Background—Angioplasty and stent placement in right ventricle-to-pulmonary artery (RV-PA) conduits have been shown to prolong the functional lifespan of a conduit. Safety and efficacy of angioplasty of obstructed RV-PA homografts using ultra-noncompliant (UNC) or ultrahigh-pressure balloons are unknown.

Methods and Results—From 2004 to 2012, 70 patients underwent 76 procedures for angioplasty of RV-PA homografts with UNC Atlas balloons. The UNC group was compared with a partially contemporaneous control cohort of 81 patients who underwent 84 angioplasty procedures with conventional balloons. Acute hemodynamic changes after angioplasty of homografts with UNC balloons included significantly reduced RV:Ao pressure ratio (P=0.02) and right ventricular outflow tract gradients (P≤0.001). Balloon waist resolution was more frequently achieved with UNC balloons (P=0.04), and balloon rupture occurred less often (P<0.001). Conduit tears of any severity occurred in 22% of patients overall and were more common in the UNC group (P=0.001). Patients with any conduit tear had significantly greater reduction in their RV:Ao pressure ratio (P<0.001) and right ventricular outflow tract gradient (P=0.004) than those with no tear. There were 4 unconfined tears, all in the UNC group, with no acute decompensations or deaths and only 1 patient who required surgical management.

Conclusions—RV-PA conduit tears are common in patients undergoing angioplasty, but clinically important tears, which only occurred during UNC angioplasty in this series, were uncommon. UNC balloons can be used to good effect with significant reduction in right ventricular outflow tract gradient and the RV:Ao ratio when compared with conventional balloons.

Key Words: angioplasty • conduit • ventricular outflow obstruction
WHAT IS KNOWN

- Angioplasty and stent placement in right ventricle to pulmonary artery conduits has been shown to prolong the functional lifespan of a conduit.

WHAT THE STUDY ADDS

- Conduit tears are significantly more common after dilation with ultra-noncompliant balloons compared with conventional balloons.
- Conduits with tears after angioplasty have a significantly greater reduction in right ventricle to pulmonary artery gradient and RV:Ao ratio than those without tears.
- Clinically important tears were infrequent, and conduit rupture with acute decompensation was not observed in this study.
- No therapeutic or confined tear progressed to an unconfined tear.

PREVIOUS STUDIES

- Patients who underwent TPV placement were also excluded because it was thought that intention to place or placement of the valve, which is effectively a covered stent, might confound our results. Patients who had a bare metal stent implanted after angioplasty were included.

Methods

Patients

The computerized database of the Cardiovascular Program at Children’s Hospital Boston was queried for patients who underwent balloon dilation of an RV-PA conduit with an Atlas balloon (Bard Peripheral Vascular, Inc, Tempe, AZ) between 2004 and 2012. A control cohort was derived comprising patients who underwent RV-PA conduit dilation between 2000 and 2012 with a conventional balloon (ie, any non-UNC balloon) measuring ≥12 mm in diameter (12 mm is the smallest diameter Atlas balloon). Patients in whom both UNC and conventional balloons were used (almost always conventional followed by UNC) were included in the UNC group. We excluded patients who did not have a fully circumferential homograft conduit (including those with a homograft conduit that had been surgically augmented, a nonhomograft conduit, or no homograft at all), those who underwent PA dilation with an UNC balloon without conduit dilation, those who had conduits of different sizes anastomosed in series, and those in whom the largest angioplasty balloon was <12 mm. Patients who underwent TPV placement were also excluded because postangioplasty pressure measurements were recorded after balloon dilation but before any stent implantation (if performed). When this information was not available, poststent pressure measurements were used. Types and sizes of balloons were recorded, but inflation pressures were not always available.

Angiographic Assessments

Angiograms and balloon inflations were imaged and acquired using a biplane system. Angiographic and fluoroscopic measurements were performed offline by a single investigator using digital imaging archives. Measurements were performed for both the first and final angioplasty balloons, and included diameters of the conduit and balloon waists. The waist:nominal balloon diameter ratio was calculated as the ratio of the first discretely identifiable balloon waist to the nominal diameter of the balloon. Successful resolution of a balloon waist was defined as a linear border without perceivable indentation along both edges of the balloon observed on both projections. Inflations that were intentionally halted before full resolution of limiting the maximum balloon diameter to no >110% of the nominal conduit diameter. Multiple dilations were often performed with gradual increases in balloon inflation pressure and size, with interval angiograms to assess for changes, including tears. When tears were identified, additional angiograms were performed to characterize the extent of the disruption more fully. Decisions about whether and when to implant a bare metal stent were at the discretion of the operator.

Conduit tears were classified into 4 categories: (1) no tear, (2) therapeutic tear (contrast extending <3 mm from conduit lumen; Figures 1 and 2), (3) confined tear (contrast extending >3 mm from conduit lumen; Figure 3), and (4) unconfined tear (contrast extravasation identified in the pericardial or pleural space or the airways; Movie in the online-only Data Supplement). Confined tears were further subdivided into lagoon shaped (contrast elongating parallel to the conduit lumen) or estuary shaped (contrast elongating perpendicular to the conduit lumen) drawing from marine science descriptions. Conduit calcification was graded as none, mild (minimally visible along a portion of the conduit), or severe (heavy, visible along entire conduit). The relationship of the conduit to the anterior chest wall or sternum was recorded as remote, partially apposed (<50% of conduit length apposed), or substantially apposed (>50% apposed). No routine or standardized follow-up imaging was performed to evaluate tears after the catheterization procedure.

Data Analysis

The primary outcome assessed was presence or absence of a conduit tear after balloon dilation of the conduit. Secondary outcomes included change in the peak RV-PA pressure gradient, RV pressure, and RV:aortic pressure ratio. Treatment for conduit tears and other procedural complications are reported descriptively. Variables analyzed for association with outcomes included balloon type (UNC versus conventional), age, conduit size, type of homograft (aortic versus pulmonary), severity of conduit calcification, conduit relationship to the chest wall, diameter of the initial and final balloons, and balloon:conduit and waist:balloon diameter ratios. For comparison of categorical variables, Fisher exact test or χ² analysis were used, and for comparison of continuous data, independent-sample t test (if normally distributed) or the Wilcoxon rank-sum test was used. ANOVA with Bonferroni post hoc testing was used to compare continuous data between >2 groups (eg, types of tears). Data are presented as means±SD, median (minimum-maximum), or frequency (%). We compared differences between preintervention and postintervention measurements among groups (when >2 groups) with ANOVA. To account for multiple comparisons, significance was set at P≤0.01.
The study was approved by the Children’s Hospital Committee for Clinical Investigations. The authors had full access to the data and take full responsibility for its integrity. All authors have read and agree to the article as written.

Results

Patients

From July 2000 to January 2012, 70 patients meeting inclusion criteria underwent 76 conduit angioplasty procedures in which UNC balloons were used (6 patients underwent 2 separate UNC balloon procedures on different conduits), and 81 patients underwent 84 procedures in which only conventional balloons were used (3 patients underwent 2 separate procedures on different conduits). Demographic, diagnostic, and procedural variables are summarized in Table 1. UNC balloon patients were slightly older than those in the conventional group, as was the age of the conduit in UNC patients (both \( P = 0.08 \)), but all other recorded demographic and preangioplasty diagnostic variables were similar between groups.

Angioplasty Outcomes

Data relating to the angioplasty procedure are summarized in Table 1. There was no difference in the initial or final waist:balloon diameter ratios between groups, but the initial and final balloon:conduit diameter ratios were significantly higher in the UNC balloon group. Among patients in the UNC balloon group, multiple different diameter balloons were used in 35 patients (46%), and a 4 cm long balloon was used in 24 patients (31%). The balloon waist was resolved in 65% of UNC procedures, which was significantly higher than in the conventional balloon group. Balloon rupture/puncture occurred significantly more often with conventional than UNC balloons. All 3 of the patients in whom the UNC balloon ruptured had severely calcified conduits; the balloon rupture in all of these cases seemed to be a point puncture with slow contrast leakage before full inflation (ie, not at high pressure) rather than an explosive rupture.

Hemodynamic Outcomes

Overall, both groups experienced a reduction in RV pressure and the peak RV-PA pressure gradient. Use of UNC balloon was associated with a significantly lower RV:Ao pressure ratio and RV-PA pressure gradient after angioplasty (Figure 4).

Conduit Tears

Data related to conduit tears are summarized in Table 2. A conduit tear was identified angiographically in 25 patients in the UNC balloon group and 10 in the conventional balloon group (\( P = 0.001 \)). The shape and location of tears varied considerably, and no clear patterns were discerned. There were 4 unconfined tears in total, all of which occurred after UNC balloon angioplasty, none of which occurred as a frank conduit rupture with acute decompensation. Confined tears were similarly more common in the UNC balloon group (\( P = 0.009 \)). In no case did a tear first characterized as therapeutic or confined progress to become unconfined.

Demographic, diagnostic, and procedural variables of patients who did and did not experience a conduit tear are summarized in Table 3. There were significantly greater reductions in the RV:Ao pressure ratio and the peak RV-PA pressure gradients in patients who had any conduit tear in comparison with those with no tear, although there were no significant differences in initial or final balloon:conduit ratio or waist:balloon ratio. The initial waist:balloon diameter ratio was smaller (ie, tighter waist) in patients who developed any tear than those who did not. Patients who experienced a confined or unconfined tear (combined) had significantly greater reduction in the RV:Ao pressure ratio than patients with either no tear or a therapeutic tear only (\(-0.35\pm0.28 \) versus \(-0.19\pm0.19; P = 0.001 \)), but there were no differences in other hemodynamic or balloon related parameters, including waist:balloon diameter ratios (Figure 5).

Unconfined Tears

Three of the 4 unconfined tears were recognized during the procedure, and none occurred as frank conduit rupture with acute decompensation. One of the cases recognized during the procedure had a bare metal stent implanted across the tear, and the patient was observed without hemodynamic compromise or enlargement of the tear. Two patients were observed in the catheterization laboratory (for \( \leq 2 \) hours) without hemodynamic change or enlargement of the tear, 1 of whom was subsequently observed in the cardiac intensive care unit, and neither underwent further intervention. The fourth patient became hemodynamically unstable in the recovery area after the procedure and was subsequently found to have hemothorax and an unconfined tear. The patient was returned to the catheterization laboratory, where chest tubes were placed and resuscitation was performed. Extracorporeal membrane oxygenation support was initiated in the catheterization laboratory, and the patient was then taken emergently to the operating room for conduit replacement. The postoperative course was uncomplicated, and there were no discernible neurological or other complications related to the period of hemodynamic compromise.

Of the 4 patients who developed unconfined tears after UNC angioplasty, 2 had truncus arteriosus, 1 had double-outlet RV with pulmonary atresia, and 1 had l-transposition of the great arteries with pulmonary atresia. Three of the 4 patients had an aortic homograft conduit that was substantially apposed.
The conduits ranged in implanted diameter from 12 to 20 mm, and 3 conduits (2 aortic, 1 pulmonary) were severely calcified. The mean initial and final balloon:conduit diameter ratios were 0.86 and 0.93, respectively, and the mean initial and final waist:balloon diameters ratios were 0.76 and 0.82. The initial waist:balloon diameter ratio was ≤0.78 in all 4 patients, which was lower than the overall population mean (and median) of 0.81, but this did not reach statistical significance ($P=0.12$). In 2 of these patients, a 4 cm long UNC balloon was used, and in 2, only a single UNC balloon was inflated. In 3 of the 4 patients, the balloon waist was resolved on the dilation that produced the tear.

**Discussion**

**RV-PA Conduit Dilation With Ultra-Noncompliant Balloons**

In our practice, UNC balloons have become a common tool for angioplasty of obstructed RV-PA homograft conduits. They tend to be effective at relieving stenoses, similar to their performance.
in resistant PA lesions but result in a substantially higher frequency of angiographically identifiable conduit wall tears than lower pressure balloons. In this study, there were a total of 4 unconfined tears, all in patients who underwent dilation with UNC balloons. Three of these were in heavily calcified conduits that were closely apposed to the anterior chest wall, and the waist on the initial dilating balloon was tighter than in other patients (≤0.78 in all 4), although the small number of events precluded robust analysis of risk factors for an unconfined tear. In light of these findings, we think it is important to perform angioplasty with an initial waist:balloon diameter ratio ≥0.8. If the initial balloon waist is smaller (ie, tighter), it may be prudent
to halt the inflation and begin with a smaller balloon, particularly when the conduit is heavily calcified or closely apposed to the anterior chest wall. These recommendations are only loosely based on data, as the number of unconfined tears in this series was small, and the degree of calcification or location of the conduit was not associated with the development of tears in general (ie, any type of tear). We do not interpret these findings to suggest that UNC balloons should not be used for right ventricular outflow tract conduit angioplasty, but rather that is important to use them cautiously and appropriately.

Our definition of unconfined conduit tear, which was intended to reflect tears that bled into the airway or a large mediastinal space and might result in important consequences, was liberal in this study. Namely, only 1 of the 4 cases resulted in significant extravascular fluid collection and hemodynamic instability. The tear in this patient was not recognized in the catheterization laboratory and was diagnosed only after hemodynamic decompression in the recovery room, with subsequent resuscitation using mechanical circulatory support and surgical conduit replacement. This case highlights the importance of thorough angiographic evaluation after balloon angioplasty of conduits. Additional invasive procedures (ie, surgery, covered stent placement, closure of the tear with a device, or drainage of extravascular blood) were not performed in any of the other 3 cases that met our definition of unconfined tear. We deliberately avoided the term conduit rupture, and the frequency of unconfined tears in this series should not be quoted as the incidence of conduit rupture without clearly stating that only 1 of our 4 cases had serious implications. Frank conduit rupture with acute hemodynamic decompensation, which is the most concerning scenario that interventionalists imagine when considering the risk of conduit injury, did not occur in this series.

In general, UNC balloons, including 4 cm long balloons, were used to good effect in this population, with few serious adverse events. Although tears in general and all of the unconfined tears were in patients who underwent angioplasty using a UNC balloon, it is not necessarily the case that such balloons are more likely to cause important tears than other types of balloons.

### Table 1. Demographic, Diagnostic, and Procedural Variables in Patients Who Underwent RV-PA Conduit Angioplasty With Ultra-Noncompliant and Conventional Balloons

<table>
<thead>
<tr>
<th>Variable</th>
<th>UNC (n=76)</th>
<th>Conventional (n=84)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient age, y</td>
<td>13.8±10.7</td>
<td>11.2±8.0</td>
<td>0.08</td>
</tr>
<tr>
<td>Implanted conduit diameter, mm</td>
<td>16.1±4.2</td>
<td>16.5±3.8</td>
<td>0.5</td>
</tr>
<tr>
<td>Age of implanted conduit, y</td>
<td>7.9±5.0</td>
<td>6.5±4.3</td>
<td>0.08</td>
</tr>
<tr>
<td>Aortic homograft conduit</td>
<td>44 (58%)</td>
<td>55 (66%)</td>
<td>0.3</td>
</tr>
<tr>
<td>Conduit severely calcified</td>
<td>49 (65%)</td>
<td>55 (66%)</td>
<td>0.9</td>
</tr>
<tr>
<td>Conduit substantially apposed to anterior chest wall</td>
<td>32 (43%)</td>
<td>36 (43%)</td>
<td>0.9</td>
</tr>
<tr>
<td>RV:aortic pressure ratio preintervention</td>
<td>0.83±0.20</td>
<td>0.85±0.20</td>
<td>0.4</td>
</tr>
<tr>
<td>RV:aortic pressure ratio postintervention</td>
<td>0.59±0.16</td>
<td>0.66±0.20</td>
<td>0.02</td>
</tr>
<tr>
<td>Change in RV:aortic pressure ratio after intervention</td>
<td>−0.25±0.20</td>
<td>−0.19±0.23</td>
<td>0.1</td>
</tr>
<tr>
<td>RVOT gradient preintervention, mm Hg</td>
<td>49±21</td>
<td>55±20</td>
<td>0.08</td>
</tr>
<tr>
<td>RVOT gradient postintervention, mm Hg</td>
<td>28±15</td>
<td>39±22</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Change in RVOT gradient after intervention, mm Hg</td>
<td>−20±19</td>
<td>−15±22</td>
<td>0.1</td>
</tr>
<tr>
<td>Initial balloon:nominal conduit diameter ratio</td>
<td>0.95±0.34</td>
<td>0.83±0.24</td>
<td>0.01</td>
</tr>
<tr>
<td>Final balloon:nominal conduit diameter ratio</td>
<td>1.01±0.35</td>
<td>0.88±0.23</td>
<td>0.004</td>
</tr>
<tr>
<td>Initial waist:balloon diameter ratio</td>
<td>0.81±0.11</td>
<td>0.81±0.11</td>
<td>0.8</td>
</tr>
<tr>
<td>Final waist:balloon diameter ratio</td>
<td>0.82±0.08</td>
<td>0.81±0.10</td>
<td>0.2</td>
</tr>
<tr>
<td>Balloon waist resolved</td>
<td>49 (65%)</td>
<td>41 (48%)</td>
<td>0.04</td>
</tr>
<tr>
<td>Balloon rupture during conduit dilation</td>
<td>3 (4%)*</td>
<td>31 (37%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Bare metal stent implanted in conduit after angioplasty during the same procedure</td>
<td>34 (45%)</td>
<td>56 (67%)</td>
<td>0.005</td>
</tr>
</tbody>
</table>

Data presented as mean±SD or frequency (% of column total), unless otherwise specified. Aortic homografts were significantly more likely to have severe calcification than pulmonary homografts (88% vs 28%; P < 0.001). RV-PA indicates right ventricle-to-pulmonary artery; RVOT, right ventricular outflow tract; and UNC, ultra-noncompliant.

*In 7 other patients in the UNC group, a conventional balloon used during the same procedure ruptured.

Our definition of unconfined conduit tear, which was intended to reflect tears that bled into the airway or a large mediastinal space and might result in important consequences, was liberal in this study. Namely, only 1 of the 4 cases resulted in significant extravascular fluid collection and hemodynamic instability. The tear in this patient was not recognized in the catheterization laboratory and was diagnosed only after hemodynamic decompensation in the recovery room, with subsequent resuscitation using mechanical circulatory support and surgical conduit replacement. This case highlights the importance of thorough angiographic evaluation after balloon angioplasty of conduits. Additional invasive procedures (ie, surgery, covered stent placement, closure of the tear with a device, or drainage of extravascular blood) were not performed in any of the other 3 cases that met our definition of unconfined tear. We deliberately avoided the term conduit rupture, and the frequency of unconfined tears in this series should not be quoted as the incidence of conduit rupture without clearly stating that only 1 of our 4 cases had serious implications. Frank conduit rupture with acute hemodynamic decompensation, which is the most concerning scenario that interventionalists imagine when considering the risk of conduit injury, did not occur in this series.

In general, UNC balloons, including 4 cm long balloons, were used to good effect in this population, with few serious adverse events. Although tears in general and all of the unconfined tears were in patients who underwent angioplasty using a UNC balloon, it is not necessarily the case that such balloons are more likely to cause important tears than other types of balloons.

**Figure 4.** Predilation and postdilation right ventricular outflow tract (RVOT) gradient. There is a significantly greater decrease in RVOT gradient with ultra-noncompliant (UNC) balloons where tears were identified relative to dilations with conventional balloons.
There were other procedural differences that may have been equally important; namely, the initial and final balloon:nominal conduit diameter ratios were significantly higher in patients who underwent UNC balloon angioplasty than those in the conventional balloon group, reflecting a tendency toward more aggressive dilation. Accordingly, compared with conventional balloons, we found that balloon dilation of RV-PA homografts with UNC balloons tended to result in greater reductions in the RV:aortic pressure ratio and RV-PA pressure gradient.

Conduit Tears

Angiographically visible conduit tears after conduit angioplasty were common in this series, particularly when UNC balloons were used, particularly confined and unconfined tears (as opposed to therapeutic tears). The appropriateness of our a priori categorization of tears is unclear. As mentioned above, unconfined tears were anticipated to reflect that the tear would result in hemodynamic or ventilatory consequences, but this did not always prove to be the case. Also, our distinction between therapeutic and confined tears was based on a somewhat arbitrary angiographic discrimination, and it is unclear whether there is any clinical or mechanistic difference between them. It is possible that a wider definition of therapeutic tear would have been more appropriate, as none of the therapeutic or confined tears were observed to progress to unconfined tears or to have other obvious clinical implications.

Studies have shown that the mechanism of action of balloon dilation of vascular stenoses is the production of tears in the vessel intima and media. However, in situ homograft conduits have distinctive features that are different from viable vessels, and the response to angioplasty is likely to differ as well. For example, studies of explanted cryopreserved allograft valves show the cellular makeup being composed primarily of collagen, fibroblasts, and calcification with a paucity of viable cuspal cells. No similar pathological studies have been published to elucidate the effects of angioplasty on RV-PA conduits, but a similar mechanism of effective angioplasty as for vascular lesions would presumably result in the creation of a conduit tear within/through the remodeled tissue.

Table 3. Diagnostic and Procedural Variables in Patients Who Did and Did Not Develop a Visible Tear in the Conduit After RVOT Conduit Angioplasty With Ultra-Noncompliant and Conventional Balloons

<table>
<thead>
<tr>
<th>Variables</th>
<th>Any Conduit Tear (n=35)</th>
<th>No Tear (n=125)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implanted conduit diameter, mm</td>
<td>17.1±2.9</td>
<td>16.1±4.1</td>
<td>0.16</td>
</tr>
<tr>
<td>Age of implanted conduit, y</td>
<td>8.2±5.1</td>
<td>6.9±4.6</td>
<td>0.13</td>
</tr>
<tr>
<td>Aortic homograft conduit*</td>
<td>23 (66%)</td>
<td>76 (61%)</td>
<td>0.6</td>
</tr>
<tr>
<td>Conduit severely calcified</td>
<td>26 (74%)</td>
<td>78 (62%)</td>
<td>0.2</td>
</tr>
<tr>
<td>Conduit substantially apposed to anterior chest wall</td>
<td>13 (37%)</td>
<td>55 (44%)</td>
<td>0.5</td>
</tr>
<tr>
<td>RV:aortic pressure ratio preintervention</td>
<td>0.92±0.23</td>
<td>0.82±0.18</td>
<td>0.01</td>
</tr>
<tr>
<td>RV:aortic pressure ratio postintervention</td>
<td>0.59±0.19</td>
<td>0.64±0.19</td>
<td>0.2</td>
</tr>
<tr>
<td>Change in RV:aortic pressure ratio after intervention</td>
<td>−0.33±0.27</td>
<td>−0.19±0.18</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>RVOT gradient preintervention, mm Hg</td>
<td>59±21</td>
<td>51±21</td>
<td>0.07</td>
</tr>
<tr>
<td>RVOT gradient postintervention, mm Hg</td>
<td>31±21</td>
<td>35±19</td>
<td>0.3</td>
</tr>
<tr>
<td>Change in RVOT gradient after intervention, mm Hg</td>
<td>−26±21</td>
<td>−15±19</td>
<td>0.004</td>
</tr>
<tr>
<td>Initial balloon:nominal conduit diameter ratio</td>
<td>0.86±0.21</td>
<td>0.89±0.0314</td>
<td>0.5</td>
</tr>
<tr>
<td>Final balloon:nominal conduit diameter ratio</td>
<td>0.94±0.18</td>
<td>0.95±0.33</td>
<td>0.9</td>
</tr>
<tr>
<td>Initial waist:balloon diameter ratio</td>
<td>0.77±0.10</td>
<td>0.82±0.10</td>
<td>0.02</td>
</tr>
<tr>
<td>Final waist:balloon diameter ratio</td>
<td>0.80±0.09</td>
<td>0.82±0.09</td>
<td>0.2</td>
</tr>
<tr>
<td>Balloon waist resolved</td>
<td>22 (63%)</td>
<td>68 (55%)</td>
<td>0.4</td>
</tr>
<tr>
<td>Balloon rupture during conduit dilation</td>
<td>10 (29%)</td>
<td>26 (21%)</td>
<td>0.03</td>
</tr>
</tbody>
</table>

RV indicates right ventricle; and RVOT, right ventricular outflow tract.

*All other conduits were pulmonary homografts.
layers, and extension into the perihomograft scar tissue would permit visualization of a tear. Absence of an angiographically visible tear does not necessarily imply that the conduit was unaffected by the angioplasty, and that there was no therapeutic effect. However, it seems likely that a higher frequency of visible tears with UNC balloons is consistent with more frequent and extensive disruption of the conduit wall, which is an important component of relieving the obstruction.

In this study, we found that when a tear was created, it was associated with a greater hemodynamic benefit (ie, reduction of the RV:Ao pressure ratio and right ventricular outflow tract gradient). We also found that tears were more common with UNC balloons than conventional balloons, which we presume contributes to or is related to more effective relief of stenosis in many cases. There were no obvious conduit-related factors (eg, calcification, aortic versus pulmonary origin, duration in situ, etc) associated with a higher probability of tears in general, although 3 of the 4 unconfined tears were in severely calcified aortic homograft conduits.

Tears can be managed but must be well defined. Our practice is to use multiple views to characterize the location, size, shape, and hemodynamic effect of the tear, including evidence of pericardial, pleural, or airway extension. Although we chose to exclude patients who were catheterized for purposes of TPV placement, these same patients are likely to derive benefit from near complete relief of RV outflow tract obstruction before valve implant. Also, the nature of the TPV (ie, a covered stent) is an obvious but unproven option for management of important tears. Nonvalved stent placement with UNC balloons in relation to the occurrence of balloon rupture.

**Balloon Rupture**

Balloon rupture may occur with particularly high frequency during angioplasty of RV-PA conduits, which often have extensive and irregular calcification. There are several mechanisms by which balloon rupture can complicate a dilation procedure, including fragment embolization, air embolization, inability to resheath the balloon, and consequent vascular damage during extraction, and possibly local vessel trauma related to high-velocity extrusion of the fluid used to inflate the balloon. The propagation of balloon rupture in a UNC balloon is mechanistically unique from conventional balloons. Although conventional balloons tend to rupture abruptly in circumferential or tangential directions, UNC balloon ruptures seem to be characterized by nonexplosive, focal/point punctures with subsequent leaking of the contrast and saline mixture into the surrounding vascular space. Balloon rupture occurred frequently with UNC balloons (4%) and significantly less often than with conventional balloons, which ruptured in more than one third of procedures. Our data suggest that use of UNC balloons may reduce the potential for such complications. Future studies will be needed to evaluate the safety and efficacy of stent placement with UNC balloons in relation to the occurrence of balloon rupture.

**Theoretical Advantages and Disadvantages of UNC Balloons**

A theoretical advantage of UNC balloons for angioplasty of RV-PA conduits is that UNC balloons do not expand beyond their nominal size even at high inflation pressures or when dilating a highly resistant lesion, unlike most other high-pressure balloons. This ensures that the actual balloon diameter does not exceed the intended diameter. Also, as discussed above, UNC balloons seem to rupture less often and less explosively than many other balloons in the difficult angioplasty substrate of an RV-PA conduit. There are also potential disadvantages of UNC balloons. For example, the Atlas balloon has a long taper, which can be awkward in curved or complex geometries, as is often the case with RV-PA conduits although newer generation balloons (Atlas Gold) have made improvements in this design limitation. The length and high-pressure inflation mandate close observation for vascular trauma related to the extensive straightening of the conduit and migration of the balloon tip that can occur during inflation. Anecdotally, some interventional cardiologists have expressed concern about the risk of RV-PA conduit angioplasty using high inflation pressures. Although high-pressure inflation intuitively may seem riskier than lower pressure inflation, it is important to recognize that the high pressure to which UNC balloons can be inflated does not necessarily impart a higher risk if the balloon is sized appropriately. Namely, using a computerized model of balloon dilatation, Capelli et al showed that balloon diameter had a greater impact on the expansion force than inflation pressure, a finding that should provide reassurance about high-pressure angioplasty, per se, and that also highlights the importance of appropriate selection of balloon diameter.

**Limitations**

This study is limited by its retrospective, nonrandomized design. Also, there are no standard definitions of types of tears, and we gauged our classification scale relative to estimated homograft wall thickness, with further characterization borrowed from marine science definitions. There was no standard practice or criteria for balloon selection. Balloon inflation pressures were not always available, so our results pertain to the use of UNC balloons.
balloons, not necessarily ultrahigh-pressure dilations, which is an important limitation. It is worth noting that, in general, when UNC balloons were used, it was the intention to inflate to high pressure if necessary, but sometimes the desired result was achieved before reaching high pressure. Some conduits already had stents in place from a previous procedure, which may alter the integrity of a conduit and hemodynamic results of angioplasty. Also, balloon waist resolution may not have been achieved because of purposeful deflation once a conduit was seen to crack, displace, or a waist seemed to pop without complete resolution. We did not capture these fluoroscopic triggers that may have been important to the outcome or the performance of the procedure (eg, cessation of balloon inflation before waist resolution), such as fracture of calcified sections of the homograft or other clear signs of therapeutic effect (eg, pop in the balloon waist without complete resolution), conduit geometry, etc. Many patients underwent placement of a bare metal stent after angioplasty, so the final hemodynamic results were often better than reported for the postangioplasty condition. However, postangioplasty hemodynamic measurements were not always available in the catheterization record, so poststenotic hemodynamic measurements were used in some cases, which may overestimate the hemodynamic changes resulting from dilation. The decision about when to proceed to stent placement was discretionary and may have varied according to balloon type and era, but we were not able to assess such variability in a robust manner because all patients did not undergo stent implantation. Repeated procedures on different conduits in 9 patients might induce correlated data, but these made up a small fraction of total observations (18/160), so we analyzed them as independent observations. No routine or standardized follow-up imaging was performed to evaluate tears after the catheterization procedure, so it is not known how tears evolved or healed, but we are not aware of any sudden unexplained deaths or clinical events suggestive of hemorrhage in this cohort. Given the infrequency of unconfined tears, the sample size of this study was not sufficient to detect patient-related, or conduit-related, or procedural variables that may be associated with a higher risk of this outcome.

Conclusions
In this study, we found that UNC balloons can be used to good effect with significant reduction of right ventricular outflow tract gradient and the RV: Ao ratio when compared with conventional balloons. Morbidity between the 2 groups was similar despite more aggressive therapy. Conduit tears were common overall, particularly among patients undergoing angioplasty with a UNC balloon, but clinically important tears were infrequent, and frank conduit rupture with acute decompensation did not occur. Careful and gradual dilation of conduits with adequate interval angiography for assessment of conduit tears is advisable, and when UNC balloons are used, we recommend that an initial waist: balloon ratio ≥0.80. Further studies will be needed to potential risk factors associated with unconfined tears and the efficacy of covered stents (with or without a pulmonary valve) and other methods of treatment in such cases. With the proliferation of TPV therapy, important conduit tears are likely to become a more prevalent problem, even if still rare. Hopefully, the data presented in this report will contribute to the evolving understanding of how to achieve safe and effective outcomes with TPV replacement.

Disclosures
None.

References
Angioplasty of Obstructed Homograft Conduits in the Right Ventricular Outflow Tract With Ultra-Noncompliant Balloons: Assessment of Therapeutic Efficacy and Conduit Tears

Michael R. Hainstock, Audrey C. Marshall, James E. Lock and Doff B. McElhinney

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Video Legend

Angiogram demonstrates an unconfined tear with extravasation of contrast from the proximal conduit into the mediastinum.