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Tolerability of Intermittent Hemodialysis in a Cohort of Patients with Left Ventricular Assist Device

Christopher Areephanthu[1], Amr El-Husseini[1, 3], Bennet George[2], Jessica McAbee[1], and B. Peter Sawaya[1*].

[1] Division of Nephrology
[2] Division of Cardiology
University of Kentucky, Lexington, KY, United States
[3] Division of Nephrology, Mansoura University, Mansoura, Egypt

* Corresponding author: *petersawaya@uky.edu*

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Abstract

Background

The use of left ventricular assist device (LVAD) has emerged as a popular treatment for patients with advanced heart failure. It is not uncommon for these patients to suffer from renal failure requiring renal replacement therapy. The purpose of this study is to assess hemodynamic parameters and ability to complete the prescribed hemodialysis session in a series of patients who underwent numerous dialysis treatments.

Methods

Nine patients with Heart Mate II LVAD received 170 intermittent inpatient hemodialysis treatments between January 1, 2010 and December 31, 2012. Assessment included vital signs, ultrafiltrate removed, hemodialysis duration, symptoms, early terminations (ET), and adverse events during each hemodialysis session.

Results

The mean age was 53 ± 18 with a range of 26-83 years, with a male predominance (7/9). Indication for LVAD was as destination therapy (DT) in the

majority of patients (6/9). Nine patients who received a total of 170 hemodialysis sessions with a mean prescribed and achieved: ultrafiltration (liters) 1.98 ± 1.5 and 1.90 ± 1.6; hemodialysis duration (hours) 3.12 ± 0.3 and 2.86 ± 0.9, respectively. Early termination was experienced in 11 sessions (6.5%). Causes of ET were hypotension in 72.7%, other causes were equally distributed between clotted extra-corporeal circuits, nausea & vomiting and LVAD alarm (9.1% in each). Serious arrhythmias were not observed in any of the hemodialysis treatments. Six out of nine patients (66.7%) recovered kidney function and became dialysis independent.

Conclusion

In a hospital setting, patients with LVAD can often tolerate and complete the prescribed hemodialysis treatment.

Keywords: Hemodialysis, Heart failure, Kidney failure, Hemodynamic instability, LVAD

Introduction

Roughly 5.7 million individuals in the United States live with heart failure (HF), 10% of which are considered to be advanced and non-responsive to conventional therapies [1]. HF can be associated with cardio-renal syndrome; a bidirectional and dysfunctional interaction between heart and kidneys in which therapy to relieve HF is limited by worsening renal function [2]. In the US, over 1 million patients are hospitalized annually for acute decompensated HF and 27-40% of these patients develop acute kidney injury (AKI) [3]. Sixty-three percent of patients hospitalized with congestive heart failure meet the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (K/DOQI) definition of Stage 3-5 chronic kidney disease (CKD) [4].

The number of patients with advanced heart failure that has become unresponsive to conventional medical therapy is increasing rapidly. One of the most promising new alternatives to heart transplantation is use of ventricular assist devices [5]. Left ventricular assist devices (LVADs) draw blood from the left ventricle and delivers it directly into the ascending aorta. Recently, it has emerged as a common therapy for patients with acute or chronic severe HF. It can be used as a bridge to transplantation or as a destination therapy (i.e., for circulatory support with no intention of transplantation). According to the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS), more than 15,000 VAD implants were performed between 2006 and 2015 [6]. Due to the limited number of heart transplants that can be performed each year and the improved efficacy of LVAD as destination therapy, LVAD implantation frequency increased exponentially each year. For example, 206 VAD implants were performed in 2006 as compared to more than 2500 in 2013 [6].

Decompensated HF patients with renal failure may require renal replacement therapy (RRT) until kidney function recovers. In one study, of 107 consecutive patients who underwent HeartMate II implantation, 14% required RRT [7]. The majority of these patients are managed on an inpatient basis which results in

intensive nursing care and accrual of high medical cost. In 2010, Medicare expenditures for patients with both CKD and HF totaled over $19.4 billion [8]. There is limited information in the literature about the tolerability of these patients to intermittent hemodialysis (IHD). The purpose of this study is to describe the experience in a cohort of patients who received LVAD and underwent a rather large number of IHD treatments in a single medical center.

Methods

Research Design and Data Collection

Information on patient demographics, medical history, and dialysis prescriptions were retrospectively obtained using the electronic medical record. Each IHD session flowsheet was individually reviewed, and the following data were recorded: blood pressure (BP), heart rate (HR), ultrafiltrate (UF) removed, dialysis duration, and symptoms documented by nursing staff. If blood pressure could be obtained by cuff, mean arterial pressure (MAP) was calculated as the sum of 1/3 systolic blood pressure (SBP) and 2/3 diastolic blood pressure (DBP). Doppler assessment of MAP was utilized in the majority of the cases [9]. Beside Doppler measurements, the nursing staff relied on patient symptoms and the continuous hemodynamic parameters of the LVAD apparatus for clinical assessment. HR was assessed by reviewing the rhythm on a telemetry monitor.

All patients were dialyzed with a Gambro Revaclear dialysis membrane (Opelika, AL) with a 2.25mEq/L calcium dialysate at 37ºC. The University of Kentucky Institutional Review Board approved the study protocol. Consent was waived given the retrospective nature of the study.

Participants and Settings

Patients included in the study received IHD between January 1, 2010 and December 31, 2012, and were selected using the procedural terminology (CPT) codes for LVAD and IHD. They were more than 18 years of age and received a HeartMate II® left ventricular assist system (Thoratec® Corporation, Pleasanton, CA). At the time of this study, the HeartMate II LVAD was the most commonly used continuous-flow pump for destination therapy in HF [10].

The HeartMate II® flow setting were predetermined by the LVAD nurse and not altered by the IHD staff. Throughout the dialysis treatment, patients were observed via telemetry, and LVAD-parameters monitor, which included pump speed (range 8600 to 9800 rpm), power, and pulsatility-index (PI). PI, an inverse measure of assistance provided by the continuous-flow pump, is an indicator of decreased circulating blood volume. LVAD nurses were instructed to use the parameters, including PI, in addition to a drop in MAP below 60 mmHg to notify the dialysis staff of hemodynamically significant events [10].

Results

Nine patients who received a total of 170 IHD sessions were identified. The mean age was 53 ± 18 with a range of 26-83 years, with a male predominance (7/9). The majority of patients (6/9) did not have prior known CKD. Indication for LVAD was as destination therapy (DT) in the majority of patients (6/9). All patients who were

bridged-to-transplant (BTT) ultimately received cardiac transplantation (3/3). Time to IHD post-LVAD insertion was quite varied, with only 3 patients started on IHD within 2 weeks of implantation. Approximately 2/3 of the IHD sessions were performed in an ICU setting. In this series the longest period of time that a patient was maintained continuously on IHD was slightly greater than 2 months. Of interest, the majority of patients (6/9) recovered kidney function and became dialysis independent (Table 1). The mean pre- and post IHD systolic blood pressures were 98 ± 13 mmHg (range: 77-116) and 98 ± 13 mmHg (range: 83-119). The average blood flow rates during dialysis were 347 ± 55 mL/min.

Table 1. Demographic and clinical characteristics of Patients

Patient	Age	Sex	Prior CKD	DM	HTN	HD initiation post LVAD implanta-tion (days)	Days on HD with LVAD	Renal Function Recovered	BTT/DT *	Final Status
1	70	M	Yes	Yes	Yes	24	3	Yes	DT	Deceased
2A	26	M	No	No	No	185	10	Yes	BTT	Alive with LVAD
2B	26	M	No	No	No	225	16	Yes	BTT	Alive/LVAD Explant
3	51	M	No	No	No	6	65	Yes	DT	Deceased
4	44	F	No	No	Yes	67	60	No	DT	Deceased
5	68	F	No	No	Yes	5	1	No	DT	Deceased
6	56	M	Yes	Yes	Yes	5	37	Yes	BTT	Alive/Transplant
7	41	M	No	No	Yes	16	57	No	DT	Deceased
8	41	M	No	No	No	109	42	Yes	BTT	Alive/Transplant
9A	83	M	Yes	No	Yes	15	22	Yes	DT	Alive with LVAD
9B	83	M	Yes	No	Yes	443	42	No	DT	Deceased

*BTT – Bridge to Transplant; DT – Destination Therapy

In the 9 reported patients there were 11 defined hemodialysis periods as patient #2 and patient #9 had two distinct time frames on IHD that were separated by 1 and 13 months respectively. On average, patients received 16 ± 13 IHD treatments, with a median of 11 sessions. The average hemodialysis prescription across all 9 patients was 3.12 ± 0.3 hours and 1.98 ± 1.5 liters of UF. Actual achieved dialysis therapy duration was 2.86 ± 0.9 hours and UF was 1.90 ± 1.6 liters (Table 2).

Table 2. Hemodialysis Characteristics per Patient

Patient	# HD Sessions	Average HD Duration Prescribed (hrs)	Average HD Duration Achieved (hrs)	# of Early Termination (%)*	Average Prescribed UF (L)	Average Net UF (L)	# of HD sessions with UF not achieved (%)**
1	3	3.0	3.0	0 (0%)	0.7	0.7	0 (0%)
2A	5	3.0	2.3	3 (60%)	1.8	1.6	2 (40%)
2B	7	2.9	2.9	0 (0%)	0.5	0.7	0 (0%)
3	32	3.4	3.4	1 (3%)	2.4	2.3	9 (28%)
4	33	3.2	3.2	2 (6%)	4.6	4.5	7 (21%)
5	1	2.5	0.5	1 (100%)	1.5	0.5	1 (100%)
6	17	3.6	3.5	1 (6%)	0.3	0.3	1 (6%)
7	32	3.5	3.4	3 (9%)	4.3	4.3	4 (13%)
8	21	3.2	3.2	0 (0%)	2.9	2.9	1 (5%)
9A	8	3.2	3.3	0 (0%)	2.8	2.8	0 (0%)
9B	11	3.0	3.0	0 (0%)	0.9	0.9	2 (19%)

* Number of HD treatments that were terminated ≥ 15 minutes before the end of the prescribed HD duration (percent of all treatments that were terminated early).

** Number of HD treatments when the patient did not achieve ≥ 250 mL of the prescribed UF (percent of all treatments)

Of the total 170 IHD treatments, LVAD parameters did not reveal any low-flow event (as defined by PI) and only one of the 170 sessions was terminated due to LVAD alarm. Nausea or emesis was experienced in 1.9 % of the IHD sessions. The most common intervention for hemodynamic instability events was the administration of albumin, which was primarily given for hypotension. There were 11 sessions (6.5%) when dialysis was terminated early. Early termination (ET) was defined as those sessions when IHD was terminated ≥ 15 minutes before the end of the prescribed IHD duration. On average, ET sessions were reduced by 60 minutes and varied in time post-LVAD implantation from 5-191 days (Table 3). Causes of ET were hypotension in 72.7%, other causes were equally distributed between clotted dialysis, nausea & vomiting and LVAD alarm (9.1% in each)

(Table 3). Failure to achieve the prescribed UF by ≥ 250 mL occurred in 27 of the 170 sessions (15.9%) and averaged roughly 1,000 mL (Table 2).

Table 3. Detailed analysis of early terminated hemodialysis sessions

Patient	# of Early Terminations Per Patient	Reduced HD Time (min)	Time since LVAD Insertion (days)	Reason of HD Termination
2A	T1	60	185	Asymptomatic Hypotension
	T2	90	189	Symptomatic Hypotension
	T3	60	191	Asymptomatic Hypotension
3	T1	15	14	Clotted Dialyzer
4	T1	30	103	Asymptomatic Hypotension
	T2	30	115	Nausea and Vomiting
5	T1	120	5	Symptomatic Hypotension
6	T1	105	17	LVAD Alarm
7	T1	30	50	Symptomatic Hypotension
	T2	45	62	Symptomatic Hypotension
	T3	120	66	Symptomatic Hypotension

Inability to register BP using standard sphygmomanometer due to LVAD-induced reduction in pulse pressure was observed in 6 of the 9 patients at some point throughout the course of their IHD sessions. During these episodes patients were mostly asymptomatic with minimal increase in HR or cardiac rhythm changes (assessed by telemetry monitoring) and had no change in mental status.

Discussion

This retrospective study details the hemodialysis parameters and overall tolerability in patients with LVAD requiring post-implantation IHD. There were very few reported adverse events and ET of dialysis occurred in less than 10% of treatments. The majority of patients achieved the prescribed ultrafiltration. All patients that were BTT recovered kidney function prior to transplantation.

All but 1 of the patients included in this study were monitored while receiving IHD within the ICU. This allowed for more frequent cardiac monitoring in addition to the availability of inotropic agents. Although a MAP < 60 mmHg was experienced at some point through the course of IHD for each patient (on average 48% of the time) the intensive monitoring and availability of cardiac vasopressors allowed for largely uneventful IHD sessions.

A minor portion of sessions requiring ET or adjustment of dialysis were mainly due to episodes of asymptomatic hypotension. Hypotension in dialysis is multifactorial with an underlying pathophysiology that includes diminished cardiac reserve, rapid fluid removal, and autonomic neuropathy [11, 12]. The reported incidence of symptomatic hypotension in the general IHD population during or shortly after dialysis ranges from 15% to 50% of sessions [13]. Although hypotension was frequently observed in our cohort of patients, it rarely required early IHD termination. In addition, LVAD monitoring parameters did not reveal any low-flow event and only one of the 170 sessions was terminated due to LVAD alarm. These results corroborate other retrospective data by Quader, et al and Borrios, et al who reported similar rates and types of adverse events [14, 15].

The continuous-flow nature of the LVAD's, such as the Heartmate II, has the potential to affect the measurement of both automated and manual cuffs. This is in large part due to a reduction in pulse pressure via a constant increase in diastolic BP generated by the pump [9]. In addition, many cardiovascular and pump related factors, including but not limited to left ventricular contractility, intravascular volume, preload, afterload, and pump speed are known to influence pulse pressure [16]. The literature has described reduced accuracy in automatic BP machines in comparison to other methods, such as invasive monitoring and Doppler, in patients with continuous-flow devices. However, if a significant amount of residual pulse pressure remains from the native left ventricle (LV) to allow pulse pressure to remain above 12.8 ± 4.8, and therefore add pulsatility to the continuous-flow provided by the LVAD, automatic BP machines have the ability to measure both the systolic and diastolic pressures [9]. Birks et al. demonstrated both an improvement in hemodynamic indices after LVAD implantation, likely, due to myocardial remodeling from a reduction in the neuroendocrine response that corresponds to HF [17]. This was echoed with a study that showed both an increase in LV function on echocardiography and a reduction in plasma catecholamine levels [18]. Thus, with extended periods of time, recovered cardiac function should provide increased native LV function to produce pulse pressure gradients detectable by an automated sphygmomanometer. For this reason, automatic BP machines were utilized along with Doppler assessment of MAP. Inability to register BP using standard sphygmomanometer due to LVAD-induced reduction in pulse pressure was a common occurrence and observed in 6 of the 9

patients at some point throughout the course of their IHD sessions. Again, during these episodes patients were largely asymptomatic and had no change in their mental status.

The most common intervention within the defined hemodynamic instability events was the administration of albumin, which was primarily given for hypotension. This often occurred in the absence of any documented symptoms of hypoperfusion. Although this was the most common intervention in our study it is noteworthy; however, that in one randomized controlled trial of maintenance hemodialysis patients, the use of 5% albumin was not superior to normal saline for the treatment of intradialytic hypotension [19]. Thus, although this was the primary intervention used in this study in the inpatient setting, equal efficacy alternatives are available for use in other centers and outpatient facilities. The albumin was used in this study due to concerns for potential volume overload if normal saline was used. Although normal saline is frequently used in outpatient centers, its use has not been evaluated in LVAD patients.

In this study, the prescribed UF and IHD duration were achieved in the majority of patients as IHD was terminated early in only 6.5% of IHD sessions. Nausea or emesis was experienced in less than 2% of the IHD sessions, which in the general IHD population can vary between 6 and 15% [20-22]. Mental status changes never occurred in any of the IHD sessions in this study. Sinus tachycardia, defined as HR > 100 bpm, was documented in 69 of the IHD sessions (41%). In the general IHD population, incidence of cardiac arrhythmias varies between 18-76% [22-27], and although the literature shows that ventricular arrhythmias are common in this patient population [28], no serious arrhythmias were encountered in this study. One-third of patients in this study had CKD prior to their LVAD implant. It is interesting to note that Hasin et al. observed an improved glomerular filtration rate after LVAD implantation in patients with CKD with abnormal renal function secondary to decreased perfusion [29].

Out-patient dialysis centers are very cautious to accept end stage renal disease patients with LVADs because of the potential complications and absence of pulsatile blood pressure for monitoring. Many patients have to stay in the hospitals for long time because of the unacceptance by the out-patient dialysis centers. Based on our findings and Quader et al. study [14] it appears that patients with LVAD are likely to tolerate out-patient in-center HD. However, specific protocols and defined parameters to adhere to are needed to be developed and assessed.

Limitations of this study include those related to any retrospective analysis. The most notable, was the reliance on IHD nurse documentation. Although unlikely, symptoms, hemodynamic parameters, UF rate, or specific interventions may not have been recorded accurately. A sample of 9 patients receiving a total of 170 hemodialysis sessions may not adequately reflect the true incidence of hemodynamic events, symptomatic episodes, or need for therapeutic interventions in this patient population.

Considerations for future investigation include the prospective evaluation of patients with LVAD and direct comparison of their hemodynamic profile to other patients receiving IHD. In addition, the efficacy of common strategies to minimize

hypotension during IHD has not yet been investigated in LVAD patient population. In particular, it is important to compare the effect of albumin to saline infusion, as albumin is not commonly used in outpatient in-center dialysis units.

Conclusion

Patients with LVAD appear to tolerate in-hospital IHD relatively well compared to non-LVAD patients. Symptoms of hemodynamic instability are rare and hypotensive episodes are readily responsive to traditional interventions. Further longitudinal studies are needed to assess whether with proper monitoring these patients can tolerate outpatient IHD well.

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