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Brief Communication

One-Way Valve Malfunction in an Extracorporeal Membrane Oxygenation Priming Circuit

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Abstract: Developing technologies have changed both the components and the management style when extracorporeal membrane oxygenation (ECMO) is used to support critically ill cardiac and respiratory patients. The Cardiohelp system™ is a small, portable extracorporeal system just recently available within the United States. Manufacturing standards and quality processes have made mechanical failure and malfunction of extracorporeal components less common; however, there is still potential for mechanical failure or component malfunction before or during extracorporeal support. This case review describes the malfunction of a Retroguard™ unidirectional flow valve integrated into the priming setup of a Cardiohelp system™ during the priming process. **Keywords:** ECMO, Cardiohelp, Retroguard, one-way valve, mechanical failure. *JECT. 2014;46:98–100*

Since 2002 there has been a steady shift in the components used for extracorporeal membrane oxygenation (ECMO) support (1–3). Centrifugal blood pumps have gained widespread use in ECMO as a result of advances in oxygenator technology. Centrifugal blood pumps are believed to be safer than roller pumps (4,5); however, these advantages are not universally accepted (6).

With changes in ECMO circuit components, there has also been a change in the medical management of some ECMO-supported patients in recent years. Historically patients on ECMO were heavily sedated and paralyzed during the ECMO run to decrease chances of unplanned extubation, accidental decannulation, and to minimize tissue oxygen demands. In contrast, some recent patients on ECMO have been weaned from sedative and paralytic medications, have received a tracheostomy, and are being actively rehabilitated and ambulated while on ECMO support (7,8).

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The Cardiohelp system™ (MAQUET GmbH & Co. KG, Rastatt, Germany) is a small, portable extracorporeal system recently made available within the United States. The Cardiohelp system™ uses an integrated centrifugal blood pump and polymethylpentene diffusion membrane as part of a stock Cardiohelp system™ disposable pack. Additional components within the stock pack include integrated pressure and temperature sensors, an integrated venous saturation and hematocrit cuvette, and sterile heparin-bonded polyvinyl chloride (PVC) tubing. A priming setup including a priming bag, PVC tubing, and a Retroguard™ (Quest Medical Inc., Allen, TX), unidirectional flow valve are also included in the stock disposable pack. The unidirectional valve is designed to prevent retrograde flow within the circuit during the priming procedure. The priming setup is used to fluid prime the Cardiohelp system™ and is disconnected and discarded before patient connection to the extracorporeal circuit. We describe the malfunction of a Retroguard™ unidirectional flow valve during blood priming of a Cardiohelp system™ at the time of ECMO initiation.

DESCRIPTION

A critically ill patient with cardiorespiratory failure secondary to primary pulmonary hypertension, expected to

require intrahospital transport, required ECMO support. The ECMO cannulation team was within the hospital and responded immediately to cannulate the patient for veno-arterial ECMO. A Cardiohelp system™ previously set up and primed with 2 L of PlasmaLyte A (Baxter International Inc., Deerfield, IL) according to the manufacturer's protocol and training was brought to the bedside. Priming of the Cardiohelp system™ was accomplished by putting 2 L of isotonic solution into the priming circuit and allowing the oxygenator and pump component to prime by gravity. Once the system was gravity-filled with isotonic solution, the fluid was circulated for 2 minutes at a rate of 3000 revolutions per minute (RPM) and an additional minute at 4000 RPM according to the manufacturer's recommendations. Our center developed a procedure for blood-priming of the Cardiohelp system™ where the included priming circuit was used for recirculation rather than being immediately excluded on completion of the crystalloid prime procedure. In this case the previously primed Cardiohelp system™ was recirculated at 3000 RPM for more than 5 minutes and then the RPM was turned to zero and the flow was intentionally stopped in preparation for blood-priming of the circuit.

Surplus PlasmaLyte A was pumped out of the priming setup to minimize hemodilution. Two units of packed red blood cells were manually pushed into the priming setup. The PlasmaLyte A within the Cardiohelp system™ was then displaced as blood was pumped into the system from the priming setup. After approximately 400 mL of PlasmaLyte A were displaced, the priming setup was reconfigured to allow for recirculation. Two hundred fifty units of heparin and 15 mEq sodium bicarbonate were added to the priming setup according to institutional policy and an attempt was made to recirculate the blood within the Cardiohelp system™. There were no Cardiohelp system™ alarms actively alarming, no visible kinks within the circuit tubing, and calcium was not administered into the system at any point. The RPM were adjusted multiple times from 0–4500 and a thorough inspection of all tubing and components was made in an attempt to establish and recirculate flow within the Cardiohelp system™ over a 5-minute period.

During this time, one of the traditional ECMO systems used at our center was retrieved. The manufacturer was called and a clinical expert from the company attempted to troubleshoot the system with the ECMO coordinator and perfusionist over the phone. When the traditional setup arrived at the bedside, the patient was placed on ECMO support using the traditional ECMO system. The Cardiohelp system™ was moved to an adjacent hallway where the manufacturer-trained ECMO coordinator continued to troubleshoot the system with the clinical expert. The clinical expert directed the ECMO coordinator to take the Retroguard™ unidirectional flow valve in hand and strike it with a metal tubing clamp. When the flow valve was struck, it opened immediately and flow was again established within the Cardiohelp system™.

COMMENT

Mechanical failure and malfunction of extracorporeal circuit components, including ECMO, is not well described in the literature. Mechanical complications requiring changeout of ECMO circuit components are reported to the registry of the Extracorporeal Life Support Organization (ELSO) by participating centers. From 2008 to 2012 there were 15,060 cases reported to the registry including mechanical failure requiring changeout of the oxygenator in 1177 instances (7.8%), the pump in 202 instances (1.3%), and the heat exchanger in 31 instances (.2%) (9). Mechanical failure of components reported to the ELSO registry are not differentiated into complications discovered around the time ECMO support is initiated and those acquired during the ECMO run. Currently, no data are reported to the ELSO registry of component failure discovered before initiation of ECMO support. Oxygenator and pump failure are more likely to develop over time as a result of the biomechanical interaction between the patient and the ECMO circuit. The low incidence of reported heat exchanger failure points to a low rate of component failure independent of biomechanical interaction. Although the incidence of mechanical failure is low, it is still an important factor to consider in any troubleshooting algorithm.

While using the Cardiohelp system™ we have experienced the described scenario, malfunction of the Retroguard™ unidirectional flow valve, multiple times in a laboratory setting with a crystalloid primed system since the described case study. Each time the valve has opened fully when the outer casing of the flow valve was struck with a hand or a metal tubing clamp. The Retroguard™ unidirectional flow valve is removed and discarded with the rest of the priming circuit before connecting the patient to ECMO support, so there is no chance for this specific scenario to occur during the ECMO run. It is important to recognize the potential for malfunction of the Retroguard™ unidirectional flow valve during the priming process before initiation of ECMO support. It is also important to educate team members about the potential component malfunction and educate team members as part of a developed troubleshooting algorithm for the inability to establish flow during priming of a Cardiohelp system™.

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