Proceedings of the 2020 Design of Medical Devices Conference
DMD2020
April 6, 7-9, 2020, Minneapolis, MN, USA

DMD2020-9033

A NOVEL TRANSCATHETER EDGE-TO-EDGE SUTURING TECHNIQUE AND PROTOTYPE FOR REPAIRING TRICUSPID VALVE REGURGITATION

Jorge D. Zhingre Sanchez[1,2,3], Paul A. Iaizzo[1,2,3]
Departments of [1]Biomedical Engineering, [2]Surgery, and [3]Visible Heart® Laboratories
University of Minnesota
Minneapolis, MN, United States

ABSTRACT

Tricuspid valve regurgitation is a major clinical issue that continues to attract interest from interventional cardiologists and medical device designers due to its rising prevalence and progressive nature. This disease impact is exacerbated among the aging population, considered as high risk of mortality for open-heart surgical procedures. Furthermore, early intervention for tricuspid regurgitation following left-sided heart procedures continues to increase. Thus, percutaneous or transcatheter interventions have emerged as the new frontier for tricuspid valve therapy. Specifically, tricuspid leaflet plication, or edge-to-edge repair, is a valvular procedure to enhance the coaptation of the leaflets and reduce regurgitation. The current landscape of approved transcatheter devices for leaflet coaptation are exclusive to the mitral valve or being investigated for tricuspid treatment. However, most of these transcatheter systems are designed with high procedure specificities, are expensive, and require extensive procedural training. Hence, there is an opportunity to percutaneously plicate the tricuspid leaflets using commonly available right-heart catheter equipment. This study details a novel transcatheter repair procedure that can plicate the tricuspid valve leaflets solely using current market released catheters and/or surgical equipment. Testing and evaluation of this prototype procedure was performed using Visible Heart® methodologies.

Keywords: Tricuspid valve, Regurgitation, Transcatheter repair, Edge-to-Edge, Suturing.

NOMENCLATURE

TV	Tricuspid valve
TR	Tricuspid regurgitation
TTVr	Transcatheter tricuspid valve repair

INTRODUCTION AND BACKGROUND

Tricuspid regurgitation (TR) is a valvular disease defined by the incomplete coaptation of associated leaflets, resulting in inappropriate right-heart function. Established surgical repair therapies for this pathology focus on enhancing valve coaptation by suturing two or three leaflets together. This plication procedure, also defined as the edge-to-edge or "Alfieri stitch" repair, results in the creation of a double-orifice or bow-tie opening of the tricuspid valve (TV). Although effective in treating TR, these methods require invasive surgery for right atrial access. As our populations age, there are growing clinical needs to treat high mortality risk patients using new minimally invasive or improved non-surgical percutaneous procedures. Simultaneously, patients treated for left-sided valve defects with percutaneous procedures would also require transcatheter tricuspid valve repair (TTVr).

The surgical leaflet plication techniques have been adapted as TTVr systems and the current landscape of coaptation devices seems promising [1,2]. The MitraClip (Abbott) is an FDA approved device used to treat mitral valve regurgitation by grasping two leaflets closed. This device has since been investigated and used as a compassionate use device for TR patients. TV specific clip-based devices have since emerged and are in clinical trials. More recently, the TriClip (Abbott), a modified version of the MitraClip, and the Pascal system (Edwards LifeSciences) have shown reduction in TR and improved clinical outcomes. Additional transcatheter systems are focused on targeting the TV annulus rather than the leaflets.

Although these clip-based transcatheter systems are demonstrating promising results, there remains no commercially available or FDA approved TTVr device. Combined with the rising prevalence of TR and desire to initiate early TV intervention therapies, there is a need for ready-made and

[1] Contact author: zhing001@umn.edu; B172 Mayo, MMC195 420 Delaware Street S.E. Minneapolis, MN 55455; 612-624-8742

practical solutions. This study describes the concept, design, and testing of a novel trancatheter based edge-to-edge suturing technique and prototype system for creating a double-orifice TV utilizing currently marketed and/or commercially available surgical tools. The testing of this non-invasive catheter based workflow was performed using Visible Heart® methodologies and is being further iterated as a catheter TV medical device.

METHODS

1.1 Overview

This proposed catheter technique is aimed at stitching together any two TV leaflets to create a double-orifice or edge-to-edge repair. The anterior, posterior, and septal leaflets can be targeted (at specified scallops) using this approach. One pilot study was performed on a perfusion fixed human heart. Additional trials highlighted the suturing of the posterior and anterior TV leaflets using in vitro reanimated swine hearts and Visible Heart® methodologies [3]. This catheter procedure is intended to be entirely intracardiac using trans-jugular access, avoids open-heart surgery, and only requires common and inexpensive surgical equipment.

1.2 Equipment

The right internal jugular vein is dissected and prepared with a 32Fr hemostasis port (Medtronic) for right atrial access. This larger bore size introducer allows for the transversal and manipulation of two separate catheters. Two flexible and steerable catheters (Medtronic) with a minimum of 180 degrees of articulation are required. A stiff guide wire (Medtronic) is selected to puncture through leaflet tissue. A loop snare and sheath (Covidien) are used to lasso and capture the distal end of the puncture guide wire. Next, this guide wire is exchanged for surgical suture (Ethicon) and remains implanted in the TV after the procedure. Finally, an endoscopic scissor or cutting tool (Covidien) is used to remove the excessive suture thread.

1.3 Procedural Steps

The following procedural steps were modified for this reanimated swine heart. The entire procedure was recorded using the endoscopic cameras as is visualized in Figure 1. The 32Fr introducer hemostasis valve port was cannulated onto the swine superior vena cava (SVC). The trans-jugular access was simulated entirely through this SVC cannula port that provided direct access to the right atrium and TV. Adjacent to the introducer port, a separate camera port was connected to allow for simultaneous endoscopic video capture within the right atrium. For this study, the posterior and anterior leaflets were targeted for clipping. The first catheter was feed through the SVC port and positioned past the TV annulus. The catheter was then deflected or curved upward to press against the underside of the posterior leaflet. Once the catheter was pressed firmly against the leaflet (tenting it), the guidewire was advanced and punctured through it (Figure 1A). The second catheter housing the loop snare was then advanced into the same SVC port and positioned above the exposed guidewire (Figure 1B). The snare was retracted and clamped on the proximal catheter end to firmly secure it. The snare and guide wire were jointly retracted and removed through the SVC port. Next, the surgical suture thread was knotted tightly on the removed guide wire end. The guide wire was pulled retrograde from the first catheter end to pass back through the initial puncture site of the posterior leaflet. The suture thread then replaced the guide wire through the leaflet (Figure 1C). The guide wire with knotted suture thread were now inside the distal end of the first catheter. This catheter was then maneuvered to push underneath the anterior leaflet. The guide wire punctures through and was again grasped by the second catheter loop snare (Figure 1D and 1E). Once snared and pulled through, the guide wire was retracted and was accompanied by the tied suture thread (Figure 1F). Both ends of the suture were clamped and secured outside of the SVC port. With both the guide wire and snaring catheters removed, the remaining suture thread was looped across both the septal and anterior leaflets (Figure 1G). A self-tightening arbor knot was used to lock the suture thread into place as one end was pulled. The knot was tightened until reaching the leaflets and this maneuver plicated the leaflets together (Figure 1H). Excess suture was removed with an endoscopic scissor, also introduced through the SVC port (Figure 1I). The result was a suture that stitched the septal and anterior leaflet closed and created a double-orifice TV.

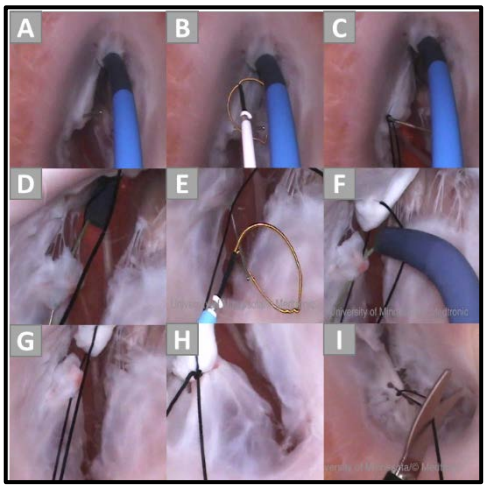

FIGURE 1: Procedural steps of the transcatheter edge-to-edge suture technique performed on a TV within a reanimated swine heart.

RESULTS

This procedure was successfully performed in two separate pilot studies. The first iteration was performed on perfusion fixed human heart tissue. The pre and post-operative TV edge-to-edge repair images are illustrated in Figure 2. The TV of the heart was fully exposed from the right atrial view (Figure 2A). This human heart tissue study was used to assess the feasibility of executing each procedural step, demonstrate catheter and guide wire maneuverability, and determine if this technique could be translated to human valvular tissue. The final edge-to-edge suture connecting the leaflets clearly resulted in a double-orifice or bow-tie TV configuration (Figure 2B).

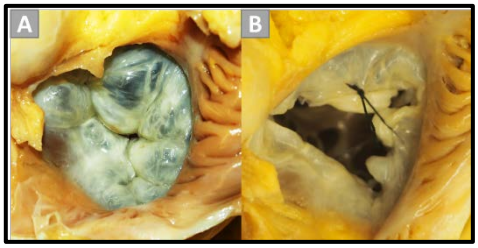

FIGURE 2: Edge-to-edge TV leaflet configuration which was performed within a perfusion fixed human heart.

In the animal pilot studies (n=3), the Visible Heart® methodologies were used to assess the performance and implementation of this prototype procedure within functional beating hearts. These swine hearts have a similar anatomical representation of the TV to humans and were functioning in a native sinus rhythm. The endoscopic cameras were used to capture the entire procedures from a superior view of the TVs and the functioning leaflets post-procedurally. After these reanimation experiments, the swine hearts were dissected and the suture repair was evaluated. The double-orifice swine TV is illustrated in Figure 3.

FIGURE 3: Double-orifice TV in a post-reanimated swine heart.

INTREPRETATION

These preliminary studies illustrate that a successful edge-to-edge or "Alfieri stitch" repair of the TV can be performed using this novel transcatheter procedure: i.e., with commercially available clinical tools. The obtained endoscopic videos demonstrate the fully functional TV in swine hearts with a double-orifice configuration which were performed using the proposed non-invasive catheter and suture technique.

Future work on this technique will consist of improving the feasibilities and efficiencies of each procedural step. Although this repair protocol can be accomplished using common surgical suture and guidewires, catheters with smaller diameter profile and greater degrees of articulation will likely be helpful and clinically preferred. Additionally, the maneuverability and handling of chosen catheters will require pre-procedural planning and practice.

This study was accompanied with endoscopic footage to clearly depict all steps required for this procedure and also highlight the results of the edge-to-edge repair using direct visualization. However, this technique could also have been simultaneously implemented with fluoroscopy to simulate a clinical application. Further validation of this procedure will be performed using pre- and post-operative assessment of TR using echocardiography. Future experimental testing protocols should consist of inducing TR in these swine hearts, either through cutting chordae tendineae or increasing pulmonary hypertension, and quantifying the amount of TR. Additionally, this catheter and suture technique could potentially be performed on reanimated human hearts when available.

Future iterations of this TV non-invasive procedure will consist of designing and developing a single transcatheter device that could combine all the required components; guide wire, loop snare, and suture. Alternatively, a comprehensive list of marketed catheters, snares, and suture threads that are available and preferred for this procedure could be assembled. Figure 4 illustrates the current prototype and tools we used for this study. Compared to current TTVr systems that are currently unavailable, this catheter-suture based technique is simple, inexpensive, and ready to use. Overall, this procedure can be further optimized for pre-clinical testing.

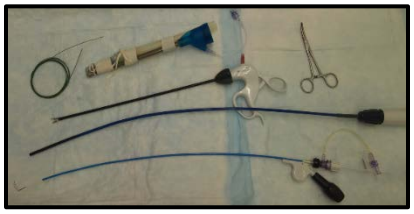

FIGURE 4: Equipment for performing the transcatheter edge-to-edge suture technique.

CONCLUSION

Today, there remains no commercially available TTVr system for treating TR. As the prevalence of TR among the patient population that cannot endure conventional surgical repair continues to rise, an immediate practical solution is urgent. This study describes a novel percutaneous technique aimed at creating an edge-to-edge repair or double-orifice leaflet configuration, using commercially marketed and available clinical tools. This catheter-suture based technique eliminates the need to rely on specific and currently unavailable transcatheter devices. Visible Heart® methodologies were used to visualize and test this catheter edge-to-edge procedure for creating a double-orifice TV, with suture. This procedure and prototype will be further iterated for future testing.

ACKNOWLEDGEMENTS

Thanks to the graduate students and staff members of the Visible Heart Laboratories for their assistance.

REFERENCES

[1] Asmarats, Lluis; et. al. "Transcatheter Tricuspid Valve Interventions." *JACC* Vol. 71 (2018): 2935-56.
[2] Kolte, Dhaval; et. al. "Current state of transcatheter tricuspid valve repair." *Cardiovasc Diagn Ther* Accepted for publication Sep 09, 2019.
[3] Chinchoy, Edward; et. al. "Isolated four-chamber working swine heart model." *Annals of Thoracic Surgery* Vol. 70 (2000): 1607-1614.

