Pulmonary Annulus Growth After the Modified Blalock-Taussig Shunt in Tetralogy of Fallot

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Background. In tetralogy of Fallot (TOF), it is well known that postoperative pulmonary regurgitation reduces right ventricular function during long-term follow-up. Complete repair without a transannular patch should help avoid pulmonary regurgitation. Recently, primary complete repair has been preferred to the staged repair with use of a Blalock-Taussig shunt (BTS) even in neonates or small infants; however, little has been reported about the influence of a BTS on pulmonary annular growth.

Methods. We examined 40 patients with TOF or double-outlet right ventricle with pulmonary stenosis. Twenty-one patients received a BTS before complete repair, whereas 19 patients underwent primary complete repair. Pulmonary annular size was measured by echocardiography before BTS, complete repair, or both, and ventricular volume was measured by cardiac catheterization.

Results. There were no significant differences in complete repair age or body size between the groups. Pulmonary annulus sizes in the BTS group were smaller than those in the primary repair group (Z score, −5.1 ± 2.5 vs −3.7 ± 1.8). After the BTS, significant annular growth (Z score, −2.8 ± 2.1) was observed (p = 0.0028), with a significant increase in left ventricular end-diastolic volume (p = 0.015). When patients with severe pulmonary stenosis (Z score > −7.0) were excluded, pulmonary annular preservation at complete repair was achieved in 64.7% (11/17) of the BTS group and 36.8% (7/19) of the primary repair group (p = 0.088).

Conclusions. The BTS increased the pulmonary annular size and the left ventricular volume during the 6 months before complete repair, resulting in preservation of the pulmonary valve function.

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In tetralogy of Fallot (TOF) and its related cardiac anomalies, there has been a tendency to perform a primary repair without a Blalock-Taussig shunt (BTS) even in small infants [1], and BTS has been indicated for only a limited number of patients with anoxic spells, ductus-dependent pulmonary circulation, severe pulmonary stenosis, or a combination of these conditions [2]. For these patients with a small pulmonary annulus or severe right ventricular outflow tract (RVOT) obstruction, an early complete repair with a transannular patch (TAP) is preferred because of the relatively high mortality with the BTS [3]. By contrast, in these anomalies, pulmonary regurgitation (PR) after intracardiac repair (ICR) has often been discussed in recent publications because they lead to several adverse events resulting from dilatation of the right ventricle (RV), such as biventricular dysfunction, heart failure symptoms, arrhythmia, and sudden death [4]. To reduce PR after ICR, pulmonary annulus preservation without an incision to the annulus should be considered, resulting in progressive PR during follow-up periods.

We hypothesized that a BTS increases pulmonary flow, resulting in increased left ventricular (LV) volume load. Then the blood flow through the pulmonary valve increases, and the pulmonary annulus and RVOT enlarge. So for patients with moderate pulmonary stenosis, we assumed that a BTS would help pulmonary annulus growth. Therefore, in the present study, we examined the impact of a BTS on a small pulmonary annulus based on a review of the clinical cases in our institute, and we attempted to determine whether a staged repair with a BTS would improve the annulus preservation rate in patients with mild to moderate pulmonary stenosis.

Patients and Methods

Patients

Forty cases were examined. Included were 19 patients with TOF and 21 with double-outlet right ventricle (DORV). In 21 patients, a staged repair with modified BTS was performed (BTS group), and in 19, a primary repair was performed (primary repair group). Patients with pulmonary atresia, major aortopulmonary collateral arteries, or both were excluded. In the BTS group, expanded polytetrafluoroethylene grafts were placed.
from the proximal brachial artery to the proximal right pulmonary artery through a median sternotomy. Grafts of 3.0, 3.5, and 4.0 mm were used in 9, 10, and 2 cases, respectively. Cardiopulmonary bypass was needed in 4 patients because of severe hypoxia during the procedure or additional procedures, such as pulmonary artery plasty.

We evaluated these patients with echocardiography and cardiac catheterization. In echocardiography, the change in pulmonary annular size was compared before and after the BTS. The pulmonary valve function was examined after the ICR in both groups. Pulmonary annular size was normalized by the body surface area and evaluated using a Z score. For pulmonary valve function, PR was evaluated according to the Sellers classification, and pulmonary stenosis (PS) was evaluated with the pressure gradient based on the Doppler flow measurements.

In cardiac catheterization just before ICR, right and left ventricular volumes during the end-diastolic phase (RVEDV and LVEDV, respectively), systolic and diastolic pressure inside the RV and LV, and pulmonary arterial size, were examined. Ventricular volume was normalized with the percent normal (LVEDV %N and RVEDV %N) divided by the normal ventricular size of each body size. The pulmonary arterial size was evaluated with the pulmonary arterial index as developed by Nakata and colleagues [5]. In the BTS group, the pulmonary arterial index before the modified BTS procedure was examined with echocardiography because most of the patients underwent a BTS in the neonatal period without cardiac catheterization. The types of surgical procedures were classified as follows: (1) TAP, (2) pulmonary valve commissurotomy, and (3) patch plasty of the pulmonary artery, RVOT, or both. The TAP was defined as an annulus nonpreserved procedure, whereas commissurotomy and patch plasty were defined as annulus-preserved procedures. In the right ventricular outflow tract (RVOT) reconstruction (RVOTR), we routinely performed direct annular measurements with a Hegar dilator and defined annulus preservation as when the remaining annular size was greater than that corresponding to a Z score of −3.0.

Because the aim of the present study was to reveal the impact of the BTS on pulmonary annular growth for annulus preservation, we were interested in patients with mild to moderate pulmonary stenosis rather than those with severe stenosis. We determined the cutoff value of the annular Z valve as −7.0 and defined severe stenosis as patients having a Z score of less than −7.0 at the initial pulmonary annulus evaluation for each patient. Seventeen patients in the BTS group and 19 patients in the primary repair group were analyzed. We examined the annulus preservation rate in patients without severe pulmonary stenosis.

**Statistical Analysis**

In the statistical analysis, continuous variables between the two groups were evaluated with a heteroscedastic Student’s t test, whereas those inside the groups such as changes of Z score were evaluated with a homoscedastic Student’s t test. Categoric variables and ordinal scales were evaluated with the $\chi^2$ The reoperation-free ratio, reintervention-free ratio, or both of the RVOT was analyzed with the Kaplan-Meier method, and p value was estimated with a log-rank test. Statistical differences for all tests were defined as significant by a two-sided test with a $p$ value less than 0.05.

Regarding the sample size of each group, we set the significance level $\alpha$ as 0.05 and the statistical power 1-$\beta$ as 0.20. The necessary sample size to detect the annular size growth after the BTS became 14.8. Therefore, we estimated the sample sizes of 21 and 19 patients of the BTS and primary repair groups, respectively, as being sufficient.

**Flow Visualization Study in a Right Ventricle With Echocardiography**

To speculate on the mechanism of the pulmonary annular growth, we directly measured the ventricular septal defect (VSD) flow direction in a few cases with the novel blood flow visualization method (VFM) (Vector Flow Mapping, Hitachi-Aloka Medical Co., Ltd., Tokyo, Japan). VFM displays blood flow vectors and streamlines based on the B-mode color Doppler data. The shot axis view at the level of the aortic valve was analyzed with VFM to examine the streamline from the VSD inside the RV. We also examined the blood flow through VSD before and after the BTS in the same patient.

**Results**

**Early Surgical Results**

Regarding the timing of the TOF repair, there were no significant differences in age or body size between the BTS group and the primary repair group. Ages at the time of repair were 7.7 ± 4.2 months and 8.7 ± 11.7 months, and body surface areas were 0.31 ± 0.04 m$^2$ and 0.64 ± 1.25 m$^2$ in the BTS group and the primary repair group, respectively. No patients underwent TOF repair in the first 2 months of life. In the BTS group, BTS was performed on 39.6 ± 34.9 days old. There were no 30-day mortalities or hospital deaths in the BTS group. The major adverse events of the BTS were two cases of excessive pulmonary flow and two cases of cardiac tamponade. For ICR, there were no 30-day in-hospital deaths and no major adverse events in either group.

We evaluated the intraoperative measurement of RV systolic pressure / LV systolic pressure. In the BTS group, the ratio was 0.52 ± 0.09, whereas that in the primary repair group was 0.45 ± 0.14, and there were no statistically significant differences ($p = 0.168$). Intraoperative RV pressure had no correlation with the pulmonary annulus Z score before the TOF repair (correlation coefficient, −0.136).

**Midterm Results**

The mean follow-up period was 69.0 ± 59.9 months. Reoperation-free ratios, reintervention-free ratios, or both of these two groups are illustrated in Figure 1. There
was no significant difference between the two groups ($p = 0.45$). One patient underwent comissurotomy and PA plasty 21 months after the ICR in the BTS group; whereas there were 2 reoperations in the primary repair group, including PA plasty at 7 months and commissurotomy and RVOTR at 52 months after the ICR.

Pulmonary Annular Growth
The pulmonary annulus size in the BTS group significantly increased from $-5.1 \pm 2.5$ to $-2.8 \pm 2.1$ in Z score before and after the BTS ($p = 0.0028$) (Fig 2A). There was a tendency for the pulmonary annulus size in the BTS group to be greater than in the primary repair group ($p = 0.15$) (Z score, $-2.8 \pm 2.1$ vs $-3.7 \pm 1.8$) (Fig 2B).

Details of the annular size growth in 21 BTS group patients are illustrated in Figure 2C. The pulmonary artery index significantly increased in the BTS group from $95.0 \pm 23.1$ mm$^2$/m$^2$ to $236.7 \pm 105.3$ mm$^2$/m$^2$ ($p < 0.000001$).

Before ICR, there was no significant difference between the two groups (BTS group $236.7 \pm 105.3$ mm$^2$/m$^2$ vs primary repair group $358.3 \pm 394.1$ mm$^2$/m$^2$ ($p = 0.27$).

Ventricular Volume
Before the ICR, the right and left ventricular volumes and bilateral pulmonary arterial size were evaluated. The cardiac catheterization parameters compared between the BTS group and the primary repair group are shown in Table 1. The LV size in the BTS group was significantly greater than that in the primary repair group. There was no difference in the RV size. There were no statistical differences between the two groups in pressure measurements or PAL.

RVOT Reconstruction and Pulmonary Valve Functions
Regarding the RVOT reconstruction, the numbers of patients in both groups who underwent patch plasty of the RVOT or the main pulmonary artery or both, valve commissurotomy, and TAP are shown in Table 2. A slightly larger number of patients underwent TAP in the primary repair group (12/19, 63.5%) compared with those in the BTS group (10/21, 47.6%); however, there was no significant difference between these groups.

When patients with severe PS with Z scores less than $-7.0$ were excluded, the pulmonary annulus could be preserved with a greater ratio in the BTS group (11/17, 64.7%) than in the primary repair group (7/19, 36.8%), even though the difference was not statistically significant ($p = 0.088$) (Table 3).

Regarding the evaluation of the pulmonary valve function (Table 4), the grade of PR was not different in
Table 1. Catheter Parameters of the Modified BTS Group and the Primary Repair Group

<table>
<thead>
<tr>
<th>Parameters</th>
<th>BTS Group</th>
<th>Primary Repair Group</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>RVSP (mm Hg)</td>
<td>85.1 ± 12.6</td>
<td>69.4 ± 31.9</td>
<td>0.091</td>
</tr>
<tr>
<td>RVDP (mm Hg)</td>
<td>7.2 ± 2.6</td>
<td>5.1 ± 3.1</td>
<td>0.046a</td>
</tr>
<tr>
<td>LVSP (mm Hg)</td>
<td>87.8 ± 11.5</td>
<td>87.3 ± 10.5</td>
<td>0.90</td>
</tr>
<tr>
<td>LVDP (mm Hg)</td>
<td>7.9 ± 2.5</td>
<td>6.4 ± 3.9</td>
<td>0.24</td>
</tr>
<tr>
<td>Arterial saturation (%)</td>
<td>83.9 ± 8.4</td>
<td>92.6 ± 5.4</td>
<td>0.0013a</td>
</tr>
<tr>
<td>RVEDV (mL)</td>
<td>18.5 ± 4.3</td>
<td>19.2 ± 7.8</td>
<td>0.75</td>
</tr>
<tr>
<td>RVESV (mL)</td>
<td>8.1 ± 2.7</td>
<td>6.7 ± 1.7</td>
<td>0.083</td>
</tr>
<tr>
<td>RVEF</td>
<td>56.7 ± 7.8</td>
<td>62.4 ± 10.7</td>
<td>0.13</td>
</tr>
<tr>
<td>RVEDV %N</td>
<td>127.8 ± 25.6</td>
<td>115.3 ± 25.2</td>
<td>0.17</td>
</tr>
<tr>
<td>LVEDV (mL)</td>
<td>18.5 ± 6.6</td>
<td>19.3 ± 9.9</td>
<td>0.81</td>
</tr>
<tr>
<td>LVEF</td>
<td>7.5 ± 3.9</td>
<td>7.3 ± 4.2</td>
<td>0.88</td>
</tr>
<tr>
<td>LVESV (mL)</td>
<td>60.8 ± 6.8</td>
<td>62.5 ± 6.7</td>
<td>0.46</td>
</tr>
<tr>
<td>LVEDV %N</td>
<td>133.9 ± 45.6</td>
<td>97.5 ± 31.0</td>
<td>0.0084a</td>
</tr>
</tbody>
</table>

*a* indicates statistical significance.

BTS = Blalock-Taussig shunt; LVDP = left ventricular diastolic pressure; LVEDV = left ventricular end-diastolic volume; LVEF = left ventricular ejection fraction; LVESV = left ventricular end-systolic volume; RVSP = right ventricular systolic pressure; RVDP = right ventricular diastolic pressure; RVEDV = right ventricular end-diastolic volume; RVEF = right ventricular ejection fraction; RVESV = right ventricular end-systolic volume.

In these two groups (p = 0.34), nor did pressure gradients through the pulmonary valve have any differences in these two groups (p = 0.30).

### Intraventricular Flow Pattern Change Before and After BTS

Figure 3 illustrates the intraventricular flow pattern change before and after BTS evaluated with echocardiography VFM. Before BTS, the blood flow through the VSD was directed toward the right ventricular wall, whereas after BTS, the left-to-right blood flow through the VSD increased and some part of it was directed toward the pulmonary annulus.

### Comment

After repair of TOF, PR causes RV deterioration, resulting in several long-term adverse events including biventricular dysfunction, heart failure, and serious ventricular arrhythmia [4]. Increased power loss generated by PR is reported to cause inefficient RV function with increased RV volume [6], and progression of PR is reported to be related to postoperative pulmonary valve function after the repair [7]. Nevertheless, the indication of the therapeutic intervention of PR after repair of TOF remains relatively unclear to date [6, 8, 9]. Therefore, prevention of PR in the RVOTR would be essential to improve the long-term outcome of patients with TOF. Although recently the timing of the ICR and the repair age are not believed to affect outcome, including the reintervention rate [1, 10], preservation of an annulus of suitable size has been thought to be important in the RVOTR for the prevention of PR in the long term after the repair [11–15]. Recently, a staged repair with a modified BTS has not been recommended in most cases [14]. Several recent investigators insisted that early-stage primary repair is safe and effective, with low mortality [1, 2, 16]. According to their results, early primary repair had no significant differences in reoperation-free ratio, reintervention-free ratio, or both compared with staged repair [2] or with repair after the neonatal period [14]. Although the overall reoperation-free ratio was also not different in the present study, we did find that BTS had advantages in annulus growth and annulus preservation. Some reports indicated that although it is seemingly simple, BTS is associated with significant morbidity and mortality [3], and these results would be a driving force to avoid staged repair. However, according to recent annual reports in Japan [16], the 30-day mortality and hospital death rates of the systemic-to-pulmonary shunt were 2.0% and 2.9%, respectively, and even in neonates, the 30-day mortality and hospital death rates were 1.7% and 2.3%, respectively. These results even included cases of univentricular heart. Therefore, BTS is a feasible palliation with an acceptable rate of mortality in Japan.

Table 2. RVOTR Procedure in the Two Groups

<table>
<thead>
<tr>
<th>Procedure</th>
<th>BTS Group</th>
<th>Primary Repair Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patch plasty of RVOT and/or main pulmonary artery</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Valve commissurotomy</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>Transannular monocuspid patch</td>
<td>10</td>
<td>12</td>
</tr>
</tbody>
</table>

BTS = Blalock-Taussig shunt; RVOT = right ventricular outflow tract; RVOTR = right ventricular outflow tract reconstruction.

Table 3. Pulmonary Annulus Preserved and Not Preserved in the Two Groups in the Cases of Mild to Moderate PS (Z Score Above –7.0)

<table>
<thead>
<tr>
<th>Annulus</th>
<th>BTS Group</th>
<th>Primary Repair Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annulus preserved</td>
<td>11</td>
<td>7</td>
</tr>
<tr>
<td>Annulus not preserved</td>
<td>6</td>
<td>12</td>
</tr>
</tbody>
</table>

BTS = Blalock-Taussig shunt; PS = pulmonary stenosis.

Table 4. Pulmonary Valve Function After Intracardiac Repair

<table>
<thead>
<tr>
<th>PR grade (No. of cases)</th>
<th>BTS Group</th>
<th>Primary Repair Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trivial</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Mild</td>
<td>8</td>
<td>3</td>
</tr>
<tr>
<td>Moderate</td>
<td>7</td>
<td>9</td>
</tr>
<tr>
<td>Severe</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Unknown (not evaluated)</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

BTS = Blalock-Taussig shunt; PR = pulmonary regurgitation.
Little is known about the impact of the BTS on the pulmonary annulus size. We observed a significant increase of pulmonary annulus size after the modified BTS and a good annulus preservation rate in the complete repair. Moreover, the function of the preserved annulus is optimal and is free from the severe pressure load to the RV (Table 4). Because the excessive enlarged pulmonary annulus with a low pressure gradient does not necessarily improve the outcome of the RV function [17, 18], we can therefore expect annulus preservation even in patients with moderate to severe PS, by using a BTS.

Our results showed that pulmonary annulus size increased with the modified BTS, although the mechanism is not clear. To explain this phenomenon, we speculate that the increased LV volume by BTS may increase pulmonary blood flow through the pulmonary valve from the VSD because LVEDV measured by cardiac catheterization significantly increased in the modified BTS group. Another possible explanation is that increased pulmonary pressure caused dilatation of the annulus even though the flow through the valve did not increase. Because the anastomosis site of the modified BTS in our institute is somewhat proximal compared with one placed through a thoracotomy, the tension of the pulmonary vessel wall was easy to increase after the BTS. The catheterization data suggested that patients with decreased arterial saturation had a high right-to-left shunt flow even after the modified BTS. Because the lumen sizes of the peripheral pulmonary arteries were small compared with those of the main pulmonary arteries, it would be difficult for the annulus to enlarge without an increase of the transvalvular forward flow. Lower arterial oxygen saturation does not mean low left-to-right shunt flow, because in TOF, the blood flow through VSD becomes left to right at the early systolic phase and right to left during the late systolic or the diastolic phase. Referring to the earlier discussion, we performed VFM flow analysis. The RVOT blood flow evaluation using a VFM is feasible and provides much more information than routine echocardiography [18]. Even though the VFM demonstrates only two-dimensional flow in a measurement plane [19–21], whereas in the present study we evaluated only a single patient, the blood flow through VSD from the dilated LV generated a straight flow toward the pulmonary valve during the systolic phase.

The present study had several limitations. Because it was a retrospective study, not prospective or randomized, a clear indication for a modified BTS based on the pulmonary annulus size (Z score) or the determination of the optimal interstage period for sufficient annular growth warrants further study. In the present series, the evaluation period of the pulmonary valvular function was not sufficiently long, especially in the annulus-preserved cases; therefore, further long-term follow-up evaluations are needed.

In conclusion, the BTS increased pulmonary annular size and left ventricular volume. A modified BTS encourages growth of the pulmonary valve annulus such that approximately two thirds of patients previously thought to be candidates for only a transannular patch can have a pulmonary valve-sparing operation.
REFERENCES


DISCUSSION

DR RALPH S. MOSCA (New York, NY): First of all you, showed us some beautiful pictures of the flow characteristics across the valve. It seems to me that regardless of whether your hypothesis is correct or not (ie, whether the annulus grows because of increased flow), the real endpoint should be how many more times can you preserve the pulmonary valve in the shunted group, assuming, as you claim, that the annulus grows? If I looked at the slides correctly, that was nonsignificant. That p value was 0.08.

DR ITATANI: Do you mean interstage or follow-up interval of these patients?

DR MOSCA: I meant how often you could preserve the pulmonary valve after.

DR ITATANI: Okay. Every 1 or 2 months, the patient goes to the outpatient clinic.

DR MOSCA: Right.

DR ITATANI: And then, after TOF repair, we usually evaluate pulmonary valve function every 6 months.

DR MOSCA: Right. My question is...

DR ITATANI: Interstage?

DR MOSCA: No. Is it true that you were able to spare the pulmonary valve more often having done the shunt?

DR ITATANI: Yes, but if we restrict the patients with mild to moderate stenosis. As I have shown in the slides, most patients with severe pulmonary stenosis with Z score below ~7.0 received BTS, but they underwent transannular monocusp patch because of the small valve size even though the annulus grew significantly.

DR MOSCA: Okay. I didn’t see that. I thought it was nonsignificant. If so, why were there a significant number of patients in each group with transannular patches and monocusp reconstructions?

DR ITATANI: Do you mean the indication of BTS considering the annulus preservation or monocusp patch in TOF repair?

DR MOSCA: Yes.
DR ITATANI: Pulmonary valve preservation in severe stenosis cases is difficult anyway, and we usually use a monocusp patch in all cases if the annulus cannot be preserved. In mild to moderate stenosis cases, we think the annulus preservation rate can improve if they receive the BT shunt and the pulmonary annulus grows.

DR CARL L. BACKER (Chicago, IL): This was a very interesting presentation. We presented our results with attempting to preserve the pulmonary valve in patients with tetralogy of Fallot at the Society of Thoracic Surgeons annual meeting in 2005. We only shunted patients that we did not think were candidates for infant repair. We had 25 patients who had a shunt, and in that group, 60% went on to have a pulmonary valve–sparing operation. We have now gone back and looked at the Z scores of the pulmonary valve annulus and the branch pulmonary arteries. We could not show that the Z score of the annulus increased in size, but the Z score of the branch pulmonary arteries improved, which combined with absolute pulmonary valve annulus growth contributed to our being able to provide 60% of this group with a pulmonary valve–sparing operation. The question I have for you is this: could you go back and look at the increase in size of the right and left branch pulmonary arteries and that relationship to whether or not you could affect a valve-sparing repair?

DR ITATANI: In many cases in the primary repair group, we do not always evaluate from the neonatal period. And in most cases, the BT shunt in our series was placed at 1 or 2 months old. We evaluated pulmonary arterial size in the BTS group with echocardiography in the neonatal period and with catheter examination before the TOF repair.

DR MOSCA: Did the pulmonary arteries enlarge significantly in the shunt group?

DR ITATANI: Yes. Pulmonary arterial size increased drastically between before and after the BT shunt. In our study, the pulmonary annulus itself also increased in size, significantly but not so drastically compared with pulmonary arterial size. Regarding the pulmonary annulus size evaluation period in our series, there were no significant differences between the staged and the primary repair group.

DR CHRISTOPHER A. CALDARONE (Toronto, Ontario, Canada): That's a really interesting study, and we're not very good at creating and manipulating growth factors in the heart, but you seem to show some influence of growth based on increasing flow across the pulmonary valve. I wonder if you could refine your analysis a bit and look at the influence of the valve leaflet morphology in terms of the ability of the annulus to grow or not grow. As you know, sometimes we see a lot of valvular stenosis in addition to a small annulus, and sometimes we see valve leaflets that aren't quite so stenotic. It's just the annulus is small. So how does the influence of leaflet morphology influence the growth potential of the pulmonary annulus?

DR ITATANI: In our series, there were several cases of bicuspid pulmonary valve. We examined the morphology of the valve regarding the bicuspid or tricuspid pulmonary valve, but there were no statistical differences in valve morphology in our series.

DR CALDARONE: Interesting. Thank you.