Candidates, 80 subjects were randomized according to a willingness to participate (40 to each group). Of the 80 subjects, 4 (10%) in each group developed postoperative atrial fibrillation. No subjects in the amiodarone plus atrial pacing group developed atrial fibrillation after pacing had been discontinued. The average length of stay was 2.2 days for the patients treated with amiodarone and 2.9 days for the patients treated with atrial overdrive pacing and amiodarone ($P = NS$).

A total of 10 adverse events occurred during the study period (Table 2); 6 adverse events were in the amiodarone group and 4 in the combination group. One patient in the combination arm died during the study period. His death was from multisystem organ failure after he had experienced a stroke; however, he had not had any episodes of atrial fibrillation.

### DISCUSSION

The major finding of the present study was that both amiodarone and the combination of atrial pacing plus amiodarone are effective and well tolerated. However, in the present pilot study, the addition of atrial pacing to amiodarone did not add to the effectiveness of amiodarone alone in reducing the incidence of postoperative atrial fibrillation. In addition, it appears that oral amiodarone can be started at surgery, without preoperative loading or intravenous therapy, without a loss of efficacy. Furthermore, amiodarone was well tolerated by the patients, with a low number of adverse events.

### References


## Handmade trileaflet valved stent graft for pulmonary valve implantation

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**Table 2. Adverse events**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Amiodarone (n)</th>
<th>Amiodarone plus pacing (n)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic hypotension</td>
<td>0</td>
<td>3</td>
<td>.24</td>
</tr>
<tr>
<td>Symptomatic bradycardia</td>
<td>2</td>
<td>0</td>
<td>.49</td>
</tr>
<tr>
<td>Symptomatic ventricular arrhythmia</td>
<td>0</td>
<td>0</td>
<td>1.00</td>
</tr>
<tr>
<td>Complete heart block</td>
<td>0</td>
<td>0</td>
<td>1.00</td>
</tr>
<tr>
<td>Acute kidney injury</td>
<td>2</td>
<td>0</td>
<td>.49</td>
</tr>
<tr>
<td>Prolonged ventilation</td>
<td>1</td>
<td>0</td>
<td>1.00</td>
</tr>
<tr>
<td>Reoperation</td>
<td>1</td>
<td>0</td>
<td>1.00</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>1</td>
<td>1.00</td>
</tr>
</tbody>
</table>

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**Handmade trileaflet valved stent graft for pulmonary valve implantation**

Ting-Wei Lin, MD, MSc, a Jieh-Neng Wang, MD, b,c Chung-Dann Kan, MD, PhD, a,d and Yu-Jen Yang, MD, PhD, a,e Tainan City, Taiwan

Children with complex congenital heart disease involving the right ventricular outflow tract (RVOT) usually need surgical repair at an early age. These patients might need a secondary operation for their degenerative or poor functional pulmonary regurgitations. Traditionally, redo open surgery is necessary to relieve the RVOT dysfunction, which carries high risks and morbidity. 1 Bonhoeffer and colleagues 1 first described the concept of a stent-mounted biological valve for a pulmonary position in 2000, which evolved into the current commercially available Melody (Medtronic Inc, Minneapolis, Minn) transcatheter pulmonary valve. 2,3 However, it cannot be applied to an RVOT larger than 22 mm in diameter because of the size limitation. Furthermore, this device is not available in our country. Chang and Chang 5 reported their strategy in treating pulmonary regurgitation after surgery for tetralogy of Fallot using...
a handmade expanded polytetrafluoroethylene (ePTFE) trileaflet conduit for valve reconstruction in 2013. Their concept inspired us to design a handmade valved stent graft for transcatheter pulmonary valve implantation.

CLINICAL SUMMARY

A 13-year-old girl with a history of tetralogy of Fallot had received a bilateral modified Blalock–Taussig shunt at the age of 2 months and then reconstruction of the RVOT, together with ventricular septal defect repair, at 2 years. Significant left pulmonary artery traction developed after a left modified Blalock–Taussig shunt, and the artery eventually became severely hypoplastic. Apparent scoliosis also developed as she grew. Severe pulmonary regurgitation had been found by echocardiography since her teenage years, and pulmonary valve replacement was considered.

According to the patient’s main pulmonary artery size measured on computed tomography angiography, an Endurant II (Medtronic Inc, Galway, Ireland) aortic extension stent graft, 23 mm in diameter and 49 mm in length, was chosen. The stent graft was deployed ex vivo first for further manipulation (Figure 1, A). It was then flipped inside out, the anchor pins were cut off, and the stent graft was trimmed to achieve a final length of 3 cm (Figure 1, B). The most distal part of the polyester graft membrane was trimmed along the M-shaped stent. One thin ePTFE membrane (Gore-Tex Preclude pericardial membrane; WL Gore & Associates Inc, Flagstaff, Ariz) was trimmed into a semilunar tricuspid shape on the basis of that introduced by Chang and Chang.4 To allow better coaptation, we modified the shape by adding a curved structure to each leaflet in addition to the 3- to 5-mm connecting junctions, turning the membrane into a bi-semilunar tricuspid shape (Figure 1, C). The trileaflet piece was then sutured to the flipped stent graft with 6-0 polypropylene continuous suture, supported with a Hegar dilator inside (Figure 1, D). After completing the suture, we flipped the stent graft back into its original form. Three additional fenestration holes were created at the distal side of stent graft to prevent catastrophic pulmonary arterial obstruction caused by stent graft malposition. The accomplished valved stent graft was then reloaded into the delivery device (Figure 1, E and F).
Through a right internal jugular vein approach, the stent graft and delivery device were advanced to the main pulmonary artery under fluoroscopic guidance. However, it was more deeply deployed in the distal pulmonary artery (Figure 2, A and B). Therefore, we performed a full sternotomy to salvage this situation. After establishment of the cardiopulmonary bypass, the main pulmonary artery was opened and the dislodged stent graft could be visualized. We pulled back the stent graft directly and fixed it to the desired main pulmonary artery at an adequate location with 6-0 polypropylene sutures (Figure 2, C). The patient was weaned from cardiopulmonary bypass. Postoperative chest x-ray showed that the stent graft was positioned adequately (Figure 2, D). The patient had an uneventful postoperative course, and the follow-up echocardiography showed trivial pulmonary regurgitation.

DISCUSSION

Pulmonary regurgitation is a serious situation in patients with congenital heart disease involving the RVOT after repair. Several reports have described the use of handmade trileaflet valve conduits for pulmonary reconstruction. On the other hand, stent-deployed valves, including the commercial Melody transcatheter pulmonary valve, are available and successfully deployed in humans and provide almost the same benefits as surgical valve replacement. By combining both of these concepts, we designed a cost-effective handmade trileaflet stent graft by suturing a semilunar tricuspid-shaped ePTFE membrane to a commercial transcatheter stent graft. In our preliminary experience, this approach is easy, reproducible, and clinically practicable for transcatheter deployment. Although malposition developed in our first case, it did not result in pulmonary flow obstruction-related immediate hemodynamic instability because of our special design—an M-shaped graft border and fenestration holes. Further clinical experience with our novel design is needed to evaluate the medium- and long-term outcomes.

References