Intervention Rivals Open Bypass in Lower Limbs

BY BRUCE JANCIN
Denver Bureau

COLORADO SPRINGS — Outcomes of percutaneous interventions to treat lower-extremity vascular disease have gotten so good in recent years that the endovascular approach has replaced traditional open bypass operations as first-line therapy at one major New York vascular surgery program.

"Our experience with these procedures in this patient population has taught us that a percutaneous approach can be beneficial in patients with limited longevity. It may offer improved quality of life over open surgical bypass and was generally preferred by patients because of its less invasive nature," Dr. Brian G. DeRobertis said at the annual meeting of the American Surgical Association.

The benefits aren't confined to quality-of-life issues, either. Procedural mortality, long-term vascular patency, and limb salvage rates with percutaneous intervention today are at least as good as with open surgery, added Dr. DeRobertis, a vascular surgery fellow at New York–Presbyterian Hospital.

"Five years ago we did many more open surgical bypass procedures than endovascular ones. But over time percutaneous intervention has become our first-line modality in almost all patients, with open surgery reserved for failures of percutaneous therapy," he said.

Dr. DeRobertis reported on 1,000 percutaneous interventions in 730 consecutive patients at the hospital during 2000-2006. A total of 830 were initial interventions; the rest were repeat procedures. All involved an overnight hospital stay. A total of 46% of interventions were for claudication. The remainder were for limb-threatening ischemia, one-third involving rest pain and two-thirds featuring tissue loss.

Overall, this was a relatively sick group of patients, Dr. DeRobertis said. In all, 85% had hypertension, 58% were diabetic, 52% had known coronary artery disease, and 22% had renal insufficiency. Their mean age was 71 years.

Claudicants tended to have more femoral/popliteal disease, whereas limb-threat patients were more likely to undergo tibial intervention. In the femoral region, the primary treatment modality was angioplasty with stent placement. In the popliteal and tibial regions, the preference was to avoid stents in favor of angioplasty and excisional atherectomy.

Overall 30-day mortality was 0.5%. The rate of major complications was 3.2%, with an 8.4% minor complication rate. "Those rates are certainly lower than those quoted in most series of open surgical bypass," Dr. DeRobertis said.

No patient required emergency bypass after a failed percutaneous intervention.

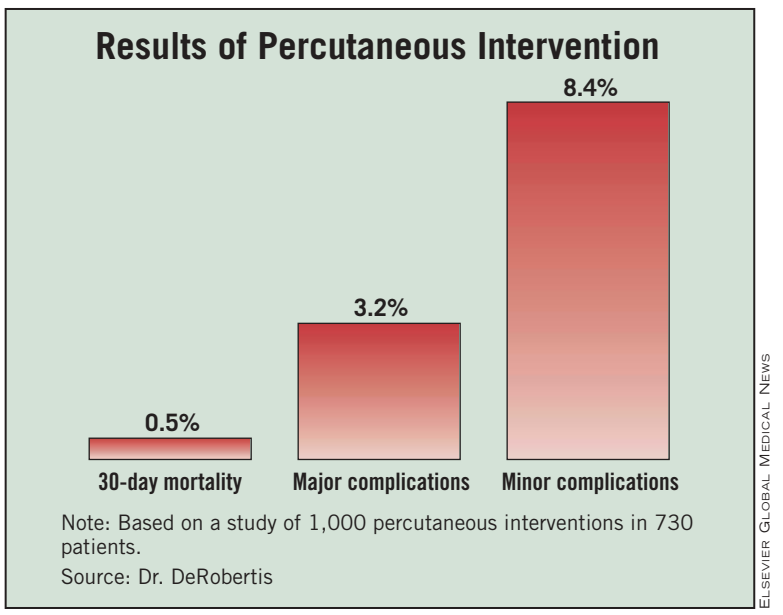
The 3-year primary patency rate—that is, uninterrupted patency without reinterventions or prophylactic procedures—was close to 50% in the claudicants. Their secondary patency rate—an end point comprising all patients with primary patency, plus those who lost primary patency but had it restored by percutaneous means—was nearly 80%.

The 3-year amputation rate in claudicants was 0.5%.

Primary and secondary patency rates in the limb-threat patients were much lower. In fact, limb-threat as an indication for percutaneous intervention was the strongest predictor of loss of patency in a multivariate regression analysis. However, the 3-year limb salvage rate of 80% in the limb-threat group was similar to results reported for surgical bypass.

Why do limb-threat patients do worse? It may be, at least in part, because they tend to be sicker. They have significantly higher rates of diabetes, hypertension, and multilevel peripheral vascular disease, according to Dr. DeRobertis.

"Your results are terrific," said Dr. Ronald M. Fairman, chief of vascular surgery and endovascular therapy at the University of Pennsylvania, Philadelphia. "I can tell you that from reviewing our results we're clearly not as good."



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Discussant Dr. Gregorio A. Sicard said that Dr. DeRobertis' series of percutaneous interventions for lower extremity vascular disease was the largest ever reported from a single center. He was particularly pleased to see that all cases were done by surgeons.

"The results are as good as or better than those in the literature for any smaller series reported by other specialists who do the procedures," observed Dr. Sicard, professor of surgery and chief of the vascular surgery section at Washington University, St. Louis.

Some vascular surgeons have worried that a failed percutaneous intervention can make a patient worse and result in loss of the extremity, but Dr. DeRobertis' series shows that's not the case when the work is done well, he added.

All papers presented at the 127th annual meeting of the ASA are subsequently submitted to the Annals of Surgery for consideration. ■

Low-Dose Aspirin After PCI Safer, as Effective as High Dose

BY BRUCE JANCIN
Denver Bureau

NEW ORLEANS — Low-dose aspirin appears to be as effective as—but considerably safer than—the higher doses favored by most American cardiologists for prevention of recurrent cardiac events after percutaneous coronary intervention, Dr. Sanjit S. Jolly said at the annual meeting of the American College of Cardiology.

He presented a retrospective observational analysis of the Clopidogrel in Unstable Angina to Prevent Recurrent Ischemic Events in Patients Undergoing Percutaneous Coronary Intervention (PCI-CURE) trial database, which concluded that the adjusted risk of major bleeding within 8 months after the procedure was 2.2-fold greater in patients on aspirin at a dosage of at least 200 mg/day than in those on 100 mg/day or less.

"This analysis suggests low-dose aspirin may be superior with regard to a lower rate of serious bleeding compared to high-dose aspirin, and with similar efficacy in terms of death, MI, and stroke," declared Dr. Jolly of McMaster University, Hamilton, Ont.

Moreover, these PCI-CURE findings are supported by two other large observational analyses in patients with acute coronary syndrome which reached the same conclusions. One, led by Dr. Eric J. Topol, involved nearly 9,200 participants in a study of the failed oral glycoprotein IIb/IIIa inhibitor lotrafiban (Circulation 2003;108:399-406). The other included more than 12,500 patients in a clopidogrel trial (Circulation 2003;108:1682-7).

'I personally have increasingly been prescribing low-dose aspirin after PCI because of [these] data.'

DR. JOLLY

"I personally have increasingly been prescribing low-dose aspirin after PCI because of the data from these three observational studies. However, I don't think we have the final word yet," Dr. Jolly said.

He stressed that observational data such as these must be considered hypothesis generating. What's needed is a definitive, large, prospective, randomized clinical trial—and it so happens that such a study is well underway under the leadership of his colleagues at McMaster. The seventh Optimal Antiplatelet Strategy for Interventions/Clopidogrel Optimal Loading Dose Usage to Reduce Recurrent Events trial (OASIS-7/CURRENT) is randomizing 14,000 patients with unstable angina or non–ST-elevation MI to either a 300- or 600-mg loading dose of clopidogrel and low- or high-dose aspirin. Results should be available in 12-18 months.

The PCI-CURE analysis involved 2,658 patients with acute coronary syndrome on four continents who underwent PCI. Aspirin dosing was left to physician preference, which in Europe strongly favored the use of 100 mg/day or less in accord with the latest European Society of Cardiology practice guidelines. In contrast, the great majority of American cardiologists prescribed at least 200 mg/day—and most commonly 325 mg/day—as recommended in current American College of Cardiology/American Heart Association guidelines.

"I think when there's such a practice difference between Europeans and Americans, it tells us that perhaps we need more data," the cardiologist observed.

At 8-month follow-up in PCI-CURE, the major bleeding rate was 1.9% in the low-dose aspirin group, compared with 3.9% with high-dose therapy. The 2.2-fold increased risk in the high-dose group was derived after adjusting for potential confounders, including age, gender, weight, hypertension, and use of clopidogrel versus placebo.

'Some patients will respond nicely to aspirin in a low dose and others won't, particularly the diabetic patients.'

DR. GURBEL

The combined end point of cardiovascular death, MI, or stroke was 7.1% in the low-dose aspirin group and 8.6% with high-dose therapy, a nonsignificant difference.

Dr. Paul A. Gurbel commented that he is deeply skeptical of a one-size-fits-all approach to antiplatelet therapy dosing in patients with CAD.

"Some patients will respond nicely to aspirin in a low dose and others won't, particularly the diabetic patients," said Dr. Gurbel, director of the center for thrombosis research at Sinai Hospital and a cardiologist at Johns Hopkins University, both in Baltimore. ■