Dual chamber stent prevents organ malperfusion in a model of donation after cardiac death

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Background. *The paradigm for donation after cardiac death subjects donor organs to ischemic injury. A dual-chamber organ perfusion stent would maintain organ perfusion without affecting natural cardiac death. A center lumen allows uninterrupted cardiac blood flow, while an external chamber delivers oxygenated blood to the visceral vessels.*

Methods. *A prototype organ perfusion stent was constructed from commercial stents. In a porcine model, the organ perfusion stent was deployed, followed by a simulated agonal period. Oxygenated blood perfused the external stent chamber. Organ perfusion was compared between controls (n = 3) and organ perfusion stent (n = 6). Finally, a custom, nitinol, dual chamber organ perfusion stent was fabricated using a retrievable "petal and stem" design.*

Results. *Endovascular organ perfusion stent deployment achieved visceral isolation without adverse impact on cardiac parameters. Visceral oxygen delivery was 4.8-fold greater compared with controls. During the agonal period, organs in organ perfusion stent–treated animals appeared well perfused in contrast with the malperfused controls. A custom nitinol and polyurethane organ perfusion stent was recaptured easily with simple sheath advancement.*

Conclusion. *An organ perfusion stent maintained organ perfusion during the agonal phase in a porcine model of donation after cardiac death organ donation without adversely affecting cardiac function. Ultimately, the custom retrievable design of this study may help resolve the critical shortage of donor organs for transplant. (Surgery 2016;160:892-901.)*

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THE SINGLE MOST IMPORTANT OBSTACLE FACING SOLID ORGAN TRANSPLANTATION remains overcoming the critical shortage of healthy donor organs. In the United States, of the >120,000 patients awaiting a solid organ transplant, only 1 of 4 actually will receive one. Among consented organ donors, periods of insufficient blood flow lead to organ injury and represent the greatest hurdle to the availability of healthy donor organs.[1,2] Rapid cooling of the organ is the best way to avoid injury to the donor organ to provide the best long-term outcome.

Ideal organs are recovered from donation after brain death (DBD) or living donors (LD), wherein blood flow remains normal until the exact moment when the organs are cooled. As the combined number of DBD and LD has plateaued, donors from these groups are unlikely to resolve

the current shortage of organs for transplant. In the past decade, growth has been demonstrated in another donor group, donation after cardiac death (DCD), which includes patients with severe nonrecoverable injuries.[3-5] An example of a potential DCD donor would be a patient with a severe head injury who would never recover but does not meet the stringent criteria for brain death. After family consent for organ donation, the patient has cardiopulmonary life support discontinued, and during the "agonal period" as the heart begins to fail, perfusion of organs becomes inadequate. This malperfusion leads to irreversible ischemic organ damage, and the longer the agonal period, the more damage to the organs. Current standards dictate that organs be discarded after agonal periods >30 minutes for the liver and >40 minutes for the kidneys. In addition to fewer organs being recovered from each consented DCD donor, organ function and patient outcomes are inferior among DCD organs[3,6-9] including failure of the transplanted organ. For these reasons, minimizing ischemic time is instrumental in improving the availability and outcomes of DCD donor organs.

The ethics of DCD organ recovery pose several important obstacles in decreasing the ischemic injury and include the following: (1) operative exposure of organs must not occur prior to cardiac death, and (2) cardiac death must not be expedited. Approaches such as dual occlusive balloon catheters have been described to isolate organ perfusion,[10,11] but the resulting complete aortic occlusion would expedite cardiac death and, therefore, cannot be used before a natural cardiac arrest. Moreover, because ischemic injury has already occurred by the time of cardiac arrest, postmortem approaches have failed to offer any benefit to the outcome of DCD organs.

To meet these challenges, we developed a novel stent approach with the goal of isolating the visceral arteries for oxygenated perfusion separate from the systemic circulation. For vascular isolation in a critically ill prospective donor, a stent design offers several clear advantages. Because the stent is placed percutaneously, it requires no incisions and is similar to the catheters a donor would already have in place. The inherent radial force of a stent mediates apposition to the vessel wall to create a vascular seal. The designs of traditional stents, however, do not meet the simultaneous objectives for visceral (abdominal organ) perfusion while maintaining uninterrupted cardiac flow.

A cornerstone of our approach is a dual-chambered organ perfusion stent (OPS). A central stent lumen provides uninterrupted flow from the heart to the rest of the body, while an external chamber consolidates perfusion of the 4 visceral vessels. With this approach, the stent isolates the aorta into 2 zones for separate "cardiac" and "organ" perfusion (Fig 1). The flow of blood in each chamber would circulate as follows: For cardiac perfusion, blood from the heart would continue to flow through the center lumen of the stent to the lower body and extremities. The blood would return to the heart through normal venous pathways from the lower body, thus avoiding strain on the dying heart. This would allow for uninterrupted, albeit agonal, blood flow to the heart, brain, and extremities. For abdominal perfusion, a standard venous cannula would deliver blood to a pump/oxygenator, and a perfusion sheath would carry oxygenated blood to the external stent chamber, thereby perfusing only the arteries of the isolated abdominal organs.

Conceptually, one of the biggest obstacles to an OPS approach is concerns about whether stent placement would expedite cardiac death in the prospective donor. Any substantial decrease in the preload (pressure of blood entering the heart) or increase in the afterload (pressure out of the heart) would expedite cardiac death and is against ethical tenets for a prospective DCD organ donor. Our proposed approach addresses this issue effectively. The OPS decreases the aorta size by <50% of normal, which is unlikely to affect blood flow by vascular hemodynamic principles.[12] As a result, we did not expect that this approach would increase cardiac work or expedite cardiac death. In fact, modern experience with endovascular aortic repair suggests that these stent grafts can remodel aortic hemodynamics rapidly without substantial risk, even among patients with substantial cardiopulmonary disease.[13]

We have designed a novel dual chamber stent to isolate the abdominal organs from the unpredictable function of the dying heart to preserve organ function during the agonal phase of DCD organ donation. This approach contrasts with any other previous approaches in that the heart would continue to function, failing on its own terms. This feature would allow visceral perfusion to be initiated prior to withdrawal of life support and provide the optimal outcome for donor organs without expediting the death of the prospective donor. The objectives of this study are to examine whether the stent deployment increases cardiac stress, if the stent can consolidate visceral arteries successfully, and whether the dual chamber approach can improve delivery of oxygen