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First Use of a Novel Extracorporeal Life Support System: Successful Application in Tracheoesophageal Fistula Repair

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Abstract: Extracorporeal life support, commonly referred to as extracorporeal membrane oxygenation (ECMO), is indicated when conventional medical and surgical measures fail to support a patient during cardiac or respiratory failure. Increased use of ECMO in recent years has led to innovation that has improved safety in appropriate candidates. This has resulted in the application of novel approaches to complex surgical problems. Herein, we describe a simple, novel, and new-to-market ECMO circuit used for successful perioperative veno-venous ECMO support of a patient undergoing complex repair of a tracheoesophageal fistula. We believe that this circuit and its use for intra-and post-operative extracorporeal support provides a framework for safe and simple ECMO support in the future, including perioperative support for patients undergoing complicated and challenging thoracic procedures. **Keywords:** ECMO, extracorporeal, veno-venous, tracheoesophageal fistula. *J Extra Corpor Technol. 2022;54:73–8*

Extracorporeal life support, commonly referred to as extracorporeal membrane oxygenation (ECMO) is indicated when conventional medical and surgical measures fail to support a patient during cardiac or respiratory failure. According to an international registry, the use of ECMO increased approximately 7-fold between 2005 and 2019 with most of that increase coming in the adult populations (1). In addition, the number of centers performing ECMO that report to the international registry has increased approximately 250% in the same time frame (1). While the reasons for increased use of ECMO are multi-factorial, improvements in technology have been a contributing factor. The increase in market size has led to the development of products that can potentially improve patient care and safety. These are important advances that we can use to strategize novel approaches to complex surgical problems.

Veno-venous (VV) ECMO is a form of extracorporeal life support that utilizes only venous cannulation sites and is used specifically for patients with respiratory disease. In recent years, VV ECMO has been shown to be feasible and safe for intraoperative support to facilitate various airway and thoracic procedures in selected patients (2–4). This has been an important part of our practice especially for complex central airway cases where surgical exposure is key and the chance to minimize the potential for ventilator injury to the reconstruction in the immediate post-operative period. This case report focuses on a simple, novel, and new-to-market circuit used for perioperative support of a patient undergoing complex repair of a tracheoesophageal fistula (TEF).

DESCRIPTION OF CASE

A 62-year-old female with history of stage IV diffuse large B-cell lymphoma status-post-chemotherapy was found to have a TEF at the previous site of her primary

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disease. She had multiple attempts at healing with esophageal and bronchial stent placement that predictably failed. The patient was failing to thrive due to recurrent pneumonias and was status-post-gastrojejunostomy for chronic aspiration. Staging imaging and biopsies demonstrated no evidence of residual malignancy and an excellent response to lymphoma treatment. Imaging and flexible bronchoscopy demonstrated that the fistula was located just distal to the left mainstem origin and extended distally to within .5 cm of the secondary carina on the left. There were also chronic inflammatory changes along with a complex stenosis that narrowed the left mainstem to about 4 mm in diameter. Bronchoscopy and imaging also confirmed post-obstructive pneumonia primarily involving the left lower lobe.

It is our practice to use the advantages afforded by VV ECMO during operative repair and minimize the deleterious effects of positive-pressure mechanical ventilation post-operatively on the surgical repair for a successful outcome. It was therefore decided to support the patient with VV ECMO both intra- and post-operatively. This has been a standard approach of ours for these complex pathologies especially in the face of the lung injury that predictably accompanies TEFs.

The patient (body surface area 1.9 M^2 and body mass index 29 kg/M^2) was pre-emptively placed on VV ECMO in the operating room just prior to the complicated procedure consisting of a right thoracotomy and TEF repair with an aortic homograft patch and intercostal muscle flap reinforcement. The esophagus could not be safely salvaged and as such ancillary procedures included planned bipolar esophageal exclusion with cervical esophagostomy, and tracheostomy placement. As part of the index procedure, we also closed the crura laparoscopically and matured the stomach by completing the resection distally at the gastroesophageal junction thereby removing the distal esophagus. At the conclusion of the procedure, the bronchial repair looked excellent bronchoscopically and we planned to return to the operating room for further management of the left mainstem stenosis in a staged fashion.

The ECMO system was made up of a TandemLife Lifesparc blood pump (Livanova PLC, London, UK), a Nautilus Smart oxygenator (MC3 Cardiopulmonary, Dexter, MI), and a Medtronic (Minneapolis, MN) custom tubing pack for aseptic setup and priming. Because the Lifesparc pump comes with pre-connected tubing (approximately 31″ on the inflow and 42″ on the outflow), we trimmed the pump outflow to approximately 18″ and connected to the inflow of the oxygenator. Instead of attempting to remove the pre-connected tubing from the pump inflow, we extended the pump inflow tubing using a 3/8″ straight connector and 3/8″ tubing to reach the drainage cannula. In addition, a 12″ segment of pressure tubing was connected to the luer connections on both the inlet and outlet of the oxygenator for sampling blood gases and these extensions were capped with three-way stopcocks. The circuit was primed with Plasmalyte-A (Baxter Healthcare, Deerfield, IL) away from the sterile field using a priming bag from the custom Medtronic tubing pack. This pack is designed to allow hand off of the sterile, primed patient lines to the surgical field, which was done just prior to cannulation. A Microtemp LT (Cincinnati Sub Zero Products, LLC, Cincinnati, OH) was used as a heater for the ECMO circuit and a Sechrist 3500 low flow air-oxygen mixer (Seachrist Industries, Inc., Anaheim, CA) was used to blend gases. A simplified illustration of the circuit (minus heater and gas blender) is shown in Figure 1.

After administration of 2,000 units of heparin and achieving an activated clotting time of 161 seconds, we began cannulation in preparation for initiation of ECMO. A 25 Fr. Biomedicus multi-stage venous cannula (Medtronic) was inserted into the right femoral vein for VV ECMO drainage. A 17 Fr Biomedicus arterial cannula (Medtronic) was used to return oxygenated blood to the right internal jugular vein. ECMO was initiated with an initial speed of 2,400 RPM to generate forward flow and was slowly increased to 5,000 RPM with a blood flow of 4.0 LPM. Gas blender settings were 100% FiO2 and 3 LPM of sweep upon initiation, and the patient was kept normothermic throughout the procedure. Arterial blood gases and activating clotting times were measured approximately every 30 minutes during the procedure. A single blood gas was sampled from the oxygenator outlet just after initiation of ECMO showing a PaO_2 of >523 mmHg and a $PaCO_2$ of 32.0 mmHg, indicating appropriate gas exchange from the oxygenator. The patient was safely and successfully supported on VV ECMO for the duration of the approximately 10-hour initial procedure. Table 1 shows ranges of ECMO-related values during the procedure, upon arrival to the intensive care unit (ICU), and the post-operative period (from arrival to the ICU to the end of support).

On post-operative day two, the patient made a planned return to the operating room. A bronchoscopy showed moderate secretions in the distal segmental airways that were irrigated and suctioned out. A balloon dilation of the left lower lobe bronchus was performed under fluoroscopic guidance as her left mainstem bronchus had been chronically inflamed and strictured. A tracheobronchial stent was also placed under fluoroscopic guidance at that time. The patient was stable on VV ECMO support throughout the procedure and returned to the ICU in stable condition. On post-operative day four, the patient was successfully and uneventfully weaned from VV ECMO after 99 hours of

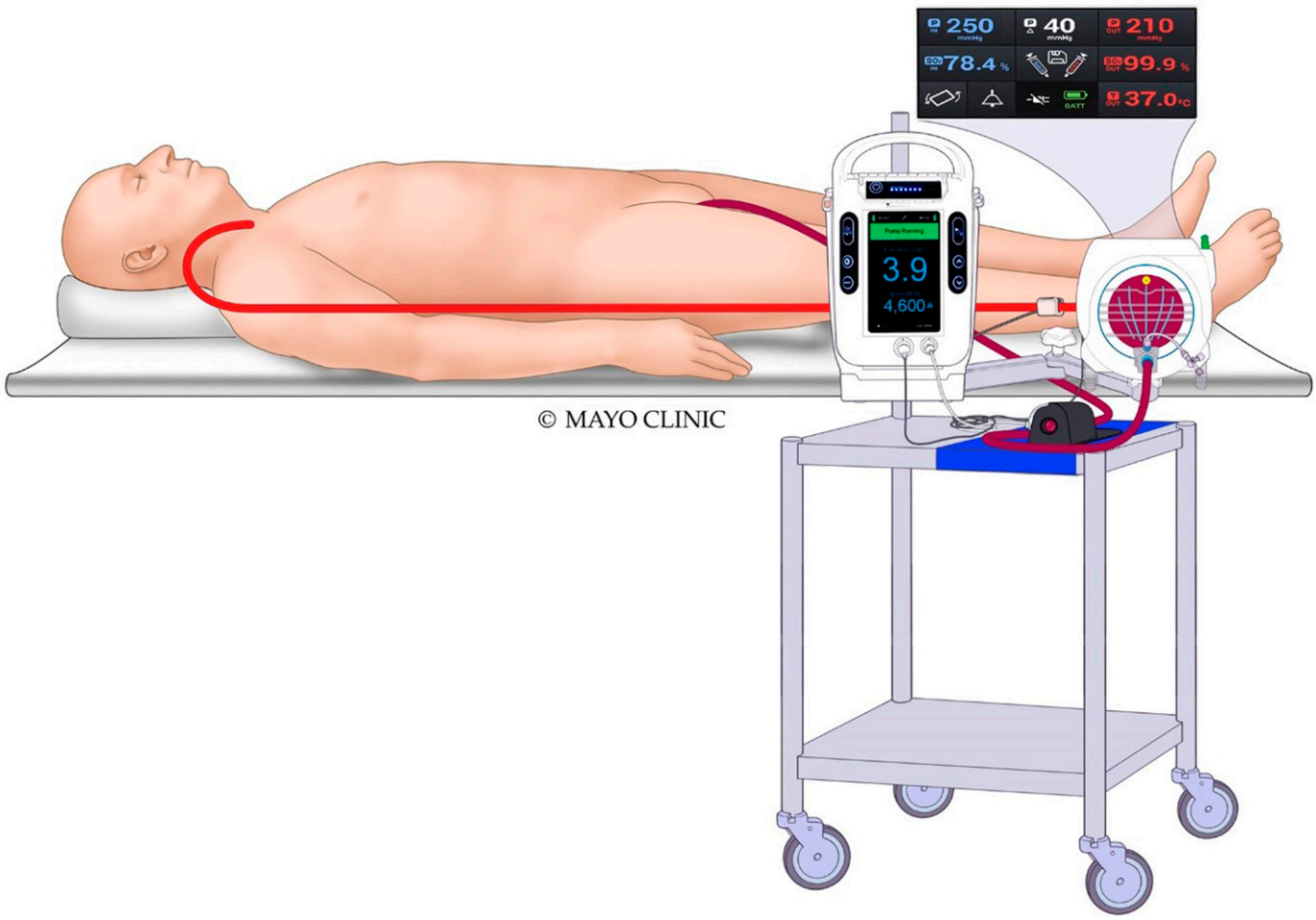

Figure 1. Illustration of extracorporeal membrane oxygenation (ECMO) circuit.

Table 1. ECMO-related values during various phases of support.

	Intraoperative			Postoperative	
	Low	High	Upon ICU Arrival	Low	High
ECMO blood flow (LPM)	3.2	3.9	3.2	3.1	3.4
Pump speed (RPM)	4,600	5,000	4,700	4,700	4,700
ECMO FiO_2 (%)	70	100	100	21	100
ECMO sweep rate (LPM)	2.0	3.0	3.0	1.0	5.0
Patient PaO_2 (mmHg)	68	303	111	57	141
Patient arterial pH	7.31	7.51	7.41	7.32	7.50
Patient $PaCO_2$ (mmHg)	25.3	41.7	35.4	35.3	53.0
ECMO arterial blood temperature (C°)	36.1	37.1	36.6	36.1	36.6
Oxygenator inlet pressure (mmHg)	140	167	151	140	157
Oxygenator outlet pressure (mmHg)	124	149	133	124	141
Trans-oxygenator pressure (mmHg)	16	19	18	13	19
Activated clotting time (s)	120	184	107	91	147
Hemoglobin (g/dL)	7.9	10.1	9.2	7.9	10.3
Lactate (mmol/L)	.86	3.11	2.01	1.0	2.6

ECMO, extracorporeal membrane oxygenation; ICU, intensive care unit.

uncomplicated support. The goal of ECMO support during this time was to allow us to avoid detrimental effects of positive pressure ventilation on the bronchial repair and allow the chronically infected left lung to aerate, clear secretions, and recover with antibiotic therapy from a pneumonia related to the TEF. Of note, peak lactate dehydrogenase during ECMO support was 234 U/L—suggesting that hemolysis was not a problematic complication during support (normal range 122–222 U/L). Sixteen days after the initial procedure, as planned as part of our routine stent management algorithm, the patient returned to the operating room for left mainstem bronchial stent removal and balloon dilation under bronchoscopic guidance. All of the left mainstem pathology was distal to the TEF repair that bronchoscopically looked excellent at every phase. Interval computerized tomography scans of the chest during this time looked excellent both in terms of the mediastinum and the lung parenchyma. The patient underwent continued planned additional left bronchial balloon dilations over the next few weeks and was removed from mechanical ventilation after 22 days. Not surprisingly for this type of patient, she spent 24 days in the ICU and was discharged from the hospital on post-operative day 31. Nutritional status was maintained through her gastrostomy tube. She is doing well as an outpatient with improving distal left mainstem bronchial stenosis, no oxygen dependence. She has had her tracheostomy removed. There is no evidence of TEF and this area is well healed. Final pathology from the surgical resection demonstrated no evidence of malignancy. She has undergone substernal gastric pull-up with esophagogastric anastomosis and recovered from this without complications. She is eating normally, her feeding tube removed, and enjoying a good quality of life.

COMMENTS

This case report highlights the first published report of the combination of the Tandem Lifesparc blood pump with the MC3 Smart Nautilus oxygenator for perioperative ECMO support. We believe there is novelty and simplicity with this combination that is not achieved by other non-integrated ECMO systems (i.e., systems that do not integrate the blood pump with oxygenator). Because the "smart" oxygenator provides continuous monitoring of circuit parameters (Figure 1 and Table 2), we were able to achieve useful circuit monitoring without external devices for monitoring circuit pressures, temperatures, and in-line blood gases. In our opinion, the interface of the Lifesparc pump also adds a degree of simplicity not offered by other blood pumps traditionally used for ECMO.

Table 2. Monitoring capabilities of the ECMO circuit.

Lifesparc blood pump	Blood flow
	Pump speed
Smart Nautilus oxygenator	Oxygenator inlet and outlet pressure
	Trans-oxygenator pressure
	Oxygenator inlet and outlet oxygen saturation
	Arterial blood temperature

ECMO, extracorporeal membrane oxygenation.

The increased use of ECMO in recent years has fueled a widening of the clinical scope of ECMO support and an increased number of products available for such support. While the reason for the increased use of ECMO in recent years is certainly multi-factorial, the timeline is concomitant with two primary triggers (1): the introduction and adoption of polymethylpentene (PMP) fiber oxygenators (5), and (2) the multi-center randomized controlled CESAR trial comparing conventional ventilatory support with VV ECMO for severe adult respiratory failure (6). While the conclusion drawn from the CESAR trial—that ECMO improves survival in adult patients with severe respiratory failure—has been a topic of much debate since the initial publication (7,8), there is little doubt that the publication made a substantial impact on the use and study of ECMO (9). The introduction of the PMP oxygenators just prior to the CESAR trial made for a "perfect storm" for ECMO growth.

PMP oxygenators have a low resistance, high efficiency, and are resistant to plasma leak. The advent of the PMP oxygenator led to a new era of ECMO, with modern circuits becoming safer and far less complex over time (10,11). As the use of ECMO has increased and technology improved, more manufacturers are entering the market leading to innovative products. While some products currently in the market are full ECMO systems, many systems are still pieced together using products from different vendors depending on the needs and preferences of the institution. It is important to note that in the U.S. ECMO products are commonly used beyond their indication for use as cleared by the Food and Drug Administration. That was the case in this report, as the Nautilus oxygenator is indicated for up to 48 hours of use, and the Lifesparc blood pump for periods lasting less than 6 hours.

While fully integrated ECMO systems offer a level of integration that is not matched by our novel circuit, it must be mentioned that there are advantages of ECMO systems having a pump that is separate from the oxygenator. First, separating the pump and oxygenator allows for more versatility of support. When separated the oxygenator could easily be added when, for example, a patient with a right ventricular assist device (RVAD) starts to become hypoxic and needs extracorporeal oxygenation due to lung failure. On the converse, an oxygenator could

be removed from an "RVAD ECMO" circuit when the patient's lungs recover, leaving only an RVAD in place. The Lifesparc system could also be used as a left ventricular assist device when an oxygenator is not required. Also, by having separate components, it is possible to change out components separately in case of failure. This latter scenario may in some cases result in a lower financial cost of long-term ECMO support.

Our center, an ELSO Gold Level Center of Excellence, relies on having two separate ECMO systems. Having two separate systems in our toolbox allows us to choose between a fully integrated system and a component-based system such as the one described in this case report. Also, having two systems provide redundancy in the case of product shortages or back orders and allow us extra capacity during times of increase needs such as influenza season or pandemics. Prior to introducing the Lifesparc pump into our program, we used the Abbott Centrimag blood pump as a component-based ECMO system. While the Centrimag pump offers superb performance and pressure monitoring capabilities, in our opinion, the Lifesparc system offers high performance with a simpler user interface. And because the Nautilus Smart oxygenator integrates pressure monitoring, the need for external pressure monitoring of the oxygenator is negated. It should, however, be noted that this system has no port to transduce or display venous line pressure and does not have an in-line hemoglobin measurement. Table 2 shows a summary of the circuit parameters we were able to monitor with this ECMO circuit.

While we were quite satisfied with our first use of the Lifesparc pump, we believe there are some disadvantages of the system. The first is the lack of a hand crank or backup driver. In case of console failure, an identical Lifesparc console must be used. We decided not to attach a second console to our ECMO cart. In the case of a console failure, a second device would be retrieved from our equipment storage area just adjacent to the ICU. While this was a topic of much discussion, we decided to treat this similarly to other non-durable circulatory assist devices (i.e., intraaortic balloon pumps and percutaneous ventricular assist devices) for which we do not have a backup console in the patient's room. In this particular patient, she had the reserve to tolerate any issues and the main goal of post-operative ECMO support was to minimize positive pressure on the bronchial repair such that this safety decision was uniformly supported by our program leadership. Modern blood pumps are generally considered very reliable with failure rates of less than 1% reported in adult ECMO (1), leaving us comfortable with this decision. A second disadvantage is the lack of a suitable pump holder for cases such as this. The only option currently offered by the vendor is designed so that the pump holster attaches with velcro to a thigh wrap. While this could be valuable for a subset of patients (e.g., ambulatory patients), many patients will not benefit from this mechanism when used for ECMO. We secured the pump to our ECMO cart by wrapping the thigh-wrap around the top shelf of our cart and using the velcro holster (see Figure 1). While this was adequate, it is far from ideal. Our intention is to create a 3D-printed holster that is more suitable to our needs.

This was our fourth use of the Nautilus Smart oxygenator (the first three were paired with the Centrimag pump). While our overall experience has been very positive and have had no functional issues related to ECMO support, we believe there are a few minor shortcomings. First, the LED monitoring screen is quite small and is designed to be viewed from above and is difficult to see from across or outside the room. This was problematic during the COVID-19 pandemic when patients were kept in isolation and doors kept closed. In this scenario, the Lifesparc pump console is still quite easy to visualize to monitor blood flow and pump speed. Also, while there is a more obvious color-coded light on the top of the oxygenator to indicate alarm conditions, the alarms audible tone is relatively quiet and not adjustable in volume.

Despite our critiques of the Lifesparc and Nautilus ECMO system, the system was very capable of supporting this patient with a high degree of simplicity and user friendliness. The ability to monitor multiple circuit parameters without adding complexity is a valued direction for ECMO technology, particularly as the number of centers performing ECMO continues to increase. Both the blood pump and oxygenator performed as expected or better. While we have not used this system for inter-hospital transport of patients on ECMO, it would seem well-suited to accomplish such a mission, particularly when paired with some ingenuity applied toward how to carry the system components. The docking feature of the Lifesparc console could be quite useful in this scenario, as the console can simply be lifted from the docking station and is relatively lightweight for carrying alongside the oxygenator and pump holders.

In summary, this case report details what we believe to be the first published report of the use of the Tandem Lifesparc blood pump with the Medtronic Nautilus Smart oxygenator for ECMO support. We believe that this circuit and the way it was used provides a framework for safe and simple ECMO support in the future, including perioperative support for patients undergoing complicated and challenging thoracic and airway procedures.

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