NEW TECHNOLOGY

Image-Based Decision-Making Treatment of Degenerated Mitroflow and Trifecta Prostheses

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Purpose. In the present report we describe our clinical experience using specific image-based decision making and anatomic considerations for transcatheter valve-in-valve (ViV) implantation in degenerated xenografts with their pericardial leaflets externally mounted around the stent (Mitroflow [SORIN Group, Milan, Italy] or Trifecta [St. Jude Medical, St Paul, MN]). This design seems to increase the risk of coronary ostia obstruction after ViV procedures.

Description. We report 5 patients with degenerated Mitroflow or Trifecta xenografts in whom different anatomic considerations led to different treatment strategies.

Evaluation. One patient underwent conventional redo aortic valve replacement, 2 patients underwent transcatheter ViV implantation with first-generation prostheses, and 2 patients underwent transcatheter ViV implantation using the Engager prosthesis (Medtronic, Minneapolis, MN). All patients were discharged alive in good clinical condition and were alive at 30 days after the procedure.

Conclusions. Transcatheter ViV procedures can be performed safely in degenerated Mitroflow and Trifecta prostheses, if the anatomy of the aortic root is taken into consideration. Precise preoperative image-based decision making is mandatory. The Engager prosthesis may allow for ViV procedures even in patients with smaller aortic roots.

Valve-in-valve implantation (ViV), using transcatheter techniques, has become a routine procedure to treat elderly high-risk patients with degenerated xenografts [1–3]. Special concerns have been raised about ViV procedures in bioprostheses with pericardial leaflets wrapped externally around the stent, such as the Mitroflow (Sorin Group, Milan, Italy) and the Trifecta (St. Jude Medical, St. Paul, MN) [4, 5]. Several case reports have described successful transcatheter ViV procedures in degenerated Mitroflow prostheses [6–8], whereas several cases of coronary obstruction with lethal outcome have been reported [5, 9]. To our knowledge, no ViV procedure into a Trifecta prosthesis has been published so far, but the similar design to the Mitroflow raises the same concerns. The more common location of the bioprosthetic leaflets inside the stent seems to provide enough space between the leaflets and the coronary ostia after ViV implantation, whereas the external location of the leaflets seems to increase the risk of coronary ostia occlusion by these leaflets.

The inconsistent results after ViV procedures subsequent to Mitroflow implantation emphasize the necessity for precise preoperative imaging to decide whether a ViV procedure is feasible or a conventional redo aortic valve replacement (AVR) should be performed. With the introduction of second-generation transcatheter prostheses, such as the Engager (Medtronic Inc, Minneapolis, MN) [10], a different technique for implantation and valve fixation is now available for clinical practice.

The key features of the Engager technique are the 3 “control arms” of the stent frame that are positioned inside the 3 sinuses of the aortic valve. They embrace the aortic valve leaflets during implantation and thereby the leaflets are pulled toward the annulus and away from the coronary ostia. We report our clinical experience using specific image-based decision making and specific anatomic considerations.

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All elderly patients who are admitted to our institution with degenerated bioprostheses undergo a specific screening protocol including a multislice computed tomography (MSCT) scan of the heart and the entire aorta. Beside other measurements, the width of the sinus of Valsalva and the distance between the coronary ostia and the sewing ring of the xenograft are measured using 3mensio Valves software (3mensio Medical Imaging BV, Bilthoven Netherlands). These measurements and the individual patient’s condition are used to decide whether a ViV procedure is possible or a conventional redo AVR is preferable. The local ethics committee approved the study and waived the need for patient consent.

**Technique**

MSCT scans were performed in a 64-slice dual-source scanner (Siemens Medical Solutions, Erlangen, Germany). Contrast-enhanced scans were performed by intravenous administration of Solutrust 370 (iopamidol, 370 mg iodine/mL; Bracco Imaging Deutschland GmbH, Konstanz, Germany) in an antecubital vein using 80 to 120 mL with a flow of 4 mL/s, followed by a bolus of 50 mL.

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**Fig 1. Examples of multislice computed tomography scans of (A, B) patient 1, (C, D) patient 3, and (E, F) patient 4. The black lines indicate the sewing ring plane, and the white lines indicate the particular coronary ostia plane. Details of the individual measurements are given in Table 1.**
isotonic saline with equal flow. Scan timing was coordinated by peak enhancement detection with the region of interest in the ascending aorta choosing a threshold of 120 Hounsfie1d Units. Exposure variables included a tube voltage of 120 kV and 320 to 400 effective mAs. Scan pitch was 0.2, scan rotation time was 330 ms, and the detector aperture was 0.6 mm. The images were postprocessed and analyzed by the 3mensio Valves software application.

After segmentation of the ascending aorta, the xenograft sewing ring was rendered using multiplanar reformation planes, followed by a computer-guided reconstruction of the resulting annular plane. The distance between the sewing ring and the coronary ostia, as well as the width of the sinus of Valsalva, was measured in stretched coronary planes (Fig 1).

A rough rule of thumb for deciding whether to perform ViV or redo AVR is that a coronary distance of more than 10 mm can be treated with any available transcatheter prosthesis independent of the width of the sinus of Valsalva. Coronary distances between 7 and 8 mm should be treated with ViV only if the sinus of Valsalva is wide. Providing absolute numbers for the width of the sinus of Valsalva is difficult because it depends on the individual patient’s aortic root anatomy in relation to the aortic annulus or, rather, the size of the implanted...
bioprostesis. A narrow sinus of Valsalva and a coronary distance of less than 7 mm should better be treated with conventional redo AVR.

Clinical Experience

Between June 2011 and September 2013, 4 patients with degenerated Mitroflow and 1 patient with degenerated Trifecta prostheses were admitted (Table 1). One patient underwent redo AVR because MSCT imaging showed a very short distance between the Mitroflow sewing ring and the coronary ostia (Fig 2). Two patients showed sufficient anatomy, and underwent ViV procedures using the first-generation Edwards SAPIEN (Edwards Lifesciences, Irvine, CA) and CoreValve (Medtronic Inc) transcatheter prostheses. The remaining 2 patients showed borderline distance of the coronary ostia in MSCT and the Engager prosthesis was chosen. Detailed information of the MSCT results and patient’s characteristics are given in Table 1. All five procedures were performed successfully (Fig 3), and all patients were discharged in good clinical condition and were alive 30 days after the procedure.

Comment

There is an ongoing debate about the feasibility of ViV treatment after previous Mitroflow implantation based on reports of coronary obstructions [4, 5, 9]. Because the Trifecta prosthesis has similar design features in that the pericardial leaflets are mounted externally around the stent and tall struts, the treatment of malfunctioning Trifecta prostheses may be discussed in a similar manner. Therefore, specific aortic root assessment using image-based decision making is required as outlined by the 5 patients presented.

Because the Trifecta prosthesis is quite new on the market, the experience and the incidence of degenerated Trifectas is limited. The reported successful Mitroflow ViV procedures [6–8] demonstrated that it is not impossible to implant a transcatheter prosthesis into a Mitroflow at all, but the patient’s anatomic conditions have to be considered. Cerillo and colleagues [8] described the method of using valvuloplasty before implantation to test if the prosthesis’ leaflets will obstruct the coronary ostia [8]. This may be a helpful tool, but it is being performed during the procedure and does not help for preoperative planning.

Several publications have reported the use of MSCT scans for planning transcatheter aortic valve implantation (TAVI) [11, 12]. MSCT scans provide information about the distance between the aortic annulus (or the sewing ring in the case of a ViV) and the coronary ostia and about the shape or width of the sinus of Valsalva. Both measurements are absolutely mandatory to plan a Mitroflow or Trifecta ViV procedure. An experienced TAVI imaging specialist should analyze the images, and the results should be discussed individually for each patient.

A rough rule of thumb is that a coronary distance of more than 10 mm can be treated with any available TAVI prosthesis independent of the width of the sinus of Valsalva. Coronary distances between 7 and 8 mm should be treated with ViV only if the sinus of Valsalva is wide. An acceptable width of the sinus of Valsalva is difficult to define in absolute numbers because it depends on the individual patient’s aortic root anatomy in relation to the aortic annulus, or rather, the size of the implanted bioprosthesis. A narrow sinus of Valsalva and a coronary distance of less than 7 mm should better be treated with conventional redo AVR.

A new option to loosen these recommendations might be the Engager prosthesis. It has 3 control arms on the frame that are placed into the sinus of the aortic root and

Table 1. Patient Characteristics and Treatment Strategy

<table>
<thead>
<tr>
<th>Variables</th>
<th>Patient No.</th>
</tr>
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<tr>
<td></td>
<td>1</td>
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<tr>
<td>Age, y</td>
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<tr>
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<tr>
<td>STS score, %</td>
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<tr>
<td>Distance LCA, mm</td>
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<tr>
<td>Distance RCA, mm</td>
<td>4</td>
</tr>
<tr>
<td>Width sinus of Valsalva, mm</td>
<td>24</td>
</tr>
<tr>
<td>Treatment</td>
<td>Redo AVR</td>
</tr>
</tbody>
</table>

* Sorin Group, Milan, Italy.  
  b St. Jude Medical, St. Paul, Minnesota.  
  c Edwards Lifesciences, Irvine, California.  
  d Medtronic, Minneapolis, Minnesota.  

AVR = aortic valve replacement; EuroSCORE = European System for Cardiac Operative Risk Evaluation; NYHA = New York Heart Association; RCA = right coronary artery; STS = Society of Thoracic Surgeons; ViV = valve-in-valve.
therefore embrace the valve leaflets [10]. Owing to this mechanism, the bioprosthetic leaflets will be pulled toward the annulus and thus are kept away from the coronary ostia. We describe 2 patients in whom the Engager ViV procedure was performed successfully although the anatomic conditions of the patients were “potentially not suitable” for ViV using other TAVI devices.

In conclusion, if the aortic root anatomy is taken into consideration TAVI ViV procedures can be performed successfully in malfunctioning Mitroflow and Trifecta prostheses. Precise preoperative image-based decision making is mandatory. When the most commonly implanted TAVI prostheses are used, ViV should only be performed in patients with large distances between the sewing ring and the coronary ostia and a wide sinus of Valsalva. The Medtronic Engager prosthesis, embracing the aortic valve cusps, may allow for ViV procedures even in patients with smaller aortic roots.

Disclosures and Freedom of Investigation

The authors had no funding source for this study and had full control of the design of the study, methods used, outcome parameters and results, analysis of data and production of the written report.

References


Disclaimer

The Society of Thoracic Surgeons, the Southern Thoracic Surgical Association, and The Annals of Thoracic Surgery neither endorse nor discourage use of the new technology described in this article.