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CYLINDRICAL PROSTHETIC VALVES FOR THE TRICUSPID POSITION: PROSPECTS AND LIMITATIONS

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Tricuspid valve (TV) replacement for primary regurgitation is a relatively rare procedure. Bioprosthetic valves are generally preferred because they do not require anticoagulant therapy and tend to degenerate more slowly in the tricuspid position than in the mitral or aortic positions; however, their durability remains limited, particularly in young patients. In contrast, mechanical prosthetic valves require rigorous anticoagulant therapy due to low blood flow in the right heart chambers. Prosthesis selection is especially challenging in cases of infective endocarditis with fibrous annular abscess. The aim of this study is to analyze experimental data on cylinder valves and to review the first clinical experiences reported worldwide. The development of new prosthesis models using inert and more durable materials may address current limitations of TV implants, optimize surgical techniques, and improve patient quality of life in the long-term.

Keywords: tricuspid regurgitation, cylinder valves, bioprosthetic valves, infective endocarditis.

Severe primary tricuspid regurgitation caused by infective endocarditis is most commonly associated with infections following pacemaker lead implantation, prolonged intravenous catheterization during chronic dialysis or cancer treatment, and intravenous drug use. Mechanical prosthetic valves in the tricuspid position are particularly prone to thrombosis due to low blood flow velocity, whereas bioprosthetic valves (BPVs) are susceptible to degeneration and calcification, especially in younger patients. Moreover, no currently available prosthetic valve accurately replicates the native ellipsoidal geometry of the tricuspid annulus or is specifically designed for this anatomical position. Tricuspid valve replacement is often complicated by conduction disturbances due to the proximity of the atrioventricular conduction system, which runs through Koch's triangle near the septal leaflet. In addition, the risk of recurrent infective endocarditis after valve replacement, especially among people who inject drugs, remains high.

The concept of a cylindrical atrioventricular prosthetic valve was first proposed by James Cox and colleagues [1] in the late 1980s, based on the hypothesis that native heart valves function as simple tubular structures whose walls collapse under external pressure. The authors tested a range of materials, including an early experimental scaffold derived from porcine small intestinal submucosa (PSIS), for implantation in both the mitral and tricuspid positions. Their findings demonstrated that the tubular valve design was capable of restoring normal hemodynamics to the prosthetic valve.

EXPERIMENTAL EVALUATION OF CYLINDRICAL PROSTHETIC VALVES

In 2013, Fallon et al. [2] published the results of a small experimental study evaluating cylindrical prostheses fabricated from CorMatrix extracellular matrix (ECM) implanted in the tricuspid position in a sheep model. Echocardiographic examination, together with macroscopic and microscopic histological analyses, showed that the cylindrical valve functioned as a competent tricuspid BPV for more than 12 months without evidence of degeneration or calcification. Histological examination of the explanted constructs further revealed signs of endothelialization and adaptive tissue remodeling.

In 2016, Ropcke et al. [3] conducted a study in a porcine model to implant a cylindrical ECM graft in the tricuspid position and to evaluate its biomechanical and physiological properties in comparison with the native TV. After implantation, the annular area and circumference of the cylindrical prosthesis were smaller than those of the native valve, despite preoperative sizing intended to reproduce the maximum circumference of the natural tricuspid annulus. On average, the circumference of the implanted cylindrical valve was 20% smaller, a discrepancy attributed by the authors to the design of the prosthesis and surgical implantation technique. Importantly, analysis of native tricuspid annular geometry was consistent with prior observations, demonstrating that the annulus assumes a multiplanar shape during systole.

Hsu et al. from Florida International University (USA) subsequently investigated the hemodynamic per-

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formance of cylindrical prosthetic valves implanted in the tricuspid and mitral positions. A 26-mm cylindrical valve constructed from PSIS (CorMatrix Cardiovascular) was sutured to a custom 3D-printed valve holder. Hydrodynamic testing was performed using a pulse duplicator system (Vivitro Labs) with 0.9% saline solution. Flow was measured between the right atrium and ventricle, while pressure sensors were positioned in the right atrium, right ventricle, and aorta. Tests utilized a heart rate of 70 beats per minute, with a stroke volume of 50 mL for the tricuspid valve and 71.4 mL for the mitral valve. The tricuspid cylindrical prosthesis demonstrated a transvalvular pressure gradient of 3.97 mmHg and a regurgitation fraction of 7.70% [4].

CLINICAL APPLICATION OF CYLINDRICAL PROSTHESES

In 2016, Murala et al. [5] reported a case involving implantation of a manually constructed cylindrical prosthetic valve in a 15-month-old male infant (10 kg) with pulmonary atresia who had previously undergone two balloon pulmonary valvuloplasty procedures, followed by open TV repair. Despite these interventions, the patient developed severe tricuspid regurgitation and stenosis, along with pulmonary valve regurgitation. An attempted repeat TV repair resulted in further clinical deterioration, prompting the decision to proceed with valve replacement.

The native tricuspid annulus measured 20 mm. The low effectiveness of stented bioprosthetic valves in this age group is well known. Therefore, the surgical team elected to fabricate a cylindrical valve from CorMatrix tissue intraoperatively. This approach was chosen with the intent of preserving the option for future transcatheter valve implantation. The proximal edge of the cylindrical prosthesis was folded inward by approximately 3 mm to create a double-layered suture ring, and the cylinder length was initially set at 24 mm (1.2 times the annular diameter). Distally, the prosthesis was secured to the three papillary muscles using mattress polypropylene sutures, while the suture ring was attached to the tricuspid annulus with a continuous polypropylene suture.

However, significant central regurgitation occurred during ventricular filling. The procedure was repeated using a longer cylindrical prosthesis measuring 35 mm (1.7 times the annular diameter), which resulted in a competent valve with good hemodynamic performance and no residual regurgitation.

Preoperative echocardiography was used to assess the extent of valvular destruction and to determine the native annular diameter and chordal length. The cylindrical prosthesis was made from a CorMatrix sheet, with the diameter matched to the patient's fibrous annulus. Prosthesis length was determined either echocardiographically as the distance from the annulus to the papillary muscle tips or according to a standardized criterion of 120% of the cylinder diameter. After clamping the aorta, protecting the myocardium, and stopping cardiac activity, all infected areas were excised down to healthy tissue. Following aortic cross-clamping, myocardial protection, and cardioplegic arrest, all infected areas were excised down to healthy tissue. Three ventricular attachment points were then identified for fixation of the cylindrical prosthesis (Fig. 1). Owing to variability in the number and spatial distribution of right ventricular papillary muscles, fixation sites were selected to be approximately equidistant, at 120° intervals, with the anterior papillary muscle typically serving as the reference point when selecting other fixation points. Depending on the condition of the subvalvular apparatus after debridement and surgeon preference, sutures were placed at the tips, bases, or bodies of the selected papillary muscles. Fixation was achieved using mattress suture (usually 4-0 or 5-0 polypropylene or polyester) with or without pledgets. Several noteworthy technical observations were reported. Notably, despite complete excision of the septal leaflet in several cases, no patients developed complete atrioventricular block, suggesting a potential advantage over conventional prosthetic valve replacement. The cylindrical prosthesis was sutured circumferentially to the annulus using a continuous suture technique. An additional advantage of the cylindrical design may be preservation of native annular geometry and the conical configuration of the right ventricle, even in cases requiring extensive excision of infected chordae.

In all but one patient, tricuspid regurgitation was of recent onset, and significant right ventricular remodeling had not yet occurred. There were no in-hospital deaths. Intraoperative papillary muscle rupture occurred in one patient, and delayed rupture developed in another patient seven days after surgery; both complications were successfully corrected. One patient required implantation of a stented xenopericardial prosthesis 22 months later due to cylindrical valve dysfunction. At 6-month follow-up, one patient with a history of intravenous drug use developed fungal endocarditis involving the cylindrical prosthesis and underwent successful reimplantation with a CorMatrix cylinder. In the remaining patients, with follow-up extending up to 18 months, prosthesis function remained satisfactory with no evidence of structural failure.

Based on echocardiographic assessment of the patient's anatomy, a cylindrical prosthesis constructed from CorMatrix extracellular matrix was fabricated intraoperatively during the reoperation. The prosthesis circumference was calculated as the tricuspid annular diameter multiplied by π, and the prosthesis length as 1.3 times the annular diameter. Three attachment points to the papillary muscles were selected at approximately 120 degrees apart and reinforced with CorMatrix tissue patches. The proximal edge of the cylindrical prosthesis was sutured circumferentially to the tricuspid annulus using a continuous suture technique.

Echocardiography performed on postoperative day 5 showed only minimal regurgitation across the prosthesis. At 11-week follow-up, the cylindrical valve showed excellent functional performance with no evidence of regurgitation. The patient was clinically well, the infection had resolved completely, and she was able to return to work and study. The authors highlighted the minimal use of non-biological material as a key advantage of the cylindrical prosthesis; however, they emphasized that definitive conclusions cannot be drawn without long-term follow-up data [7].

SYNTHETIC AND BIOLOGICAL SCAFFOLDS FOR VALVE SURGERY

In recent years, various synthetic and natural scaffolds have been employed in tissue engineering and regenerative medicine to create tissues and organs seeded with autologous or stem cells, with the aim of overcoming immunological barriers. After implantation of synthetic scaffolds into the human body, the immune system initiates a foreign body response characterized by early neutrophil and macrophage infiltration and release of proinflammatory cytokines at the implantation site. As a result, most synthetic implants become covered by dense fibrous tissue and functionally isolated from the host. This foreign body response may persist until the implant is completely destroyed or surgically removed; otherwise, it can progress to chronic inflammation [8].

Tissue-engineered decellularized ECM scaffolds have great potential to address donor shortages and reduce immunological rejection. ECM scaffolds are biomaterials derived from various tissues and are intended to function as temporary biological scaffolds that allow the patient's own cells to colonize and repair tissues. These materials have demonstrated the ability to promote constructive tissue remodeling across a wide range of tissues in both preclinical animal models and human clinical trials. However, the host immune response to decellularized tissues is influenced by several factors, including the effectiveness and methodology of the decellularization process, the tissue of origin, the implantation site, and recipient-specific characteristics. Decellularization is a critical step in ECM scaffold production, as it removes immunogenic cellular components and thereby significantly reduces immunogenicity, enhancing the biocompatibility of the resulting scaffold.

However, the use of these bioscaffolds continues to pose significant immunological challenges. Decellularization is defined as the removal of DNA and other cellular components while preserving the native architecture and biochemical composition of the ECM. It is currently the most effective strategy for reducing tissue and organ immunogenicity. However, incomplete removal of cellular remnants during decellularization may trigger a strong immune response after implantation. On the other hand, complete removal of cellular materials can damage the ultrastructural integrity of the scaffold, adversely affecting scaffold function, durability, and regenerative capacity. Thus, the immunogenicity of ECM scaffolds is influenced by multiple interrelated factors. First, decellularization protocols must be optimized to ensure effective removal of cellular components while preserving ECM composition and structural integrity. Second, additional antigen-removal strategies are required to eliminate residual immunogenic epitopes after

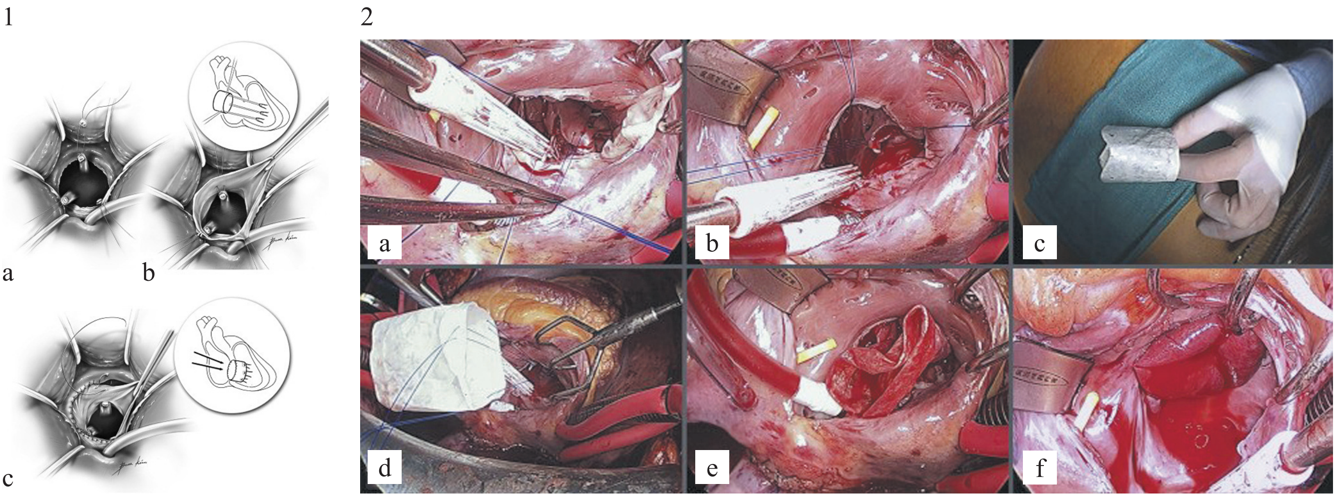

Fig. 1: 1 – schematic representation of the operation (a, suturing the pappilary muscles, b, fixing the suturers to the lower edge of the prosthesis, c, fixing the sutures to the rings); 2 – intraoperative view of the stages of the operation (a, b, suturing at the papillary muscle attachment points, c, extracellular matrix valve prior to implantation, d, distal edge of the valve secured to the attachment points, e, proximal edge of the valve circumferentially sutured to the annulus, f, demonstration of valve function during saline insufflation)

decellularization. Third, reliable detection methods and more effective washing protocols must be developed to remove residual cytotoxic agents. Fourth, source tissues should be selected for greater immunocompatibility. Fifth, the degradation rate of the decellularized scaffold must be carefully controlled to prevent either a persistent foreign body reaction with chronic immune activation or excessively rapid degradation leading to acute cytokine release and graft failure. Finally, sterilization methods must be chosen to minimize damage to the decellularized scaffold [9–11].

In a study by Padalino et al. evaluating the long-term outcomes of ECM scaffolds used for reconstructive surgery in congenital heart disease, 5 of 13 patients (38.4%) who underwent valve reconstruction required repeat valve replacement after a mean follow-up of 25.2 months. The authors concluded that the durability of ECM scaffolds appeared inferior to that of autologous pericardium [12].

Nevertheless, the flexibility and reduced thickness of ECM scaffolds may represent an advantage in patients with low body weight, in whom even autologous pericardium can be excessively thick and bulky for small anatomical structures. Moreover, the potential for colonization by autologous cells remains a promising feature of ECM-based materials. In addition, implantation of ECM into viable native valve tissue for augmentation purposes may facilitate tissue regeneration and adaptive remodeling. In contrast, leaflet enlargement using ECM in the setting of a dysplastic valve may result in infiltration by inflammatory cells and neointimal thickening, without any cellular remodeling.

Histological analysis comparing two materials, CorMatrix and autologous pericardium, conducted by Zaidi et al. at the Boston Pediatric Cardiology Center, showed significant differences between the two materials. CorMatrix remained structurally intact with minimal macroscopic change throughout the observation period; however, it elicited a pronounced inflammatory response lasting up to 9 months. This response was characterized by dense infiltration of eosinophils and multinucleated giant cells. No evidence of scaffold resorption, constructive remodeling, or formation of tissue resembling native valve structures was identified. In many specimens, a thick neointimal layer developed over the material, suggesting that CorMatrix was covered with a membrane. In contrast, autologous pericardium did not provoke a significant inflammatory response. Although this difference may partly reflect longer implantation durations for pericardial samples – during which inflammation would be expected to have resolved – even specimens retrieved at earlier time points (e.g., 14 and 163 days) showed no inflammation. By comparison, CorMatrix samples continued to exhibit active inflammatory changes at similar intervals. Notably, focal calcification was observed in autologous pericardial patches, typically localized around suture lines [13].

CYLINDRICAL PROSTHETIC VALVES MADE FROM AUTOLOGOUS PERICARDIUM

In 2023, Miyamoto et al. [14] developed a template for constructing cylindrical bioprosthetic valves from autologous pericardium for use in atrioventricular valve replacement. For each bioprosthetic valve, the circumference of the native mitral or tricuspid annulus was first measured precisely. Then, the appropriate template, which was originally designed to correspond to the native annular dimensions, was then selected, and the pericardial patch was cut accordingly. The harvested pericardium was treated with 0.6% glutaraldehyde for 2 minutes and subsequently rinsed three times in saline. The proximal edge of the pericardial patch was folded outward to create a loop, and the lateral edges were sutured with several stitches to form a complete cylindrical structure corresponding to the annular circumference. To assess the reproducibility and functional consistency of the cylindrical autopericardial prosthesis across different cardiac anatomies, the authors conducted experiments in 15 animal hearts, including 9 Dorset sheep, 3 goats, 2 dogs, and 1 miniature pig. Prior to valve implantation, the native mitral or tricuspid valve, along with its tendinous cords, was excised.

During implantation of the cylindrical prosthetic valve, the posterior leaflet of the new valve was aligned with the septal leaflet of the tricuspid valve. After implantation, saline was injected into the ventricle to assess valve After. The closed configuration of the implanted valves, leaflet mobility, coaptation length, and the presence or absence of regurgitation were carefully evaluated. Coaptation length was determined using a staining technique. None of the implanted valves showed regurgitation.

The authors emphasized that the *ex vivo* findings demonstrate the structural advantages and potential clinical benefits of the developed cylindrical prosthesis. Nevertheless, further *in vivo* studies, including long-term follow-up, are required to fully assess the potential of this novel BPV.

Researchers from Poland [15] proposed that eliminating artificial materials and implanting exclusively autologous biological tissue could reduce the risk of recurrent infective endocarditis (IE). Their study included seven consecutive patients with active IE who underwent implantation of a cylindrical valve constructed from the patient's own pericardium in the tricuspid position. The decision to use a pericardial cylinder was made due to complete destruction of the native tricuspid leaflets.

Transthoracic echocardiography was performed to evaluate the extent of leaflet destruction, the severity of regurgitation, the size of the fibrous annulus, and leaflet height (defined as the distance from the annular edge to the heads of the papillary muscles).

All procedures were performed via median sternotomy, which also allowed harvesting of pericardial tissue. A rectangular pericardial patch measuring 10×4 cm was excised and fashioned into a cylinder with a diameter of 30–32 mm. The cylinder length was approximately 120% of its diameter. Three fixation points were marked at 120° intervals, corresponding to the anticipated attachment sites at the right ventricular papillary muscles. In two patients, the cylinder was made from a xenopericardial patch.

The native tricuspid valve, along with all infected tissue, was completely excised. The papillary muscle heads were identified, and the three marked points on the pericardial cylinder were secured to the posterior and septal papillary muscles using 5-0 Gore-Tex sutures. If the anterior papillary muscle was underdeveloped, the corresponding fixation point on the cylinder was attached to the interventricular septum at the level of the other papillary muscle heads. The proximal end of the cylinder was then anastomosed to the tricuspid annulus using a continuous 5-0 Prolene suture, with gradual adjustment to accommodate any diameter mismatch between the native annulus and the prosthetic cylinder. After implantation, a saline (water) test was performed to verify valve competence and ensure adequate sealing (Fig. 2).

Isolated implantation of the pericardial cylinder was performed in only two patients. The remaining five patients required additional surgical procedures, including prosthetic valve implantation in other positions, radiofrequency ablation for atrial fibrillation, closure of a ventricular septal defect (VSD), closure of a patent foramen ovale (PFO), and coronary artery bypass grafting (CABG).

The postoperative follow-up period ranged from 2 to 32 months (mean duration: 17 months). During follow-up, no cases of recurrent IE involving the pericardial cylinder were observed. However, degeneration of the pericardial cylinder leading to stenosis occurred in three patients. Two of these patients had a history of intravenous drug use. One of them died five months after surgery due to recurrent IE affecting an aortic prosthesis. The second patient developed early cylinder degeneration three months postoperatively and required reoperation. The third patient with cylinder degeneration underwent a successful transcatheter valve-in-valve procedure.

The authors concluded that implantation of a pericardial cylinder in the tricuspid position effectively eradicates tricuspid valve IE and minimizes the risk of recurrence. The use of either autologous or bovine pericardium allows complete restoration of valve function and represents an effective and reproducible surgical technique. Furthermore, degeneration of the cylindrical prosthesis with subsequent stenosis can be managed using balloon valvuloplasty or transcatheter valve-in-valve implantation.

As can be seen, substantial efforts have been made toward the development and clinical implementation of cylindrical BPVs for the tricuspid position. Nevertheless, the choice of material for prosthesis fabrication remains a central challenge. The absence of a supporting frame reduces tissue stress at the attachment sites, which may enhance durability, even when using well-established biomaterials such as fixed xenopericardium or autologous pericardium.

Tissue-engineered constructs represent a promising alternative; however, their clinical application remains uncertain due to limited availability and inconsistent data regarding long-term durability and immunogenicity. In addition, certain technical challenges related to implantation persist and require further refinement.

Overall, the development of a cylindrical prosthetic valve for the tricuspid position is a highly promising direction in cardiac surgery. Its adaptable sizing is particularly advantageous for underweight or small-framed

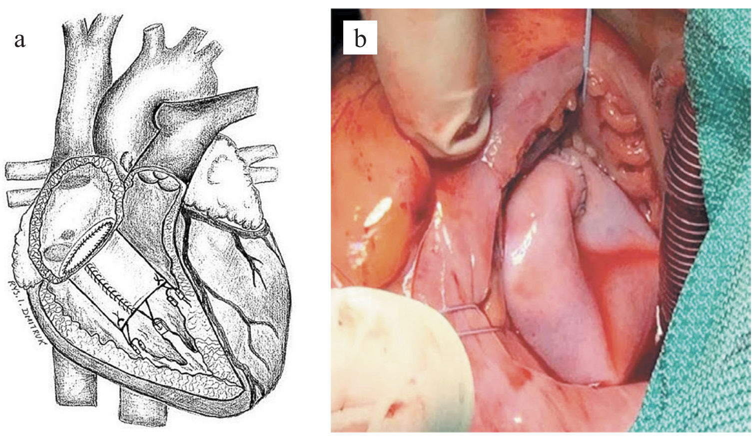

Fig. 2. (a) Schematic representation of an implanted cylindrical prosthesis. (b) Intraoperative view of a cylinder made from pericardium

patients. Continued investigation and accumulation of clinical experience are therefore essential.

The authors declare no conflict of interest.

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