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PII: S1936-8798(16)30877-9
DOI: 10.1016/j.jcin.2016.06.020
Reference: JCIN 2670

To appear in: JACC: Cardiovascular Interventions

Received Date: 23 May 2016
Revised Date: 13 June 2016
Accepted Date: 13 June 2016

Please cite this article as: Khan JM, Rogers T, Schenke WH, Mazal JR, Faranesh AZ, Greenbaum AB, Babaliaros VC, Chen MY, Lederman RJ, Intentional Laceration of the Anterior Mitral Valve Leaflet to Prevent Left Ventricular Outflow tract ObstructioN (LAMPOON) during Transcatheter Mitral Valve Implantation: Preclinical Findings, JACC: Cardiovascular Interventions (2016), doi: 10.1016/j.jcin.2016.06.020.

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Intentional Laceration of the Anterior Mitral Valve Leaflet to Prevent Left Ventricular Outflow tract Obstruction (LAMPOON) during Transcatheter Mitral Valve Implantation: Preclinical Findings

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Running title: LAMPOON: Splitting the Anterior Mitral Leaflet to Enable TMVR

Word Count: 3595

Conflicts of Interest:
ABG serves as a proctor for Edwards Lifesciences and St Jude Medical, which manufacture transcatheter heart valves.
VCB is a consultant for Edwards Lifesciences and for Abbott Vascular, and his employer has research contracts for multicenter investigation of transcatheter aortic and mitral devices from Edwards Lifesciences, Abbott Vascular, Medtronic, St Jude Medical, and Boston Scientific. No other author has a financial conflict of interest related to this research.
ABSTRACT

Objectives

We propose a novel transcatheter transection of the anterior mitral leaflet to prevent iatrogenic outflow tract obstruction during transcatheter mitral valve implantation (TMVR).

Background

Left ventricular outflow tract (LVOT) obstruction is a life-threatening complication of TMVR, caused by septal displacement of the anterior mitral leaflet.

Methods

In vivo procedures in swine were guided by biplane X-ray fluoroscopy and intracardiac echocardiography. Retrograde transaortic 6Fr guiding catheters straddled the anterior mitral leaflet. A stiff 0.014” guidewire with polymer jacket insulation was electrified and advanced from the LVOT, through the A2 leaflet base, into the left atrium. The wire was snared and externalized; forming a loop that was energized and withdrawn to lacerate the anterior mitral leaflet.

Results

The anterior mitral leaflet was successfully lacerated in seven live and one post-mortem heparinized swine. Lacerations extended to 89 ± 19% of leaflet length and were located within 0.5 ± 0.4mm of leaflet centerline. The chordae were preserved and retracted the leaflet halves away from the LVOT. LVOT narrowing after benchtop TMVR was significantly reduced with LAMPOON than without (65% ± 10% vs. 31 ± 18% of pre-implant diameter, p<0.01).
LAMPOON caused mean blood pressure to fall (54 ± 6 to 30 ± 4mm Hg, p<0.01), but remained steady until planned euthanasia. No collateral tissue injury was identified on necropsy.

Conclusions

Using simple catheter techniques we transected the anterior mitral valve leaflet. Cautiously applied in patients, this strategy can prevent anterior mitral leaflet displacement and LVOT obstruction caused by TMVR.

Key Words: Transcatheter mitral valve implantation, Left ventricular outflow tract obstruction, Structural heart disease, Valvular heart disease, Mitral valve, Subvalvular aortic stenosis

CONDENSED ABSTRACT

Left ventricular outflow tract (LVOT) obstruction is a potentially fatal complication of transcatheter mitral valve implantation, caused by septal displacement of the anterior mitral leaflet. Patients at risk are denied potentially life-saving intervention. We propose a novel transcatheter transection of the anterior mitral leaflet, which was performed successfully in swine under X-ray fluoroscopy and intracardiac echocardiography guidance. 6Fr guiding catheters straddled the anterior mitral leaflet and an electrified guidewire traversed the A2 base between catheters. Further traction lacerated the anterior leaflet, enabling transcatheter mitral valve implantation without outflow obstruction.

Abbreviations

LAMPOON Laceration of the Anterior Mitral leaflet to Prevent Outflow Obstruction

LVOT Left ventricular outflow tract
TMVR  Transcatheter mitral valve implantation
INTRODUCTION

Transcatheter stent valves (both purpose-built and off-label) are implanted to relieve mitral valve failure — whether native, bioprosthetic, or after annuloplasty — when the risk of mitral valve surgery is prohibitive\(^1,2\). These transcatheter mitral stent valves may cause acute left ventricular outflow tract (LVOT) obstruction by displacing the anterior mitral valve leaflet towards the septum. Formal criteria have not been established, but as in surgery \(^3,4\), contributors to LVOT obstruction include angulated mitral and aortic annular planes, long or redundant anterior mitral leaflets, small ventricles, bulging septums or narrow leaflet-to-septum distance \(^5-7\). Preparatory or bailout transcoronary alcohol septal ablation can debulk the septum \(^8,9\), but risks important myocardial and conduction system injury. Moreover, alcohol septal ablation is not feasible when the septal thickness is normal, and typically requires a delay of 4-6 weeks for remodeling before TMVR, in highly symptomatic patients. The anterior mitral leaflet can be resected during hybrid surgical TMVR but requires cardiopulmonary bypass [Mayra Guerrero, Personal Communication and reference\(^1\)]. We propose a transcatheter alternative.

We describe a simple catheter technique to prevent LVOT obstruction by transecting the anterior mitral valve leaflet, called laceration of the anterior mitral leaflet to prevent outflow obstruction (LAMPOON). The procedure uses an electrified guidewire that traverses the leaflet base, between two retrograde aortic catheters, and which then is pulled outward toward the leaflet tip [FIGURE 1 A, B]. The split anterior mitral leaflet no longer obstructs the LVOT after stent valve implantation, and is displaced around the implant by intact chordae tendinae [FIGURE 1 C-F]. We developed and tested the technique \textit{in vivo} and \textit{ex vivo} in swine.
METHODS

LAMPOON technique

The technique has two steps: leaflet traversal followed by leaflet laceration [FIGURE 2]. Traverse is intended to be performed before, and laceration after, positioning of the transcatheter mitral valve. This would allow rapid valve implantation during expected hemodynamic compromise from intended mitral leaflet laceration.

For leaflet traversal, dual retrograde 6Fr guiding catheters (Vista Brite Tip, Cordis) were positioned using 0.035” guidewires, one into the left atrium taking care to cross the main mitral orifice without chordal entanglement, and the other in the LVOT abutting the aorto-mitral curtain. The LVOT catheter was positioned immediately below the hinge point of the aorto-mitral curtain, as confirmed by contrast angiography in a projection that corresponds to a 3-plane echocardiogram. Alignment along the center of the anterior leaflet, corresponding to the commissure between the left- and non-coronary cusps of the aortic valve, was achieved using contrast angiography in a projection corresponding to a short-axis echocardiogram. Intracardiac echocardiography (Acunav, Siemens) confirmed this position. A closed-loop snare (10mm Amplatz Gooseneck, Medtronic) was positioned through the left atrial catheter behind the atrial base of the anterior mitral leaflet. Through the LVOT catheter, a stiff 0.014” guidewire (Astato XS 20, Asahi-Intecc) was extended through an electrically insulating 0.035” polymer jacket (Piggyback Wire Converotor 145cm, Vascular Solutions), and directed toward the snare. The proximal guidewire was connected via forceps to a monopolar electrosurgery pencil and diathermy generator (Valleylab Force FX, Medtronic) set at 30W continuous duty cycle (“cutting” mode). After traversal, the Piggyback polymer jacket is withdrawn and the free end of
the guidewire is externalized through the retrograde left atrial catheter, positioned to protect against inadvertent tissue injury. The result is a transcatheter guidewire loop around the anterior mitral valve leaflet. No traction is applied until the laceration procedure is initiated, to avoid causing or exacerbating mitral valve regurgitation. Correct traversal is confirmed by angiography through the LVOT catheter and by echocardiography.

*Laceration* entails traction on both ends of the guidewire that has crossed the leaflet base, during electrification. The intended result is longitudinal transection of the anterior mitral valve leaflet, so that two remaining flaps are displaced medially and laterally by the transcatheter mitral valve implant, without causing LVOT obstruction. To facilitate radiofrequency ablation energy delivery on the inner (cutting) side of the guidewire, a 5-10mm section of the middle shaft of the 0.014” guidewire insulation was denuded by non-circumferential scalpel abrasion [FIGURE 3A], and then deliberately kinked to confine the denuded section to the inner curvature. The original insulating *Piggyback* is positioned to mark and abut one margin of the denuded shaft, locked in place, and then the kinked denuded section is positioned at the intended laceration site. The guiding catheter tips are apposed within 2-5 mm to provide mechanical and electrical protection during laceration. The guidewire-catheter relationships are locked using torque devices, and the guidewire is clamped to an electrosurgery pencil. To lacerate, both locked guiding catheters are retracted during brief two-step electrification. Retraction force was measured using a force meter (ZP-11, Imada). Afterwards, the guiding catheters are further apposed, and one guidewire limb pulled through to allow catheter removal.

**Animal procedures**

Non-survival procedures on Yorkshire swine (51 ± 7 kg) were approved by the institutional
animal care and use committee and conducted according to contemporary NIH guidelines. Bilateral percutaneous femoral artery and vein introducer sheaths were placed during isoflurane anesthesia with mechanical ventilation, animals received intravenous heparin (150 i.u./kg) to achieve an activated clotting time > 350s. Biplane X-ray fluoroscopy (Artis Zee, Siemens) and intracardiac echocardiography (Acunav 8.5Fr, Siemens) guided procedures. Euthanasia and necropsy were performed hours after the procedure.

To test the consequences of wrong crossing along the aorto-mitral curtain, an intentionally high traversal and laceration was performed. To test whether flowing blood would obscure thermal injury, the procedure was also performed in another heparinized animal, immediately after euthanasia.

At the conclusion of these non-survival experiments, animals were euthanized. In all animals, the mitral and aortic structures were examined carefully for thermal or mechanical injury. The laceration positions and lengths were recorded.

Transcatheter mitral valve implants were not performed in these naïve animals absent a suitable fixation mechanism, and instead were performed ex-vivo. Native LVOT length (from aortic root to mitral annulus) and minimum LVOT antero-posterior diameter were measured in explanted hearts following in vivo LAMPOON. Transcatheter heart valves (23mm Sapien 3, Edwards) were implanted at the benchtop at a 70:30 ventricular position across the annulus and LVOT geometry was measured with- and without LAMPOON modification.

**In vitro heating**

We performed infrared photography (FLIR E40, FLIR Inc, Portland, OR) to test focal mid-shaft heating during electrification of the insulation-stripped guidewire. A two-catheter and guidewire
crossing system was partially submerged in a saline bath including the electrosurgery indifferent electrode, and held in place by a steel clamp to simulate potential electrical coupling with a transcatheter mitral valve [FIGURE 3B].

**Imaging and data analysis**

Post-procedure contrast-enhanced CT was performed on a 320-row volume scanner (Aquilion One Vision, Toshiba). Surface renderings were generated on an image processing workstation (Vitrea v6.7, Toshiba).

Data are expressed as mean ± standard deviation. LVOT diameters were compared, before and after simulated TMVR with- and without LAMPOON, using one-way ANOVA and a Student t-test with Dunnet’s correction for multiple comparisons (Prism v6, Graphpad Inc.).

**Results**

**In vivo findings**

The LAMPOON procedure was performed in seven live animals, and in one heparinized post-mortem animal. A representative procedure is depicted in [FIGURE 2]. The procedure was successful in all animals. The mean procedure time was 55 ± 22 minutes, including imaging but excluding anesthesia and vascular access. LAMPOON caused mean blood pressure to fall 44% (54 ± 6 to 30 ± 4mm Hg, p<0.01), as expected, but remained steady until planned euthanasia for approximately 4 hours. Retraction force was high (50kg, 5.1kg) with an intact and electrified lacerating guidewire *in vivo*; retraction force was reduced (to 15N, 1.5kg) using a denuded cutting surface surrounded by an insulated polymer jacket.

In one animal, the traversal was intentionally performed “low” to simulate avoiding a
calcified basal leaflet, and traversed 52% of the length of the A2 leaflet. In another animal, the traversal was intentionally performed “high” or above the aorto-mitral curtain, across the transverse sinus, into the left atrium, to test a serious complication. This caused a small pericardial effusion without hemodynamic change, and the animal was excluded from further analysis. No other animal had pericardial effusion after 2 ± 1 hours of survival.

Intracardiac echocardiography demonstrated cavitation micro-bubbles as expected during both traversal and laceration steps of the procedure. Intracardiac echocardiography also demonstrated not only laceration but also splaying of the A2 mitral leaflet and acute mitral valve regurgitation, as expected, after LAMPOON [FIGURE 4A]. Concomitantly, in vivo computed tomography demonstrated splitting and splaying of the A2 mitral valve leaflets [FIGURE 4B and video supplement]

Postmortem findings

Postmortem examination of leaflets revealed jagged transections of the A2 anterior mitral leaflet in all animals [FIGURE 5F]. All transections were located between major chordal insertions as intended. The transection lengths were 19 ± 3 mm in leaflets that were 21 ± 4mm long (89 ± 19% of leaflet length). The average intercommissural distance was 32 ± 6mm; the average position of the laceration was 0.5 ± 0.4mm from the center of the anterior mitral leaflet, as intended. Leaflets were 0.9 ± 0.1mm thick and showed no visible eschar.

There was no necropsy evidence of injury to the aortic root or aortic valve, nor disruption of the mitral subvalvular apparatus, on any animal whether LAMPOON was performed in-vivo or post-mortem in situ.
**In vitro and ex vivo findings**

Infrared photography demonstrated that heat during application of radiofrequency ablation energy emanated from a single location, the denuded portion of the guidewire suspended between insulated guiding catheters [FIGURE 3B]. A nearby stainless steel clamp, positioned to simulate a potentially conductive metallic transcatheter heart valve, did not exhibit heating, which would reflect radiofrequency coupling with the ablation guidewire.

**Impact on LVOT obstruction**

[Figure 5] demonstrates LVOT obstruction after benchtop TMVR with- and without preparatory LAMPOON. [Figure 5F] shows a typical post-mortem result after in vivo LAMPOON. The two halves of the A2 leaflet are parted by the intact subvalvular apparatus. After benchtop TMVR, the LVOT antero-posterior diameters fell from 17 ± 3mm to 5 ± 4mm, p<0.01 without LAMPOON, and to 11mm ± 2mm, p<0.01 with LAMPOON. This represented a 69 ± 18% reduction in LVOT diameter following transcatheter valve implantation compared with a 35 ± 10% reduction following LAMPOON (p<0.01).

**DISCUSSION**

We demonstrate a new application for transcatheter electrosurgery to mitigate a life-threatening complication of TMVR. Using simple catheter techniques we can split the anterior mitral valve leaflet that otherwise would be displaced anteriorly by the mitral valve implant and cause LVOT obstruction. The split leaflet edges are displaced around the transcatheter valve by chordal structures.

The potential for LVOT obstruction is a key barrier to TMVR, and remains a devastating
complication of early and investigational TMVR for native and post-annuloplasty mitral valve failure(1,10,11). Imaging may predict risk of LVOT obstruction(5,6,9) but their sensitivity and specificity remain uncertain. Nevertheless, it is clear that many patients are excluded from clinical and investigational transcatheter mitral valve therapy out of concern for iatrogenic LVOT obstruction.

LAMPOON may be especially helpful applied prophylactically in patients deemed high risk for LVOT obstruction: those with unfavorable left ventricular geometry, acute aorto-mitral-plane angulation, long leaflets, and a prominent septal bulge(5,6,9). Without LAMPOON, operators may feel compelled to implant TMVR devices higher into the left atrium, which risks embolization. LAMPOON may allow lower implant position and more aggressive flaring of the implant, measures that otherwise would increase the risk of LVOT obstruction.

By comparison, intentional alcohol infarction to reduce interventricular septal thickness would best be performed in a separate procedure, is not suitable for patients with thin interventricular septa, and risks conduction injury and exacerbation of myocardial dysfunction (12).

The procedure sequence in patients would first be LAMPOON traversal and guidewire externalization, followed by pre-positioning of the TMVR device into the left atrium or unexpanded across the mitral valve, followed by LAMPOON laceration, followed by TMVR implantation. Patients without baseline severe mitral valve regurgitation might be expected to experience severe hypotension between the laceration and implantation steps, which with proper planning could be achieved quickly.
Limitations

We use radiofrequency ablation to traverse and then lacerate the anterior mitral leaflet. Our traversal technique is the same employed to obtain transcaval access to the aorta(13,14), and relies on radiofrequency power concentration on the guidewire monopole tip, further insulated by the Piggyback polymer jacket. For laceration, we overcome the tendency of charge to concentrate on the outer curvature of the intentionally kinked guidewire shaft by selectively denuding the inner curvature. During laceration we minimize the length of exposed denuded guidewire by closely approximating the two guiding catheters. Both in vitro and in vivo we observed no evidence of electrical coupling to nearby conductive structures, which might heat the transcatheter mitral valve frame or hinder electrosurgical laceration (15).

Many of the risks and limitations of LAMPOON are related to incorrect catheter placement and to electrosurgery. An eccentric or low crossing of the anterior leaflet would result in suboptimal parting of the leaflets. A high crossing may exit into the transverse sinus risking pericardial effusion, but the guidewire can probably be withdrawn and the traversal repeated in the desired position. Entanglement with chordae could cause chordal injury or deleterious leaflet draping over the prosthetic valve, and must be avoided by proper LA catheter positioning. We predict 3-dimensional transesophageal echocardiography, of limited use in swine due to unfavorable anatomy, will be superior to 2-dimensional intracardiac echocardiography in guiding catheter position in patients. The risk of thrombus and gas embolism is mitigated by lower ablation energy and anticoagulation (16). Thrombus may form on the free edges of the lacerated leaflet, although we did not observe it, and may require postprocedure anticoagulation. There is a risk of bystander injury to the aortic valve, which is mitigated by proper insulation of the electrified guidewire. The role of LAMPOON is unclear for valve-in-valve TMVR, where
chordal attachments are absent. Bailout LAMPOON is not an option in its current form as the stent struts of the implanted valve prosthesis would prevent leaflet laceration.

This preclinical experience is limited to healthy juvenile swine, which unlike human patients have pristine non-calcified mitral leaflets and non-tortuous aligned aortas and aorto-mitral structures. These structures may be more difficult to align and to lacerate in patients. Post-mortem distortion of cardiac geometry probably confounds our ex-vivo measurements of LVOT obstruction with and without LAMPOON. LAMPOON was not combined with TMVR in vivo in these animals, absent suitable valve devices. LAMPOON would appear better suited in combination with specific TMVR devices that do not rely on the intact anterior mitral leaflet for fixation. LAMPOON may induce hemodynamic compromise of different severity in human patients with pre-existing mitral valve disease and abnormal left atrial compliance.

CONCLUSION

LAMPOON has a promising role in therapy for patients ineligible for surgery and who have a risk of developing LVOT obstruction with TMVR. Serious risks can be mitigated by intraoperative echocardiographic guidance, adequate anticoagulation and safe electrosurgery practice. Cautious application may be warranted in patients requiring TMVR expected to cause LVOT obstruction, but who have no alternative options.

PERSPECTIVES

What is Known?

Transcatheter mitral valve replacement risks life threatening left ventricular outflow tract obstruction by displacing the anterior mitral leaflet
What is New?

LAMPOON is a catheter technique to transect the anterior mitral leaflet, in order to prevent iatrogenic left ventricular outflow tract obstruction.

What is Next?

Based on this series of preclinical experiments, LAMPOON may be ready for cautious investigation in selected patients at high risk of left ventricular outflow tract obstruction.

ACKNOWLEDGEMENT

Supported by the Division of Intramural Research (Z01-HL006040), National Heart Lung and Blood Institute, National Institutes of Health.

We thank Alan Hoofring of the NIH Division of Medical Arts, and Katherine Lucas, Shawn Koslov, and Joni Taylor from the NHLBI Animal Surgery and Resources Core.
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electrophysiology 2016;9:e003226.
FIGURE LEGEND

Figure 1. Illustrations of the LAMPOON technique.

A, two Judkins Left catheters are positioned on either side of the A2 mitral leaflet base. An energized guidewire is advanced from the LVOT catheter into the LA catheter snare. B, the snared tip is externalized to form a guidewire loop around the A2 leaflet. This is energized and pulled outward to lacerate the leaflet lengthwise into two halves. C+E, A transcatheter mitral valve implant tents the anterior mitral leaflet into the septum, obstructing the LVOT. D+F, splitting the leaflet by the LAMPOON procedure instead causes the two tethered halves to displace along either side of the transcatheter valve, preventing LVOT obstruction.

Figure 2. Fluoroscopy demonstration of the LAMPOON procedure, in a left oblique projection.

A, angiography through the LVOT catheter shows good positioning of this catheter at the base of the anterior leaflet, below the aortic valve, with a loop snare positioned through the LA catheter. B, the electrified guidewire is advanced through the A2 mitral leaflet base into the LA snare. C, a denuded kinked section of the guidewire, insulated and marked proximally with a polymer wire convertor further insulated by the two guiding catheters, is electrified while the left atrial catheter is pulled back into the LVOT (position D) during stage 1 of the two step electrosurgical laceration. D, stage 2 of the laceration. Both catheters are pulled in tandem during a burst application of radiofrequency energy, lacerating the leaflet completely and freeing the catheter-guidewire loop.

Figure 3. Guidewire electrosurgery.
A, a short midshaft section of the electrically insulating PTFE coating of a 0.014” guidewire is stripped using a scalpel and then kinked, with a polymer jacket wire convertor locked alongside. 

B, Infrared images of a saline bath with a denuded guidewire loop through two catheters, replicating *in vivo* LAMPOON. The guidewire is clipped to an electrosurgery pencil and electrified, revealing a hotspot (bright yellow, arrow) only at the exposed guidewire loop. C, a close-up of the guidewire loop reveals no heating around the nearby metallic hemostat, suggesting freedom from electrical coupling

**Figure 4. Images of the lacerated anterior mitral leaflet after LAMPOON.**

A, Short axis intraoperative intracardiac echocardiographic image of the mitral valve showing the anterior leaflet split in two equal halves. B, the corresponding post-procedure surface rendering of a contrast enhanced CT also displaying split and splayed leaflets. AML, anterior mitral leaflet; PML, posterior mitral leaflet; LCC, left coronary cusp; NCC, non-coronary cusp.

**Figure 5. Benchtop assessment of LVOT geometry impact.**

The base of the left ventricle is viewed in cross-section after the apex is cut away. A, A naïve heart with the anterior mitral leaflet intact. The trajectory of a LAMPOON laceration is depicted by the dashed line. B, TMVR with intact anterior leaflet showing reduced LVOT area. C, LAMPOON modification made to the same heart with the anterior leaflets displaced to the side by the TMVR and reduced LVOT obstruction. Flow would be possible through uncovered stent struts. D, explant after *in-vivo* LAMPOON heart showing lacerated anterior leaflet. E, TMVR in the explanted heart after LAMPOON showing displacement of the anterior leaflet away from the LVOT. F, explanted heart after isolated *in-vivo* LAMPOON viewed from the posterior wall showing central laceration down the complete length of the anterior leaflet. The intact subvalvular apparatus displaces the leaflet tips away from the LVOT.
VIDEO LEGEND

Video Supplement. This video demonstrates the LAMPOON technique.