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Case Report

Tricuspid Valve Replacement by Made to Measure ProxiCor® Extracellular Matrix Valve (Elutia, US)

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Abstract

Primary tricuspid regurgitation due to infective endocarditis in young patients with a history of intravenous substance abuse represents a dilemma in terms of prosthesis selection if reconstruction is not a feasible option. We present a novel approach for tricuspid valve replacement in adults by a customized intraoperatively assembled neo-valve using the Elutia (US) Proxicor® Extracellular Matrix (ECM).

Keywords: Extracellular Matrix; Endocarditis; Proxicor; Tricuspid Valve Replacement

Abbreviations: TTE, Trans-Thoracic Echocardiogram; TOE, Trans-Oesophageal Echocardiogram; Mm, Millimeters; POD, Postoperative Day; CIED, Cardiac Implantable Electronic Devices; PWID, People Who Inject Drugs; ECM, Extracellular Matrix; VKA, Vitamin K Antagonists.

Case Report

A 53-year-old man with a history of intravenous substance abuse presented due to fever, body aches and malaise for several days. Initial Trans-Thoracic Echocardiographic (TTE) examination revealed a 20x15mm vegetation on the anterior leaflet of the tricuspid valve with moderate regurgitation. Early blood samples detected Staphylococcus aureus bacteremia and a calculated antibiotic regimen with cefazoline and fosfomycin was initiated. Further evaluation for infectious diseases showed active HIV as well as a Hepatitis C infection. After several days on antibiotic therapy, TTE exam was performed to evaluate the previously confirmed vegetation. Although the vegetation appeared to be reduced, worsening of the tricuspid regurgitation was detected and the patient transferred for surgery.Intraoperative Trans-Oesophageal Echocardiography (TOE) confirmed severe tricuspid regurgitation as well as vegetation on the anterior leaflet. Utilizing careful 2D- as well as 3D TOE examination the necessary parameters for constructing the personalized ProxiCor valve were measured: The valvular annulus showed a diameter of 40mm (millimetres), the distance from annulus to septal papillary muscle attachment during diastole measured 42mm. Using these measurements, the neo-valve was crafted from a single 10x5cm ProxiCor Patch during the time period of opening the chest. Using 5-0 Prolene (Ethicon US, LLC) the short ends of the patch were sutured to form a tubular structure. From this assembled matrix the anterior, posterior and septal commissures were excised at 1/3 of the height and the neo-attachment points doubled reinforced utilising Teflon felt. Before implantation the neo-tricuspid valve was rehydrated and flushed in sterile saline (Figure 1).After excision of the severely destructed native valve and chordae the neo-valve was implanted starting with the neo-attachment points by suturing them to the base anchor points of the former papillary muscles using Teflon-patches. The

neo-annulus of the ProxiCor valve was then sutured to the native tricuspid annulus with 5-0 prolene in running fashion Initial water test confirmed a fully competent valve with no signs of regurgitation. TOE examination after decannulation showed good biventricular function and confirmed a competent neo-tricuspid valve. A repeat TTE was performed on the 10 t^{h} Postoperative Day (POD) showing no residual vegetations, only minimal tricuspid regurgitation, no stenosis or paravalvular leak (Figure 2).

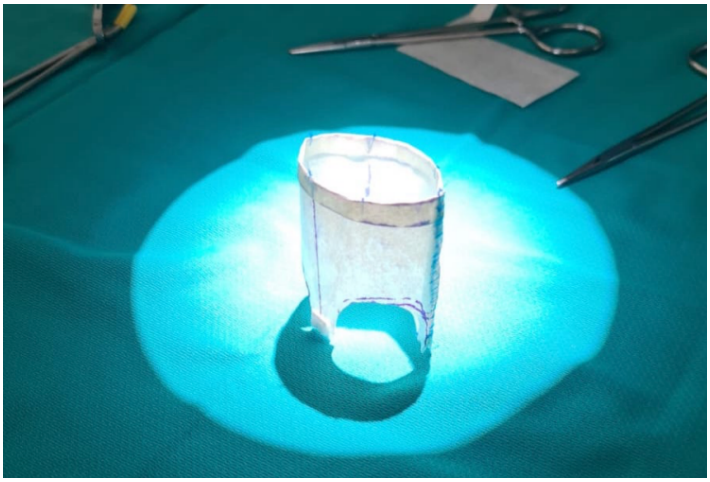

Figure 1: ProxiCor ECM valve.

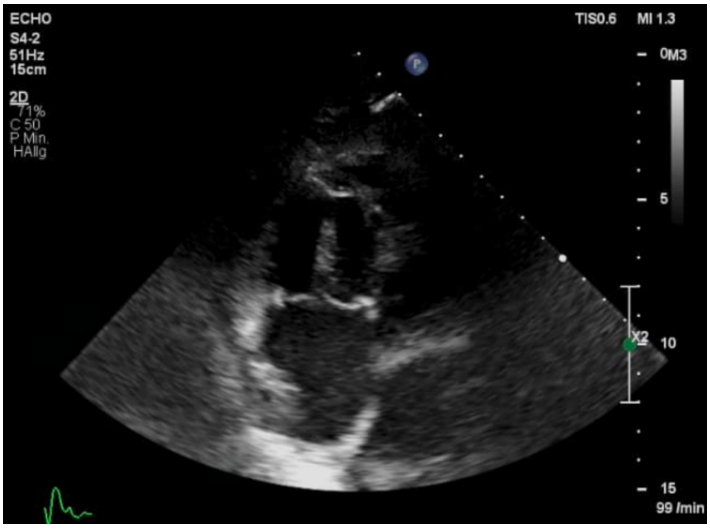

Figure 2: Postoperative Transthoracic Echocardiogramm.

Discussion

Infective endocarditis remains a challenging disease with a reported mortality of up to 15-30% [1]. After careful evaluation in a multidisciplinary team the core tenets of therapy consist of calculated antibiotic therapy and surgical intervention if deemed necessary. Optimal management has been shown to increase survival up to 20% in the first year after surgery [2]. Crucial components in surgical therapy remain the timing of surgery as well as choosing the optimal approach of valve replacement in patients with valvular involvement and indication for replacement [2]. Infective endocarditis of the right heart most commonly occurs in patients with cardiac Implantable Electronic Devices (CIED) as well as in People Who Inject Drugs (PWID) and tends to affect the tricuspid valve more than the pulmonary valve [2]. PWID especially present a challenging subgroup as they are in general of a younger age, have a lower mortality but also a higher rate of recurrence [3]. In cases requiring tricuspid valve surgery this poses the question of the best possible surgical approach. While mechanical valves generally tend to outlast their biological counterparts their management especially the need for lifelong anticoagulation with Vitamin-K Antagonists (VKA) is no small concern in PWID. Although modern conservation techniques have increased the lifetime of conventional biological valve replacement substantially – re-intervention is all but guaranteed. Most commonly made from bovine or porcine pericardium biological valves have been shown to degenerate, calcify or suffer from structural dysfunction after 10-20 years [2]. This dilemma is where we propose this novel approach of a custom made, intraoperatively hand crafted ProxiCor Extracellular Matrix (ECM) valve. The ECM is derived from porcine small intestinal submucosa which is decellularized and already widely used as material for cardiac as well as vascular repair procedures. It has been proven as a well-suited material for valve repair by leaflet augmentation.

The unique biological properties of decellularized ECM allow migration and growth of endogenous cells – including Leukocytes, an important property in the case of infective endocarditis. This allows this neo-valve to function as close to a native valve as possible – by allowing individual endogenous adaptation and being resistant to reinfection without the need for anticoagulation [4,5].In combination with the personalized approach to crafting the valve by taking the distinctive, patient specific measurements of valvular annulus and distance from annulus to septal papillary muscle attachment during diastole it is possible to construct a neo-valve in line with a modern, patient-centred approach. As seen in our early follow-up TTE a postoperative result equal or even superior to a traditional valve replacement is achievable by realizing optimal patient specific hemodynamics with this neo-valve. Not to overlook are the challenges of utilizing this surgical approach: Patient selection is crucial in achieving the best possible results. Furthermore, multidisciplinary collaboration is essential to minimize pitfalls such as taking exact intraoperative TEE measurements and transferring those to the ProxiCor ECM template.While positive long-term results of similar ECM valves used in neonates have recently been published there are more

studies necessary in order to evaluate the long-term outcome of this approach to Tricuspid valve replacement in patients with infective endocarditis [5].

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