THE CCU CORNER

Balloon Valvuloplasty for Severe Aortic Stenosis

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The Patient

A 79-year-old male with diabetes and peripheral vascular disease presented with pneumonia, diabetic ketoacidosis, and a non-ST elevation myocardial infarction. He developed pulmonary edema after gentle hydration, and echocardiography revealed a left ventricular ejection fraction of 35% and severe aortic stenosis (AS). His extended CCU course was complicated by paroxysmal atrial fibrillation with resultant hypotension, intermittent vasopressor dependence, renal failure requiring temporary hemodialysis, and intubation with eventual tracheostomy. He was eventually stabilized but failed ventilator weaning trials owing to recurrent angina and heart failure. Cardiac catheterization revealed 50% stenosis in the mid-left anterior descending artery. It was felt that his chest pains and heart failure related to his severe AS; however, he was not an ideal surgical candidate owing to his ventilator dependence, active medical issues, and deconditioned state. He therefore underwent aortic balloon valvuloplasty as a bridge to eventual valve replacement. Following valvuloplasty, the mean transvalvular gradient decreased from 63 mm Hg to 28 mm Hg and the valve area increased from 0.5 cm^2 to 1.0 cm^2. Over the next 48 hours his renal function improved and he was weaned from ventilatory support. He is currently undergoing physical therapy in anticipation of aortic valve replacement (AVR) in the near future.

The Problem

Aortic stenosis is the most common valvular heart disease in industrialized countries, occurring in 2%-7% of patients over age 65. While patients with symptomatic severe AS clearly benefit from AVR, they may present with hemodynamic instability or have significant comorbid conditions that make AVR less ideal. Balloon aortic valvuloplasty (BAV) may be an appropriate option for some of these patients.

Pathophysiology

Aortic stenosis most commonly arises from degeneration of a trileaflet aortic valve. Congenitally bicuspid valves and rheumatic heart disease are less common causes. Degenerative AS has pathophysiologic similarities to atherosclerosis and is an active process involving inflammation, lipid accumulation, and calcification. In addition, AS and atherosclerosis share common risk factors, including hypertension, diabetes, smoking, and hyperlipidemia. The normal AV area is greater than 3.5 cm^2. Aortic stenosis is defined as follows:

Gradient	AV Area	Mean Transvalvular
Mild AS	> 1.5 cm^2	< 25 mm Hg
Moderate AS	1.0-1.5 cm^2	25-40 mm Hg
Severe AS	< 1.0 cm^2	>40 mm Hg

In patients with symptomatic AS (chest pain, syncope, or heart failure), relief of the mechanical obstruction by AVR results in significant mortality benefit; 10-year survival rates after AVR approach those for patients without AS. The mechanical obstruction may also be reduced by BAV, during which a balloon is inflated across the stenotic valve, thereby increasing the AV area by fracturing leaflet and/or commissural calcification and mildly dilating the aortic annulus.

The Evidence

Studies suggest that BAV results in a modest increase in valve area and an immediate reduction in transvalvular gradient by about 50%; however, patients are usually left with at least moderate residual AS, as the postprocedural AV area rarely exceeds 1.0 cm^2. The rate of significant procedural complication is approximately 10%, including a 2%-5% risk of mortality. Additionally, while BAV often produces significant symptomatic improvement, studies have not demonstrated sustained benefit. In one study of 165 patients treated with BAV, 60% of patients either died or required AVR or repeat valvuloplasty at 1 year, and 94% either died or required a repeat valve procedure at 3 years. Other studies have found that the restenosis rate is at least 50% at 6 months after BAV, that only patients with preserved left ventricular function have symptomatic benefit, and that the mortality after BAV is similar to that of untreated severe AS. Nonetheless, in a group of patients who underwent BAV and subsequently underwent AVR, the 3-year survival was 84%, suggesting that valvuloplasty may have a role as a bridge to AVR.

Discussion

Clinical trial data have curbed enthusiasm for this procedure as an effective way to treat AS, and our approach has been to use the procedure in a very select group of patients. In accordance with current American College of Cardiology/American Heart Association guidelines, we feel that it may be reasonable to perform BAV as a bridge to surgery in hemodynamically unstable patients who are at high risk for complications of AVR in the acute setting, but in whom BAV may result in temporary clinical improvement and allow for medical stabilization prior to surgical AVR. However, the palliative use of BAV is extremely limited by its lack of benefit on mortality or disease course. Importantly, valvuloplasty should not be used as an alternative to AVR in patients with severe AS.

Other approaches to the treatment of AS are currently being investigated. Percutaneous AVR via the femoral arterial approach has recently been reported. Using this technique, a stent-mounted bioprosthetic valve is deployed in the aortic position at the time of balloon valvuloplasty. In patients in whom vascular disease precludes the transfemoral approach, stent-mounted valves may be placed via direct puncture of the left ventricular apex through an intercostal incision. While initial studies have shown these techniques to be feasible, further study is needed to assess their long-term safety and efficacy and define appropriate patient selection criteria.

Summary

The only proven effective therapy for symptomatic severe aortic stenosis is AVR. However, in a very select group of patients BAV may be considered, primarily as a bridge to subsequent AVR. Newer percutaneous or transapical approaches using stent mounted valves are being investigated in patients who are not candidates for standard surgical AVR. Referral to a center that performs these procedures may be appropriate in such patients.

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Percutaneous Repair of Functional MR Promising in EVEREST

BY BRUCE JANCIN
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CHICAGO — Percutaneous mitral leaflet repair using the investigational MitraClip device in patients with functional mitral regurgitation improves symptoms, reduces echocardiographic mitral regurgitation severity, and results in favorable left ventricular remodeling over time, according to preliminary results of a small pilot study.

The MitraClip procedure is designed to mimic percutaneously the edge-to-edge Alfieri isolated leaflet open-chest surgical repair. Placed via a transseptal approach, the MitraClip creates a double-orifice, figure eight–shaped mitral valve by coapting tethered leaflets, thereby reducing the force of closure, Dr. James Hermiller explained at the annual meeting of the American College of Cardiology.

The future outlook for the percutaneous procedure proved to be a matter of disagreement at the meeting, however.

Dr. Hermiller reported that of 23 patients with moderate to severe functional mitral regurgitation (FMR) enrolled in the multicenter uncontrolled first Endovascular Valve Edge-to-Edge Repair Study (EVEREST I), acute procedural success was achieved in 19. In three others, the clip was placed but FMR wasn't significantly reduced, while one patient required bailout emergent cardiac surgery for pericardial effusion related to a transseptal complication. Two patients required transfusions of two units or more.

Twelve patients have completed 1 year of follow-up. Nine of the 12 continued to experience significant improvement at 1 year, compared with baseline, with only mild FMR and New York Heart Association functional class I or II status. Two patients were unchanged, compared with baseline, and one was worse, according to Dr. Hermiller of St. Vincent Heart Center, Indianapolis, who has received research grants from Evalve Inc., maker of the MitraClip.

Indicators of left ventricular (LV) remodeling provided important objective evidence of benefit, he added. The mean LV end diastolic dimension dropped from 6.0 cm at baseline to 5.4 cm at 12 months. The LV end systolic dimension decreased from 4.5 cm to 4.0 cm. And LV end diastolic volume fell from 208 mL to 178 mL.

Reaction to EVEREST I split along specialty lines. Interventional cardiologists called the early results impressive, with the caveat that the number of patients was small and follow-up was too brief to assess durability. But the potential applicability could be huge. Although the MitraClip was initially developed to address degenerative mitral regurgitation (MR), it's estimated that 60% of the 250,000 patients diagnosed with MR per year in the United States have FMR without degenerative structural changes—and the notion of treating them without resorting to open-chest surgery is highly attractive.

On the other hand, discussant Dr. Todd Rosengart, a cardiothoracic surgeon at Stony Brook (N.Y.) University, said their early experience with minimally invasive surgical repair of MR in 40 patients has been zero in-hospital mortality; a 2.5% rate of major morbidity at 30 days; a 1-day shorter length of stay than with open surgery; and a total operating room time of about 3 hours, similar to open surgery. But the percutaneous procedure has a major shortcoming: It aims to bring about functional recovery and improvement in FMR at the cost of destroying the integrity of the mitral structure, whereas surgical repair preserves structural integrity. ■