Transcatheter tricuspid valve implantation: A multicentre French study

Implantation percutanée d’une valve tricuspide : une étude multicentrique française

Francois Godarta,*, Alban-Elouen Baruteaub, Jérôme Petitb, Jean-Yves Rioub, Francois Sassoлас, Jean R. Lussond, Alain Fraisse, Younes Boudjemlinef

a EA 2693, service de cardiologie infantile et congénitale, université Lille 2 Nord de France, hôpital Cardiologique, CHRU de Lille, 59037 Lille cedex, France
b Centre chirurgical Marie-Lannelongue, Le Plessis-Robinson, France
c Cardiologie pédiatrique, hôpital Louis-Pradel, Lyon, France
d Service de cardiologie et maladies cardiovasculaires, hôpital Gabriel-Montpied, CHU de Clermont-Ferrand, Clermont-Ferrand, France
e Cardiologie pédiatrique, hôpital de la Timone-Enfants, Marseille, France
f Cardiologie infantile, université Paris Descartes, hôpital Necker Enfants-Malades, Paris, France

Received 30 May 2014; received in revised form 17 July 2014; accepted 23 July 2014
Available online 2 October 2014

KEYWORDS
VIV implantation; Tricuspid; Melody valve; Edwards SAPIEN valve

Summary

Background. — Transcatheter valve-in-valve (VIV) implantation in failing bioprosthesis is an emerging field in cardiology.

Aim. — To report on a French multicentre experience and a literature review of tricuspid VIV implantation.

Methods. — We approached different institutions and collected 10 unpublished cases; a literature review identified 71 patients, including our 10 cases. Clinical aspects and haemodynamic data are discussed.

Results. — Among our 10 unpublished cases, the reason for implantation was significant tricuspid stenosis (n = 4), significant tricuspid regurgitation (n = 1) or mixed lesion (n = 5). Implantation was performed under general anaesthesia at mean age 28 ± 17 years. The 22 mm Melody valve was...

Abbreviations: NYHA, New York Heart Association; VIV, valve-in-valve; VIR, valve-in-ring.

* Corresponding author.
E-mail addresses: francois.godart@chru-lille.fr, cfda.godart@orange.fr (F. Godart).

http://dx.doi.org/10.1016/j.acvd.2014.07.051
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MOTS CLÉS
Remplacement valvulaire VIV ; Tricuspid ; Valve Melody ; Valve SAPIEN d'Edwards

Résumé
Contexte. — Le remplacement valvulaire percutanée avec la technique « valve-in-valve » (VIV) dans une bioprothèse défaillante est une technique innovante en cardiologie.
Objectifs. — Le but de cette étude est de rapporter une expérience française dans le remplacement tricuspid VIV et une revue de la littérature.
Méthodes. — Nous avons approché différents centres et collecté 10 cas non publiés. Une revue de la littérature a pu identifier 71 patients incluant nos 10 patients.
Résultats. — Cas non publiés : les raisons du remplacement étaient une sténose tricuspid significative (n = 4), une fuite tricuspid significative (n = 1) et une lésion mixte (n = 5). La mise en place a été effectuée à un âge moyen de 28 ± 17 ans. Une valve Melody de 22 mm a été implantée chez 7 patients, une valve SAPIEN d'Edwards chez 3 patients. L'implantation a réussi chez tous les patients malgré 2 embolisations dans les cavités droites : la valve a été stabilisée contre l’anneau tricuspid avec un stent auto-expansif avant l’implantation d’une seconde valve SAPIEN d’Edwards. Chez tous les patients sauf un, la classe fonctionnelle s’est améliorée. Le gradient tricuspid est passé de 9 ± 2,45 mmHg à 3,65 ± 0,7 mmHg (p = 0,007), et les patients n’avaient plus de fuite tricuspid ou une minuscule. La revue de la littérature : une valve Melody a été implantée chez 41 patients, une valve Edwards SAPIEN chez 29 patients, et une valve Braile chez un patient. Les résultats immédiats sont comparables à ceux de cette série mais les résultats à moyen terme ne sont pas encore disponibles. Les aspects cliniques et hémodynamiques sont discutés.
Conclusion. — Le remplacement tricuspid par une technique VIV utilisant la valve Melody ou la valve SAPIEN d’Edwards est réalisable et efficace chez des patients sélectionnés avec une bioprothèse défaillante.
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Background
Tricuspid valve disease is not rare, and can be observed in Ebstein’s anomaly and after ventricular septal defect closure or Fallot repair, rheumatic valve disease or endocarditis; it can also be caused by annulus dilatation secondary to pulmonary hypertension. Patients with this disease often require tricuspid valve replacement with a bioprosthesis, and need reinterventions over time because of valve degeneration [1–3]. However, reoperative valve replacement carries a higher risk of mortality and morbidity for these patients, who are usually in poor clinical condition compared with when they had the initial valve replacement [1–3]. The procedure may be also very challenging in terms of the technical aspects of the correction itself, with a risk of extensive damage to the myocardium and the atrioventricular junction. Transcatheter VIV implantation has recently emerged as a therapeutic approach for failing bioprosthetic valves. The presence of prosthetic material provides a support for the valve stent. There are a few publications on the use of both the Edwards SAPIEN™ valve (Edwards Lifesciences, Irvine, CA, USA) and the Melody® valve (Medtronic Inc., Minneapolis, MN, USA), but most are case reports. This study describes a French multicentre experience (unpublished) and a literature review of tricuspid VIV implantation; technical aspects are discussed.

Methods
A data sheet was circulated to different centres involved in percutaneous pulmonary valve implantation and known to have performed transcatheter tricuspid VIV implantation. For each patient, the following data were collected: age; weight; sex; initial diagnosis; number of previous surgical interventions; number of previous tricuspid valve...
Tricuspid VIV implantation

585

Procedures; preprocedure clinical condition; indication for tricuspid valve repair; characteristics of the implanted tricuspid prosthesis; pre- and postechocardiographic data; complications; and follow-up. We report here on 10 cases from four centres. Most of the investigators belong to the "Groupe de cathétérisme interventionnel pédiatrique et congénitale, filiale de cardiologie pédiatrique et congénitale de la Société française de cardiologie".

In addition, we searched the online medical database 'PubMed' for all publications on 'tricuspid VIV implantation' using both the Melody and the Edwards SAPIEN valves. We reviewed patient data, procedural details, valve performance and outcome.

Continuous data are presented as means ± standard deviations (range). Paired t tests and Wilcoxon tests were used to compare pre- and post-procedure gradients within patients.

Results
French multicentre experience of tricuspid VIV implantation

Patient population

Table 1 outlines the baseline characteristics of the 10 study patients; most of the patients had congenital heart disease. Mean age at implantation was 28±17 years (range 9–60 years); five patients were aged ≤18 years at implantation. The mean time period between tricuspid bioprosthesis implantation and dysfunction requiring VIV implantation was 12±9.7 years (range 3–32 years). The size of the dysfunctional valve ranged from 23 to 33 mm (mean 29.5±3.6 mm). All patients presented signs of right heart failure. Five patients were in New York Heart Association (NYHA) functional class III, three were in class II and two were in class IV. In addition, two patients presented with protein-losing enteropathy. After a multidisciplinary discussion, the patients were referred for percutaneous VIV implantation.

At baseline, the tricuspid maximal gradient was 16±2.5 mmHg and the mean gradient was 9±2.4 mmHg. Reason for VIV implantation was a predominant tricuspid stenosis (defined as mean gradient > 5 mmHg) (n=4), a significant tricuspid regurgitation (moderate-to-severe tricuspid regurgitation) (n=1) or a mixed lesion combining significant tricuspid stenosis and regurgitation (n=5).

Procedures

Informed consent was obtained from all patients. The procedure was done under general anaesthesia. Owing to potential complications requiring emergency surgery, surgical backup was available for most of the implantations. Balloon sizing, using a low-pressure balloon catheter to delineate the dimension of the annulus, was employed in nine patients; predilatation using a high-pressure balloon was performed in five patients. Before implantation, prestenting was done in six patients, including one who had four stents implanted to reduce the annulus size before implantation of a 22-mm Melody valve. All patients underwent successful VIV implantation: the Melody valve was used in seven patients; the Edwards SAPIEN valve was used in three patients.

No periprocedural death, myocardial infarction, stroke or stent fracture occurred. Two embolizations of the Edwards SAPIEN valve within the right ventricle and the right atrium were observed. In both cases, the valve was stabilized close to the tricuspid annulus by overlapping stents, using a self-expandable Sinus-XL stent (OptiMed, Ettingen, Germany) and then a balloon-expandable stent, before successful implantation of a second Edwards SAPIEN valve (Fig. 1). Ventricular ectopics were noticed in two patients; these resolved in a few days.

Haemodynamic outcomes

The mean gradient decreased from 9±2.45 mmHg to 3.65±0.7 mmHg (p=0.007). The degree of valve regurgitation improved in all patients (Table 2).

Early and mid-term outcomes

No patients died during hospitalization. Patients left the hospital about 2 days after implantation. The mean follow-up was 11.6±7.7 months (range 2–24 months). The clinical conditions of all patients but one were ameliorated: eight patients were in NYHA class II, one was in class I and one was in class III. For the two patients with protein-losing enteropathy, a significant increase in albumin level was noticed following the procedure. Two deaths were observed.

Table 1: Patient data: unpublished cases of tricuspid valve-in-valve implantation (n=10).

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age (years)</th>
<th>Sex</th>
<th>Weight (kg)</th>
<th>Pathology</th>
<th>Valve size (mm)</th>
<th>Valve type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>16</td>
<td>M</td>
<td>45</td>
<td>Ebstein’s anomaly</td>
<td>27</td>
<td>Mosaic</td>
</tr>
<tr>
<td>2</td>
<td>15</td>
<td>M</td>
<td>59</td>
<td>Ebstein’s anomaly</td>
<td>33</td>
<td>CE</td>
</tr>
<tr>
<td>3</td>
<td>60</td>
<td>F</td>
<td>61</td>
<td>Ebstein’s anomaly</td>
<td>33</td>
<td>CE</td>
</tr>
<tr>
<td>4</td>
<td>14</td>
<td>F</td>
<td>54</td>
<td>Ventricular septal defect closure</td>
<td>23</td>
<td>Mitroflow</td>
</tr>
<tr>
<td>5</td>
<td>26</td>
<td>F</td>
<td>68</td>
<td>Tricuspid dysplasia</td>
<td>31</td>
<td>CE</td>
</tr>
<tr>
<td>6</td>
<td>9</td>
<td>M</td>
<td>22</td>
<td>Arterial duct, pulmonary artery hypertension</td>
<td>27</td>
<td>CE</td>
</tr>
<tr>
<td>7</td>
<td>33</td>
<td>F</td>
<td>59</td>
<td>Cardiomyopathy</td>
<td>33</td>
<td>CE</td>
</tr>
<tr>
<td>8</td>
<td>44</td>
<td>M</td>
<td>85</td>
<td>Tricuspid atresia, Fontan type</td>
<td>33</td>
<td>CE</td>
</tr>
<tr>
<td>9</td>
<td>49</td>
<td>M</td>
<td>57</td>
<td>Rheumatic</td>
<td>29</td>
<td>CE</td>
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<tr>
<td>10</td>
<td>17</td>
<td>M</td>
<td>55</td>
<td>Ebstein’s anomaly</td>
<td>29</td>
<td>CE</td>
</tr>
</tbody>
</table>

CE: Carpentier-Edwards; F: female; M: male.
after implantation: one at 10 months due to a non-cardiac cause; and another at 5 months because of heart failure unrelated to tricuspid valve dysfunction. At latest follow-up, the mean gradient remained stable at 4.1 ± 0.7 mmHg (range 3–5.7 mmHg) (Fig. 2).

Literature review of tricuspid VIV implantation

Including our 10 patients, there were 71 reported cases of tricuspid VIV implantation for a failing bioprosthetic valve in the literature. The initial pathology included rheumatic disease (n = 13), Ebstein’s anomaly (n = 12), endocarditis (n = 8), cardiomyopathy (n = 7), Fontan tube failure (n = 7), tricuspid dysplasia (n = 4), tricuspid regurgitation following ventricular septal defect closure (n = 5) and miscellaneous lesions, including atrioventricular septal defect repair and carcinoid pathology.

Patient data at implantation are listed in Table 3. There were 41 women and 29 men (the sex of one patient was not mentioned), and 18 patients were aged ≤18 years at implantation. To delineate the valvular stenosis, balloon sizing and/or predilatation was employed in 45 patients. Preenting was performed in only 11 patients: five had a mixed lesion, four had a predominant tricuspid stenosis and two had a predominant tricuspid regurgitation. Seven of these 11 patients had subsequent implantation of the Edwards SAPIEN valve and four had implantation of the 22 mm Melody valve. Valve deployment was always realized under fluoroscopy, and additive transoesophageal echocardiographic guidance was used in 45 patients. Postimplantation dilatation was performed in 12 patients (after Melody valve implantation in 11 patients and Edwards SAPIEN valve implantation in one patient). Usually, the valve performance was good after implantation: the maximal gradient decreased from 17.9 ± 4.9 to 7.6 ± 2.4 mmHg (p = 0.005) and the mean gradient decreased from 11.0 ± 4.0 mmHg to 3.8 ± 2.0 mmHg (p = 0.001). Regurgitation was no more than trivial-to-mild after implantation in all but one patient, who had moderate regurgitation (Table 4). The clinical condition of most of the patients was ameliorated, with a reduction in signs of right heart failure, and all but three patients were in NYHA class I–II. The major complications were embolization (n = 4), death (n = 2) and endocarditis (n = 1). The mean follow-up was 6.7 ± 6.5 months (range 0.25–30 months), and at latest follow-up the mean gradient remained stable at 4.4 ± 1.3 mmHg.

Discussion

VIV procedures are being performed increasingly as a treatment for degenerated bioprostheses. In fact, when a circumferential valvular ring is present, it may provide the minimal landing zone to anchor a valved stent, thus allowing transcatheter VIV implantation [1,4]. Although this latter procedure has been performed preferentially in degenerated aortic bioprostheses, there have been many reports of transcatheter VIV implantation in the tricuspid position since the first implantation in 2010. A series of 10 patients is presented here and a review of literature identified a total of 71 implantations. The valved stent was implanted successfully in all patients using either a Melody valve or an Edwards SAPIEN valve. Our report demonstrates that transcatheter VIV implantation can be achieved and has now become a real alternative to surgery for bioprosthetic tricuspid valve failure.

Access route

For tricuspid VIV implantation, different approaches have been proposed (e.g. from the superior vena cava, the right jugular vein and the standard femoral vein, as well as the surgical open transatrial or transapical approaches) [5–12]. The last two approaches would probably not be
Table 2  Pre- and postimplantation haemodynamic data: unpublished cases of tricuspid valve-in-valve implantation (n = 10).

<table>
<thead>
<tr>
<th>Patient</th>
<th>Type of lesion</th>
<th>Valved stent</th>
<th>Mean gradient (mmHg)</th>
<th>Regurgitation</th>
<th>Balloon sizing</th>
<th>Prestenting</th>
<th>Pacing</th>
<th>Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Pre</td>
<td>Post</td>
<td>Pre</td>
<td>Post</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>TS + TR</td>
<td>Edwards 23</td>
<td>10</td>
<td>4</td>
<td>Moderate</td>
<td>Yes</td>
<td>No</td>
<td>Migration</td>
</tr>
<tr>
<td>2</td>
<td>TS + TR</td>
<td>Edwards 26</td>
<td>6</td>
<td>4</td>
<td>Severe</td>
<td>Yes</td>
<td>One Max™ LD stent; Two covered CP™ stents; one Max LD stent + one CP stent</td>
<td>Yes</td>
</tr>
<tr>
<td>3</td>
<td>TS + TR</td>
<td>Melody 22</td>
<td>8</td>
<td>5</td>
<td>Severe</td>
<td>Yes</td>
<td>No</td>
<td>Migration; ectopics</td>
</tr>
<tr>
<td>4</td>
<td>TS</td>
<td>Melody 22</td>
<td>9</td>
<td>4</td>
<td>Mild</td>
<td>Yes</td>
<td>No</td>
<td>Changs</td>
</tr>
<tr>
<td>5</td>
<td>TS</td>
<td>Edwards 29</td>
<td>10</td>
<td>4</td>
<td>None</td>
<td>Yes</td>
<td>No</td>
<td>Changs</td>
</tr>
<tr>
<td>6</td>
<td>TS</td>
<td>Melody 22</td>
<td>14</td>
<td>3</td>
<td>Mild</td>
<td>Yes</td>
<td>One Max LD stent; one CP stent</td>
<td>No</td>
</tr>
<tr>
<td>7</td>
<td>TR</td>
<td>Melody 22</td>
<td>2.9</td>
<td>2.9</td>
<td>Severe</td>
<td>Yes</td>
<td>No</td>
<td>Changs</td>
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<tr>
<td>8</td>
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<td>Melody 22</td>
<td>10</td>
<td>3.6</td>
<td>Mild</td>
<td>Yes</td>
<td>No</td>
<td>Changs</td>
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<tr>
<td>9</td>
<td>TS + TR</td>
<td>Melody 22</td>
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<td>3</td>
<td>Severe</td>
<td>Yes</td>
<td>No</td>
<td>Changs</td>
</tr>
<tr>
<td>10</td>
<td>TS + TR</td>
<td>Melody 22</td>
<td>6</td>
<td>3</td>
<td>Severe</td>
<td>Yes</td>
<td>No</td>
<td>Changs</td>
</tr>
</tbody>
</table>

CP: Cheatham-Platinum; TR: tricuspid regurgitation; TS: tricuspid stenosis.

* ev3 Endovascular, Inc., Plymouth, MN, USA.
*b NuMED, Inc., Hopkinton, NY, USA.

well tolerated in some high-risk patients and would increase postprocedural morbidity. Because the tricuspid valve is often directed towards the superior vena cava, many authors have recommended the jugular approach, to obtain a better angle and a more stable aligned position during valve deployment [1,4,13–26]. However, this is more theoretical than real, especially with the use of an extra-stiff guidewire or the steerable balloon catheter of the Edwards SAPIEN valve [3,27]. In fact, many reports have shown the successful employment of the more classical femoral venous route, which offers the advantage of convenience and familiarity [3,16,20,22,24,27–36].

Choice of valved stent and deployment

Exact knowledge of the true internal diameter of the failed bioprosthesis (minimal diameter and its delineation) is the key point for VIV implantation; this can be measured by transoesophageal echocardiography and/or computed tomography [2,3,7,12,15,16,27,28,32]. In fact, the manufacturer’s information about the characteristics of the valve itself is most important when making the decision, with knowledge of internal (inner stent) diameter, prosthesis height, type of base ring and position and angulation of stent posts [2,12,37]. However, calcified, bulky or torn leaflets and pannus may also reduce the internal diameter. Balloon sizing with a low-pressure balloon catheter is another technique for delineating the true inner diameter [4,16,18,21,22,24,31,32,36]. Sometimes, a true balloon dilatation may also be employed, especially if the valve is severely stenosed [3,7,11,18,19,22,25–31,34], but this is rarely necessary due to antegrade crossing as performed for tricuspid VIV implantation [2]. Furthermore, dilatation is not always recommended because of concerns about possible valve disintegration and damage following inflation, but this risk seems low [2,37].

In fact, the external diameter of the valved stent should match and even exceed the true internal diameter of the failed bioprosthesis, to avoid dislocation [2,37]. Ideally, the radio markers at the basal ring (if available) should be ‘straight’ aligned and perpendicular to the axis of the delivery sheath on fluoroscopy during valve deployment. Additional imaging using (three-dimensional) transoesophageal [3,16,10,12,14–21,24–27,29,32–34] or intracardiac echocardiography has also been used for appropriate deployment.
Figure 2. Transthoracic echocardiography 15 months after implantation (patient 1) demonstrates adequate position and function across the tricuspid valve by colour (A) and pulsed-wave (B) Doppler.

There are two valves available for VIV implantation in the tricuspid position (the Melody valve and the Edwards SAPIEN valve); superiority of one over the other has not been established. The advantage of the latter is its availability in larger sizes, increasing the number of patients who can be treated. However, this may be limited by the small length of the stent and the possible risk of embolization.

Prestenting

It has been reported that prestenting is not mandatory for VIV implantation in the tricuspid position. However, as observed in two of our patients, it is advisable to obviate valve dislocation [33]. In fact, this is related to different factors, including the bioprosthesis type and its anatomical characteristics [2]. For the interventionists, the real landing zone and target for VIV implantation is the sewing ring and stent posts. It seems that for patients with just a ring, prestenting is wise, as it provides a longer 'landing zone'; this is also true for some of the short Edwards SAPIEN valves [2,18,19,24,33]. Prestenting has also been employed in a patient with predominant tricuspid regurgitation, using the Edwards SAPIEN valve for a similar reason [27,33]. Other than under the above conditions, prestenting is not necessary for the vast majority of patients.

Of interest is the technique of annulus reduction as performed in our "patient 3"; no Edwards SAPIEN valve was available at this time. By implanting four stents, the annulus reduction was effective, allowing successful implantation of a 22 mm Melody valve. The use of an Edwards SAPIEN valve might have been an alternative strategy.

Rapid pacing

Rapid pacing with a lead placed in the left ventricle (rarely in the coronary sinus) has also been proposed to obtain a stable position during valve deployment [1,3,6,7,9—12,15,19,20,25,27,28]. Sometimes, the heart is fibrillated with 'spinal' needles during implantation, using a transatrial approach [6,9]. However, with the low gradient across the tricuspid valve, this may be not necessary [2,26]. Pacing is, in fact, mainly dependent on local preferences and can be recommended if cardiac motions are problematic, especially in case of significant tricuspid regurgitation [2,27].

Complications

Embolization of the valved stent in the right-sided cardiac chambers or pulmonary artery is the major complication associated with this technique [38], and may be related to the lack of coaxiality during inflation and/or suboptimal deployment position and/or valve mismatch. Cocchiere et al. reported distal embolization in the pulmonary artery due to undersizing after using a transatrial approach [7]. In this setting, different options could be considered: stenting
Table 4  Procedural data: literature review of tricuspid valve-in-valve implantation (n = 71).

<table>
<thead>
<tr>
<th>Approach</th>
<th>Femoral</th>
<th>Jugular</th>
<th>Transatrial</th>
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<th>Predilatation</th>
<th>Prestenting</th>
<th>Valved stent</th>
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<tbody>
<tr>
<td>22 mm Melody valve</td>
<td>36</td>
<td></td>
<td></td>
<td>9</td>
<td>16</td>
<td>22</td>
<td>11</td>
<td>40</td>
</tr>
<tr>
<td>26 mm Edwards SAPIEN valve</td>
<td></td>
<td></td>
<td>6</td>
<td>2</td>
<td>23 mm Edwards SAPIEN valve</td>
<td>3</td>
<td>18 mm Melody valve</td>
<td>1</td>
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<tr>
<td>29 mm Edwards SAPIEN valve</td>
<td></td>
<td></td>
<td></td>
<td>6</td>
<td>23 mm Edwards SAPIEN valve</td>
<td>3</td>
<td>28 mm Braile valve</td>
<td>1</td>
</tr>
<tr>
<td>Postimplantation dilatation</td>
<td>12</td>
<td></td>
<td></td>
<td>17.9 ± 4.9 (7–27)</td>
<td>Mean gradient preimplantation (mmHg)</td>
<td>11.0 ± 4.0 (3–20)</td>
<td>Mean gradient postimplantation (mmHg)</td>
<td>3.8 ± 2.0 (0–9)</td>
</tr>
<tr>
<td>Peak gradient TR</td>
<td></td>
<td></td>
<td></td>
<td>7.6 ± 2.4 (3–12)</td>
<td>Preimplantation TR</td>
<td>Mild-to-trivial regurgitation</td>
<td>7</td>
<td>Moderate-to-severe regurgitation 17</td>
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<td>Not mentioned 16</td>
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<td>Postimplantation TR</td>
<td>Trivial regurgitation</td>
<td>13</td>
<td>None 18</td>
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<td>Not mentioned</td>
<td>26</td>
<td>26</td>
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</tbody>
</table>

Data are number or mean ± standard deviation (range). TR: tricuspid regurgitation.

a Braile Biomedica, Sau Paulo, Brazil.

the dislocated valve in the pulmonary artery branch; extraction into a large sheath with a biopsy forceps [7]; or surgical extraction with tricuspid valve replacement. True embolization in the right ventricle or atrium — as reported here in two patients with an Edwards SAPIEN valve — has not yet been reported. Some have proposed positioning the short Edwards SAPIEN valve more atrially within the tricuspid annulus to reduce this risk [15]. In fact, anchoring the embolized valve close to the tricuspid annulus by overlapping stents was the strategy employed in these patients. This was made possible by implantation of a self-expandable stent and then stiffer stents, allowing a second successful VIV implantation. We clearly recommend this approach for embolization in the right ventricle if no wall protrusion by the stent can be anticipated. A similar overlapping stents approach has also been reported in a patient with slight migration of an Edwards SAPIEN valve in the ventricular direction [20].

Endocarditis is another matter for concern and a classic risk with bioprostheses. To our best knowledge, only one case has been reported after a Melody valve implantation, in a 9-year-old patient following four tricuspid replacements for Ebstein’s anomaly [22]. Such limited risk has to be interpreted with great caution because of the short-term follow-up. In addition, we clearly insist on the necessity of antibiotic prophylaxis after the procedure.

Valvular failure is another issue usually observed over time with all bioprostheses. Progressive early regurgitation was noticed in a patient who received the 22 mm Melody valve implanted over a 24 mm balloon [22], but this may have been the consequence of overdilatation. One early valve thrombosis has also been reported (18 days after a Melody valve implantation), but this was, in fact, related to heparin-induced thrombocytopenia [16].

Other drawbacks have included third-degree heart block requiring pacemaker implantation [22], minor neck haematoma [21], phlebitis, femoral artery pseudoaneurysm [16] and pleural effusion [15]. Pulmonary artery bleeding due to perforation by the distal wire tip has also been reported; this was corrected successfully by coil implantation [32]. Some of these vascular complications are clearly related to the use of a large delivery sheath and (probably) to patient comorbidities [16].

Death has been reported twice in the literature after implantation of the Melody and Edwards SAPIEN valves [6,22]. In fact, although transcatheter VIV implantation seems less aggressive than surgery for these patients in poor conditions, there is a persistent minimal risk of morbidity and/or mortality following such a procedure.

Finally, stent fracture is another matter for concern, and has been reported mainly with the Melody valve implanted in the right ventricular outflow tract. By comparison, VIV implantation in the tricuspid position seems less problematic because the valved stent is placed within a bioprosthetic valve with less mechanical restraint.

Implantation in native valve

Implantation within a native tricuspid annulus is clearly a more challenging procedure. This issue has already been addressed in an animal model by Iino et al. [38] and Boudjemline et al. [39]. Both groups developed an original self-expandable stent in which a bioprosthesis was mounted, allowing reduction of the tricuspid annulus. Although this concept was effective and promising in animals, creating a potential landing zone for further deployment of the valved stent, unfortunately it has not yet been developed in humans.

There is only one case report in the literature of tricuspid valve implantation in a native valve repaired three times, but without previous surgical ring or bioprosthesis [32]. In the same way, but less challenging, tricuspid valve-in-ring
(VIR) has also been reported within a Carpentier-Edwards ring in one patient [10] and a Physio ring combined with a mitral homograft in two other patients, thus enabling VIR and VIV procedures [19,40]. Here, the stiffness of the ring allowed appropriate anchoring of the Edwards SAPIEN valve [4]. These authors proposed placing the valve stent more distally in the ring, with one third in the atrium and two thirds in the ventricle, for two reasons: first, to reshape the asymmetric form of the ring into a circular form; and second, to reduce the risk of paravalvular leak by the short basal cuff of the Edwards SAPIEN valve [10]. All these strategies will probably modify the current standard of care for atrioventricular valve replacement, by first placing a bioprosthesis or performing an annuloplasty ring. Then, when the valve degenerates, a VIV or VIR implantation will be performed, thus avoiding another surgical repair.

Limitations

There are some limitations to the present review. Data were collected from a "PubMed" search and we may have missed a few cases, including failed procedures, which are often not published. Most of the implantations were performed 'off label', mainly on high-risk patients, which may have modified the rate of complications. In addition, some results and drawbacks may also have been influenced by the learning curve associated with this early experience. Furthermore, we should acknowledge that small numbers of cases are insufficient to enable final recommendations to be made. Collection of more data and longer follow-up by creation of a registry are needed in the future to establish the best strategy for patients with a failing tricuspid bioprosthesis. Finally, long-term deterioration of these valved stents should also be anticipated, as classically observed with all bioprosthetic valves.

Conclusion

Tricuspid VIV implantation using the Melody valve or the Edwards SAPIEN valve is a relatively new technique and a reproducible therapeutic option; it is an interesting alternative to surgery for selected high-risk patients with a failing tricuspid bioprosthesis, which provides a less aggressive approach. However, further experience is required to help in the standardization and dissemination of this appealing procedure.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

References

Tricuspid valve implantation


