

CASE REPORT

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Fusion imaging guided implantation of a Tricento transcatheter heart valve for severe tricuspid regurgitation

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Abstract

We report the case of a 64-year-old patient with history of chronic kidney disease on dialysis who was repeatedly hospitalized due to hydropic decompensation. Right heart failure with secondary severe tricuspid regurgitation was diagnosed. An interventional approach was recommended due to the heavy calcification of the sinus venosus and the perioperative risk (EuroScore II 3.2%) and taking into account the explicit request of the patient. After analysis of a full-cycle computed tomography, the patient was eligible for the implantation of the Tricento transcatheter heart valve. The custom-made prosthesis was implanted successfully using periprocedural transoesophageal guidance supported by fusion imaging that integrates live co-registration. After implantation of the valve prosthesis, the primary result was excellent. The patient was discharged without further complications shortly after the procedure and her status is being closely monitored.

KEYWORDS

fusion imaging, interventional cardiology, structural heart disease, tricuspid regurgitation

1 | INTRODUCTION

Tricuspid regurgitation (TR) is a common valvular heart disease with high morbidity and mortality rates.¹ Congestion may lead to oedema, ascites, and ultimately to impaired organ function (e.g., kidney). Patients may be asymptomatic for a prolonged period, not becoming symptomatic until right heart function decreases. Management of TR is still a matter of debate, and few patients are treated surgically as surgical outcome can be suboptimal and operative risk tends to be high.^{2–4} Following the success of percutaneous treatment of other valves, devices specifically designed for the tricuspid valve have been developed.⁵

2 | CASE REPORT

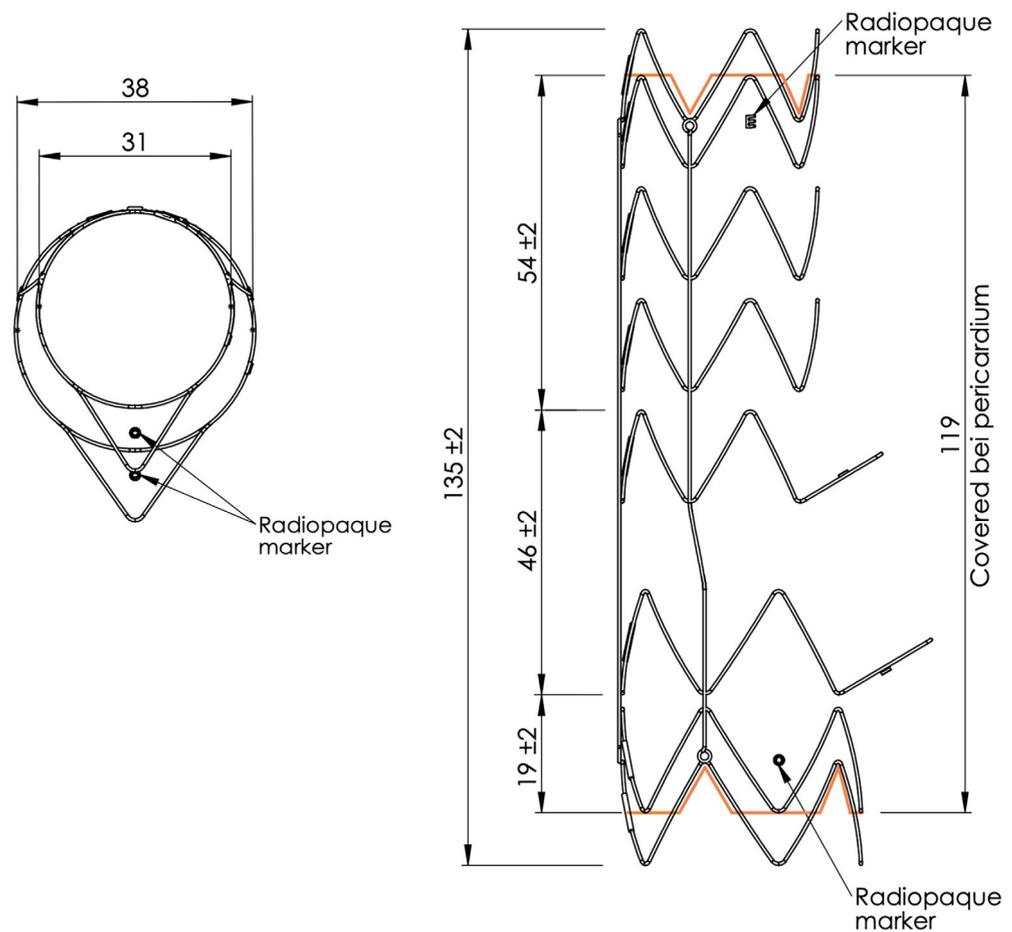
A 64-year-old female was known to have chronic kidney disease due to a membranoproliferative glomerulonephritis and had been on

intermittent dialysis since 2012. In June 2019 she underwent kidney transplantation. The donor was described as being a “full-house match,” and therefore transplantation on short-term notice was deemed successful (creatinine 1.3 mg/dl, glomerular filtration rate 44 ml/min). However, the patient was repeatedly hospitalized due to hydropic decompensation. An echocardiogram documented normal systolic and diastolic function of the left heart. Atria were enlarged. The base of the right ventricle in the apical four-chamber view showed a margin of 42–43 mm. The tricuspid valve displayed severe regurgitation. The right ventricle showed marginal longitudinal function (tricuspid annular plane excursion of 17 mm) and also visually marginal radial function, so that the right heart function was described as being depressed overall. Pulmonary artery pressure was computed to be high (26 mmHg) as was central venous pressure (approximately 15 mmHg, taking the severe dilatation of the hepatic veins into consideration). The severe TR was confirmed by means of quantitative parameters during transoesophageal echocardiography

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FIGURE 1 3D-model of the rendered tricuspid prosthesis by the manufacturer with the help of the planning computed tomography



(TOE): effective regurgitation orifice 0.4 cm^2 ; regurgitation volume by isovelocity surface area 43 ml , vena contracta 10 mm . Furthermore, TOE showed a rounded calcification just below the tricuspid annulus that corresponded to a calcified sinus venosus as assessed by magnetic resonance imaging (Video S1). Right-heart catheterization showed a slightly elevated mean pulmonary artery pressure (26 mmHg) and pulmonary capillary wedge pressure (14 mmHg). Pulmonary vascular resistance was computed to be above 3 Wood units. Further comorbidities included paroxysmal atrial fibrillation (on phenprocoumon), a stroke without residue, unspecific connective tissue disease, and coronary artery sclerosis (Figures S1 and S2).

The case was discussed by the heart team and an interventional approach was recommended due to the heavy calcification of the sinus venosus but also at the explicit request of the patient and the estimated peri-operative risk (EuroScore II 3.2%). Full-cycle computed tomography was performed to evaluate the implantation of a custom-made tricuspid valve prosthesis as a large coaptation defect made edge-to-edge repair not possible. It includes the measurement of the right atrium, the superior and inferior vena cavae, the identification of the hepatic and azygos veins inflow. After analysis, the patient was eligible for the implantation of the Tricento transcatheter heart valve (THV) (MEDIRA GmbH, Balingen, Germany). The device is manufactured with oversizing the

upper and lower stent part by 20–30% to control for the risk of endoleaks (Figure 1).

The intervention was performed under general anesthesia and TOE guidance and fusion monitoring. The Tricento THV was delivered through a 24 Fr delivery system via transfemoral access using a 0.035-in. J-tipped Amplatz Extra-Stiff guidewire. A 5 Fr pigtail catheter was advanced into the right ventricle for ventriculography and invasive measurements.

Using Siemens TrueFusion echo-fluoroscopy guidance (Siemens Healthcare GmbH, Erlangen), relevant anatomical and functional landmarks can be easily added from echo volume to the live fluoroscopy. TOE was synchronized with fluoroscopy, and outer and inner edges of the superior and inferior vena cava were defined with markers after aligning the planes along the wire in the bicaval view. These markers were then superimposed onto the fluoroscopy images (Figure 2 and Video S2). Markers at the superior cavoatrial junction (SCAJ) and inferior cavoatrial junction (ICAJ) flagged and served as the landing zone for the custom prosthesis. The implantation was performed top-down, while it remained fully repositionable and retrievable up to its final release (see also Figure 3 for stepwise description, Video S5). No rapid pacing was necessary. After successful delivery of the valve, TOE and fluoroscopy showed a good function of the prosthesis (Figure 4). The postoperative monitoring was uneventful, and the patient was discharged 5 days later.

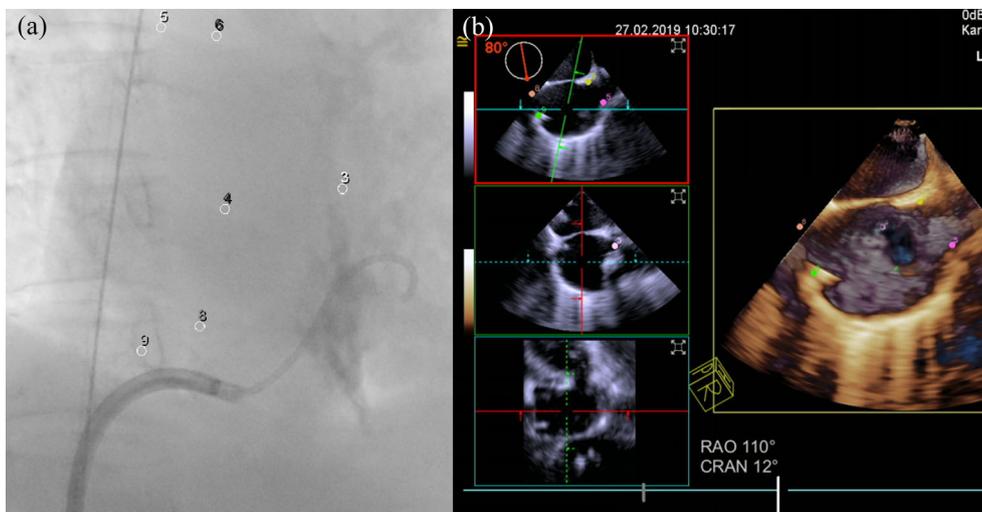


FIGURE 2 (a) Fluoroscopy during the procedure (conventional anterior-posterior projection). The guidewire used to deploy the valve extends from the femoral vein into the superior vena cava. (b) The bicaval view is used to align the planes and to mark the corresponding lateral and medial borders of the superior (points 5 and 6) and inferior (points 8 and 9) vena cava

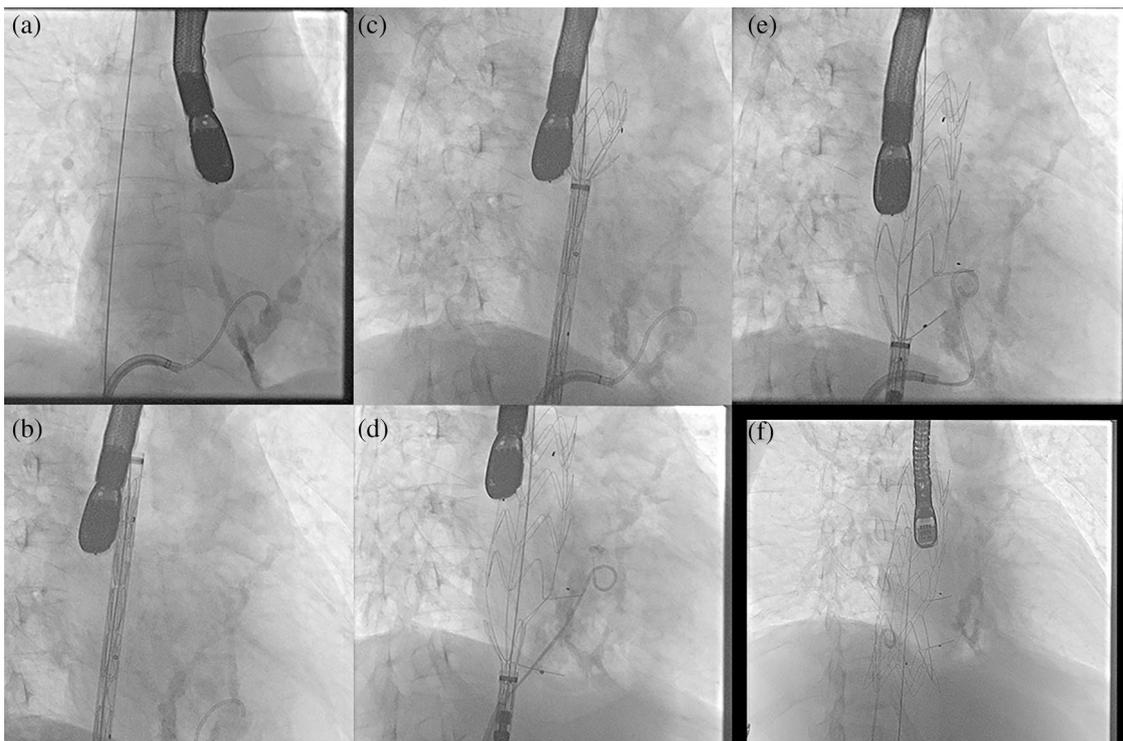


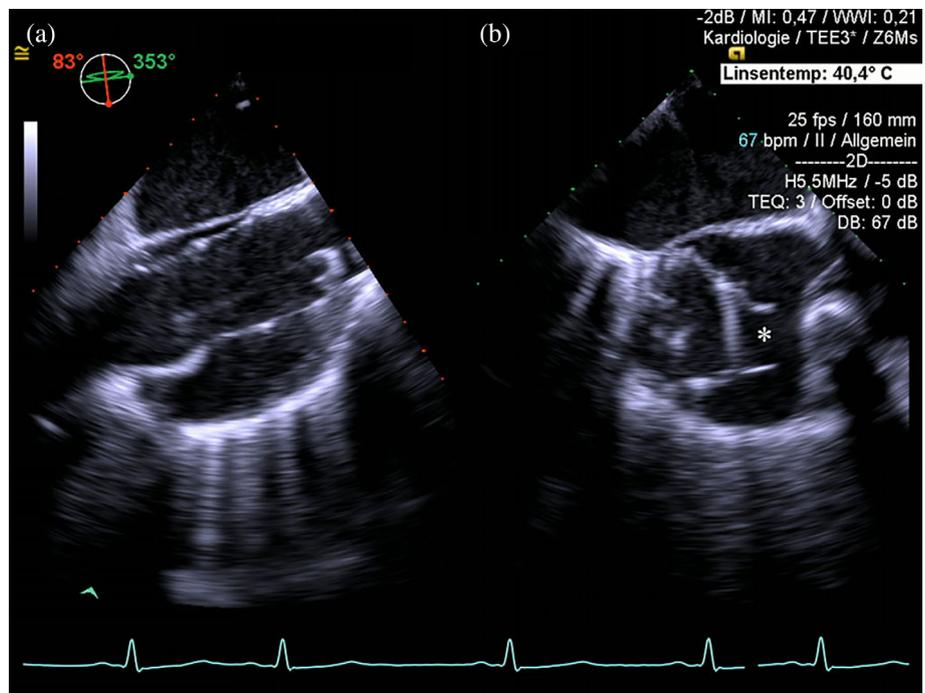
FIGURE 3 Fluoroscopy during implantation: (a) guidewire extending from the distal approach to the superior vena cava; (b) delivery sheet with custom-made prosthesis is advanced over the wire and placed in the superior vena cava; (c) the custom-made valve is slowly deflated; (d) until superior and inferior opening of the cage releases the bioprosthesis; (e and f) and the prosthesis is completely deflated and the distal portion is anchored in the inferior vena cava

3 | DISCUSSION

We present the case of a patient who was treated with a custom-made tricuspid valve prosthesis for highly symptomatic recurrent right-heart decompensation due to severe TR. Percutaneous treatment with devices specifically designed for the tricuspid valve has been developed but has proved to have many technical difficulties.⁵ A catheter-based concept with bicaval implantation was recently introduced, the Tricento THV. It is a covered stent with a lateral bicuspid

valve that is made of thin porcine pericardial leaflets. The stent itself is made of nitinol and features radiopaque markers. As patient anatomy is highly variable, the stent length and diameter must be custom made. Following the success after the first-in-man report,⁶ we made use of the Siemens TrueFusion echo-fluoroscopy fusion guidance to guide the procedure. After co-registration of the fluoroscopic images and True Volume TOE (Siemens ACUSON SC2000), the fusion technique allows for continuous integration of TOE-derived image information into live fluoroscopy with machine learning-based probe

FIGURE 4 Bicaval view (a) showing custom-made prosthesis anchored in superior and inferior vena cava. (b) Second plane of transoesophageal echocardiography probe that was produced with the help of a full-cycle computed tomography scan shows opening of the valve and valve leaflets (asterisk)



detection and automated registration updates. Hereby, landmarks can be marked directly on the TOE instrument and send to the angiography system. Synchronizing the images from TOE and angiography facilitates orientation and communication within the team. In the present case the outer and inner edges of the SCAJ and ICAJ were defined with markers after aligning the planes along the wire in the bicaval view. These markers helped the interventional cardiologist substantially in advancing the custom-made prosthesis to just the right height in the vena cava to ensure an optimal result in the superior and inferior vena cava. In a previous case Montorfano et al. used a superior vena cava angiography to identify the SCAJ after insertion of a pigtail through the right jugular vein.⁷ We think the demonstrated concept in our case is superior to the previously demonstrated case as it does not need the additional jugular access with consequentially lower risk for bleeding and pneumothorax. Furthermore, the procedure thereby may be faster with respect to the overall time in the operation theater and less contrast medium is required. The primary result of implantation was successful with no relevant residual TR (Videos S3 and S4). This underlines the ability to deploy the THV very precisely. Barrel et al. investigated the accuracy of two-dimensional (2D) versus three-dimensional (3D) image fusion for thoracic endovascular aortic repair (TEVAR) image guidance. They were able to show higher image fusion accuracy and lower contrast volume and irradiation dose usage for 3D image fusion than for 2D during TEVAR.⁸

Other percutaneous tricuspid techniques have already yielded follow-up data. Mehr et al. evaluated the procedural and 1-year clinical and echocardiographic outcomes of patients treated with tricuspid edge-to-edge repair.⁹ A successful procedure with reduction of TR to grade $\leq 2+$ was achieved in 77%. TR severity and New York Heart Association functional class significant improvements were observed at 1-year follow-up. Asmarats et al. evaluated the long-term outcomes

following transcatheter tricuspid valve repair with the FORMA Transcatheter Tricuspid Valve Repair System (Edwards Lifesciences, Irvine, California).¹⁰ They found a favorable long-term safety profile with sustained functional improvement and acceptable TR reduction for up to 3 years with a 6-min walk test of over +54 m and a Kansas City Cardiomyopathy Questionnaire score of more than 16 points.

Percutaneous tricuspid valve intervention (both repair and replacement) is still in its infancy, but it may become a reliable option in the future, especially for high-risk patients that are deemed not to be operable by the heart team. We found the custom-made valve to be a promising solution for this highly selected cohort that otherwise eventually would not specifically be treated. There has been a tremendous growth in the number and complexity of percutaneous structural heart procedures. Therefore, the use of fusion imaging techniques may improve the implantation process, both in terms of safety and procedural time.

4 | CONCLUSION

The successful treatment of severe symptomatic TR with a long-term positive influence on mortality remains difficult. Here we report the safe deployment of a custom-made Tricento THV. Peri-procedural TOE guidance with a fusion imaging technique that integrates live co-registration substantially supported the interventional cardiologist in placing the prosthesis at the designated landing zone in the superior and inferior vena cava with an excellent primary result.

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CONFLICTS OF INTEREST

The authors have no conflicts to declare.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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