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Editorial Comment

Percutaneous Balloon Valvuloplasty: Long-Term Studies Are Needed*

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The cardiac catheterization laboratory is undergoing a remarkable transition. What was originally a diagnostic laboratory is becoming a therapeutic suite where interventional procedures may, in many cases, replace surgery altogether. Percutaneous balloon angioplasty or valvuloplasty has been used for several years in pediatric cardiology centers for treatment of congenital valvular pulmonary stenosis, pulmonary artery stenosis and recurrent postoperative coarctation of the aorta; in fact, angioplasty is now the procedure of choice for these three lesions (1). During the past 2 to 3 years balloon angioplasty has also been utilized for congenital valvular aortic stenosis (2,3), subaortic stenosis (4), mitral stenosis (5,6) and native coarctation (7,8), and transcatheter techniques for closure of patent ductus arteriosus and atrial septal defect (9) and ablation of accessory pathways (10) have been developed. In adult cardiology percutaneous transluminal coronary angioplasty has become a routine procedure. Further, balloon valvuloplasty of calcific aortic stenosis (11) and rheumatic mitral stenosis has recently aroused tremendous interest. At the 1986 American Heart Association meeting in Dallas 15 abstracts were presented on these two topics alone.

Balloon mitral valvuloplasty. McKay and coworkers (12) have made a significant contribution to our understanding of balloon mitral valvuloplasty. In the current issue of the Journal they have carefully documented the acute, short-term benefits of percutaneous balloon valvuloplasty for rheumatic mitral stenosis. In 18 adult patients mitral valvuloplasty resulted in a 78% increase in mitral valve area, associated with a 40% decrease in mean valve gradient and a 19% increase in cardiac output. The procedure was not associated with any important complications and, notably, severe mitral regurgitation and embolic events were not observed. On follow-up all patients reported lessening of their symptoms of dyspnea, orthopnea and fatigue.

McKay et al. (12) have also helped to elucidate the mechanisms by which balloon valvuloplasty relieves rheumatic mitral stenosis. Balloon dilation in five postmortem hearts relieved the mitral obstruction through separation of fused commissural edges and fracture of calcified areas within the leaflets. These changes are consistent with those described in aortic valves after balloon dilation of congenital and calcific aortic stenosis (2,11). In no instance has damage to the anulus, tearing of leaflets or liberation of calcific debris been detected. These observations may help to explain the apparent infrequency of severe valvular regurgitation and embolic events after balloon mitral and aortic valvuloplasty.

Technical aspects. Comments regarding some technical aspects of the procedure are in order. Percutaneous mitral valvuloplasty requires one or two transseptal punctures and dilation of the puncture site to introduce the valvuloplasty catheter or catheters into the left atrium. It is important to recognize that the atrial septal defect that is produced could improve hemodynamic indexes of mitral stenosis, without any real change in mitral valve function. By decompressing the left atrium an atrial septal defect alone would decrease left atrial and pulmonary artery wedge pressures, decrease the mitral valve gradient, increase the cardiac output (as spuriously measured by thermodilution technique in the pulmonary artery) and, thereby, increase the calculated mitral valve area. McKay et al. (12) correctly appreciated the potential confounding effects of an atrial septal defect, and noted that hemodynamic improvement was similar in patients with and without a detectable atrial shunt. Furthermore, improved mitral valve function was confirmed by echocardiographic and radionuclide studies. Nevertheless, it is prudent to minimize the size of the atrial septal defect required for the procedure. This may be accomplished by use of the double-balloon technique in which smaller valvuloplasty catheters are necessary than when a single catheter is employed. In addition, both catheters can be introduced into the left atrium through a single transseptal puncture by use of a double-lumen exchange catheter (as described by McKay et al.), or by passing two exchange wires through a single transseptal sheath positioned in the left atrium or ventricle.

Long-term studies are lacking. Although several studies have now documented short-term effectiveness of percutaneous balloon mitral and aortic valvuloplasty, more data are needed before these procedures should become routine. Long-term data are lacking, and real questions remain. Which patients are most likely to benefit from the procedure? How long will gradient relief persist after balloon valvuloplasty? What is the course of mitral or aortic insufficiency after balloon valvuloplasty? Will the atrial sep-

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tal defect created during mitral valvuloplasty become hemodynamically important if mitral stenosis recurs or left ventricular end-diastolic pressure increases with time? Perhaps most importantly, how do the results of balloon valvuloplasty compare with those of surgical valvotomy? These questions will be answered only through careful evaluation of balloon valvuloplasty in strict clinical protocols, ideally in controlled clinical trials. Such studies are needed soon. There exists a critical window in time during which proper evaluation of a new therapy is feasible: after effectiveness is documented, but before the new therapy is accepted as routine medical practice. For percutaneous balloon valvuloplasty the time is now. Balloon mitral and aortic valvuloplasty are exciting new techniques but, at present, they should be used only in the context of investigative protocols. Such studies, and preferably controlled clinical trials, must be performed to determine the ultimate role of percutaneous balloon valvuloplasty in the treatment of children and adults with mitral or aortic stenosis.

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