

Percutaneous Balloon Valvuloplasty for Critical Aortic Stenosis: A Bridge to Safer Noncardiac Surgical Procedures

In this issue of the *Proceedings* (pages 753 to 757), Hayes and associates describe their experience with use of percutaneous aortic balloon valvuloplasty to decrease the risk of noncardiac surgical and invasive diagnostic procedures in 15 elderly patients (mean age, 79 years) who had critical aortic stenosis. All 15 patients had dyspnea on exertion, 8 had symptoms of angina, and 3 had syncope. The noncardiac conditions for which surgical treatment was needed were hip fractures, known cancers, undiagnosed lung masses, and active gastrointestinal or urinary tract bleeding. Of the 15 patients, 7 were thought not to be candidates for aortic valve replacement because of active bleeding or other medical contraindications. The other eight patients were not candidates because of known or suspected metastatic cancer.

Balloon valvuloplasty, performed with use of either single or double balloons and standard valvuloplasty techniques, resulted in hemodynamic improvement. The results were comparable to those previously reported for aortic valvuloplasty. The mean aortic gradient decreased from 58 to 32 mm Hg, and the aortic valve area increased from 0.49 to 0.85 cm². The cardiac index was unchanged.

Of the 15 patients, 5 had major complications related to the aortic valvuloplasty. One patient died after left ventricular perforation. In two other patients, left ventricular perforation was successfully treated by pericardiocentesis. One patient required surgical repair of bilateral femoral pseudoaneurysms, and one patient had left bundle-branch block and transient congestive heart failure.

The noncardiac surgical and invasive diagnostic procedures that were performed included total hip

arthroplasty, colonic resection, bilateral mastectomy, pulmonary resection, closed reduction and internal fixation of the hip, resection of a gallbladder tumor, colonoscopy, bronchoscopy, and cystoscopy. These noncardiac procedures in the 14 patients who survived valvuloplasty were all uncomplicated. In two patients in whom a preoperative diagnosis of cancer was considered likely, carcinoma was excluded and the patients subsequently underwent aortic valve replacement. Thus, in this relatively small patient group, the strategy of prior aortic valvuloplasty was associated with uncomplicated subsequent noncardiac procedures.

Currently, considerable interest exists in determining the appropriate clinical role for percutaneous aortic valvuloplasty. When this procedure was initially reported in 1986,^{1,2} investigators were cautiously optimistic that aortic valvuloplasty might be an appropriate therapeutic modality for a substantial number of patients with critical valvular aortic stenosis. Countering this initial optimism were reports that described the effect of balloon valvuloplasty on the calcified aortic valve.^{3,4} The demonstration of a limited effect of valvuloplasty on these heavily calcified valves suggested that the clinical results of valvuloplasty would be similarly limited.⁴

Although valvuloplasty has been performed, for the most part, in only elderly and high-risk patients with contraindications for aortic valve replacement, early hemodynamic results have been encouraging.^{1,2,5} Most treated patients have had appreciable hemodynamic benefit and a relatively low rate of associated serious complications. In contrast, medical therapy for similar patients seems to be associated with a much greater risk of fatal and nonfatal outcomes.⁶ These initial results led to considerable enthusiasm for the procedure. From the outset, however, clinicians recognized that a more definitive assessment of the value of valvuloplasty would depend on the follow-up observations. Several follow-up studies have now been published.⁷⁻⁹ These studies suggest that the rate of early recurrence of symptoms is approximately 50% and that recurrent symptoms are often due to restenosis. Occasionally, aortic valvuloplasty has been associated with serious complications. Reported complications include death, stroke, myocardial infarction, and, most commonly, vascular complications related to the arterial entry sites of the large valvuloplasty catheters. Major complications of val-

Address reprint requests to Dr. E. R. Powers, Division of Cardiology, Box 158-22, University of Virginia Health Sciences Center, Charlottesville, VA 22908.

valvuloplasty occurred in a third of the patients described by Hayes and associates. Thus, aortic valvuloplasty is not the primary therapy of choice for most elderly patients with critical aortic stenosis without an important contraindication to aortic valve replacement. In the presence of contraindications to surgical intervention, however, valvuloplasty may be the most appropriate treatment for symptomatic aortic stenosis in some patients.

If most patients with critical aortic stenosis are not appropriate candidates for aortic valvuloplasty, is there a subgroup (or subgroups) of patients who are? The study by Hayes and co-workers suggests that patients who require urgent or nonurgent high-risk noncardiac procedures may be such a subgroup.

The risks associated with noncardiac operations in elderly patients with severe cardiac disease have been the subject of several studies. The risk of death associated with major noncardiac surgical procedures in patients with critical aortic stenosis reportedly ranges from 13 to 20%.^{10,11} Goldman and colleagues¹² developed a multifactorial risk index for patients with cardiac disease undergoing noncardiac surgical procedures. Factors that were identified as being major contributors to risk, in descending order of importance, included evidence of heart failure on physical examination, recent myocardial infarction, arrhythmias, age older than 70 years, requirement of an emergency operation, intrathoracic or intraperitoneal surgical site, valvular aortic stenosis, and poor medical condition. Patients with a combination of these risk factors that classified them in the highest risk group had a 22% risk of nonfatal cardiac complications and a 56% risk of dying of a cardiac cause. Although the risk index of Goldman and associates cannot be directly applied to the patients described in the study by Hayes and colleagues, many—if not most—of the patients of Hayes and co-workers would likely be classified in the highest risk category with use of this index. Thus, the absence of any cardiac complications during the noncardiac procedures in the patients described by Hayes and associates is a striking result and suggests that valvuloplasty did, in fact, substantially reduce the risk of cardiac complications in their patients.

Two other small studies have recently reported on the use of aortic valvuloplasty before noncardiac surgical procedures. Roth and colleagues¹³ described the use of aortic valvuloplasty in seven patients before colectomy, stabilization of hip fractures, exploratory laparotomy, or resection of an abdominal aortic aneurysm. Good results of valvuloplasty were ob-

tained in all seven of their patients. In this patient group, no complications were associated with the noncardiac procedures, and the only complication of valvuloplasty was a femoral artery pseudoaneurysm in one patient. Levine and co-workers¹⁴ described their experience with seven patients who underwent valvuloplasty before pulmonary resection, prostatectomy, treatment of hip fracture, gastrectomy, or colectomy. In six patients, both the valvuloplasty and the noncardiac surgical procedure were uncomplicated. In the other patient, despite valvuloplasty, severe hypotension developed during mobilization of the colon before colectomy; consequently, the surgical procedure was discontinued. Subsequently, aortic valve replacement was performed, followed by colonic resection. Thus, the previously published experience with use of aortic valvuloplasty to decrease the risk of subsequent noncardiac procedures is consistent with the results presented by Hayes and co-workers.

In summary, studies of aortic valvuloplasty are now beginning to focus on the appropriate application of this new technique. It has become apparent that aortic valvuloplasty provides only limited and relatively short-term palliation of critical aortic stenosis for a substantial fraction of treated patients; therefore, aortic valvuloplasty is inappropriate primary therapy for valvular aortic stenosis in patients without important contraindications to aortic valve replacement. Nevertheless, aortic valvuloplasty seems to have a therapeutic role in patients with aortic stenosis and substantial contraindications to aortic valve replacement. In addition, the current study by Hayes and co-workers and two previous reports^{13,14} suggest that aortic valvuloplasty may be appropriate when an important noncardiac illness necessitates either a major operation or a high-risk diagnostic test in patients who also have severe aortic stenosis. Their data suggest that initial aortic valvuloplasty may substantially decrease the risk of the subsequent noncardiac procedure.

Whether the strategy of aortic valvuloplasty followed by a noncardiac procedure results in an overall lower risk to the patient than if the noncardiac surgical procedure is performed without prior valvuloplasty but with careful hemodynamic monitoring and optimal use of ideal anesthetic agents and other appropriate medications cannot be definitely settled without more experience with this strategy. For the final answer to this question, a controlled clinical trial may be necessary. Despite the absence of a control group in the study by Hayes and co-workers, their experience suggests that aortic valvuloplasty before noncar-

diac procedures in patients with severe aortic stenosis may be an important application of this new technique.

Eric R. Powers, M.D.
Division of Cardiology
University of Virginia
Health Sciences Center
Charlottesville, Virginia

REFERENCES

1. Cribier A, Savin T, Saoudi N, Rocha P, Berland J, Letac B: Percutaneous transluminal valvuloplasty of acquired aortic stenosis in elderly patients: an alternative to valve replacement? *Lancet* 1:63-67, 1986
2. McKay RG, Safian RD, Lock JE, Mandell VS, Thurer RL, Schnitt SJ, Grossman W: Balloon dilatation of calcific aortic stenosis in elderly patients: postmortem, intraoperative, and percutaneous valvuloplasty studies. *Circulation* 74:119-125, 1986
3. Safian RD, Mandell VS, Thurer RE, Hutchins GM, Schnitt SJ, Grossman W, McKay RG: Postmortem and intraoperative balloon valvuloplasty of calcific aortic stenosis in elderly patients: mechanisms of successful dilation. *J Am Coll Cardiol* 9:655-660, 1987
4. Robicsek F, Harbold NB Jr: Limited value of balloon dilatation in calcified aortic stenosis in adults: direct observations during open heart surgery. *Am J Cardiol* 60:857-864, 1987
5. Cribier A, Savin T, Berland J, Rocha P, Mechmeche R, Saoudi N, Behar P, Letac B: Percutaneous transluminal balloon valvuloplasty of adult aortic stenosis: report of 92 cases. *J Am Coll Cardiol* 9:381-386, 1987
6. O'Keefe JH Jr, Vlietstra RE, Bailey KR, Holmes DR Jr: Natural history of candidates for balloon aortic valvuloplasty. *Mayo Clin Proc* 62:986-991, 1987
7. Letac B, Cribier A, Koning R, Bellefleur J-P: Results of percutaneous transluminal valvuloplasty in 218 adults with valvular aortic stenosis. *Am J Cardiol* 62:598-605, 1988
8. Safian RD, Berman AD, Diver DJ, McKay LL, Come PC, Riley MF, Warren SE, Cunningham MJ, Wyman RM, Weinstein JS, Grossman W, McKay RG: Balloon aortic valvuloplasty in 170 consecutive patients. *N Engl J Med* 319:125-130, 1988
9. Block PC, Palacios IF: Clinical and hemodynamic follow-up after percutaneous aortic valvuloplasty in the elderly. *Am J Cardiol* 62:760-763, 1988
10. Skinner JF, Pearce ML: Surgical risk in the cardiac patient. *J Chronic Dis* 17:57-72, 1964
11. Goldman L, Caldera DL, Southwick FS, Nussbaum SR, Murray B, O'Malley TA, Goroll AH, Caplan CH, Nolan J, Burke DS, Krogstad D, Carabello B, Slater EE: Cardiac risk factors and complications in non-cardiac surgery. *Medicine* 57:357-370, 1978
12. Goldman L, Caldera DL, Nussbaum SR, Southwick FS, Krogstad D, Murray B, Burke DS, O'Malley TA, Goroll AH, Caplan CH, Nolan J, Carabello B, Slater EE: Multifactorial index of cardiac risk in noncardiac surgical procedures. *N Engl J Med* 297:845-850, 1977
13. Roth RB, Palacios IF, Block PC: Percutaneous aortic balloon valvuloplasty: its role in the management of patients with aortic stenosis requiring major noncardiac surgery. *J Am Coll Cardiol* 13:1039-1041, 1989
14. Levine MJ, Berman AD, Safian RD, Diver DJ, McKay RG: Palliation of valvular aortic stenosis by balloon valvuloplasty as preoperative preparation for noncardiac surgery. *Am J Cardiol* 62:1309-1310, 1988