Percutaneous Treatment Options for Recurrent Mitral Valve Disease after Failed Mitral Valve Surgery

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Abstract

Objectives: Percutaneous treatment options have been described as an alternative to redo-surgery in high-risk patients with recurrent Mitral Regurgitation (MR) after failed Mitral Valve (MV) surgery. We aim to analyze the outcome of percutaneous MV interventions in such patients.

Methods: Seventeen consecutive surgical intermediate to high-risk patients with recurrent MV disease not considered suitable for redo surgery were analyzed. Percutaneous MitraClip repair (n=11), valve-in-ring (n=3) or valve-in-valve (n=3) replacement were performed.

Results: Median age was 76.0 years (53.6 to 89.4 years). Median EuroSCORE II and STS mortality score were 4.5% (0.5 to 14.4%) and 4.9% (1.5 to 20.9%), respectively. Pre-operative MR grade was moderate-severe (n=4, 24%) or severe (n=13, 76%). Interventional success was obtained in all but three cases (82%). 30 day survival rate was 100%. At last follow-up (mean 270 days, range 31 to 1559 days), the overall survival rate was 76%. MR grade was none-mild in 76% was 100%. At last follow-up (mean 270 days, range 31 to 1559 days), the overall survival rate was 76%. MR grade was none-mild in 76% and moderate in 24% of patients. Reduction of dyspnea was achieved in all but 2 patients (88%).

Conclusion: Percutaneous MV treatments after failed MV surgery are feasible and associated with a lower than expected peri-interventional mortality in carefully selected patients not suitable for redo MV surgery. The interventions proved effective regarding reduction in MR and symptoms as well as lowering of pulmonary pressure.

Keywords: Percutaneous mitral valve interventions; Transcatheter mitral valve replacement; MitraClip; Valve-in-ring; Valve-in-valve; Redo mitral valve surgery

Introduction

Mitrval valve regurgitation (MR) is one of the most common valvular diseases [1]. For severe symptomatic mitral valve disease, mitral valve repair or replacement is highly recommended [2]. In the last few years, a better long-term outcome in patients undergoing repair instead of replacement has been shown for patients with primary mitral regurgitation [3,4]. For patients with ischemic MR, there appears to be no benefit of repair over replacement [5]. In surgical high-risk patients, percutaneous mitral valve repair using the MitraClip (MC) has shown to be an important alternative [6,7]. However, surgical mitral valve replacement or repair is more effective in reducing MR than minimal-invasive procedures, so that surgical correction of MR is still regarded the gold standard in patients with a low-risk profile [8].

Nevertheless, the initial surgical treatment may fail over time, resulting in recurrent mitral valve disease. If the patient is old or otherwise at high-risk for redo-surgery, the management of recurrent mitral valve disease can be challenging. For such patients, percutaneous treatment approaches are commonly preferred and are associated with good peri-interventional success [9,10]. Percutaneous mitral valve repair with a MC has been described as a valid option to surgery [11]. However, MC insertion is not always technically feasible, so that other interventions like percutaneous valve-in-ring (VIR) and valve-in-valve (VIV) replacement have been described [12].

The aim of this study was to analyze the outcome of the three percutaneous therapy options (MC in repaired mitral valve, VIR and VIV replacement) in a cohort of selected high-risk and symptomatic patients with a recurrent mitral valve disease not suitable for redo surgery.

Methods

Population

Our retrospective study included 17 symptomatic patients who presented with recurrent mitral valve pathology (MR or mitral stenosis (MS)) after initial mitral valve surgery between September 2011 and September 2015. All patients were reviewed by the local heart team (either at the University Hospital of Zurich or at the Heart Clinic Hirslanden Zürich). The heart teams were composed of cardiac surgeons, interventional
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Cardiologists, cardiac imaging specialists, clinical cardiologists and cardiac anesthetists. The decision on how to proceed with a patient was taken considering all relevant clinical, anatomical and technical aspects. The clinical assessment included the two most commonly used surgical risk scores [EuroSCORE II and STS Risk of Mortality] [13,14]. Age itself is an important risk factor. While lower age was not automatically considered low surgical risk, all octogenarians were considered high risk for redo mitral valve replacement [15]. In addition, the heart teams also considered clinical risk factors missed by both scores, including frailty (clinically assessed, no formal score used), presence of osteoporosis, liver disease, previous complicated surgical course, status post chest radiation and simply the patients unwillingness to undergo redo cardiac surgery at a reduced clinical status. One patient refused redo-surgery despite low peri-operative risk and insisted on a catheter based intervention. Depending on the type of procedure, patients gave informed consent to the appropriate national registry (MitraSwiss registry for MC or the Swiss TAVI registry for VIR and VIV). The study protocol was approved by the ethical committee of Zurich, Switzerland.

Clinical data

Baseline and follow-up clinical data as well as echocardiographic and invasive data were gathered by reviewing the patient’s chart. Follow-up data also consisted of data from the last available report by a cardiologist or family physician.

Procedure

All redo procedures of this study were elective. The type of percutaneous intervention was defined and performed by the local heart team: percutaneous edge-to-edge repair by MC in formerly repaired mitral valves, percutaneous mitral VIR replacement or percutaneous mitral VIV replacement (Figure 1).

**Figure 1:** Types of percutaneous mitral valve interventions

Legend: Examples of the three performed interventions are shown before (A, C, E) and after (B, D, F) the procedure. A) Patient with a recurrent flail of the P2 segment after mitral valve repair with ring annuloplasty ring and B) after MitraClip implantation. C) Patient with restrictive posterior mitral leaftet after ring annuloplasty, resulting in severe recurrent mitral regurgitation and D) after transapical valve-in-ring implantation of a 26mm Sapien XT prosthesis. E) Patient with a degenerated mitral valve prosthesis with flail of the posterolateral cusp, and F) after transapical valve-in-valve implantation of a 26mm Sapien XT prosthesis.

**MitraClip**

The MC intervention as performed at the two centers has been described else were [16]. If feasible, the MC procedure was the procedure of choice in all patients post MV repair and the only option in cases with anuloplasty rings too large for implantation of a Sapien prosthesis. Both pre- and peri-interventional three-dimensional (3D) transesophageal echocardiography (TEE) was performed to ensure optimal imaging guidance and assessment of peri-interventional MR [17]. Meticulous care was taken to ensure visualisation and sufficient height of the posterior mitral valve leaflet and to guarantee minimal mitral valve opening before the procedure (> 3cm²). If the mitral valve orifice area after redo MC was expected to be lower than 2 cm², we opted for a valve in ring procedure. Peri-interventional measurement of transvalvular gradients by continuous wave Doppler was used to assess the peri-interventional change of mitral valve opening area [18].

**Valve-in-ring mitral valve replacement**

As with the MC procedure, pre-interventional 3D TEE and computed tomography was used to assess the exact size and height of the implanted annuloplasty ring as well as the length, calcification and mobility of the anterior mitral leaflet and the width of the left ventricular outflow tract (Figure 2).

**Figure 2:** Transapical mitral valve-in-ring replacement

Legend: Image demonstrating important steps for valve-in-ring replacement. Before the intervention, details of the implanted annuloplasty system, in this case a 28mm Edwards Physio II ring, are studied in vivo using 3D TEE and specialized software for post-processing. The height of the ring is estimated at 4mm, and the landing zone (skirt zone) of the chosen prosthesis (in this case a 26mm Sapien XT prosthesis) measures 8.7mm. During the intervention, precise positioning is guaranteed using fluoroscopy. Post implantation, the position of the prosthesis within the ring is re-analysed. In this case, optimal position could be achieved, leaving no paravalvular regurgitation at all.

Based on these measurements, the size of the percutaneous heart prosthesis (Edwards Sapien XT and Edwards Sapien 3) was defined. Prostheses were implanted using a transapical [9] or transseptal approach, depending on anatomy and concomitant pulmonary disease. The prosthesis was deployed under rapid pacing and simultaneous fluoroscopic and echocardiographic guidance.
Valve-in-valve mitral valve replacement

VIV mitral procedures were performed using an apical or transseptal approach as described above for VIR and as previously described by others [10]. The choice of valve prosthesis was based on pre-interventional 3D TEE imaging, computed tomography and in accordance with the mitral VIV app by Dr. Vinayak Bapat (http://www.ubqo.com/vivmitral) and the website www.valveguide.ch [19].

Definitions of outcome

MR, MS and tricuspid regurgitation (TR) were graded according to European Association of Cardiovascular Imaging’s recommendations [20]. Procedural success was defined as modified device success and absence of adverse events at 30 day post-intervention according to the MVARC criteria [21].

Statistics

Continuous data are expressed as median and range (minimal-maximal value), and categorical data as number and percentage (%). No p-values were calculated due to the small number of subjects. We used Excel version 2007 for statistical analysis.

Results

Baseline characteristics

Patients’ baseline characteristics are summarized in Tables 1 and 2.

<table>
<thead>
<tr>
<th>Table 1: Baseline characteristics</th>
<th>Population (n=17)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- male, n (%)</td>
<td>11 (65%)</td>
</tr>
<tr>
<td>- age at redo intervention, years (range)</td>
<td>76.0 (53.6/89.4)</td>
</tr>
<tr>
<td>- duration of hospital stay, days (range)</td>
<td>5 (2/11)</td>
</tr>
</tbody>
</table>

Clinical Data

- Body surface area, m² (range) | 1.9 (1.2/2.5) |
- BMI, kg/m² (range) | 25.7 (14.9/39.7) |
- Blood Pressure s, mmHg (range) | 118 (93/162) |
- Blood Pressure d, mmHg (range) | 70 (52/88) |
- Heart rate, bpm (range) | 69 (49/91) |
- NYHA ≥ III, n (%) | 12 (71%) |
- EuroScore II, % (range) | 4.5 (0.5/14.4) |
- STS Score Risk of Mortality, % (range) | 4.9 (1.5/20.9) |

Comorbidities

- Hypertension, n (%) | 8 (47%) |
- Coronary artery disease, n (%) | 3 (18%) |
- Atrial fibrillation, n (%) | 4 (22%) |
- Chronic kidney disease ≥ 3, n (%) | 8 (47%) |
- Diabetes mellitus, n (%) | 0 (0%) |
- COPD, GOLD ≥ 3, n (%) | 0 (0%) |
- history of neoplasia, n (%) | 5 (29%) |
- Osteoporosis, n (%) | 2 (12%) |

Drugs

- Diuretics, n (%) | 14 (82%) |
- ACE-inhibitors, n (%) | 7 (41%) |
- Beta blockers, n (%) | 11 (65%) |
- Angiotensin II receptor antagonist, n (%) | 7 (41%) |
- Spironolactone, n (%) | 5 (29%) |
- Statins, n (%) | 9 (53%) |

All data are given as median (range) or numbers (percentage). Abbreviations: BMI: body mass index; NYHA: New York Heart Association; STS: Society of thoracic surgeons; COPD: chronic obstructive pulmonary disease.

<table>
<thead>
<tr>
<th>Table 2: Baseline echocardiographic, invasive and laboratory measurements</th>
<th>Population (n=17)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Echocardiography</td>
<td></td>
</tr>
<tr>
<td>- Ejection fraction, % (range)</td>
<td>63 (40/72)</td>
</tr>
<tr>
<td>- LVEDV, mL/m² (range)</td>
<td>70 (40/114)</td>
</tr>
<tr>
<td>- LAV, mL/m² (range)</td>
<td>68 (41/98)</td>
</tr>
<tr>
<td>- RV/RA, mmHg* (range)</td>
<td>49.2 (20/70)</td>
</tr>
<tr>
<td>- MR ≥ moderate, n (%)</td>
<td>17 (100%)</td>
</tr>
<tr>
<td>- diastolic transmirtal gradient, mmHg (range)</td>
<td>3.2 (1/11)</td>
</tr>
<tr>
<td>- TR grade ≥ moderate**, n (%)</td>
<td>4 (27%)</td>
</tr>
<tr>
<td>Invasive hemodynamic (n = 8)</td>
<td></td>
</tr>
<tr>
<td>- Systolic PAP, mmHg (range)</td>
<td>58 (48/75)</td>
</tr>
<tr>
<td>- Pulm. VR, mmHg* min/mL (range)</td>
<td>373 (240/807)</td>
</tr>
<tr>
<td>Labor</td>
<td></td>
</tr>
<tr>
<td>- Hemoglobin, g/L (range)</td>
<td>130 (95/157)</td>
</tr>
<tr>
<td>- Glomerular filtration rate, ml/ min (range)</td>
<td>53 (24/95)</td>
</tr>
</tbody>
</table>

All data are given as median (range) or numbers (percentage). Abbreviations: LVEDV: left ventricular end diastolic volume, index; LAV: left atrial volume, index; RV/RA: right ventricle/right atrium ratio; MR: mitral regurgitation; TR: tricuspid regurgitation; PAP: pulmonary arterial pressure; VR: vascular resistance. *n= 13, **n = 15

MR grade at baseline was moderate-severe (n=4, 24%) or severe (n=13, 76%). Two patients presented with a concomitant moderate (n=1, 6%) and severe (n=1, 6%) MS, respectively. 8 (47%) patients had a EuroSCORE II > 5 and/or a STS risk mortality score > 8. 8 of the remaining 9 patients with lower risk scores had one or several clinical indicators for a complicated perioperative course and were therefore turned down for redo cardiac surgery. Patient #9 insisted on a minimal invasive procedure despite a low-risk profile (EuroSCORE II 0.5% and STS Score Risk of Mortality 1.5%). No patient with coronary artery disease had signs of ongoing ischemia or relevant stenosis in pre-intervention workup.

Procedures

The index open-heart operations on native mitral valves were mitral valve repair with (n=8; 47%) or without (n=6; 35%) ring-annuloplasty. A mitral valve replacement was performed in the remaining 3 patients (18%, Table 3). Median time to repair failure was 7.9 years (range 1.0 to 18.6 years). The redo-interventions were MC (n=11, 64%), VIR (n=3, 18%) and VIV.

### Table 3: Patient's history and procedure

<table>
<thead>
<tr>
<th>Patient</th>
<th>Reason for 1. intervention</th>
<th>1. Intervention</th>
<th>time to failure (y)</th>
<th>Mode of failure</th>
<th>Age at 2. Intervention (y)</th>
<th>2. Intervention</th>
<th>MR Grade at FU</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Mixed primary &amp; secondary</td>
<td>MV repair without ring</td>
<td>11.4</td>
<td>Recurrent prolapse</td>
<td>86</td>
<td>MitraClip</td>
<td>Mild</td>
<td>Death at 31d</td>
</tr>
<tr>
<td>2</td>
<td>Prolapse</td>
<td>MV repair without ring</td>
<td>7.9</td>
<td>Recurrent prolapse &amp; Flail leaflet</td>
<td>76</td>
<td>MitraClip</td>
<td>Moderate</td>
<td>Alive</td>
</tr>
<tr>
<td>3</td>
<td>Unknown</td>
<td>MV repair without ring</td>
<td>7.7</td>
<td>Degeneration</td>
<td>84</td>
<td>MitraClip</td>
<td>Mild</td>
<td>Death at 1093d</td>
</tr>
<tr>
<td>4</td>
<td>Unknown</td>
<td>MV repair without ring</td>
<td>11.1</td>
<td>Flail leaflet</td>
<td>76</td>
<td>MitraClip (3x)</td>
<td>Moderate</td>
<td>Alive</td>
</tr>
<tr>
<td>5</td>
<td>Prolapse</td>
<td>MV repair without ring</td>
<td>7.0</td>
<td>Flail leaflet</td>
<td>69</td>
<td>MitraClip</td>
<td>Mild</td>
<td>Alive</td>
</tr>
<tr>
<td>6</td>
<td>Prolapse</td>
<td>MV repair without ring</td>
<td>10.5</td>
<td>Recurrent prolapse</td>
<td>73</td>
<td>MitraClip</td>
<td>Mild</td>
<td>Alive</td>
</tr>
<tr>
<td>7</td>
<td>Prolapse</td>
<td>MV repair with ring</td>
<td>18.6</td>
<td>Recurrent prolapse</td>
<td>69</td>
<td>MitraClip in ring</td>
<td>Mild</td>
<td>Alive</td>
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<tr>
<td>8</td>
<td>Unknown</td>
<td>MV repair with ring</td>
<td>15.2</td>
<td>Flail leaflet</td>
<td>88</td>
<td>MitraClip in ring</td>
<td>Mild</td>
<td>Death at 427d</td>
</tr>
<tr>
<td>9</td>
<td>Flail leaflet</td>
<td>MV repair with ring</td>
<td>1.4</td>
<td>Flail leaflet</td>
<td>62</td>
<td>MitraClip in ring (2x)</td>
<td>Moderate</td>
<td>Alive</td>
</tr>
<tr>
<td>10</td>
<td>Functional MR</td>
<td>MV repair with ring</td>
<td>3.2</td>
<td>Dehiscence</td>
<td>54</td>
<td>MitraClip in ring (3x)</td>
<td>None</td>
<td>Alive</td>
</tr>
<tr>
<td>11</td>
<td>Prolapse</td>
<td>MV repair with ring</td>
<td>1.2</td>
<td>Recurrent prolapse</td>
<td>58</td>
<td>MitraClip in ring (2x)</td>
<td>Moderate</td>
<td>Alive</td>
</tr>
<tr>
<td>12</td>
<td>Anulusdilatation &amp; Tethering</td>
<td>MV repair with ring</td>
<td>2.3</td>
<td>Restrictive posterior leaflet</td>
<td>79</td>
<td>Valve-in-ring, Sapien XT 26mm (transapical)</td>
<td>Mild</td>
<td>Alive</td>
</tr>
<tr>
<td>13</td>
<td>Infectious endocarditis</td>
<td>MV repair with ring</td>
<td>1.0</td>
<td>Degenerative/ Stenotic</td>
<td>73</td>
<td>Valve-in-ring, Sapien 3 26mm (transapical)</td>
<td>None*</td>
<td>Alive</td>
</tr>
<tr>
<td>14</td>
<td>Unknown</td>
<td>MV repair with ring</td>
<td>7.0</td>
<td>Flail leaflet</td>
<td>77</td>
<td>Valve-in-ring, Sapien 3 29mm (transseptal)</td>
<td>Mild</td>
<td>Alive</td>
</tr>
<tr>
<td>15</td>
<td>Infectious endocarditis</td>
<td>MV replacement</td>
<td>13.3</td>
<td>Flail leaflet</td>
<td>89</td>
<td>Valve-in-valve, Sapien XT 26mm (transapical)</td>
<td>None</td>
<td>Death at 394d</td>
</tr>
<tr>
<td>16</td>
<td>Unknown</td>
<td>MV replacement</td>
<td>9.8</td>
<td>Flail leaflet</td>
<td>80</td>
<td>Valve-in-valve, Sapien 3 29mm (transapical)</td>
<td>None</td>
<td>Alive</td>
</tr>
<tr>
<td>17</td>
<td>Post-rheumatic</td>
<td>MV replacement</td>
<td>8.2</td>
<td>Degeneration</td>
<td>85</td>
<td>Valve-in-valve, Sapien 3 26mm (transseptal)</td>
<td>None*</td>
<td>Alive</td>
</tr>
</tbody>
</table>

Abbreviations: MV: mitral valve; MR: mitral regurgitation; FU: Follow-up. *minimal trace of paravalvular regurgitation
Clinical findings

NYHA class was available from 16 patients (94%). Of those, a reduction in NYHA class was achieved in 14 cases (88%, Figure 3).

Dyspnea reduction by 1, 2 or 3 classes was described in 6 (43%), 7 (50%) and 1 (7%) patients, respectively. The two patients (12%) who did not show improvements concerning dyspnea both underwent MitraClip repair.

Echocardiographic findings

MR grade was reduced in all patients after the second intervention (Figure 4).

A moderate MR was observed in 4 patients (24%), all of whom had undergone MC repair. All 4 patients were alive at last follow-up. The two patients with intra-procedural complications showed both optimal echocardiographic findings. The paravalvular leaks in the patient #13 and #17 did not worsen until last follow-up. The median transmitral diastolic gradient increased from 3.2 mmHg at baseline to 5.2 mmHg (range 3.0 to 9.0 mmHg). In 6 (40%) of 15 available cases a reduction in TR was observed,
while there was progression from a mild to a moderate TR after the intervention in 2 MC patients (13%). The percutaneous redo-intervention reduced the RV/RA pressure gradient by a median of 15.4 mmHg (Figure 5).

**Impact of Treatment Strategy on Technical Result**

In addition to the data published on MC interventions in patients who had undergone mitral valve repair, our study demonstrates that MC treatment can also be safely and effectively offered to patients who had undergone repair without ring. In experienced hands, the MC intervention can be performed with a procedural time of around 30 minutes, thus offering the advantage of very short general anesthesia with minimal installations. On the downside, mitral valve repair by MC shows generally lower reduction of MR compared to mitral valve replacement [28]. In patients undergoing MC procedures in native valves, moderate or more residual MR was associated with worse outcome compared to mild or trace MR [29]. Based on the scarce literature it is not known whether the same holds true for patients with moderate residual MR following redo interventions using MC.

The valve prosthesis and access route of choice for redo transcatheter mitral valve replacement is a matter of debate. At this time, balloon-expandable aortic Sapien XT or Sapien 3 valves (Edwards Life sciences, Irvine, California) are predominantly reported in series describing percutaneous mitral VIR or VIV replacement [9,12,23,25]. Other types of valves are either under investigation, anatomically not suitable or described only in few number of studies. Based on the experiences of transcatheter aortic valve implantations, the initial access route for percutaneous mitral valve replacement was transapical, enabling good alignment with the ring/prosthesis in mitral position [10]. The development of third and fourth generation percutaneous valves with advanced steering capabilities of the catheter has promoted the transseptal approach in recent publications [23,25,27]. The use of the recently developed real time fusion imaging techniques like EchoNavigator (Phillips Healthcare, Amsterdam, Netherlands) further facilitates such interventions [30,31]. The rate of mild paravalvular MR of 33% in our cohort reflects the results of others [26]. Considering an occurrence rate of paravalvular MR after surgical MV replacement in native valves between 5-17% [32], these initial studies may suggest that paravalvular MR are more likely to occur during VIR and VIV. Access route might play a role in this regard as optimal axonal orientation of the prosthetic valve within the annuloplasty ring is more easily reached using an apical compared to a transeptal approach.

**Heart Team Approach**

To be able to offer therapy across such a large field of interventional cardiology and cardiac surgery asks for a true

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heart team approach. As is demonstrated by our data, it is not sufficient to be able to perform the one or other strategy. It is the ability to cope with unexpected events or complications that make such demanding interventions successful. In order to prevent emergency treatments, pre-interventional imaging plays a crucial role, in particular in patients with a repaired mitral valve. The decision whether a MC procedure or a percutaneous implantation of a mitral prosthesis is feasible and will result in durable benefit largely depends on morphological criteria, including definition of MR etiology, visibility of mitral valve leaflets, assessment of the mitral valve area and anterior mitral leaflet length, mobility and calcification as well as left ventricular outflow tract anatomy and annuloplasty ring characteristics [18,33]. The decision on the procedure of choice was taken based on a patient by patient analysis, taking into account all available clinical and imaging data as described above. Even then, prediction of procedural success was not perfect, as demonstrated by the two patients where the interventions were complicated and additional ‘ad-hoc’ strategies had to be developed during the procedure.

**Study limitations**

The main limitation of the present study is the small number of study subjects and the retrospective non-randomized study design. Moreover, follow-up time differed quite a bit between patients, so that statistically significant comparisons are difficult. As described above, mainly patients not suitable for redo-surgery due to elevated surgical risk were recruited, so that the interventions under investigation may not show similar results in patients with lower risk profile. It’s important to point out that the supporting medical therapy was different from patient to patient. This may have additionally influenced outcome differences between the three procedures.

**Conclusion**

Percutaneous mitral valve treatments (MitraClip repair, valve-in-ring or valve-in-valve replacement) are feasible and safe treatment options for carefully selected patients with failing previous mitral valve operation not suitable for redo MV surgery. The interventions are associated with a lower than expected 30 day mortality. Overall survival during a mean follow-up time of 270 days was 76%. The interventions proved effective regarding mortality. Overall survival during a mean follow-up time of 270 days was 76%. The interventions proved effective regarding mortality. Overall survival during a mean follow-up time of 270 days was 76%.

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