

HEART PRESERVATION WITH THE ORGAN CARE SYSTEM IN GERMANY - REVIVAL IN HIGH RISK RECIPIENTS

Fabio Ius¹, Michael Berchtold-Herz², Sebastian V Rojas¹, Tim Kaufeld¹, Johannes Scheumann², Murat Avsar¹, Jawad Salman¹, Christoph Bara¹, Friedhelm Beyersdorf², Axel Haverich¹, Matthias Siepe^{2, 3}, Gregor Warnecke^{1,3}.

¹Department of Cardiothoracic, Transplant and Vascular Surgery, Hannover Medical School, Hannover, Germany

²Department of Thoracic and Cardiovascular Surgery, University of Freiburg, Freiburg, Germany

³These two authors share senior authorship.

Objectives. The Organ Care System (OCS) Heart® (figure 1) is non-inferior compared to standard cold storage for preservation of donor hearts. We hypothesized that its properties for prolonged heart preservation might be especially beneficial for complex high risk recipients with previous cardiac surgery.

portable ex-vivo heart perfusion system

OCS perfusion parameters are reported in figure 4. In addition, 8 distant retrievals (Northern Ireland, Lithuania, Italy, Croatia, Austria and Slovenia) were only realized for their respective recipients with previous surgery without exceeding the maximum ischemic time because the OCS was available.

Organ Care System Console Portable, integrated perfusion & assessment system, fits in all standard modes of transportation for donor organs TransMedics

Wireless
Monitor
Displays physiologic and functional parameters of

Perfusion
Module
A sterile chamber
housing the heart and
circulating perfusate

Heart Solution
Set
Infused into blood
circulation; provides

nutrients and substrates

Figure 1.

The OCS™ Heart

Methods. Patients transplanted using the OCS Heart[®] at our 2 institutions between 10/2016 and 03/2018 were prospectively followed. All recipients were potentially considered eligible, but an effort was made to apply the OCS Heart[®] especially in challenging cases with previous cardiac surgery (figure 2).

Applications of The OCS™ Heart: high-risk recipients & donors <u>High risk recipients:</u>

LVAD/BiVAD and previous other cardiac operations.

High risk donors (extended criteria donors):

- Prolonged predicted ischemic time (> 4 hours).
- Left ventricular hypertrophy.
- Unknown coronary artery disease status (lack of coronary angiography) or coronary sclerosis.
- · Reduced left ventricular ejection fraction.

Figure 2.

Results. During the study period, among the 51 transplanted patients, 28 (55%) high risk recipients were transplanted using the OCS for donor heart preservation. Recipient and donor characteristics are reported in figures 3.

Recipient characteristics (n=28)		Donor characteristics (n=28)	
Variable	N (%) or median (IQR)	Variable	N (%) or median (IQR)
Sex (Male)	18 (64)	Sex (Male)	16 (57)
Age (years)	49 (32, 61)	Age (years)	45 (30 - 57)
Previous operations	25 (89)	Max. norepinephrine support	0.08 (0.04 – 0.15)
LVAD	18 (64)	(gamma)	
BiVAD	1 (4)	Smoking history	12 (43)
Other	6 (21)	Alcohol/substance abuse	13 (46)
Time on VAD (months)	30 (17, 54)	Arterial Hypertension	8 (29)
Number of cardiac redo	2 (1, 3)	Left ventricular hypertrophy (any degree)	10 (36)
Reason for HU			1 (4)
VAD/Driveline infection	7 (29)	Coronary artery disease (any degree)	1 (4)
VAD Dysfunction	5 (21)	Cardiopulmonary resuscitation	9 (32)
Other	12 (50)	Reduced (<60%) LV function	4 (14)
Preoperative ECMO	2 (7)	Donor outside Germany	9 (32)
support			Figure 3.

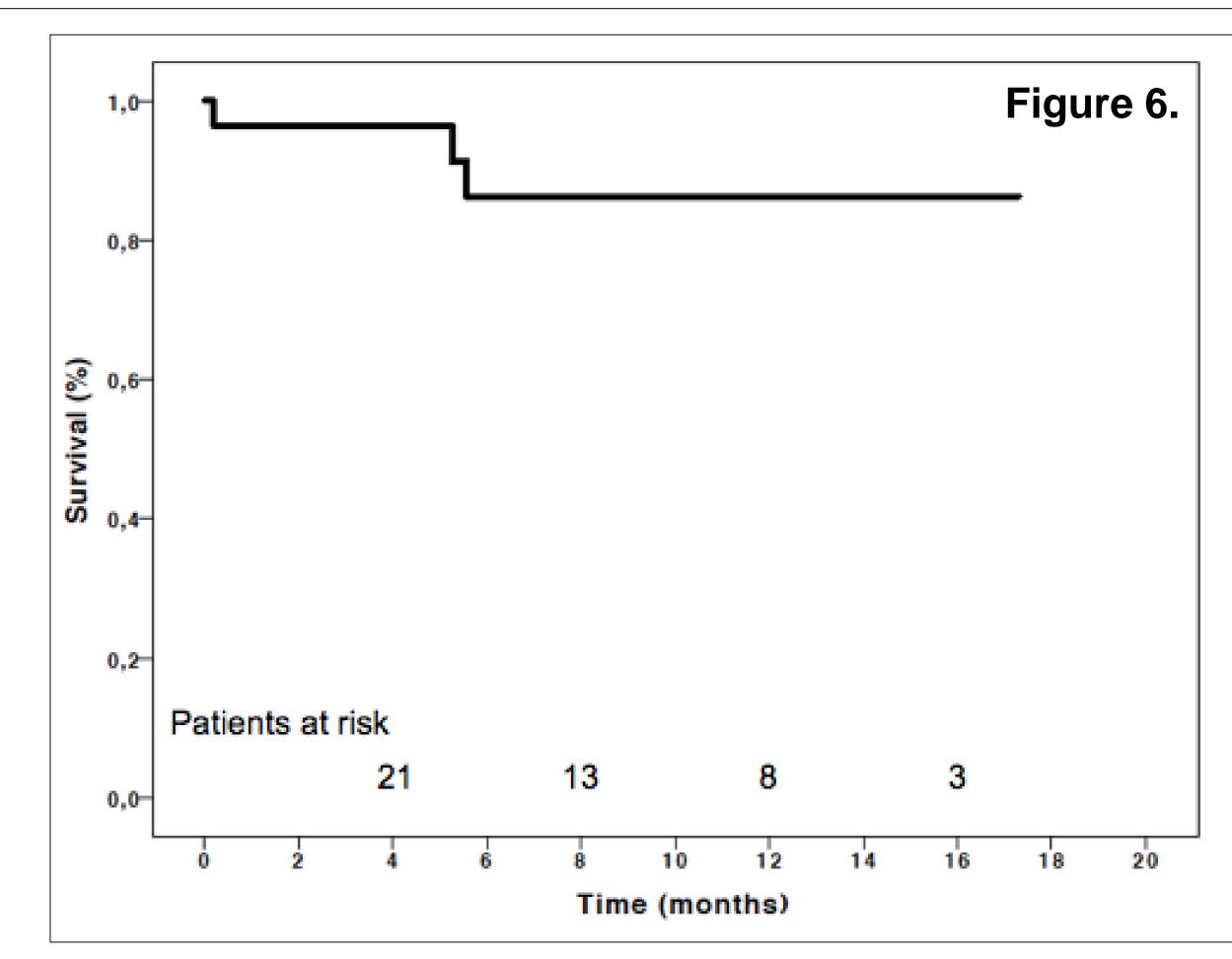
Most of the patients (89%) had already undergone a cardiac operation, being a VAD implant in 68% of patients. Three (11%) patients had required at least one VAD exchange. Four (14%) patients had undergone complex cardiac operations due to congenital defects and 2 (7%) patients cardiac transplantation.

Figure 4. OCS perfusion paral	meters (n=28)
Variable	mean (SD)
OCS perfusion time (hours)	4.81 ± 0.92
"Out of body" time (hours)	6.73 ± 0.92
Pump flow (mL/min)	$1,038 \pm 38$
Coronary flow (mL/min)	788 ± 51
Mean aortic pressure (mmHg)	86 ± 6
Arterial lactate (mmol/L)	
Beginning	1.85 ± 0.49
End	2.49 ± 1.40
Venous lactate (mmol/L)	
Beginning	1.91 ± 0.51
End	2.45 ± 1.42
Hearts on OCS and not transplanted	0 (0)

Postoperative course is reported in figure 5. Three (11%) patients required postoperative ECLS. The first patient showed pulmonary embolism and ECLS was successfully weaned after 4 days support. The second and third patient showed severe PGD of the left ventricle. The donor heart had developed elevated lactate levels in the OCS. In both patients, ECLS was successfully weaned after 6 days support respectively.

Figure 5.	Postoperative course (n=28)			
	Variable	N (%), median (IQR) or mean (SD)		
Rethoracotomy for bleeding		3 (11)		
Temporary ne	w dialysis treatment	19 (68)		
	At discharge	2 (7)		
Postoperative v.a. ECMO		3 (11)		
	Weaned	3 (11)		
Severe PGD I	left ventricle (ISHLT Consensus)	2 (7)		
Tracheostomy	/	2 (7)		
Ventilation tim	ne (days)	2 (1, 3)		
ICU stay time	(days)	7 (5, 12)		
In-hospital mo	ortality	1 (4)		
LV EF >= 60%	6 at discharge	27 (96%)		

At follow-up end (median 8 months), survival (figure 6) and freedom from biopsy-confirmed rejection (ISHLT grade >1R) were 86% and 96%.



Conclusions. OCS Heart[®] allowed safe transplantation of surgically complex recipients. Despite preservation time was approaching 7 hours, enabling allocations otherwise not acceptable, patient and graft outcomes were favourable.