

## Review

## Mustard baffle obstruction and leak – How successful are percutaneous interventions in adults?



Elisa A. Bradley\*, Amanda Cai, Sharon L. Cheatham, Joanne Chisolm, Tracey Sisk, Curt J. Daniels, John P. Cheatham

Nationwide Children's Hospital Department of Pediatric Medicine & The Ohio State University Department of Internal Medicine, Columbus, OH, USA

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## ABSTRACT

Atrial switch operations for D-Transposition of the great arteries (D-TGA) were performed until the late 20th century. These patients have substantial rates of re-operation, particularly for baffle related complications. This study sought to analyze the efficacy of percutaneous transcatheter intervention (PTI) for baffle leak and/or stenosis in adult atrial switch patients. Adult patients with a prior atrial switch operation who underwent heart catheterization (2002–2014) at a tertiary adult congenital heart disease referral center were retrospectively analyzed. In 58 adults ( $30 \pm 8$  years, 75% men, 14% New York Heart Association (NYHA) functional class  $\geq 2$ ) who underwent 79 catheterizations, PTI was attempted in 50 (baffle leak ( $n = 10$ , 20%), stenosis ( $n = 27$ , 54%), or both ( $n = 13$ , 26%)). PTI was successful in 45 and 5 were referred for surgery due to complex anatomy. A total of 40 bare metal stents, 18 covered stents, 16 occlusion devices, 2 angioplasties, and 1 endovascular graft were deployed. In isolated stenosis, there was improvement in NYHA functional class after PTI (8 vs. 0 patients were NYHA FC  $> 2$ ,  $p = 0.004$ ), which was matched by improvement in maximal oxygen consumption on exercise testing ( $\text{VO}_2$ ) ( $25.1 \pm 5.4$  mL/kg/min vs.  $27.9 \pm 9$  mL/kg/min,  $p = 0.03$ ). There were no procedure-related deaths or emergent surgeries in this cohort.

This single-center cohort is the largest reported series of adult atrial switch operation patients who have undergone PTI for baffle stenosis and/or leak. We demonstrate that PTI with an expert multi-disciplinary team is a safe and effective alternative to surgery in adult patients with an atrial switch operation.

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### 1. Introduction

Cyanotic congenital heart patients have benefitted from cardiothoracic surgical innovation that occurred in the mid to late 20th century, without which, these conditions would not be survivable. Among this group, patients with dextro-transposition of the great arteries (D-TGA) are unique. Atrial switch operations, such as the Mustard [1] or Senning [2] procedures, became available in 1963 and 1957 respectively, and have subsequently been supplanted by the arterial switch (Jatene) operation [3]. Late re-operation is often required after Mustard/Senning repairs, and most frequently this is for baffle-related complications such as stenosis and/or leak. In an effort to avoid the morbidity and mortality associated with re-operation, percutaneous transcatheter interventions (PTI) aimed at treating baffle stenosis and leaks are often sought. To date, there is limited data describing the efficacy and outcomes with currently available percutaneous treatment options. We sought to analyze the efficacy of PTI in adult atrial switch patients undergoing PTI for baffle leak and/or stenosis at a large U.S.

tertiary referral adult congenital heart disease center with expertise in both routine and high risk percutaneous interventions.

### 2. Methods

Adult patients with a prior atrial switch operation who underwent heart catheterization (2002–2014) at our center were retrospectively analyzed. We collected basic demographics, exercise test results, echocardiograms and advanced cardiac imaging (computed tomography or magnetic resonance imaging) when available, as well as the results of cardiac catheterization/PTI. More specifically, when collecting invasive hemodynamic results, we included baseline and post-PTI oxygen saturation, baffle diameter, and baffle gradient measurements. Information specific to the intervention performed, devices used, presence of post-angiographic leak, and major adverse events (death, need for emergent operation, bleeding requiring transfusion, need for urgent/emergent repeat percutaneous intervention) were also collected. In patients who received an electrophysiology study (EPS) or device (pacemaker or defibrillator), data specific to this procedure was reviewed: inducible arrhythmia, ablation, device placed, and lead extraction if required.

Given the retrospective nature of this study comprised of data from the previous 12 years, consent waiver was obtained, and the local

\* Corresponding author at: 700 Children's Drive, NCH Heart Center, Columbus OH 43205. Tel.: +614 722 562; fax: 614-722-5638.

E-mail address: [elisa.bradley@nationwidechildrens.org](mailto:elisa.bradley@nationwidechildrens.org) (E.A. Bradley).

institutional review board approved this study. Descriptive data analyzing baseline characteristics of the total population, those with isolated baffle stenosis, isolated baffle leak, and combination leak/stenosis was generated. Descriptive characteristics of devices placed, with respect to the underlying baffle abnormality (leak or stenosis), were also generated. When evaluating for differences between pre-PTI and post-PTI parameters, dependent T-tests were used to compare continuous variables and Fisher's exact tests were used to analyze categorical and ordinal variables. All significance tests were evaluated with type I error rate of 5% ( $\alpha = 0.05$ ). All data are presented as means with standard deviation. The data were analyzed using SPSS (IBM Corp. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY).

### 3. Results

There were 58 adults ( $30 \pm 8$  years, 75% men) who underwent 79 catheterizations at our institution over 12 years. In those who underwent catheterization, PTI was attempted in 50 cases, 45 of which received successful PTI. Of these, there were 2 cases where combination PTI/surgery was done. Ultimately there were 5 cases where PTI was not performed, and the patient was referred for surgery due to complex anatomy. (Fig. 1) At baseline, a minority of patients had advanced New

#### Database query patients with prior atrial switch operation and cardiac catheterization (n=79 , in 58 patients)

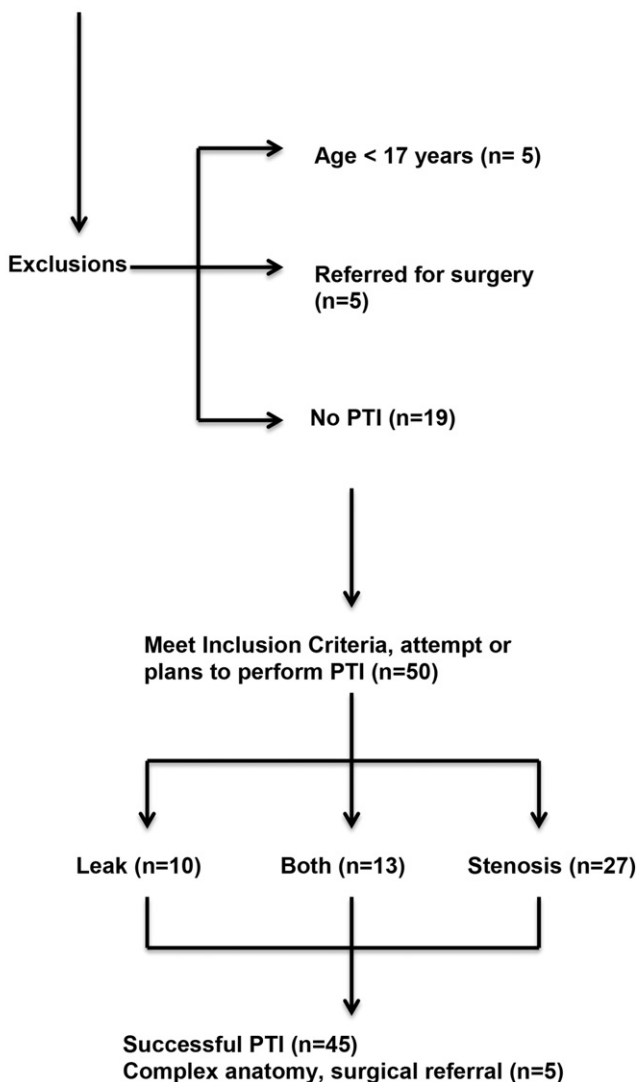


Fig. 1. Search methods.

York Heart Association (NYHA) functional class defined as NYHAFC  $\geq 2$  ( $n = 11$ ) or significant systemic (right) ventricular dysfunction ( $n = 23$ ). In patients with an isolated baffle leak, the nadir oxygen saturation on  $VO_2$  testing was low ( $87 \pm 6\%$ ). The remainder of baseline patient characteristics is outlined in Table 1.

Patients undergoing PTI had baffle leak ( $n = 10$ , 20%), stenosis ( $n = 27$ , 54%), or both ( $n = 13$ , 26%). A total of 40 bare metal stents, 18 covered stents, 16 occlusion devices, 2 angioplasties, and 1 endovascular graft were deployed. Covered stents were placed in 11 patients, and of those 8 patients received the device under compassionate use criteria and 3 under emergency use criteria. Stenoses were found in the superior limb of the systemic venous baffle (SVC) ( $n = 39$ ), the inferior limb (IVC) ( $n = 13$ ), and in the pulmonary venous baffle ( $n = 1$ ). In this cohort average fluoroscopy time was  $53 \pm 33$  min and average procedure length was  $178 \pm 84$  min.

#### 3.1. Isolated baffle stenosis

In patients with isolated baffle stenosis ( $n = 27$ ), there was significant improvement in NYHA functional class after PTI, which was matched by improvement in  $VO_2$ . In this group, the average pre-PTI mean gradient was  $5 \pm 11$  mmHg and post-PTI was  $0.6 \pm 1.6$  mmHg. Stenosis diameter went from  $6 \pm 5$  mm to  $18 \pm 7$  mm post-PTI (Fig. 2A). Of the 11 patients with a pre-existing device (pacemaker or implantable cardiac defibrillator – ICD), a total of 4 patients with isolated stenosis required lead extraction and re-implantation at the time of PTI. Three additional patients received a device at the time of PTI. Individual characteristics of each intervention are outlined in Table 2. Representative angiography from an example case which required lead extraction and intervention to the SVC and IVC limbs of the systemic venous baffle is demonstrated in Fig. 3.

#### 3.2. Isolated baffle leak

In the 10 patients with isolated baffle leak, the resting  $O_2$  was  $93 \pm 4\%$  and post-PTI was  $96 \pm 2\%$ . Leaks were documented in the SVC ( $n = 16$ ), IVC ( $n = 11$ ), and pulmonary venous baffle ( $n = 2$ ). A combination of covered stents, septal and patent foramen ovale (PFO) occluders, and endovascular stents were used to treat isolated leaks. Although the nadir  $O_2$  level on  $VO_2$  improved post-PTI, it was not significantly different than pre-PTI levels (Fig. 2B). In this group, 2 patients had a prior pacemaker or ICD, one of which required lead extraction and re-implantation at the time of PTI. Of the remainder, 2 patients had a new device placed at the time of catheterization. (Table 3).

#### 3.3. Combined baffle leak and stenosis

Several patients had both baffle leak and stenosis ( $n = 13$ ) and were treated with a combination of bare metal stents, covered stents, and septal/PFO occluders. There was no significant difference in pre and post-PTI oxygen saturation ( $94 \pm 5\%$  vs.  $97 \pm 2\%$ ,  $p = 0.07$ ) and post-PTI gradients and diameters were similar to the isolated stenosis group. In these patients, 7 had a pre-existing pacemaker or ICD, 2 of which required lead extraction and replacement at the time of PTI. In addition, 2 new devices were placed at the time of PTI. Individual characteristics and results of PTI are reviewed in Table 4. Angiography from a case requiring covered stenting to treat both baffle leak and stenosis along with pacemaker removal and reimplantation by a combined EP-interventional catheterization team is illustrated in Fig. 4.

In the entire group (stenosis, leak, combination stenosis/leak), there were no major adverse events: death, need for emergent surgery/intervention, or blood loss requiring transfusion. On average, patients were observed overnight, and discharged from the hospital within 24 h after PTI.

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