



Peer-Reviewed Original Research

# Does Left Ventricular Assist Device Implantation Affect Driving Patterns in Patients With End-Stage Heart Failure?

Citation: Pinniti M. et al. (2017)  
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*The VAD Journal*, 3. doi:  
<https://doi.org/10.13023/VAD.2017.05>

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

Received: February 15, 2016

Accepted: March 16, 2017

Published: March 16, 2017

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Funding: Not applicable

Competing interests: Not applicable

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## Abstract

### Background

In 2012, the Canadian Society of Cardiology indicated that patients supported with left ventricular assist device (LVAD) may drive a private vehicle 2 months after implantation, provided they are deemed clinically stable. Objective evidence supporting this recommendation is limited. We sought to compare data regarding driving habits in our patients following LVAD implantation.



## **Methods**

A standard questionnaire addressing driving patterns before and after LVAD implantation was sent to all living patients who had received an LVAD between January 2010 and January 2014. Ninety-four of 124 patients responded (average age 58 years, 69.2% men, 77.7% bridge to transplant).

## **Results**

Prior to LVAD, all were living at home, 33% were employed, and 93% were driving. Sixty-nine percent indicated they drove after LVAD implantation; they were younger (56 vs 62 years,  $p=0.02$ ) and had providers recommendation ( $p=0.004$ ). Four of seven patients who had not driven before started driving ( $p<0.0001$ ). Most patients (56%) initiated driving between weeks 2 and 8 after discharge. Ten (16%) patients experienced alarms while driving (6 related to batteries, 2 suction events, 2 other); all were safely addressed. One patient had syncope and a motor vehicle accident without fatalities. Ninety four percent believed driving positively impacts quality of life, and 26% believed having an LVAD significantly affects driving ability.

## **Conclusions**

Most patients returned to driving after LVAD implantation. A minority had LVAD-associated alarms that were easily addressed. We suggest inclusion of driving habits in registries to provide clarity on the safety of driving while being supported with LVAD.

**Keywords:** left ventricular assist device, end-stage heart failure, driving, automobiles, cars

## **Introduction**

Left ventricular assist devices (LVADs) have demonstrated increased quantity and quality of life for both destination therapy and bridge to transplantation (BTT) indications. Due to the significant morbidity and mortality associated with the older models of pulsatile ventricular assist devices, Canadian Cardiovascular Society 2003 guidelines and several European countries recommended that LVAD patients cease driving both private and commercial vehicles. As a result, several institutions advised patients to not drive after LVAD implantation. However, the current generation of continuous-flow devices are substantially more reliable, and thus in 2012, the Canadian Cardiovascular Society revised its recommendations to indicate that stable patients supported with LVAD may drive a private (not commercial) vehicle 2 months after implantation. This new recommendation was based on a "Risk of Harm" formula.<sup>1,2</sup> Currently, only some institutions follow these guidelines, and as a result there is limited data on the driving patterns of patients



supported with continuous-flow LVADs. Hence, we decided to study driving patterns and outcomes among patients supported with continuous-flow LVADs at our institution using a standard questionnaire.

In order to understand the driving patterns of the patients before and after LVAD implantation, we collected data on demographics, social and employment status, clinical features and symptoms, driving habits, driving record, and personal preferences that affected their decision to drive a private vehicle. In addition, we obtained data regarding the driving instructions given by health care personnel at the time of discharge. Lastly, we assessed the association between quality of life and independent driving after LVAD implantation.

## **Methods**

This study employed the use of an Institutional Review Board-approved study design and questionnaire to address patient driving patterns before and after LVAD implantation. The study population comprised all patients who received a continuous-flow LVAD (HeartMate II [Thoratec Corp., Pleasanton, CA] or HeartWare [HeartWare, Framingham, MA]) between January 2010 and January 2014 at our tertiary care center, who were alive at the time of the study. An informed consent form and questionnaire were mailed to all the patients for voluntary enrollment in research. Enrolled patients were encouraged to complete the questionnaires and return the forms to our research personnel. We linked data obtained from the questionnaire with an established clinical LVAD database and analyzed factors associated with driving patterns after LVAD implantation. Data are analyzed using descriptive statistics. Continuous variables are expressed as mean±standard deviation (SD) or median±SD (when appropriate), and categorical variables are expressed as frequency and percentage (%).

## **Results**

There were 156 patients who underwent LVAD implantation between January 2010 and January 2014; 32 had died prior to our study and the remainder were eligible for this protocol. The questionnaires were mailed to the homes of the 124 patients who were still alive and had received a continuous-flow LVAD. A total of 94 of 124 patients (75.8%) responded to the survey; the average age of the respondents was 58 years, 69.2% were male, and 77.7% were supported for a BTT indication. The majority of the patients were INTERMACS 3 or 4 (62.7%) at the time of implantation, and 51% had ischemic cardiomyopathy. The average ejection fraction was 16%, and the average body mass index was 28.7. Before LVAD implantation, all 94 patients were living at home, 33% were employed, 98% had a valid driver's license, and 93% (87) were driving. Of those who drove, 56% were driving daily for more than half an hour and 72% were driving more than 5 miles daily. Of the 87 patients who drove, 7 had had motor vehicle accidents during the 12 months before LVAD implantation (Tables 1 and 2).



**Table 1. Baseline Demographics**

<b>Characteristics</b>	<b>n=94</b>
Age	58.0±10.9
Male sex	65 (69.2)
Reason for LVAD	
BTT	73 (77.7)
DT	17 (18.1)
DT to BTT	4 (4.3)
INTERMACS number	
1	7 (7.4)
2	22 (23.4)
3	21 (22.3)
4	38 (40.4)
5	4 (4.2)
NA	2 (2.1)
Diagnosis	
Idiopathic	38 (40.4)
Ischemic	51 (54.3)
Other	5 (5.3)
Ejection fraction	16.0±4.8
Body mass index	28.7±6.0
Hemoglobin	8.4±2.7
Creatinine	1.7±1.5
Living arrangement	
Living at home	94 (100.0)
Living in urban area	62 (68.1)
Living alone	13 (17.1)
Employed	31 (33.3)
Pre-LVAD hospitalization	60 (65.2)

Data are presented as n (%) or mean±standard deviation.

BTT = bridge to transplant, DT = destination therapy.



**Table 2 Baseline Driving Characteristics (n = 94)  
Before LVAD Implantation**

<b>Characteristics</b>	<b>n (%)</b>
Valid driver's license	91 (97.9)
Driving	87 (92.6)
Afraid to drive	17 (18.3)
Driving distance (n = 87)	
Less than 5 miles	24 (27.5)
5-20 miles	47 (54.0)
More than 20 miles	15 (17.2)
NA	1 (1.2)
Driving frequency (n = 87)	
Daily	43 (49.4)
Less than 3 times/week	18 (20.6)
More than 3 times/week	25 (28.7)
NA	1 (1.2)
Drive duration (n = 87)	
30 minutes	37 (43.8)
30-120 minutes	44 (49.4)
>2 hours	6 (6.7)
Automobile accident (n = 87)	7 (8.0)
ICD shock (n = 94)	
Yes	33 (35.1)
No	50 (53.2)
No ICD	11 (11.7)

ICD = implantable cardioverter defibrillator,  
LVAD = left ventricular assist device, NA = not available.



After LVAD implantation, 86 patients were discharged to home and 8 patients were discharged after a rehabilitation stay. Most often, patients initially had assistance with their transportation needs from either a significant other (74%) or friends and relatives (17%). A total of 41 patients had assistance with driving for up to 2 months. A total of 69 patients (77%) indicated that they remembered some sort of instructions given by their health care providers regarding driving, and 95% of them said they followed the instructions. After LVAD implantation, 12 patients returned to gainful employment. Out of all patients in our cohort, 59 (69%) admitted to driving (57 patients drove a car, 2 patients drove other vehicles) after LVAD implantation, and 38 drove more than 5 miles daily, 26 drove more than 30 minutes daily, and 17 drove more than 100 miles at a time. Patients who drove after LVAD implantation were younger (56 vs 62 years,  $p=0.02$ ), had a shorter length of hospital stay after LVAD implantation (13.7 vs 21.5 days,  $p=0.0134$ ), and were more likely to have been advised by their health care provider that they may drive after LVAD implantation ( $p=0.004$ ) (Table 3).

After discharge, 7 patients (11%) started driving within 2 weeks and 36 (56.2%) drove within 2 to 8 weeks. Twenty-eight percent of the patients were afraid to start driving; however, 75% of all patients were eventually confident in driving after LVAD implantation. Twenty-six (30.2%) patients who were driving prior to LVAD implantation stopped driving after their surgery, and 4 (4.3%) who were not driving prior to LVAD started driving after the LVAD implantation ( $p<0.0001$ ). Thirty-two percent of the patients who were not afraid of driving before the LVAD developed a fear of driving after LVAD implantation ( $p<0.01$ ) (Table 3).

Ten patients had alarms while driving: 6 related to batteries, 2 related to suction events, and 2 related to other reasons. All of these patients were able to safely pull over to the side of the road and address these alarms without consequence. One patient reportedly passed out while driving, resulting in a motor vehicle accident without permanent injuries or fatalities. Prior to LVAD implantation, 83 (88.3%) patients had an implantable cardioverter defibrillator (ICD), with 35.1% with a history of previous ICD shock. During the LVAD support period, only 2 patients had ICD shocks, and none occurred while driving.



**Table 3. Post-LVAD Driving Data**

Characteristics (total n)	n	%
<i>Discharge driving instructions (n = 94)</i>		
Driving instructions were provided	60	63.8
N/A	3	3.2
Physician advised that they can drive	69	73.4
N/A	4	4.3
Driving advice followed (n = 69)	61	88.4
N/A	5	5.3
<i>Post-LVAD (n = 94)</i>		
Had help with driving after LVAD		
Spouse	56	59.6
Others	20	21.3
N/A	18	19.1
Patients who were driving after LVAD	64	68.1
N/A	1	1.1
<i>Post-LVAD Drivers Only (n=64)</i>		
Afraid to drive initially	20	31.0
N/A	5	7.8
Eventually confident to drive	48	75.0
N/A	8	12.5
Time to resuming driving		
≤2 weeks	7	10.9
2-8 weeks	36	56.3
>2 months	15	23.4
N/A	6	9.4
LVAD alarms while driving	16	25.0
N/A	5	7.8
<i>Quality of life (n=94)</i>		
Happy that they were advised not to drive	11	11.7
N/A	1	1.1
Driving impacts quality of life	88	93.6
LVAD impacts driving ability	23	24.5
N/A	6	6.4

LVAD = left ventricular assist device, N/A = not available; remaining % represents the percentage of patients who responded “No” for the respective questions.



Among our cohort, 59 (62.7%) responded that they were satisfied with their ability to drive. Eighty-two (87%) patients replied that they would not be happy if they were advised not to drive at all, and 11 (12%) patients were happy they were advised not to drive. Eighty-eight (94%) patients responded that they believe driving impacts quality of life, and 23 (26%) believed that an LVAD affects driving ability (33% positively and 66% negatively). Eighty-eight percent of patients said they think that having an LVAD impacts the overall quality of life (of these, 76% felt it was a positive impact and 24% negative) (Table 4, Figure 1).

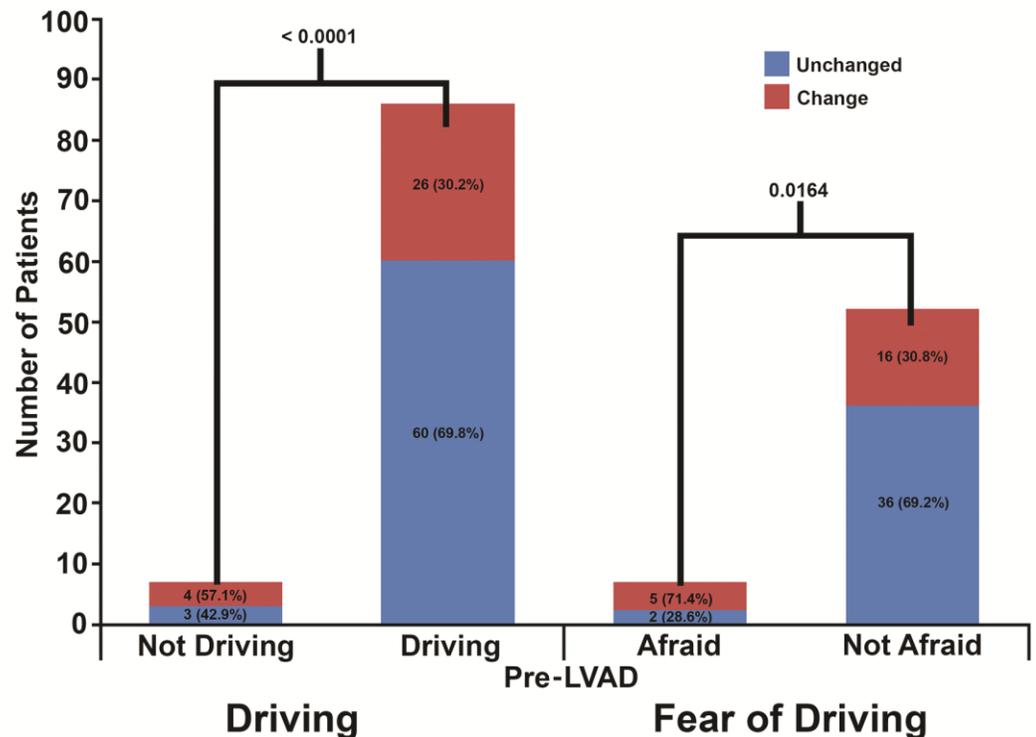
**Table 4. Differences in Characteristics of Patients Who Continued to Drive and Who Stopped Driving After LVAD Implantation**

Characteristics	Drivers Who Stopped Driving After LVAD (n = 26, 30.2%)	Drivers Who Continued Driving After LVAD (n = 60, 69.8%)	p
Age (years)	62.4 ± 8.5	55.7 ± 11.5	<b>0.0067</b>
Length of hospital stay	21.5 ± 15.8	13.7 ± 6.6	<b>0.0134</b>
Male sex	20 (76.9)	41 (68.3)	0.4204
Reason for LVAD			
BTT	19 (73.1)	48 (80.0)	0.6043
DT	5 (19.2)	10 (16.7)	
DT to BTT	2 (7.7)	2 (3.3)	
INTERMACS number			
1 to 2	10 (40.0)	16 (27.1)	0.2430
3 to 5	15 (60.0)	43 (72.9)	
Pre-LVAD employed	13 (50.0)	17 (28.3)	0.0528
Pre-LVAD hospitalization	16 (61.5)	38 (64.4)	0.8002
Pre-LVAD afraid to drive	7 (26.9)	6 (10.2)	<b>0.0480</b>
Living in urban area	14 (58.3)	41 (69.5)	0.3297
Doctor approved driving post discharge	14 (60.9)	50 (84.8)	<b>0.0189</b>

Data are presented as n (%) or mean ± standard deviation.

Bold represents statistical significance.

BTT = bridge to transplant, DT = destination therapy, LVAD = left ventricular assist device.



**Figure 1.** Trends of driving and fear of driving before and after LVAD implantation. LVAD = left ventricular assist device.

## Discussion

The current study shows that the majority of the patients (64 out of 94 [69%]) were able to drive after LVAD implantation, and 17 (26%) patients were able to continuously drive for more than 100 miles when needed. A few (n=10, 16%) patients had alarms while driving, mostly related to battery changes. Only 1 (1.5%) patient had syncope and a major motor vehicle accident; there were no fatalities. In another similar, although multicenter, study of 201 patients with LVADs, 85% of patients drove and 17% (29) had alarms, mostly related to battery changes (2 were because of device malfunction); there were 5 (2.9%) vehicle accidents, but none were serious.<sup>3,4</sup> Ambardekar *et al.* provided a survey to 83 ventricular assist device coordinators regarding their practice's policy for LVAD-supported patients and driving and received responses from 33 of them.<sup>5</sup> Of the respondents, 67% reported that their programs allowed patients to return to driving after they recovered from LVAD surgery, and 33% indicated that they did not allow LVAD patients to drive. Eighty-seven percent of centers counseled their patients not to drive if they had syncope.<sup>5</sup>

Driving recommendations are based on the estimation of risk of harm while driving and the general consensus on the threshold of an acceptable risk of harm. The annual risk of harm while driving can be estimated by this formula: driving time (%)



× vehicle type (commercial or private) × annual risk of incapacitation × probability of injury or accident.<sup>2</sup> In general, it is an acceptable standard for a patient with cardiovascular disease to drive if the risk of sudden cardiac incapacitation is less than 22% per year for a private vehicle driver or less than 1% for a commercial vehicle driver. Newer generation LVADs have demonstrated improved quality of life and low risk for sudden cardiac incapacitation.<sup>6</sup> Published contemporary trials of continuous-flow LVAD devices and a large national data registry (INTERMACS) demonstrate that 1-year mortality among LVAD patients is approximately 20%, with one-third of deaths occurring in the first month. Most of the deaths during follow-up are not sudden and reflect progressive deterioration and physical debility. Estimates indicate an 8% to 12% rate of sudden cardiac incapacitation per year after LVAD implantation in this population, which is substantially less than the 22% per year risk limit to drive a private vehicle.<sup>7</sup> Hence, it was concluded that a stable LVAD patient can drive a private vehicle 2 months after implantation.<sup>1</sup>

In our study, there were 2 ICD shocks after LVAD implantation. The American Heart Association (AHA)/Heart Rhythm Society (HRS) guidelines recommend that patients not drive for 6 months following an ICD discharge for ventricular tachycardia or ventricular fibrillation, and the European Heart Rhythm Association (EHRA) guidelines recommend they don't drive for 3 months after such an event. Also, for primary prevention ICD implantation, AHA/HRS guidelines recommend patients should not drive for 1 week after implantation to allow for surgical recovery and EHRA guidelines recommend a 4-week period before a return to driving.<sup>8-10</sup> Appropriate shocks were reported in 24% of LVAD patients with ICDs for ventricular arrhythmias at one center, but the rate of syncope was unknown.<sup>11</sup> Ventricular fibrillation and ventricular tachycardia often result in syncope or near-syncope among advanced heart failure patients not supported by LVAD, while those supported with LVAD often maintain consciousness or are minimally symptomatic despite these rhythm disturbances. Alarms related to suction events caused by either positional inflow cannula obstruction or low volume state often do not present with syncope. Suction events also are more common in the first month after LVAD implantation and improve with pump speed adjustment during follow-up. Finally, cerebrovascular events occur in approximately 10% of LVAD-supported patients and can cause motor function incapacitation. Two patients in our study had suction events while driving and neither had any syncope or motor vehicle accidents.

Some limitations of the study include recall bias, which is common to similarly designed voluntary questionnaire studies. Furthermore, these responses only take into account views from patients who are ambulatory and presumably stable from a clinical perspective, and exclude those who have expired or may have suffered various incapacitating complications that made them unable to respond to these queries.



## **Conclusions**

Our data support the hypotheses that most patients who are ambulatory and stable can safely return to driving after LVAD implantation without an increased risk of motor vehicle accident and that the ability to drive substantially improves quality of life in the LVAD-supported patient population. The present study provides valuable information regarding driving patterns among a contemporary patient population supported with continuous-flow LVADs. The data add to established literature and may provide the basis for including lifestyle metrics to larger registries (eg., INTERMACS). Furthermore, driving safety assessed by the present protocol will extend and support current Canadian guidelines and conceivably alter other national society guidelines (AHA, American College of Cardiology, International Society for Health and Lung Transplantation). We believe the information obtained from this study may help change clinical practice recommendations and improve the quality of life for patients living with LVAD support.

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