-40). The incidence of overall tracheotomy complications in COVID-19 patients is higher than in the general population. Percutaneous dilatory tracheotomy and open surgical tracheotomy are characterized with the same post operative rates of complications in severe patients with COVID-19 (41), but there are contrary figures in the literature on the risks and complications of these two methods of tracheotomy (42-45).

Open surgical tracheotomy is related to higher incidence of early wound infections and forms larger scars on the neck.

Bleeding in the tracheostoma area in group A was noticed in 21.9% of the patients, out of which in 15.6% cases bleeding was noted during the surgery, 9.4% in the early postoperative period and 3.1% in the later period. Two patients had bleeding in all three periods. 10% of the patients in group B had bleeding that occurred during the surgery and in early the postoperative period (up to 24 hours).

The statistically significant difference in the death of the patients in the two subject groups after tracheotomy is related to the condition of COVID-19 patients with ARDS, who are on IMV, and who have a higher death rate in general. In our study, we determined a statistically significant correlation of patients' age and death rate with tracheotomy (r_{pb}=0.41, p=0.00). We think that a higher death rate in group A is related to the critical condition of the patients infected with COVID-19 and that it is not associated with tracheotomy.

Comorbidities, including hypertension, diabetes, cardiovascular diseases, cerebrovascular diseases, COPD, and malignoma significantly affect the seriousness and prognosis of the disease in patients suffering from COVID-19 (46).

In our study, we analyzed the comorbidities that were present in 75% of cases, where the most common were arterial hypertension (51.3%), diabetes mellitus (17.35%), obesity (11.5%). The patients suffering from COVID-19 with diabetes mellitus were more susceptible to overactive inflammation and non-balanced immune responses, which is the key element in the deterioration of patients suffering from COVID-19 (47, 48).

In group A, which consisted of patients with critical COVID-19, 18.7% of the cases were without comorbidities, which is not in accordance with the published figures by Perez et al. The authors published that arterial hypertension was present in 40% of cases, and that there were 38% of subject patients without comorbidities (49).

In the study, there was neither a statistically significant difference in comorbidity variables between the subject groups, nor was there a confirmed correlation between the comorbidities and complications of tracheotomy. There was no correlation between the comorbidity and death rate either.

After the analysis of tracheostoma or aspirate swab samples from trachea, it was determined that the bacteria were isolated in 37.5% of the patients in group A, and the most common was Klebsiella pneumoniae (in 12.5% of the patients). In that group, the inflammation in the tracheostoma area was noted in 25% of the patients. In group B, the bacteria were isolated in 55% of the patients, and the most present one was Acinetobacter species (in 35.0% of the patients). It is generally known that Acinetobacter baumannii easily colonizes the tracheostoma area and it is one of the leading causes of hospital epidemics among immunocompromised patients in the world, especially in intensive care units. The epidemics of infections with this bacterium are attributed to contamination and transmission in the hospital environment. The presence of mycosis in both groups was noted in individual cases, which is contrary to the previous studies that published a high incidence of Candida wound infection in 47-66% (41, 50, 51).

CONCLUSION

According to our study results, COVID-19 elderly patients who are on Invasive Mechanical Ventilation (IMV) have an uncertain prognosis. It is necessary to estimate the time of performing the tracheotomy so as not to further traumatize the patients. There is a statistically significant difference in the mortality rate between the examined groups of covid and non-covid patients after tracheotomy.

Ethics Committee Approval: This study was approved by University Clinical Center Tuzla Ethics Committee (Date:02-09/2-83-2/21, No: 17.11.2021).

Informed Consent: Written informed consent was obtained.

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