Supplementary Materials

Supplementary Materials 1. Clinical parameters

Table 1 reports the comprehensive list of clinical variables to be collected for both prospective and retrospective patients. Specifically, the relevant variables for the Impella and ECMO groups are specified, along with the timing for measurements during the observation period.

	Target patients		**Timing of measurement**			
Patients' characteristics	Impella group	ECMO group	T0 (Baseline)			
Age (years)	X	X	X			
Sex (male/female)	X	X	X			
BMI (kg/m2)	X	X	X			
Arterial Hypertension (yes/no)	X	X	X			
Diabetes Mellitus (yes/no)	X	X	X			
Chronic kidney disease (yes/no)	X	X	X			
Peripheral artery disease(yes/no)	X	X	X			
ICD/CRT (yes/no)	X	X	X			
Previous PTCA (yes/no)	X	X	X			
Previous CABG (yes/no)	X	X	X			
Chronic heart failure (yes/no)	X	X	X			
Cause of acute heart failure:						
*Acute coronary syndrome (yes/no)	X	X	X			
*Myocarditis (yes/no)	X	X	X			
*End stage dilatative cardiomyopathy (yes/no)	X	X	X			
*Arrhythmia/ arrhythmic storm(yes/no)	X	X	X			
*Other (specify)	X	X	X			
Phenotype of cardiogenic shock:						
* LV dominant (yes/no)	X	X	X			
*RV isolated (yes/no)	X	X	X			
* Biventricular failure(yes/no)	X	X	X			
Onset of shock (hours)	X	X	X			
Hemodynamic presentation of shock:						
* Wet and cold (classic CS) (yes/no)	X	X	X			

* Wet and warm (vasodilatory CS) (yes/no)	X	X	X			
* Dry and cold (euvolemic CS) (yes/no)	X	X	X			
Revascularization procedure with stent implantation (yes/no)	X	X	X			
Cardiac arrest(yes/no)	X	X	X			
eGFR (ml/min/m2)	X	X	X			
AKI requiring CRRT yes/no)	X	X	X			
Mechanical ventilation yes/no)	X	X	X			
Days of mechanical ventilation yes/no)	X	X	X			
Mortality risk score	Impella group	ECMO group	T0 (Baseline)			
NYHA	X	X	X			
INTERMACS score	X	X	X			
SCAI class	X	X	X			
CARDshock score (see below)	X	X	X			
RESCUE SCORE	X	X	X			
SAVE score	X	X	X			
MCS strategy and data	Impella group	ECMO group	Event (Y/N)			
Implantation pathway:						
* MCS escalation (yes/no)	X	X	X			
* MCS de-escalation (yes/no)	X	X	X			
* First support (yes/no)	X	X	X			
Device implantation pre PCI (yes/no)	X	X	X			
Device implantation post PCI (yes/no)	X	X	X			
Implantation strategy[1]*:*						
* Bridge to recovery (yes/no)	X	X	X			
* Bridge to LVAD (yes/no)	X	X	X			
* Bridge to transplant (yes/no)	X	X	X			
* Bridge to candidacy (yes/no)	X	X	X			
Implantation route:						
*Axillar (yes/no)	X	X	X			
* Femoral (yes/no)	X	X	X			
Successful implantation (yes/no)	X	X	X			

[1] Typically reassessed also at the end of the patient journey, as it might be subject to changes from the original plan

Need for surgical implant (yes/no)	X	X	X			
Duration of implantation (min)	X	X	Y, minutes			
Hemodinamic and Lab Parameters Trend	Impella group	ECMO group	T0 (Baseline)	24 h post implantation	48-72 h post implantation	First measurement after device removal
Mean arterial pressure (mmHg)	X	X	X	X	X	X
Systolic arterial pressure (mmHg)	X	X	X	X	X	X
Heart rate (bpm)	X	X	X	X	X	X
CVP (mmHg)	X	X	X	X	X	X
CI (l/min/mq)	X	X	X	X	X	X
PCWP (mmHg)	X	X	X	X	X	X
SvO2 (%)	X	X	X	X	X	X
RVSWI (g/m/beat/m^2)	X	X	X	X	X	X
Creatinine (mg/dl)	X	X	X	X	X	X
Lactates (mmol/L)	X	X	X	X	X	X
Troponin (pg/ml)	X	X	X	X	X	X
Inotropic score	X	X	X	X	X	X
NT-proBNP (ng/L)	X	X	X	X	X	X
Platelets (per microliter)	X	X	X	X	X	X
D-dimers (µg/mL)	X	X	X	X	X	X
Bilirubin (mg/dl)	X	X	X	X	X	X
LV EF (%)	X	X	X	X	X	X
RV EF (%)	X	X	X	X	X	X
Mechanical ventilation (yes/no)	X	X	X	X	X	X
Safety in-hosp complications	Impella group	ECMO group	Event during support(yes/no)	Eventual comments/event description		
Bleeding (and site):						
*Major (yes/no)	X	X				
*Moderate (yes/no)	X	X				
*Minor (yes/no)	X	X				
Bleeding requiring surgery (yes/no)	X	X				
Bleeding from Impella (ECMO insertion site (yes/no)	X	X				
Limb ischemia (yes/no)	X	X				
Vascular complication requiring intervention/surgery (yes/no)	X	X				
Ischemic stroke (yes/no)	X	X				
Device malfunction(yes/no)	X	X				
LV perforation (yes/no)	X					

Aortic valve injury (yes/no)	X			
Mitral valve injury (yes/no)	X			
Lesion to other intracardiac structure (yes/no)	X	X		
aortic dissection (yes/no)	X	X		
Other device related injury (yes/no)	X	X		
Major Hemolysis (yes/no)	X	X		
Minor Hemolysis (yes/no)	X	X		
AKI requiring CRRT (yes/no)	X	X		
Sepsis (yes/no)	X	X		
Extracorporeal purification (i.e. Cytosorb) (yes/no)				
EC transfusion, numbers of unit	X	X		
FFP transfusion, numbers of unit	X	X		
PLT transfusion, numbers of unit	X	X		
Device related outcomes	Impella group	ECMO group	Variable	Eventual comments/event description
Duration of MCS support (days)	X	X		
mobilization (chair) with MCS and physiotherapy (yes/no)	X	X		
mobilization (walk) with MCS and physiotherapy (yes/no)	X	X		
Major device malfunction (yes/no)	X	X		
Device exchange (yes/no)	X	X		
Reason for device exchange	X	X		
Survival and cardiac outcomes	Impella group	ECMO group	Event (yes/no)	Eventual comments/event description
30-day mortality (yes/no)	X	X		
ICU mortality (yes/no)	X	X		
Hospital mortality (yes/no)	X	X		
Survival to next therapy (yes/no)	X	X		
Weaning from MCS (yes/no)	X	X		
Myocardial recovery (yes/no)	X	X		
Bridge to LVAD (yes/no)	X	X		
Bridge to Transplant (yes/no)	X	X		
Cause of death	X	X		
Duration of ICU stay, days	X	X		
Duration of hospital stay, days	X	X		
Sequelae of hospital complication at discharge (yes/no)	X	X		

Details of sequelae	X	X		
Duration of mechanical ventilation(days)	X	X		
Tracheostomy (yes/no)	X	X		
Able to perform self-care at discharge (yes/no)	X	X		
Able to return to work at discharge (yes/no)	X	X		

CARDshock score calculation:

Age > 75 years (yes/no)

Confusion at presentation (yes/no)

Prior myocardial infarction of CABG (yes/no)

Acute coronary syndrome ethology (yes/no)

Blood lactate level (<2/2-4/>4)

eGRF (>60/30-60/<30 ml/min/m2)

To the eCRF section dedicated to DTI, it should be added bivalirudin.

It should be added a section that recaps the types of antibiotics use and the duration of therapy (to estimate costs):

Antibiotic class	**Use (yes/no)**	**Duration of therapy (days)**
Cephalosporines (yes/no)		
Pennicillins (yes/no)		
Penicillins (yes/no)		
Glycopeptides (yes/no)		
Fluoroquinolones (yes/no)		
Macrolides (yes/no)		
Carbapenems (yes/no)		
Lyncosamids (yes/no)		
Aminoglicosides (yes/no)		
Tetracyclins (yes/no)		
Sulfonamides (yes/no)		
Oxazolidinones (yes/no)		
Polypeptides (yes/no)		
Other (yes/no) – specify class		
Second line antibiotic therapy needed (yes/no)		

Supplementary Material 2. Healthcare resource use variables (hospital data)

The health services performed to follow-up the patients will be measured by recording the number of assessments performed over the study observation period. These data represent the items necessary to determine the direct healthcare costs incurred by the healthcare system which will be included in the Cost Effectiveness Analysis (CEA). These data are normally traced by hospital records (e.g., eHRs, administrative data), and should be only transferred into the Register platform from treating clinicians. These data are not to be asked to patients. These variables will be measured throughout the patient's the hospital stay. In this study, the following data will be recorded by the doctors during the 6-month follow-up period.

Section 1. Hospitalizations

1.1 Reason for hospitalization

- Heart failure: yes/no/unknown + number
- Ictus ischemic: yes/no/unknown + number
- Ictus hemorrhagic: yes/no/unknown + number
- Bleeding: yes/no/unknown + number
- Renal failure: yes/no/unknown + number
- Respiratory failure: yes/no/unknown + number
- Arrhythmia: yes/no/unknown + number
- Other (please specify): _____ [maximum 5 reasons]

1.2 Number of bed-days in regular ward (e.g., cardiac care ward, other): n (units)

1.3 Number of days in ICU (i.e., intensive care unit): n (units)

1.4 Procedures performed (0 if no procedures are performed)

- Blood transfusion: yes/no/unknown + number
- Dialysis: yes/no/unknown + number
- Ventilatory support: yes/no/unknown + number
- Surgery: yes/no/unknown + number
- Type of surgery (qualitative comment)
- Local interventions: Gastroscopy: yes/no/unknown + number
- Local interventions: Thoracic drainage: yes/no/unknown + number
- Local interventions: Endoscopy: yes/no/unknown + number
- Local interventions: other (please specify name and units): _____
- Physiotherapy: yes/no; nr. of weekly cycles: n (units)
- Ambulatory visit: n (units)

1.5 Exams

- CT Scan: yes/no; n (units)
- MRI: yes/no; n (units)
- Angiography: yes/no; n (units)
- Other (please specify): _____

Section 2: Pharmaceutical consumption during hospitalization

2.1 Drugs used

- Antibiotics: yes/no; days on antibiotics (units)

2.2 Medical devices used

- Nr. of Impella devices used (units)
- Nr. of ECMO devices used (units)
- Dialysis: yes/no
- Extracorporeal purification: yes/no
    - (If yes) Cytosorb: yes/no
    - (If yes) Other (please specify): yes/no + name
- Other (please specify) _____

Section 3: Emergency department

- ER access for heart failure-related symptoms: yes/no
- ER access with no subsequent hospitalization: yes/no + number
- ER access leading to hospitalization: yes/no + number
- Use of the ambulance services: yes/no

Section 4: Other relevant information

- Recovery time needed to go back to work or to "normal life" (from clinician's perspective): 30 days/60 days/120 days/NA

Supplementary Material 3. Patient questionnaire to assess the societal impact of the disease

The following questionnaire will be answered by patients. It has been translated in Italian and will be administered to patients in Italian, however it will be inserted in the Register in English. Both Italian and English versions are provided hereafter. The questionnaire is comprised of two parts:

A. baseline questionnaire, to be administered at signature of informed consent/at ICU-discharge (typically in-person);
B. follow-up questionnaire, to be administered at 6 months, typically over the phone.

*****

A. Baseline questionnaire

1. Employment status:
1.1 What is your current employment status?
If employee:
- factory worker
- employee
- manager, director

If self-employed:
- businessman/woman, freelancer
- other self-employed

If non-professional status:
- retired
- student
- housewife
- other, not employed

1.2 If you are a worker, what is your employment status?
- Full time
- Part-time: 20 hours/week
- Part-time: 24 hours/week
- Part-time: 30 hours/week
- Part-time: 36 hours/week

2. Travel information:
2.1 How much do you spend on average to reach the hospital?
€ _____

2.2 How do you typically reach the hospital?
- By car
- By public transport
- By taxi

- Other (specify)

***

B. Follow-up questionnaire

1. Out-of-pocket (OOP) expenses information:
1.1 In the past 3 months, did you sustain any expense due to cardiogenic shock?
Yes
No
1.2 If yes, what where the healthcare expenses related to?
Medical care
- Specialty visits/exams (e.g., second opinion)
- Drugs (e.g., non-reimbursable drugs, supplements)
- Psychological support
- Other (specify)

1.3 If yes, how much did you spend for each health event?
€ _____
€ _____
€ _____

2. Hospitalizations outside the clinical site of study:
2.1 In the past 3 months, were you hospitalized in a different hospital from this one?
- Yes
- No

2.2 If yes, please indicate the reason: _____ and the hospitalization duration (days): _____

2.3 Did you use emergency services?
- Emergency department
- Ambulance
- None

2.4 Did you pay for any of these services?
- Yes
- No

2.5 If yes, how much did you spend?
€ _____

3. Informal or formal assistance:
3.1 Who gave you informal assistance following your episode of cardiogenic shock? If more than one person, please indicate the one who gives you the most help.
- No one
- Spouse/cohabitant/partner

- Child
- Parent
- Brother/Sister
- Friend
- Other

3.2 If you indicated that someone assists you, how many days does this person assist you, on average, each month, due to issues related to cardiogenic shock? If you want to indicate half a day, write 0,5.
_____ days

3.3 If you indicated that someone assists you, considering the total time you receive as informal assistance from this person, please indicate what percentage you are assisted in the following activities (the sum of the percentages must make 100%):

Activities	%
Nursing activities (eg. drugs administration) and personal care (eg. getting dressed, personal washing)	
Daily activities (eg. work, study, house works, family activities, entertainment, travel)	
Psychological support	

3.4 In the past 3 months, because of complications following your case of cardiogenic shock, have you turned to paid contractors/workers for household help (e.g., babysitter, domestic helper)? (1 answer only)
1. No
2. Yes; How much did you spend? ____ €

4. Limitations caused by the pathology:
4.1 In the past 3 months, approximately how many days of work (professional or home) have you lost due to problems related to cardiogenic shock (if half a day, indicate 0.5)? Exclude any days you have missed for visits, examinations or hospitalizations.
_____ days

4.2 In the past 3 months, how many days have you missed out on activities related to your personal and social life (e.g., going out with friends, hobbies, sports, family activities, etc.) due to problems related to cardiogenic shock (if half a day, indicate 0.5)? Exclude any days you have missed for visits, examinations or hospitalizations.

_____ days

Supplementary Material 4. Patient questionnaire to assess quality of life (EQ-5D-5L)

The EQ-5D-5L questionnaire will be administered to patients included prospectively in the study. The Italian validated version of the questionnaire will be employed. The questionnaire will be administered in a paper-based format, with the clinicians supporting the administration phase (e.g., reading out loud the questions to the patients and making their answers). The questionnaire will be administered to patients in Italian, and inputted in English in the Register. The questionnaire will be administered in three time points following Impella or ECMO implantation: i) after 7 days (i.e., while the patient is still in the hospital); ii) after 30 days; iii) after 6 months of follow-up.A formal request to use the EQ-5D-5L questionnaire has been submitted via the official website (ID: 48771).

Questionario sulla salute

Versione italiana per l'Italia

(Italian version for Italy)

VERSIONE PER LA SOMMINISTRAZIONE DA PARTE DELL'INTERVISTATORE/INTERVISTATRICE

Nota per l'intervistatore/intervistatrice: sebbene si debba tenere conto del particolare stile di conversazione dell'intervistatore/intervistatrice, il testo delle istruzioni del questionario dovrà essere seguito il più fedelmente possibile. Nel caso del sistema descrittivo EQ-5D-5L a pagina 2 del questionario, il testo deve essere seguito fedelmente.

Se l'intervistato/a ha difficoltà nello scegliere una risposta, o chiede chiarimenti, l'intervistatore/intervistatrice dovrà ripetere la domanda parola per parola e chiedere all'intervistato/a di rispondere in un modo che sia il più vicino ai suoi pensieri sulla sua salute oggi.

INTRODUZIONE

(Nota per l'intervistatore/intervistatrice: legga quanto segue all'intervistato/a.)

Desideriamo conoscere ciò che pensa della sua salute. Le spiegherò cosa fare man mano che procedo, ma mi interrompa pure nel caso in cui non dovesse comprendere qualcosa o ritenesse che qualcosa non le fosse chiaro. Non ci sono risposte giuste o sbagliate. Siamo interessati solo al suo personale punto di vista.

Per prima cosa, leggerò alcune domande. Ogni domanda ha una scelta di cinque risposte. Mi dica quale risposta descrive meglio la sua salute OGGI.

Non scelga più di una risposta per ogni gruppo di domande.

(Nota per l'intervistatore/intervistatrice: per prima cosa, legga tutte e cinque le opzioni per ogni domanda. Quindi, chieda all'intervistato/a di scegliere quella che pensa si applichi a se stesso/a. Ripeta la domanda e le opzioni se necessario. Contrassegni la casella appropriata sotto ciascun titolo. Potrebbe essere necessario ricordare regolarmente all'intervistato/a che l'intervallo di tempo è OGGI.)

Ardito V, *et al. BMJ Open* 2024; 14:e078358. doi: 10.1136/bmjopen-2023-078358

SISTEMA DESCRITTIVO EQ-5D

Per prima cosa, vorremmo chiederle della CAPACITÀ DI MOVIMENTO. Direbbe che:

1. Non ha difficoltà nel camminare ❑
2. Ha lievi difficoltà nel camminare ❑
3. Ha moderate difficoltà nel camminare ❑
4. Ha gravi difficoltà nel camminare ❑
5. Non è in grado di camminare ❑

Quindi, vorremmo chiederle della CURA DELLA PERSONA. Direbbe che:

1. Non ha difficoltà nel lavarsi o vestirsi ❑
2. Ha lievi difficoltà nel lavarsi o vestirsi ❑
3. Ha moderate difficoltà nel lavarsi o vestirsi ❑
4. Ha gravi difficoltà nel lavarsi o vestirsi ❑
5. Non è in grado di lavarsi o vestirsi ❑

Quindi, vorremmo chiederle delle ATTIVITÀ ABITUALI, per es. lavoro, studio, lavori domestici, attività familiari o di svago. Direbbe che:

1. Non ha difficoltà nello svolgimento delle attività abituali ❑
2. Ha lievi difficoltà nello svolgimento delle attività abituali ❑
3. Ha moderate difficoltà nello svolgimento delle attività abituali ❑
4. Ha gravi difficoltà nello svolgimento delle attività abituali ❑
5. Non è in grado di svolgere le attività abituali ❑

Quindi, vorremmo chiederle quanto DOLORE O FASTIDIO prova. Direbbe che:

1. Non prova alcun dolore o fastidio ❑
2. Prova lieve dolore o fastidio ❑
3. Prova moderato dolore o fastidio ❑
4. Prova grave dolore o fastidio ❑
5. Prova estremo dolore o fastidio ❑

Infine, vorremmo chiederle dell'ANSIA O DEPRESSIONE. Direbbe che:

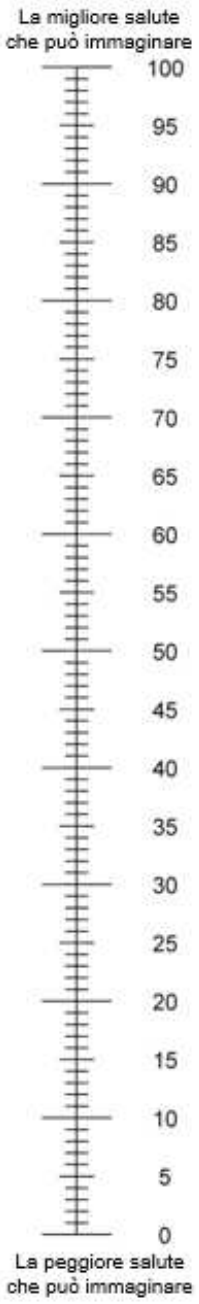
1. Non è ansioso/a o depresso/a ❑
2. È lievemente ansioso/a o depresso/a ❑
3. È moderatamente ansioso/a o depresso/a ❑
4. È gravemente ansioso/a o depresso/a ❑
5. È estremamente ansioso/a o depresso/a ❑

EQ-5D VAS

- **Adesso, vorremmo sapere quanto è buona o cattiva la sua salute OGGI.**
- **Vorremmo che immaginasse una linea verticale numerata da 0 a 100.**
  (Nota per l'intervistatore/intervistatrice: in caso di intervista faccia a faccia, mostrare all'intervistato/a la linea VAS.)
- **100 in cima alla linea rappresenta la migliore salute che può immaginare.**

  0 in fondo alla linea rappresenta la peggiore salute che può immaginare.
- **Vorrei che ora mi indicasse un punto sulla linea per indicare com'è la sua salute OGGI.**
  (Nota per l'intervistatore/intervistatrice: contrassegni la linea nel punto che indica la salute dell'intervistato/a OGGI. Ora, scriva il numero indicato sulla linea nella casella sottostante.)

LA SALUTE DELL'INTERVISTATO/A OGGI = ☐



Grazie per il tempo dedicato a rispondere a queste domande.