Transcatheter Procedure for Residual Mitral Regurgitation After MitraClip Implantation Using Amplatzer Duct Occluder II

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ABSTRACT

OBJECTIVES This study reports a novel transcatheter procedure for residual mitral regurgitation (MR) after MitraClip implantation using the Amplatzer Duct Occluder II (ADO II).

BACKGROUND Although the MitraClip procedure is a transcatheter treatment option for patients at high surgical risk with severe MR, management of significant residual MR after MitraClip implantation is still challenging.

METHODS We describe a case series of 9 consecutive patients who underwent transcatheter deployment of the ADO II plug for significant residual MR after MitraClip implantation from April to October 2015.

RESULTS The mean age was 79.3 ± 11.4 years. The deployment of the ADO II plug was performed at the initial MitraClip procedure in 7 patients and at the second procedure for recurrent symptoms in 2 patients. There were 2 types of residual MR seen after MitraClip implantation: residual commissural MR (n = 3) and residual intraclip MR (n = 6). The ADO II was successfully deployed with significant reduction of MR flow and left atrial pressure in all patients. The ADO II plug was retrieved in 1 patient because of device embolization to the ostial right coronary artery. However, all patients were discharged 1.8 ± 1.2 days after the procedure, with no significant MR on pre-discharge transthoracic echocardiography. In 8 patients who underwent 1-month symptomatic assessment, clinical symptoms were diminished to New York Heart Association functional class I or II.

CONCLUSIONS Transcatheter deployment of the ADO II plug was effective for the reduction of residual commissural MR and intraclip MR after MitraClip implantation. The potential role of this technique should be established for challenging cases. (J Am Coll Cardiol Intv 2016;9:1280–8) © 2016 by the American College of Cardiology Foundation.

Severe mitral regurgitation (MR) is associated with mortality, left ventricular dysfunction, and progression of congestive heart failure (1-3). Currently, surgical mitral valve repair or replacement is the standard treatment for symptomatic patients with significant MR. However, a large number of patients who have high surgical risk or comorbidities are not referred to open heart surgery (4). Percutaneous mitral valve repair with the MitraClip (Abbott Vascular, Santa Clara, California) system has emerged as a transcatheter treatment option for selected patients at high surgical risk with significant MR. The EVEREST II (Endovascular Valve Edge-to-Edge Repair Study) randomized trial showed better safety and similar clinical outcomes of MitraClip therapy compared with mitral valve surgery (5). After
MitraClip implantation, residual MR is observed between the clips as well as laterally and medi ally to the clips. Several studies have found that significant residual MR was associated with worse clinical outcomes after the MitraClip procedure (6–8). Therefore, residual MR has been a clinically important problem.

However, the management of residual MR remains a challenging issue, because the mitral anatomy and limited space can prohibit the placement of an additional clip. On the basis of the concept of percutaneous mitral paravalvular leak closure (9), residual MR can be managed using the Amplatzer occluder device. One case report showed successful management of residual MR between clips by transcatheter deployment of the occluder device (10). However, the optimal strategy, efficacy, and potential complications of this technique remain unclear. In this report, we present a case series of management for residual MR after MitraClip implantation using the Amplatzer Duct Occluder II (ADO II, St. Jude Medical, Minneapolis, Minnesota).

METHODS

STUDY POPULATIONS. From July 2014 to October 2015, the MitraClip procedure was performed in 129 patients with significant MR. Among them, this report describes 9 consecutive patients who underwent transcatheter deployment of the ADO II plug for significant residual MR after MitraClip implantation. All procedures were performed in the cardiac catheterization laboratory at Cedars-Sinai Medical Center from April to October 2015 (a total of 70 MitraClip procedures were performed in this period). All patients were evaluated by a cardiac surgeon and an interventional cardiologist and were deemed at high or prohibitive risk for mitral valve surgery. All patients provided written informed consent for the MitraClip procedure and for additional device implantation if adequate MR reduction was not obtained only by MitraClip implantation.

PROCEDURE. The procedure was performed under general anesthesia with fluoroscopic and transesophageal echocardiographic (TEE) guidance. Percutaneous femoral vein access was obtained after the pre-closure technique using a Perclose ProGlide suture (Abbott Vascular). Transseptal puncture was performed with a Brockenbrough needle through an SL-1.0 sheath (St. Jude Medical). At this point, unfractionated heparin was administered to maintain an activated clotting time longer than 250 s. The MitraClip procedure was performed as previously described (5). After clip implantation, we discussed the severity and location of residual MR with the cardiac echocardiographer and cardiac anesthesiologist. In patients with significant residual MR, we decided to deploy the ADO II plug if additional clip implantation was deemed unfeasible because of limited space. After the clip delivery system was removed, a 0.032-inch guidewire was advanced through the MitraClip guide catheter to the left atrium. The guide catheter was exchanged to the 16-F venous sheath, and an 8.5-F Agilis steerable sheath (St. Jude Medical) was advanced to the left atrium. When deployment of the ADO II plug was performed just after transseptal puncture at the second procedure for residual MR after the initial MitraClip procedure, a 0.032-inch guidewire was advanced to the left upper pulmonary vein, and the 8.5-F Agilis steerable sheath was introduced to the left atrium. The Agilis catheter was flexed and steered toward the residual leak of the mitral valve. A 6-F Multipurpose guide catheter was telescop ed through the Agilis sheath and used to direct a 0.035-inch straight Glidewire (Terumo Medical Corporation, Tokyo, Japan) or a 0.018-inch v-18 guidewire (Boston Scientific, Marlborough, Massachusetts) through the residual leak. The 6-F Multipurpose guide catheter was then passed over the wire into the left ventricle. On the basis of TEE and fluoroscopic findings, an optimal size of the ADO II plug was selected and deployed. The ADO II is made of a fabric-free, micronitinol mesh pattern that may reduce the incidence of hemolysis and has low-profile retention disks at either end that are larger than the connecting waist diameter. The distal disk of the ADO II was deployed through the Multipurpose guide catheter in the left ventricle. The entire unit was then pulled back until the distal disk was in place. The plug was stabilized as the Multipurpose catheter was pulled back to unseat the waist and proximal disk. After the deployment of the ADO II plug in the residual leak, residual regurgitant flow, mitral valve pressure gradient, and device stability were assessed. Once these were confirmed, the device was released. All catheters were removed, and venous access was closed using the Perclose ProGlide suture system.

FOLLOW-UP. Follow-up transthoracic echocardiographic (TTE) imaging was performed before discharge. New York Heart Association (NYHA) functional class assessment, laboratory testing, and TTE
imaging were scheduled to be performed at the 1-month follow-up office visit. If patients were unable to present at follow-up, their survival and NYHA functional class status at 1 month were collected by hospital records or telephone interview. Baseline and post-procedural MR severity was assessed as previously reported (11,12).

**DATA ANALYSIS.** Data are expressed as mean ± SD for continuous variables. Categorical variables are reported as numbers with relative percentage. SPSS version 20 (IBM Corporation, Armonk, New York) was used for all statistical analysis.

**RESULTS**

**BASELINE CHARACTERISTICS.** Baseline demographic and echocardiographic characteristics of the 9 patients are shown in Table 1. The mean age was 79.3 ± 11.4 years, and the mean Society of Thoracic Surgeons score was 9.0 ± 4.9. The proportion of patients in NYHA functional classes III and IV was 88.9%. Initial MR etiology was degenerative in 6 patients (66.7%), functional in 2 patients (22.2%), and mixed in 1 patient (11.1%). Among the 6 patients with degenerative MR, 1 patient had an anterior commissural flail leaflet. The mean left ventricular ejection fraction was 53.5 ± 18.8%. The deployment of the ADO II plug was performed immediately following the initial MitraClip procedure in 7 patients (77.8%) and as a second procedure for recurrent heart failure symptoms in 2 patients (22.2%).

**MITRACLIP PROCEDURE AND RESIDUAL MR TYPE.** During the MitraClip procedure, the mean time from femoral vein puncture to transseptal puncture was 15.8 ± 5.8 min and from transseptal puncture to release the last clip was 97.7 ± 35.9 min (7 patients). Two patients received 1 clip, 4 patients received 2 clips, and 1 patient received 3 clips (Table 2). In the 2 patients with recurrent heart failure symptoms, 2 clips were implanted in 1 patient and 3 clips in the other patient at the time of the initial MitraClip procedures. Neither patient received additional clip implantation at the second procedure. There were 2 types of residual MR observed on TEE imaging before device deployment: residual MR between the clip and mitral valve annulus (residual commissural MR) (Figure 1A, case 1) and residual MR between the clips (residual intraclip MR) (Figure 1B, case 4). Residual commissural MR was observed in 3 patients (33.3%) and residual intraclip MR in 6 patients (66.7%) (Table 2).

**ADO II DEPLOYMENT.** For residual MR closure using the ADO II, the guidewire was first successfully inserted through the residual leak into the left ventricle in all patients (Figures 2A and 2B). On the basis of TEE and fluoroscopic findings, we used the 6/6-mm ADO II in 5 patients, the 6/4-mm ADO II in 1 patient, the 5/6-mm ADO II in 1 patient, and the 5/4-mm ADO II in 2 patients (Table 2). The ADO II was then successfully deployed in all patients for the commissural or intraclip position for their respective regurgitant jet origins (Figure 3). The mean time from the last clip release (or transseptal puncture) to device release was 31.0 ± 10.0 min.

Residual MR grade was significantly improved after device deployment (Table 3), and fluoroscopic and TEE images confirmed stable ADO II plug positioning either between the clip and the mitral valve annulus (Figure 4A, case 1) or between the clips.
Figure 4B, case 4). TEE imaging showed improvement of pulmonary vein flow pattern after device deployment (Table 3). Hemodynamically, marked reductions of V-wave and mean left atrial pressure were observed after the device deployment (V-wave, from 27.3 ± 7.7 mm Hg to 17.6 ± 8.3 mm Hg; mean left atrial pressure, from 18.6 ± 4.1 mm Hg to 12.9 ± 5.6 mm Hg) (Table 3). Mitral valve mean pressure gradient was not elevated after ADO II deployment (from 4.1 ± 2.0 mm Hg to 3.4 ± 1.5 mm Hg).

**IN-HOSPITAL COURSE.** In 1 patient undergoing ADO II deployment for residual intraclip MR, acute chest pain occurred 9 h after the procedure, with ST-segment elevation on electrocardiography (case 7). Coronary angiography was performed on the

**TABLE 2** Procedural Summary of 9 Patients Undergoing Transcatheter Deployment of Amplatzer Duct Occluder II for Residual Mitral Regurgitation

<table>
<thead>
<tr>
<th>Case #</th>
<th>Timing of Procedure</th>
<th>MR Type</th>
<th>No. of Clips</th>
<th>Residual MR Location</th>
<th>ADO II Size (mm)</th>
<th>Final MR Grade</th>
<th>Device Deployment Time (min)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Initial DMR (anterior commissural flail)</td>
<td>1</td>
<td>Lateral to clip (commissural MR)</td>
<td>6/6</td>
<td>1+</td>
<td>34</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Second FMR (nonischemic)</td>
<td>2</td>
<td>Between clips (intraclip MR)</td>
<td>6/6</td>
<td>1+</td>
<td>51</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Second DMR (P2-P3 flail)</td>
<td>3</td>
<td>Between medial 2 clips (intraclip MR)</td>
<td>6/6</td>
<td>2+</td>
<td>27</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Initial Mixed MR (ischemic, P2 flail)</td>
<td>3</td>
<td>Between medial 2 clips (intraclip MR)</td>
<td>5/6</td>
<td>1+</td>
<td>31</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Initial DMR (P3 flail)</td>
<td>1</td>
<td>Medial to clip (commissural MR)</td>
<td>6/4</td>
<td>1+</td>
<td>33</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Initial DMR (A1-A2 prolapse)</td>
<td>2</td>
<td>Between clips (intraclip MR)</td>
<td>5/4</td>
<td>2+</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Initial DMR (P2 flail)</td>
<td>2</td>
<td>Between clips (intraclip MR)</td>
<td>5/4</td>
<td>1+</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Initial FMR (nonischemic)</td>
<td>2</td>
<td>Between clips (intraclip MR)</td>
<td>6/6</td>
<td>2+</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Initial DMR (P1-P2 flail)</td>
<td>2</td>
<td>Lateral to clips (commissural MR)</td>
<td>6/6</td>
<td>1+</td>
<td>38</td>
<td></td>
</tr>
</tbody>
</table>

*Time from last clip release (or transseptal puncture) to device deployment.
ADO II = Amplatzer Duct Occluder II; DMR = degenerative mitral regurgitation; FMR = functional mitral regurgitation; MR = mitral regurgitation.

**FIGURE 1** Residual Commissural Mitral Regurgitation and Intraclip Mitral Regurgitation After MitraClip Implantation

(A) Severe eccentric mitral regurgitation (MR) with anterior commissural prolapse on baseline transesophageal echocardiography (TEE) (top). After 1 clip was implanted as close as possible to the anterior commissure, TEE showed moderate to severe residual commissural MR with residual commissural prolapse (red arrow) lateral to the clip (bottom). (B) Severe wide central MR on baseline TEE (top). After 3 clips were implanted, there was still moderate to severe residual intraclip MR (red arrow), mainly originating between the most medial 2 clips (bottom). Ao = aortic valve; LA = left atrium; LAA = left atrial appendage; LV = left ventricle.
diagnosis of acute myocardial infarction, and the ADO II plug was embolized in the ostium of the right coronary artery on coronary angiography (Figure 5). The device was successfully retrieved by a snare catheter. After removal of the device, the clinical symptoms and ST-segment changes were alleviated. The mean length of hospital stay after the procedure was 1.8 ± 1.2 days. TTE imaging at discharge
showed no significant MR, with grade 2+ MR in 5 patients and grade 0/1+ MR in 4 patients.

**EARLY OUTCOMES.** All 9 patients were alive at 1 month. NYHA functional class was assessed in 8 patients and had improved to class I or II in all patients (class II in 6 patients and class I in 2 patients). Laboratory test and TTE results were obtained in 5 patients. Serum creatinine level assessed by laboratory testing was not changed from baseline (1.90 ± 0.69 mg/dl) to 1-month follow-up (1.68 ± 0.62 mg/dl). Hemoglobin level at 1-month follow-up (10.9 ± 0.7 mg/dl) was similar to baseline (10.8 ± 1.2 mg/dl), and there was no evidence of hemolytic anemia. TTE results showed grade 1+ MR in 2 patients, grade 2+ MR in 2 patients, and grade 3+ MR in 1 patient. The ADO II plugs were stable in all 5 patients.

**DISCUSSION**

This case series demonstrates a novel procedure using the ADO II plug for 2 different types of residual

### Table 3: Echocardiographic and Hemodynamic Changes After Amplatzer Duct Occluder II Deployment

<table>
<thead>
<tr>
<th></th>
<th>Pre-MitraClip</th>
<th>Pre-ADO II</th>
<th>Post-ADO II</th>
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<tbody>
<tr>
<td>Mitral regurgitation grade</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0/1+</td>
<td>0</td>
<td>0</td>
<td>6 (66.7)</td>
</tr>
<tr>
<td>2+</td>
<td>0</td>
<td>0</td>
<td>3 (33.3)</td>
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<tr>
<td>3+</td>
<td>1 (14.3)</td>
<td>7 (77.8)</td>
<td>0</td>
</tr>
<tr>
<td>4+</td>
<td>6 (85.7)</td>
<td>2 (22.2)</td>
<td>0</td>
</tr>
<tr>
<td>MV mean pressure gradient, mm Hg</td>
<td>3.4 ± 2.4</td>
<td>4.1 ± 2.0</td>
<td>3.4 ± 1.5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pulmonary vein flow pattern</th>
<th></th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Systolic reversal</td>
<td>5 (71.4)</td>
<td>2 (22.2)</td>
<td>0</td>
</tr>
<tr>
<td>Systolic blunted</td>
<td>2 (28.6)</td>
<td>7 (77.8)</td>
<td>3 (33.3)</td>
</tr>
<tr>
<td>Normal pattern</td>
<td>0</td>
<td>0</td>
<td>6 (66.7)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Left atrial pressure, mm Hg</th>
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<tbody>
<tr>
<td>A-wave pressure</td>
<td>21.6 ± 9.3</td>
<td>18.7 ± 6.3</td>
<td>13.7 ± 5.7</td>
</tr>
<tr>
<td>V-wave pressure</td>
<td>43.6 ± 18.5</td>
<td>27.3 ± 7.7</td>
<td>17.6 ± 8.3</td>
</tr>
<tr>
<td>Mean pressure</td>
<td>23.0 ± 8.7</td>
<td>18.6 ± 4.1</td>
<td>12.9 ± 5.6</td>
</tr>
</tbody>
</table>

Values are n (%) or mean ± SD. *Seven patients underwent MitraClip implantation just before ADO II deployment.

ADO II = Amplatzer Duct Occluder II; MV = mitral valve.

**FIGURE 4** Deployment of Amplatzer Duct Occluder II in 2 Types of Residual Mitral Regurgitation

(A) Mild mitral regurgitation (MR) after Amplatzer Duct Occluder II (ADO II) deployment for residual commissural jets (left). There was a well-seated device (white arrows) just lateral to the clip, and no residual commissural prolapse was seen on 3-dimensional (3D) trans-esophageal echocardiography (TEE) (middle) and by fluoroscopy (right). (B) Mild residual MR after ADO II deployment (left). There was a well-seated device (white arrows) between the 2 clips on 3D TEE (middle) and fluoroscopy (right). Ao = aortic valve; LA = left atrium; LAA = left atrial appendage; LV = left ventricle.
MR after the MitraClip procedure. The transcatheter deployment of the ADO II plug between the 2 clips was useful to reduce significant intraclip MR after MitraClip implantation. When residual MR is treated after the first clip implantation, the second clip should be delivered and implanted parallel to the first clip to grasp the maximum amount of leaflet tissue (13). However, in some cases with more complex mitral valve anatomy and morphology, residual MR cannot be treated completely using multiple clips, and residual jets are left between the clips. Because additional clip implantation can interfere with the existing clips, transcatheter occluder device deployment would be an attractive solution for these intraclip jets. Furthermore, we also successfully treated residual commissural MR using the ADO II plug. Although noncentral MR can be treated using the MitraClip system (14), mitral valve commissural leaks present unique anatomic challenges. The maneuver of the clip around the mitral valve commissural area increases the risk for complications because of the complex structure of the chordae tendineae (15). Therefore, the treatment option of percutaneous closure of residual MR after MitraClip placement can avoid the risk for clip entanglement and ruptured chordae. This strategy can expand the indication of percutaneous treatment for significant MR within this anatomic subtype. ADO II plug deployment improved MR flow and hemodynamic status in these 2 types of residual jets. Importantly, device deployment did not affect the mitral valve pressure gradient. This technique should be considered to treat anatomically challenging high-risk cases using the MitraClip procedure.

Our technique was simplified and applied in all patients. It can be performed during the index MitraClip procedure or as a secondary procedure as needed. Also, procedure time to proceed to deployment of the ADO II was much shorter compared with the MitraClip procedure itself. As recently reported, a 6-F guiding catheter can be advanced through the deflectable MitraClip guiding catheter when the residual leak is crossed (10). In this study, a deflectable left atrial sheath such as the Agilis sheath was used because it can allow easier crossing of a small intraclip or commissural leak regardless of the leak position. After insertion of the guiding catheter, the ADO II can be easily delivered through the same guiding catheter, which may enhance deliverability and limit interaction and stress on previously placed clips. A previous case report described an intraclip jet treated with the Amplatzer Vascular Plug II (St. Jude Medical) (10). However, we chose the ADO II plug in this situation because the larger retention disks than waist size may hold the device steady between the clips. Additionally, the smaller central soft waist of the ADO II may limit interaction with the recent implanted clips. We believe the current technique is a reasonable option to fix the residual MR after the MitraClip procedure.

Device size was chosen according to fluoroscopic and TEE findings. Fluoroscopic assessment is useful for residual intraclip jets. The gap width between the clips can be estimated on the basis of the fluoroscopic gap between the clips, because the clip generally grasps the wider leaflet tissue compared with the clip width. On TEE imaging, 3-dimensional quantification measurement of the

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**FIGURE 5** Device Embolization After Amplatzer Duct Occluder II Deployment for Residual Intraclip Mitral Regurgitation

Severe mitral regurgitation (MR) and wide P2 fail with calcified chordae (red arrow) (left). After 2 clips were implanted, Amplatzer Duct Occluder II (ADO II) (white arrow) was deployed between the clips (middle). In fluoroscopic images 9 h after the procedure, ADO II embolization (white arrow) was seen in the ostium of the right coronary artery (right). LA = left atrium; LV = left ventricle.
residual regurgitant orifice is helpful to select the optimal device size (Figure 6). A device waist length of 4 or 6 mm was used in this series. When the greater leaflet tissue seems to be grasped into the MitraClip, a waist length of 6 mm may be better to hold the leaflet tissue between the distal disks.

The potential complications of this technique are device embolization and hemolysis. Device embolization occurred after the procedure in 1 patient; however, the device was successfully retrieved. In this case, there was a wide P2 flail leaflet with calcified chordae (Figure 4), and it was difficult to close the lateral clip completely, because of the thick calcified tissue. The residual hole was potentially larger than expected. Furthermore, the highly mobile leaflet even after 2 clips are implanted might leave the device unstable. Therefore, a larger device should be selected to keep the device steady in this situation. Before releasing the device, a strong tug test would be recommended to check the device's stability. Postprocedural hemolysis was not observed in this case series. However, hemolysis was documented after using the Amplatz Septal Occluder and Ventricular Septal Defect Occluder (St. Jude Medical) in different clinical settings (16,17). The high-velocity blood flow through a larger caliber nitinol mesh with fabric structure can cause hemolysis in these devices (18). Because residual MR jets have high-velocity flow, fine nitinol mesh and fabric-free devices such as the ADO II and Amplatzer Vascular Plug II may be more suitable to treat residual MR after MitraClip placement.

At 1-month follow-up in 5 patients, there was no evidence of hemolysis or device embolization. Therefore, device durability may be expected if the optimal size of the occluder device is selected during the procedure.

**STUDY LIMITATIONS.** First, this was a single-center and observational study in a small case series of highly selected patients with only a short-term follow-up period. Longer follow-up observation with a larger population would be necessary to confirm long-term efficacy and safety. Second, because the maximum size of the ADO II is 6 mm at the waist, greater residual leakage areas become more difficult to treat. Therefore, it is important to reduce the residual gap either between the clip and mitral valve annulus or between the clips during the MitraClip procedure.

**CONCLUSIONS**

Our report reveals the efficacy of transcatheter deployment of the ADO II for 2 different residual leak types after the MitraClip procedure to achieve MR reduction and hemodynamic improvement. The potential role of this technique should be established for challenging cases such as residual commissural MR and intraclip MR.

**REPRINT REQUESTS AND CORRESPONDENCE:** Dr. Saibal Kar, Heart Institute, Cedars-Sinai Medical Center, 8631 West 3rd Street, #415E, Los Angeles, California 90048. E-mail: karsk@cshs.org.
WHAT IS KNOWN? The MitraClip procedure is a transcatheter treatment option for patients at high surgical risk with severe MR. However, management of significant residual MR after MitraClip implantation is still challenging.

WHAT IS NEW? This case series demonstrates a newer transcatheter procedure using the ADO II plug for 2 different types of residual MR (intraclip and commissural MR) after the MitraClip procedure. This technique is a simple solution to achieve MR reduction and hemodynamic improvement for residual MR after MitraClip implantation.

WHAT IS NEXT? Longer follow-up observation with a larger population is necessary to confirm the long-term efficacy and safety of this procedure.

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KEY WORDS Amplatzer Duct Occluder II, edge-to-edge mitral valve repair, mitral regurgitation