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ADVANCED

CASE REPORT: CLINICAL CASE

Electrostatic Discharge Causing Pump Shutdown in HeartMate 3

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ABSTRACT

Left ventricular assist devices (LVADs) improve symptoms and outcomes in advanced heart failure. Although device malfunction has decreased significantly with later generation LVADs, it has not been eliminated. We describe the clinical course of a patient with HeartMate 3 LVAD who experienced device malfunction, involving temporary pump shutdown suspected to be caused by electrostatic discharge. (**Level of Difficulty: Advanced.**) (J Am Coll Cardiol Case Rep 2021;3:459-63) © 2021 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

INTRODUCTION

Left ventricular assist devices (LVADs) improve symptoms and outcomes in appropriately selected patients with heart failure (1); however, LVAD technology is still limited by a significant incidence of complications. Although pump malfunctions due to hemocompatibility-related adverse events or other causes have decreased since the introduction of more technically advanced devices, serious adverse events still occur (1,2).

We describe the clinical course of a serious incident of device malfunction in a patient with HeartMate 3 (HM3), involving pump shutdown suspected to be secondary to electrostatic discharge (ESD).

LEARNING OBJECTIVES

- To recognize the potential risks associated with technologically sophisticated medical devices.
- To identify the different causes of LVAD malfunction and to explain their impact on LVAD.

HISTORY OF PRESENTATION

A 60-year-old man with HM3 presented following a "vibrating feeling" in the chest, a loud sound from the pump, and "red heart" alarms.

AT TIME OF RED HEART ALARMS. The patient presented to the hospital 21 days after discharge after experiencing an event with a loud sound from the pump, a vibrating feeling in the chest, and red heart alarms (the most serious type of HM3 alarms, which occur for conditions that are immediately life-threatening and should prompt an immediate response to avoid serious patient injury or death) for 4 min early in the morning while he was connected to the HM3 mobile power unit (MPU).

He felt well at the time of admission and had pacemaker rhythm, 70 mm Hg mean arterial pressure, pump speed of 5,200 revolutions/min (RPM),

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ABBREVIATIONS AND ACRONYMS

CRT-D = cardiac resynchronization therapy defibrillator

ESD = electrostatic discharge

FDA = U.S. Food and Drug Administration

HM3 = HeartMate 3

ICD = implantable cardioverter-defibrillator

LVAD = left ventricular assist device

MPU = mobile power unit

calculated average LVAD flow of 4.9 l/min, and motor power 4.0 W. Echocardiographic examination showed an appropriately unloaded left ventricle (reduced left ventricular end-diastolic diameter), aortic valve opening with every beat, no mitral regurgitation, and no signs of pump thrombosis or obstruction. His international normalized ratio was 3.0 at the time of admission.

Analysis of log files data showed many alarms including low flow alarms, LVAD faults, and red heart alarms (Figure 1). There was 1 event of pump stoppage with a duration of 10 s and a maximum power of 36 W. The rest of the speed drops were either due to a brief interruption in communication (0 rpm) or the motor control algorithm having difficulty maintaining speed under the loss of bearing control (Figure 2).

The elevations of motor power were associated with motor instability fault flags, and there was also an increase of LVAD temperature with activation of circuit over temperature fault flags and LVAD internal fault flags. The motor instability, high current, and circuit over temperature fault flags continued until there was loss of external power causing both the pump and the system controller to reset.

PAST MEDICAL HISTORY

PRE-LVAD. The patient is a 60-year-old man with idiopathic dilated cardiomyopathy, atrial fibrillation, morbid obesity, and type 2 diabetes mellitus. He was in New York Heart Association functional class IIIB and INTERMACS 3, was inotrope dependent, and underwent HM3 implantation as a bridge to decision for potential heart transplantation.

POST-LVAD. The post-operative course was uneventful, and the patient was discharged 2 weeks after HM3 implantation. He was treated with aspirin 75 mg daily, warfarin adjusted to international normalized ratio of 2 to 3, bisoprolol, amlodipine, and

FIGURE 1 Log Files Showing the Sudden Shutdown of HM3 Secondary to High Motor Power Causing Red Heart Alarms

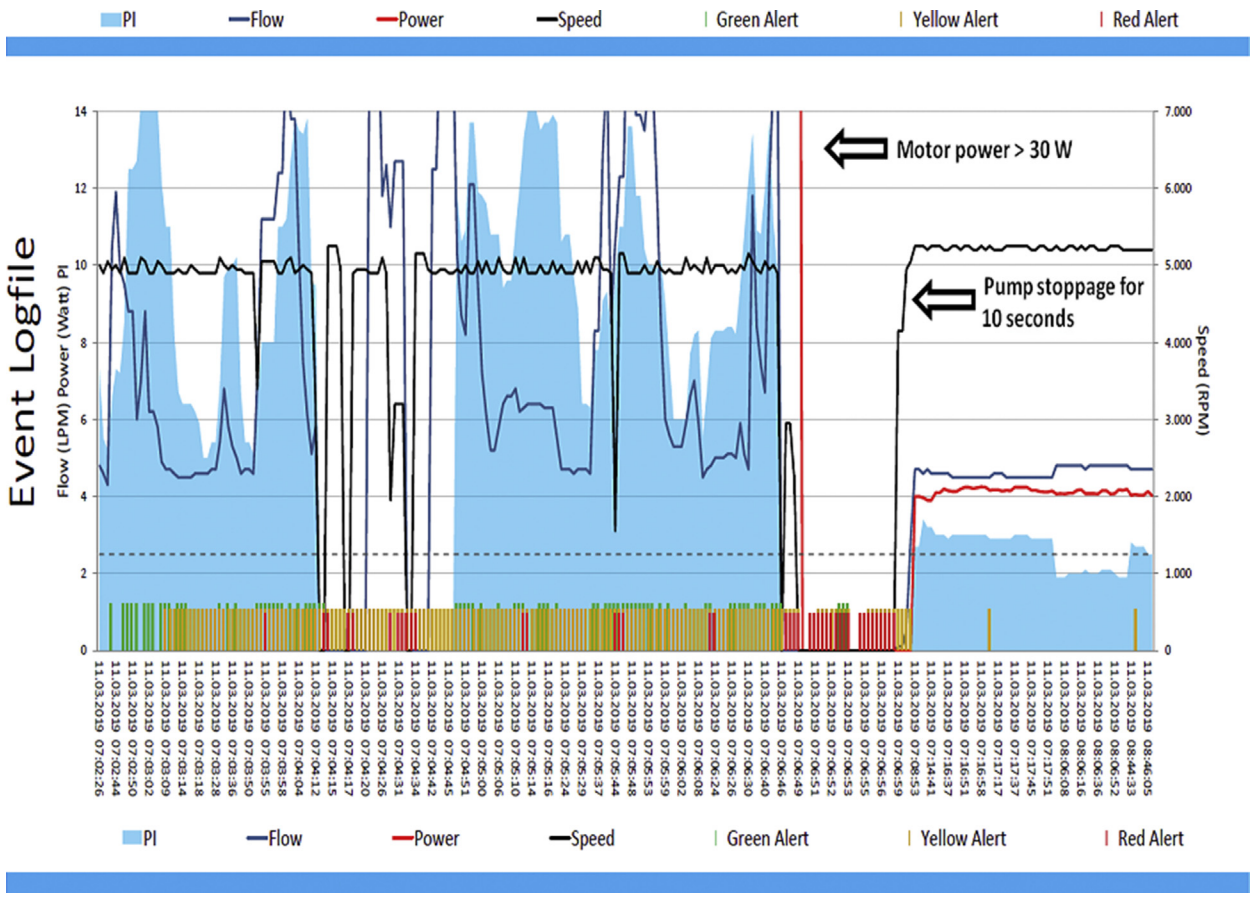

FIGURE 2 Log Files Showing an Increase of Motor Power to Over 30 W Prior to Pump Shutdown and Reduced or Stopped Blood Flow From the Device

Time	Stored Patient Speed (RPM)	Patient Low Speed (RPM)	Actual Motor Speed (RPM)	Calculated Average Flow (LPM)	Motor Power (W)	Calculated PI Average
07:04:31	5200	4900	3200	12,7	33,8	0,0
07:04:32	5200	4900	3200	12,7	34,4	0,0
07:04:33	5200	5000	0	0,0	35,2	0,0
07:04:34	5200	5000	0	0,0	35,6	0,0
07:04:34	5200	4900	5150	0,0	35,7	0,0
07:04:35	5200	4900	5150	0,0	35,4	0,0
07:04:35	5200	4900	5150	0,0	35,4	0,0
07:04:35	5200	4900	4950	0,0	35,9	0,0
07:04:42	5200	4900	4900	12,5	35,1	0,0
07:04:42	5200	4900	4900	12,5	34,7	0,0
07:04:43	5200	4900	4950	16,4	34,3	0,0
07:04:44	5200	4900	4950	16,4	34,1	0,0
07:04:45	5200	4900	4900	15,7	33,8	0,0
07:04:46	5200	4900	4900	15,7	33,2	0,0

The "0" displayed for pump speed and flow here is due to the brief interruption of controller-pump communication caused by the high-power event.

torsemide. Pump speed was 5,200 RPM and mean arterial pressure was 70 mm Hg at the time of discharge. Aortic valve was continuously closed and mitral regurgitation was minimal. The patient's implantable cardioverter-defibrillator (ICD) was reactivated 2 weeks after LVAD implantation. No other changes to the patient's cardiac resynchronization therapy defibrillator (CRT-D) prior to pump stoppage were made.

DIFFERENTIAL DIAGNOSIS

Different explanations were discussed after data analysis to clarify the cause of pump stoppage. The first possible scenario was a pump thrombus that passed through the pump causing increased motor power; however, the patient had adequate anticoagulation, unloaded left ventricle, and low lactate dehydrogenase, and there were no clinical signs or symptoms of pump thrombosis or hemolysis. The second possible scenario was an inappropriate connection to the MPU causing loss of power and pump stoppage but that would not explain the high levels of current and motor power. Damage to percutaneous driveline and short-to-shield phenomenon were also discussed as a possible explanation, but the incident was transitory and no such complications have been reported with HM3 (short-to-shield cannot occur in the HM3 as there is no metallic current carrying layer in contrast to the HM 2 driveline). Another possibility was electromagnetic interaction between the LVAD and CRT-D. Previous reports have noted a potential interference from LVADs on ICDs that may cause impaired telemetry communication and hinder ICD interrogation (3), but no reports on potential interference from CRT-D or ICD on LVAD leading to LVAD malfunction were found in the literature. Finally, the issue of ESD and its impact on HM3 and MPU was suggested.

INVESTIGATIONS

The patient was admitted to the hospital for monitoring, CRT-D interrogation, and LVAD interrogation. CRT-D interrogation in our case showed normal CRT-D function with biventricular pacing >99%.

The patient was asked about his clothes and bedsheets, which are a common source of ESD, and he had a fleece robe and blanket, worn on the same day of the event. The patient did not experience any electrostatic discharge at that day and no other possible events related to the fleece clothes were reported. After review of the situation and log files by our clinical team and the Abbott engineering team, we hypothesized that excessive ESD generated by fleece clothes was most likely responsible for disturbance of internal circuity of the pump and device malfunction. Further analysis by the Abbott engineering team indicated that a high-power condition may cause an interruption in pump power resulting in a pump reset, thereby reinitializing the pump and resolving the rotor instability. This incident is the first reported case of HM3 device malfunction involving temporary pump shutdown suspected to be secondary to electrostatic discharge; however, incidents of MPU failure secondary to suspected ESD were previously reported and resulted in U.S. Food and Drug Administration (FDA) class II device recall; warning doctors of the potential risk for static electricity to cause power loss to patients' MPUs (4).

MANAGEMENT

A report summarizing the event was sent to the Swedish regulatory authorities for further analysis. The patient was instructed to switch to battery power (due to the known ESD-MPU interference) when doing things that cause static electricity and to avoid fleece clothes and bedsheets that can generate static electricity.

DISCUSSION

This case report addresses the possible effects of ESD on LVADs and highlights the potential risks associated with technologically sophisticated medical devices sustaining life.

In recent years, the implantation of cardiac implants including LVADs and pacemakers has increased exponentially and also the exposure to electromagnetic interference and ESD from different sources has increased.

Although current evidence has not indicated that ESD has adverse biological effects in humans or animals (5), numerous malfunctions of medical devices due to ESD have been reported in the published data and the FDA database (6).

Indeed, the general consensus is that ESD-related device malfunctions are under-reported and not well understood (6), despite the strict requirements imposed by the European Medicine Agency (7).

HM3 received FDA and CE mark approval several years ago, and no cases of HM3 device malfunction causing pump stoppage have been reported in the final MOMENTUM 3 (Multicenter Study of MagLev Technology in Patients Undergoing Mechanical Circulatory Support Therapy With HeartMate 3) randomized clinical trial results and in the HM3 CE Mark Study (1,2). The second annual International Society of Heart and Lung Transplantation Mechanically Assisted Circulatory Support Registry report from 2018, which included different types of LVADs, reported various adverse events, including infection, bleeding, neurological dysfunction, and 233 events of device malfunction representing 2% of all patients; no specific information on device malfunction potentially due to ESD was provided (8).

The current LVADs do relieve symptoms and save lives in advanced heart failure patients; yet, further innovation, like transcutaneous energy transfer systems (9) or the production of miniaturized percutaneously deployable wireless LVADs (10), are ongoing and may be necessary to justify utilization of LVADs in earlier stages of heart failure or for more widespread acceptance, especially for destination therapy, in advanced HF. Possible disturbance by external electrical sources like ESD of such devices must be proactively considered.

FOLLOW-UP

Fourteen months after the event, the patient is still on LVAD, now as destination therapy with no reported serious LVAD events or red heart alarms.

CONCLUSIONS

ESD is a potential cause of LVAD dysfunction and must be considered in the diagnostic workup of HM3 pump stoppages. The possibility of ESD interfering with mechanical circulatory support should be included in strategies of new device development.

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Dr. Najjar has received speaker honoraria from Novartis. Dr. Jorde has served as a consultant for Abbott. Dr. Lund has received research grants from AstraZeneca and Boston Scientific; and has received consulting or speaker honoraria from Novartis, AstraZeneca, Bayer, St. Jude, Medtronic, Vifor Pharma, and Abbott, all unrelated to this work. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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REFERENCES

1. Mehra MR, Uriel N, Naka Y, et al. A fully magnetically levitated left ventricular assist device - final report. N Engl J Med 2019;380:1618–27.

2. Schmitto JD, Pya Y, Zimpfer D, et al. Long-term evaluation of a fully magnetically levitated circulatory support device for advanced heart failure-two-year results from the HeartMate 3 CE Mark Study. Eur J Heart Fail 2019;21:90–7.

3. Yalcin YC, Kooij C, Theuns D, et al. Emerging electromagnetic interferences between implantable cardioverter-defibrillators and left ventricular assist devices. Europace 2020;22:584–7.

4. U.S. Food and Drug Administration. HeartMate 3 left ventricular assist system (LVAS) - P160054/S008. 2018. Available from: https://www.fda.gov/medical-devices/recently-approved-devices/heartmate-3-left-ventricular-assist-system-lvas-p160054s008. Accessed January 12, 2020.

5. Petri AK, Schmiedchen K, Stunder D, et al. Biological effects of exposure to static electric fields in humans and vertebrates: a systematic review. Environ Health 2017;16:41.

6. Mehdi Kohani MP. Malfunctions of medical devices due to electrostatic occurrences big data analysis of 10 years of the FDA's reports. IEEE access 2018;6:5805–11.

7. Egbosimba D. Medical devices industry: the problem of clinical evaluation reports. Ann Biol Clin (Paris) 2019;77:514–6.

8. Kirklin JK, Xie R, Cowger J, et al. Second annual report from the ISHLT Mechanically Assisted Circulatory Support Registry. J Heart Lung Transplant 2018;37:685–91.

9. Pya Y, Maly J, Bekbossynova M, et al. First human use of a wireless coplanar energy transfer coupled with a continuous-flow left ventricular assist device. J Heart Lung Transplant 2019;38:339–43.

10. Letzen B, Park J, Tuzun Z, Bonde P. Design and development of a miniaturized percutaneously deployable wireless left ventricular assist device: early prototypes and feasibility testing. ASAIO J 2018;64:147–53.

KEY WORDS **complications, device, device malfunction, heart failure, HeartMate 3, left ventricular assist device**