Transcatheter Valve Implantation in Patients With Dysfunctional Left and Right Sided Heart Valves

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SUMMARY

Many forms of congenital and structural heart disease require surgical placement of prosthetic valves and conduits. These conditions include many common congenital heart abnormalities such as Tetralogy of Fallot, Double Outlet Right Ventricle, Truncus Arteriosus and patients who require the Ross procedure for aortic stenosis. There are a variety of acquired conditions, including calcific aortic valve stenosis that may require surgical or transcatheter valve treatment. Unfortunately, when valved conduits are placed surgically, they ultimately become narrowed or regurgitant and require periodic replacement, Thus, patients with these conditions often undergo multiple open-heart surgeries during their lifetime. Although the risk of mortality with this kind of surgery is low, surgical intervention is associated with significantly longer recovery times and greater patient discomfort when compared to transcatheter interventions. Over the last decade, techniques have been developed to palliate these forms of congenital and structural heart disease using catheters inserted through blood vessels in the groin. These transcatheter techniques have allowed patients to delay or avoid open-heart surgery.

The Medtronic Melody Transcatheter Valve and the Edwards SAPIEN Transcatheter Heart valve are both bioprosthetic valves mounted within metal stents. Their entire structure is collapsible, allowing it to be inserted through delivery sheaths and threated into the heart, typically without the need of surgical cardiopulmonary bypass. Some of these procedures may be performed using a hybrid technique of minimal surgical access and transcatheter valve delivery. The valves can then be expanded into place by inflating a balloon (similar to how stents are placed elsewhere in the heart, like the coronary artery). The Melody Valve received a humanitarian device exemption (HDE) from the FDA and the Edwards SAPIEN Valve has market approval from the FDA for implantation in the aortic position. The investigators plan to offer these transcatheter valves as alternatives to eligible patients who require replacement of a stenotic or regurgitant valve in all left and right sided positions.

The Melody Valve and Edwards SAPIEN Valve are presently being utilized at multiple United States centers for valve replacement in all positions (pulmonary, aortic, tricuspid, and mitral) in patients who are considered high-risk candidates for surgical valve replacement. The use of the devices on this protocol are for medical treatment and are not part of a clinical trial.

OBJECTIVES

The risks of cardiac surgery include bleeding, stroke, renal failure, and death among other potential complications. The use of cardiopulmonary bypass allows surgeons to operate on the non-beating heart; however, cardiopulmonary bypass is associated with acute potential complications as well as long-term sequelae such as neurologic damage, decreased cognitive

capacity, and heart damage. Furthermore, the pain associated with cardiac surgery is significant and recovery times range from weeks to months. The goal is to improve the quality of patient long-term survival by lifetime patient management. To this end, the transcatheter deployment of the Melody and SAPIEN devices aim to reduce the number of surgeries required over a lifetime by this patient population.

The intended role of the Melody Transcatheter Valve is to restore pulmonary valve function in patients with a dysfunctional right ventricular outflow tract (RVOT) conduit and a clinical indication for pulmonary valve replacement. Unlike currently available options for pulmonary valve replacement, the transcatheter pulmonary valve (TPV) is intended to be placed with a transcatheter delivery system, and thus does not require surgical incisions, open-heart surgery, or cardiopulmonary bypass. The ultimate goals and durability of the TPV may differ among patients with different indications. At a minimum, the intention is that the TPV will improve the hemodynamic function of the existing conduit, mitigate the adverse impact of pulmonary regurgitation and/or RVOT obstruction, and effectively extend the longevity of the existing conduit and defer the need for conduit replacement. In some patients, delaying surgical conduit re-intervention may reduce the number of open-heart surgeries required over the course of their lifetime, thereby decreasing the cumulative morbidity and risk associated with such operations.

Use of the Melody valve and the Edwards SAPIEN Valve outside of their approved indications for valve replacement have been published but the data is limited. The available reports suggest that both the Melody Valve and the Edwards SAPIEN Valve are efficacious and can be safely deployed in the positions outside of their intended use. We intend on offering this intervention to patients that are deemed to be high-risk for traditional surgical valve replacement.

DESIGN & METHODS

Patients and/or their legal guardians will be consented for implantation of the TPV prior to the procedure by the implanting physician(s). Transcatheter valves are typically implanted in the cardiac catheterization laboratory under general anesthesia. Patients will recover in the post-anesthesia care unit (PACU) and will be admitted to the hospital for observation following the procedure. Patients may be offered treatment with a transcatheter valve replacement when there is no other reasonable option (when they are deemed at a high risk for adverse events by a consulting cardiac surgeon).

Prior to implantation, financial authorization will be obtained from patients' medical insurance providers. Patients will be informed that they and/or their medical insurance provider will be responsible for the cost of the procedure. Patients will also be informed of the estimated costs associated with implantation of a transcatheter valve. They will be given the opportunity to discuss these costs with the implanting physician and/or UCLA Patient Business Services prior

to the procedure. Patients will be advised to check with their insurance to see if it will cover the costs of the device implantation, and removal if deemed unsuccessful.

The Edwrads SAPIEN Valve will be preferred over the Melody Valve when the annulus or circumference of the landing zone is greater than 23 mm in diameter. For valve replacements in regions smaller than 23 mm in diameter, The Melody Valve will be used.