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***Original Article** / Özgün Makale*

Percutaneous dilatational tracheostomy in patients with mechanical circulatory support: Is the procedure safe?

Mekanik dolaşım destek cihazı olan hastalarda perkütan dilatasyonel trakeostomi: İşlem güvenli midir?

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ABSTRACT

Background: We aimed to investigate the efficacy and safety of percutaneous dilatational tracheostomy procedure following cardiac surgery in patients receiving extracorporeal membrane oxygenation and/or left ventricular assist device.

Methods: A total of 42 patients (10 males, 32 females; mean age 51±14.6 years; range, 18 to 77 years) who underwent percutaneous dilatational tracheostomy procedure under extracorporeal membrane oxygenation and/or left ventricular assist device support between January 2017 and January 2019 were retrospectively analyzed. Laboratory data, Simplified Acute Physiology Score-II and Sequential Organ Failure Assessment scores, and major and minor complications were recorded. The 30-day and one-year follow-up outcomes of the patients were reviewed.

Results: Of 42 patients, 17 (42.5%), 14 (33.3%), and 11 (26.2%) received left ventricular assist device, extracorporeal membrane oxygenation, and extracorporeal membrane oxygenation + left ventricular assist device, respectively. During percutaneous dilatational tracheostomy, the laboratory values of the patients were as follows: international normalized ratio, 2.3±0.9; partial thromboplastin time, 59.4±19.5 sec; platelet count, 139.2±65.8×10^9/L, hemoglobin, 8.8±1.0 g/dL, and creatinine, 1.6±1.0 mg/dL. No peri-procedural mortality, major complication, or bleeding was observed. We observed minor complications including localized stomal ooze in four patients (8.3%) and local stomal infection in three patients (6.2%).

Conclusion: Our study results suggest that percutaneous dilatational tracheostomy is an effective and safe technique in this patient population.

Keywords: Anticoagulant, extracorporeal membrane oxygenation, left ventricular assist device, percutaneous dilatation tracheostomy.

ÖZ

Amaç: Bu çalışmada kalp cerrahisi sonrasında ekstrakorporeal membran oksijenizasyonu veya sol ventrikül destek cihazı uygulanan hastalarda perkütan dilatasyonel trakeostomi işleminin etkinliği ve güvenliliği araştırıldı.

Çalışma planı: Ocak 2017 - Ocak 2019 tarihleri arasında ekstrakorporeal membran oksijenizasyonu veya sol ventrikül destek cihazı desteği ile perkütan dilatasyonel trakeostomi uygulanan toplam 42 hasta (10 erkek, 32 kadın; ort. yaş 51±14.6 yıl; dağılım 18-77 yıl) retrospektif olarak incelendi. Laboratuvar verileri, Basitleştirilmiş Akut Fizyoloji Skoru-II ve Ardışık Organ Yetmezliği Değerlendirme skorları ve majör ve minör komplikasyonlar kaydedildi. Hastaların 30 günlük ve bir yıllık takip sonuçları gözden geçirildi.

Bulgular: Kırk iki hastanın 17'sine (%42.5) sol ventrikül destek cihazı, 14'üne (%33.3) ekstrakorporeal membran oksijenizasyonu ve 11'ine (%26.2) ekstrakorporeal membran oksijenizasyonu + sol ventrikül destek cihazı uygulandı. Perkütan dilatasyonel trakeostomi sırasında, hastaların laboratuvar değerleri şu şekildeydi: uluslararası normalleştirilmiş oran 2.3±0.9, parsiyel tromboplastin zamanı 59.4±19.5 sn., trombosit sayısı 139.2±65.8×10^9/L, hemoglobin 8.8±1.0 g/dL ve kreatinin 1.6±1.0 mg/dL olarak saptandı. İşlem sırası ölüm, majör komplikasyon veya kanama gözlenmedi. Dört hastada (%8.3) lokal stomada sızıntı ve üç hastada (%6.2) lokal stoma enfeksiyonu şeklinde minör komplikasyonlar gözlendi.

Sonuç: Çalışma sonuçlarımız, perkütan dilatasyonel trakeostominin bu hasta grubunda etkili ve güvenli bir teknik olduğunu göstermektedir.

Anahtar sözcükler: Antikoagülan, ekstrakorpereal membran oksijenizasyonu; sol ventrikül destek cihazı, perkütanöz dilatasyonel trakeostomi.

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Over the last decade, the use of mechanical circulatory support techniques including left ventricular assist device (LVAD) and extracorporeal membrane oxygenation (ECMO) has dramatically increased.[1,2] Patients may require long-term intensive care follow-up and prolonged airway management with tracheal intubation.[3,4] To minimize complications of prolonged tracheal intubation, early surgical or percutaneous tracheostomy can be used.[5,6] The percutaneous approach has many advantages compared to surgical tracheostomy including reduced risk of infection, speed insertion, decreasing complication rate, and better cosmetic results with smaller wound areas.[6] Therefore, percutaneous tracheostomy has been widely adopted in many centers.

In Turkey, our center is a specialized research hospital in cardiac and pulmonary surgery. Although our center has many years of experience in mechanical circulatory support application, including LVAD and ECMO, the implementation of percutaneous dilatational tracheostomy (PDT) in these patients has only increased in recent years due to safety concerns. The use of anticoagulants for the risk of thrombosis in patients undergoing mechanical circulatory support is the major safety concern due to the risk of major bleeding and/or other complications.[7,8]

In the literature, there is a limited number of data on the experience of the PDT procedure in patients receiving ECMO and/or LVAD support.[9-12] To the best of our knowledge, there is no study on the experience of PDT in patients receiving both LVAD and ECMO support. In this study, we aimed to investigate the efficacy and safety of the PDT procedure in patients receiving both LVAD and ECMO support.

PATIENTS AND METHODS

This retrospective study was conducted at Türkiye Yüksek İhtisas Training and Research Hospital between January 2017 and January 2019. A total of 42 patients (10 males, 32 females; mean age 51±14.6 years; range, 18 to 77 years) who underwent PDT in the cardiac intensive care unit (ICU) and who received LVAD, veno-arterial ECMO (VA-ECMO), or both were included in the study. Patients under 18 years of age and having an anatomical difficulty for PDT, such as an extremely short neck, unstable cervical spinal injuries, and goiter or thyroid tumors were excluded from the study. A written informed consent was obtained from each patient. The study protocol was approved by the Ankara Türkiye Yüksek İhtisas Training and Research Hostipal Ethics Committee. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Persistent LVAD support cannulas were used in the patients. The following systems for LVAD were used: The HeartMate II™ (Thoratec Corp., CA, USA; n=16); HeartMate 3™ (HM3, Abbott Inc., IL, USA, n=4); and HeartWare™ HVAD™ (HeartWare Inc., MA, USA; n=8). The ECMO circuit consisted of a Medos® oxygenator (Medos Medizintechnik, Stolberg, Germany) and a centrifugal pump. The LVAD and VA-ECMO were performed using the techniques mentioned in our previous studies.[13,14] Temporary right ventricular assist device (RVAD), intra-aortic balloon pump (IABP), and continuous veno-venous hemodialysis (CVVHD) performed according to the general condition of the patient were recorded during the peri-procedural period. The CentriMag™ (Levitronix LLC, MA, USA) RVAD was used.

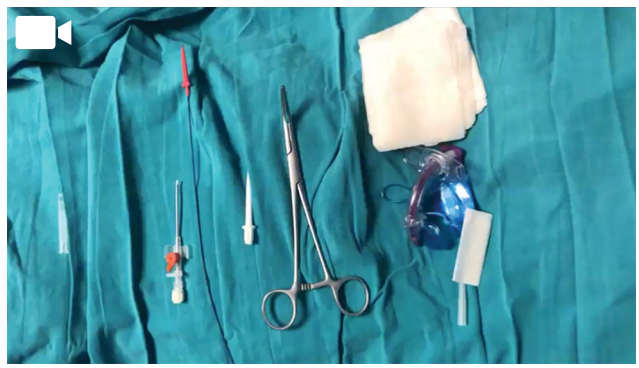
Baseline demographic and clinical characteristics of the patients including age, sex, diagnosis, ejection fraction (EF) and Simplified Acute Physiology Score-II (SAPS-II) and Sequential Organ Failure Assessment (SOFA) scores and laboratory test results were recorded. The time duration of heparin cessation (≤4h before PDT) was defined as the pre-procedural time. The period encompassing 24 h before and after PDT was defined as the peri-procedural period. The amount of blood products used was recorded 24 h before and after PDT.

PDT anticoagulation and procedure

Patients undergoing LVAD support received anticoagulation with heparin and warfarin. Once the desired international normalized ratio (INR) (≥2) was achieved, heparin was discontinued and anticoagulation was continued with warfarin alone. The patients who received ECMO support were anticoagulated with heparin. Heparin was discontinued 4 h before the PDT procedure in patients with ECMO. Heparin was continued after the PDT procedure. The procedure was performed in all patients with respiratory failure who required long-term mechanical ventilation.

All procedures were performed at the bedside in the ICU. Patient preparation included premedication with sedative, midazolam (0.1 mg/kg), analgesic, fentanyl (2 μg/kg), and local infiltration of lidocaine 1%. A total of 100% oxygen was applied to the patient for 10 to 15 min immediately prior to the procedure to prevent intraoperative hypoxia. The PDT procedure was performed by two experienced bronchoscopists using Portex® Griggs™ forceps percutaneous dilation

tracheotomy kits (Portex Ltd., Hythe, Kent, UK). An endotracheal tube (ETT) and tracheal suctioning were done thoroughly with the aid of flexible fiberoptic bronchoscope (Pentax Ltd., Slough, UK). The ETT cuff was lowered and drawn back in such a way to remain immediately under the vocal cords. A 14-G intravenous cannula was moved between the second and third tracheal cartilage determined by palpation 1.5 to 2-cm below the cricoid, until air was inspired and the cannula entered the tracheal lumen. After placing the guidewire in the tracheal lumen, the cannula was withdrawn and expanded with an 8-F dilatator. The skin and trachea were enlarged with forceps. A No. 7 tracheostomy cannula was placed for female patients and a No. 8 tracheostomy cannula for male patients. The ETT withdrawal was done under the visual control of the bronchoscope. All steps were done by the visual control of the bronchoscope thus avoiding any structural injury (Video 1). The procedure was performed using the technique described in our previous studies.[15]



Video 1. Percutaneous dilatational tracheostomy procedure.

Table 1. Baseline demographic and clinical characteristics of patients (n=42)

	n	%	Mean±SD
Age (year)			51±14.6
Sex			
Male	10	23.8	
Female	32	76.2	
Body mass index			26±2.5
Ejection fraction (%)			32±14.7
SAPS-II			48±13.7
SOFA-ICU			11±2.7
Mechanical circulatory support			
LVAD (%)	17	42.5	
LVAD + ECMO (%)	11	26.2	
ECMO (%)	14	33.3	
LVAD indications*			
Dilated cardiomyopathy (%)	9	32.1	
Ischemic cardiomyopathy (%)	8	28.6	
Postcardiotomy syndrome (%)	11	39.3	
VA-ECMO indications†			
Acute myocardial infarction (%)	5	20	
Postoperative lung transplantation (%)	2	8	
Dilate cardiomyopathy (%)	2	8	
Ischemic cardiomyopathy (%)	3	12	
Postcardiotomy syndrome (%)	13	52	
LVAD + ECMO indications‡			
Dilated cardiomyopathy (%)	2	18.2	
Ischemic cardiomyopathy (%)	3	27.3	
Postcardiotomy syndrome (%)	6	54.5	

SD: Standard deviation; SAPS-II: Simplified Acute Physiology Score-II; SOFA: Sequential Organ Failure Assessment; ICU: Intensive care unit; LVAD: Left ventricular assist device; ECMO: Extracorporeal membrane oxygenation; VA: Veno-arterial; * 28 patients with LVAD (Only LVAD, LVAD + ECMO); † 25 patients with ECMO (Only ECMO, LVAD + ECMO); ‡ 11 patients with LVAD + ECMO; SOFA (min: 4; max:24); SAPS-II (min:0; max:163).

Table 2. Peri-procedural data

	n	%	Mean±SD
PDT time (days)			19±9.7
Laboratory at time of PDT			
INR			2.3±0.9
PTT (sec.)			59.4±19.5
Platelet count, $\times 10^9$/L			139.2±65.8
Hemoglobin (g/dL)			8.8±1.0
Creatinine (mg/dL)			1.6±1.0
Patients on CVVHD	10	23.8	
Patients on temporary RVAD	4	9.5	
Patients on temporary IABP	6	14.8	

SD: Standard deviation; PDT: Percutaneous dilatational tracheostomy; INR: International normalized ratio; CVVHD: Continuous veno-venous hemodialysis; RVAD: Right ventricular assist device; IABP: Intra-aortic balloon pump.

Major complications included procedure-related death, cardiac arrest, hypotension requiring vasopressor therapy, acute hypoxemia, loss of airway, major bleeding (requiring open surgery or transfusion, or reducing hemoglobin levels by >20%), tracheal wall injury, false passage cannulation, pneumothorax, tracheostomy-related sepsis, and tracheostomy cannula obstruction. Minor complications included localized minor bleeding (localized stomal ooze or self-limiting bleeding), localized subcutaneous emphysema, short-term desaturation, and local stomal infections.

Statistical analysis

Statistical analysis was performed using the SSPS for Windows version 15.0 software (SPSS Inc., Chicago, IL, USA). All variables were analyzed for normal distribution. Descriptive data were expressed in mean and standard deviation (SD), median (min-max) or number and frequency. Continuous variables were compared using the Student's t-test or the Mann-Whitney U test, where applicable. The chi-square test was used to check proportions. A p value of <0.05 was considered statistically significant.

RESULTS

Of the patients, 17 (42.5%), 14 (33.3%), and 11 (26.2%) received LVAD, ECMO and ECMO + LVAD, respectively (Table 1). The mean EF was 32±14.7% (range, 18 to 77), the mean SAPSII score was 48±13.7 (range, 11 to 76), the mean SOFA (ICU) score was 11±2.7 (range, 4 to 18), and the mean SOFA (peri-procedural) score was 12±3.3 (range, 4 to 19). The indications for patients who received LVAD support were dilated cardiomyopathy in nine (32.1%), ischemic cardiomyopathy in eight (28.6%), and post-pericardiotomy syndrome in 11 (39.3%) patients. The indications for patients who received ECMO support were acute myocardial infarction in five (20%), postoperative lung transplantation in two (8%), dilated cardiomyopathy in two (8%), ischemic cardiomyopathy in three (12%), and postcardiotomy syndrome in 13 (52%) patients (Table 1).

The peri-procedural laboratory data are shown in Table 2. The mean duration of PDT was 19±9.7 (range, 6 to 44) days after mechanical circulatory support. In the peri-procedural period, six patients (14.8%) underwent temporary IABP, four patients (9.5%) underwent temporary RVAD, and 10 patients (23.8%) underwent CVVHD. In the LVAD group, four patients (9.5%) with right heart failure had RVAD, six patients (14.8%) requiring positive inotropic support

Table 3. Follow-up data

	n	%
Procedural success of PDT (%)	42	100
Major complications (%)	0	0
Minor complications		
Minor bleeding* (%)	4	8.3
Local stomal infections (%)	3	6.2
30 day follow-up		
Death (%)	18	42.8
Multiorgan failure (%)	10	23.8
Sepsis (%)	3	7.1
Cardiac (%)	5	11.9
One year follow-up		
Death (%)	12	28.5

PDT: Percutaneous dilatation tracheostomy; * Stomal oozing.

Table 4. Follow-up data according to the type of mechanical circulatory support

	LVAD (n=17)		LVAD + ECMO (n=11)		ECMO (n=14)		
	n	%	n	%	n	%	*p*
Procedural success of PDT (%)	17	100	11	100	14	100	NS
Major complications (%)	0	0	0	0	0	0	NS
Minor complications							NS
Minor bleeding* (%)	2	11.7	1 (9)		1 (7.1)		
Local stomal infections (%)	1	5.8	1 (9)		1 (7.1)		
30 day follow-up							
Death (%)	8	47	5	45.4	5	35.7	NS
MOF (%)	4	23.5	3	27.2	3	21.4	NS
Sepsis (%)	1	5.8	1	9	1	7.1	NS
Cardiac (%)	2	11.6	1	9	2	14.2	
One year follow-up							
Death (%)	6	35.2	4	36.3	2	14.2	NS

LVAD: Left ventricular assist device; ECMO: Extracorporeal membrane oxygenation; PDT: Percutaneous dilatational tracheostomy; MOF: Multiorgan failure; * Stomal oozing; NS: Non significant.

underwent IABP, and six patients (14.8%) with an increased creatinine level underwent CVVHD. The other four patients (9.5%) requiring CVVHD were in the ECMO group. In addition, there was no significant difference between the mechanical circulatory support in terms of hematological and coagulation parameters.

No peri-procedural mortality or major complications were observed in any of the patients. However, we observed minor complications including localized stomal ooze in four patients (8.3%) and local stomal infection in three patients (6.2%). During the procedure and follow-up, none of the patients required transfusion of erythrocytes, platelets, fresh frozen plasma, or other blood products. Mortality was observed in 18 patients (42.8%) after 30 days of follow-up. The causes of mortality were multiorgan failure in 10 (20.8%), sepsis in three (6.2%), and cardiac conditions (right ventricular failure) in five (10.4%) patients. In the first year of follow-up, additional 12 patients (25%) died (Table 3).

The 30-day and one-year follow-up outcomes according to the mechanical circulatory support techniques including LVAD, LVAD + ECMO and ECMO are summarized in Table 4. Accordingly, there was no significant difference in terms of outcome and follow-up data based on the mechanical circulatory support techniques used.

DISCUSSION

In the literature, PDT has been shown to be more effective and safe compared to surgical tracheostomy.[16-18] It has been also demonstrated that it is a faster and less traumatic method and associated with fewer early and late complications.[19,20] In addition, PDT is a cost-effective method that it does not require surgery and is applicable at bedside with a low local infection rate and, most importantly, it has a short procedural time.[19,20] In particular, PDT a frequently used method for patients which may be subjected to a prolonged stay in the ICU. Long-term intensive care and mechanical ventilatory support are required in patients receiving mechanical circulation support. Considering its benefits, PDT may be a feasible procedure in patients requiring long-term ICU stay or mechanical ventilation. However, the risk of bleeding due to the use of anticoagulants in these patients limits the PDT procedure, particularly with regard to the safety concerns. Current experience in patients receiving anticoagulants, due to LVAD and ECMO after cardiac surgery, is very limited.[11,21-23] Life-threatening bleeding or other major complications have not been specifically reported in previous studies. However, experience with PDT in patients with combined LVAD and ECMO administration has not been reported in the literature, yet. The PDT procedure was evaluated in separate studies of patients receiving LVAD or ECMO support.[9-12,16] To the best of our knowledge, therefore, this is the first study to evaluate the PDT procedure in patients with combined LVAD and ECMO administration and is valuable as it evaluates experiences for both LVAD and ECMO.

To date, a limited number of studies has shown that the PDT procedure is safe in patients with

LVAD support. In a study including 31 patients, Gregoric et al.[23] observed no complication in the early (≤30 days) and late (>30 days) periods, except for minor complications. Pasin et al.[24] administered phenprocoumon, a coumarin derivative, to their patients and phenprocoumon was used together with heparin until the desired INR value was obtained. Although the mean INR and PTT in 36 patients were 2.1±0.9 and 68.9±19 sec, respectively, they did not observe any significant intra- or peri-procedural complications. In our study, the mean INR and PTT before the PDT procedure in patients with LVAD support were 2.4±0.9, 59.6±11.0 sec, respectively. No major complications, including major bleeding and death, were observed. Consistent with previous studies, our findings also support the safety of PDT in patients with LVAD.

The safety of the PDT procedure in patients receiving ECMO support has been demonstrated in very few studies. Braune et al.[11] showed that 68 patients (31.4%) who received ECMO support during PDT had minor bleeding, while 1.7% of them had major bleeding requiring surgical control or causing hypoxia. Kruit et al.[9] also performed PDT in 50 patients with ECMO support, and 40% of these patients had bleeding complications. Of these complications, 32% were minor bleeding and 8% were major bleeding. In our study, we performed PDT in 14 patients with ECMO support and did not observe any major complications or major bleeding. The third group in our study was the LVAD + ECMO support group who underwent PDT. We observed no major bleeding and complications.

The non-endothelial surface of the ECMO circuit causes the activation of clotting factors.[25,26] Therefore, anticoagulant therapy is very important for ECMO support. Current evidence suggests that the continuation of heparin administration during percutaneous tracheostomy is not associated with an increased risk of bleeding in the general ICU population.[22,24,27,28] In a recent study, Kruit et al.[9] found no significant difference in terms of bleeding risk between patients receiving and not receiving heparin during the PDT procedure. In our study, although the mean PTT during the procedure was 59.4±19.5 sec, we observed no major complications or bleeding. In previous studies, major bleeding was reported mostly in patients with platelet dysfunction and refractory coagulopathy.[25,26] Deppe et al.[27] found no major complications in 48 cardiothoracic patients with valve replacement who had a PTT of greater than 50 sec and continued heparin infusion. A systematic review reported that bleeding was associated with mechanical factors such as a low tracheal incision, prolonged intubation, malpositioned cannula tip, and the lack of bronchoscopic guidance during insertion.[29] Therefore, we believe that the incidence of bleeding may be increased due to technical and mechanical factors rather than hemostatic factors.

Nonetheless, there are some limitations to this study. First, the study is retrospective with a small sample size. Therefore, minor bleeding and complications may have been overlooked or underestimated due to the lower clinical relevance of the study. Second, there was no significant decrease in the platelet counts; however, further investigations evaluating platelet function were unable to be performed. Third, although the PTT of the patients was found to be favorable for anticoagulation during PDT, heparin was discontinued 4 h before the procedure, which can be deemed another limitation of the study. Implementation of the PDT procedure during ongoing heparin infusion may be the subject of further studies.

In conclusion, this is the first study to examine the percutaneous dilatational tracheostomy procedure in patients receiving both left ventricular assist device and extracorporeal membrane oxygenation support. Our study results suggest that percutaneous dilatational tracheostomy is an effective and safe technique in this patient population. However, further large-scale and long-term, prospective studies are needed to confirm these findings.

Declaration of conflicting interests

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