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Transcatheter Interventions for Tricuspid Valve Disease:

What to Do and Who to Do it On

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ABSTRACT

Tricuspid valve disease, and particularly the management of severe tricuspid regurgitation (TR), has gained momentum in recent years. Although it is well known that this frequent condition is associated with poor clinical outcomes, these patients have been classically managed medically, leading to end-stage right ventricular heart failure. Moreover, late referral to surgery has contributed to a high rate of periprocedural complications and in-hospital surgical mortality. Thus, the development of a less-invasive catheter-based therapy would be of high clinical relevance in this context.

Several transcatheter tricuspid valve intervention (TTVI) devices have been developed in recent years. The particular characteristics of the tricuspid valve (large non-calcific annulus, presence of chief surrounding structures such as the conduction system or the right coronary artery) make multimodality imaging (e.g. transesophageal echocardiography, computed tomographic) key in the preprocedural assessment of TTVI. According to their mechanism of action and therapeutic target, TTVI includes transcatheter repair either with coaptation or annuloplasty systems, caval valve devices, and transcatheter tricuspid valve replacement. The initial TTVI experience showed that most procedures were well-tolerated, with high procedural success and low in-hospital and early mortality. Also, most TTVI recipients improved their functional status and recent data suggested improved outcomes compared to medical management. However, the rate of significant residual TR following transcatheter TV repair remains high and very scarce data exist on longer term (beyond 6-12 months) outcomes. The present review provides an overview regarding the framework of chronic TR and TTVI therapeutic options, describing the updated current evidence in this challenging field.

SUMMARY

Tricuspid valve disease and particularly severe tricuspid regurgitation (TR) is a frequent condition that has been associated with poor outcomes and high surgical mortality rates. In recent years, transcatheter tricuspid valve interventions (repair, replacement) have emerged as less invasive therapy for treating severe TR. The present review depicts the current evidence regarding the available transcatheter options for TR patients.

ABBREVIATIONS

CE = Conformité Européenne

CIED: Cardiovascular implantable electronic device.

CT: Computed tomographic.

EROA: Effective regurgitant orifice area.

MRI: Magnetic resonance imaging.

NYHA: New York Heart Association.

PH: Pulmonary hypertension.

RA: Right atrium.

RV: Right ventricle.

TA: Tricuspid annulus.

TEE: Transesophageal echocardiography

TR: Tricuspid regurgitation.

TTVI: Transcatheter tricuspid valve intervention.

TTVR: Transcatheter tricuspid valve replacement.

TV: Tricuspid valve.

INTRODUCTION

Tricuspid valve (TV) disease, particularly tricuspid regurgitation (TR), is a frequent condition that affects about 1.6 million patients in the USA[1]. Moreover, chronic progressive TR is associated with an increased risk of heart failure hospitalization and cardiovascular mortality[2-5]. TR is frequently secondary to left-sided valve disease, and the surgical approach of the primary left valvular disorder has been traditionally recommended to improve secondary ("functional") TR[6]. However, functional TR occurs after successful treatment of the primary left valve disorder in a significant proportion of patients[7]. In addition to severe TR within the years following left valve surgery, long lasting atrial fibrillation and the presence of pacemaker leads are also important factors associated with the development of isolated TR[8].

Isolated chronic TR has been medically managed in a significant proportion of patients, leading to progressive right ventricular dysfunction and long lasting heart failure[8]. In fact, late referral has been one of the most important factors contributing to the high in-hospital mortality rates following isolated TV surgery[9-11]. In recent years, several transcatheter tricuspid interventions (TTVI) have emerged as a less invasive alternative to surgery for managing patients with severe isolated TR[12]. The present review aimed to provide an overview of TTVI, including a description of current devices, periprocedural and follow-up results and future perspectives in the field.

TTVI: PRE-PROCEDURAL EVALUATION

The TV apparatus.

The TV apparatus is composed of the annulus, the tricuspid leaflets, the chordae tendineae, and the papillary muscles[13]. It is a complex structure whose comprehension is of paramount importance for the pre-procedural planning of TTVI (**Figure 1**) [14]. Compared to the mitral valve, the TV leaflets are thinner and more fragile, and the TV valve is a larger heart valve, with a valve orifice ranging from 7 to 9 cm2[15]. The papillary muscles are usually disposed in three groups: anterior (the most prominent and implanted in the anterior wall of the apex, fusing with the

moderator band), posterior (with smaller multiple heads implanted in the posterior RV free wall), and septal (sometimes absent).

Several important structures (conduction system, right coronary artery, coronary sinus) surround the TV (**Figure 1**)[14] and are at potential risk of mechanical interaction and damage during TTVI procedures.

Finally, the particular features of the TV imply additional challenges regarding TTVI[16]: the lack of calcium in the large TA, the thin RV wall discouraging transapical approach, the angulation concerning the superior and inferior vena cava, the trabeculated RV and prominent subvalvular TV apparatus, and the possible presence of a cardiovascular implantable electronic device (CIED).

Clinical context

TR is of functional origin in most cases (>90%)[17], caused by annular dilatation and leaflet tethering due to right ventricular remodeling in the context of pressure and/or volume overload. **Figure 2** summarizes the different TR etiologies and depicts the mechanisms involved in TR progression.

To date, several studies have shown poorer clinical outcomes in patients with functional TR, regardless of the presence of elevated pulmonary artery pressures or other comorbidities[3, 18, 19]. However, patients with significant TR may remain mildly symptomatic and with good initial response to medical (diuretic) therapy, in line with the chronic and progressive nature of TR. Over time, symptoms of anterograde right ventricular heart failure (reduced cardiac output) and systemic congestion (hepatosplenomegaly, ascites, and limb oedema) will appear, along with the development of hepatic and renal dysfunction[20, 21].

Following an appropriate assessment of TR etiology and after ruling out the presence of severe pulmonary hypertension (PH), patients with isolated TR and persistent symptoms despite optimal medical treatment should be evaluated for surgical intervention, as recommended by clinical guidelines[22, 23]. However, a significant proportion of patients are rejected due to high or prohibitive surgical risk. In fact, the surgical treatment of isolated severe TR has been associated

with a high perioperative mortality (~10%)[9-11], partially due to the late referral along with the redo factor in a significant proportion of patients. In this context and in the absence of severe right ventricular dysfunction and/or PH, TTVI may offer a less-invasive therapeutic alternative to surgery, with a lower procedural risk and potential benefits (vs. medical management) regarding heart failure hospitalization and mortality.

Multimodality imaging evaluation

Echocardiography. The transthoracic and transesophageal echocardiographic assessment remains the cornerstone of the TR evaluation and also allows an assessment of RV function and PH estimation. Nevertheless, TR grading is challenging and important inter-observer variability has been reported[24]. Current guidelines classify TR in three grades (mild, moderate, and severe) according to qualitative and quantitative parameters[25, 26]. A vena contracta ≥0.7cm, an effective regurgitant orifice area (EROA) of ≥0.40cm2, and a regurgitant volume ≥45 mL, defines TR as severe[25]. However, the preliminary experience with TTVI included patients with long-lasting chronic TR, often categorized as "massive" and frequently presenting quantitative parameters that may double the conventional criteria for severe TR grade[27]. Thus, a new five-class categorization (mild, moderate, severe, massive, and torrential) has been proposed to better classify the severity of TR[28] (**Table 1**).

Computed tomography (CT) imaging. The complexity of the TV apparatus and surrounding structures have determined an important role for CT imaging in the TTVI pre-procedural planning[29-31]. CT imaging adds complementary insights regarding TV anatomy including the geometry and dimensions of TA, relation to adjacent structures (e.g. right coronary artery) or sizing of the vascular access. In addition, CT imaging may help regarding the analysis of the subvalvular apparatus to allow proper navigation of the TTVI device along with the prediction of the best fluoroscopic projection during the procedure.

Other complementary studies. Cardiac magnetic resonance imaging (MRI) has an excellent spatial resolution and provides precise volumetric quantification of TR. It is considered the gold

standard imaging technique for RV assessment and therefore can be additive to echocardiography and CT imaging in the pre-procedural planning of TTVI[29]. Also, a recent study has shown its utility regarding the measurement of the TA[32]. On the other hand, coronary angiography may be used intraprocedurally to assess the relationship between the right coronary artery and TA when the device targets the annulus. Finally, right heart catheterization is not mandatory before TTVI and its use is limited to the cases where is part of the diagnostic assessment (e.g. need to properly categorize PH) or when is necessary to rule out the presence of severe PH.

Table 2[33] depicts the eligibility criteria, main imaging views and measures regarding preprocedural imaging in TTVI (echocardiography and CT) using the current devices and techniques.

TR TREATMENT: THE TRANSCATHETER APPROACH.

TTVI has emerged in recent years as an alternative treatment of isolated TR and several devices have shown promising preliminary results[12]. According to their mechanism of action and therapeutic target, TTVI includes transcatheter TV repair either with coaptation or annuloplasty systems, caval valve devices, and transcatheter tricuspid valve replacement (TTVR).

Transcatheter TV repair: Coaptation devices

Coaptation devices (**Figure 3**)[8,34,35] are designed to improve the amount of TR by valve leaflet plication (edge-to-edge repair) or occupying the regurgitation gap with a spacer. To date, the MitraClip device (Abbott, Santa Clara, CA, USA), the PASCAL system (Edwards Lifesciencies, Irvine, CA, USA), the FORMA device (Edwards Lifesciencies, Irvine, CA, USA), and the Mistral device (Mitralix Lt, Israel) have been used as coaptation devices in the context of TTVI. A new interation of the MitraClip device enhancing the delivery system to address the TV anatomy has been developed (TriClip, Abbot, Santa Clara, CA, USA)[36].

Mitraclip/Triclip. The MitraClip/TriClip system includes two parts: a steerable guide catheter and the clip delivery system, which consists of a steerable sleeve, a delivery catheter and the 4 mm (size NT) or 7 mm (size XTR) wide chrome-cobalt clip with two articulated arms to grasp and draw the

leaflets.

Transesophageal echocardiography (TEE) is of chief importance to establish the feasibility of the edge-to-edge repair using de Mitraclip/TriClip device. A predominant central/anteroseptal jet and smaller TV coaptation gaps (cutoff of 7.2mm) have been identified as predictors of procedural success and greater TR tenting and EROA as predictors of procedural failure[37-39]. Moreover, the first-in-human publication using the new third-generation MitraClip G4 (NT, XT, NTW, and XTW) has been recently reported[40]. This new system allows independent leaflet capture and has 50% wider clip arms (NTW and XTW devices).

Two different procedural techniques have been described[41]. First, the triple-orifice technique, where clips are placed centrally between the septal and anterior tricuspid leaflet and between the septal and posterior tricuspid leaflet. On the other hand, the bicuspidization technique can be used, where clips are placed between the septal and anterior tricuspid leaflets[41].

In cases with poor TEE images, alternative techniques as intracardiac echocardiography or fusion imaging (fluoroscopic and echocardiographic views) can be an option[42, 43] . Of note, the use of intracardiac echocardiography with the probe in the RA may enable to performing the TriClip procedure under conscious sedation.

The main characteristics and early outcomes in the 2 publications including the largest number of patients treated with the MitraClip/TriClip systems to date are summarized in **Table 3**[36, 39] . Little evidence exists regarding the use of the MitraClip XTR system in the context of TTVI. A recent study reported the procedural and early outcomes of 31 patients[44], with good safety and feasibility results (procedural success in 87% of patients). Nevertheless, a high rate of singlet leaflet device attachment was observed (25% among patients with coaptation gap ≥7mm). Finally, the only publication focusing on patients with CIEDs and using exclusively the Mitraclip device did not show significant differences compared with the patients without CIEDs[45].

Pascal. The Edwards Pascal transcatheter mitral valve repair has also been used for TTVI[46]. The Pascal device consists of a 10 mm central nitinol woven spacer that acts as a filler in the regurgitant

orifice and is attached to the valve leaflets by two paddles and clasps (**Figure 3-B**)[34]. The Pascal device allows independent grasping of the leaflets and is repositionable and recapturable. The first-in-human experience (n=28) with this device has been recently published (**Table 3**)[34]**.**

Forma. The FORMA spacer device was a foam-filled polymer balloon that aimed to improve the tricuspid valve coaptation by occupying the regurgitant orifice (**Figure 3-C**)[47]. The device was advanced through a rail anchored at the septal portion of the RV apex. A steerable delivery catheter was used to deliver the rail system to the ideal location in the RV. Of note, the FORMA system is not currently available for medical use. Two studies reported the first experience with the device, and the main characteristics are summarized in **Table 3**[48, 49.]

Mistral. The spiral-shaped Mistral device (Mitralix Lt, Israel) aims to improve leaflet coaptation by grasping the chordae tendineae (**Figure 3-D**). Its spiral is advanced through the femoral vein using an 8.5F delivery system and is rotated in the RV to grasp the chordae of two adjacent leaflets that are pulled together. The first-in-man experience has been recently reported, showing improvement in TR grade in 7/7 patients[35]. The completion of the first-in-human Matters study (NCT04071652) along with the Matters II study (NCT04073979) will provide further data regarding the safety and efficacy of the device.

Transcatheter TV repair: Annuloplasty devices

The annuloplasty devices (**Figures 4 and 5**)[50-55] tried to mimic conventional surgical techniques and can be classified as follows: direct suture (Trialign, TriCinch, minimally invasive annuloplasty, pledget-assisted suture tricuspid annuloplasty [PASTA]) and ring annuloplasty devices (direct: Cardioband, Millipede IRIS; DaVingi™ TR system, indirect: trans-atrial intrapericardial tricuspid annuloplasty [TRAIPTA]). **Table 4**[50, 56, 57] outlines the clinical, procedural, and follow-up data from the main reported cohorts using annuloplasty devices.

Trialign. The Trialign is a transjugular suture-based device (Mitralign, Tewksbury, Massachusetts) that reproduces the Kay surgical technique (obliteration of the posterior leaflet)[58] (**Figure 4-A**). A defectable tricuspid guide catheter is advanced into the RV. Afterwards, an insulated

radiofrequency wire is advanced to cross the annulus from the ventricular to the atrial side, and two pledgets are placed at the posteroseptal and anteroposterior commissures. Then, the pledgets are cinched resulting in plication of the posterior leaflet and TV bicudispization. The results of the first-in-man experience are depicted in **Table 4**[50, 56]. The ongoing SCOUT II Conformité Européenne (CE) Mark Trial (Safety and Performance of the Trialign Percutaneous Tricuspid Valve Annuloplasty System) is a prospective, single□arm, multicentre study enrolling 60 patients to further evaluate the performance of the Trialign system (NCT03225612).

Tricinch. The TriCinh System (4Tech Cardio, Galway, Ireland) aims to reproduce the Kay procedure by cinching the anteroposterior commissure (**Figure 4-B**)[51]. The 18F system is advanced transfemorally and is located in the RA. Afterwards, a corkscrew anchor is fixed near the anteroposterior commissure. Once implanted and after right coronary angiography, the corkscrew is connected to a self-expanding nitinol stent delivered in the inferior vena cava using an adjustable Dacron band. The screw tip has been replaced by a nitinol coil anchor in a second-generation device[59].

Preliminary data from the PREVENT (Percutaneous Treatment of Tricuspid Valve Regurgitation with the TriCinch System) trial (NCT02098200) using the first-generation device is depicted in **Table 7**[57]. Further data regarding safety and performance of the device will be tested in two single-arm studies (Early Feasibility Study of the Percutaneous 4Tech TriCinch Coil Tricuspid Valve Repair System [NCT03632967] and Clinical Trial Evaluation of the Percutaneous 4Tech TriCinch Coil Tricuspid Valve Repair System [NCT03294200], enrolling 15 and 90 patients, respectively.

Minimally invasive annuloplasty. The minimally invasive annuloplasty (MIA™) technology (Micro Interventional Devices) consists of low-mass, polymeric, self-tensioning PolyCor anchors that are tensioned by the thermoplastic MyoLast polymer (**Figure 4-C**)[60]. The system aims to obliterate the posterior leaflet by implanting the anchors between the posterolateral and anteroposterior commissures. After testing the feasibility with the first 3 surgically implanted

devices, the percutaneous approach using a 12F delivery catheter is being tested in the STTAR trial (NCT03692598).

Pledget-assisted suture tricuspid annuloplasty (PASTA). The transcatheter PASTA is a "percutaneous surgical" procedure using pledgeted sutures to create a double-orifice tricuspid valve[52]. The procedure can be performed via apical right ventricular or internal jugular access and replicates the Hetzer double-orifice suture technique. 2 pledgeted sutures are placed at the mid-anterior and the posteroseptal annulus and then tied together to create a double-orifice valve (**Figure 4-D**). The first-in-human case has been recently reported[52]. After successful reduction of TR (from torrential to trace), the tension applied to TA caused septal annular dehiscence that required a nitinol plug. The patient was discharged alive with recurrence of severe TR.

Cardioband. The Cardioband tricuspid repair system (Edwards Lifesciencies, Irvine, CA, USA) is a direct, adjustable, incomplete surgical-like Dacron ring that is fixed along the atrial side of the anterior and posterior TA through a transfemoral 24-F sheath (**Figure 5-A)**. The TA length (from the anterior leaflet to the coronary sinus) assessed by CT will determine the size of the implant. Also, careful evaluation of the distance to the right coronary artery is needed, as deformation resulting from the reduction of the TA might occur[61]. After the first-in-human use[62], the results of the TRIREPAIR study reporting the preliminary safety and efficacy features of the device have been recently published (**Table 7**)[53]. The Cardioband device has received the CE mark for the treatment of functional TR.

Millipede IRIS. The Millipede mitral and tricuspid ring (Boston Scientific, MA) is a semi-rigid, complete ring that replicates a surgical complete annuloplasty ring (**Figure 5-B**)[63]. The device is placed in the supra-annular position and is then anchored and cinched, reducing the TA size. The initial experience consisted of two successful surgical implants that established safety and efficacy[64]. A transcatheter delivery system is currently under development.

TRAIPTA. The preclinical tran-satrial intrapericardial tricuspid annuloplasty (TRAIPTA) device consists of an adjustable nitinol loop that is inserted into the pericardial space through a right atrial

appendage puncture (**Figure 5-C**). Afterwards, the system is adjusted according to the dimension of the tricuspid annulus, resulting in external compression to the TA along the atrioventricular groove[54]. After preclinical data showing acute feasibility in swine[54], a newer version is being developed for human use.

DaVingi™ TR system. The DaVingi™ TR system (Cardiac Implants LLC, Wilmington, DE, USA) is a two-step annuloplasty device that starts with the delivery of a complete, flexible, barbed-ring surrounding the TA. The resulting chronic healing response creates a tissue bond that will secure the implant allowing the cinching of the neo-annulus in a second-stage procedure (**Figure 5-D**)[55]. A first-in-human study is currently ongoing (NCT03700918).

Caval valve devices

Caval valve device implantation with either balloon-expandable or self- expandable valves in the vena cava (inferior or both superior and inferior vena cava) aims to decrease the backflow into the venous system thereby reducing congestion. Furthermore, it may increase the systolic right atrial pressure, leading to a reduction in regurgitant volume[65]. Hemodynamic and technical suitability include the demonstration of pulsatile caval backflow (large ventricular (v-) wave in the RA) and adequate caval measures (≤30 mm for balloon-expandable and ≤42 mm for self-expandable valves), respectively. Of note, a self-expandable stent tailored to IVC diameter is required before the implantation of a ballon-expandable valve. Lauten et al published the first compassionate series of patients (n=25) using 3 different devices (the ballon-expandable Sapien XT/3 [Edwards Lifesciencies, Irvine, CA, USA] valve in 18 patients and the self-expandable valves TricValve [P&F Products Features Vertriebs, Vienna, Austria] and Directflow [Direct Flow Medical, Inc., Santa Rosa, CA] in 6 and 1 patient, respectively)[66]. Procedural success was achieved in 23/25 (96%) patients, with single (only inferior) or bicaval implantation in 19 (76%) and 6 (24%) of them, respectively. 2 valve migrations requiring surgical intervention were reported. Significant improvements in NYHA functional class were observed at 30 days (NYHA class grade improved in at least 1 grade in 83.2% of patients).

After this initial experience demonstrating the feasibility and safety of the intervention, several studies are testing the clinical outcomes of the following devices in this context (**Figure 6**)[67-69]: the non-dedicated Sapien valve and the dedicated TricValve and Tricento (New Valve Technology, Muri, Switzerland) systems. Nevertheless, some concerns have arisen in the interventional cardiology community regarding long-term hemodynamic consequences of the therapy (RA ventricularization or progressive remodeling secondary to increased overload)[8], which has prevented the spread of the technique mainly limiting its use as symptomatic therapy in severely ill patients with TR.

Transcatheter tricuspid valve replacement

The devices specifically designed for native TV replacement are currently in its infancy and must overcome many anatomic challenges. First, the dimensions of the TA in this subset of patients may require large transcatheter valves along with very large bore venous access. Second, the anchoring of the valve in the non-calcific and non-circular TV represent a major challenge. Third, it remains unknown whether the interaction with the conduction system may result in permanent conduction disturbances, which could represent an important issue as the transcatheter valve itself may prevent the subsequent adequate implantation of a CIED.

The first case of TTVR in a native TV required TA pre-stenting followed by the implantation of a ballon-expandable valve[70], but this strategy was rapidly replaced by dedicated TTVR systems. To date, three transcatheter devices have been implanted in humans: the NaviGate stented-valve (NaviGate Cardiac Structures, Inc, Lake Forest, CA), the LUX-Valve (Jenscare Biotechnology, Ningbo, China), and the EVOQUE system (Edwards Lifesciences, Irvine, California) (**Figure 7**)[71-73]. Other transcatheter tricuspid valve systems are under preclinical evaluation, including the Trisol (TriSol Medical Ltd., Inc., Yokneam, Israel) and TriCares (TRiCares GmbH, München, Germany) valves.

NaviGate bioprosthesis. The self-expanding tricuspid NaviGate bioprosthesis is a cone-shaped nitinol tapered stented-valve with annular atrial winglets and radially arranged ventricular graspers

for secure anchoring (**Figure 7-A**). The low profile (21 mm) reduces the risk of outflow tract obstruction. Available in 5 sizes (36, 40, 44, 48, and 52mm), the valve is introduced through a 42-F delivery catheter. The first ortothopic use of a dedicated TTVR device in a native TV was first published in 2017 using the GATE tricuspid valved-stent in two patients, using anterolateral mini-thoracotomy for direct trans-atrial access in one patient and transjugular access in the other one[73].

A recent publication reported the early outcomes from the first 30 patients treated with this device (**Table 8**)[74] . The development of a transfemoral delivery system is currently under investigation.

LUX-Valve. The self-expanding bovine LUX-Valve system is composed of a trileaflet prosthetic valve mounted in a skirt-shaped self-expandable nitinol stent, an interventricular anchorage system, and two anterior clampers for leaflet fixation. After satisfactory results in a preclinical model[74], the first-in-human experience (n=12) was recently published (**Table 5**)[72].

Evoque. The first-in-human transfemoral TTVR has been recently published using the 28-F EVOQUE system[73]. The EVOQUE valve consists of a trileaflet bovine pericardial tissue valve, a nitinol frame, and a fabric skirt (**Figure 7-B**). The outer diameter is 44mm, 48mm, and 52 mm. The performance of the EVOQUE valve along with the transfemoral delivery system is currently being tested in the prospective, single-arm TRISCEND study (NCT04221490).

CLINICAL PERSPECTIVES

Global results of TTVI and comparison with medical treatment

The initial experience with TTVI demonstrated that despite the high-risk profile of TR patients undergoing TTVI, most procedures were well tolerated and associated with low in-hospital mortality rates[12]. To date, the TriValve registry (NCT03416166) represents the largest worlwide cohort of patients treated with TTVI using different devices[27.] The last report of the TriValve registry (n=470) showed that the included patients exhibited a high estimated surgical risk (mean EuroSCORE II of 10±8%), and 73% of them had been admitted for RV failure before the

procedure[76]. The etiology of the TR was functional in 9 out of 10 patients. The echocardiographic examination at baseline showed that most of the patients had severe or greater TR, since they often presented parameters consistent with massive or torrential regurgitation (mean vena contracta and EROA of 1.4 +/- 0.9 mm and 0.78 +/- 0.6 cm2). Procedural success (patient alive and TR grade ≤2) was achieved in 80% of cases, and the most used device was the MitraClip system (79%). In-hospital and 30-day mortality was low (3.2% and 3.8%, respectively). Also, several factors were identified as predictors of poorer clinical outcomes[76]: procedural success (HR: 0.22; 95% CI: 0.01 to 4.50; p <0.01), baseline systolic pulmonary artery pressure (HR: 16.20; 95% CI: 2.00 to 135.80; p = 0.01), and the presence of ascites (HR: 3.10; 95% CI: 1.50 to 16.50; p = 0.01). These 3 factors summarize the major key elements in the pre-procedural evaluation of TTVI recipients. Since obtaining a substantial reduction in TR is associated with better outcomes irrespective of other comorbidities, a cautious multimodality imaging assessment focusing on predictors of procedural success (e.g. coaptation depth) is of paramount importance before the procedure[77]. On the other hand, TTVI might be futile in patients with severe PH and/or with the presence of sings of end-stage disease as ascites.

Whereas the feasibility and preliminary efficacy of TTVI has been well demonstrated, data focusing on clinical outcomes with extended follow-up remain scarce. Orban et al[78] reported the effect of transcatheter edge-to-edge repair (93% MitraClip, 7% Pascal) on the rate of heart failure hospitalization in 119 patients. The study showed that the mean annual rate of heart failure hospitalization was reduced by 22%, improving from 1.21 to 0.95 hospitalizations per patient/year (p= 0.02). Also, TR grade reduction persisted at 1-year follow-up (72% with moderate or less TR grade) and NYHA class improved significantly compared to baseline (grade I-II in 67% of patients at 1 year vs 9% at baseline, p<0.001).

In the absence of randomized trials, Taramasso et al aimed to compare the outcomes of TTVI (using data from the TriValve registry) to a control group with conservative treatment obtained from two large tertiary centers[79]. A total of 268 matched patient pairs were identified.

Compared to controls, TTVI patients had lower 1-year mortality (23 ±3% vs 36 ±3%, p=0.001) and rehospitalization (26 ±3% vs 47 ±3% p<0.0001) (**Figure 8**)[79]. Of note, patients with TTVI and procedural failure shared similar outcomes with the group managed with medical treatment, further supporting the prognostic importance of TR reduction. These results suggest that TTVI might be associated with a clinical benefit regarding survival and heart failure rehospitalization compared to medical therapy, which should be confirmed in subsequent randomized studies.

Device selection

The selection of the appropriate TTVI system will depend on different factors, also including device availability in each center (most of TTVI systems are still in its infancy) and familiarity of operators with each device. To date, the off-label edge-to-edge repair technique with the MitraClip system has been the most used device (around 80% of patients included in the TriValve registry)[76] , due to the knowledge and experience acquired in mitral regurgitation.

Overall, patients with annular dilatation and leaflet tethering would potentially be good candidates for edge-to-edge repair or annuloplasty devices. On the other hand, patients with more advanced stages of right heart failure with important RV remodeling and severely dilated TA may be best suited for caval valve devices. While TTVR would be an option for the majority of TTVI patients, caution is needed in those with severe right ventricular dysfunction as the complete elimination of TR could trigger RV failure caused by acute afterload mismatch. On the other hand, the complete reduction of TR with TTVR would potentially prevent further RV remodeling, which in turn would have a positive impact on functional outcomes and survival over time. The last steps towards the development of definitive TTVR systems during the next years will likely provide a paradigm shift in the treatment of chronic TR, as the less-invasive nature of the transcatheter approach (especially trans-venous vs. trans-atrial approach) along with the advantages of valve replacement would probably be superior to both surgical and current transcatheter options. However, other aspects as the need for long-term anticoagulation in TTVR recipients should also be considered.

Future perspectives

Future data in the TTVI field should face several unresolved issues. First, more studies are needed regarding the optimal timing of intervention in patients with TR. The chronic nature of TR and the initial good response to diuretic therapy should not postpone the intervention in the presence of symptoms, even if mild. The identification of objective parameters (e.g. TA dimension, RV dilatation and function, PH, and specific cut-off NT-proBNP values or systemic markers of congestion as liver and renal function) will be important to guide an adequate identification of TTVI candidates. Second, pre-procedural assessment using TEE and CT imaging should be adapted to the particular features of TR. The treatment of patients with massive or torrential TR underscores the need to adopt a novel echocardiographic quantification scheme to guide TTVI procedures (e.g. definition of procedural success in case of transcatheter repair)[28]. Also, standard cut-offs and definitions regarding CT imaging are needed to better identify adequate candidates to transcatheter repair or replacement[31]. Finally, since early safety has been demonstrated, future efforts are needed to improve post-procedural residual TR and achieve sustained good clinical and valve performance outcomes at long-term follow-up. In cases with anatomical factors increasing the risk of procedural failure with transcatheter repair techniques, TTVR should probably be selected. In the end, transcatheter repair and replacement techniques should be considered as complementary, and a tailored approach including the potential risks and advantages of each treatment should be adapted when evaluating patients with severe TR.

CONCLUSIONS

In conclusion, the management of chronic TR remains challenging with limited therapeutic options (beyond medical treatment) in a large proportion of patients. In this context, several less-invasive catheter-based therapies focusing on different anatomic targets have been developed in recent years. TTVI is in its early stages and most devices are still in its infancy, with room for improvement regarding patient and device selection, optimization of the acute results (residual TR),

and long-term data. However, the good outcomes in terms of early safety and efficacy for most devices have provided a new alternative treatment for this group of patients. Future studies along with device iterations will be key to establish TTVI as the new preferred treatment for severe TR.

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FIGURE LEGENDS

Figure 1

Reprinted with permission from Taramasso et al.[14]. Yellow dashed line = triangle of Koch; star =atrioventricular node. TV = tricuspid valve.

Figure 2. Tricuspid regurgitation etiologies and mechanisms involved in TR progression.

ICD: Implantable cardiac defibrillator; LV: Left ventricular; RV: Right ventricle; TR: Tricuspid regurgitation.

Figure 3. Transcatheter Tricuspid Valve Intervention: Coaptation Devices.

A. Illustration of the Mitraclip system and echocardiography after grasping. Illustration reproduced with permission of Abbot, 2021 (Santa Clara, CA, USA). All rights reserved.

B. Illustration of the Pascal system and echocardiography after grasping.

C. Illustration of the FORMA system and echocardiography after device implantation.

D. Illustration of the Mistral system and fluoroscopic view after device implantation (reproduced with permission from Mitralix Ltd, Yokne'am Moshava, Israel)

RA, Right atrium; RV, Right ventricle. Reproduced from Asmarats et al.[8] and Fam et al.[34] and modified for the authors.

Figure 4. Annuloplasty devices: direct suture.

A. Trialign system. Reproduced from Hahn et al[50].

B. TriCinch system. Reproduced from Latib et al[51].

C. Picture of MIA (minimally invasive annuloplasty technology), reprinted with permission of Micro Interventional Devices, Inc.

D. Picture of the pledget-assisted suture tricuspid annuloplasty system (PASTA). Reproduced with permission from Greenbaum et al[52].

Figure 5. Ring annuloplasty devices: direct suture.

A. Illustration of the Cardioband system. Reproduced from Nickenig et al[52] and with permission of Edwards Lifesciences LLC (Irvine, CA).

B. Millipede. Illustration reproduced from Rogers et al[63] and provided courtesy of Boston Scientific. © 2021 Boston Scientific Corporation or its affiliates. All rights reserved. Fluoroscopic imaging of a double implant of the Millipede device in the tricuspid and mitral position. Courtesy of Dr. Jason Rogers, University of California, Davis, Medical Center (Sacramento, California).

C. The trans-atrial intrapericardial tricuspid annuloplasty system. Illustration and fluoroscopy reprinted with permission from Rogers et al.[54]

D. DaVingi™ TR system. Illustration and fluoroscopy reprinted with permission from Leon[55].

Figure 6. Caval valve devices.

A. Heterotopic caval Edwards Sapien valve Reproduced from Dreger et al[67].

B. TricValve. Reproduced from Lauten et al[68].

C. Tricento system. Reproduced from Toggweiler et al[69].

Figure 7. Transcatheter tricuspid valve replacement.

A. NaviGate bioprosthesis. Reprinted with permission from Asmarats et al[12]. Illustration of the valve courtesy of Navigate Cardiac Structures (Lake Forest, CA).

B. Evoque valve. Reproduced from Fam et al[72]. Illustration of the valve courtesy of Edwards Lifesciences LLC (Irvine, CA).

Figure 8. Transcatheter tricuspid valve intervention compared to medical treatment.

Kaplan-Meier curves for TTVI (red curve) *versus* controls (blue curve) according to heart failure hospitalization (A) and survival (B) at 12 months of follow-up.

TTVI: Transcatheter Tricuspid Valve Intervention; HF: Heart Failure. Reproduced from Taramasso et al[79].

TABLES

Table 1. Proposed grading scheme for tricuspid regurgitation severity assessment[28]

Variable	Mild	Moderate	Severe	Massive	Torrential
Vena contracta (biplane) (mm)	<3	3-6.9	7-13	14-20	≥21
EROA (PISA) (mm^2)	<20	20-39	40-59	60-79	≥80
3D VCA or quantitative EROA	-	-	75-94	95-114	≥115

EROA: effective regurgitant orifice area; PISA: proximal isovelocity surface area; VCA: vena contracta area.

Table 2. Multimodality imaging in Transcatheter tricuspid valve intervention.		
General eligibility	**Echocardiography (TTE/TEE)**	**Computed Tomography**

All devices	Use mid- and deep-esophageal and transgastric (short- and long-axis) views. Assess severity (VC width ≥7 mm, EROA ≥40 mm2, RV ≥ 45 ml). No severe LV dysfunction (LVEF ≥30%). No severe RV dysfunction. No severe PAH (systolic PAP < 60 mm Hg).	Required for some devices (see below)
Specific eligibility criteria		
Edge-to-edge repair	Use mid- and deep-esophageal and transgastric (short- and long-axis) views. Secondary TR with normal leaflets or primary TR with valve prolapse. Coaptation depth <10 mm. Coaptation gap <7.2 mm (ideally <4.0 mm). Leaflet length >10 mm. Location of main TR jet: central/antero-septal. No pacemaker leads or no interaction between pacemaker leads and tricuspid valve leaflets.	Not required.
Restrictive annuloplasty	Use mid- and deep-esophageal and transgastric (short- and long-axis) views. Adequate TA dimensions (e.g., TA diameter ≤55 mm and >2–4 mm posterior annular depth required for Trialign implantation). If pacemaker lead: not adherent and not interfering with the native leaflet motion.	TA dimensions. Evaluate risk of RCA injury (RCA course and distance to TA). Target anchoring area (e.g., TriCinch, between the mid-anterior TA and the antero-posterior commissure). Predicting optimal fluoroscopic planes.
Caval valve devices	Use mid- and deep-esophageal views of the cavo-atrial junction. Use transgastric views of the inferior vena cava and hepatic vein. Confirm presence of significant backward flow in the venae cava.	Measure SVC at the level of the innominate vein confluence, of the pulmonary artery and of SVC-RA junction; measure IVC at the level of IVC-RA junction, at top of hepatic veins and at 5 cm below IVC-RA transition. Landing zone ≤35 mm for TricValve and <42 mm for Tricento. Height between IVC-RA junction and hepatic veins >10 mm.
Transcatheter tricuspid valve replacement	Preserved native leaflet mobility (if prior pacemaker lead) to ensure leaflet capture. Use 2D and 3D mid- and deep-esophageal and transgastric views 3D planar cross-sectional area of the TA in early systole and mid-diastole.	TA diameter: 36-52 mm with valve. oversizing <10%. RA length ≥6 or 7 cm for transatrial or transjugular access. RIJV to SVC distance ≥14 mm. Assess RCA course and distance to TA. Assess Risk of RVOT obstruction. Co-axial deployment angle.

EROA= effective regurgitant orifice area; IVC: Inferior vena cava; LV = left ventricular; LVEF = left ventricular ejection fraction; PAH = pulmonary arterial hypertension; PAP = pulmonary artery pressure; RA = right atrium; RCA = right coronary artery; RIJV= right internal jugular vein; RV = right ventricular; RVOT =right ventricular outflow tract; SVC = superior vena cava; TA = tricuspid annulus; TEE = transesophageal echocardiography; TR = tricuspid regurgitation; TTE = transthoracic echocardiography; VC = vena contracta. Adapted from Agricola et al[33].

Table 3. Clinical, procedural, and follow-up characteristics from the main studies using coaptation devices.

		MITRACLIP		PASCAL	FORMA	
		Mehr et al[39] (n=249)	Nickenig et al[36] (n= 85)	Fam et al[34] (n= 28)	Perlman et al[48] (n= 18)	Kodali et al[49] (n= 29)
Baseline characteristics						
Age, years		77 +/-9	78 +/- 8	78 +/- 6	76 +/- 10	76 +/- 8
Female, n (%)		128 (51)	56 (66)	15 (54)	13 (72)	19 (66)
Atrial fibrillation, n (%)		183 (74)	78 (92)	26 (93)	16 (89)	24 (83)
NYHA III-IV, n (%)		238 (96)	64 (75)	28 (100)	17 (94)	25 (86)
Transtricuspid CIED, n (%)		74 (30)	12 (14)	1 (3)	3 (17)	n/a
EuroSCORE II, %		6.4 (4-14)	8.6 +/- 11	6.2 +/- 5.2	9 +/- 5.7	8.4 +/-5.3
Echocardiography						
LVEF, %		49 +/- 14	59 +/- 8	59 +/- 6	59 +/- 9	57 +/-12
TAPSE, mm		16 +/-4	14+/-0.3	16 +/-3	15 +/- 5	14 +/-0.4
TR grade	TR 5+ (%)	n/a	31/84 (37)	12 (43)	11 (61)	n/a
	TR 4+ (%)	129 (52)	24/84 (29)	9 (32)	6 (33)	n/a
	TR 3+ (%)	112 (45)	24/84 (29)	7 (25)	1 (6)	n/a
Maximum gap width, mm		5.3 +/- 3.3	n/a	6.9 +/- 3	n/a	n/a
Vena contracta width, mm		9.9 +/- 4.1	17+/-0.6	11.4 +/-5	12,1 +/- 3.3	16 +/- 0.5
EROA, cm2		0.70 +/- 0.5	0.65 +/-0.3	1.3 +/- 2.4	1 +/-0.6	2,2 +/- 1.5
Mitral regurgitation ≥ moderate, n (%)		108 (43)	0 (0)	n/a	4 (22)	n/a
Procedural and 30-day outcomes						
Procedural success, n (%)		192 (77)	76/84 (91)	24 (86%)	16 (89)	27 (93)
Number of implants, n		2 +/- 1	2,2 +/- 0.8	1,4 +/- 0.6	n/a	n/a
Post-Procedural tricuspid gradient, mmHg		2,4 +/- 1.5	2.12 +/-1.2*	1.6 +/- 1	n/a	n/a
Procedural Death, n (%)		0 (0)	0 (0)	0 (0)	0 (0)	2 (7)
Need for cardiac Surgery, n (%)		1 (0.4)	0 (0)	0 (0)	1 (6)	3 (10)
30-day TR grade > moderate, n (%)		n/a	36/83 (43)	4/26 (15)	7/16 (44)	n/a
30-day mortality, n (%)		n/a	0 (0)	2 (7)	0 (0)	2 (7)
Follow-up						
Follow-up time		290 days	6 months	30 days	12 months	30 days
Mortality, n (%)		44 (19)	4/84 (5)	2 (7)	0 (0)	N/A
TR grade > moderate, n (%)		46 (28%)	30/70 (43)	4/26 (15)	12/13 /92)	2 (7)
NYHA I-II, n (%)		121 (69)	63/73 (86)	23/26 (88)	11/14 (79)	18/25 (72)

Values are mean SD or n/N (%).* At 30 days. CIED: Cardiac implantable electronic device; EuroSCORE: European System for Cardiac Operative Risk Evaluation; NYHA: New York Heart Association; TAPSE: Tricuspid annular plane systolic excursion; TR: Tricuspid regurgitation. Rest of abbreviations as in Table 2.

Table 4. Clinical, procedural, and follow-up data from the main cohorts using annuloplasty devices.

	Trialign	**Tricinch**	**Cardioband**
	Hahn et al[50, 56] (n=15)	Denti et al[57] (n= 24)	Nickenig et al[53] (n= 30)
Baseline characteristics			
Age, years	74 +/-7	74 +/- 8	75 +/- 6.6
Female, n (%)	13 (87)	20 (83)	22 (73)
Atrial fibrillation, n (%)	10 (67)	n/a	28 (93)
NYHA III-IV, n (%)	10 (67)	14 (58)	25 (83)
Transtricuspid CIED, n (%)	0 (0)	n/a	4 (13)
EuroSCORE II, %	n/a	5.5	4.1 +/- 2.8
Echocardiography			
LVEF, %	60 +/- 12	n/a	57 +/- 11
TAPSE, mm	16 +/- 4	n/a	n/a
Vena contracta width, mm	13+/-3	n/a	12.6 +/- 4.5
EROA, cm2	0.7 +/- 0.5	n/a	0.79 +/- 0.5
Procedural and 30-day outcomes			
Procedural success, n (%)	15 (100)	18 (81%)	30 (100)
Procedural Death, n (%)	0 (0)	n/a	0 (0)
Need for cardiac Surgery, n (%)	0 (0)	n/a	0 (0)
30-day TR grade > moderate, n (%)	n/a	0 (0)	5 (24)
30-day mortality, n (%)	n/a	n/a	2 (7)
Follow-up			
Follow-up time, months	12	6	6
Mortality, n (%)	2 (13)	0 (0)	3 (10)
TR grade > moderate, n (%)	n/a	(~75)	5 (28)
NYHA I-II, n (%)	5/10 (50)	n/a	22 (88)

Values are mean SD or n/N (%). Abbreviations as in previous tables.

Table 5. Clinical, procedural, and follow-up characteristics from the main studies using caval valve devices and transcatheter tricuspid valve replacement.

	Caval valve devices	Transcatheter tricuspid valve replacement	
		NaviGate	LUX-Valve
	Dreger et al[67] (n=14)	Hahn et al[78] (n= 30)	Lu et al[75] (n= 12)
Baseline characteristics			
Age, years	77 (68.2-82.0)	78 (70-80)	69 (66-74)
Female, n (%)	12 (86)	17 (56)	7 (58)
Atrial fibrillation, n (%)	n/a	27 (90)	10 (83)
NYHA III-IV, n (%)	12 (86)	26 (87)	12 (100)
Transtricuspid CIED, n (%)	n/a	9 (30)	5 (42)
EuroSCORE II, %	n/a	11.1	n/a
Echocardiography			
LVEF, %	58 +/- 7	55 (46-60)	59 +/- 9
TAPSE, mm	15 +/- 5.1	14 (12-18)	15 +/- 5
TR vena contracta mean, cm	n/a	1.37 (1-1.7)	n/a
EROA, cm2	1.4 +/-1	0.75 (0.7-1.1)	n/a
Procedural and 30-day outcomes			
Procedural success, n (%)	14 (100)	26 (87)	12 (100)
Procedural Death, n (%)	0 (0)	0 (0)	0 (0)
Need for cardiac Surgery, n (%)	4 (29)	2 (7)	0 (0)
30-day mean transvalvular gradient, mmHg	n/a	2 (1-8-3.4)	2.9 (2.2-4.2)
30-day TR grade > moderate, n (%)	11/11 (100)	0 (0)	1 (9)
30-day mortality, n (%)	3 (21)	3 (12.5)	1 (9)
Follow-up			
Follow-up time	12 months	127 days	30 days
Mortality, n (%)	8 (57)	4 (13)	0 (0)
TR grade > moderate, n (%)	14 (100)	n/a	1(9)
NYHA I-II, n (%)	6/6 (100)	(67)	6/11 (55)

Values are mean SD or n/N (%). Abbreviations as in previous tables.

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Regarding two figures that depict the Cardioband (fig 5-A) and Evoque devices (7-C) (see attached files), I've asked permission from the publisher. However, the journal also needs permission from the manufacturer.

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RE: [EXTERNAL] permission for figures (EVOQUE and Cardioband)

Julian Mesa <Julian_Mesa@edwards.com> 15 de gener de 2021, a les 14:32
Per a: Guillem Muntané <guillem.muntane@gmail.com>

Dear Dr. Muntane,

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Hello dear Edwards colleagues,

I am Guillem Muntané-Carol, "fellow" of Dr Rodés in Quebec. I've been working on a review article that focuses on tricuspid devices that will be published in 2021 in the Canadian Journal of Cardiology (already accepted).

Regarding two figures that depict the Cardioband (fig 5-A) and Evoque devices (7-C) (see attached files), I've asked permission from the publisher. However, the journal also needs permission from the manufacturer.

I hope you can help me with this issue.

Thank you very much.

Guillem Muntané-Carol

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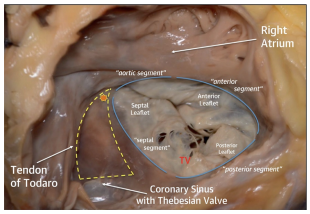

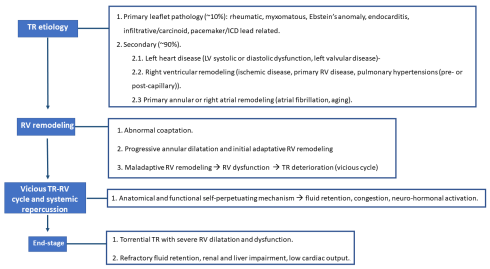

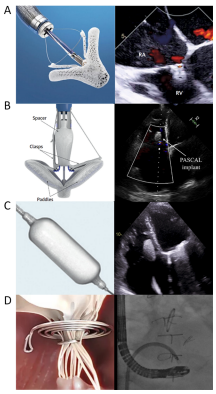

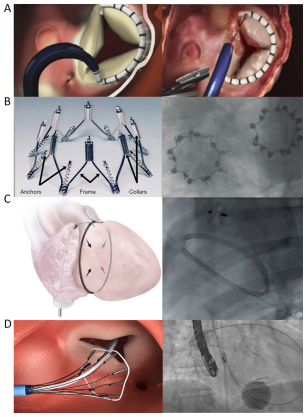

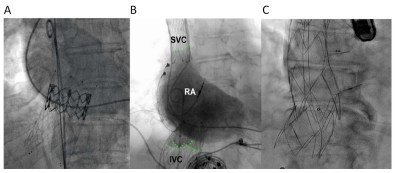

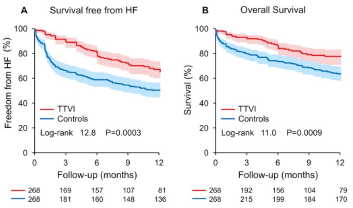

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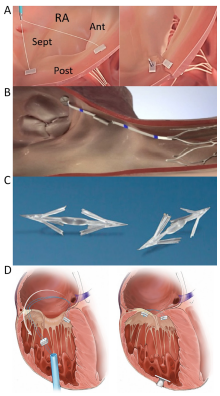

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Response to request for MIA PolyCor image for review article publication

Katherine Whitman <kwhitman@microinterventional.com> 3 de gener de 2021, a les 17:47
Per a: Guillem Muntané <guillem.muntane@gmail.com>

Thank you. You have our approval to publish. I apologize I didn't understand the initial request.

Happy new year. Please let me know if you need any additional information from me.

Warm regards,

Katherine Whitman

On Dec 30, 2020, at 3:57 PM, Guillem Muntané <guillem.muntane@gmail.com> wrote:

Dear Katherine,
Thank you for your interest.

The article is already accepted by the journal (after two revisions) and will be published soon. At this point, no more modifications regarding the manuscript and/or figures will be done.
The reason for having contacted you is that the journal (Canadian Journal of Cardiology) demanded permission from the company in order to publish the image of the MIA technology.

Thank you very much! Happy 2021.

Guillem Muntané-Carol

Thanks

Missatge de Katherine Whitman <kwhitman@microinterventional.com> del dia dc., 30 de des. 2020 a les 16:22:

> Dear Dr. Muntane-Carol,
>
> I hope that you are enjoying the holidays.
>
> Thank you very much for your interest in the MIA technology and for including it in your paper. Can you please advise of what you need from me in order to finalize the paper? Would you like me to provide edits to the content of the draft? We are planning on taking new photographs of the device in early January. When do you need the final approved photos of MIA by?
>
> Please let me advise how I can help and when the deadline is.
>
> Warm Regards,
>
> Katherine Whitman
>
> On Tue, Dec 29, 2020 at 9:50 AM Jeremy West <jwest@microinterventional.com> wrote:
>
> > Dear Dr. Muntane-Carol,
> >
> > Thank you for sending this information. The paper looks very interesting. I am copying Katherine Whitman on this email. She will provide you with what you need.
> >
> > Best,
> > Jeremy
> >
> > On Thu, Dec 24, 2020 at 2:45 PM Guillem Muntané <guillem.muntane@gmail.com> wrote:
> >
> > > Dear Jeremy,

The title is: Transcatheter interventions for tricuspid valve disease: What to do and who to do it on.
Find enclosed the figure (4-C) and the part of the manuscript where we talk about the PolyCor anchors. Find also a "screenshot" of the final acceptance by the journal (Canadian journal of cardiology) and my CV.
Merry Christmas!
Guillem Muntané-Carol

Missatge de Jeremy West <jwest@microinterventional.com> del dia dc., 23 de des. 2020 a les 13:26:

> Dear Dr. Muntane-Carol,
>
> Thank you for your interest in MIA and for wanting to include MIA PolyCor anchors in your tricuspid review article. Can you please send me the content of what is planned to be said regarding the MIA device as well as the title of the article? In addition, do you have a CV you can provide?
>
> Thank you,
> Jeremy West
>
> --
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>
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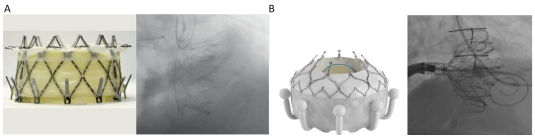

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De

I share with you the outstanding publication in the September 2020 edition of the JACC Cardiovascular Intervention - the prestigious Journal of the American College of Cardiology, Washington DC.

The publication "First-in-Human Transcatheter Tricuspid Valve Repair - 30-Day Follow-Up Experience With the Mistral Device" was written by David Planer, MD, Ronen Beeri, MD and Haim D. Danenberg, MD – the investigators in the Clinical Study preformed at the Hadassah Medical Center in Jerusalem Israel. This paper analyzes their experience with 7 Tricuspid valve repair treatments implanting the Mistral device and with 30 days of follow- up.

We attach here with the paper and a very favorable editorial comment written by Holger Thiele, MD and Philipp Lurz, MD, PHD – from the Department of Internal Medicine/Cardiology, Heart Center Leipzig at University of Leipzig, Germany.

The paper can also be accessed in the link:

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Thanks, Yoni

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Thank you very much. I hope I can add this publication in the review (currently under revision).

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