Case Report

Ventricular Assist Device Malfunction: Sometimes It Is a Zebra

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Abstract: Humans and machines fail. It is a matter of fact. Preventing, recognizing, and troubleshooting problems with the many intricate systems used by perfusionists are key skills within the profession. Preventive measures are used in an attempt to fend off errors before they occur. Skills are taught during the educational process to enable clinicians to recover from, and mitigate the effects of, critical events when they do occur. Diagnostic procedures have been developed to step through the troubleshooting process for device and procedural failures. The most common cause of an event is at the top of the list along with its solution. Sometimes, however, the most common issue is not the cause of the problem. Sometimes the problem cannot be diagnosed within the clinical setting. This case is a report of such a situation.

Keywords: ventricular assist device, troubleshooting, mechanical circulatory support, VAD, MCS, PVAD, IVAD, Thoratec, giant cell myocarditis.

In medicine, there is a common aphorism: “When you hear hoof beats, think horses, not zebras.” It means that when presented with a set of signs or symptoms, you should think of the most common causes first. For example, when the CO2 rises on cardiopulmonary bypass (CPB), the perfusionist should not immediately think oxygenator failure; rather, the patient may be waking up and their metabolism is increasing. Maybe the CO2 flush at the field has been manipulated. Is the sweep gas simply too low? Unfortunately, however, although the most common solution is usually the answer, sometimes it is the zebra.

The healthcare industry has developed a system that provides a high level of safety to protect patients from the people and the machines used to treat them. Healthcare providers have minimum standards of education and continuing education. The devices used have preventive maintenance performed regularly. Backup systems and redundancies are used. With a system of checks and balances, a human may catch a device failure or humans may catch other human errors. Some devices are even capable, by design, of preventing a human from making a mistake. Unfortunately, even with our complex system of protection, devices fail and humans make mistakes.

Algorithms are used to troubleshoot unexpected events. Somewhere near the top of the list is whether the device in use is functioning correctly. When the problem is associated with one of the many machines that perfusionists use, one of the choices for correction is obtaining a backup system. In many cases, this is the only option, because systems get more and more complicated and have fewer and fewer remedies that can be applied by the end user. However, what happens when the backup malfunctions? What if this device is a critical life support system such as a ventricular assist device?

DESCRIPTION

In the 1980s Thoratec developed and deployed a system that we still use today. That system began supporting patients in 1983 and, although cumbersome, and comparatively old, is still one of the most dependable ventricular assist systems available. The system referred to is the Paracorporeal Ventricular Assist Device (PVAD) and the Dual Drive Console (DDC) (Thoratec Corporation, Pleasanton, CA) (Figure 1).
The PVAD is a paracorporeal, pulsatile, pneumatically driven device that is capable of providing both univentricular and biventricular support. The patient is cannulated most commonly through the left ventricular (LV) apex and the ascending aorta for LV support and through the right atrium and main pulmonary artery for right ventricular (RV) support. The device has a polyurethane sac, which is pneumatically driven to provide blood flow through the pump, and two mechanical valves ensure the directionally correct flow of blood thorough the device. On the outside shell of the pump is a sensor called the Hall Switch used to determine the point at which the pump is full and the ejection portion of the cycle should commence.

A similar device, the Implantable Ventricular Assist Device (IVAD) (Thoratec Corporation), was developed more recently. It functions in the same manner as the PVAD with two main exceptions. First, it can be implanted completely within the patient with only a single driveline exit site. The PVAD, an extracorporeal device in contrast, has two cannulas that exit the skin. The second difference is in the way the clinician determines if the device is completely emptying. The PVAD is positioned completely outside of the body and has a clear plastic chamber allowing direct visualization of the blood chamber. By this design, emptying of the blood chamber can be directly observed. Because the IVAD is implanted within the patient, it has an empty signal within the electrical circuitry that indicates complete emptying of the device with a flashing green light.

The DDC console provides the pneumatics that actuate the devices. This console has the capability to control every aspect of the cardiac cycle, something that is not available in many mechanical circulatory support (MCS) systems. The ability exists to control the ejection duration or systolic portion of the cycle and, in conjunction, the diastolic portion as well. In addition, the amount of force the device uses to eject blood out of the pump and how much vacuum is applied to draw volume into the pump can be manipulated. Along with the volume and asynchronous modes of this device, this console provides a number of ways to optimize the device’s function. The asynchronous or fixed mode runs the device at a set rate, whereas the volume mode runs the device based on the fill signal. As the Hall Switch is actuated by the complete filling of the pump sack, the device initiates the systolic portion of the cycle and forces blood out of the pump. If, when in volume mode, the device does not report a fill signal, it will slow down until it acquires a fill signal or reaches the base rate. The base rate is set by the clinician and is the rate at which the device will pump if in asynchronous mode. If the system drops to the base rate and still sees no fill signal, an alarm will sound.

The DDC, which has been used in over 260 institutions and supported over 4400 patients worldwide, along with the IVAD, proven in over 560 patents, is the system that was chosen to provide support for the patient (1,2). This patient presented with dilated cardiomyopathy secondary to giant cell myocarditis. Giant cell myocarditis is a very rare, difficult to diagnose disease. The symptoms range from fatigue to sudden death (3). Giant cells are abnormal masses produced by the fusion of inflammatory macrophages. Giant cell myocarditis is an idiopathic condition in which inflammation is caused by the widespread infiltration of giant cells associated with other inflammatory cells resulting in heart muscle cell destruction (4). As a result of this condition, the patient was brought emergently to the operating room (OR) for placement of a biventricular assist device (BiVAD). Shortly after induction, the patient experienced acute cardiovascular collapse with a blood pressure in the 30s and was dangerously close to cardiac arrest. Chemical resuscitation and cardiopulmonary resuscitation were administered. After approximately 10 minutes of resuscitation efforts, the patient’s blood pressure and cardiac
function returned to satisfactory levels allowing the surgeon time to heparinize, cannulate, and initiate CPB.

The implantation of biventricular devices was relatively uneventful. The only item of note during the implantation was the removal of a small amount of thrombus from the left ventricle. Issues arose when CPB was terminated and BiVAD support was initiated. Hand pumping was used to ensure complete deairing of the devices per standard protocol. After complete deairing, biventricular support was initiated using the DDC. By convention at our institution, the LVAD is run from the top module of the DDC and the RVAD from the bottom module. As we separated from CPB in fixed mode at a rate of 50 beats per minute, the RVAD was filling and emptying appropriately. However, the LVAD was not providing the support expected and a fill signal was intermittent to nonexistent. Systemic blood pressure waveforms were very minimal and resembled a significantly dampened waveform.

As a result of the lack of a fill signal, the vacuum was decreased to ~25. Negative 25 is the maximum recommended setting while the patient’s chest is open as a result of the risk of entraining air into the system through fresh suture lines. An occasional fill signal resulted with this change, but nothing regular. The heart was mildly manipulated in an attempt to ensure proper placement of the LVAD ventricular cannula with no change in support. After a couple of minutes, the pneumatic drive portion of the LVAD was disconnected from the DDC and the device was hand pumped. With this, the blood pressure waveforms got better, yet the bulbs used to hand pump seemed to be sluggish to fill. However, support seemed to improve with the hand pump.

It is our department’s policy to maintain a backup device for emergency use during any device implant. As such, a spare DDC was warmed up, calibrated, and available in the hallway just outside of the OR. Because the hand pump seemed to better support the patient, it was felt that a console failure may have been the cause of the poor support. The backup DDC console was brought into the room and the settings for the LVAD were programmed to the patient’s requirements. The LVAD electrical leads were moved from the primary DDC to the backup and the hand pump was disconnected from the pneumatic line and the line connected to the backup console. Support was initiated with the backup console for the LVAD while the RVAD continued to be supported by the primary console. In retrospect, this is where the train left the tracks, but there was no way of knowing this at the time.

Support through the backup console was identical to the primary, low blood pressure waveform with minimal ejection and no fill signals. The pump performed just as it did on the primary console. Again, decreases in the vacuum setting to aid filling were unsuccessful and increases in eject pressures did not increase systemic blood pressure waveform deflections. After 1 or 2 minutes attempting to optimize the device’s function, hand pumping was again initiated.

At this point in our troubleshooting algorithm, we felt the console had been eliminated as the problem as a result of the identical performance on the backup console as the primary. This being the case, both the 7- and 5-foot sections of the electrical leads were changed out to ensure proper functioning of those cables. No change in the performance of the device was observed. As mentioned before, the hand pumps seemed to fill a bit on the sluggish side. This, combined with the inability to get a consistent fill signal, identical operation on both the primary and backup consoles, and the presence of intraventricular thrombus observed before implantation, turned our attention to the possibility of inflow cannula obstruction.

Although no obstruction was demonstrated through transesophageal echo, biventricular support was discontinued and CPB was initiated. The LV cannula was removed, the LV was inspected, and the cannula placement was adjusted. In addition, the device was inspected and a small amount of debris was removed from the inflow valve. Hoping that this debris was the cause of the problems, the ventricular cannula was connected to the device, the patient weaned from CPB, and biventricular support was again initiated. On initiation, the RVAD continued to perform properly. However, the LVAD continued to have the same problems.

Each of the modules on the DDC operates independently of each other. Each has its own electrical and pneumatic systems. With this in mind, the LVAD was again connected to the backup console but this time to the lower module rather than the top module to double-check the possibility of a console failure. Again the device functioned in the same manner as it did on the primary console and the device was again hand pumped.

None of the troubleshooting efforts had been effective. The IVAD pump has a “Y” connector at the base of the device, which allows the connection of the electrical and pneumatic lines to the pump. This portion of the electrical system was the only thing left to change other than the pump itself. This Y comes included in the device kit and, therefore, an entire pump would need to be opened to gain access to this part (Figure 2). Another pump was opened and the Y was changed out. Unfortunately, replacing this Y did not solve the problems.

At this point, with the combined experience of three perfusionists including the Chief, an MCS coordinator, the MCS Section Lead, and two surgeons, we were at a loss. Why was this pump working while being hand pumped but not when connected to any one of the three other modules on two different consoles? Why was the RVAD working, whereas the LVAD was not? Having
exhausted all of our troubleshooting processes, Thoratec was contacted for assistance. They ran down all of the options, which we had already covered. Soon Thoratec was out of suggestions as well.

With all of our options seemingly exhausted, the conversation turned to removing the IVADs and implanting an Abiomed AB 5000 ventricle system (Abiomed, Danvers, MA). This device is similar to the IVAD but not quite as versatile or controllable. In addition, at the time, this device could not be discharged from the hospital. During this discussion, it was suggested that we try a Thoratec TLCII driver (Thoratec Corporation) (Figure 3) before a device change out was done. The staff had very little confidence in this solution because we had already tried another console and three different modules. Additionally, the Thoratec specialist literally laughed out loud at the suggestion, not believing that it would solve the problem.

For those not familiar with the TLCII console, it is the device that Thoratec has developed to allow patients to be discharged from the hospital on IVAD or PVAD support. It has the ability to run BiVADs but lacks some of the control options that the DDC has, yet it is a quite capable system. Recently a newer version of this system, the TLCII+ (Thoratec Corporation), has become available. The TLCII+ is designed to overcome some of the original TLCII’s shortcomings but was unavailable at the time this case was performed. A TLCII console was brought to the OR, programmed to the patient’s requirements, and biventricular support was initiated. This approach surprisingly solved the problem. The TLCII console was appropriately supporting the patient.

After the case was completed, the patient was transported to the unit on the TLCII driver with another TLCII driver as a backup. Both DDCs were removed from service, rental systems were ordered, and an investigation was initiated. A root cause analysis was completed by a team of investigators comprised of biomedical engineers, nurses, doctors, and lawyers. The biomedical engineers disassemble the devices to determine if a condition exists that would cause the described situation. Once completed and a cause is found, the panel examines the situations and conditions that led up to the events at hand. Action items and corrections to the procedure are suggested and implemented in an attempt to eliminate the conditions that cause a failure to arise.

There are many valves and switches within the DDC that must function in perfect harmony to allow the system to perform correctly. The zebra was discovered during the root cause analysis. According to the biomedical engineer’s analysis, two of the three modules that were functioning improperly had a component called the Humphrey valve installed incorrectly. In addition, the third malfunctioning
module had the wiring to the Clippard valve wired backward. This electrical issue caused the device to function in the same manner as if the Humphrey valves were improperly installed. This resulted in three of the four modules functioning the very same way but incorrectly. Unfortunately, we were unable to diagnose this condition in the clinical setting. The alarms that are available on the DDC are for lack of fill signal and pressure or vacuum out of range alarms. Although we were getting the fill alarm, which can be caused by many conditions including inflow obstruction, hypovolemia, and RV failure, the pressure and vacuum were set within normal ranges and therefore were not alarming. There was no alarm to let us know the device was functioning incorrectly. With all three modules performing the exact same way but with the valves out of sync, the DDC was not delivering the appropriate amount of pressure during each phase of the cycle. This resulted in the inability to fill the pump completely or eject with the proper force.

**COMMENT**

How can this situation be prevented in the future? What could be done in the OR and with the devices that may detect an improperly functioning device before it is used on a patient? During the root cause analysis of this event, it was discovered that the design of the DDC had a number of system components that could be improperly assembled. Valves could be installed upside down, wires could be connected backward, and many of the same colored wires could lead to confusion. Development of these systems should take into account the human factor and components designed that are well labeled and may only be installed one way.

These systems are very complex and should be serviced by highly trained personnel. Manufacturer service personnel are very familiar with these systems. They work inside these machines daily. In this author’s opinion, these life support systems should be serviced by the manufacturers' highly trained personnel and not by someone who is only inside these machines once or maybe twice a year.

There are system checks that can be performed, which will indicate whether the DDC is supplying the appropriate amount of pressure during a given portion of the cycle. This check is part of a multipoint system review that is done after any preventive maintenance. Unfortunately in this case, the results of this portion of the check were improperly interpreted or the check was not properly completed. As a result, we have added this check to our preimplant system preparation. This test may not catch other malfunctions. As mentioned, this is simply a small portion of a multipoint check that is to be completed. Running the entire checklist is too time-consuming and simply not practical. Quite frankly, perfusionists are not the best personnel to perform this check. This should be performed by qualified personnel trained to service and completely check out the system.

We all have backup consoles at our disposal to provide support when the primary systems go down. Unfortunately in this case, we were unable to determine that both consoles and each of the three modules were malfunctioning in exactly the same way. When both the backup and primary systems are functioning in the same way, the supposition is that there is nothing wrong with either one. Sometimes the right answer is not the most common. Sometimes it is the zebra.

**REFERENCES**