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EDITORIAL COMMENT

# MitraClip With Occluder

## Augmenting a Proven Therapy*

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MitraClip therapy is a well-established transcatheter treatment for patients with symptomatic mitral regurgitation (MR) and high surgical risk. To date, more than 30,000 patients have been treated worldwide. Restoring coaptation between the anterior and posterior mitral leaflets with satisfactory reduction of MR can generally be accomplished with the use of 1 or more MitraClips, but in some cases there remains significant (grade ≥3+) residual MR.

The mechanisms for residual MR after MitraClip therapy are multiple. There are anatomic reasons for inadequate reduction of MR, such as adverse leaflet pathology with flail leaflets and/or loss of chordal support. In these cases, the leaflets are challenging to grasp because of hypermobility and wide flail gaps; consequently, the leaflets at the area of maximal MR cannot be easily grasped. Some patients have focal calcification of the mitral leaflet edge that precludes placement of a clip at that location. Other anatomic reasons include commissural (or noncentral) MR, in which complex leaflet and chordal arrangements make clip placement challenging. There may also be some degree of mitral stenosis that limits the total number of clips that can be placed, especially in patients with thickened leaflets or with mitral annular calcification. Technical challenges to MitraClip therapy include poor transesophageal echocardiographic windows that limit leaflet visualization, or difficulty aligning and positioning the clips in patients with rotated cardiac anatomy or kyphosis. In these cases, the final result can be suboptimal despite best efforts, and alternative strategies for MR reduction should be considered.

The report by Kubo et al. (1) in this issue of *JACC: Cardiovascular Interventions* provides a possible alternative for challenging MitraClip cases with residual MR. This report describes the experience of a single high-volume center in treating 9 patients with a newer (though not entirely novel) technique for addressing residual MR. These 9 patients, treated over a 7-month period, had inadequate MR reduction (MR grade 3 or 4+) and were therefore treated with the Amplatzer Duct Occluder (ADO) II device at the time of the initial MitraClip procedure (n = 7) or during a separate, second procedure (n = 2). The investigators were able to show a significant acute reduction of MR using this technique in all 9 patients.

SEE PAGE 1280

The ADO II Occluder is a self-expanding nitinol mesh device originally designed for the occlusion of patent ductus arteriosus. The device consists of a central waist with 2 retention discs. The central waist is designed to fill the patent ductus arteriosus, and the 2 retention discs are deployed on the arterial and venous sides of the patent ductus arteriosus. The device is sized by 2 dimensions, X and Y, where X is the diameter of the central waist and Y is the length of the central waist. The investigators chose this device because the larger retention discs would theoretically be deployed on the atrial and ventricular sides of the mitral leaflets, thereby securing the waist in the defect. The available diameters of the central waist vary from 3 to 6 mm in 1-mm increments, and each diameter is available in a waist length of either 4 or 6 mm. For instance, if the central waist of the ADO II is 6 mm wide and 4 mm long, it is named the 6/4 mm ADO II device. The retention discs vary in diameter from 9 to 12 mm depending on the waist diameter, and all ADO II devices can be placed through a 6-F

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coronary guide. Alternately, I and others have used the Amplatzer Vascular Plug (AVP) II for the occlusion of residual regurgitant jets after MitraClip therapy (2). This device differs from the ADO II in that the waist and 2 retention discs are all the same diameter (Figure 1). The AVP II device is available in diameters ranging from 3 to 22 mm; up to a 12-mm AVP II device can be delivered through a 6-F coronary guide. The deployment technique for an AVP II device is similar to that for an ADO II: the distal retention disk is deployed in the left ventricle, the waist is deployed in the residual regurgitant orifice, and the proximal disc is deployed on the left atrial side of the leaflets.

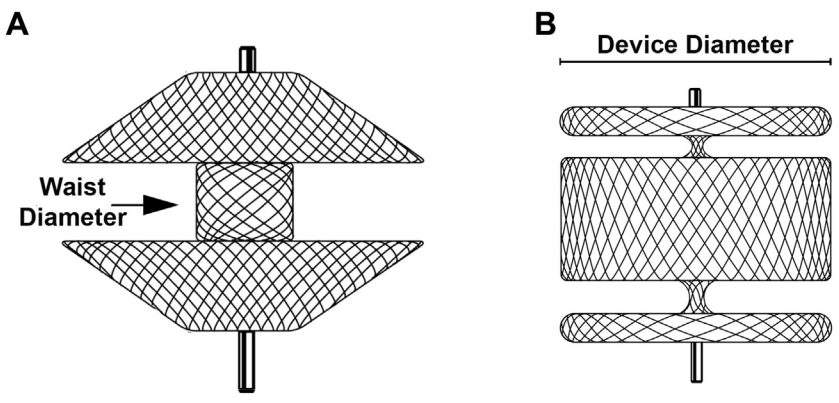
A challenge to the technique of occluder placement for residual MR is defining an algorithm for appropriate device sizing. The investigators evaluated the location and size of residual regurgitant jets using a combination of fluoroscopy, echocardiography, and best clinical judgment. All patients received either 5- or 6-mm diameter waist ADO II devices, and in all cases, the ADO II device was delivered successfully to the intended location through a 6-F multipurpose guiding catheter nested inside an 8.5-F Agilis steerable guide (St. Jude Medical, St. Paul, Minnesota). The mean occluder placement procedure time of 31 min was fairly brief. In all 9 patients, MR was acutely reduced to ≤2+, with decreases in left atrial pressure and normalization of systolic pulmonary vein flow. Importantly, there was no increase in the transmitral diastolic gradient after ADO II deployment, nor was there evidence of hemolysis.

One significant complication of this technique was ADO II embolization to the right coronary artery and inferior ST-segment elevation myocardial infarction 9 hours after the procedure. The device was successfully snared and retrieved percutaneously, apparently without further sequelae. However, the mechanism of device embolization to the right coronary artery in this particular case is not clear. It is possible that the device was undersized to the defect or that the leaflet integrity at the occluder location was suboptimal. Perhaps the flanking MitraClips were not stable enough to anchor the occluder. Unfortunately, it is not certain how this complication could have been prevented, except to perform a vigorous "tug test" prior to releasing the device. Even so, 1 of 9 patients (11%) experiencing an acute ST-segment elevation myocardial infarction may not be an acceptable hazard profile in a population at high surgical risk.

Limitations of this study include relatively short and incomplete clinical follow-up. Although New York Heart Association functional status is available in 8 of 9 patients at 30 days, echocardiographic follow-up is available in only 5 patients at 30 days. Of these 5 patients, all had stable ADO II position, and 2 patients had grade 1+ MR, 2 patients had grade 2+ MR, and 1 patient had grade 3+ MR. The longer term durability of this approach is currently unknown, and further attempts at follow-up are warranted.

In summary, this report is of interest to readers who perform the MitraClip procedure. Although there have been multiple anecdotal reports of this technique from various operators, this represents the first published series using a consistent occluder device (ADO II) for the treatment of residual intraclip or commissural MR. Although the results are encouraging, with only short-term follow-up and

**FIGURE 1 Amplatzer Duct Occluder II and Amplatzer Vascular Plug II Devices**




(**A**) Amplatzer Duct Occluder (ADO) II device. Note the central waist and 2 larger retention discs on either side. (**B**) Amplatzer Vascular Plug (AVP) II. The waist and 2 discs are all the same diameter.

1 embolization, this technique should not currently be encouraged on a routine basis. One must remember that these results are from a highly experienced center and that results from less experienced operators may be worse. Importantly, every attempt was made by the investigators to place MitraClips as the primary strategy for MR reduction. Mechanistically, the use of the MitraClip is more stable than the use of occluder devices, because the MitraClip actively grasps both leaflets, is secure, and enhances native leaflet coaptation. But despite best attempts, over the 7-month time period of this study, 9 of 70 MitraClip procedures (12.9%) required the use of the adjunctive occluder method. The risks of occluder placement are not fully defined. The use of an occluder at this point should be considered a "bail-out" strategy after a conscientious attempt at clip placement is made. Operators should be discouraged from performing this procedure ad hoc without patient consent. For those interested in performing this procedure, a discussion of the method and potential risks should be part of the informed-consent process prior to the procedure. Finally, we should all adopt a "MitraClip first" and "occluder second only if needed" approach.

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