Table 1. Preliminary core outcome and variable set classified by main domains

|  |  |  |
| --- | --- | --- |
| **Domain** | **Outcome** | **Variable** |
| **Baseline patients’ characteristics** | * Variables related to the patient/comorbidities
 | Age, sex, BMI, smoking, alcohol, diabetes, renal dysfunction, hepatic dysfunction, chronic pulmonary obstructive disease, dyslipidemia, hipertension |
| * Cardiovascular history
 | Prior LVEF, arrhythmia, atrial fibrillation, acute myocardial infarction, stroke, peripheral vascular disease, cardiac surgery, LVAD, pacemaker/CRT/ ICD, PCI or CABG  |
| **Pharmacological management** | * Cardiovascular and antithrombotic drugs
 |
| **Factors related to the technique** | * Device trademark
* Availability of transplant unit
* Learning curve
 |
| **Safety**  | * In-hospital death
 | * Date of death
* Cause of death (CV and non-CV death)
 |
| * Cardiac adverse events
 | * Acute myocardial infarction
* Right-sided heart failure
* Chronic right-sided heart failure
* Atrial fibrillation/flutter
* Ventricular arrhythmia requiring defibrillation therapy
* Acute endocarditis
 |
| * Neurological adverse events
 | * Stroke (type and severity)
* Transient ischaemic attack
 |
| * Other serious adverse events
 | * Renal dysfunction requiring dialysis
* Respiratory failure
* Hepatic dysfunction
* Sepsis
* Bleeding requiring blood transfusion
* Multiple organ failure
 |
| * LVAD device-related adverse event
 | * Major infection LVAD-related
* Pump thrombus
* Aortic regurgitation
* Aortic regurgitation grade
* LVAD major failure
 |
| **Effectiveness** | * Overall survival
 | * Date of death
* Cause of death
* Loss follow-up
 |
| * Survival free of events
 | * Date of acute myocardial infarction
* Date of right heart failure
* Date of ventricular arrhythmia requiring defibrillation therapy
* Date of atrial fibrillation/flutter
* Date of stroke
* Date of LVAD replacement or explant
* Date of other surgical interventions LVAD-related
 |
| * Functional capacity
 | * 6-min walk test (6 MWT)
* NYHA class
* End-diastolic volume
 |
| * Quality of life
 | * Kansas City Cardiomyopathy Questionnaire (KCCQ-12)
* EuroQol-5D (EQ-5D)
 |
| **Patient or caregiver acceptability or satisfaction** | Adaptation of the SATISCORE patient satisfaction questionnaire for cardiac surgery (Spanish)1 |
| **Health system impact** | * LOS for LVAD implantation
 | * Date of admission
* Date of discharge
 |
| * LOS in ICU post-intervention
 | * Date of ICU admission
* Date of ICU discharge
 |
| * LOS in cardiac unit readmission
 | * Date of cardiac unit readmission
* Date of cardiac unit discharge
 |
| * LOS in ICU readmission
 | * Date of readmission in ICU
* Date of ICU discharge
 |
| * LOS in other hospital unit readmission
 | * Date of other hospital unit readmission
* Date of other hospital unit discharge
 |
| * LVAD-related specialized care consultations
 | * Number of specialized care consultations
 |
| * LVAD-related primary care consultations
 | * Number of primary care consultations
 |
| * LVAD-related home consultations
 | * Number of home consultations
 |

**Abbreviations:** BMI, body mass index; CV, cardiovascular; ICU, intensive care unit; LVAD, left ventricular assist device; LOS, length of hospital stay.

1The following issues are proposed to measure the satisfaction and acceptability of the patient / caregiver (5-points Likert scale: 1=very dissatisfied; 2=dissatisfied; 3=neither satisfied nor dissatisfied; 4=satisfied; 5=very satisfied): (a) In general, how satisfied are you living with LVAD and (b) Indicate the degree of agreement with the following statement: “If I found myself the same as before, I would have surgery again”.