Evaluation of the Organ Care System in Heart Transplantation With an Adverse Donor/Recipient Profile

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Background. **A severe shortage of available donor organs has created an impetus to use extended criteria organs for heart transplantation. Although such attempts increase donor organ availability, they may result in an adverse donor-recipient risk profile. The TransMedics Organ Care System (OCS) (TransMedics, Inc, Boston) allows preservation of the donor heart by perfusing the organ at 34°C in a beating state, potentially reducing the detrimental effect of cold storage and providing additional assessment options. We describe a single-center experience with the OCS in high-risk heart transplant procedures.**

Methods. **Thirty hearts were preserved using the OCS between February 2013 and January 2014, 26 of which (86.7%) were transplanted. Procedures were classified as high risk based on (1) donor factors, ie, transport time more than 2.5 hours with estimated ischemic time longer than 4 hours, left ventricular ejection fraction (LVEF) less than 50%, left ventricular hypertrophy (LVH), donor cardiac arrest, alcohol/drug abuse, coronary artery disease or (2) recipient factors, ie, mechanical circulatory support or elevated pulmonary vascular resistance (PVR), or both.**

Results. **Donor and recipient age was 37 ± 12 years and 43 ± 13 years, respectively. Allograft cold ischemia time was 85 ± 17 minutes and OCS perfusion time was 284 ± 90 minutes. The median intensive care unit stay was 6 days. One death (3.8%) was observed over the follow-up: 257 ± 116 (109–445 days). There was preserved allograft function in 92% of patients, with a mean LVEF of 64% ± 5%.**

Conclusions. **Use of the OCS is associated with markedly improved short-term outcomes and transplant activity by allowing use of organs previously not considered suitable for transplantation or selection of higher risk recipients, or both.**

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Despite ongoing improvements in mechanical circulatory support, heart transplantation remains the gold standard treatment for appropriately selected patients with advanced heart failure, leading to the best long-term outcome [1]. However, heart transplantation has a high early mortality, caused almost entirely by donor organ failure. Under conventional conditions of donor organ preservation, ie, cardioplegic arrest and cold storage, prolonged cold ischemia time is by far the greatest risk factor for primary allograft dysfunction and death [2, 3]. Moreover, cold ischemia time multiples other risk factors, such as donor left ventricular hypertrophy (LVH).

The TransMedics Organ Care System (OCS) is the first commercially available system that allows the beating donor heart to be maintained in a warm (34°C) perfused oxygenated state during transfer from donor to recipient. This allows for an extended "out of body" time and minimizes the detrimental effects of cold ischemic storage [4].

The OCS also allows ex vivo donor heart assessment. Data presented by Hamed and colleagues [5] along with interim results from the PROCEED II trial (a prospective, randomized [1:1] multicenter noninferiority study comparing the safety and efficacy of the OCS with the cold storage of donor hearts) suggest that a

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Abbreviations and Acronyms

HVAD = HeartWare left ventricular assist device
IABP = intraaortic balloon pump
LVAD = left ventricular assist device
LVEF = left ventricular ejection fraction
OCS = Organ Care System
PVR = pulmonary vascular resistance

rising lactate level is a reliable marker of donor heart abnormality [5, 6]. The heart OCS may be particularly well suited to the assessment of "extended criteria" donor hearts with reduced left ventricular ejection fraction (LVEF), LVH, previous donor cardiac arrest, prolonged predicted ischemic time (> 4 hours), alcohol/substance abuse, and unknown coronary artery disease status because of a lack of coronary angiography [7–9].

Previous attempts to use extended criteria allografts, with the aim of addressing the severe shortage of available donor organs has increased organ availability but has also resulted in high-risk organ/recipient combinations and poor outcomes [2]. The individual risk-benefit ratio is further affected by the ever-increasing complexity of today's recipients, such as the presence of left ventricular assist devices (LVADs) and severe pulmonary hypertension. In particular, transplantation in patients with LVADs is challenging, and the concept of LVAD bridging on outcomes after transplantation has been controversial. Some experienced centers have comparable posttransplantation results in this group [10, 11]; however, the international registries continue to identify it as a risk factor for increased mortality [12, 13].

In this article, we report a single-center experience of 30 consecutive donor procurements using the OCS, 26 of which were subsequently used for high-risk heart transplantation.

Material and Methods

The Heart OCS

The heart OCS (Transmedics Inc, Boston, MA) is composed of an organ-specific perfusion module with disposable and nondisposable parts and a compact wireless monitor. The monitor displays real-time system and organ measurements, such as aortic pressure, coronary flow, blood temperature, and heart rate. The heart is perfused in the resting mode (Fig 1). Warm oxygenated blood is pumped into the aorta, thereby perfusing the coronary arteries, and deoxygenated blood enters the right atrium through the coronary sinus and passes through the tricuspid valve to the right ventricle. The blood is then ejected through the pulmonary artery to the blood oxygenator and is returned to the reservoir.

Organ Procurement and Connection to the OCS

After provisional acceptance of the donor hearts based on available clinical information, our team performed a detailed organ assessment at the time of donation that included transesophageal echocardiography, cardiac output studies using a pulmonary artery catheter, direct evaluation of the coronary arteries, and measurement of left and right atrial pressures.

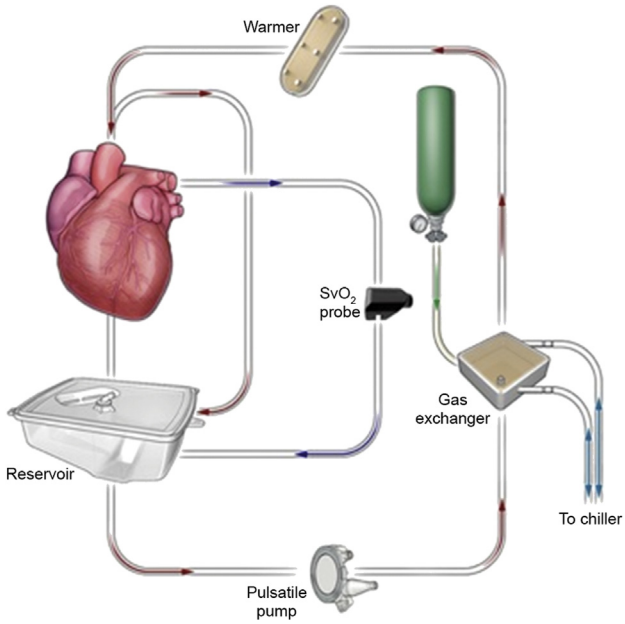

Fig 1. Organ Care System (OCS) support unit (resting perfusion mode).

Donors were transfused with red blood cells, if necessary, to raise the serum hemoglobin level to 10 g/dL. Immediately before aortic cross-clamping, the right atrial appendage was cannulated using a 34F venous cannula, thereby allowing approximately 1.5 L of donor blood to be collected to prime the OCS module. Unfractionated heparin 10,000 IU was added to the blood collection bag in addition to the standard donor heparinization protocol (300 IU/kg). Cardioplegia was instituted with Custodiol HTK (Essential Pharmaceuticals, Ewing, NJ) at 4°C (800–1,000 mL depending on donor size) was used to induce cardiac arrest and protect against ischemic injury during the period before the heart was connected to the OCS.

Heart Management and Assessment on OCS

Donor hearts were implanted on the OCS using the proprietary heart instrumentation tool set. Four double-pledgeted 2-0 Ethibond sutures (Ethicon, Inc, Somerville, NJ) were applied at 90-degree intervals to the cut edge of the ascending aorta, and an appropriate aortic tip insert (4 different sizes from 19.1–31.8 mm) was placed in the aorta. A cable tie tool was used to secure the tip of the aorta to the aortic tissue. The pulmonary artery was cannulated using a 30F cannula, which was inserted into the lumen of the pulmonary artery and secured with a 3-0 polypropylene purse-string suture. The pulmonary artery cannula was then retracted to avoid any interference with the pulmonary valve motion and was secured with a