Hemodynamic changes after pulmonary balloon valvuloplasty in tetralogy of Fallot patients

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Objective : To study the effect of pulmonary balloon valvuloplasty in tetralogy of Fallot patients.

Setting : Division of Pediatric Cardiology, Department of Pediatrics, Faculty of Medicine, Chulalongkorn University.

Design : Prospective study.

Subject : Thirteen tetralogy of Fallot patients who attended the pediatric cardiology clinic, Department of Pediatrics, Faculty of Medicine, Chulalongkorn University.

Patients : Thirteen tetralogy of Fallot patients with an age range of 44.62 ± 16.02 months were enrolled in the study. They were moderately to severely cyanotic with histories of progressive hypoxic spells.

Method : Data on hypoxic spells, hemoglobin, oxygen saturations and echocardiographic measurements of pulmonary annulus, pulmonary arteries, aorta diameters and ventricular volumes were obtained immediately after, and one and two months after the pulmonary balloon valvuloplasty.

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Results: There were significant increases in systemic oxygenations, diameters of pulmonary valve annulus, pulmonary arteries, left ventricular volume, and right ventricular volume \((p<0.05)\) after balloon valvuloplasty. These persisted during the 2 month period of follow-up. Frequencies of hypoxic spells decreased, but there were no significant differences in hemoglobin levels and aortic diameters. Even though the number of cases of our experience.

Conclusion: Even though the number of cases of our experience. Balloon pulmonary valvuloplasty showed beneficial effects in improved hemodynamics especially increases in ventricular volume and pulmonary arteries size in the tetralogy of Fallot patients. It might be a palliative treatment comparable to systemic in pulmonary shunt operations.

Key words: TOF, Balloon valvuloplasty, Palliative treatment.

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วัสดุประสงค์ : เพื่อศึกษาผลของโรคโป่งหลายหัวใจโพเลนิก ในผู้ป่วย tetralogy of Fallot.

สถานที่ทำการศึกษา : คลินิกโรคหัวใจเด็ก หน่วยการรักษาสาขาโรคหัวใจ ภาควิชา หน่วยการรักษาสาขาโรคหัวใจ ภาควิชากายวิทยา.

รูปแบบการจัดการศึกษา : การศึกษาแบบเปรียบเทียบ

ผู้ป่วยที่มีการศึกษา : การศึกษานี้ได้ติดตามผู้ป่วย จำนวน 13 ราย อายุระหว่าง 44.62 ± 16.02 เดือน โดยผู้ป่วยที่มีการศึกษา จะมีภาวะเชื้อ ประสานและ/or ภาวะhypoxic spells เพิ่มขึ้น.

วิธีการศึกษา : เทียบชั้นหยุดภายนอกภาวะ hypoxic spells ความมืดต่ำอักชินในเลือด ไขมันสูง ทำให้ตรวจวัดค่าทางเบ็ด ของเลือด เด็ก มี 1 เดือน ทุกเดือน ทั้งนี้ 2 เดือน.

ผลการศึกษา : พบว่ามีการเพิ่มขึ้นอย่างมีนัยสัมพันธ์ทางสถิติ (p<0.05) ของค่าความมืดต่ำเกิดขึ้น ในเด็ก, ขนาดของเลือดเป็นพื้นฐาน และปรับปรุงของหัวใจโรคหัวใจเด็กทั้งสองซึ่งจะส่งผลต่อการเต้น ทำให้เวลาที่น่าจะนานขึ้นของภาวะ hypoxic spells ถึงตลอดกิจวัตร และไม่พบความเปลี่ยนแปลงใน ความชื้นข้น ของเลือดแดง และขนาดของหลอดเลือด เลือดโภชนาการ.

วิจารณ์และสรุปผล : หลังจากมีงานผู้ป่วยที่มีการศึกษา, ดังนั้นการใช้ชุดโปรแกรมมีประโยชน์ในการช่วยให้ภาวะการทำงาน เรียบ ได้ผลในทางการรักษาพยาบาล ช่วยเพิ่มขนาดของหลอดเลือดแดง ของเลือด และปรับปรุง ของภาวะเด็กซึ่งจะเป็นทางเลือกที่ดีของ การรักษาผู้ป่วย ทั้งนี้จะทำให้การผ่านค้นแก้ไขความคิด ปกติที่เหมาะสมต่อไป.
Pulmonary balloon valvuloplasty had been performed for cyanotic heart disease with right ventricular outflow tract obstruction for palliative treatment, especially in patients with tetralogy of Fallot (TOF), but it remains a controversial procedure in TOF patients. Because of unpredictable improvements in clinical manifestations and growth of pulmonary arteries as compared to systemic in pulmonary shunt procedures. The purpose of this report is to evaluate the effects of balloon valvuloplasty on severity of cyanosis, the pulmonary artery sizes, ventricular volumes, descending aorta sizes and complications of the procedure. All patients were followed up monthly for two months. (Table 1)

Protocol for dilatation:

After the diagnosis was confirmed by right sided heart catheterization and right ventricular angiogram. The pulmonary balloon dilatation was performed using a single balloon technique with a balloon diameter/diameter of pulmonic valve anulus ratio of $1.35 \pm 0.31$ (x ± SD). The diameter of the pulmonic valve anulus was measured from lateral view of the right ventricular angiogram in end systolic period. The balloon dilatation technique was performed by advancing an endhole catheter across the right ventricular outflow tract to the pulmonary artery and a 0.032 inch Teflon-coated guidewire was threaded through the catheter. The introducing catheter was then exchanged for a Manfields balloon dilatation catheter. When the balloon was passed through the stenotic site, it would be inflated (with contrast media diluted 1:2 with normal saline) $2.77 \pm 0.93$ times (mode 3 times) until no waste was seen in the balloon. The balloon was then withdrawn. A right ventricular angiogram was repeated after the

Table 1. Follow-up protocol.

<table>
<thead>
<tr>
<th>Data</th>
<th>Spell</th>
<th>Medication</th>
<th>O2sat.</th>
<th>PA</th>
<th>LPA</th>
<th>RPA</th>
<th>AO</th>
<th>LVEDV</th>
<th>RVEDV</th>
<th>Hb</th>
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<tr>
<td>Pre-balloon</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Post-balloon</td>
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<td></td>
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<td></td>
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<tr>
<td>Post-balloon</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>every mo.</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

O2 sat.:cutaneous oxygen saturation; PA: pulmonic valve anulus(end systole); RPA, PA: pulmonary artery size (bifurcation in end systole) AO: des.AO at diapharm level (end systole); LVEDV:LV end diastolic volume and RVEDV:RV end diastolic volume $^{0.13}$ by modified Simson rule, *Hb:hemoglobin (2mo.after balloon valvuloplasty)
procedure. After the dilatation procedure data was collected. (Figure 1.)

relation between ventricular volume and balloon size, and oxygen saturations were assessed by linear regression A

Figure 1. A

Figure 1. B

Figure 1. C

Figure 1. Pulmonary balloon valvuloplasty technique. A. Selective right ventricular angiogram in lateral view showing thickening annulus and infundibular stenosis. B. Lateral view of a partially inflated valvuloplasty. A slight "waist" can be noted in the mid portion of the balloon. C. Lateral view showing increase of pulmonary annulus, left and right pulmonary arteries after balloon dilatation, increase infundibular stenosis.

Statistical Analysis:

Data analysis was conducted with the use of the SPSSPC program for Windows version 6.0. Some variables were transformed into ratios. The changes after balloon dilatation were tested with a paired t test. The value of p < 0.05 was considered significant. The result was presented as mean ± SD with 95% CI for difference means when required.
Results

Patients:

Thirteen children, aged 44.62 ± 16.02 months (median 47 months), 58.3% male were enrolled in this protocol. Their weights ranged from 9 to 18.6 (mean 13.14 ± 3.04) kg. The mean hemoglobin (Hb) level was 19.88 ± 3.43 g%. Three of the 13 patients mainly had infundibular pulmonic stenosis. One patient had obstruction of a previously done right modified Blalock Taussig shunt. The clinical data, severity of cyanosis, and medication treatment are summarized.

(Table 2)

supportive treatment. The systemic oxygen saturations increased from a mean value of 74.85 ± 7.15% to 85.92 ± 4.46% (95% CI, 14.31 to -7.85, p < 0.001) after balloon dilatation. The oxygen saturations remained stable with mean value of 84.31 ± 5.89% (95% CI, -13.21 to -5.6, p < 0.001) 2 months after the procedure (Figure 2). All patients were continued on propanolol 2.05 ± 0.38 mg/kg/d. There was a decrease in the frequencies of the cyanotic spells from more than 15 times/mo. (76.9%) to less than 5 times/mo (92.3%) with no significant change in Hb concentrations. (p > 0.05).

Table 2. Clinical summary

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Age (mo)</th>
<th>Wt (Kg.)</th>
<th>Hb (%)</th>
<th>spell (time/month)</th>
<th>propanolol (mg/kg/d)</th>
<th>O2 sat. (%)</th>
<th>level of RVOT obstruction</th>
<th>balloon/PA size ratio</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>54</td>
<td>12.6</td>
<td>22.3</td>
<td>&lt;5</td>
<td>2.33</td>
<td>75</td>
<td>short segment</td>
<td>moderate</td>
</tr>
<tr>
<td>2</td>
<td>60</td>
<td>13.3</td>
<td>17.3</td>
<td>10-20</td>
<td>1.13</td>
<td>77</td>
<td>segment</td>
<td>mild</td>
</tr>
<tr>
<td>3</td>
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<td>13.8</td>
<td>26.6</td>
<td>&gt;30</td>
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<td>77</td>
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<tr>
<td>4</td>
<td>48</td>
<td>15</td>
<td>20.7</td>
<td>&gt;30</td>
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<td>69</td>
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<tr>
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<td>47</td>
<td>12.5</td>
<td>18</td>
<td>5-10</td>
<td>2.5</td>
<td>69</td>
<td>tubular segment</td>
<td>severe</td>
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<td>18.6</td>
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<td>&lt;5</td>
<td>1.61</td>
<td>69</td>
<td>tubular segment</td>
<td>severe</td>
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<tr>
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<td>15.1</td>
<td>&gt;30</td>
<td>2.04</td>
<td>75</td>
<td>tubular segment</td>
<td>moderate</td>
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<td>8</td>
<td>36</td>
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<td>18.2</td>
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<td>77</td>
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<td>9</td>
<td>24</td>
<td>9</td>
<td>16.1</td>
<td>&gt;30</td>
<td>2.5</td>
<td>83</td>
<td>segment</td>
<td>mild</td>
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<tr>
<td>10</td>
<td>68</td>
<td>17.7</td>
<td>16.2</td>
<td>&gt;30</td>
<td>2.26</td>
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<tr>
<td>11</td>
<td>25</td>
<td>9.3</td>
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<td>&gt;30</td>
<td>2.15</td>
<td>60</td>
<td>tubular segment</td>
<td>moderate</td>
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<tr>
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<td>1.89</td>
<td>75</td>
<td>tubular segment</td>
<td>no</td>
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<tr>
<td>13</td>
<td>30</td>
<td>11.2</td>
<td>14.6</td>
<td>10-20</td>
<td>1.79</td>
<td>78</td>
<td>segment</td>
<td>moderate</td>
</tr>
</tbody>
</table>

Clinical manifestations:

After balloon dilatation, two children exhibited hypoxic spells which were corrected by

Complications of valvuloplasty:

No patient demonstrated any serious local complication or severe ventricular arrhythmia. Two
Changes in left and right ventricular volume:

After balloon pulmonary valvuloplasty the left and right ventricular volumes were increased from $10.02 \pm 2.87 \text{ ml}$ to $12.83 \pm 4.72 \text{ ml}$ (95% CI: 4.8 to -0.84, $p < 0.009$) and from $12.29 \pm 2.41 \text{ ml}$ to $14.63 \pm 4.76 \text{ ml}$ (95% CI: -4.66 to -0.02, $p < 0.05$) respectively (Figure 3, 4) and they are not statistically correlated with

Figure 2. Immediate and short term follow-up showing (mean ± SD) significant increase in systemic oxygen saturation after balloon valvuloplasty. ($p < 0.001$)

children (15.38%) had hypoxic spells during the first day after balloon dilatation. Minimal tricuspid valve regurgitation was detected by echocardiogram in two cases after the procedure.

Growth of pulmonary annulus valve and pulmonary arteries:

Balloon pulmonary valvuloplasty increased pulmonary annulus sizes from $1.05 \pm 0.18 \text{ cm.}$ to $1.28 \pm 0.27 \text{ cm.}$ (95% CI: -0.31 to -0.15, $p < 0.001$). The sizes of the left pulmonary artery and the right pulmonary artery increased from $0.67 \pm 0.15 \text{ cm.}$ to $0.78 \pm 0.145 \text{ cm.}$ (95% CI: -0.2 to -0.02) and from $0.64 \pm 0.16 \text{ cm.}$ to $0.75 \pm 0.14 \text{ cm.}$ (95% CI: -0.19 to -0.03) respectively ($p < 0.02$). However, these changes were not seen in the aortic diameters which remained from $0.92 \pm 0.15 \text{ cm.}$ to $0.94 \pm 0.11 \text{ cm.}$ ($p > 0.05$) and the pulmonary pressure gradient across the pulmonic valve ($p > 0.05$).

Figure 3. Immediate and short term follow-up showing (mean ± SD) significant increase in left ventricular end diastolic volume after balloon valvuloplasty. ($p < 0.009$)

Figure 4. Immediate and short term follow-up showing (mean ± SD) significant increase in right ventricular end diastolic volume after balloon valvuloplasty. ($p < 0.05$)
balloon size/pulmonary annulus ratios or the increase in systemic oxygen saturations.

**Discussion**

Pulmonary balloon valvuloplasty has been suggested in TOF as a palliative treatment but it is questionable in regard to risks and benefits. As previously reported the procedure proved to improve systemic oxygenations, pulmonic valve annulus growth and hematocrits. This study found significant increases in systemic oxygenations, pulmonary artery growth, and improvement in cyanotic spells but not in hemoglobin as found by Boucek MM. et al. Lock JE. et al. reported encouraging initial results with clear-cut clinical or hemodynamic deterioration in 2 months periods. In our report, follow-up periods of 2 months was appropriate for short term evaluation of pulmonary balloon valvuloplasty but long term effects need further evaluation as Battistessa SA. et al. reported no correlation of pulmonary annulus growth and balloon valvuloplasty in surgical findings. Ventricular volume has been well demonstrated to be comparable in echocardiograms and ventricular angiograms. We found that after balloon valvuloplasty, both the right and left ventricular volumes increased, thus confirming improvement of pulmonary blood flow, as in arteropulmonary shunt operations in TOF. Balloon valvuloplasty promotes pulmonary artery growth leading to improved ventricular volume thus decrease the chance for needing a transanular patch that increases risks of morbidity and mortality after surgery in long term follow-up.

Complications of balloon valvuloplasty in this study were minimal. Many studies found severe complications such as severe cyanotic spells, venous thrombosis, cardiac tamponade, severe tricuspid valve trauma and sepsis. Complications depend on the patients status, technique and especially balloon size. It has been demonstrated in normal newborn lambs that trauma is minor if the balloon is 30% larger than the pulmonary annulus. Some investigators suggested smaller balloon size (equal to the pulmonary annulus) to prevent increases in hypoxic spells. This study showed improvement of hypoxic spells and better physical activity.

**Conclusions**

Even though the number of cases of our experience is limited, pulmonary balloon valvuloplasty showed beneficial effects in significant improvement of oxygenation, left and right ventricular end diastolic volumes pulmonary annulus, pulmonary arteries and quality of life in tetralogy of Fallot patients that might be a palliative treatment as well as systemic to pulmonary shunts in moderate to severe cyanosis cases before total correction.

**References**


15. Hirachi S, Jarmakani JM, DiSessa TG, Nakanishi T, Isabel Jones JB, Friedman WF. Simplified


20. Ring JC, Kulik TJ, Burke BA, Lock JE. Morphologic changes induced by dilation of the pulmonary valve annulus with overlarge balloons in normal newborn lambs. Am J Cardiol 1989; 55: 210-14