Transcatheter replacement of pulmonary valve with Venus P-Valve: a single center experience in 15 patients

Jou-Kou Wang, Ming-Tai Lin, Chun-An Chen, Shuenn-Nan Chiu, Chun-Wei Lu, Mei-Hwan Wu.
Department of Pediatrics, National Taiwan University Hospital, Taipei, Taiwan

Objectives:
- Pulmonary regurgitation (PR) occurs quite common in patients with Tetralogy of Fallot, particularly, when a transannular patch is used in surgery.
- Long-standing severe PR may result in right ventricular dilatation and dysfunction.
- Valve replacement is required in time to avoid irreversible dilatation of right ventricle.
- Percutaneous pulmonary valve replacement has been successfully performed with good long-term results.
- We report the short-term results of transcatheter Venus P-Valve implantation in a single center.

Methods & Patients:
Patients:
- In 12-month period, a total of 15 patients underwent attempted transcatheter implantation using Venus P-Valve. (Venus Medtech, Shanghai)
- MRI study was performed in each patient. (Table 1)

Indications:
- Moderate-to-severe PR, PR index ≥ 30%
- RVEDVi > 150 ml/m²
- RVEF ≤ 45%

Methods:
- Balloon sizing and multiple measurements of pulmonary valve annulus, main pulmonary artery (MPA) length and diameter
- Coronary artery compression test
- Select a valve diameter 3 ~ 4 mm larger than pulmonary annulus, and valve length equal to MPA length
- After Venus-P valve deployment, aspirin 100 mg and plavix 37.5 mg per day were given for 6 months

Results:
- Deployment of Venus P-valve was successful in all 15 patients.
- No major complications occurred.
- 3 patients had transient mild fever.

Follow-up:
- Follow-up echocardiography showed diminished paradoxical motions and decrease in right ventricular dimension in all 15 patients.
- MRI studies at 6-month follow-up in 11 patient showing significant decreased in RVEDVi, RVESVi and PR index, but RVEF remained unchanged. (Table 2)
- No fracture in the valve was detected.

Adverse event:
- Gastrointestinal bleeding in 1 in whom aspirin was discontinued.
- Infective endocarditis occurred in 1 who was treated with antibiotics for 8 weeks.

Discussion:
- Transannular patch has been commonly used in Tetralogy of Fallot repair.
- Dilatation of pulmonary valve annulus is quite common as the patient grow up.
- Venus P-Valve can be used in patients with native right ventricular outflow tract.

Conclusions:
- Transcatheter replacement using Venus P-Valve is safe and effective in patients with a large pulmonary annulus.
- A longer follow-up is mandatory.

Table 1: Demographic features of 15 patients

<table>
<thead>
<tr>
<th>Sex</th>
<th>Age (F, M)</th>
</tr>
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<tbody>
<tr>
<td>F</td>
<td>16.5 ± 12 years (13 ~ 54 years, median 24)</td>
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<tr>
<td>M</td>
<td></td>
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<table>
<thead>
<tr>
<th>MRVI (ml/m²)</th>
<th>164.1 ± 145.6 ml/m² (127.6 ~ 185.5 ml/m²)</th>
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<tbody>
<tr>
<td>RVESVi (ml/m²)</td>
<td>90.3 ± 135.7 ml/m² (70.8 ~ 119.7 ml/m²)</td>
</tr>
<tr>
<td>PR index (%)</td>
<td>41.5 ± 9.7% (33.9 ~ 49.5%)</td>
</tr>
<tr>
<td>RVEF (%)</td>
<td>44.5 ± 7.7% (23 ~ 54.7%)</td>
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Table 2: MRI data at 6-months follow-up (n=11)

<table>
<thead>
<tr>
<th></th>
<th>Pre</th>
<th>Post</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>RVEDVi (ml/m²)</td>
<td>168.7 ± 9.9</td>
<td>127.2 ± 8.4</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>RVESVi (ml/m²)</td>
<td>92.5 ± 13.7</td>
<td>63.2 ± 5.4</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>PR index (%)</td>
<td>45.5 ± 8.5</td>
<td>46.3 ± 3.5</td>
<td>0.57</td>
</tr>
<tr>
<td>RVEF (%)</td>
<td>45.5 ± 2.2</td>
<td>49 ± 5.1</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

Figure 1

Figure 2

Figure Legends:
Figure 1: a. MPA angiogram showing mild stenosis at LPA origin and moderate PR
   b. MPA angiogram showing a Venus P-Valve in good position without PR

Figure 2: a. MPA angiogram in lateral view showing moderate PR
   b. MPA angiogram showing Venus P-Valve in good position without PR

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