Multivariate Analysis of Risk Factor for Mortality and Feasibility of Extracorporeal Membrane Oxygenation in High-Risk Thoracic Surgery

Do Hyung Kim, MD,¹ Jong Myung Park, MD,² Joohyung Son, MD,¹ and Sung Kwang Lee, MD¹

Background: Extracorporeal membrane oxygenation (ECMO) as intraoperative cardio-respiratory support during lung transplantation is well known, but use for other types of surgery are limited. To assess risk factor for mortality after high-risk thoracic surgery and feasibility of ECMO, we reviewed.

Methods: This study was an observational study. Between January 2011 and October 2018, 63 patients underwent thoracic surgery with ECMO for severe airway disease, pulmonary insufficiency requiring lung surgery, and other conditions.

Results: In all, 46 patients remained alive at 30 days after surgery. The mean patient age was 50.38 ± 16.16 years. ECMO was most commonly used to prevent a lethal event (34 [73.9%]) in the Survival (S) group and rescue intervention (13 [76.5%]) in the Non-survival (N) group. In all, 11 patients experienced arrest during surgery (S vs N: 2 [4.3%] vs 9 [52.9%], p ≤0.001). The multivariate analysis revealed that arrest during surgery (odds ratio [OR], 24.44; 95% confidence interval [CI], 1.82–327.60; p = 0.016) and age (OR, 7.47; 95% CI, 1.17–47.85; p = 0.034) were independently associated with mortality.

Conclusions: ECMO provides a safe environment during thoracic surgery, and its complication rate is acceptable except for extracorporeal cardiopulmonary resuscitation (ECPR).

Keywords: thoracic surgery, extracorporeal membrane oxygenation, cardiopulmonary resuscitation

¹Department of Thoracic and Cardiovascular Surgery, Pusan National University Yangsan Hospital, Yangsan, Korea
²Department of Thoracic and Cardiovascular Surgery, Busan Medical Center, Yeonje-Gu, Busan, Korea

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Corresponding author: Sung Kwang Lee, MD. Department of Thoracic and Cardiovascular Surgery, Pusan National University Yangsan Hospital, Pusan National University College of Medicine, 20 Geumo-ro, Mulgeum-eup, Yangsan-si, Gyeongsangnam-do, 50612, Korea
Email: drlsk@naver.com

Introduction

Extracorporeal membrane oxygenation (ECMO) is widely used in patients with respiratory or cardiac failure who do not respond to conventional life support therapy. The feasibility of ECMO as intraoperative cardiorespiratory support during lung transplantation is well known; however, there were rare reports of ECMO used for thoracic surgery.¹⁻⁷) These reports have analyzed only 10–20 cases and simply confirmed the surgical results. In many cases, it is difficult to achieve clinical significance beyond the expansion of ECMO indications, and there are no reports of efficacy in specific areas.³⁻¹¹)
We have experienced various advantages and problems since the introduction of ECMO in thoracic surgery in 2006. Here, we present our experience and analyze the clinical outcomes of ECMO support in thoracic surgery to report tips on its use, factors influencing surgical outcomes, and indications for ideal ECMO support. The purpose of this study is to be used as basic data for risk factors related to mortality after high-risk thoracic surgery and ECMO indications. Please indicate at the end of the Introduction section: We present the following article in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting checklist.

Materials and Methods

Patient selection
Between January 2011 and October 2018, 110 patients underwent thoracic surgery under ECMO support. Of them, 47 who underwent lung transplantation were excluded; thus, a total of 63 patients supported on ECMO were analyzed in this report. The indications for ECMO were needed for surgical correction to solve problems related to clinical disease as follows: severe airway disease such as trachea stenosis, pulmonary insufficiency requiring lung surgery such as hemoptysis due to the destroyed lung, pneumonia, sepsis, ventilator-induced lung injury (VILI), and other conditions that can cause cardiac arrest during surgery such as advanced huge thoracic cancer and major vessel injury leading to hypovolemic shock or tamponade (Fig. 1). We did not randomly remove all patients who met the selection criteria to reduce selection bias.

Preoperative characteristics
The medical records of these 63 patients were reviewed. The following routine clinical baseline data were collected: age, sex, body mass index (BMI), diagnosis, purpose for ECMO, type of ECMO support, and preoperative clinical condition (such as major multiple trauma, advanced thoracic malignancy, infectious disease, airway obstruction, bleeding before surgery, diabetes, hypertension, renal failure, and coagulopathy).

ECMO and anticoagulation protocol
ECMO was administered based on guidelines from the Extracorporeal Life Support Organization. The ECMO system consisted of an EBS (Terumo, Tokyo, Japan) or PLS (Maquet, Mahwah, NJ, USA) machine, centrifugal pumps (Maquet, Rastatt, Germany), and simplified Bioline-coated circuits (Maquet). All patients were cannulated peripherally through the femoral vein and artery or internal jugular vein using the Seldinger technique under ultrasound guidance. Venovenous (VV) ECMO was used for respiratory support. In the majority of cases involving VV ECMO, the right femoral vein was used for venous drainage and the internal jugular vein for venous return; if additional heart support was necessary during VV ECMO, a return cannula was added to the femoral artery and VVA ECMO was implemented. If hemodynamic support was required rather than respiratory support, venoarterial (VA) ECMO was performed. Cannulation mainly used the configuration of femoral vein drain and femoral artery return. If cardiac arrest occurred, VA ECMO was performed regardless of the cause of arrest.

Preoperative extracorporeal cardiopulmonary resuscitation (ECPR) or preoperative elective ECMO was performed once with a 50–70 IU/kg heparin bolus immediately before insertion of the cannula for ECMO; no additional heparin was injected until the end of the operation. Patients with ongoing bleeding did not start anticoagulation therapy. After the end of the operation, if
support of ECMO was needed, anticoagulation was initiated after 24 hours. Anticoagulation was monitored by activated clotting time (ACT) and activated partial thromboplastin time (aPTT). ACT was maintained for approximately 160–190 s.

Because most surgeries are accompanied by massive bleeding, we applied autologous transfusion using a cell saver to prevent hypovolemic shock in trauma patients. Generally, cardiopulmonary bypass (CPB) with sucker could be used for direct infusion of blood loss, but to operate CPB which is an open circuit, sufficient dose of heparin and ACT prolong must be needed, which causes more bleeding. We decided to create a configuration of autologous transfusion circuit using ECMO which is a closed circuit. The circuit was configured as follows to quickly replenish the blood loss. After the blood was suctioned into the reservoir, it was sent from the reservoir to the cell saver and recycled. The collected blood in the cell saver bag was directly connected to the Rapid Infusion System for infusion directly through the patient’s central line.

**Fig. 2** Configuration of autologous transfusion using a cell saver with a rapid infusion system. We applied autologous transfusion to prevent hypovolemic shock in trauma patients. After the blood was suctioned into the reservoir, it was sent from the reservoir to the cell saver and recycled. The collected blood in the cell saver bag was directly connected to the Rapid Infusion System for infusion directly through the patient’s central line.

**Statistical analysis**

Continuous variables are expressed as mean ± standard deviation, and differences between continuous variables were analyzed using the unpaired Student’s t-test. Categorical variables are expressed as numbers and their percentages were compared by the Pearson’s chi-squared test or Fisher’s exact test as appropriate. According to the latest European Association of Cardio-Thoracic Surgery statistical and data reporting guidelines, we entered the threshold value of dichotomous variables with univariable p values <0.20 into a multivariable binary logistic-regression model to identify the independent risk factors for 30-day mortality. To provide concise and informative factors for the prediction of 30-day mortality, the continuous variables in the multivariate logistic regression model were dichotomized according to the clinically meaningful cutoffs widely accepted for risk stratification in routine clinical practice, including geriatric state, age >65 years; and overweight/obese state, BMI >25 kg/m². Results are expressed as odds ratios (ORs) with 95% confidence intervals (CIs), and two-tailed p values <0.05 were considered significant. We used SPSS for Windows (version 21.0, IBM Corp., Armonk, NY, USA) for the statistical analysis.

**Results**

During the study period, 63 patients underwent thoracic surgery under ECMO support for hemodynamic or respiratory support. Their baseline characteristics are
Presented in Table 1. To assess risk factors affecting mortality, we divided the patients into two groups according to mortality status: 46 patients survived, while 17 died by 30 days after surgery.

Patient characteristics of survival patients
Our study consisted of 42 (66.7%) male patients (Survival group (S) vs Non-survival group (N): 28 [60.9%] vs 14 [82.4%], p = 0.139) with a mean age of 50.38 ± 16.16 years (S vs N: 47.4 ± 15.8 vs 58.35 ± 14.7, p = 0.016). ECMO was often applied to prevent a lethal event (34 [73.9%]) in the Survival group and to rescue life (13 [76.5%]) in the Non-survival group (p <0.001). There were significant intergroup differences. ECMO support types included VV (only respiration support) ECMO (37 [80.4%]) in the Survival group and VA (cardiopulmonary support) ECMO (12 [70.6%]) in the Non-survival group (p <0.001). There were significant intergroup differences. Surgery types and preoperative clinical conditions did not differ significantly between the two groups.

Postoperative results of survival patients
In all, 11 patients experienced arrest during surgery (S vs N: 2 [4.3%] vs 9 [52.9%], p <0.001). The mean operation time was 250.56 ± 125.77 min (S vs N: 249.0 ± 115.6 vs 254.7 ± 153.9, p = 0.875). Surgery-related complications did not differ significantly between the two groups. There were no significant intergroup differences.

Multivariate analysis of risk factors for mortality
We entered the threshold value of dichotomous variables with a univariate p value <0.20 into a multivariate binary logistic regression model to identify the independent risk factors for mortality. A multivariate logistic regression model involving age, sex, ECMO indication, ECMO support type, intraoperative arrest, and postoperative bleeding is shown in Table 2. Multivariate analysis including these factors showed that age (OR, 7.47; 95% CI, 1.17–47.85; p = 0.034), arrest during operation (OR, 24.44; 95% CI, 1.82–327.60; p = 0.016) were independently associated with complications for mortality (Table 2).

Operative and postoperative results as groups of ECMO indications
The operation time did not differ significantly among groups. Intraoperative arrest was more common in the Other group than the other groups (Airway group (A) vs Lung group (L) vs Other group (O), 2 [10.5%] vs 3 [11.1%] vs 6 [35.3%], p = 0.940), but there were no significant differences. The Other group included advanced malignancy patients and great vessel injury patients. Thus, this group showed larger estimated blood losses (A vs L vs O: 590.63 ± 474.77 vs 2308.00 ± 4847.69 vs 7728.57 ± 8728.33, p = 0.003), red blood cell transfusions (A vs L vs O: 3.11 ± 6.67 vs 9.70 ± 15.78 vs 25.41 ± 23.66, p <0.001), and fresh frozen plasma transfusions (A vs L vs O: 1.89 ± 5.69 vs 7.48 ± 13.29 vs 13.94 ± 13.38, p = 0.011) than the other groups. The O group had more case of bleeding after surgery due to a large amount of estimated blood loss and transfusion leading to a bleeding tendency (A vs L vs O: 1 [5.3%] vs 3 [11.1%] vs 7 [41.2%], p = 0.014). The L group included preoperative respiratory failure due to pneumonia, sepsis, and VILI. Thus, these groups showed a longer duration of ventilator and ECMO use and longer mean hospital stay than the other groups. Lung failure after surgery was more common in the L group than the other groups (A vs L vs O: 0 [0%] vs 15 [55.6%] vs 5 [29.4%], p <0.001) (Table 3).

Discussion
Most thoracic surgeries could be performed with continuous one-lung ventilation and a triple-lumen central line. However, surgery is impossible if continuous ventilation is difficult, lung function is poor, or a large amount of bleeding occurs. It was recently reported that surgery is possible with ECMO use.1–7) The usefulness of ECMO in thoracic surgery is divided into three categories.3,11) First, the most useful indication of ECMO is airway obstructive disease.7,12–14) Most causes of death in patients with airway disease are respiratory failure due to airway obstruction. ECMO helps maintain life before surgical correction. The airway surgery is highly risky and very difficult despite being performed by an expert surgeon, because most conventional airway surgeries should be performed alternately between ventilation and non-ventilation for a limited time and the surgical field is poor due to endotracheal tube insertion into the distal trachea. However, ECMO can provide oxygen support and CO2 removal without ventilation, making it possible to perform airway surgery with or without ventilation.11) ECMO enables safe airway surgery in an emergency state, even for inexpert trachea surgeons.

The second indication for ECMO support for thoracic surgery is the state of lung failure due to pneumonia, sepsis, and VILI.9) These patients are generally contraindicated for thoracic surgery by traditional criteria. It is
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difficult to decide to perform conventional surgery without ECMO support; even if the surgery is decided, there are many cases in which the vital signs are not maintained and the operation cannot be started, or if the surgery is performed, pulmonary insufficiency cannot be recovered after surgery. However, the use of ECMO allows maintenance of cardiopulmonary support during perioperative period. It is very helpful in patients who underwent ECMO support during preoperative period. If surgical risk factors have been eliminated, it is reasonable to perform surgery to resolve the disease focus. ECMO also prevents worsening of lung function or additional cardiopulmonary damage in VILI and reduces many risks (hypoxia, shock, or arrest during surgery) that can occur during surgery. Since 2012, aggressive surgical correction using ECMO has been performed with these concepts in our institute. Despite the very high operative risk group, the mortality rate was relatively reasonable (16.7%).

The third indication is ECMO support for cardiopulmonary support during thoracic surgery.\textsuperscript{8,15,16} It is mainly used to maintain hemodynamic function in surgery for advanced huge thoracic cancer and thoracic trauma with major vessel injury. Intraoperative mass manipulation can deteriorate cardiac function. In severe cases, cardiac arrest may occur. Most intraoperative arrests lacking emergency preparation result in death. The hemodynamic support of ECMO prevents unexpected lethal events during surgery and ensures that surgery proceeds safely. ECMO is simultaneously possible rapid volume replacement during surgery. We already reported the effects of ECMO as a life-saving method in the treatment of shock from heart and major vessel injury.\textsuperscript{17}

If indications have been determined, the next question is “When is it effective to apply ECMO?” In our risk factor analysis, the mortality was higher when the arrest occurred intraoperatively. Since ECPR is performed

| Table 1 Clinical value according to mortality |
|---------------------------------------------|
| Variables | Total (n=63) | Survivor (n = 46) | Non-survivor (n = 17) | p value |
| Age (years) | 50.38 ± 16.16 | 47.4 ± 15.8 | 58.35 ± 14.7 | 0.016 |
| Sex (male) | 42 (66.7%) | 28 (60.9%) | 14 (82.4%) | 0.139 |
| BMI (kg/m\textsuperscript{2}) | 23.07 ± 4.04 | 22.9 ± 4.3 | 23.7 ± 3.0 | 0.523 |
| Purpose of ECMO | | | | <0.001 |
| Prevention of lethal event | 38 (60.3%) | 34 (73.9%) | 4 (23.5%) | |
| Rescue of life | 25 (39.7%) | 12 (26.1%) | 13 (76.5%) | |
| Types of support | | | | <0.001 |
| VA Cardiopulmonary support | 21 (33.3%) | 9 (19.6%) | 12 (70.6%) | |
| VV (Only respiration support) | 42 (66.7%) | 37 (80.4%) | 5 (29.4%) | |
| Types of operation | | | | 0.153 |
| Airway surgery | 19 (30.2%) | 17 (37.0%) | 2 (11.8%) | |
| Lung | 27 (42.9%) | 18 (39.1%) | 9 (52.9%) | |
| Others (mediastinum, major vessel) | 17 (27.0%) | 11 (23.9%) | 6 (35.3%) | |
| Preoperative clinical conditions | | | | |
| Major multiple trauma | 22 (34.9%) | 14 (30.4%) | 8 (47.1%) | 0.246 |
| Advanced thoracic malignancy | 15 (23.8%) | 10 (21.7%) | 5 (29.4%) | 0.740 |
| Infectious disease | 12 (19.0%) | 10 (21.7%) | 2 (11.8%) | 0.487 |
| Airway obstruction | 14 (22.2%) | 12 (26.1%) | 2 (11.8%) | 0.316 |
| Bleeding before surgery | 26 (41.3%) | 18 (39.1%) | 8 (47.1%) | 0.388 |
| Diabetes | 13 (20.6%) | 9 (19.6%) | 4 (23.5%) | 1.000 |
| Hypertension | 15 (23.8%) | 10 (21.7%) | 5 (29.4%) | 0.740 |
| Renal failure | 1 (1.6%) | 0 (0%) | 1 (5.9%) | 0.270 |
| Coagulopathy | 27 (42.9%) | 16 (34.8%) | 11 (64.7%) | 0.460 |
| Postoperative results | | | | |
| Arrest during operation | 11 (17.5%) | 2 (4.3%) | 9 (52.9%) | <0.001 |
| Operation time | 250.56 ± 125.77 | 249.0 ± 115.6 | 254.7 ± 153.9 | 0.875 |
| Operation-related complications | | | | |
| Bleeding | 11 (17.5%) | 6 (13.0%) | 5 (29.4%) | 0.149 |
| Cerebral injury | 8 (12.7%) | 3 (6.5%) | 5 (29.4%) | 0.280 |
| Lung failure | 20 (31.7%) | 10 (21.7%) | 10 (58.8%) | 0.191 |
| Other | 7 (11.1%) | 4 (8.7%) | 3 (17.6%) | 0.375 |

ECMO: extracorporeal membrane oxygenation; VA: venoarterial; VV: venovenous
preoperatively, ECMO can be performed relatively quickly. The operation can begin after the patient’s vital signs have stabilized. However, if ECPR (as sudden cardiac arrest) during thoracic surgery occurs without femoral cannula site preparation, ECMO insertion and recovery of vital signs were delayed due to the lateral decubitus position of patients. Although ECMO was started, most patients presented with hypoxic brain damage or irreversible cardiopulmonary dysfunction due to delayed time to resuscitation. Min et al.\textsuperscript{18} reported an overall success rate (i.e., neurological deficit-free operation) of 26% with intraoperative ECPR. In our study, only two of 11 (18.1%) intraoperative ECPR patients survived. One patient was in a supine position and the other had an event during surgical draping, so ECMO could be applied relatively quickly. Based on these results, preventive ECMO insertion comparing the intraoperative ECPR may have helped increase patient survival. In the patients who have a risk of developing cardiopulmonary failure during surgery, it is necessary to establish indications for preventive ECMO insertion. In our institute, indication of preventive ECMO insertion is as follows: (1) tachycardia occurs due to compression on the heart by a huge mass, (2) maintain of PaO\textsubscript{2} is difficult due to active and massive hemoptysis, (3) airway is collapsed below 5 mm, (4) maintain the airway is difficult due to bilateral thoracic surgery or carina surgery, and (5) maintain ventilation is difficult due to pneumonia or acute respiratory distress syndrome (ARDS) of the opposite lung.

If thoracic surgery with ECMO support is chosen, the correction of preoperative coagulation defects is important for operation mortality. Anticoagulation should generally be used to prevent blood clots in extracorporeal circuits. However, it is important to consider whether it is reasonable to implement prophylactic anticoagulation in patients with major bleeding. In particular, when ECMO is inserted to support surgery, its short-term use is planned, so the probability of thromboembolic events is lower than the other ECMO applications.

There are many reports of surgery with heparin-free ECMO in trauma. Muellenbach et al.\textsuperscript{19} first reported three cases of prolonged heparin-free VV ECMO in multiple-injury ARDS patients with severe traumatic brain injury in whom conventional mechanical ventilation had failed. Arlt et al.\textsuperscript{20} reported that six of 10 multiple trauma patients with coexisting pulmonary failure or cardiopulmonary failure and hypovolemic shock due to bleeding survived with the use of heparin-free ECMO. Ried et al.\textsuperscript{21} reported an overall survival rate of 79% in 52 patients with severe thoracic trauma and acute lung failure refractory to conventional therapy using extracorporeal lung support. Heparin-free ECMO was used in patients at high risk of further bleeding complications or showing signs of intracranial bleeding.

It is theoretically possible to support patients with ongoing massive bleeding by ECMO without anticoagulation. First, patients with massive bleeding often have coagulation defects prior to ECMO insertion because a mild coagulation defect is induced by blood loss and hemodilution due to massive crystalloid volume replacement. It is possible to maintain ECMO flow and function without anticoagulation during ECMO cannulation.\textsuperscript{22} Second, newer circulatory systems utilizing heparin-bonded catheters, low-pressure oxygenators, and centrifugal pumps allow for the use of less anticoagulant during ECMO without circuit thrombotic complications.\textsuperscript{23} Third, most thromboses occur at sites of stasis or turbulent flow in the circuit, that is, on the venous (pre-oxygenator) side of the circuit rather than on the arterial (post-oxygenator) side.\textsuperscript{24,25} We performed ECMO intraoperatively without heparin except a loading dose during elective ECMO insertion to reduce bleeding due to anticoagulation use.

The last point to mention is that ECMO can be used postoperatively. All patients undergoing surgery with ECMO have a high-risk medical problem. Therefore, in many cases, cardiopulmonary failure occurs after surgery. Maintaining vital signs is often difficult despite maximal conventional support. In these cases, ECMO support is required to maintain cardiopulmonary stability.

| Table 2  Multivariable analysis of risk factors for mortality | Odds ratio | 95% CI | p value |
| --- | --- | --- | --- |
| Estimated factors | | | |
| Age (years) | 7.47 | 1.17–47.85 | 0.034 |
| Sex | 0.20 | 0.01–3.03 | 0.245 |
| Types of support | 4.60 | 0.48–43.93 | 0.185 |
| Arrest during operation | 24.44 | 1.82–327.60 | 0.016 |
| Purpose of ECMO | 0.64 | 0.09–4.52 | 0.652 |
| Postoperative bleeding | 0.45 | 0.05–3.97 | 0.470 |

ECMO: extracorporeal membrane oxygenation
function after surgery. Because ECMO rescues life or reduces respiratory dependence in the immediate postoperative critical period, patients who require maximal ventilator support could prevent VILI or diaphragm dysfunction by postoperative ECMO support. Yeo et al.26) reported an 80% survival rate of postoperative ARDS through ECMO therapy. In general, the survival rate of postoperative ARDS is 50–60%, a high success rate.27) If ECMO is used during surgery, it can be easily determined to which extent it should be used immediately after surgery; thereby, we can prevent secondary cardiopulmonary function damage from occurring after surgery. The limitation of this study was that it was a small case number and was not various thoracic surgery.

**Conclusion**

ECMO is useful during thoracic surgery in high-risk patients with respiratory or cardiac failure. ECMO provides a safe environment during thoracic surgery with acceptable mortality and complication rates. However, as shown in our results, unprepared ECMO insertion does not increase the survival rate due to delayed resuscitation in intraoperative arrest. For patients at high risk of surgery with a high chance of a lethal event, elective ECMO insertion to prevent a lethal event is recommended.

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**Disclosure Statement**

None.

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