The VAD Journal: *The journal of mechanical assisted circulation and heart failure*

Peer-Reviewed Original Research

Fatal Flaw – Driveline Fracture as a Rare But Serious Complication Of Mechanical Circulatory Support With Left Ventricular Assist Devices

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Citation: Boyechko Y.et al. (2017)

"Fatal Flaw – Driveline Fracture as a Rare But Serious Complication Of Mechanical Circulatory Support With Left Ventricular Assist Devices".

The VAD Journal, 3. doi: https://doi.org/10.13023/VAD.2017.06

Editor-in-Chief: Maya Guglin, University of Kentucky

Received: December 30, 2016

Accepted April 30, 2017

Published: April 30, 2017

Funding: Not applicable

Competing interests: Not applicable

Abstract

Background

Patients with advanced heart failure have seen decreased mortality and improved quality of life due to mechanical circulatory support with left ventricular assist devices (LVAD). Regardless of such outcomes, many complications still exist and remain a significant cause of morbidity and mortality. Our purpose is to study the prevalence, clinical course, and outcomes specifically of patients with LVAD driveline (DL) fractures.

Methods

This single-center, retrospective review included all patients at our institution who had continuous flow LVADs and experienced DL fracture/injury from January 2012 - December 2015.

Results

Thirteen of 110 LVAD patients (11.8%) had DL fractures (Table 1). Time from implant to time of fracture was 23+/-16.5 months. The majority of fractures were external (62%), due to trauma (i.e. cut during dressing change). Internal injury, proximal to the cutaneous exit site, occurred in 38% of patients, usually due to unknown causes. Only one patient (7.6%) survived on LVAD support. One survived LVAD explant, two underwent pump exchange, and four others underwent heart transplantation. The remaining 5 expired. All patients with untreated internal fractures died (60%).

Conclusions

Driveline fracture is a rare complication of LVAD and is often lethal when it occurs. Only one patient in our cohort survived without the need for heart transplant, LVAD exchange, or explant. Internal driveline fractures portend a very high mortality. Driveline fracture, especially one that cannot be promptly repaired or if internal fracture is suspected, requires immediate pump exchange or listing for heart transplantation.

Keywords: driveline fracture, left ventricular assist device, driveline, complications, heart failure

Introduction

Despite advances in left ventricular assist device (LVAD) therapy, complications often negate gains in mortality benefit and can ultimately be fatal. The goal of this study was to investigate the clinical course, management, prevalence, and outcomes of “driveline (DL) fracture”. Information on DL fracture, per se, is not reportable to INTERMACS, hence, data regarding this complication is not consistently analyzed1, and medical literature on the subject is lacking.

Methods

All LVAD patients at our institution are included in a local registry, approved by the Institutional Review Board, permitting chart reviews. We retrospectively reviewed the records of patients who had LVAD implantation from January 2012 through December 2015 and analyzed all cases of DL fracture, including the data on initial symptoms, device alarms, fracture location, clinical course, management, and outcomes. Available manufacturer reports were also reviewed.

Results

Between January 2012 and December 2015, 110 patients were implanted with continuous flow LVADs at our institution, including 90 HeartMate II (HMII) and 20 Heartware devices. Thirteen of the 110 (11.8%) experienced DL fracture, all with HMII LVADs. Approximately 8% of affected patients were women.

Mean patient age was 52 years (range 23 to 69).

Symptoms associated with the DL fracture ranged from chest pain, to sensations of motor revving, to fall secondary to arrest, and were experienced by approximately half of the patients (46%). Device alarms were also varied and displayed no predictive pattern as to the type of injury; however, the "Red Heart" visual signal was most common (46%). Only 4 of 13 fractures (30%) could be detected radiographically.

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We divided the patients into 2 subgroups based on fracture location. The majority of DL fractures (62%) were external, due to trauma – most frequently due to accidental cuts during dressing changes but also included mechanisms such as falling off of a ladder. Internal fractures, proximal to the cutaneous exit site (below the skin), constituted 38% of DL injury. The cause of internal fractures was usually unknown.

Average time from implant to fracture was 23+/-16.5 months (30.6+/-14 months for internal; 18+/-14 months for external).

Attempts at repair of the DL fractures were dependent on each individual case. Most patients required placement of an ungrounded cable in order to attempt repair. Management ranged from fixes as simple as rescue tape to complex procedures such as pump exchange or ECMO. Only one patient (7.6%) survived on LVAD support after distal end replacement. One survived LVAD explant, two underwent pump exchange, and four others underwent heart transplantation. The remaining 5 expired. The causes of death were varied and did not correlate with whether or not a repair was attempted. Death occurred in 3 patients due to post-operative complications or device malfunction after intervention, in one during intervention, and in another due to the patient declining intervention. Overall mortality of DL fracture was 38%; however, mortality was only 25% for external fractures and 60% for internal fractures (Table 1).

Table 1: Summary of individual driveline fracture cases, January 2012 – December 2015.

Case	Age	Sex	Cause of fracture	Time to fracture (months)	Symptoms	Alarms	Location	Treatment	Outcome
1	23	M	Hit door running	8	Abdominal pain, erythema	RH / low speed	E	Distal end replaced	Alive on LVAD
2	55	M	Cut DL (scissors)	26		?	E	Pump exchange (thrombosed due to stoppage)	Died within 1 month from complications during pump exchange surgery
3	46	M	?	20		RH / low flow	E	Rescue tape, ungrounded cable	Heart transplant, alive
4	64	F	Cut DL	<1		RH / pump stop / low flow	E	Distal end repaired	Heart transplant, alive
5	54	M	?	12		?	E	Distal end repaired	Alive after LVAD explant
6	50	M	Cut DL	5		RH / low flow / low voltage	E	Rescue tape	Died in 4 months CVA due to pump thromboembolism
7	57	M	?	41	Sensation of pump motor revving	Yellow & red advisory	E	Distal end repaired	Heart transplant, alive
8	52	M	Slammed car door	35		Low voltage	E	Rescue tape	Heart transplant, alive
9	66	M	?	49	Chest / epigastric pain	Pump stop	I	None - refused pump exchange	Died within 1 month
10	53	M	Fall from ladder	12		Pump stop / low flow / low speed	I	Pump exchange	Alive on LVAD
11	33	M	Dropped controller	24	Subjective discomfort	Low flow / pump off / DL disconnect	I	Pump exchange	Alive on LVAD
12	69	M	?	39	Chest pain	Audio / RH, low speed / low flow	I	Ungrounded cable	Died suddenly 10 month after the event
13	55	M	?	26	Fall / cardiac arrest	Audio/ RH / green power symbol	I	ECMO	Died after family withdrew care

? = unknown, DL = driveline, RH = red heart, E= external, I = internal

This study sought to characterize driveline fracture and its clinical implications. The driveline or percutaneous lead is vulnerable as it is exposed to the environment and is therefore prone to infection and mechanical damage. The design of the DL has multiple security features to prevent fatal interruption of energy supply.

The driveline consists of a single silicone cable extending from the implanted LVAD through the external abdominal wall and carries power to the LVAD via a system controller. The internal components of the driveline consist of a central strength member cable surrounded by six electrical conductors (3 primary and 3 backup) that provide power to the LVAD. The electrical conductors are protected by a copper- braided shield that is covered by an inner polyurethane protective jacket, which is enclosed by a silicone outer jacket that encompasses the entire outer portion of the DL (Figure 1).

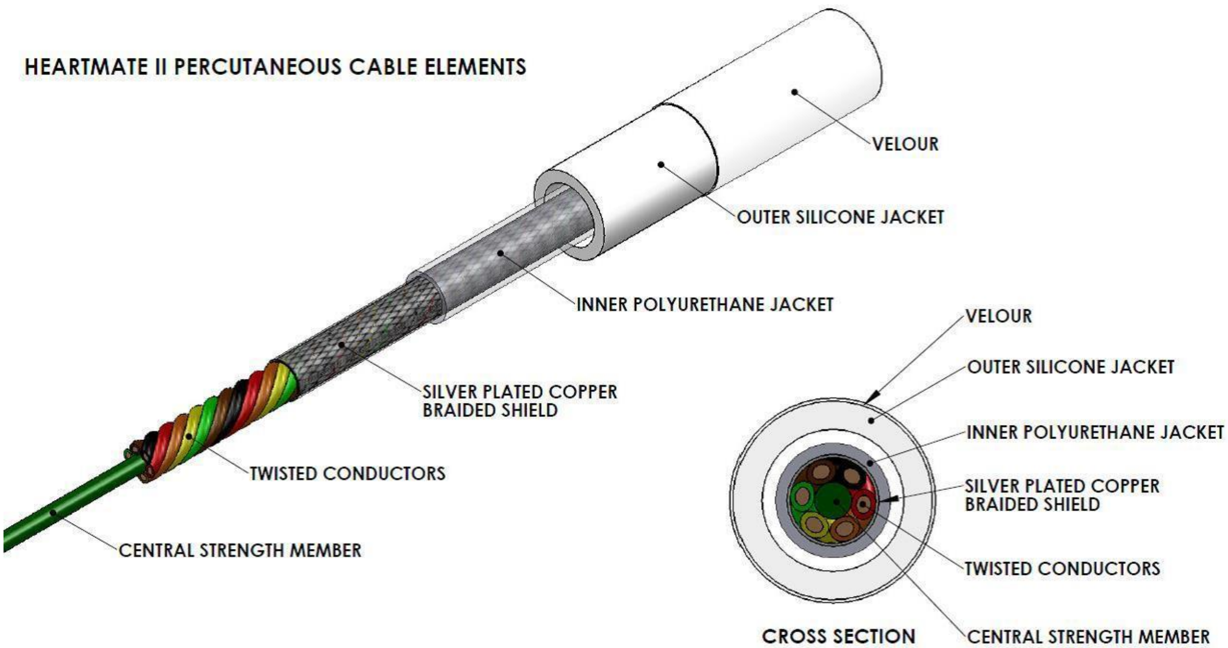

Figure 1. Structure of the driveline (reproduced with permission of Thoratec)

According to HMII LVAD malfunction data reported to the manufacturer, the incidence of driveline dysfunction was 9.2% compared with our incidence of 11.8%. As of this writing, no aggregate data regarding Heartware driveline malfunction was publically available. Also, similar to our findings, lead failure was mostly in the externalized part of the cable - 87.2%[2] vs. our 62%. Minor external damage accounted for 76% of dysfunction, whereas major damage, such as internal and external wire damage and fracture, accounted for the remaining 24%[2] compared to our 38%. Major damage can be caused by normal wear, line manipulation, inattention to care and maintenance, and traumatic damage. Younger age, female sex, and larger body surface area were identified as factors associated with DL damage[2].

Although manufacturers have been able to decrease incidence of mechanical complications with design improvements[2], the contribution of human error cannot be completely eliminated. A previously published series reported four cases of external DL fracture, all due to patient-related lead twisting or kinking. In all cases, the device was exchanged[3]. Data from more than 1,000 patients participating in both HMII bridge- to-transplant and destination therapy trials show the most common reason for LVAD replacement is DL damage, accounting for 47% of all pump replacements and occurring in 3% of implanted HMII devices[4]. Device exchange is relatively safe with a 30-day surgical mortality of 6.5%[4].

Although driveline fracture is rare, it is often lethal. As evidenced by the data, only one patient in our cohort (7.6%) survived without the need for major intervention such as heart transplantation, LVAD exchange, or device explant. Furthermore, internal driveline fractures portended a very high mortality. This is likely due to two factors: access to the injury site and appropriateness of the patient to undergo surgery, which in itself carries a morbidity and mortality risk. External fractures carried a 2.5-fold lower mortality as the injury could be physically accessed and repaired, despite a patient's clinical status which may have precluded them from surgery.

We propose that patients who present with an internal DL fracture or one that cannot be expeditiously repaired require immediate pump exchange or listing for heart transplantation. Although this was a single- center study, it is nonetheless evident that immediate interventions must be undertaken if the patient is to survive the event.

Limitations

The majority of our patients had HMII LVADs, which were therefore disproportionally represented.

Conclusions

Driveline fracture is a relatively common, often preventable, but frequently fatal complication of LVAD. Providers must educate patients regarding risks of driveline damage. Once diagnosed, this condition requires urgent measures such as device exchange or listing for transplantation.

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