Open Transapical Approach to Transcatheter Paravalvular Leakage Closure
A Preliminary Experience

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Background—Significant prosthetic paravalvular leakage (PVL) could have serious clinical consequences and impairs survival. Reoperation is associated with a high mortality rate, and transcatheter closure is a new treatment modality for high-risk patients. The goal of this study was to determine safety and midterm clinical efficacy of transcatheter PVL closure using an open transapical approach.

Methods and Results—All consecutive patients who underwent transcatheter PVL closure in our center were prospectively enrolled. Pre- and postprocedural quality of life and 6-minute walk test were ascertained. All outcomes were defined according to the Valve Academic Research Consortium-2 consensus document. In total, 37 consecutive patients (mean age 67±12 years, 65% male, logistic European System for Cardiac Operative Risk Evaluation 27±17%, Society of Thoracic Surgeons score 7±4%) with severe symptomatic PVL in mitral (81%) or aortic (19%) position underwent transcatheter PVL closure. Procedure success was 86%. Early safety at 30 days (ie, event-free survival) was 84%. The 1-year survival rate was 66%. New York Heart Association functional class and quality of life significantly improved. Clinical efficacy (ie, survival free of stroke, rehospitalization, New York Heart Association 3/4, and device-related dysfunction) was 49% at 3 months and 31% at 1 year. Moderate to severe residual PVL was associated with all-cause mortality (hazard ratio, 3.9; 95% confidence interval, 1.2–12.1; P=0.03).

Conclusions—The open transapical approach to PVL closure in high-risk patients has a high procedural success rate with an acceptable risk of adverse outcomes. This is the first study to prove an increased functional capacity and quality of life after transapical PVL closure. Residual PVL is associated with 1-year mortality. (Circ Cardiovasc Interv. 2014;7:611-620.)

Key Words: heart failure ■ heart valve diseases ■ heart valve prosthesis ■ mitral valve insufficiency ■ quality of life ■ septal occluder device ■ surgical procedures, minimally invasive

Prosthetic paravalvular leakage (PVL) is a well-known complication of surgical valve implantation. PVL is defined as a peri-prosthetic regurgitation through a defect between the annulus of the native valve and the sewing ring. The occurrence of PVL has been recognized for quite some time but gained more attention since the introduction of transcatheter interventions and the concurrent relatively high rate of PVL. Significant PVL could have major clinical consequences and impacts long-term survival. Until the late 1990s, reoperation was the only solution despite a mortality rate of ≥5% to 14%. With the use of transcatheter interventions and the introduction of vascular plugs, efforts have been made to seal PVLs percutaneously mainly by transfemoral approach, with variable success. By contrast, we opt for a standard transapical approach using a minithoracotomy because we think that this enables a simpler crossing of the PVL and a more stable catheter position to deliver the plugs.

Conclusive literature is not available on transcatheter PVL closure via the open transapical approach. Accordingly, we examined the procedural and midterm clinical outcomes of transapical transcatheter PVL closure in consecutive patients.

Methods

Patient Population
All consecutive patients with a significant PVL who underwent a transcatheter PVL closure by means of an open transapical approach in the period between October 2009 and April 2013 at the St Antonius Hospital were enrolled in this study. PVL was graded semiquantitatively using Doppler transoesophageal echocardiography and color-flow imaging by echocardiographers experienced in the intraoperative assessment of mitral and aortic valve repair and replacement. Circumference of PVL was measured on 3-dimensional
WHAT IS KNOWN

- Paravalvular leakage after surgical prosthetic valve replacement can cause severe symptoms of congestive heart failure and hemolytic anemia.
- In high-risk or inoperable patients, transcatheter closure of a paravalvular leak has been reported as an alternative to surgery that is successful in ≥80% of patients.

WHAT THE STUDY ADDS

- Transcatheter paravalvular leak closure using an open transapical approach was associated with improvements in functionality, quality of life, hemolytic anemia, and congestive heart failure, with a similar success rate as other methods of closure.
- Moderate to severe residual paravalvular leakage was associated with a higher rate of 1-year mortality than lower grades of residual leakage.

Procedure

In brief, we exposed the left ventricular apex by a small anterolateral left thoracotomy at the fifth intercostal space using single-lumen tube ventilation only. After removal of some pericardial fat, we opened the pericardium longitudinally and sutured it to the thoracic wall to permit ventilation only. After removal of some pericardial fat, we opened the left thoracotomy at the fifth intercostal space using single-lumen tube ventilation only. After removal of some pericardial fat, we opened the left thoracotomy at the fifth intercostal space using single-lumen tube ventilation only. After removal of some pericardial fat, we opened the left thoracotomy at the fifth intercostal space using single-lumen tube ventilation only. After removal of some pericardial fat, we opened the left thoracotomy at the fifth intercostal space using single-lumen tube ventilation only. After removal of some pericardial fat, we opened the left thoracotomy at the fifth intercostal space using single-lumen tube ventilation only. After removal of some pericardial fat, we opened the left thoracotomy at the fifth intercostal space using single-lumen tube ventilation only. After removal of some pericardial fat, we opened the left thoracotomy at the fifth intercostal space using single-lumen tube ventilation only. After removal of some pericardial fat, we opened the left thoracotomy at the fifth intercostal space using single-lumen tube ventilation only. After removal of some pericardial fat, we opened the left thoracotomy at the fifth intercostal space using single-lumen tube ventilation only. After removal of some pericardial fat, we opened the left thoracotomy at the fifth intercostal space using single-lumen tube ventilation only. After removal of some pericardial fat, we opened the left thoracotomy at the fifth intercostal space using single-lumen tube ventilation only.
Efficacy
Clinical efficacy was defined as freedom of all-cause mortality, stroke, rehospitalization for PVL-related symptoms (anemia or congestive heart failure), NYHA functional class 3 or 4, and closure device-related dysfunction (moderate or severe PVL). Clinical efficacy was measured at 3 months and 1 year.

Follow-Up
Before discharge, a transthoracic echocardiography was performed within 7 days after PVL closure. Ambulatory visit and laboratory tests were scheduled at 3, 6, and 12 months and yearly thereafter. At each visit, the patient was asked to fill in the Minnesota Living with Heart Failure Questionnaire and perform a 6-MWT. Standard transthoracic echocardiography was performed at 3 and 12 months and yearly thereafter. Patients’ vital status was ascertained from the national death registry. Cause of death was determined by contacting the referring physician or general practitioner.

Data Analysis
Data are presented as mean±SD or as median with the 25th and 75th percentiles as appropriate. Categorical variables are shown as frequencies and percentages. For continuous variables, a Student t test or Mann–Whitney U test was used for comparison between 2 groups. For prepost comparison we used paired-sample t test or the Wilcoxon signed-rank test as appropriate. Proportions were compared using Fisher exact test. Correlations were examined by calculating Spearman rank correlation coefficient. Survival estimates were calculated for study end points using the Kaplan–Meier method and compared by means of the log-rank test. To examine the role of PVL type, patients were grouped according to aortic and mitral PVL. To examine the role of residual PVL on outcome, patients were grouped according to none or mild and moderate or severe PVL before discharge. To examine the impact of the distance covered during the preprocedure 6-MWT on the outcome, patients were grouped according to distances of <300 m or ≥300 m. Hazard ratio with 95% confidence interval (CI) was calculated using Cox proportional hazards regression, and odds ratio with 95% CI was calculated using binominal logistic regression. Statistical significance was inferred at P<0.05.

Results
Patients
The study comprised 37 consecutive patients (mean age 67±12 years, 65% male, logistic European System for Cardiac Operative Risk Evaluation 27±17%, Society of Thoracic Surgeons score 7±4%). All patients had congestive cardiac failure and had an NYHA functional class>2. Hemolytic anemia was present in 28 patients (76%) and significant comorbidity was common. Baseline characteristics are listed in Table 1.

Paravalvular Leakage
The treated defects most commonly involved mechanical (76%) and mitral prostheses (81%). Most patients had a severe PVL (76%). Most mitral PVLs were located posterolaterally. Most aortic PVLs were located between the native noncoronary and right coronary cusps. Mean PVL circumference was higher for mitral versus aortic lesions (19±9% versus 10±5%, P=0.02). PVL characteristics are listed in Table 1. PVL locations are visualized in Figure 2.
Procedure success (ie, procedural survival free of incorrect closure device positioning and residual moderate or severe PVL) was present in 32 of 37 procedures (86%; 95% CI, 74–92%). The mean procedure time was 89±31 minutes. The mean procedure time was longer for patients with an aortic (126±35 minutes) versus mitral PVL (79±23 minutes; P=0.07). The grade of PVL or its circumference did not correlate with the procedure success.

No patients had device embolization, but device malpositioning occurred in 2 cases. In the first case, device migration occurred without distal embolization of 1 of 3 implanted AVP III plugs involving a mechanical mitral prosthesis. This patient died at day 1 due to a significant residual PVL with severe deteriorated congestive heart failure. In the second case, impingement of a mechanic mitral prosthesis occurred with a severe residual PVL and valvular regurgitation due to interference with a muscular ventricular septal defect occluder and the inability of the lateral leaflet to close (Figure 3; Movie I in the Data Supplement). This patient underwent a successful redo mitral valve replacement at day 5. One patient required a rethoracotomy at day 0 because of a hematothorax and developed severe fixed suprasystemic pulmonary hypertension and died at day 4 due to refractory cardiogenic shock. Despite device implantation, 2 patients had a persistent severe PVL for which reoperation was performed. No transcatheter reintervention was performed. Procedure outcomes are listed in Table 2.

Adverse Events
The safety end point (ie, survival free of stroke, life-threatening bleeding, severe acute kidney injury, coronary artery obstruction requiring intervention, major vascular complication, and device-related valvular dysfunction requiring repeat procedure) was met in 31 of 37 patients (84%; 95% CI, 69–92%). Four patients developed a hematothorax for which a left-sided rethoracotomy was required. Three out of four hematothoraces occurred within the first 10 patients. In 3 cases, no active bleeding site could be found. In 1 case, an active apical bleeding was identified and sutured. The overall rate of bleeding complications was 19% at 30 days. Major bleedings consisted of melena (n=2) and minor bleedings consisted of hematuria (n=2). All complications are listed in Table 3.

Efficacy
The efficacy end point (ie, survival free of stroke, rehospitalization, NYHA 3/4, and moderate or severe PVL) was met in 19 of 37 patients (51%) at 3 months and in 9 of 29 patients (31%) at 1 year. At 3 months, 3 patients (8%) died, 4 patients (11%) were rehospitalized due to decompensated heart failure, 12 patients (32%) had a NYHA functional class >2, and 2 patients (5%) developed a new severe PVL. At 1 year, 10 of 29 patients (34%) had died, 9 patients (31%) were rehospitalized due to decompensated heart failure (n=7) or anemia requiring blood transfusion (n=2), 15 patients (52%) had a NYHA functional class >2, and 3 patients (10%) had a moderate to severe PVL.
Table 2. Procedure

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mitral (n=30)</th>
<th>Aortic (n=7)</th>
<th>Total (n=37)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anesthesia, min</td>
<td>123±24</td>
<td>180±52</td>
<td>134±38</td>
</tr>
<tr>
<td>Procedure, min</td>
<td>79±23</td>
<td>126±35</td>
<td>89±31</td>
</tr>
<tr>
<td>PVL closure, min</td>
<td>48 (31–74)</td>
<td>90 (53–115)</td>
<td>50 (33–80)</td>
</tr>
<tr>
<td>Fluoroscopy, min</td>
<td>19 (13–29)</td>
<td>35 (24–46)</td>
<td>20 (15–34)</td>
</tr>
<tr>
<td>Radiation dose (DAP)</td>
<td>77±46</td>
<td>160±150</td>
<td>93±80</td>
</tr>
<tr>
<td>Hospitalization, d</td>
<td>8 (6–18)</td>
<td>8 (6–11)</td>
<td>8 (6–15)</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Plug type</th>
<th>Mitral (n=30)</th>
<th>Aortic (n=7)</th>
<th>Total (n=37)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVP</td>
<td>2 (4)</td>
<td>1 (13)</td>
<td>3 (5)</td>
</tr>
<tr>
<td>AVP III</td>
<td>44 (90)</td>
<td>7 (88)</td>
<td>51 (89)</td>
</tr>
<tr>
<td>Figulla Flex ASD</td>
<td>1 (2)</td>
<td>0 (0)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Amplatzer VSD occluder</td>
<td>2 (4)</td>
<td>0 (0)</td>
<td>2 (4)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of plugs implanted</th>
<th>Mitral (n=30)</th>
<th>Aortic (n=7)</th>
<th>Total (n=37)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>16 (53)</td>
<td>6 (86)</td>
<td>22 (60)</td>
</tr>
<tr>
<td>2</td>
<td>10 (33)</td>
<td>1 (14)</td>
<td>11 (30)</td>
</tr>
<tr>
<td>3 or 4</td>
<td>4 (13)</td>
<td>0 (0)</td>
<td>4 (11)</td>
</tr>
</tbody>
</table>

Continuous values are mean±SD or median (25th–75th percentile). Categorical values are n (%). ASD indicates atrial septal defect; AVP, Amplatzer vascular plug; DAP, dose area product; PVL, paravalvular leakage; and VSD, ventricular septal defect.

Follow-Up

Median follow-up was 9.5 (4.1–19.9) months. One-year follow-up was completed for 29 patients (76%). At 1-year follow-up, 10 patients (34%) had died. Cardiovascular mortality was 31% (n=9) due to congestive heart failure in 8 patients and of unknown cause in 1 patient. Noncardiovascular death occurred in 1 patient, who died of a pneumosepsis after 7.5 months.

At 1-year follow-up, 100% of patients with an aortic lesion were alive versus 57% of patients with a mitral lesion. Moderate to severe PVL before discharge was associated with all-cause mortality (hazard ratio, 3.9; 95% CI, 1.2–12.1; P=0.03) as shown in Figure 4A. Survival free of reoperation was 62% (n=18) at 1 year (Figure 4B). Furthermore, 1-year survival was higher in patients with ≥300 m than <300 m walking distance at baseline (100% versus 60%, P=0.03; Figure 4C). No sex-based differences were present.

Discussion

The principle findings of this study are that (i) transapical transcatheter PVL is associated with a similarly low incidence of adverse procedural events compared with other closure methods in patients with high surgical risk, (ii) transapical transcatheter PVL closure has a moderate efficacy but improves symptoms and QoL, and (iii) residual moderate to severe PVL is associated with higher 1-year mortality.

Transapical Access

Transcatheter PVL closure can be performed using either a retrograde or anterograde approach. We preferentially perform...
transcatheter PVL closure using an open transapical access, which provides a retrograde mitral and anterograde aortic approach. The advantages are that (i) both valves are easily accessible, (ii) a mechanical heart valve does not preclude the route, (iii) the short distance to both the mitral and aortic valve allows a direct control and manipulation of the guidewires and encounters less hinder of severe regurgitant jets in crossing a defect, (iv) simultaneous occluder device implantation is easily performed, (v) coaxial alignment of the catheter and the leaflets, a single device with larger discs might be more appropriate. Although previously described as a purpose specific device, the AVPIII is a vascular closure device not designed to seal PVL. This might explain why we experienced some degree of residual PVL. Even with numerous devices, we regularly had to accept a trace to mild residual PVL. Often, residual PVL originated from between the devices, indicating some form of malcoaptation. Improvement due to endothelialization in a later stadium did not occur, possibly due to a high regurgitant flow.

### Table 4. Paired Sample Statistics of Functional, Laboratory, and Echocardiographic Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baseline</th>
<th>3 mo</th>
<th>6 mo</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>NYHA functional class (1–4)</td>
<td>3 (3–4)</td>
<td>2 (2–3)</td>
<td>2 (2–3)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>6-MWT, m</td>
<td>247±149</td>
<td>364±124</td>
<td>297±139</td>
<td>0.15</td>
</tr>
<tr>
<td>MLHF (0–105)</td>
<td>55±28</td>
<td>43±26</td>
<td>49±28</td>
<td>0.01</td>
</tr>
</tbody>
</table>

**Functional classification**

**Laboratory**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin, mmol/L</td>
<td>6.3±1.2</td>
</tr>
<tr>
<td>Reticulocytes, x10³/L</td>
<td>209±160</td>
</tr>
<tr>
<td>Potassium, mmol/l</td>
<td>4.3±0.6</td>
</tr>
<tr>
<td>LD, U/L</td>
<td>841 (428–1400)</td>
</tr>
<tr>
<td>NT-proBNP, log₁₀(pg/mL)</td>
<td>3.3±0.5</td>
</tr>
</tbody>
</table>

**Echocardiography**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PVL grade (0–3)</td>
<td>3 (3)</td>
</tr>
<tr>
<td>LVEF, %</td>
<td>61±13</td>
</tr>
<tr>
<td>PASP, mmHg</td>
<td>39±15</td>
</tr>
</tbody>
</table>

Values are mean±SD or median (25th–75th percentile). This table represents only patients who survived during 6-month follow-up (n=31). P values signify paired-sample t test or Wilcoxon signed-rank test between baseline and 6 mo. A lower score of Minnesota Living with Heart Failure Questionnaire indicates a better quality of life. 6-MWT indicates 6-minute walk test; LD, lactate dehydrogenase; LVEF, left ventricular ejection fraction; MLHF, Minnesota Living with Heart Failure Questionnaire; NT-proBNP, N-terminal prohormone of brain natriuretic peptide; NYHA, New York Heart Association; PASP, pulmonary artery systolic pressure; and PVL, paravalvular leakage.

### Device Selection

For transcatheter PVL closure, no dedicated devices are currently available. We mainly use the AVPIII, which is not available in the United States where the AVPII is most commonly used. In contrast to the AVPII, the AVPIII is oval shaped instead of circular. This results in a decreased surface area with a reduced risk of overlapping with the valve area. Furthermore, the retention rims of the AVPIII are relatively small (2 mm), further minimizing the risk of leaflet interference. In longer defects, we try to use multiple plugs rather than another type of device. In broader defects further located from the prosthetic leaflets, a single device with larger discs might be more appropriate. Although previously described as a purpose specific device, the AVPIII is a vascular closure device not designed to seal PVL. This might explain why we experienced some degree of residual PVL. Even with numerous devices, we regularly had to accept a trace to mild residual PVL. Often, residual PVL originated from between the devices, indicating some form of malcoaptation. Improvement due to endothelialization in a later stadium did not occur, possibly due to a high regurgitant flow.

### PVL Closure

The overall procedure success in this cohort was 86%. Procedure success was highest in aortic lesions. No other relevant anatomic or procedural factors could be identified. In a review of 100 patients, procedure success was reported 82%. However, procedure success was generously defined as a correct device position without dislodgement or embolization. There are 2 large cohorts described by Ruiz et al⁹ and Sorajja et al.⁹ Ruiz et al⁹ reported a procedure success of 86% in 43 patients, without 30-day mortality (5%) and residual moderate to severe PVL (unknown). Sorajja et al.¹⁶ reported a procedure success of 77% in a large cohort of 115 patients, of which 13 were treated via transcatheter transapical approach. More recently, the same authors reported a procedure success of 90% in 200 patients.¹¹ The 30-day mortality in our cohort series was 5%. The 1-year survival rate was 63% in our cohort compared with 30% to 88% at 8 to 10 years after reoperation.³²,³³ This difference could be partially explained by the high-risk population treated in our cohort (mean logistic European System for Cardiac Operative Risk Evaluation of 27%). Also, residual PVL is important: we found that moderate to severe residual PVL was associated with all-cause mortality (hazard ratio, 3.9; Figure 4A).

### Mitral PVL

In our cohort, most treated PVLs were in mitral position (81%) and located posterolaterally (56%). Previous associations between PVL and chronic kidney disease or atrial size could not be confirmed.¹⁴ The PVL location was not associated with outcome.
Because of the direct nature of the approach, the short distance, and coaxial alignment to the defect, the transapical approach facilitates crossing and advancing sheaths and delivery catheters through the PVL, especially for posteromedially located defects, which are often difficult to access from the trans-septal antegrade approach. The mitral defects in this cohort were relatively large, with a mean circumference of 19%. The procedure time was short: 79 minutes of surgery and 48 minutes of PVL closure. Procedure success was 83%, which is comparable with current literature.9,16,30,31

Aortic PVL
In our limited experience with the transfemoral retrograde approach for aortic PVL, we noticed that the crossability was relatively easy, but the pushability of the catheters was impaired compared with the transapical approach. To provide adequate support of the device delivery catheter, the use of an arteriovenous wire loop might be an option. Alternatively, we decided to close all aortic defects in a transapical manner. Using the transapical approach, the crossability of an aortic PVL is more difficult because the alignment is less straightforward compared with mitral defects. This is especially the case for anterior located aortic defects (9 o’clock; Figure 2). Moreover, subaortic septal hypertrophy may further impede the crossability. Procedure success was 100%, although this could have been biased by the low sample size for aortic lesions (n=7).

Functional Outcomes
To our knowledge, this is the first study that analyzed 6-MWT and QoL after transcatheter PVL closure. Overall,
the mean distance covered by 6-MWT improved with ≈ 50 m at 6 months. This is above the range of previously reported thresholds (31–42 m). Furthermore, a distance covered by 6-MWT<300 m has been previously found to predict mortality. In our cohort, a 6-MWT of ≥300 m at baseline was associated with improved 1-year survival (Figure 4C).

Efficacy at 3-month and 1-year follow-up was 51% and 31%, respectively. This composite was primarily driven by a persistent NYHA functional class >2. Despite a moderate efficacy, QoL and functional capacity measured with the 6-MWT increased. In our opinion, these factors should be the main goal of intervention in this high-risk population.

Clinical efficacy seemed to be only dependent of baseline parameters and comorbidities. Hemolytic anemia was most prevalent in patients without efficacy and with a trace of PVL at follow-up. This might indicate that a small residual PVL remains symptomatic due to a persistent hemolytic anemia due to a high regurgitant flow.

**Assessment of Outcomes**

Evidence on transcatheter PVL closure is limited because most publications are single case reports and no uniformity

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**Table 5. Current Publications on Transapical Transcatheter PVL Closure**

<table>
<thead>
<tr>
<th>First Author</th>
<th>Year</th>
<th>Patients (Mitral, Aortic)</th>
<th>Approach (Minithoracotomy, Transcutaneous)</th>
<th>Used Occluder Device*</th>
<th>Procedure Success</th>
<th>Early Safety</th>
<th>Reoperation</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lim et al18</td>
<td>2008</td>
<td>4 (4, 1)</td>
<td>0, 4</td>
<td>VSD, ASD</td>
<td>?</td>
<td>2 (50)</td>
<td>1 (25)</td>
<td>Iatrogenic VSD requiring surgery (n=1); hematothorax requiring thoracocentesis (n=1)</td>
</tr>
<tr>
<td>Brown et al19</td>
<td>2009</td>
<td>3 (3, 0)</td>
<td>1, 2</td>
<td>VSD</td>
<td>?</td>
<td>?</td>
<td>0 (0)</td>
<td>Hematothorax requiring thoracocentesis (n=1); coronary artery dissection conversion to minithoracotomy (n=1)</td>
</tr>
<tr>
<td>Lang et al19</td>
<td>2010</td>
<td>1 (1, 0)</td>
<td>1, 0</td>
<td>ASD</td>
<td>?</td>
<td>?</td>
<td>0 (0)</td>
<td>Localized pericardial hematoma (n=1); hematothorax requiring rethoracotomy (n=1). Clinical efficacy is 75% (n=3)†</td>
</tr>
<tr>
<td>Larman et al20</td>
<td>2010</td>
<td>1 (1, 0)</td>
<td>1, 0</td>
<td>AVP III</td>
<td>?</td>
<td>?</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Nietlispach et al21</td>
<td>2010</td>
<td>4 (4, 0)</td>
<td>2, 2</td>
<td>AVP III</td>
<td>4 (100)</td>
<td>3 (75)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Martinez et al22</td>
<td>2010</td>
<td>1 (1, 0)</td>
<td>0, 1</td>
<td>VSD</td>
<td>1 (100)</td>
<td>1 (100)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Ruiz et al‡</td>
<td>2011</td>
<td>43 (33, 10)</td>
<td>0, 24</td>
<td>VSD, ASD, PDA, AVP II</td>
<td>35 (81)‡</td>
<td>?</td>
<td>1 (2)</td>
<td></td>
</tr>
<tr>
<td>Sorajja et al§</td>
<td>2011</td>
<td>115 (90, 25)</td>
<td>0, 13</td>
<td>VSD, ASD, PDA, AVP II</td>
<td>11 (85)†</td>
<td>9 (69)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Hammerstingl et al‡</td>
<td>2012</td>
<td>1 (1, 0)</td>
<td>1, 0</td>
<td>AVP III</td>
<td>?</td>
<td>?</td>
<td>?</td>
<td>Device instability and severe recurrent PVL requiring reoperation at 2 wk. Clinical efficacy is 0% (n=0)</td>
</tr>
<tr>
<td>Smith et al‡</td>
<td>2012</td>
<td>1 (1, 0)</td>
<td>1, 0</td>
<td>VSD</td>
<td>1 (100)</td>
<td>0 (0)</td>
<td>1 (100)</td>
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</tr>
<tr>
<td>Guler et al‡</td>
<td>2012</td>
<td>1 (1, 0)</td>
<td>1, 0</td>
<td>ASD</td>
<td>1 (100)</td>
<td>1 (100)</td>
<td>0 (0)</td>
<td>Residual moderate PVL which had resolved at 9 mo (n=1). Clinical efficacy is 100% (n=3)†</td>
</tr>
<tr>
<td>Thourani et al‡</td>
<td>2012</td>
<td>3 (3, 0)</td>
<td>3, 0</td>
<td>ASD, PDA</td>
<td>2 (67)</td>
<td>3 (100)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Nietlispach et al‡</td>
<td>2012</td>
<td>1 (1, 0)</td>
<td>0, 1</td>
<td>VSD</td>
<td>1 (100)</td>
<td>1 (100)</td>
<td>0 (0)</td>
<td>Clinical efficacy is 100% (n=1)†</td>
</tr>
<tr>
<td>Goktekin et al‡</td>
<td>2013</td>
<td>1 (1, 0)</td>
<td>1, 0</td>
<td></td>
<td></td>
<td></td>
<td>1 (100)</td>
<td>1 (100)</td>
</tr>
<tr>
<td>Smolka et al‡</td>
<td>2013</td>
<td>7 (7, 0)</td>
<td>7, 0</td>
<td>AVP III</td>
<td>6 (86)</td>
<td>7 (100)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Nijenhuis et al‡</td>
<td>2014</td>
<td>37 (30, 7)</td>
<td>37, 0</td>
<td>VSD, ASD, AVP, AVP III</td>
<td>32 (86)</td>
<td>30 (81)</td>
<td>6 (16)</td>
<td>Major bleeding (n=4); prosthetic interference requiring reoperation (n=1); recurrent PVL requiring reoperation (n=1). Clinical efficacy is 49% (n=18)†</td>
</tr>
</tbody>
</table>

? indicates unknown due to lack of data; ASD, atrial septal defect; AVP, Amplatzer vascular plug; PDA, patent ductus arteriosus; PVL, paravalvular leakage; and VSD, ventricular septal defect.

*The listed occluder devices concern all the devices used in the complete study, and not all of them may have been used for transapical PVL closure.

Clinical efficacy at 3 mo.

‡Twenty-four of 43 procedures were performed via the transapical transcutaneous approach, results are provided for the entire cohort.

§Thirteen of 115 procedures were performed via the transapical transcutaneous approach for which the results are provided.

║New designed device.
in end point definition exists, compromising comparability and interpretability of the study results. To overcome this issue, we emphasize the use of uniformly defined end points in further studies. In our opinion, the VARC-2\(^{10}\) consortium on end point definition for transcatheter aortic valve implantation procedures provides most suitable success, safety, and efficacy measures for analysis of transcatheter PVL closure.\(^{10}\)

**Future**

Besides the lack of a uniform definition, variability in clinical success in the current literature might partially be explained by an incomplete closure of the defect in the absence of a specifically designed device. The first use of a specifically designed device has recently been reported.\(^{17}\) Until devices like these become available, transcatheter PVL closure should be reserved for high-risk patients who had severe symptoms related to significant PVL in whom optimal medical treatment fails and a heart team agrees that medical factors either preclude operation or are high risk for surgical valve replacement.

**Study Limitations**

The present investigation is a single-center prospective study with consequent inherent limitations. This is reflected by our limited experience with the retrograde or trans-septal approach. Furthermore, the sample size is relatively small, and the follow-up for laboratory tests and the 6-MWT and Minnesota Living with Heart Failure Questionnaire is partially incomplete. Finally, no control group is described to allow comparison with reoperation or optimal medical treatment.

**Conclusions**

Transcatheter PVL closure using an open transcatheter approach in high-risk patients has a high procedural success rate with an acceptable risk of adverse outcomes, similar to other reported approaches to closure. This is the first study to prove a moderate efficacy with an increased functional capacity and QoL after transapical PVL closure. Residual PVL is associated with 1-year mortality. PVL is associated with 1-year mortality.

Disclosures

None.

References


Open Transapical Approach to Transcatheter Paravalvular Leakage Closure: A Preliminary Experience
Vincent J. Nijenhuis, Martin J. Swaans, Martijn C. Post, Robin H. Heijmen, Thomas L. de Kroon and Jurrien M. ten Berg

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Supplemental Material

Video 1. Malpositioned Amplatzer® Muscular VSD Occluder device. Real-time live 3D TEE image of the mitral annulus and mechanical prosthesis en face from the left atrium 4 days after implantation of a Amplatzer® Muscular VSD Occluder device. The device is located anterolateral and shows interference with the lateral mechanic leaflet. Impingement of the prosthesis resulted in a severe valvular regurgitation due to the inability of the lateral leaflet to close.