In 2000, Bonhoeffer et al. described transvenous placement of a pulmonary-valve prosthesis and speculated that similar technology might be used in other cardiac valves, including the aortic position. Two years later, the first transcatheter insertion of an aortic-valve prosthesis was performed by Cribier et al. Transcatheter aortic-valve implantation has developed rapidly, and two relatively mature technologies are in clinical use: the SAPIEN Transcatheter Heart Valve (Edwards Lifesciences) and the CoreValve Revalving System (Medtronic). In contrast to surgical valve replacement, in which the diseased, calcified cusps are removed, these and other catheter-based techniques in development rely on forcibly spreading the stenotic aortic-valve cusps and anchoring the stented bioprosthesis without sutures.

In this issue of the Journal, Smith et al. report the results of a cohort in the Placement of Aortic Transcatheter Valves (PARTNER) trial, which tested the hypothesis that transcatheter aortic-valve replacement (with transfemoral or transapical placement) would be noninferior to surgical replacement in the 1-year survival of patients with severe aortic-valve stenosis and high operative risk. Perioperative rates of death were low for these patients. In the intention-to-treat population, 30-day mortality was 3.4% in the transcatheter group and 6.5% in the surgical group (P = 0.07), and the 1-year overall mortality was 24.2% versus 26.8%, confirming noninferiority.

However, the avoidance of a sternotomy by transfemoral or transapical aortic-valve implantation appears to come at the price of some potentially serious vascular and technical complications and increased hazards of embolic stroke and paravalvular leakage. The technical problems and imperfect seating of the prosthesis may be eliminated or largely overcome by increased operator experience and refinement of the implantable device. Newer, more flexible, and smaller delivery systems should increase the number of patients who are eligible for transfemoral insertion and may decrease vascular injury.

But the increased risk of stroke associated with transcatheter replacement, as compared with surgical replacement, is a special concern. Smith and colleagues report a 5.5% risk of stroke or transient ischemic attack within 30 days after transcatheter replacement, and this risk increased to 8.3% after 1 year. In contrast, among patients undergoing surgical replacement, early and late risks of neurologic injury were 2.4% and 4.3%, respectively (P = 0.04 for both comparisons). Are these increased risks of neurologic injury consistent with other studies? And if so, how did a procedure in which the risk of neurologic complications is twice that of surgical replacement become adopted so widely and rapidly? Perhaps most important, what are the mechanisms of stroke and how might these be mitigated?

Despite efforts to standardize definitions, the reported risk of clinically apparent neurologic complications with transcatheter replacement has varied from 0 to 11% in series that include single institutions and registries. The 5.5% early risk of stroke or transient ischemic attack in the PARTNER trial is consistent with previous studies and is similar to the 6.7% risk in patients who were not candidates for surgery. In most centers, transcatheter replacement has been used in patients who are at high operative risk, and the same clinical characteristics that increase such risk for patients (e.g., previous surgery, atherosclerotic vascular disease, and systemic hypertension) also increase the risk of stroke with any major cardiovascular intervention. Thus, the 1-in-20 occurrence of stroke or transient ischemic attack after transcatheter replacement might be considered a complication that comes with the territory in treating elderly patients with multiple coexisting conditions.

However, previous outcome studies of transcatheter replacement have not provided a com-
parison with similar patients undergoing surgical replacement, and in this respect, the study by Smith et al. is highly revealing. For patients who would not be candidates for surgical replacement, such an increased rate of neurologic complications might be acceptable, but for those who are candidates for either transcatheter or surgical replacement, the findings present a dilemma in balancing the risks of increased neurologic complications against the benefits of avoiding sternotomy and cardiopulmonary bypass.

It is not surprising that neurologic complications occur with transcatheter replacement in patients with senescent (degenerative) aortic-valve stenosis. Deposits of calcification in aortic-valve cusps are usually covered by endothelium, but dilatation of the valve may lead to fracture of the calcified portion and exposure to the circulation. Some patients have friable ulcerations of calcified cusps that are especially prone to embolization (Fig. 1). Indeed, the simple passage of a catheter across a stenotic calcified aortic valve for left ventricular pressure measurement can cause emboli. Omran et al.9 found new focal abnormalities on magnetic resonance imaging (MRI) in 22% of patients undergoing retrograde left ventricular catheterization for assessment of aortic-valve stenosis; most of these abnormalities were silent, with only 3% of patients showing neurologic signs or symptoms. Kahlert and associates10 reported new defects on cerebral MRI in 84% of patients undergoing transcatheter replacement, but these defects were not associated with clinical events or neurocognitive dysfunction during 3 months of follow-up. In other studies, this high rate of new cerebral emboli after transcatheter replacement was found to be similar for both transfemoral and transapical approaches during SAPIEN valve implantation.11 It seems clear that calcific atherosclerotic emboli are common during catheter and device manipulation of a stenotic aortic valve.

Continued surveillance of patients in this study will be critically important to determine the durability of the transcatheter prosthesis and to assess the risk of late thromboembolic events. The insertion of a prosthesis without removal of the diseased aortic valve creates an irregular zone around the stent that may predispose to thrombus formation. This concern might explain the investigators’ use of dual antiplatelet therapy in patients undergoing transcatheter replacement. In contrast, antiplatelet therapy with aspirin alone seems adequate for those undergoing surgical replacement who have no additional risk factors for thromboembolism.12

Technological refinement of transcatheter valves and adjunctive procedures, such as the use of embolic protection devices,13 will facilitate transcatheter replacement and may improve outcomes, but these new devices should be evaluated in controlled trials with randomization against current standard techniques. The future introduction of prostheses for surgical replacement should be held to the high standard of clinical evaluation demonstrated in this evaluation of transcatheter aortic-valve implantation.

Disclosure forms provided by the author are available with the full text of this article at NEJM.org.
Ensuring Equal Access to Specialty Care
Thomas D. Sequist, M.D., M.P.H.

Improving access to specialty care represents an important component of a comprehensive plan to address disparities in health care. At a time when our nation is struggling to rein in health care spending and potential overuse of specialty services,1,2 it is critical to consider the needs of many rural and underserved communities in which access to specialty services is often severely limited. In the Indian Health Service, a federal health system providing care to American Indians and Alaskan natives, less than one third of primary care physicians report that they have regular access to specialty care.3 This limited access to specialty care also exists in community health centers and other settings that serve predominantly rural, minority, and low-income groups.4,5

Limited access to specialty services can lead to worsened outcomes. Management of many complex, yet readily treatable, conditions is beyond the comfort zone of most primary care physicians. Up to one half of primary care physicians caring for underserved populations report that they are expected to manage conditions beyond their training or expertise.3,5 An understandable hesitancy of primary care physicians to provide complex specialty treatment can result in progression of their patients’ chronic diseases to more advanced stages that are even more challenging to manage.

The reasons for decreased access to specialty care in underserved communities are multifactorial, involving financial and health insurance barriers,4 disparities in the rates of referral for specialty services,6 and lack of availability of specialists.3,5 When considered in this context, strategies to improve access to specialty care for underserved populations should involve both expanded insurance coverage and programs aimed at reducing inappropriate disparities in referrals to specialists for complex treatments, including renal transplantation and coronary revascularization.

The lack of available specialists is particularly challenging. It can be difficult to recruit specialists to work in remote or isolated settings, where resources are scarce, opportunities to interact with specialist colleagues are limited, and the clinical caseload may not justify the presence of a full-time subspecialist. As a result, even when funding is available and referral is desired, it may be impossible for primary care physicians and their patients to gain access to specialty care.

The project reported by Arora and colleagues in this issue of the Journal represents an important step forward in addressing this barrier.7 The Extension for Community Healthcare Outcomes (ECHO) program is designed to spread the substantial specialty resources of an academic medical center to community-based physicians and

From the Division of Cardiovascular Surgery, Mayo Clinic, Rochester, MN.


Copyright © 2011 Massachusetts Medical Society.