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Defining Metrics for Short Term Success After LVAD Implant: An Analysis of the Society of Thoracic Surgeons Intermacs Registry

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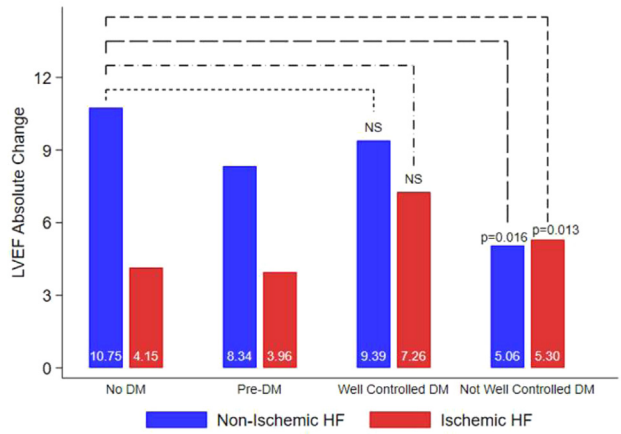
Purpose: Type 2 diabetes mellitus (DM) and poor glycemic control portend a higher risk for cardiovascular morbidity and mortality. We sought to assess their impact on left ventricular assist device (LVAD)-mediated cardiac recovery in chronic advanced heart failure (HF).

Methods: Consecutive patients (N=477) receiving a durable continuous-flow LVAD were prospectively evaluated. After excluding patients with acute HF etiologies or inadequate follow-up after LVAD (<3 months), 396 patients were stratified based on pre-LVAD DM status into non-diabetics (n=121; no history of DM and HbA1c <5.7) and diabetics/prediabetics (n=275; history of DM or HbA1c ≥5.7). Diabetics/prediabetics were further divided into 3 groups: prediabetics, n=106; well-controlled DM (HbA1c <7%), n=90; or not well-controlled DM, n=79. The absolute left ventricular ejection fraction (LVEF) change (ΔLVEF = LVEF post-LVAD - LVEF pre-LVAD) within one year on LVAD support was compared between groups with linear regression. DM is frequently associated with ischemic cardiomyopathy (ICM), so patients were stratified a priori into ICM and non-ICM (NICM).

Results: Compared to non-diabetics, diabetics/prediabetics were older, more likely male, with a higher BMI, and more commonly had an ICM, remote history of hypertension, and a longer HF symptoms duration. The **Figure** depicts the ΔLVEF between the study groups stratified into ICM or NICM. After adjusting for age, sex, BMI, HF symptoms duration, and history of hypertension, patients with well-controlled DM responded more favorably compared to patients with poor glycemic control. Overall, NICM patients responded more favorably than ICM patients.

Conclusion: DM appears to negatively affect functional cardiac improvement on LVAD support and effective glycemic control seems to be beneficial in enhancing the favorable myocardial functional response. Further research is warranted to investigate the underlying mechanisms driving the differential responses.

Figure. Absolute Left Ventricular Ejection Fraction Change in the Four Study Groups Stratified into Non-Ischemic and Ischemic Heart Failure.



DM: Diabetes Mellitus, HF: Heart Failure, LVEF: Left Ventricular Ejection Fraction, NS: Non-Significant

(856)

Using Pulsatility Responses to Breath-Hold Maneuvers to Predict Readmission Rates in Left Ventricular Assist Device Patients

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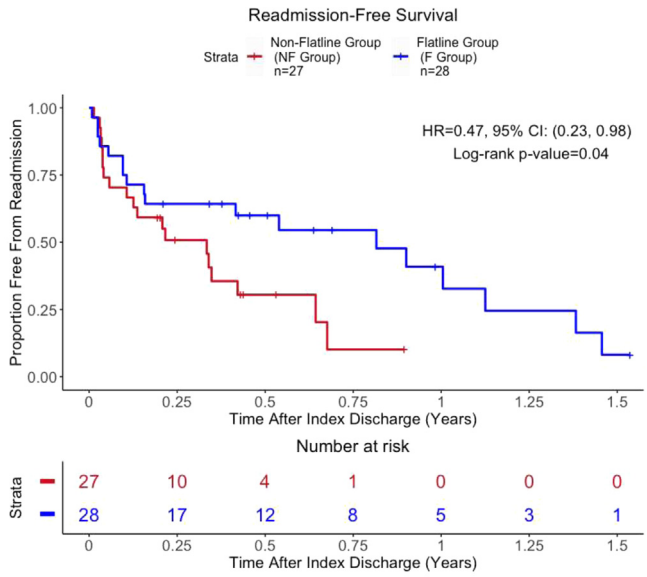
Purpose: Respiratory maneuvers induce heterogenous changes to flow pulsatility in continuous flow left ventricular assist device patients. We assessed the association of these pulsatility responses with patient hemodynamics and outcomes.

Methods: Responses obtained from Medtronic HVAD outpatients during weekly clinics were categorised into three ordinal groups according to the percentage reduction in waveform pulsatility (*peak - trough flow*) upon inspiratory breath hold, IBH (%ΔP): (1) Minimal Change (MC, %ΔP≤50), (2) Reduced Pulsatility (RP, 50<%ΔP<100), (3) Flatline (FL, %ΔP=100). Waveforms were also assessed for IBH-induced suction. Same day echocardiography and right heart catheterization (RHC) were performed. To assess readmissions, patients with ≥1 flatline response (F group) were compared to those without (NF group) and patients with ≥1 suction (S group) were compared to those without (NS group).

Results: In total, 712 responses were obtained from 55 patients (45 male, age 56±12). The F group (n=28) experienced numerically lower all-cause readmissions (1.51 vs 2.79 events/y, hazard ratio [HR]=0.67, p=0.12), reduced heart failure readmissions (0.07 vs 0.56 events/y, HR=0.15, p<0.01) and superior readmission-free survival (HR=0.47, p=0.04, *figure*). Readmissions for syncope/presyncope occurred solely in the S group (n=18) (0.25 events/y, p=0.01). Echocardiography was performed in 50 patients and RHC in 31. When compared to MC, RP and FL responses were associated with lower right atrial (14.2 vs 11.4 vs 9.0mmHg, p=0.08) and pulmonary capillary wedge pressures (19.8 vs 14.3 vs 13.0mmHg, p=0.03), lower rates of >mild mitral regurgitation (48% vs 13% vs 10%, p=0.01) and >mild right ventricular impairment (62% vs 25% vs 27%, p=0.03), and increased rates of aortic valve opening (32% vs 50% vs 75%, p=0.03).

Conclusion: Responses to IBH predicted hemodynamics and readmissions. The impact of IBH on pulsatility can noninvasively guide patient management and optimization.



(857)

Defining Metrics for Short Term Success After LVAD Implant: An Analysis of the Society of Thoracic Surgeons Intermacs Registry

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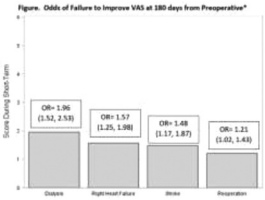
Purpose: While clinical trials evaluating left ventricular assist device (LVAD) technology typically use composite outcomes to assess efficacy, composite outcomes including patient reported outcomes (PROs) have not been utilized as benchmarks for LVAD implant center performance improvement initiatives or quality ranking. The objective of the study was to assess the feasibility of generating a patient composite outcome measure including PROs from a real world registry.
Methods: Short term (ST, 180 days) adverse events (AEs) and mortality were tallied for Intermacs patients undergoing LVAD implant between 1/2012 and 12/2019. ST postoperative events included mortality on first device and frequencies of stroke, reoperation (device malfunction/other), right heart failure (RHF), prolonged respiratory failure, and/or dialysis on first device. Logistic regression was used to generate odds ratios for mortality for each AE. Separately, the EuroQOL visual analog scale (VAS) was assessed at baseline and 180 days in ST survivors.
Results: Of 20,115 patients, 37% suffered at least one event, most commonly death, reoperation and stroke (Table, column A). Stroke, prolonged respiratory failure, and dialysis attributed the most to ST mortality (Table, column B). Of the 16725 patients alive at 180 days, 43% completed a VAS with 82.0% showing VAS improvement. Renal failure and RHF contributed most to failure to improve VAS (Figure).
Conclusion: Assessment of a ST composite outcome metric after LVAD implant from a real world data source is feasible but limited by incomplete PRO reporting. ST adverse events display differential effects on mortality and PROs that can be used in development of global rank outcome scores. While reoperation is common, stroke, prolonged respiratory failure and renal failure conferred highest risks of ST deaths within Intermacs. Assessment of PROs should become a priority for LVAD centers to allow the field to generate a complete assessment of patient-centered outcomes.

Table. Definitions and Short Term (180 days) Outcomes after LVAD

	Definition	N	Column A 180 day Frequency in 20115 Intermacs patients, (%)	% of 7444 Composite Events*	Unadjusted OR 180 day Death (95% CI)	Column B Adjusted OR 180 day Death (95% CI)
Death	Within 180 days	2568	12.8%	34.5%	–	–
Stroke	Ischemic or hemorrhagic	1602	8.0%	21.5%	5.60 (5.01,6.25)	5.19 (4.61,5.84)
Prolonged Respiratory Failure	Trach or intubation >14 days	1348	6.7%	18.1%	6.93 (6.15,7.77)	3.99 (3.49,4.55)
Dialysis	Dialysis >30 days postop.	1419	7.1%	19.1%	5.85 (5.21,6.57)	3.62 (3.17,4.14)
Right Heart Failure	RVAD or >30 days inotropes	1507	7.5%	20.2%	2.87 (2.54,3.24)	1.53 (1.32,1.76)
Reoperation	Nonexchange indications*	3296	16.4%	44.3%	1.73 (1.57,1.91)	1.21 (1.08,1.35)

*could include bleeding, infection, device repositioning, etc. †Patient can have multiple events yielding >100% sum.

Figure. Odds of Failure to Improve VAS at 180 days from Preoperative*



*Too sick to complete VAS was placed in failure to improve group and not omitted. Respiratory failure was not significant in the analysis [OR= 1.15 (0.87, 1.53)]. OR= Odds Ratio. VAS= Visual Analog Score

(858)

Single-Center Analysis of Patients with HeartMate 3 LVAD External Outflow Graft Obstruction

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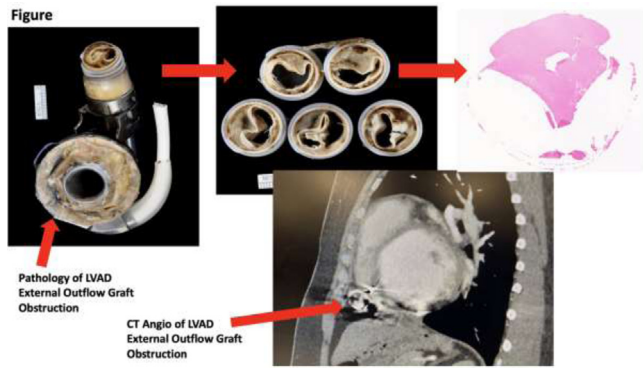
Purpose: There is limited published data regarding external outflow graft obstruction (EOGO) of the Heartmate 3 (HM3) left ventricular assist device (LVAD) (Abbott Labs, Chicago, IL) and its clinical consequences despite the suspicion that it is a commonly observed complication in practice.
Methods: The cohort included adults with HM3 LVADs at a single center. Chart review was completed to assess baseline characteristics, serial right heart catheterization and echocardiographic data while on support, as well as if there was suspicion or confirmation of EOGO including symptoms, CT of the LVAD, and pathology of the explanted device. Hospital readmissions for obstruction concerns and upgrade of status on the heart transplant list while on support were recorded.
Results: The cohort consisted of 24 patients with a mean age of 55 +/- 13, 25% were classified as destination therapy, and 75% had nonischemic cardiomyopathy. 12/24 patients had suspected and/or confirmed EOGO, of which 7/12 were symptomatic. The other 5/12 were discovered at the time of transplant (Table). 3/12 patients were readmitted for concerns of EOGO and 5/12 required status upgrade on the transplant waitlist. CT findings and pathology of the explanted LVADs showed compressive material between the outflow graft and the bend relief (Figure).
Conclusion: Although EOGO of HM3 LVADs is commonly seen in clinical practice, it has been under reported in the literature. Our study shows it is a common finding with potential of serious complications. A large multicenter study of EOGO is needed to completely understand the full scope of EOGO, and its clinical impact on patient care.

Table

Patient	Symptoms Concerning for EOGO	Frequent Alarms	Admission for Low Flows or Symptoms	UNOS Upgrade Status	CTA While on LVAD	EOGO Seen on CTA	Pathology Positive for EOGO	Baseline LVIDD cm	Most Recent LVIDD cm	Baseline PCWP mmHg	Most Recent PCWP mmHg*
A	No	No	No	No	No	-	Yes	4.8	5.7	10	15
B	No	No	No	No	No	-	Yes	6.4	5.8	7	7
C	No	Yes	No	3	No	-	Yes	6.1	7.5	6	18
D	No	Yes	No	3	No	-	Yes	4.5	6.9	14	22
E	Yes	Yes	Yes	No	Yes	No	-	5.9	7.1	7	2
F	Yes	Yes	No	2E	Yes	No	Yes	5.8	6.1	10	20
G	Yes	No	No	No	Yes	Yes	-	7.7	8.1	21	30
H	Yes	Yes	No	No	Yes	Yes	-	4.4	4.5	9	6
I	Yes	Yes	Yes	1E	Yes	Yes	-	5.1	6.3	18	20
J	Yes	Yes	Yes	No	Yes	No	-	4.6	6.0	15	9
K	No	Yes	No	2E	No	-	Yes	4.8	4.8	22	21
L	Yes	Yes	No	-	Yes	Yes	-	4.6	5.4	29	21

Legend: EOGO: External Outflow Graft Obstruction; UNOS: United Network for Organ Sharing; CTA: computed tomography angiography; LVAD: left ventricular assist device; LVIDD: left ventricular internal diameter end diastole; cm: centimeter; mmHg: millimeters of mercury; * while still on LVAD support prior to transplant if applicable

Figure



(859)

LVADs: The Western Australian Experience

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Purpose: Review outcomes of the Western Australian (WA) LVAD program.
Methods: Retrospective review of medical records and local databases.
Results: In 23 years, 140 LVADs (no RVAD/BIVADs) have been inserted in WA: 46 HeartWare HVAD (HW), 26 HeartMate III (HM3), 16 HeartMate II (HM2), and 52 earlier generation devices. Abstract data refers to HW/HM2/HM3. Insertion indications were non-ischaemic cardiomyopathy (60%) and ischaemic (40%). 89% were inotrope dependant pre-