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"Mind the Gap": An 85-Year-Old Man with Severe Tricuspid Valve Regurgitation Who Underwent Percutaneous Edge-to-Edge Valve Leaflet Plication Using the New and Advanced MitraClip XTR System

S Da	s' Contribution: Study Design A ta Collection B tical Analysis C	ABCDEFG 1 A 1 AE 1	Rezo Jorbenadze	1 Department of Cardiology and Angiology, University Hospital, Eberhard Karls University Tuebingen, Tuebingen, Germany 2 Hospital Ostalb gkAöR, Aalen, Germany			
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	Patient: Male, 85-year-old						
	Final I	Diagnosis:	Severe tricuspid regurgitation				
	S	ymptoms:	Cardiac decompenstion • dyspnea				
	M	edication:	—				
		Procedure:	Edge-to-edge valve repair using MitraCLip System XTR				
		Specialty:	Cardiology				
		Objective:	Unusual clinical course				
	Ba	ickground:	Severe tricuspid valve regurgitation (TR) is associated with high cardiovascular mortality. Safe and feasible in- terventional approaches to treat severe TR are of clinical relevance. The MitraClip is a device that has been approved by the US Food and Drug Administration (FDA) for the repair of mitral valve lesions. Percutaneous femoral venous access with fluoroscopic and echocardiographic guidance is used to deliver a cobalt-chromi- um clip to secure the mitral valve leaflets. We report on an 85-year-old man with tricuspid valve regurgitation who underwent percutaneous edge-to-edge tricuspid valve leaflet plication with the new, advanced MitraClip XTR System.				
	Ca	ise Report:	An 85-year-old man with severe TR due to annulus dilation of the right ventricle and short septal leaflet pre- sented repeatedly at our hospital with severe right heart failure symptoms. Transesophageal echocardiogra- phy revealed severe TR with a large coaptation gap size of 10.6 mm. Percutaneous edge-to-edge valve repair with the new-generation MitraClip System XTR with wider clip arms could overcome the large coaptation gap. We achieved a strong reduction of TR after deploying 2 MitraClips XTR. The patient recovered quickly and has not been admitted to hospital due to heart failure symptoms since the intervention for more than 6 months.				
		onclusions:	Previous studies have shown the safety and effectiveness of the MitraClip device and supported FDA approval for tricuspid valve repair. This report of a patient with complex tricuspid regurgitation demonstrated the feasible use of the new MitraClip XTR System, which improved edge-to-edge tricuspid valve repair due to its increased span and improved grip.				
	MeSH I	Keywords:	Administration, Cutaneous • Cardiac Valve Annuloplasty • Heart Valves • Mortality • Tricuspid Valve Insufficiency				
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Background

In March 2019, the MitraClip system was the first percutaneous device to be approved by the US Food and Drug Administration (FDA) for the repair of moderate-to-severe and severe functional mitral valve regurgitation of heart failure patients with impaired left ventricular function [1,2].

The results from the COAPT trial showed that transcatheter mitral valve repair resulted in a lower rate of hospitalization for heart failure and lower all-cause mortality at two-month followup compared to medical therapy alone [1]. The Endovascular Valve Edge-to-Edge Repair Study (EVEREST) II reported that transcatheter mitral-leaflet approximation with the MitraClip device was safer than open mitral valve surgical repair but not as effective in reducing the severity of mitral regurgitation [3].

However, if untreated, severe tricuspid valve regurgitation (TR) is also associated with progressive right heart failure, increased rates of hospitalization, and high cardiovascular mortality rates [4]. Therefore, the establishment of feasible and safe treatment approaches is of clinical relevance for patients who are not suitable for a surgical valve repair or replacement. Several percutaneous techniques are currently in clinical use, among which, edge-to-edge repair employing the MitraClip system (Abbott, Menlo Park, CA) is the most common approach of interventional treatment of severe TR [5]. This device is used with percutaneous femoral venous access with fluoroscopic and echocardiographic guidance to deliver a cobalt-chromium clip to secure the mitral valve leaflets [6-8]. Hence, the MitraClip system involves certain limitations due to tricuspid valve morphology, coaptation gap size, and location of the regurgitation jet.

Previous studies stated that small coaptation gap size ≤ 10 mm and central or anteroseptal main jet location can be used as predictors of procedural success employing the MitraClip System NT [5,9]. A cut-off value of ≤ 7.2 mm coaptation gap size has been described to predict successful transcatheter treatment [9].

Using the new-generation MitraClip XTR system for percutaneous edge-to-edge tricuspid valve repair procedure, however, may be more feasible in patients with severe TR, large coaptation gap size (>7.2 mm), or unfavorable valve morphology, especially in complex patients with rather challenging technical interventions.

This report is of an 85-year-old man with tricuspid valve regurgitation who underwent percutaneous edge-to-edge valve leaflet plication with the new and advanced MitraClip XTR System.

Case Report

Here, we report the case of an 85-year-old patient with severe tricuspid regurgitation (TR) due to anulus dilation of the right ventricle and a short septal leaflet with displacement. He presented with dyspnea and generalized anasarca, including ascites and pleural effusions. He had been admitted to the hospital due to heart failure symptoms every 3 to 4 weeks during the past 6 months. The patient's medical history included poorly controlled arterial hypertension, severe coronary artery disease treated via coronary artery bypass surgery in 2012, and renal impairment. In transthoracic echocardiography at the current hospital admission, we found preserved left ventricular ejection fraction but diastolic dysfunction grade III with restrictive filling pattern along with impaired right ventricular function. Laboratory parameters were measured and revealed increased NT-pro-BNP levels of 3554 ng/dL and renal impairment with creatinine clearance of 24.7 mL/min. The interdisciplinary heart team recommended interventional tricuspid valve repair because of the increased surgical risk due to his severe comorbidities.

Intraprocedural transesophageal echocardiography revealed that the severe TR was caused by a main TR regurgitation jet located between the anterior and the septal leaflet (Figure 1A–1F) with a coaptation gap size of 10.6 mm. Therefore, we decided to use the new-generation MitraClip System XTR with wider clip arms to overcome the coaptation gap.

After deploying 2 XTR clips between the anterior and septal leaflet, we achieved a strong reduction of TR (Figure 1G, 1H). The patient has not been admitted to hospital due to heart failure symptoms since the intervention for more than 6 months.

Discussion

The new and advanced MitraClip XTR system in severe and complex TR is a feasible and safe treatment approach for patients not suitable for a surgical valve repair or replacement. Our presented case convincingly illustrates that the MitraClip System XTR can overcome coaptation gap size >10 mm with good technical and clinical results due to its improved span and grip technology. This is an important novel aspect, as procedure success has been associated with gap sizes \leq 7.2 mm, as described before [9]. Different devices have been established for clinical use dependent on valve morphology and comorbidities. The TriValve Registry compared percutaneous treatment options with different devices in 312 high-risk patients with severe TR [10]. Interventions in this registry included edge-to-edge repair of the leaflets with the MitraClip System (Abbott Vascular, Santa Clara, CA) and the PASCAL-System (Edwards Lifesciences, Irvine, CA), the repair at the annulus



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Figure 1. Intraprocedural images of the percutaneous edge-to-edge tricuspid valve repair employing the MitraClip XTR system by transesophageal echocardiography (TEE). (A–D) TEE revealed severe tricuspid valve regurgitation between the anterior and the septal and the posterior and the septal leaflet, coaptation gap size 10.6 mm (A: Mid-esophageal 4 chamber view, B: Corresponding color Doppler imaging, C: Transgastric 3D imaging of tricuspid valve, D: Corresponding color Doppler imaging visualizing origin of TR). (E, F) TEE-view for correct clip rotation of the MitraClip XTR system (E: 3D imaging of clip for correct rotation. F: Corresponding color Doppler imaging, (G, H), After implantation of 2 XTR clips, we achieved significant reduction of TR, with a mild-to-moderate residual TR, Pmean 3 mmHg (G: Mid-esophageal 4 chamber view with XTR clips in final position, H: Corresponding color Doppler imaging). TR – tricuspid regurgitation; S – septal leaflet; A - anterior leaflet; P – posterior leaflet; c – clip, * clip arms.

(Cardioband, Edwards Lifesciences; TriCinch, 4tech, Galway, Ireland; Trialign, Mitraling, Tewksbury, MA) or at coaptation level (FORMA, Edwards Lifesciences), and valve replacement (Caval Implants, NaviGate, NaviGate Cardiac Structures, Lake Forest, CA) [10]. This registry confirmed that all interventional techniques were feasible and had a reasonable procedural success rate. Treated patients showed significant improvement of quality of life and low peri-interventional mortality. Greater coaptation size was associated with reduced procedural success [9,10].

Our presented clinical case supports these findings, and also confirms that the MitraClip System XTR has several advantages in the treatment of complex TR with a wide coaptation gap at this point. The system has been used over the last decade and there is substantial experience in this technology using it in edge-to-edge repair of the mitral and, consequently, of the tricuspid valve. Therefore, this system is the tool of choice, especially in high-risk patients with complex valve anatomy and severe TR. In experienced hands, we have reduced procedure times and achieved a low peri-interventional risk compared to alternative treatment approaches, such as repair at the annulus level. Head-to-head comparison of the different edge-to-edge leaflet repair technologies are needed to confirm whether one device might be superior to another in patients with coaptation gap size > 10 mm. The new TriClip-System by Abbott also was shown to be a safe and feasible approach in the TRLUMINATE study [11]. Randomized studies are needed to further evaluate how the TriClip-System can further influence and improve procedure time and technique, as well as successful reduction of TR, and thereby improve peri-interventional and clinical outcome [11].

The MitraClip XTR system can significantly improve edge-toedge tricuspid valve repair due to its increased span and improved grip and may facilitate procedures in complex TR cases of patients not eligible for conventional surgery.

Conclusions

The new MitraClip System XTR can overcome coaptation gap size >10 mm of the tricuspid valve, thus making it accessible to high-risk patients with complex TR not eligible for conventional surgery. Previous studies have shown the safety and effectiveness of the MitraClip device and supported FDA approval for tricuspid valve repair. This report of a patient with complex tricuspid regurgitation demonstrates the use of the new MitraClip XTR System, which improved edge-to-edge tricuspid valve repair due to its increased span and improved grip.

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