The current issue of Circulation: Cardiovascular Interventions reports two interesting series of structural intervention focusing on plugging the holes. Problems of paravalvular leak and left ventricular pseudoaneurysm are encountered infrequently, and data on transcatheter management are sketchy. Both series represent the largest reported experience in their respective areas. The reported procedural outcomes are impressive, but long-term outcomes and generalizability of these experiences remains to be tested.

Although there is no obvious similarity between the two disease processes, there are several common themes for structural interventions from these reports. Paravalvular leak and ventricular pseudoaneurysm are relatively uncommon and have surgical options that are less than optimal. Percutaneous options are not well studied in the literature, and the procedures are not standardized, requiring constant procedural modifications and innovations. Appropriate patient selection requires surgical opinion and close collaboration. Procedures must be performed as a harmonious teamwork, including physical setup for “hybrid” approaches. There are no catheters or occluding devices specific to these procedures. This “orphan” status is partly due to low frequency of the disease states and partly due to the extreme variability of the target morphology. Thus tools used for the procedures should be carefully assembled from the other procedural areas, including coronary, peripheral, and structural catheterization laboratories. Procedures are performed with the guidance of advance imaging, and success is directly related to “visualization” of the anatomy. Finally, overall outcome is dependent on “successful bailout,” either surgically or with additional percutaneous procedures. Finally, for both procedures, long-term data are still awaited.

Paravalvular leak is an infrequent problem that affects the mitral valve more frequently than it affects the aortic valve. Patients typically present with heart failure or hemolysis, but many are recognized on routine screening echocardiography. Indications of paravalvular leak closure are largely similar to those with native valve regurgitation, as far as heart failure is concerned. In patients with hemolysis, severity of problem, potential risks of treatment, and likelihood of success are taken into account to determine if corrective action is necessary. Asymptomatic patients with paravalvular leak are typically monitored with periodic evaluations of functional status as well as anatomic consequences. In the present study, all but 8 patients required intervention primarily because of heart failure symptoms. Although hemolytic anemia was noted in 37% of the patients, it was not the primary reason for closure in most. Due to multiple comorbidities, it is at times difficult to determine whether symptoms are from paravalvular leak or other medical problems. Determination of chronicity and temporal relation of the paravalvular leak to symptoms can be very helpful. Patient selection process is influenced by referral process, in which only symptomatic and high-risk patients are being referred to few centers with technical expertise. Watchful waiting, surgical treatment, and percutaneous closure options should be considered individually for each patient. Technical details of the procedure, not being the focus of the study, were not highlighted in the report. Role of proper equipment selection, 3D imaging guidance, and technical challenges of the procedure should not be underestimated.

The technique of paravalvular leak closure is largely dependent on exact localization of the leak on transesophageal echocardiography and guiding the devices to that target in a safe and efficient manner. Several different methods to overlay 3D information from either transesophageal echocardiography or CT scan to fluoroscopic images have been used. Three-dimensional transesophageal echocardiographic guidance for device manipulation is also critically important. Understanding of the anatomy and details of the devices is paramount to the success of these procedures, and the authors should be congratulated for their technical skills. Which device is better for the closure remains unclear because there is no specific device that is available for this application in the United States. Selection of the type of device depends on several factors. Devices that have a waist

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and two disks on either side, such as atrial septal defect or ventricular septal defect occluders, may be desirable because they plug the hole tightly, and the disks on either side allow endothelialization and better sealing, along with minimizing the risk of embolization. The downside of these devices includes the risk of impinging of the prosthetic valve with the overhanging disk. This may be a serious problem, particularly in the mechanical valves, as experienced by the authors in the only patient who required emergency cardiac surgery. Impingement of leaflets is sometimes difficult to predict and may not occur until the device is released. A patent ductus arteriosus device with one disk may provide advantage in some situations. The authors briefly mention that they used several small, circular devices next to each other to close the semilunar defects, a concept that has gained acceptance among many experienced operators. They used this technique rather infrequently (7 of 115 patients, 6%). Techniques to place several devices next to each other vary for different locations of the leaks and by operator, but general concepts are to use a large-size access and place several wires and delivery sheaths after initially crossing the defect. The authors predominantly used vascular plugs, which have advantages of requiring smaller delivery systems and relatively lower cost. However, their shape and lack of fabric may not allow complete closure, but this remains to be studied. Furthermore, most commonly the defects are semilunar in shape and the devices are circular with one exception, Amplatz Vascular Plug III, which is only available outside of the United States. How this device adds to the armamentarium remains to be seen.

Methods to cross the defect are also variable and can be challenging (Figure). In the current report, inability to cross the defect with wire was the primary cause of failure only in one patient. Retrograde or antegrade crossing strategy selection for mitral paravalvular leak largely depends on the location of the leak. In this report, apical access was necessary in 13 patients (11%). Anterior and lateral defects are easier cross through transseptal access, whereas posterior and medial defects can be difficult. Retrograde crossing from the ventricle or through the transapical approach are alternatives when the defect is difficult to approach from the left atrium. Percutaneous versus the surgical approach to the left ventricular apex is dependent on proposed sheath size and local expertise. Using a small sheath to cross the defect from the apical access and then exteriorizing the wire from the transseptal approach to deliver the devices from the femoral vein eliminates the need for large apical access but makes the procedure somewhat longer. Percutaneous closure of large apical access has been reported but is still very early in its experience.

The transseptal puncture location is of paramount importance in closing mitral paravalvular leaks in retrograde fashion. If the leaks are posterior and medial, a low and posterior puncture can be helpful to avoid acute turns in delivery catheters. For anterior and lateral defects, more conventional puncture in the posterior part of the fossa can be
useful. If anterior or high puncture is made, the procedure can become difficult and at times impossible. Proper imaging guidance can help to determine the precise location, but, because of frequently scarred and deformed septum, precise entry into left atrium can be challenging.

In the article by Sorajja et al,1 acute procedural success was defined as successful deployment of an occluder device that resulted in significant reduction in paravalvular regurgitation to mild or less residual regurgitation, in the absence of the need for emergency surgery or procedural death. This is a less than optimal definition for clinical use. Clinical benefit or leak that was less than 1+ may be a more relevant goal. There were 27 (23%) patients with grade III or IV regurgitation at the end of the procedure. The authors also failed to provide information about hemodynamic impact of the procedure. The changes that occurred in left atrial pressure, pulmonary pressure, and cardiac output after the closure provide valuable information in predicting the clinical response of the patient. Hemolysis is another end point that is important to consider in the early phase after closure of a leak. Although the residual leak is mild or trivial, hemolysis can be dramatic, requiring several units of blood transfusion. Milder forms can be treated with erythropoietin, although this information is not reported in this article. Most importantly, mid- and long-term outcomes and their relation to “procedural success” would be important to fully assess the value of this treatment modality.

Reports about transcatheter closure of left ventricular pseudoaneurysms almost always include chronic cases. The goal of treatment typically is to prevent rupture and heart failure, although chronic pseudoaneurysms tend to be fairly stable by definition. The authors have demonstrated the safety of percutaneous closure, which is a clinically very relevant message, although it must be recognized that the authors are highly skilled and experienced structural interventionalists with a setup that is conducive to complex and innovative procedures. Generalizability of their findings is therefore limited, but the approach should be considered as a treatment option in appropriate situations.

In summary, the two reports highlight the expanding horizons of structural interventions and demonstrate that with proper imaging and devices, the sky will be the limit.

Disclosures

None.

References


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Plugging Holes: Expanding Horizon for Structural Interventions
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