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A Percutaneous Tracheostomy Experience in The ICU During The COVID-19 Pandemic

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ABSTRACT

Aim: During the COVID-19 pandemic, some procedural changes for the percutaneous tracheostomy (PT) procedure were necessary to prevent virus transmission to the operators. In this prospective study, it was investigated whether there were clinical differences in COVID-19 and non-COVID-19 patient groups who needed PT.

Study design: All patients who were greater than 18 years, who underwent PT in the tertiary COVID-19 and Internal Medicine ICU between January 2020 and January 2022 were included. Demographic and laboratory informations, pre– and post PT chest X-rays, and other clinical data during ICU follow-up were collected.

Materials and methods: All necessary protective equipment was used by the PT team for the COVID-19 patients. Required sedoanalgesia and neuromuscular muscle blockade were applied. PT was performed by applying the forceps dilatation method defined by Griggs.

Results: A total of 40 patients were included, 19 (47%) of them were female, median age was 78 [67–83] years. APACHE II score and SOFA score of the patients were 19.5 [17.0–22.7] and 7.5 [6.0–9.0]. Mortality rate was 16 (40%) and was not different between groups (p=0.289). Percutaneous tracheostomy procedure time was 8 [5–10] minute and did not differ between groups (p=0.865). A total of 4 (10%) VAP (ventilator-associated pneumonia), 2 (5%) sepsis, and 4 (10%) local hemorrhage developed after PT procedure. The length of ICU stay after the PT procedure was 11 [5–30] days and not statistically significant (p=0.066).

Conclusion: PT can be safely applied in COVID-19 patients with similar mortality and complication rates as non-COVID-19 patients.

Keywords: percutaneous tracheostomy, ICU, COVID-19, complications

Introduction

Percutaneous tracheostomy (PT) is a procedure frequently performed with different indications in the intensive care unit (ICU) (1). During the pandemic due to Coronavirus-2019 (COVID-19) disease, prolonged intubation was often required in patients followed in ICU due to ARDS (Acute respiratory distress syndrome) (2). At the same time, tracheostomy is seen clinically beneficial in patients with prolonged intubation associated with COVID-19 disease (especially for intubation duration greater than 10-15 days) (2). These positive effects are often associated with early weaning from the mechanical ventilator and shortening of the length of ICU stay (3). In addition, it is another advantage that it creates an additional option in terms of transferring patients to home or palliative care centers under home-type mechanical ventilator support. Considering the increased intubated patient load in ICU during the COVID-19 pandemic, these positive effects provide an additional option for the "intensivist" to reduce this patient burden. For this reason, it can be predicted that there is an increase in the number of patients who need tracheostomy in the COVID-19 pandemic period. However, the physician performing the PT procedure should use some extra protective equipment and may apply some changes in PT technique in order to reduce the risk of transmission of COVID-19 disease to the operators (4). Therefore, there are significant differences in the progression and implementation of the PT procedure during the COVID-19 pandemic compared to patients without the risk of viral transmission by airway to the operators. For example, when performing PT for COVID-19 patients, deep sedation and complete neuromuscular blockade are recommended for prevention of coughing of patients (5). Also, patients should be apneic during the procedure

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and ventilator support should be interrupted intermittently at necessary periods during the procedure. At the same time, the use of protective FFP3 masks, water-repellent suits and glasses during the procedure may adversely affect the movement and vision of the operator. Another factor that can have a negative effect is to perform the procedure with a minimum of staff in order to reduce the risk of viral transmission (6). Do these extra protective measures and changes in the PT technique cause any increase in the complication rate or cause any decrease in beneficial effects that can be seen after PT? We think that answering this question will further reinforce our commitment to the procedures to be applied during the percutaneous tracheostomy in cases of respiratory failure and prolonged intubation due to respiratory viral diseases spread through the respiratory tract. We planned this prospective observational study to investigate the effect of procedural differences applied during percutaneous tracheostomy to protect the team performing the procedure from viral transmission, on complications and possible positive effects of tracheostomy.

Materials and Methods

Patient Population

Ethical approval for this study was obtained from local ethics committee with the decision numbered E.22,998 at 08 June 2022. All patients over then 18 years of age who were planned to undergo percutaneous tracheostomy among patients hospitalized for COVID-19 pneumonia or other reasons in the tertiary ICUs of the internal medicine department of Ankara Training and Research Hospital between January 2020 and January 2022 were included in the study. Patients with pregnancy status were not included in the study. Written informed consent was obtained from all patients or their relatives who were included in the study. The decision for percutaneous tracheostomy was made by the clinician who followed the patient regardless of the inclusion status to this study, according to the clinical condition of the patient. The following criteria were expected to be met in order to make a percutaneous tracheostomy decision for the patients; continued intubation status for greater than one week, expected prolonged intubation status as greater than 2 weeks, arterial oxygen saturation greater than 90% or partial arterial oxygen pressure greater than 60 mmHg when FiO_2 in inhaled air less than 60%, to be in a hemodynamically stable condition (mean arterial pressure greater than 65 mmHg and noradrenaline or adrenaline infusion rate less than 0.1 mcg/kg/min), international ratio of prothrombin time less than 1.4, thrombocyte count in blood greater than 50000/mm^3, hemoglobin level of blood greater than 8 gr/dL. Patients who had a mass, a prominent goiter, the open or infected wound on the anterior region of the neck, patients who received radiotherapy to the neck before, patients who had lower distance between the bottom edge of the cricoid cartilage and incisura jugularis (less than 2.5 cm), patients with significant tracheal deviation, patients who could not be sufficient neck extension were not included in the study. Anticoagulant treatment of patients was stopped at least 12 hours before the PT procedure. At the same time, if approval of the associated primary department (cardiology or neurology) can be obtained antithrombotic drug treatments (clopidogrel or acetyl salicylic acid) were stopped 3 days before the planned PT procedure for patients who received antithrombotic drug therapy for various indications.

Clinical Data of the Patients

Information about APACHE II score according to first day of ICU admission, SOFA score on the day of PT procedure, blood test results, vital signs, vasopressor, anticoagulant, antithrombotic drugs and doses before the tracheostomy procedure were recorded from all patients included in the study. Also, the observed complications during the PT procedure, duration of the procedure, diameter of the tracheostomy cannula used, sedative, analgesic and neuromuscular drugs and doses applied before and during the procedure were recorded. In order to better define the complications in the patients, direct chest radiographs were taken before and after the procedure. At the same time, possible complications were investigated by performing a detailed physical examination after the PT procedure.

Percutaneous tracheostomy procedure in non-COVID-19 patients

The FiO_2 value of the inhaled air given to the patients 10 minutes before the procedure was increased to 100%. For the sedation and analgesia, 5 mg midazolam and 50 mg fentanyl were given to the patients intravenously before PT procedure. An additional 50 mg of propofol IV infusion was given for patients who could not achieve sufficient depth of sedation. Richmond agitation and sedation score (RASS) for sedation depth is planned as equal or less than -3 score. Neuromuscular blocking agents were not administered to patients unless necessary. In patients who had difficulty in positioning the head and neck, and in patients who could not achieve sufficient relaxation in the upper airway muscles, 0.5 mg/kg rocuronium IV therapy was administered as a neuromuscular blocking agent. During the procedure, patients were monitored for possible hypotension and insufficient blood circulation, and intravenous bolus crystalloid fluid and noradrenaline infusion were administered when necessary. After adequate sedation approximately 10 cm thick sheet was placed under the shoulders to bring the patients' heads to hyperextension as much as possible. Afterwards, the patients were extubated and the necessary mouth and pharynx cleaning was provided. Then, I-gel LMA (laryngeal mask) was placed after extubation in all patients and ventilator support was continued under pressure-controlled mode. Necessary skin cleaning was done with povidone iodine solution. Standard sterile dressing for operator and total patient covering by sterile sheets was provided. The tracheostomy team did not use any extra protective equipment other than a hair cap and surgical mask. Tracheostomy was performed by an intensive care specialist. The other doctor was present at the bedside to manage the airway and adjust the ventilator setting. A ready mix of lidocaine and adrenaline (40 mg lidocaine with 0.025 mg adrenaline) was applied subcutaneously to the skin area where the incision would be made. Approximately a 2 cm wide skin incision was made under the first or second tracheal ring, approximately 1 cm below the cricoid cartilage. The incision line was extended with a fine-tipped forceps until it reached the trachea. After providing the necessary bleeding control in the skin and subcutaneous region, PT procedure was performed. Percutaneous tracheostomy procedure was performed in accordance with the method described by Griggs. No bronchoscopy or ultrasonography was used during the procedure. During the PT procedure, the ventilator was not turned off and continued to operate at the same pressures.

Percutaneous tracheostomy procedure in COVID-19 patients

Some of the differences implemented during the preparation and PT procedure for COVID-19 patients are summarized below. The same sedation and analgesia protocol was applied as non-COVID-19 patients. Total 0.5 mg/kg of rocuronium was administered to each patients by IV route. An additional 0.5 mg/kg of rocuronium was given to patients whose respiratory effort was not completely suppressed. Laryngeal mask was not used for the maintenance of airway during the procedure. Protective FFP3 masks, total body water-repellent suits and glasses were used by the tracheostomy team. The only intensive care specialist, who performed the PT procedure, wore a sterile gown and sterile gloves over this protective equipment. Similarly, the skin area where the procedure will be performed was cleaned in a large area by povidone iodine and the patient was covered totally with sterile sheets. Similarly, an incision line was created up to trakea following the application of local anesthesia and adrenaline. The endotracheal tube was retracted as far as possible, but the cuff was not deflated. After palpating the trachea, the needle tip was advanced into the trachea midline through the incision line. The needle tip was considered as in the trachea by seeing the bubbles of the air that came easily into the physiological saline in the injector chamber after aspiration. At this stage, the ventilator support was stopped and the needle and its chamber were separated and the wire guide was advanced through the needle. Afterwards, the trachea was dilated firstly by advancing the plastic dilator through wire guide. Once again, the main dilatation procedure was performed with the use of dilatation forceps. Finally, the existing endotracheal tube was removed, tracheostomy cannula was slid over the guide wire and placed into the trachea, the cuff of the cannula was inflated, the ventilator support was restarted after the wire guide was pulled back and the ventilator connection with tracheostomy cannula was achieved.

Statistical Analysis

Statistical analysis was performed using the IBM Statistical Package for Social Sciences (SPSS) program version 22 (IBM, NY, USA). Continuous variables were described as median (interquartile range). Categorical variables were described as frequencies and percentages. Comparison between survivors and non-survivors, covid and non-covid patient groups were made by using the Mann-Whitney U test for continuous variables and the $\chi 2$ test for qualitative data. P values lower than 0.05 were considered as statistically significant.

Result

Some demographic characteristics and clinical data of the patients are presented in Table 1. At the same time, the differences of these clinical data according to mortality are also shown in Table 1. Intensive care unit length of stay, SOFA score and APACHE II score did not have a significant difference in terms of mortality. Patients with COVID-19 pneumonia who underwent percutaneous tracheostomy had a similar distribution in terms of mortality. The procedural time for PT or the time spent in the ICU after PT did not differ significantly in terms of mortality. Table 2 shows the vital signs, arterial blood gas analysis results and some laboratory test results of the patients before PT procedure and their differences according to mortality. It is seen that blood gas values before the procedure are not critical and do not show a significant change according to mortality. Table 3 shows the incidence of complications that may develop after PT procedure and their differences according to mortality. Tracheoesophageal fistula developed in one patient occurred 10 days after the PT procedure and the tracheoesophageal fistula was repaired after

Table 1. Distribution of some demographic and clinical parameters according to mortality

Parameters	All patients (N=40)	Survivors (N=24)	Non – Survivors (N=16)	p value
Age, (years)*	78 [67 – 83]	76 [66 – 82]	78 [70 – 84]	0.423
Gender, F, n (%)	19 (47,5)	9 (37.5)	10 (62.5)	0.126
ICU length of stay, (days)*	27 [15-43]	30 [15 – 66]	24 [16 – 33]	0.327
SOFA score*	7.5 [6.0 – 9.0]	7.0 [5.2 – 9.0]	8 [6 – 10]	0.160
APACHE II score*	19.5 [17.0 – 22.7]	19.5 [17.2 – 23.7]	19 [17 – 22]	0.618
GKS*	4.0 [3.0 – 7.7]	4.5 [3 – 7]	4 [3 – 8]	0.920
Tracheostomy procedure time, (min)*	8 [5 – 10]	10 [5 – 10]	8 [5 – 10]	0.865
Cannula diameter, (cm)*	7.5 [7.5 – 8.0]	7.5 [7.5 – 8.0]	8 [7.5 – 8.0]	0.283
ICU stay after tracheostomy, (days)*	11 [5.0 – 30.5]	20 [2 – 39]	10 [5 – 15]	0.214
Indications for admission to intensive care				
Bacterial infection, n (%)	28 (70.0)	15 (62.5)	13 (81.3)	0.211
Pulmonary, n (%)	24 (60.0)	12 (50)	12 (75)	0.118
COVID-19 pneumonia, n (%)	20 (50.0)	10 (41.7)	10 (62.5)	0.279
Neurological, n (%)	**9 (22.0)**	**8 (33.3)**	**1 (6.3)**	**0.047**
Sepsis, n (%)	6 (15.0)	3 (12.5)	3 (18.8)	0.592
Cardiovascular, n (%)	4 (10.0)	2 (8.3)	2 (12.5)	0.671
Nephrological, n (%)	3 (7.5)	3 (12.5)	-	0.147
Septic shock, n (%)	3 (7.5)	1 (4.2)	2 (12.5)	0.333
Gastroenterological, n (%)	1 (2.5)	-	1 (6.3)	0.221
Endocrinological, n (%)	1 (2.5)	1 (4.2)	-	0.414

*: median value [interquartel range]
ICU: intensive care unit; **SOFA:** Sequential Organ Failure Assessment; **F:** female; **APACHE:** The Acute Physiology and Chronic Health Evaluation; **GKS:** Glaskow Coma Scale;

Table 2. Blood gas analysis, laboratory tests and vital signs of patients before tracheostomy according to mortality

Parameters	All patients (N=40)	Survivors (N=24)	Non – Survivors (N=16)	p value
SBP, (mmHg)*	116 [98 – 127]	116 [102 – 129]	117 [97 – 124]	0.668
DBP, (mmHg)*	67 [60 – 72]	68 [60 – 74]	65 [61 – 71]	0.471
SpO_2 (%)*	97 [94 – 98]	97 [95 – 98]	95 [91 – 97]	0.088
FiO_2 (%)*	50 [40 – 58]	40 [40 – 53]	50 [40 - 60]	0.244
Arterial blood gas analysis				
PH*	7.43 [7.39 – 7.49]	7.43 [7.40 – 7.49]	7.41 [7.37 – 7.45]	0.184
HCO_3 (mEq/L)*	26.2 [23.7 – 28.9]	26.1 [23.7 – 28.9]	26.7 [22.8 – 29.3]	0.978
pCO_2 (mmHg)*	38.8 [34.0 – 44.3]	38.2 [34.2 – 41.2]	40.0 [32.6 – 48.4]	0.334
Laktat (mmol/L)*	1.5 [1.3 – 1.8]	1.4 [1.2 – 1.8]	1.6 [1.4 – 2.0]	0.438
SO_2 (%)*	96 [93 – 97]	96 [94 – 97]	95 [90 – 96]	0.135
Some serum and blood laboratory tests				
CRP (mg/L)*	101 [60 – 155]	101 [60 – 173]	100 [54 – 150]	0.581
Pro-calcitonin (ng/mL)*	**0.32 [0.23 – 0.90]**	**0.31 [0.21 – 0.40]**	**0.80 [0.24 – 1.51]**	**0.030**
INR	1.17 [1.1 – 1.34]	1.17 [1.07 – 1.36]	1.17 [1.12 – 1.26]	0.890
aPTT (sn)*	**36.1 [30.4 – 43.2]**	**39.5 [32.7 – 45.7]**	**33.6 [29.2 – 37.0]**	**0.038**
Platelet (10^3 x count/mm^3)*	220 [152 – 309]	244 [177 – 340]	170 [97 – 296]	0.230
Hb (gr/dL)*	**8.7 [8.0 – 10.1]**	**8.6 [8.0 – 9.3]**	**9.6 [8.0 – 12.0]**	**0.034**
Urea (mg/dL)*	102 [56 – 151]	105 [42 – 156]	98 [66 – 139]	0.879
Creatinine (gr /dL)*	0,89 [0.58 – 1.55]	0.85 [0.54 – 1.96]	0.89 [0.60 – 1.39]	0.967

*: median value [interquartel range]
N: number of the patients in the groups
SBP: Systolic blood pressure; **DBP:** Diastolic blood pressure; **SpO_2:** Fingertip pulse oximeter value; **PH:** Power of hydrogen; **HCO_3:** Serum bicarbonate level; **pCO_2:** partial carbon dioxide pressure; **SO_2:** blood oxygen saturation; **CRP:** C-reactive protein; **INR:** international ratio of prothrombin time; **aPTT:** activated partial thromboplastin time; **Hb:** Hemoglobin;

Table 3. Distribution of complications after tracheostomy procedure according to mortality

Parameters	All patients (N=40)	Survivors (N=24)	Non – Survivors (N=16)	p value
VAP, n (%)	4 (10)	3 (12.5)	1 (6.3)	0.524
Sepsis, n (%)	2 (5)	1 (4.2)	1 (6.3)	0.770
TEF, n (%)	1 (2.5)	1 (4.2)	-	-
Mediastinitis, n (%)	-	-	-	-
Local hemorrhage, n (%)	**4 (10)**	**-**	**4 (25)**	**0.011**
Pneumothorax, n (%)	-	-	-	-
Pneumomediastinum, n (%)	-	-	-	-
Local infection, n (%)	-	-	-	-
Major vascular damage, n (%)	-	-	-	-
Subcutaneous emphysema, n (%)	-	-	-	-

N: number of the patients in the groups
VAP: ventilator-associated pneumonia; **TEF:** tracheoesophageal fistula;

operation. At the same time, it is seen that all local hemorrhage complications of the skin occurred in the non-survivor group and also in COVID-19 group. All these local hemorrhagic complications were controlled within 48 hours and they were not-massive or not-arterial. Finally, Table 4 shows the distribution and significant differences of some demographic data, complications that may belong to the procedure, specific information about the tracheostomy procedure, and some laboratory test results according to the presence of COVID-19 pneumonia. It was detected that there was no significant difference in mortality in terms of the presence of COVID-19 pneumonia, the bleeding profile was worse in the COVID-19 group, also the duration of stay in the ICU was shorter after the PT procedure.

Discussion

According to the results of this study, some differences applied during the percutaneous tracheostomy procedure in the patient groups with and without COVID-19 pneumonia did not cause any important difference in terms of mortality or possible complications related PT procedure. Serious complications may develop after percutaneous tracheostomy (7). Correct patient selection, correct determination of contraindications, appropriate bleeding profile, evaluation of drug use, appropriate preparation and appropriate technique are very important in minimizing these complications in the application of percutaneous dilatational tracheostomy (8). The percutaneous tracheostomy technique which we routinely apply, has undergone some changes in

Table 4. Comparison of COVID-19 and non-COVID-19 patients in terms of clinical parameters

Parameters	All patients (N=40)	COVID-19 (N=20)	Non – COVID-19 (N=20)	p value
Age, (years)	78 [67 – 83]	77 [68 – 81]	79.5 [66.5 – 84.7]	0.616
Gender, F, n (%)	19 (47.5)	9 (45.0)	10 (50)	0.755
ICU length of stay, days*	27 [15 – 43]	19.5 [14.0 – 28.7]	35.5 [23.0 – 72.0]	0.003
SOFA score*	7.5 [6.0 – 9.0]	7 [6.0 – 10]	8.0 [6.0 – 9.0]	0.785
APACHE II score*	19.5 [17.0 – 22.7]	20.0 [17.2 – 23.5]	19.0 [16.2 – 22.7]	0.625
GKS*	4.0 [3.0 – 7.7]	3 [3 – 7]	6.0 [3.2 – 8.7]	0.130
Tracheostomy procedure time, (min)*	8 [5 – 10]	8 [5 – 10]	10 [5 – 10]	0.749
Cannula diameter, (cm)*	7.5 [7.5 – 8.0]	7.5 [7.0 – 8.0]	7.7 [7.5 – 8.0]	0.199
ICU stay after tracheostomy, (days)*	11.0 [5.0 – 30.5]	8 [2 – 22]	17.0 [6.2 – 32.5]	0.066
VAP, n (%)	4 (10)	2 (10)	2 (10)	1
Sepsis, n (%)	2 (5)	1 (5)	1 (5)	1
TEF, n (%)	1 (2.5)	-	1 (5)	0.317
Mediastinitis, n (%)	-	-	-	-
Local hemorrhage, n (%)	4 (10)	4 (20)	-	0.037
CRP*	101 [60 – 155]	91 [34 – 165]	105 [76 – 149]	0.314
Pro-calcitonin*	0.32 [0.23 – 0.90]	0.53 [0.23 – 1.44]	0.31 [0.22 – 0.43]	0.137
INR*	1.17 [1.1 – 1.34]	1.26 [1.12 – 1.40]	1.14 [1.07 – 1.23]	0.050
aPTT*	36.1 [30.4 – 43.2]	36.3 [31.0 – 45.9]	34.2 [30.3 – 41.6]	0.279
Platelet*	220 [152 – 309]	184 [115 – 283]	282 [166 – 363]	0.091
Hb*	8.7 [8.0 – 10.1]	9.3 [8.1 – 10.7]	8.6 [8.0 – 9.6]	0.386
Urea*	102 [56 – 151]	103 [74 – 143]	87 [40 – 157]	0.543
Creatinine*	0,89 [0.58 – 1.55]	0.96 [0.71 – 1.65]	0.68 [0.48 – 1.50]	0.127
Mortality, n (%)	16 (40)	10 (50)	6 (30)	0.289

*: median value [interquartel range]
N: number of the patients in the groups
ICU: intensive care unit; **SOFA:** Sequential Organ Failure Assessment; **APACHE:** The Acute Physiology and Chronic Health Evaluation; **GKS:** Glaskow coma scale; **VAP:** ventilator-associated pneumonia; **TEF:** tracheoesophageal fistula; **F:** female; **CRP:** C reactive protein; **INR:** International ratio of prothrombin time.; **aPTT:** activated partial thromboplastin time; **Hb:** Hemoglobin;

order to protect the team performing the procedure during the COVID-19 pandemic (9). For example, before the PT procedure, the operator team should use protective equipment covering the whole body against virus transmission. In our experience, such protective clothing can reduce comfort of the PT operator and complicate the working conditions. During the PT procedure in COVID-19 patients, another important point is that patients must be totally paralyzed and must be able to remain apneic for a while during the procedure. Therefore, patients who are predicted to be able to tolerate this apnea period before the PT procedure in COVID-19 patients are selected for the PT procedure. These two situations mentioned above may have an effect in terms of adverse effects that may occur during and after the applied PT procedure. According to our knowledge, it is seen that there is no data in the literature on this subject that we can discuss further here. However, according to our experience, procedural differences in tracheostomy performed in COVID-19 patients and other patient groups did not cause any difference in terms of complications observed in patients. According to the data obtained in this study, the frequency of complications after tracheostomy is not high when compared to another study (10). All of the local hemorrhages observed in our study were minor hemorrhages and did not require any intervention.

According to our study, the duration of stay in the ICU after the tracheostomy procedure in the COVID-19 patient group is significantly shorter than in the other group. This situation is related to the transfer of patients who underwent PT to palliative centers at the point of struggling with the increasing intubated patient load during the COVID-19 pandemic. Other factors such as need for less sedation, increased ventilator compliance, and ease of patient care after PT procedure would accelerated this process (11).

Our study has some limitations. First of all, our results are associated with a small experience and number of patients. With the decrease in the number of patients admitted to the ICU towards the end of the COVID-19 pandemic, the need for PT decreased, and the number of patients for this group remained at 20. After transfer to the palliative centers, the clinical status of the patients related PT could not be evaluated due to the fact that the centers could not included in the study, clinical data registration problems in the relevant centers and the number of centers were relatively high.

Conclusion

The procedural changes required in the percutaneous dilatational tracheostomy procedure in COVID-19 patients do not increase the frequency of procedure-related complications in ICU patients and can be safely preferred. The results obtained in this study should be supported by large-scale studies.

AUTHOR CONTRIBUTIONS:

Concept: UO; **Design:** UO; **Supervision:** UO; **Fundings:** UO; **Materials:** UO, MS; **Data Collection and/or Processing:** UO, MS; **Analysis and/or Interpretation**: UO, MS; **Literature Search:** UO, MS; **Writing Manuscript**: UO, MS; **Critical Review:** UO, MS.

Ethics Committee Approval: Ethical approval for this study was obtained from local ethics committee of Ankara training and research hospital with the decision numbered E.22,998 at 08 June 2022.

Informed Consent: Written informed consent was obtained from all patients or their relatives who were included in the study.

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