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Experience with intraoperative extracorporeal membrane oxygenation in lung transplantation: intraoperative indicators

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Ethics Committee approval was taken from the Ankara City Hospital 1° Ethics Committee (E1-22-2541, 06.04.2022).
All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

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Abstract

Background/Aim: Intraoperative extracorporeal membrane oxygenation (ECMO) is being used with increasing frequency in lung transplantation. However, the factors associated with the use of intraoperative ECMO in lung transplant patients are not yet conclusive. In this study, we aimed to determine the effective factors for providing intraoperative ECMO support in patients undergoing lung transplantation. In addition, we aimed to evaluate the effect of ECMO support on morbidity and mortality.
Methods: In this retrospective cohort study evaluating lung transplant patients, patients were divided into two groups: those who received intraoperative ECMO support and those who did not. Demographic data, the lung allocation score (LAS) and pulmonary arterial pressure (PAP), intraoperative data, postoperative complications, duration of mechanical ventilation (MV), length of stay (LOS) in intensive care and hospital, and mortality rates were recorded for both groups. Factors affecting entry to ECMO were analyzed by Multivariate Logistic Regression.
Results: In this period, 51.9% of 87 patients who underwent lung transplantation required intraoperative ECMO. The mean age, LAS, and PAP of the ECMO group were significantly higher than the non-ECMO group (P = 0.043, P = 0.007, and P = 0.007, respectively). In multivariate analysis, it was found that lower MAP averages were a predictive parameter in intraoperative ECMO requirements (OR: 1.091; CI: 1.009-1.179; P = 0.028). The ECMO group's mechanical ventilation time and hospital mortality were significantly higher than the other group (P = 0.004 and P = 0.025, respectively).
Conclusion: Preoperative indicators of intraoperative ECMO support were determined as age, LAS, and PAP elevation. In addition, low MAP levels and high lactate levels were always determined as intraoperative indicators in lung transplantation until the transition to ECMO support.

Keywords: Lung transplantation, Intraoperative extracorporeal membrane oxygenation, Mean arterial pressure, Age, Pulmonary arterial pressure, Lung allocation score

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Introduction

Lung transplantation (LT) is an effective treatment method for end-stage lung diseases. Thanks to the developing technology, experience and scoring systems in lung transplantation, the rate of critically ill patients who underwent lung transplantation have increased significantly. This made the management of these patients more complex. Due to excessive comorbidities in lung transplant recipients, it may be necessary to increase the frequency of cardiopulmonary support in the intraoperative period [1].

Extracorporeal membrane oxygenation has been used for years to provide cardiopulmonary support in patients with severe respiratory and heart failure [2]. In recent years, ECMO has been preferred to provide intraoperative cardiopulmonary support instead of cardiopulmonary bypass (CPB) in lung transplantation. Intraoperative ECMO is often used due to pulmonary hypertension, hemodynamic instability, and intolerance of single-lung ventilation [3-5].

Advances in ECMO technology, gained experience, and the fact that survival has increased from 25% to 75% over the years have played a convincing role in increasing the use of this treatment in lung transplantation [6]. Although some centers recommend the routine use of ECMO in lung transplantation, the decision to use intraoperative ECMO largely depends on the individual and institutional practice, and there is insufficient data in this area [7]. Considering the cost, morbidity-mortality, it is important to define the determinants of the use of intraoperative ECMO in lung transplantation.

In this study, we aimed to determine the effective factors for providing intraoperative ECMO support in patients undergoing lung transplantation and to evaluate the effect of ECMO support on morbidity and mortality.

Materials and methods

Study group and selection criteria

This study with retrospectively collected data was conducted by the principles of the Declaration of Helsinki. We evaluated data from all patients who had a lung transplant between March 2013 and April 2022 after approval by the Clinical Research Ethics Committee of a local hospital (E1-22-2541, 06.04.2022). Of 87 patients who underwent lung transplantation, three were excluded. Two patients were bridged to preoperative transplantation, and one was supported by intraoperative cardiopulmonary bypass (CPB). Patients who met the study criteria were divided into two groups: those who received intraoperative ECMO support and those who did not. The indication for intraoperative ECMO was determined in the detection of hemodynamic instability after clamping the pulmonary artery and when faced with severe hypoxemia (SO2 < 90%) due to impaired gas exchange and intolerance of one-lung ventilation [8]. Demographic and clinical data, intraoperative data, postoperative complications, duration of mechanical ventilation (MV), length of stay (LOS) in intensive care and hospital, and mortality rates were recorded for both groups.

Anesthetic management

Premedication was not preferred due to low respiratory reserves. Since severe dyspnea may develop in the supine position, oxygen was delivered through a face mask in the semi-sitting position. Vascular access was established with two 16 G intravenous cannula. Ringer's lactate (LR) solution was used as a maintenance fluid. Continuous systemic arterial monitoring was achieved via a 5-lead electrocardiogram (ECG), pulse oximetry, and radial artery cannulation. The double-lumen tube (DLT) placement was confirmed with a fiberoptic bronchoscope (FOB). For intraoperative and postoperative systemic and pulmonary arterial pressure monitoring, two central venous routes, one for the Swan-Ganz catheter, were established through the right internal jugular vein following intubation. A bispectral index (BIS) (BIS™, Covidien, MN, USA) sensor was placed on the patient's forehead to determine the depth of anesthesia. Anesthesia was induced in all patients by titrating 1 mcg kg^{-1} fentanyl, 0.15 mg kg^{-1} midazolam, and 1–2 mg kg^{-1} propofol. When the BIS became stable between 40 and 50, 0.6 mg kg^{-1} rocuronium was administered to facilitate tracheal intubation. Following intubation, the O_2/air mixture (fraction of inspired oxygen, FiO_2: 0.5), 5 cm H_2O positive end-expiratory pressure (PEEP), tidal volume (TV) of 7–8 ml kg^{-1} (ideal body weight), and volume-controlled ventilation VCV were given. After switching to single-lung ventilation (SLV) following the transplantation of one lung, monitoring was continued in pressure-controlled ventilation (PCV) mode with titrated FiO_2 to maintain adequate arterial saturation (>92%), TV <6 ml kg^{-1}, moderate PEEP, and inspiratory pressure <20 cm H_2O. The respiratory rate was adjusted to maintain the end-tidal CO_2 pressure in the 35–45 mmHg range. During the maintenance of anesthesia, total intravenous anesthesia (TIVA) consisting of titrated remifentanil and propofol was administered. Besides, 0.2 mg kg^{-1} rocuronium was infused approximately every 45 min throughout the operation to keep BIS between 40 and 60. The oropharyngeal temperature was monitored. While removing the lungs and sequentially placing the new lungs, norepinephrine (0.05–2 mcg kg^{-1}min), which increases the systemic vascular resistance (SVR), was frequently administered to prevent hemodynamic fluctuations due to surgical manipulations or cold protective fluids filled into the thorax, especially during the pulmonary arterial and venous anastomoses. The patients were administered liquid infusion to maintain MAP >65 mmHg, heart rate at 120 beats per minute, and serum lactate level >2 mmol L. Erythrocyte suspension was administered to keep the hemoglobin level >10 g/dL. Cell salvage was used to recover blood loss. At the end of the surgery, the DLT was replaced with a single-lumen tube (SLT), and bronchoscopy was used to clear anastomotic lines and secretions. Before tube replacement, gastric contents were evacuated with a nasogastric or orogastric tube. The patients were transferred to the intensive care unit under propofol and remifentanil infusion and appropriate monitoring. Extubation was performed after the patient responded consciously and took deep breaths on verbal command in the ICU.

Surgical procedure

A clamshell incision was performed in all patients undergoing double-lung transplantation. In single-lung transplantation, a sternum-sparing anterior thoracotomy incision was performed in the supine position. Following the incision, the thoracic cavity adhesions were released, and the lungs were fully mobilized. Subsequently, the pulmonary artery and vein stumps were prepared for implantation. After the donor's lung arrived in the operating room, pneumonectomy was performed, starting with the lung with poorer pulmonary function. Meanwhile, the patient's hemodynamics, pulmonary arterial pressure (PAP), and contralateral lung pulmonary function were closely monitored until implantation, and ECMO was provided when necessary. Following the sequential implantation of the donor's lungs, the clamps were removed, cold ischemia was terminated, and pulmonary function was evaluated by ventilation of the lungs. After checking the vascular anastomosis site for bleeding, and the bronchial anastomosis site for air leak, the surgical procedure was completed by drain placement and chest closure.

ECMO procedure

The need for intraoperative ECMO is often due to pulmonary hypertension, hemodynamic instability, and the inability to tolerate one-lung ventilation [1]. When ECMO was required, heparinization was performed with an activated clotting time (ACT) range of 145–180. Nipro® Membrane Oxygenator (Affinity® NT Integrated CVR/Membrane Oxygenator, Medtronic, Minneapolis, MN) was used for ECMO support at 36°C and 1.5–2.4 L min m^2 flow rate. Central v-a ECMO was preferred. ECMO's prime volume composition included LR and other additives. The patients were admitted to the ICU with or without postoperative support devices (central or peripheral v-a ECMO).

Postoperative management

Early postoperative monitoring was a continuation of intraoperative monitoring. We targeted weaning the patients from mechanical ventilation at the earliest possible time to minimize ventilator-associated pneumonia and ventilator-associated lung injury. The amount of fluid to be administered was generally determined according to the restrictive approach to maintaining the oncotic pressure. Immunosuppressive therapy was started. We evaluated the patients as per the standardized definition of primary graft dysfunction by the International Society for Heart and Lung Transplantation (ISHLT), introduced in 2005 and updated in 2016 (Table 1) [9]. Therefore, we decided on the treatment modalities according to the patients' PaO2/FiO2 (P/F) ratios and chest radiographs at the postoperative 6th, 24th, 48th, and 72nd hours.

Table 1: The International Society for Heart and Lung Transplantation standardized definition of primary graft dysfunction

PGD stage	P/F ratio (mmHg)	Chest radiograph
0	>300	Normal
1	>300	Diffuse allograft infiltration/ pulmonary edema
2	200-300	Diffuse allograft infiltration/ pulmonary edema
3	<200	Diffuse allograft infiltration/ pulmonary edema

PGD: Primary graft dysfunction, P/F: PaO2/FiO2

Statistical analysis

Mean standard deviation, median, and minimum-maximum values were given as descriptive statistics for continuous data, and percentage values were given for discrete data. The Shapiro-Wilk test was used to examine the conformity of continuous data with normal distribution. In comparing continuous data in two groups, the t-test was used for normal distribution, and the Mann-Whitney U test was used for non-normal distribution. Chi-square and Fisher's Exact tests were used for group comparisons (cross tables) of nominal variables. Factors affecting entry to ECMO were analyzed by Multivariate Logistic Regression. Log-rank test was used in the survival analysis of the patients. IBM SPSS Statistics 20 program was used in the evaluations, and $P < 0.05$ was accepted as the statistical significance limit.

Results

Intraoperative ECMO support was required in 43 (51.9%) patients included in the study. Two patients who were bridged to transplantation with ECMO in the preoperative period and one patient who was supported by intraoperative CPB were excluded. Of the 84 patients included in the study, 67 (79.8 %) were male, and the mean age was 47.13 (13.51) (range, 15–67 years) years. The mean age of the ECMO group was significantly higher than the non-ECMO group (50.05 [12.85] and 44.35 [13.69] years, respectively, $P = 0.043$). Means of LAS and PAP in the ECMO group were significantly higher than those in the non-ECMO group (43.32 [14.01] and 38.25 [8.09], $P = 0.007$; 35.35 [16.77] and 28.63 [12.61], $P = 0.007$, respectively). There was no difference between the groups in terms of gender, body mass index (BMI), Charlson comorbidity index (CCI), transplant indications, and transplant types ($P > 0.05$) (Table 2).

Table 2: Baseline characteristics of lung transplant recipients with and without ECMO

	Total (n=84) Mean (SD) Median (min-max)		Non-ECMO (n=41) Mean (SD) Median (min-max)		ECMO (n=43) Mean (SD) Median (min-max)		*P*-value
Age, years	47.13 (13.51) 51 (15-67)		44.35 (13.69) 47 (15-64)		50.05 (12.85) 54 (19-67)		0.043*
BMI, kg/m2	22.22 (4.01) 22 (15-31)		21.81 (3.55) 21.32 (15.08-31)		22.62 (4.39) 22.5 (15-31)		0.359**
LAS	40.85 (11.72) 36.83 (31.90-90.36)		38.25 (8.09) 34.60 (31.90-63.20)		43.32 (14.01) 39.01 (32.32-90.36)		0.007*
CCI	1.80 (1.05) 1.5 (1-7)		1.88 (0.82) 2 (1-4)		1.72 (1.22) 2 (1-7)		0.104*
PAP, mmHg	31.07 (15.18) 28 (15-100)		28.63 (12.61) 25 (18-90)		35.35 (16.77) 30 (15-100)		0.007*
Indications	n	%	n	%	n	%	*P*-value
Bronchiectasis	12	14.3	7	17.1	5	11.6	0.080***
COPD	34	40.5	22	53.7	12	27.9	
IPF	18	21.4	6	14.6	12	27.9	
Cystic fibrosis	4	4.8	2	4.9	2	4.7	
Histiocytosis	3	3.6	1	2.4	2	4.7	
Silicosis	2	2.4	1	2.4	1	2.3	
Others	11	13.1	2	4.9	9	20.9	
Sex, Male	67	79.8	35	85.4	32	74.4	0.212***
Lung transplantation	n	%	n	%	n	%	*P*-value
Single	8	9.5	3	7.3	5	11.6	0.713***
Double	76	90.5	38	92.7	38	88.4	

BMI: Body mass index, LAS: Lung allocation score, CCI: Charlson comorbidity index, PAP: Pulmonary arterial pressure, COPD: Chronic obstructive pulmonary disease, IPF: Idiopathic pulmonary fibrosis, *Mann Whitney U test, ** Independent Samples t-test, *** Chi-Square/Fisher's Exact test

The mean intraoperative MAP of the ECMO group was significantly lower than that of the non-ECMO group (73.44 [6.69] and 77.55 [6.04] mmHg, respectively, $P = 0.001$). The mean intraoperative lactate of the ECMO group was significantly higher than that of the non-ECMO group (2.71 [1.30] and 2.48 [4.39], respectively, $P < 0.001$). The amount of blood and blood products used intraoperatively in the ECMO group was significantly higher than in the non-ECMO group ($P < 0.001$). The duration of mechanical ventilation of the ECMO group was significantly higher than that of the non-ECMO group (239.37 [371.59] and 87.63 [206.04] days, respectively, $P = 0.004$). Other variables are shown in Table 3. There was no significant

difference between the groups in terms of complications. The hospital mortality of the ECMO group was significantly higher than the non-ECMO group (11 [25.6%] and 3 [7.3%], respectively, P = 0.025) (Table 4). Overall survival rates were similar in lung transplant recipients with and without ECMO (P = 0.253) (Figure 1).

Table 3: Comparison of intraoperative and postoperative variables in lung transplant recipients with and without ECMO

	Total (n=84) Mean (SD) Median (min-max)	Non-ECMO (n=41) Mean (SD) Median (min-max)	ECMO (n=43) Mean (SD) Median (min-max)	*P*-value
MAP, mmHg	75.44 (6.67) 76.4 (55.1-88.7)	77.55 (6.04) 78.5 (55.1-87.1)	73.44 (6.69) 73.5 (60-88.7)	0.001*
Hematocrit, %	33.58 (3.78) 33.7 (24.9-40.5)	33.50 (3.60) 34.3 (26.2-39.1)	33.66 (3.98) 33 (24.9-40.5)	0.841**
pH	7.39 (0.06) 7.39 (7.22-7.55)	7.38 (0.05) 7.38 (7.24-7.54)	7.40 (0.06) 7.39 (7.22-7.55)	0.267**
Glucose, mg dl-1	158.68 (27.43) 157 (99-253)	158.01 (29.01) 151 (104-253)	159.31 (26.17) 163 (99-231)	0.271*
Lactate, mmol/L	2.59 (3.18) 2.05 (0.37-29.58)	2.48 (4.39) 1.50 (0.95-29.58)	2.71 (1.30) 2.55 (0.37-6.04)	<0.001*
Urine, ml	923.87 (732.53) 775 (60-4200)	917.07 (526.02) 800 (250-2500)	930.35 (892.64) 700 (60-4200)	0.270*
Crystalloid, ml	2137.50 (881.32) 2050 (400-4500)	1952.93 (877.82) 2000 (400-4500)	2284.88 (869.21) 2500 (500-4000)	0.117**
Colloid, ml	189.29 (223.89) 200 (0-1200)	209.76 (270.92) 200 (0-1200)	169.77 (168.37) 200 (0-700)	0.745*
FFP, U	12.24 (3.67) 11 (4-19)	9.45 (3.08) 9 (4-17)	12.91 (3.42) 13 (7-19)	<0.001**
RBCC, U	3.90 (2.88) 3 (0-12)	2.43 (2.34) 1 (0-9)	5.28 (2.67) 5 (0-12)	<0.001*
PC, U	0.27 (0.54) 0 (0-2)	0.05 (0.22) 0 (0-1)	0.47 (0.66) 0 (0-2)	<0.001*
Operative time, minutes	615.77 (98.45) 600 (435-1080)	599.51 (68.90) 600 (480-735)	631.28 (118.86) 615 (435-1080)	0.259*
Length of ICU stay, days	17.63 (17.23) 12 (3-96)	13.20 (8.26) 12 (6-51)	21.86 (22.10) 14 (3-96)	0.077*
Length of hospital stay, days	35.42 (22.44) 28 (0-120)	31.90 (17.48) 29 (7-119)	38.77 (26.09) 28 (0-120)	0.237*
Duration of MV, hours	165.31 (310.08) 28 (8-1680)	87.63 (206.04) 24 (10-1104)	239.37 (371.59) 72 (8-1680)	0.004*

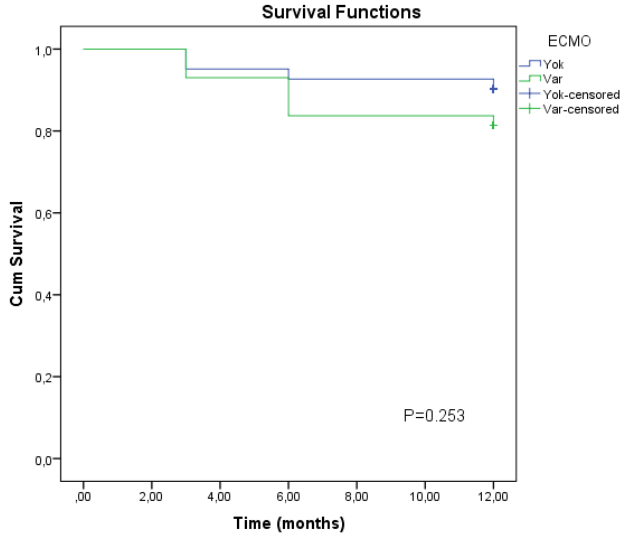
MAP: Mean arterial pressure, FFP: Fresh frozen plasma, RBCC: Red blood cell components, PC: Platelet concentrate, MV: Mechanical ventilation, *Mann Whitney U test, ** Independent Samples t-test

Table 4: Comparison of complication rates in patients with ECMO and patients without ECMO

	Total (n=84)		Non-ECMO (n=41)		ECMO (n=43)		*P*-value
	n	%	n	%	n	%	
Cardiovascular system	26	31	14	34.1	12	27.9	0.536*
PGD 3	15	17.9	4	9.8	11	25.6	0.058*
Neurological system	19	22.6	10	24.4	9	20.9	0.705*
Gastrointestinal system	3	3.6	0	0	3	7.0	0.241*
Bleeding/revision	12	14.3	4	9.8	8	18.6	0.247*
Acute kidney injury	15	17.9	5	12.5	10	23.3	0.186*
Mortality(Hospital)	14	16.7	3	7.3	11	25.6	0.025*
Mortality (one year)	12	14.3	4	9.8	8	18.6	0.247*

PGD: Primary graft dysfunction, *Chi-Square/Fisher's Exact test

Figure 1: Overall survival in lung transplant recipients with and without ECMO



Age, LAS, PAP, MAP, and lactate, which were thought to be associated with ECMO and were found to be significant in univariate analysis, were included in the Multivariate Logistic regression analysis to obtain a final model. As a result of the logistic model, intraoperative MAP was an effective risk factor. Other variables were not significant (Table 5).

Table 5: Logistic Regression model for preoperative and intraoperative risk factors affecting intraoperative ECMO

Variable	Regression Coefficient (SE)	OR	95 % CI		*P*-value
Age, years	-0.022 (0.022)	1.021	0.977	1.068	0.334
LAS	0.038 (0.027)	1.039	0.986	1.095	0.152
PAP, mmHg	0.034 (0.019)	1.035	0.998	1.074	0.068
Lactate, mmol/L	0.056 (0.072)	1.057	0.919	1.217	0.435
MAP, mmHg	-0.087 (0.040)	1.091	1.009	1.179	0.028

OR: Odds Ratio, CI: Confidence Interval, LAS: Lung allocation score, PAP: Pulmonary arterial pressure, MAP: Mean arterial pressure

Discussion

In this study, we aimed to determine the factors affecting the use of intraoperative ECMO in lung transplant patients and to evaluate the effect of ECMO use on morbidity and mortality. The rate of intraoperative ECMO use in the patients in our study was 51.9%. When the relationship between ECMO use and preoperative data was evaluated, age, LAS, and PAP were effective factors. Low intraoperative MAP and increased lactate levels were associated with ECMO use. In the logistic model, we determined that MAP is an effective risk factor for intraoperative ECMO use.

The widespread use of ECMO in lung transplantation occurred after Aigner et al. [10]. presented the first large case series in 2001, and its use as an intraoperative support device for complex cases, primary pulmonary hypertension (PPH), or patients who are not stable intraoperatively has increased over the past 15 years However, there are also studies reporting that more practices are needed before advocating ECMO as a standard of care to provide intraoperative support during LT [11]. It is known that ECMO support may cause complications, such as bleeding, revision, infection, and vascular injury, that may affect postoperative results and require more blood and blood product replacement. We use ECMO in our clinic for patients with preoperative ECMO requirements and intraoperative indications. We do not have routine intraoperative ECMO use. In this study, we observed that intraoperative ECMO support was higher in elderly recipients in accordance with the literature [1, 12]. With the expansion of lung transplant indications, lung transplantation is increasingly being applied to older recipients with various comorbidities. These recipients with high LAS scores prioritize transplant allocation and may require intraoperative ECMO due to their comorbidities. This study found that high LAS scores were effective in intraoperative ECMO support.

It has been reported that high PAP levels in lung transplantation are associated with ECMO requirements [13]. We also found that recipients requiring intraoperative ECMO had higher PAP levels. Patients with severe pulmonary hypertension often experience significant right heart failure. Hemodynamic instability caused by anesthesia induction and surgical manipulations can be balanced with ECMO support. Contrary to the literature [14], the indications for transplantation were not associated with the use of ECMO in this study. This may be because the patient population is relatively small.

Intraoperative ECMO decision is often made if PAP > 2/3 SAB, hemodynamic instability (MAP < 60 mmHg), hypoxia, and acidosis develop during the clamping of the pulmonary artery for 5–10 min [15]. In this study, intraoperative MAP values were significantly lower in patients with ECMO than in the group without ECMO. In addition, higher lactate levels were found in patients who used intraoperative ECMO.

Hoetzenecker et al. [10] showed that using preemptive ECMO in lung transplantation resulted in lower PGD rates and superior survival compared to transplantation without ECMO. However, they could only classify the PGD rates of patients who used intraoperative ECMO. They could not evaluate the postoperative prolonged ECMO group. A subsequent observational study reported that the intraoperative routine use of ECMO was associated with excellent PGD rates in lung transplant patients [7]. Contrary to the literature, PGD3 rates were higher in the ECMO group in this study, but this was not statistically significant. The fact that the patients we supported with ECMO in our clinic were more critical may have affected the results. Consistent with the clinic, the duration of mechanical ventilation was longer in the ECMO group.

It has been reported that the use of intraoperative ECMO in lung transplantation yields 100% superior results in terms of survival compared to the non-ECMO group [10]. In a study addressing intraoperative ECMO application, perioperative mortality was 11.1%, and 1-year survival was 81.5% in the ECMO group and 4.5% and 81.8% in the non-ECMO group [16]. Bermudez et al. [17] stated that there was no difference between ECMO and non-ECMO groups in terms of 1, 3, and 12 months and hospital mortality. In this study, the in-hospital mortality rate in the ECMO group was three times higher than in the non-ECMO group. When 1-year survival was evaluated, there was no difference between the two groups. We have already stated that the patients given ECMO support are more critical patients. It was observed that the survival of patients after undergoing the critical process was similar.

In this study, one of our limitations is the relatively small lung transplant patient population. Since it is a single-center and retrospective study, the inability to reach pulmonary artery pressure and oxygenation parameters at all intraoperative times is another important limitation of our study.

Conclusion

We show that age, LAS, and PAP elevation are preoperative indicators in determining intraoperative ECMO support in lung transplant patients. In addition, we found that lower MAP averages were evaluated at all times until intraoperative ECMO support was a predictive parameter in need for intraoperative ECMO. However, hospital mortality was higher in patients with ECMO, and survival after lung transplantation was similar in patients with and without ECMO after the acute phase. We believe multicenter studies with larger numbers of patients are needed to detect intraoperative ECMO determinants.

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