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LAMPOON to Facilitate Tendyne Transcatheter Mitral Valve Replacement

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Transcatheter mitral valve replacement may cause fatal left ventricular outflow tract (LVOT) obstruction due to septal displacement of the anterior mitral leaflet. "Geometric obstruction" from the transcatheter valve can be predicted by calculating the "neo-LVOT" on 3-dimensional computed tomography (CT) reconstructions. "Dynamic obstruction" from systolic anterior motion (SAM) of the anterior mitral leaflet may be predicted from acute aortomitral angulation, prominent septal bulge, long anterior mitral leaflet, and redundant mitral chordae (1–3). The technique of intentional electrosurgical laceration of the anterior mitral leaflet to prevent left ventricular outflow obstruction (LAMPOON) has been used successfully in patients to prevent LVOT obstruction after Sapien 3 valve (Edwards Lifesciences, Irvine, California) implantation in annuloplasty rings or mitral annular calcification (4,5) and is the subject of an ongoing trial (NHLBI DIR LAMPOON Study: Intentional Laceration of the Anterior Mitral Leaflet to Prevent Left Ventricular Outflow Tract Obstruction During Transcatheter Mitral Valve Implantation; NCT03015194).

We report the first use to our knowledge of LAMPOON with a dedicated transcatheter mitral valve (Tendyne, Abbott, Abbott Park, Illinois) to prevent LVOT obstruction due to SAM.

The Tendyne bioprosthetic mitral valve system is a trileaflet pericardial valve mounted in a coaxial dual-frame covered stent, fixed using an adjustable apical tether. In certain cases where Tendyne implantation creates a narrow LVOT—in the setting of aforementioned risk factors for SAM—LVOT obstruction, malapposition, and paravalvular leak (PVL) are potential complications.

The procedure was tested in an anesthetized pig predicted to have LVOT obstruction following Tendyne valve implantation. The pig had transapical Tendyne implantation, followed by valve retrieval, LAMPOON, and repeat Tendyne implantation. LVOT gradients were measured by echocardiography and catheterization after each implantation.

A Yorkshire pig with a 23-mm anterior mitral leaflet had visible SAM after initial Tendyne implantation with LVOT gradients of 26 mm Hg by echocardiography and 16 mm Hg by catheterization. There was a severe anterior PVL because SAM prevented sealing of the valve on the anterior side. Following full retrieval of the Tendyne valve, LAMPOON and

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reimplantation of the Tendyne valve in the same animal, there was no SAM, with 3 mm Hg LVOT gradient by echocardiography and no gradient by catheterization. The PVL resolved completely (Figure 1).

A 79-year-old man with severe functional mitral regurgitation failed screening for Tendyne valve implantation due to predicted LVOT obstruction from SAM, based on the long anterior leaflet length (27 mm), redundant chordae, and acute aortomitral angulation (115°). The U.S. Food and Drug Administration approved "compassionate use" of the Tendyne device using the LAMPOON technique. Two retrograde transfemoral guiding catheters directed a guidewire through the base of the A2 scallop. Apical access was obtained and a chord-free trajectory established before LAMPOON laceration. The leaflet was lacerated down the centerline by electrifying the guidewire, and then the large sheath was introduced and Tendyne valve implanted.

The patient had successful LAMPOON and Tendyne implantation with no LVOT obstruction by catheterization or echocardiography, and there was no detectable SAM (Figure 1). Final mitral valve gradient was 2 mm Hg. There was no paravalvular mitral regurgitation.

This is the first report of LAMPOON being combined with a dedicated transcatheter mitral valve, enabling implantation despite predicted LVOT obstruction. It is the first retrievable valve, and therefore the first control-arm experiment to be performed with LAMPOON in an animal model. We also report a novel mechanism of PVL caused by SAM preventing sealing on the anterior surface of the transcatheter mitral valve. Leaflet laceration did not cause severe hemodynamic compromise in the patient, similar to the early LAMPOON experience with trans-septal transcatheter mitral valve replacement with Sapien 3 valves (Edwards Lifesciences) (5). By performing LAMPOON first with only balloon- catheter and stiff wire across the mitral valve, the duration of large-bore apical access, and associated morbidity, was not prolonged.

Like splitting a sail, splitting the anterior leaflet may prevent Bernoulli forces from dragging the leaflet toward the septum, which in turn could obstruct outflow and impair prosthetic sealing. However, LAMPOON can only alleviate "geometric" LVOT obstruction, caused by valves that protrude toward the septum, in transcatheter valves with uncovered stent cells across the LVOT.

Transcatheter laceration of the anterior mitral leaflet may enable implantation of certain dedicated transcatheter mitral valves where SAM is predicted to cause LVOT obstruction or PVL. Improved prediction models would aid selection of patients for this treatment.

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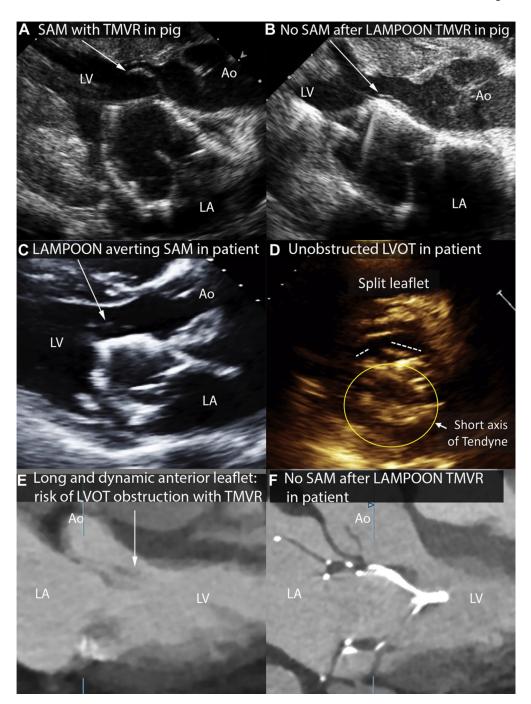


FIGURE 1. LAMPOON to Facilitate Tendyne Transcatheter Mitral Valve Replacement

(A) Transthoracic echocardiogram of Tendyne implantation without LAMPOON in a pig demonstrating SAM (**arrow**) causing LVOT obstruction and anterior PVL. (**B**) Following LAMPOON, SAM, LVOT obstruction, and PVL are abolished (**arrow**). Transthoracic (**C**) and transesophageal (**D**) echocardiograms following LAMPOON and Tendyne valve implantation in a patient showing a split anterior leaflet (**dashed lines**) and no SAM (**arrow**). (**E**) CT with motion artefact in diastole with long anterior mitral leaflet with close approximation to the interventricular septum and acute aortomitral angulation. (**F**) Post-

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procedure CT in systole with no evidence of LVOT obstruction. Ao = aorta; CT = computed tomography; LA = left atrium; LAMPOON = laceration of the anterior mitral leaflet to prevent left ventricular outflow obstruction; LV = left ventricle; LVOT = left ventricular outflow tract; PVL = paravalvular leak; SAM = systolic anterior motion; TMVR = transcatheter mitral valve replacement.

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