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Tricuspid Valve Annular Mechanics: Interactions with and Implications for Transcatheter Devices

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Abstract—In the interventional treatment of tricuspid valve regurgitation, the majority of prosthetic devices interact with or are implanted to the tricuspid valve annulus. For new transcatheter technologies, there exists a growing body of clinical experience, literature, and professional discourse related to the difficulties in delivering, securing, and sustaining the function of these devices within the dynamic tricuspid annulus. Many of the difficulties arise from circumstances not encountered in open-heart surgery, namely; a non-arrested heart, indirect visualization, and a reliance on non-suture-based methods. These challenges require the application of procedural techniques or system designs to account for tricuspid annular motion, forces, and underlying tissue strength. Improved knowledge in these interactions will support the goals of improving device systems, their procedures, and patient outcomes. This review aims to describe current concepts of tricuspid annular mechanics, key device and procedural implications, and highlight current knowledge gaps for future consideration.

Keywords—Tricuspid regurgitation, Percutaneous repair, Transcatheter devices, Annular biomechanics.

ABBREVIATIONS

AVN	Atrioventricular node
RA	Right atrium
RCA	Right coronary artery
RV	Right ventricle
TTVD	Transcatheter tricuspid valve device
TV	Tricuspid valve

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INTRODUCTION

Open-heart tricuspid valve (TV) surgery has existed for more than half a century. New devices and reconstructive techniques have since been introduced but their underlying procedures have remained substantially the same. In an arrested or fibrillating heart, suture-based techniques are used to secure a prosthetic device or reconstruct the annulus under direct visualization. Clinical data suggest these methods to have acceptable results with trending improvement with surgeon and center experience. With general satisfaction in these outcomes, the motivation to study the influence of tricuspid annular mechanics on surgical devices or their techniques has been low.

Enthusiasm to better understand these interactions has recently become significant. This shift has resulted from the growing body of clinical experience, literature, and professional discourse related to the difficulties in delivering, securing, and sustaining the function of transcatheter tricuspid valve devices (TTVDs).[1,5,7,13,14] Many of these difficulties arise from circumstances not encountered in open-heart surgery, requiring the application of new procedural techniques or designs to account for the mechanics of tricuspid annular motion, its forces, and the strength of the underlying tissue.

Greater clinical understanding of tricuspid annular mechanics may support the further improvement of TTVD procedures, designs, and patient outcomes. However today, data to support these efforts are not cohesively reported. Such data may pertain to TV anatomy, structure, dynamics, annular forces, annular tissue holding strength, and the influence of surrounding anatomical structures among other related phenomena. This review aims to describe current

concepts of tricuspid annular mechanics, key procedural and device implications, and highlight current knowledge gaps for future consideration.

TRICUSPID VALVE FUNCTION, STRUCTURE AND HEMODYNAMICS

The TV is a complex tri-leaflet valve existing between the heart's right atrium (RA) and right ventricle (RV) (Fig. 1). Its purpose is to maintain unidirectional flow from the atrium to the ventricle while preventing reversed flow during ventricular ejection. This critical function is accomplished by four anatomical structures that include the tricuspid annulus, leaflets, chordae tendineae, and papillary muscles (PMs). The unique arrangement of these structures within the RA, fibrous skeleton, and RV of the heart facilitates healthy TV function.

Of the TV's anatomical structures, the annulus consists of a discontinuous band of elastic and fibrous tissue in continuity with the tricuspid leaflets and myocardium of the RA and RV. The tricuspid annular structure, dynamics, forces, tissue strength, and associated phenomena are described later in detail.

The anterior, posterior, and septal leaflets function as the passive opening and closing structures of the valve. Each leaflet differs in size and shape with the anterior being the largest and the septal being the smallest. The leaflets are named for their relative position in the heart. The anterior leaflet shares its insertion with the RV outflow tract and aorta, the posterior leaflet with the free wall of the RV, and the septal leaflet with that of the septum.

The TV's subvalvular apparatus connects the leaflets to the RV. The subvalvular apparatus provides the dual function of maintaining valvular competence and ventricular geometry by providing cross-ventricular support. It consists of PMs that extend upwards from the RV endocardium, with chordae tendineae fanning outwards from each PM tip to the free edge, belly, and base of the TV leaflets.

The hemodynamic conditions associated with TV function are well known. Population based values for normotensive right heart hemodynamics include a heart rate of approximately 70 beats/min, a forward flow volume of 70 mL, a RA pressure that ranges from 0 to 6 mmHg, and a RV pressure that ranges from 0 to 35 mmHg.[16] In addition to ranging appreciably among patients, these values also vary within an individual with respiratory cycle as well as loading conditions; and can be exacerbated or diminished with varying TV etiologies, lesions, and dysfunctions.

TRICUSPID ANNULAR STRUCTURE AND ANATOMY

The TV annulus consists of a discontinuous band of elastic and fibrous tissue in continuity with the tricuspid leaflets, the RA, and the RV.[8] The annulus may be anatomically defined by a septal, posterior, and anterior segment with corresponding leaflet attachments.[42] The septal segment exhibits a leaflet attachment that is at a lower level than the septal attachment of the mitral valve, such that a portion of the membranous septum separates the left ventricle from the RA (Figs. 1 and 2).[52] The posterior segment of the annulus exists along the free wall of the RV, while the anterior segment is in direct proximity to the right outflow tract and aorta. The approximate lengths of these regions are known to vary in both healthy and diseased patient populations.[8,20]

To demonstrate the relative anatomical and structural complexity of the TV annulus, histological sections were taken of a human cadaver heart (Fig. 2). These slices are remarkable for the relative heterogeneity in muscle, fibroelastic, and fatty tissues that may be observed in or near the tricuspid annulus. Comparison of opposing segments reveals structural and anatomical complexity for which TTVDs may be delivered and attached. These slices demonstrate the discontinuous existence of the tricuspid annulus, which is generally considered to be more indistinct than that for the mitral, containing a greater density of myocardial fibers.[52] It should be further considered that inter-heart differences in tricuspid annular structure can exist, as demonstrated by qualitatively evaluating a histological slice taken from the approximately same location of three ovine hearts (Fig. 3).

A critical aspect when considering the tricuspid annulus' positioning within the heart is its proximity of the atrioventricular node (AVN), Bundle of His, aortic root, and right coronary artery (RCA) (Figs. 1 and 2). The AVN is located anterior to the coronary sinus ostium and directly superior to the septal leaflet, while the Bundle of His is located apically to the AVN within the ventricular septum. The tricuspid annulus also shares a portion of its perimeter with the aortic root. These anatomical structures are routinely avoided in open-heart TV surgery.

The RCA is increasingly identified as a critical structure to avoid during TTVD procedures. The RCA courses from the aortic root along the atrioventricular groove, and its distance from the anterior and posterior annular segments varies across patients.[3,10] A recent comprehensive study evaluated the position of the RCA relative to the tricuspid annulus in 250 patients using computed tomography.[60] The results demon-

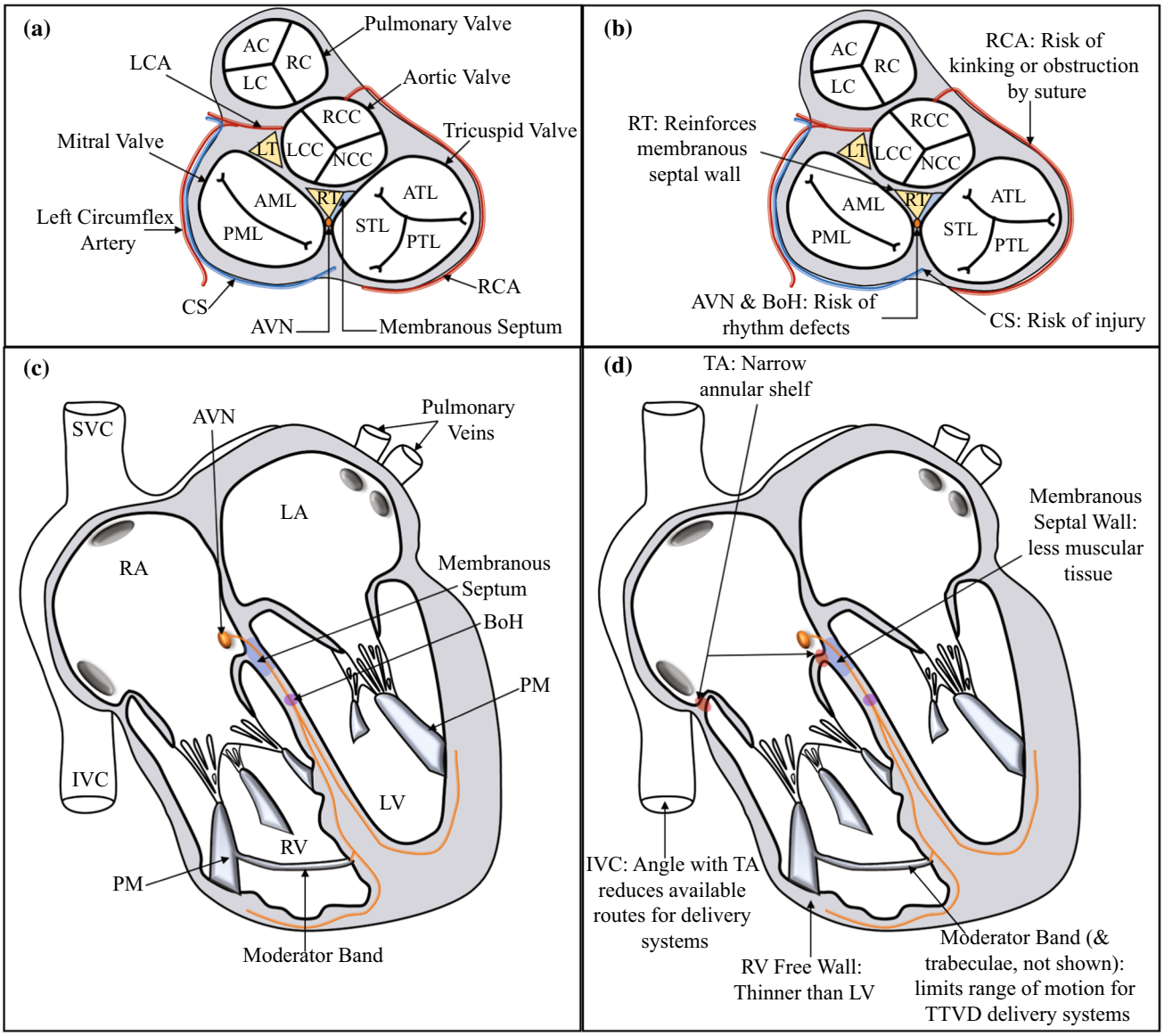

FIGURE 1. Illustration of the structures surrounding the tricuspid valve (a, c) and potential risks associated with attaching transcatheter tricuspid valve devices to the tricuspid annulus (b, d). *AC* anterior cusp, *ALC* anterior-lateral commissure, *AML* anterior mitral leaflet, *APC* anterior–posterior commissure, *ASC* anterior-septal commissure, *ATL* anterior tricuspid leaflet, *AVN* atrioventricular node, *BoH* Bundle of His, *CS* coronary sinus, *IVC* inferior vena cava, *LA* left atrium, *LC* left cusp, *LCC* left coronary cusps, *LT* left trigone, *LV* left ventricle, *MV* mitral valve, *NCC* non-coronary cusps, *PM* papillary muscle, *PMC* posterior-medial commissure, *PML* posterior mitral leaflet, *PSC* posterior-septal commissure, *PTL* posterior tricuspid leaflet, *RA* right atrium, *RC* right cusp, *RCA* right coronary artery, *RCC* right coronary cusps, *RT* right trigone, *RV* right ventricle, *SVC* superior vena cava, *STL* septal tricuspid leaflet), *TA* tricuspid annulus, *TV* tricuspid valve, *TTVD* transcatheter tricuspid valve device.

strated that in approximately 65% of the studied patients, the RCA coursed the annulus at the same level as the anterior and posterior leaflet insertions, exhibited a crossing course, that is, was part-superior and part-inferior to the anterior and posterior leaflet insertions, in approximately 25% of patients, and coursed superior to the anterior and posterior leaflet insertions in the remaining. Regional variations in distance between the annulus and RCA were observed: at the levels of the anterior leaflet insertion, mean transverse and vertical distances were 8.8 ± 4.5 and 4.4 ± 1.8 mm, respectively, vs. 3.6 ± 3.4 and 4.6 ± 2.3 mm, respectively, at the level of the posterior leaflet insertion.

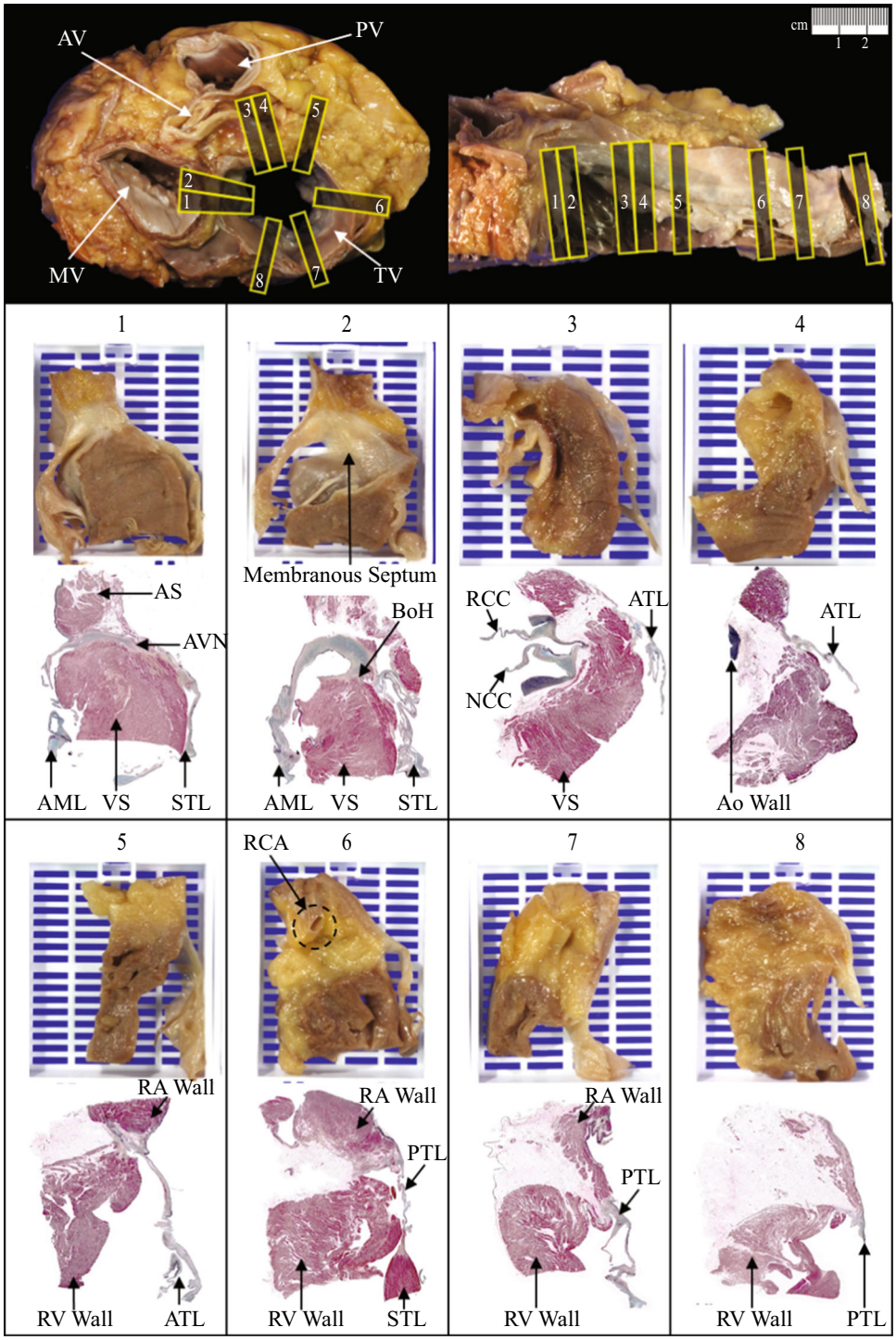

FIGURE 2. Excised and stained segments of the tricuspid valve of a human cadaver heart in work performed by CV Path. Shown here are eight selected segments around the valve (labelled from 1 to 8), which depicts the variation in muscular, fibrous and fatty tissue as well as adjacent. *Ao* aorta, *AML* anterior mitral leaflet, *AS* atrial septum, *ATL* anterior tricuspid leaflet, *AV* aortic valve, *AVN* atrioventricular node, *BoH* bundle of his, *MV* mitral valve, *NCC* non-coronary cusp, *PTL* posterior tricuspid leaflet, *PV* pulmonary valve, *RA* right atrium, *RCC* right coronary cusp, *RV* right ventricle, *STL* septal tricuspid leaflet, *TV* tricuspid valve, *VS* ventricular septum.

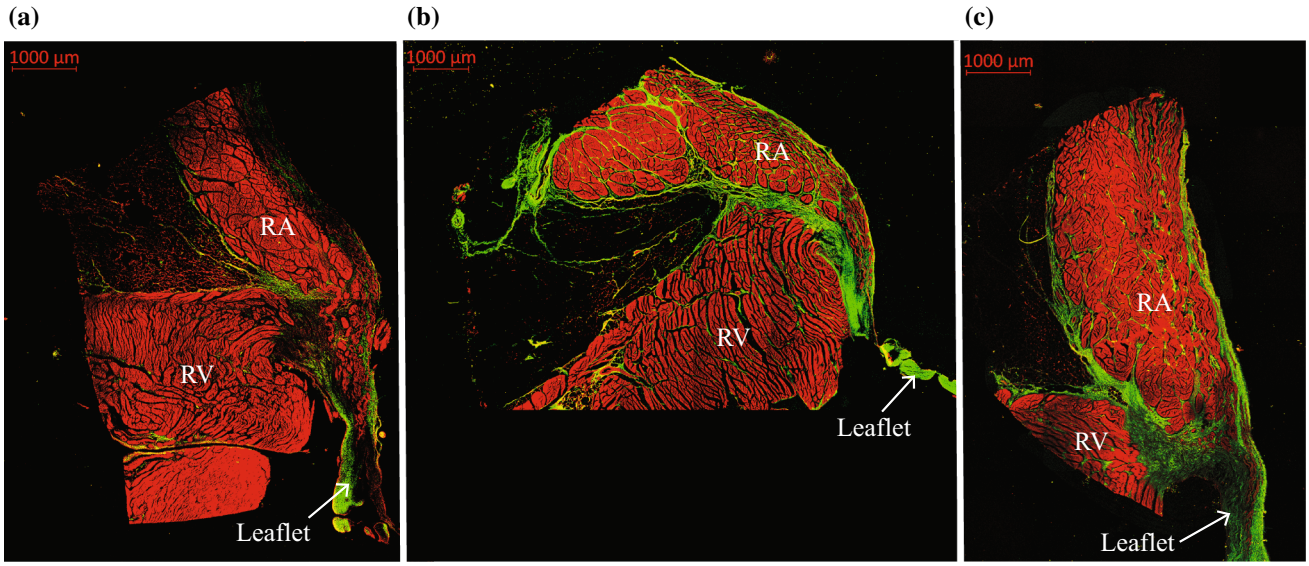

FIGURE 3. Representative images collected by two-photon autofluorescence for three different ovine tricuspid annuli (a, b and c), each at the posterior-septal commissure. Green, collagen fibers: red, non-specific structures. *RA* right atrium, *RV* right ventricle.

Combined, these data suggest the tricuspid annulus provides a non-trivial landing zone for devices to attach and secure. The spatial and regional variation in tissue structures advises caution when defining expectations for the performance of TTVD annular attachments. Acknowledgement of the tricuspid annulus's surrounding anatomical structures is critical for addressing risks of potential injury based on device system design and procedure. Combined with other known aspects, such as the thin chamber walls of the right heart and sometimes indistinct annular ledge, the tricuspid annulus and its surrounding structures is a critical area of understanding for the design and application of TTVD systems.

TRICUSPID ANNULAR SIZE, SHAPE, DYNAMICS, AND FORCES

The size, shape, and position of the TV annulus changes throughout the cardiac cycle. The systolic reduction in tricuspid annular size decreases the area that the leaflets must occlude and maximizes the available leaflet surface area for coaptation. Cyclic changes in atrioventricular valve shape are believed to contribute to reductions in leaflet stress and chordal tethering.[48,53,58] This knowledge, among others, has been a significant factor for the sizing and shape of many devices and techniques used for tricuspid annular reconstruction.

The projected two-dimensional shape of the healthy TV orifice is generally considered to be oval. The mean systolic annular area and circumference of heathy adults have been reported to range from approximately 7 to 11 cm^2 and 10 to 12 cm, respectively.[2,12,28–30,34,46,57] Tricuspid annular size, however, has been demonstrated to increase in the setting of disease. Select data from studies evaluating tricuspid regurgitation have reported the mean systolic annular area and circumference to range from approximately 11 to 15 cm^2 and 12 to 14 cm, respectively.[4,12,29,46,57] These data also demonstrate the annular orifice to become more circular than oval, although the exact degree of circularity varies among diseased patients.

The tricuspid annulus cyclically reduces in size throughout the cardiac cycle. Clinical data demonstrate TV diseases to decrease but not eliminate cyclic reductions in annular size. In examining differences between healthy and tricuspid regurgitation patients, cyclic reductions in annular area and circumference decrease from approximately 28 to 15% and from 14 to 8%, respectively.[4,12,28,29,34,46,57] These decreased levels are comparable to cyclic annular area reductions (range 11–22%) and circumferential reductions (range 5–10%) of healthy porcine and ovine animal models for which many TTVDs are tested and developed.[11,15,17,19,32,33] Of note, additional studies have demonstrated segmental differences in the cyclic reduction of the anterior, posterior, and septal annular regions.[11,32,45]

The systolic shape of the healthy TV annulus is generally regarded to be three-dimensional. The most elevated position of the annulus is near the aortic segment while the most apically depressed segments are at or near the posteroseptal and anteroseptal commissures. While the exact magnitude and location of annular height can differ between available studies,

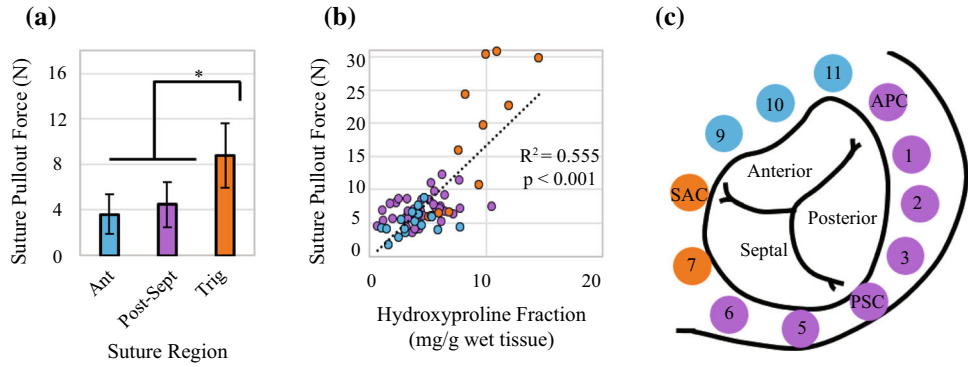

FIGURE 4. (a) Suture pullout forces from the human tricuspid annulus by suture region (shown: mean ± SD; *$p < 0.001$). (b) Correlation between suture pullout force and associated hydroxyproline fraction (a measure of collagen content). (c) Suture placement locations around the tricuspid annulus. *Ant* anterior region, *APC* anterior–posterior commissure, *Post-Sept* posterior-septal region, *PSC* posterior-septal commissure, *SAC* septal-anterior commissure, *Trig* trigonal region.

it is generally accepted that a flattening of the tricuspid annular shape occurs in diseased populations,[15,28,29,32,33,44–46] such that most patients presenting for TTVDs may exhibit a planar annulus.

In addition to cyclic changes in tricuspid annular size and shape, select studies have quantified cyclic tricuspid annular displacements and angulations within the heart.[28,34] In healthy adults, the tricuspid annulus has been demonstrated to systolically and apically displace by approximately one centimeter, with the anterior and posterior segments of the annulus displacing further than the septal. These displacements are notably larger for the tricuspid than for the mitral.[28]

Data for in-plane, out-of-plane, or other forces associated with tricuspid annular dynamics are lacking. Preliminary animal and *in vitro* simulator data have been reported.[6,23] In a pilot porcine animal experiment, Kragsnaes *et al.* reported a peak force of 0.4 N to act on the anteroseptal commissural segment of an annuloplasty ring.[23] In 2016, Basu *et al.* measured the tension between the TV leaflets and the annulus within an *in vitro* simulator. The average tension measured in simulated healthy and dilated annular conditions was 0.1 ± 0.02 and 0.3 ± 0.1 N/cm, respectively.[6] The forces measured in these studies are lower than what may otherwise be anticipated based on comparisons to mitral based measurements, comparisons in left and right heart structure and function, and the relative magnitude of TV chordae tendineae force measurements.[41,58] Further complimentary evaluations are warranted to contextualize these findings, as well as to more generally describe the full scope of annular force dynamics.

Together, these data suggest most patients who are too high-risk for open-heart surgery will likely present with an enlarged and flattened annulus with some degree of cyclic annular dynamics. Delivering a device in the setting of these dynamics is a circumstance not encountered during surgery on an arrested or fibrillating heart on cardiopulmonary bypass. These dynamics should be accounted for during product/procedure development, with emphasis on the delivery system, intraoperative imaging, and physician training. Provided many TTVDs must be comparably more flexible and foldable than surgical devices to permit a percutaneous delivery, annular dynamics may also be considered in developing the device structure, ensuring its durability, and sustaining its intended function within the limitations of the device system.

SECURING DEVICES INTO THE ANNULAR TISSUE

The mechanics of securing devices into the tricuspid annular tissue can be fundamentally described by a mechanistic balance between the holding force of the device's annular attachments, the strength of the underlying tissue, and the forces acting on the device. These areas of interest are influenced by the design of the device's annular attachment(s), their application, how and where the attachment is implanted, the composition of the underlying annular tissue, and the native function of the heart. Greater details for each of these factors are now described.

The variety of TTVD annular attachment designs is diverse and includes wired closures, anchors, stakes, hooks, tacks, and cork screws, among others.[1,21,24,47,49,56] The methods by which they generate holding force can differ. Wired closures are fundamentally similar to surgical sutures. They aim to distribute their tension over a maximal volume of tissue to minimize local tissue stress. When these closures are used with pledgets, the pledgets may further distribute concentrated stress on and through the tissue.

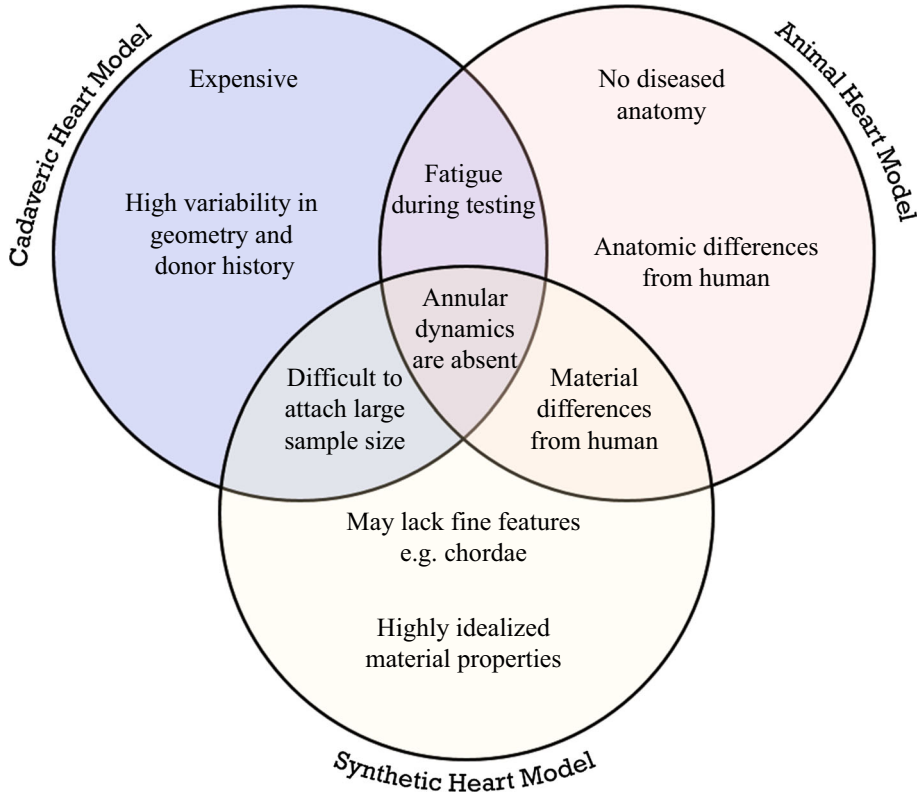

FIGURE 5. Major potential limitations of common *in vitro* models for the study of transcatheter tricuspid valve device (TTVD) interaction with the native tricuspid annulus.

This approach was recently emphasized by Khan *et al.*, who demonstrated pledgeted closures gain an advantage when they are allowed to penetrate the full thickness of the annular shelf.[21]

Anchors, stakes, tacks, and similar designs typically exhibit external barbs to prevent tissue disengagement. The insertion, the resulting tissue damage, the depth and breadth of surrounding tissue, and the barb design all influence the acute attachment holding force. The actual purpose of these designs can vary, with some designed to provide a functional holding force and others for positioning purposes only.

Based on the strategy of sutures or closures, cork screw or worm designs offer appeal. The screw or worm generates hold by distributing its force along the length of tissue for which it displaces. The number of revolutions, length, thickness, and diameter of the helix all influence the acute attachment holding force. Chan *et al.* observed superior pullout forces from the mitral annulus using a cork screw as compared to a tack design in an acute setting.[9]

One strategy for maximizing the TTVD holding force is increasing the total number of device-annulus attachments. In this strategy, the force required to secure the device is distributed to a greater number of attachments, effectively lowering the required holding force of each annular attachment. This strategy is logical but requires several circumstances to be considered. One is the potential for unequal loading of attachments. This can occur due to segmental differences in annular dynamics, heterogeneous loading, or local differences in tissue composition that lead to greater focal loading (Fig. 2). Such regional differences have been previously demonstrated in studies evaluating tricuspid valve dynamics, suture force measurement studies, and annular strain for the mitral and tricuspid valves.[11,31,32,35,37,39,45] Another potential circumstance is the physical space for which the attachments can be placed. Limitations in attachment size and placement may reduce the net holding force of the device that can be achieved.

When considering any annular based attachment, the holding strength of the underlying tissue must be considered. Recent studies have evaluated the suture pullout strength at varying positions around the tricuspid annular perimeter. In previously frozen ovine hearts, Paul *et al.* determined a global mean suture pullout strength around the tricuspid annulus of 6.5 ± 2.2 N (range 1.9–17 N).[35] Observed variation in positional holding strength was attributed to regional variations in collagen content as demonstrated in Fig. 4. More recently, these experiments were repeated

in previously cryopreserved frozen human hearts with no history of heart disease. From this study, the global mean suture pullout strength around the tricuspid annulus was 8.2 ± 6.1 N.[27] This mean value was noted to be strongly influenced by position. When analysing results by region, the trigonal region had higher pullout force than the posterior-septal and anterior regions, respectively (17.4 ± 10.1 N vs. 6.8 ± 2.0 N, 5.1 ± 1.8 N, $p < 0.001$).

When evaluating holding strength of the tissue vs. the forces acting on the annular attachments, combinations of device design and mechanism of action can have a significant effect. The more aggressively the device remodels the annulus, the more force is necessary to secure it to the tricuspid annular tissue. At the time of implantation, the magnitude of these forces must be managed to mitigate the risk of the device and its attachments dehiscing from the annular tissue. This concept has been demonstrated clinically, where an increased risk of dehiscence after TV repair with rigid annuloplasty rings was reported.[36] Clinical reports and adverse event data from the Food and Drug Administration's Manufacturer and User Facility Device Experience Database suggest that the risk for this failure is in the early post-operative period before fibrous encapsulation of the device and its attachments can occur.[18,26,43,50,59]

The forces that may act on the annular attachments themselves are device and application specific, but some common sources may be identified. Ambient hemodynamic loading is particularly relevant to valves, where the transvalvular pressure acting on the leaflets may induce device deformation and a transfer of loads to the attachments. Relative motion between device structures may also result in load transfers to the annular attachments, which may be exacerbated once a reconstructive or replacement effect is achieved. Such examples may include devices utilizing anatomical features external to the annulus for device fixation or anchoring.

Within the beating heart, the attachments may be loaded by tissue motion, myocardial tissue contraction-relaxation, or both. These intra-tissue forces may consist of varying combinations of tension, compression, bending, and torsion. While these mechanisms of loading are discussed in isolation, it is important to remember that these modes among others may occur in combination.

Reference data can be critical to assess the comparative holding strength of TTVD attachments. Recent studies have evaluated the holding strength of sutures and annuloplasty rings within the mitral annulus.[35,37–39,54] These studies have demonstrated the effects of ring type, ring-annular sizing, suture technique, elevated left ventricular pressure, and suture position on cyclic beating heart suture forces and their positional holding strength. These data may aid in informing the general values that may be expected, within the limitations of their applicability to the device annular attachment in question.

DEVICE SECUREMENT AND THE RIGHT CORONARY ARTERY

Injury to the RCA is a rare but serious complication in open-heart TV procedures.[10] This event can occur by placing a suture through or around the RCA, resulting in its obstruction or kinking, with or without the disruption of fibrotic plaque and embolization. The rarity of this event is likely attributed to the accuracy and precision with which sutures can be placed under direct visualization during open-heart surgery. Critically, TTVDs exhibit differing methods to guide and secure the device to the tricuspid annular tissue. For these reasons, among others, literature reports have identified TTVDs to exhibit a risk for RCA injury.[7,25,56,60]

The potential of RCA injury for TTVDs largely exists because of the physical dimensions of TTVD attachments, methods of driving the device's attachments into the annular tissue, potential limitations in intraoperative visualization, delivery system accuracy, and the relative proximity of the RCA to the annular tissue.[60] For these reasons, many device systems and heart teams employ pre-operative and intraoperative imaging techniques to mitigate these risks, where possible, within the limitations of the device and its delivery system.

In the event of RCA injury, bailout procedures or conversions to open-heart surgery may be considered. The ability to pursue an alternative procedure however may be limited based on circumstances relating to device design, tissue mechanics, or both.

LEVERAGING MEDICAL IMAGING

Baseline knowledge of the biomechanical environment in which a TTVD may be delivered can be gained through pre-operative medical imaging such as echocardiography, magnetic resonance imaging, and computed tomography. Such modalities may reveal the anticipated degrees of annular dynamics, understanding how and where the device will be attached to the annulus, attachment zone thickness, and the proximity of adjacent structures to plan for the mitigation of known device risks.[5,40,61]

Intraoperative medical imaging is critical to the majority of TTVD systems. Clinical operators must guide, track, position, and implant the device to the dynamic annulus within the limitations of the system. The extent to which the physician can accomplish these tasks relies on their skill, experience, and training, but also on intraoperative fluoroscopy, echocardiography, and/or fusion imaging. Real-time 2D or 3D imaging can be limited in temporal and spatial resolution, as well as by the field of view. These factors further challenge the heart team's ability to assess and account for the patient's specific annular dynamics when attempting to position and implant the device. This may require a team understanding of the TTVD and its limitations, the imaging system and its limitations, the dynamic annular environment, and, where possible, the patient's specific characteristics.

PRODUCT TESTING

Available international standards and regulatory guidance suggest the testing of TTVDs under conditions at least as severe as those anticipated *in vivo*.[16] This objective is challenged by the scarcity of available biomechanical data requiring many developers to seek out methods and models to define relevant biomechanical loading conditions. During preclinical development, device developers commonly employ large animal models to evaluate device system performance in the setting of the beating heart. Where applicable, large animal experiments can be directly supplemented by bench models within the limited extent to which the models mimic physiological phenomena.[51] The most common of these include explanted cadaveric hearts, explanted animal hearts, and synthetic models (e.g., silicone); selected limitations of each are described in Fig. 5.

Computational models are often commonly employed; however, these too suffer from the availability of biomechanical boundary conditions. Indeed, regulatory bodies recognize the value of such models, together with bench, *in vivo* and clinical studies, for evaluation of the safety and efficacy of medical devices. The complex nature of device-tissue interaction seems particularly well-suited for computational modeling, yet, existing computational models and simulations of the native tricuspid valve are limited.[22,55] These gaps suggest significant academic and commercial opportunity in developing methods, techniques, and data to supplement the development of TTVD systems. Continued knowledge and opportunities may further supplement these activities.

CONCLUSION

A significant variety of transcatheter tricuspid valve devices are known to be in development or under clinical evaluation. Baseline knowledge for tricuspid annular mechanics and its variation with disease and implanted devices is critical to improving device design, procedures, function, and clinical outcomes. Future studies will supplement the knowledge contained herein, and further contribute to the improved treatment of tricuspid regurgitation.

COMPLIANCE WITH ETHICAL STANDARDS

CONFLICT OF INTEREST

Shelly Singh-Gryzbon, Eric L. Pierce and Ajit P. Yoganathan have no conflicts of interest relevant to this review article. Andrew W. Siefert is an employee of Cardiac Implants LLC.

ETHICAL APPROVAL

No human or animal studies were carried out by the authors for this article.

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