Percutaneous Lead Dysfunction in the HeartMate II Left Ventricular Assist Device

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Background. The incidence of percutaneous lead failure among patients supported with a HeartMate II left ventricular assist device is unknown.

Methods. All HeartMate II left ventricular assist device driveline dysfunctions reported to Thoratec Corporation were retrospectively reviewed. The location and severity of driveline failures and their association with adverse clinical outcomes were examined. Also, the effect of design modifications was evaluated.

Results. Between 2004 and October 2012, 12,969 HeartMate II pumps were implanted worldwide. The incidence of percutaneous lead dysfunction was 1,418 events occurring in 1,198 pumps (9.2% of pumps) over a cumulative support period of 13,932 patient-years (maximum, 8 years). Lead failure was mostly in the externalized part of the cable (87.2%). Lead dysfunction was managed by clamshell reinforcement of the external connector strain relief or by tape or silicone cable reinforcement in 76% of cases. Mortality or significant morbidity, including pump exchange or urgent transplant, or more complex cable repair occurred in 2.3% of all implanted pumps. The cumulative incidence of lead failures leading to major adverse clinical events has decreased with two lead design revisions: at 18 months postimplantation, the incidence was 6.2% ± 1.2% for the original design versus 2.2% ± 0.5% for the latest design change introduced in 2010 (log-rank \( p < 0.001 \)).

Conclusions. Lead failures remain an important factor in the durability of left ventricular assist devices during long-term support. Most lead failures in the HeartMate II occurred in the externalized portion of the driveline, suggesting lead fatigue. The incidence of both internal and external lead failures has diminished since 2004 with improvements in lead design.


In patients supported with durable mechanical circulatory assist devices, particularly the subset of patients considered for destination therapy, the long-term durability and optimal functioning of the various left ventricular assist device (LVAD) components are extremely relevant. Valve and bearing failures were the major causes of early mechanical device failure in the pulsatile-flow HeartMate (HM) XVE LVAD (Thoratec Corporation, Pleasanton, CA), and a dismal 37% freedom from device replacement at 2 years contributed to its eventual disappearance from clinical use [1, 2]. Conversely, in the HM II destination therapy randomized trial [3, 4], bearing or pump failures were not observed [5, 6], and the need for pump replacement was 6 events per 100 patient-years, almost one eighth the incidence observed in the HM XVE group. Recently published data from more than 1,000 patients participating in both the HM II bridge-to-transplant and destination therapy trials show that the most common reason for LVAD replacement is damage of the percutaneous lead, accounting for 47% of all pump replacements and occurring in 3% of implanted HM II devices [6].

In the current era, the incidence of percutaneous lead failure attributable to wear or traumatic fracture in the expanded patient population supported with an HM II LVAD since the pivotal trials were reported is unknown. Also, there have been two major revisions in lead design by the manufacturer, and the extent to which these have influenced lead dysfunction is not clear. Therefore, the aim of this study was (1) to examine percutaneous lead wear and failure by location and severity, (2) to elucidate the clinical significance of lead failures and the incidence of adverse clinical outcomes, and (3) to determine the impact of the manufacturer’s lead improvements on the incidence of lead dysfunction.

Patients and Methods

The study is a retrospective review of all HM II LVAD percutaneous driveline dysfunctions reported to Thoratec Corporation.

Drs Moazami, Starling, Fryc, Heatley, and Farrar disclose financial relationships with Thoratec Corporation.
Corporation between 2004 and October 2012. The incidence of percutaneous lead dysfunction was examined, and lead events were further characterized by location along the lead that extends from the implanted pump housing through the patient’s skin to the external system controller. The association between lead events and clinical outcomes was also examined. A lead dysfunction was described as major if it was associated with one or more of the following significant adverse clinical events: urgent complex repair of the lead, replacement of the device, urgent listing for heart transplantation, or death. Data were collected by Thoratec Corporation. Adjudication of lead dysfunction and clinical events as well as data analysis were performed conjointly by Thoratec Corporation-affiliated authors (R.F., G.H., and D.J.F.) and Cleveland Clinic-affiliated authors (D.K., M.Z.T., A.M., and N.M.). Interpretation of the data and writing of the manuscript were performed solely by Cleveland Clinic-affiliated authors (D.K., M.Z.T., R.C.S., A.M., E.S., N.G.S., and N.M.).

**Structural Changes in Lead Design**

During the study period, two modifications in the design of the percutaneous lead were made by the manufacturer as clinical experience with the device accrued: changes to the external connector bend relief at the controller (June 2007), and changes to the internal pump-end bend relief (December 2010; Fig 1). The cumulative incidence of lead failure as a function of time among these later iterations of lead design was compared with the original lead design (2004–2007).

**Statistical Analysis**

The distribution of baseline clinical variables is reported as the median and range for continuous variables and proportions for categorical variables. Comparisons among groups were made using the Mann-Whitney U test, χ² test, or Fisher’s exact test as appropriate. Nonparametric estimates of the cumulative incidence of lead dysfunctions were performed using the Kaplan-Meier method, and log-rank statistics were used to compare the event curves of three separate patient cohorts according to lead design iteration. Comparisons were considered statistically significant when the two-tailed probability value was less than 0.05. Analyses were performed using SAS version 9.2 (SAS Institute Inc, Cary, NC).

The study was approved by our institutional research ethics review board. Given the retrospective nature of the data, individual patient informed consent was waived.

**Results**

Between 2004 and October 31, 2012, 12,969 HM II devices were implanted worldwide. The incidence of percutaneous lead dysfunction was 1,418 lead events occurring in 1,198 pumps (9.2% of 12,969 pumps) during a cumulative support period of 13,932 patient-years (maximum supported period, 8 years). The baseline clinical characteristics of patients who experienced a major lead dysfunction compared with those who did not are shown in Table 1. Patients who had a lead dysfunction associated with a major adverse clinical event were younger, more often female, and were more likely to be implanted using a strategy of destination therapy at initial implant compared with patients who did not have a major lead dysfunction. The majority of lead events (n = 1,075 events, 75.8% of total events) was not associated with major adverse clinical morbidity and was managed with external reinforcement of the lead, either by clamshell reinforcement of the connector strain relief (n = 800; Fig 2) or by tape or silicone reinforcement of the cable (n = 275). Conversely, the remainder was classed as a major lead event (n = 343, 24.2% of all lead events) and was associated with urgent complex lead repair, device exchange, urgent transplant, or death. These major events occurred in 293 pumps, or 2.3% of all pumps implanted during the study period. Slightly more than half of all major lead events occurred in the externalized portion of the percutaneous lead (Fig 3). Overall, lead dysfunctions involving the externalized part of the cable accounted for 87.2% of the total number of lead events (n = 1,237 of 1,418 events).

During the study period, there were two major revisions in lead design by the manufacturer. The first design change occurred in June 2007 and involved a redesigned external connector strain relief at the controller end (n = 6,352 pumps). The median duration of support was 1.4 years (maximum, 5.4 years). The second revision was a redesigned internal pump-end bend relief, which occurred in December 2010 (n = 5,745 pumps). The median duration of support with this most recent iteration of the device was 0.6 years (maximum, 1.9 years). The remaining pumps included in the study had the original...
design (n = 872), and the median duration of support of these pumps was 1.4 years (maximum, 8 years).

The cumulative incidence of lead failures associated with a major clinical event has significantly decreased with the introduction of the two lead design revisions (Fig 4): at 18 months postimplantation, the incidence was 6.2% ± 1.2% for the original design versus 2.2% ± 0.5% for the latest design change introduced in 2010 (redesigned internal pump-end bend relief; log-rank p < 0.001). When major lead events were stratified according to the location of the lead dysfunction (portion of the lead that lies internal or external to the body), similar significant decreases in the incidence of major lead events were observed with subsequent iterations of lead design both for internal and external lead dysfunctions (Fig 5). Furthermore, the incidence of clamshell repair of the external lead connector strain relief has significantly decreased at 18 months after device implant after lead design revision: 33.2% ± 2.1% (original design) versus 6.6% ± 0.7% (internal lead improvement; log-rank p = 0.02; Fig 6).

Comment

Several findings of this study are noteworthy. First, the overall incidence of percutaneous lead dysfunction among patients supported with an HM II LVAD is 9.2%. More than three quarters of lead dysfunctions were minor events not leading to significant clinical sequelae such as urgent complex repair of the driveline, urgent listing for cardiac transplantation, device exchange, or death. In this cohort of patients with minor events, all were successfully managed by external repair of the lead, either by clamshell reinforcement of the connector strain relief at the system controller or, in the event of a break in the integrity of the main body of the cable or underlying Teflon sheath, with a tape or silicone reinforcement. Percutaneous lead dysfunction associated with a major adverse clinical event occurred in 24% of patients with lead events, or 293 pumps (2.3% of the total number of HM II LVADs implanted). These events were distributed approximately evenly among those involving the portion of the lead located internally or externally to the body. The cumulative incidence of lead failures associated with a major clinical event has significantly decreased with the introduction of the two lead design revisions (Fig 4): at 18 months postimplantation, the incidence was 6.2% ± 1.2% for the original design versus 2.2% ± 0.5% for the latest design change introduced in 2010 (redesigned internal pump-end bend relief; log-rank p < 0.001). When major lead events were stratified according to the location of the lead dysfunction (portion of the lead that lies internal or external to the body), similar significant decreases in the incidence of major lead events were observed with subsequent iterations of lead design both for internal and external lead dysfunctions (Fig 5). Furthermore, the incidence of clamshell repair of the external lead connector strain relief has significantly decreased at 18 months after device implant after lead design revision: 33.2% ± 2.1% (original design) versus 6.6% ± 0.7% (internal lead improvement; log-rank p = 0.02; Fig 6).

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### Table 1. Baseline Clinical Characteristics of Patients Who Experienced a Major Lead Dysfunction Compared With Those Who Did Not

<table>
<thead>
<tr>
<th>Variable</th>
<th>Major Lead Dysfunction (n = 257)</th>
<th>No Major Lead Dysfunction (n = 12,727)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (median years, range)</td>
<td>55 (14–81)</td>
<td>58 (10–91)</td>
<td>0.03</td>
</tr>
<tr>
<td>Male</td>
<td>74%</td>
<td>80%</td>
<td>0.02</td>
</tr>
<tr>
<td>BSA (median m², range)</td>
<td>2.1 (1.5–2.9)</td>
<td>2.01 (1.0–3.2)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Etiology of cardiomyopathy</td>
<td></td>
<td></td>
<td>0.21</td>
</tr>
<tr>
<td>Ischemic</td>
<td>38%</td>
<td>42%</td>
<td></td>
</tr>
<tr>
<td>Nonischemic</td>
<td>62%</td>
<td>58%</td>
<td></td>
</tr>
<tr>
<td>Strategy at implant</td>
<td></td>
<td></td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Bridge-to-transplant</td>
<td>48%</td>
<td>58%</td>
<td></td>
</tr>
<tr>
<td>Destination therapy</td>
<td>48%</td>
<td>35%</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1%</td>
<td>1%</td>
<td></td>
</tr>
<tr>
<td>Not reported</td>
<td>3%</td>
<td>6%</td>
<td></td>
</tr>
</tbody>
</table>

* Associated with urgent repair, device exchange, urgent transplant, or death.

BSA = body surface area.
of the lead inside the body (wire damage owing to wear and fatigue, and pump-end bend relief fracture) and those involving the externalized portion of the lead (wire damage owing to wear and fatigue, and accidental mechanical damage; Fig 3). Second, the risk of both internal and external lead failures has significantly decreased with iterative changes in the design of the percutaneous lead. In June 2007, the external strain relief of the driveline at its connection to the system controller was modified. In December 2010, the internal pump-end strain relief was redesigned; both of these changes by the manufacturer have had a profound impact on the incidence of lead dysfunction. These design changes were timely given that almost 20% of patients implanted with an HM II between 2004 and 2007 comprising the original design had experienced a major lead dysfunction by 36 months of support.

The mechanical reliability and durability of currently available continuous-flow devices greatly surpass those of older-generation pulsatile pumps, in which valve and bearing failures were the major drivers of pump failure [1–4]. In the latest report from the Interagency Registry for Mechanically Assisted Circulatory Support, patients supported with a continuous-flow device could expect a greater than 90% freedom from device exchange or death as a result of device dysfunction at 24 months, compared with less than 40% for those supported with an implantable pulsatile device (p < 0.0001) [7]. Given that the occurrence of bearing or rotor failure is essentially unheard of in clinical practice for currently approved continuous-flow devices [5–9], the determinants of device durability and the indications for device exchange in these devices are markedly different than those in older-generation LVADs. Jafar and colleagues [10] published their experience with four percutaneous lead failures among 82 patients supported with an HM II LVAD. All 4 patients were readmitted to the hospital with new congestive heart failure symptoms and audible LVAD alarms. All 4 patients were found to have a frayed percutaneous lead near its connection to the system controller, attributed to excessive twisting and kinking; all 4 were supported with devices containing the original lead design. Two of the 4 patients were younger than 20 years of age. All were urgently exchanged using a left
subcostal approach with peripheral cardiopulmonary bypass without perioperative morbidity or mortality. Moazami and associates [6] recently reported that nearly half of all HM II LVADs that were replaced in the setting of the bridge-to-transplant and destination therapy pivotal trials were as a result of dysfunction of the percutaneous lead, which occurred in 3% of the total number of HM II LVADs implanted during the trials at a median duration of support of 428 days. Pump thrombus, the second leading cause of device exchange, accounted for 36% of pump replacements. In a smaller, single-center study that also included patients with pulsatile pumps, Stulak and coworkers [11] reported that pump thrombus and infection were the most common indications for device exchange after a median duration of support of 14.1 months, with mechanical or electrical failure occurring in 3 of 25 patients supported with a continuous-flow pump. In both studies, device exchange was associated with a low operative mortality and did not affect long-term survival. The merits of a less-invasive left subcostal approach using cardiopulmonary bypass with femoral cannulation for pump replacement in terms of decreased perioperative morbidity have been suggested in recent reports [11–13]. This approach may be ideally suited for device exchanges caused by percutaneous lead failures because typically the outflow graft need not be exchanged in these cases. Device exchange may be completely obviated by the development of modular drivelines that would allow for lead exchange without the need for pump replacement by disconnecting and replacing the damaged portion of the lead in the subcutaneous tissue. Modular drivelines are not yet available for clinical use, and any theoretic benefit both in terms of facilitating exchange and mitigating infection risk remain speculative.

This is a retrospective study and as such causality cannot be established. Driveline infection has been associated with younger age [14] and is becoming an increasingly common indication for pump exchange as clinical outcomes associated with rotary pumps continue to improve and duration of support increases [6, 11]. In our study, younger age was also associated with major lead dysfunction. Moreover, there was a greater proportion of destination therapy patients in the subcohort of patients who experienced a major lead event, which may serve as a surrogate of prolonged duration of support, which may be associated with higher infection risk [15, 16]. However, the complex interplay between driveline infection, age, and a potentially greater likelihood of traumatic or accidental lead damage among active patients or those with a longer duration of support could not be examined from the present data, and a prospective study is warranted. Furthermore, recent data suggest that a “double tunnel” technique for driveline tunneling may have a favorable impact on subsequent infection rates by increasing the distance between the location of the fascial transition and the skin exit site [17, 18]. The huge variability in both the surgical approach to HM II LVAD implantation, including the recent trend of completely internalizing the velour portion of the driveline, and the postoperative management of the driveline exit site precludes meaningful analysis using the present data.

In conclusion, the risk of HM II LVAD dysfunction owing to failure of the percutaneous lead has significantly diminished with changes made to the lead design by the manufacturer. Most lead failures were successfully managed by external repairs not requiring reoperation. Patient- and design-related factors influencing optimal driveline reliability and durability need to be further elucidated for further improvements in the clinical outcome of patients supported with the HM II LVAD, until transcutaneous energy transfer and totally implantable devices become available.

References


INVITED COMMENTARY

This paper by Kalavrouziotis and associates [1] is relevant in our world of increasing left ventricular assist device (LVAD) patients, most of whom are or will be long-term destination therapy patients. As their quality of life improves and they become more active, the external VAD components are subject to more wear and tear, so it is not surprising that driveline failures have become more important than driveline infections. The latter usually occur earlier in the postoperative course, rarely require serious intervention, and are less common owing to certain changes in practice (the velour is no longer externalized and driveline fixation at the exit site is maintained for weeks to months).

While the rate of serious driveline failure—leading to complex repair, urgent transplant, device exchange, or death—has been reduced dramatically (from 6.2% to 2.2%) owing to design improvements, these mechanical failures continue to be an ever-present problem and are more likely to occur in patients who are younger, female, and destination VAD patients. The overall driveline failure rate of 9.2% compares with other serious LVAD complications recently reported by the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) [2] for patients over the age of 65: device malfunction (all), 11.5%, neurologic dysfunction, 18.5%, renal dysfunction, 12.7%, and 3-month mortality, 14.4%.

It is, therefore, important to be aware of the scope of the problem and what can continue to be done to reduce its occurrence. Before this well-written and timely report, the incidence of serious lead failures in the largest population of continuous-flow LVAD patients was unknown. We have also learned that lead failures and pump thrombosis are the two most common indications for device exchange, which is a major operation through either the redo sternotomy or subcostal approach. Kalavrouziotis and colleagues [1] suggest what many VAD surgeons had hoped for years ago: modular drivelines that would enable lead exchange, rather than pump replacement. However, with the race to develop the first tetherless transcutaneous system that would eliminate external leads, it is unlikely that competitive VAD companies will spend resources developing modular drivelines.

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