HEART FAILURE COLLABORATORY

Digital Health | Regulatory Policy & Implementation
Representative Populations | Research Networks

HFC Lean CRF: Durable Mechanical Circulatory Support

Pre-Implant Mechanical Circulatory Support CRF Elements

Current Durable VAD O Yes O No

If Yes, Indication for Initial VAD Implant
o DESTINATION THERAPY
o BRIDGE TO DECISION/CANDIDACY
o BRIDGE TO RECOVERY
o BRIDGE TO TRANSPLANT
o NO INTENT DESIGNATION

If yes, Reason for replacement of current durable VAD
o DEVICE MALFUNCTION
o DEVICE THROMBOSIS
o INFECTION
o OTHER: ____
Prior Durable LVAD that was explanted O Yes O No,
If yes, date prior durable LVAD implanted/explanted:

Intravenous inotropic agents O Yes O No

-Dobutamine	O Yes O No	Dose:
-Milrinone	O Yes O No	Dose:
-Epinephrine	O Yes O No	Dose:
-Dopamine	O Yes O No	Dose:
-Norepinephrine	O Yes O No	Dose:
-Nitroprusside	O Yes O No	Dose:
-Other	O Yes O No	Dose:

Is the subject on continuous or intermittent (i.e. more than two infusions per week) intravenous inotropic drug therapy? O No O Yes

Mechanical ventilation O Yes O No

- Ultrafiltration O No O Yes
- Dialysis (acute) O No O Yes

Previous Temporary Mechanical Circulatory Support device(s) that were removed during current hospitalization. O no O yes
If Yes, specify type(s) of prior temporary mechanical circulatory support and dates of implant/removal:
O BALLOON PUMP: (Implant Date, Explant Date)
O ECMO: (Implant Date, Explant Date)
O PERCUTANEOUS MICROAXIAL PUMP, E.G. IMPELLA: (Implant Date, Explant Date)
O Other: ____ (Implant Date, Explant Date)

Current Temporary Mechanical Support O no O yes
If Yes, specify type of mechanical support: O BALLOON PUMP
O ECMO
O PERCUTANEOUS MICROAXIAL PUMP, E.G. IMPELLA O Other temporary MCS
device: ____
******Cross link here with Lean CRF Temporary MCS Module and pull details about type/duration of temporary support devices such as vessel cannulation, settings of temporary MCS, etc.******

If Yes, specify duration of mechanical support_____days (or implant date)

INTERMACS Patient Profile ____
Duration at current INTERMACS Patient Profile ___

If subject is not a transplant candidate, indicate reason(s)
☐ Age
☐ Insulin Dependent Diabetes Mellitus (IDDM)
☐ Obesity
☐ Renal Insufficiency
☐ Pulmonary Hypertension
☐ Peripheral Vascular Disease (PVD)
☐ Chronic Obstructive Pulmonary Disease (COPD)
☐ Cancer
☐ Social Issue/Compliance: tobacco use, alcohol/drug abuse
☐ High Panel Reactive Antibodies (PRA) Levels
☐ Subject Choice

Pre-VAD Implant Elements to Capture
Prior Cardiac Surgery Type of surgery: Approach:
Number of prior median sternotomies?

Additional Lab Values to Capture
ABO Blood Type Albumin
Total Bilirubin
Serum alanine aminotransferase (ATL) International normalized ratio
(INR) Total Cholesterol
Platelet Count Lymphocyte Percentage
Uric Acid

Echocardiogram Details
******Cross link with Lean CRF Echocardiography Module. Data elements that will be needed include LVEF (also on baseline lean CRF), measures of LV size (LVIDd), and assessment of RV Function (RV FAC, TAPSE, etc)******

Hemodynamic Data
******Cross link with Lean Hemodynamic Data Module. Data elements that will be pulled from this module include the following:***
Body Surface Area (auto-calculated w/o repeat data entry from Height and Weight on Lean CRF)
Heart rate (at time of hemodynamic measurements)
Systolic blood pressure (at time of hemodynamic measurements) Diastolic blood pressure (at
time of hemodynamic measurements)
Mean arterial blood pressure (auto-calculated w/o repeat data entry from SBP and DBP)
Right atrial pressure
Pulmonary artery systolic pressure Pulmonary artery diastolic
pressure
Mean pulmonary artery pressure (auto-calculated w/o repeat data entry from PA systolic and diastolic pressure)
Pulmonary capillary wedge pressure
Cardiac index
Pulmonary vascular resistance (auto-calculated w/o repeat data entry from above values)

Mechanical Circulatory Support Implantation and Index Hospitalization CRF Elements
VAD Implant procedure
Date of Hospitalization___(DD/MMM/YYYY)
Date Of Implant___(DD/MMM/YYYY)
Time Entering Operating Room___(HH:MM)
Date Of Chest Incision___(DD/MMM/YYYY)
Time Of Chest Incision___(HH:MM)
Date Of Chest Closure___(DD/MMM/YYYY)
Time Of Chest Closure___(HH:MM)
Chest left open/delayed closure

Surgical Approach:
O CONVERSION, THORACOTOMY TO STERNOTOMY O FULL STERNOTOMY
O LEFT LATERAL THORACOTOMY AND RIGHT THORACOTOMY
O LEFT LATERAL THORACOTOMY AND UPPER HEMI-STERNOTOMY
O Other (specify)

Cardiopulmonary Bypass Support O NO O YES If Yes, specify total time on bypass_____min

Aortic Cross Clamp Used O NO O YES
If Yes, specify total aortic cross clamp time____min

Was a transfusion in operating room performed O NO O YES If Yes, specify product(s) and units transfused _____

Driveline Location
O RUQ - RIGHT UPPER QUADRANT O RLQ - RIGHT LOWER QUADRANT O LUQ - LEFT UPPER QUADRANT
O LLQ - LEFT LOWER QUADRANT
O No driveline (specify)
Were additional techniques used to prevent infections O NO O YES If Yes, specify_ _____

Was outflow graft anastomosed to the ascending aorta O NO O YES If No, specify outflow graft anastomosis location
O DESCENDING AORTA
O LEFT SUBCLAVIAN ARTERY O RIGHT SUBCLAVIAN ARTERY
O OTHER, specify ____

Time Leaving Operating Room_____(HH:MM)

Were concurrent cardiac procedures performed O NO O YES If Yes,
Procedures Performed:
☐ ASD Closure
☐ PFO Closure
☐ RVAD Implant
☐ CABG
☐ VSD Closure
☐ Congenital Cardiac Surgery
☐ Valve Surgery: Aortic Repair
☐ Valve Surgery: Aortic Replacement
☐ Valve Surgery: Mitral Repair
☐ Valve Surgery: Mitral Replacement
☐ Valve Surgery: Tricuspid Repair
☐ Valve Surgery: Tricuspid Replacement
☐ Valve Surgery: Pulmonic Repair
☐ Valve Surgery: Pulmonic Replacement
☐ ECMO Implant
☐ ECMO Decannulation
☐ LV Aneurysmectomy
☐ ICD Insertion
☐ Pacemaker Insertion
☐ ICD/Pacemaker/Lead removal
☐ LVAD Removal
☐ Left Atrial Appendage (LAA) Ligation
☐ Ascending Aorta Replacement
☐ RVAD Explant
☐ IABP Removal
☐ Other

Intraventricular Thrombus Present O No O Not assessed O Present
If Present, Attempt to Remove Thrombus O EXCISE O NONE O SUCTION

Discharge
Was the subject extubated O NO O YES
If Yes, Date Extubated____(DD/MMM/YYYY)

Number Of Days in ICU Post Implant ___

Was subject discharged O NO O YES Date of
Discharge_____(DD/MMM/YYYY) Discharged
to
O HOME
O HOME WITH SERVICES O HOSPICE
O INPATIENT REHABILITATION FACILITY O LOCAL
HOTEL
O SKILLED NURSING CARE FACILITY O OTHER
If Other, specify __

Device Name / Outflow Graft / Controller
For each one, specify:
Serial Number _____

LVAD Parameters Available o NO o YES Speed__RPM or
Not Done ☐
Flow___L/min or Not Done ☐ Peak__L/min or Not
Done ☐ Trough_____L/min or Not
Done ☐ Power_____Watts or Not Done ☐
Pulsatility index__ or Not Done☐
Other LVAD parameters: ___
Is the controller Hct level within 5% of the latest serum Hct o NO o YES
Is there evidence of suction events in the monitor/wave forms o NO o YES
Are there any significant changes in waveforms o NO o YES

Durable Mechanical Circulatory Support Adverse Events
******Reference MCS ARC consensus Definitions document for categorization and formal definitions of each Adverse Event*** (Kormos RL, Antonides CFJ, Goldstein DJ, et al. Updated definitions of adverse events for trials and registries of mechanical circulatory support: A consensus statement of the mechanical circulatory support academic research consortium. J Heart Lung Transplant. 2020 Aug;39(8):735-750).***
Bleeding events (within 30 days of implant): Categorization based on Table 1 of MCS ARC definitions
Bleeding events (>30 days of implant): Categorization based on Table 1 of MCS ARC definitions
Infection Adverse Event: Categorization based on Table 2 of MCS ARC definitions
Neurologic Dysfunction Adverse Event: Categorization based on Table 3 of MCS ARC definitions
Severity, Recovery, and long-term disability of Neurologic Dysfunction: Categorization based on Table 4 of MCS ARC definitions
Device Malfunction Adverse Event: Categorization based on Table 5 of MCS ARC definitions
Hemolysis Adverse Event: Categorization based on Table 6 of MCS ARC definitions
Right heart failure Adverse Event: Categorization based on Table 7 of MCS ARC definitions
Renal Dysfunction Adverse Event: Categorization based on Table 8 of MCS ARC definitions
Other Adverse Events, specify: Categorization based on Table 9 of MCS ARC definitions

For Device Malfunction Adverse Events:
Was device malfunction a failure of the pump or non-pump component o PUMP FAILURE
o NON-PUMP FAILURE

Specify type of device malfunction CONTROLLER
FAULT
CRITICAL LOW BATTERY DAMAGED BATTERY
DAMAGED CABLE DAMAGED CONTROLLER
DAMAGED DRIVELINE
DISPLAY NOT PROPERLY FUNCTIONING ELECTRICAL FAULT
INSUFFICIENT BATTERY CHARGING POWER FAILURE
PUMP MALFUNCTIONPUMP THROMBOSIS
If Other, specify

Was the subject treated medically for this device malfunction O no O yes If Yes, was it successful O no O yes

Was device failure iatrogenic or recipient-induced O no O yes
Was pump thrombus suspected O no O yes If pump thrombus suspected,
specify why it was suspected:
specify location:
☐ Inflow cannula
☐ Outflow graft
☐ Pump body (impeller)
☐ Unknown

If pump thrombus suspected, what treatment was administered
☐ Exchange
☐ Explant
☐ Medical therapy; If Medical therapy, specify medication(s) and dose(s) ____

If pump thrombus suspected, was it confirmed O no O yes
If pump thrombus confirmed, specify method of confirmation
☐ Imaging study
☐ Visual inspection
☐ Manufacturer's report

Device System Modification Information
Date of System Modification:
Type of System Modification:
o DEVICE TURNED OFF, NOT REMOVED
o EXCHANGED
o EXPLANTED, NOT REPLACED
If Exchanged, specify replacement device type
☐ ECMO
☐ HEARTMATE II
☐ HEARTMATE III
☐ HVAD
☐ Other, specify (eg. newer LVAD, Total Artificial heart etc.)

If Returned, were any unusual findings identified O no O yes If Yes, specify
unusual findings _____
Primary Reason for System Exchange/Explant
☐ DEVICE MALFUNCTION
☐ DEVICE THROMBOSIS
☐ INFECTION
☐ RECOVERY
☐ RIGHT HEART FAILURE
☐ TRANSPLANT
☐ OTHER, specify ___
If Transplant, indicate reason :
O IMPROVEMENT IN CONDITION THAT PREVIOUSLY EXCLUDED SUBJECT FROM TRANSPLANTATION O PATIENT EMERGENTLY TRANSPLANTED
If Patient Emergently Transplanted, specify reason _____
If Improvement in Condition, indicate condition(s) improved:
☐ Insulin Dependent Diabetes Mellitus (IDDM)
☐ Obesity
☐ Renal Insufficiency
☐ Pulmonary Hypertension
☐ Peripheral Vascular Disease (PVD)
☐ Chronic Obstructive Pulmonary Disease (COPD)
☐ Cancer
☐ Social Issue/Compliance: tobacco use, alcohol/drug abuse
☐ High Panel Reactive Antibodies (PRA) Levels
☐ Other, specify
Is Device System Modification associated with an Adverse Event O no O yes
If Yes, enter primary adverse event associated with System Modification ____