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Endoscopic Harvesting Worsens CABG Outcomes

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MUNICH — Endoscopic vein harvesting may not be the best way to obtain vein graft material for patients undergoing coronary artery bypass grafting, based on a review of 3,000 patients.

In a nonrandomized study, patients who underwent coronary artery bypass grafting (CABG) using saphenous veins harvested by endoscopy had significantly worse 3-year survival and more total cardiac events than did patients whose vein grafts were harvested without endoscopy using open surgery, Dr. Renato D. Lopes said while presenting a poster at the annual meeting of the European Society of Cardiology.

The apparent reason why patients who received endoscopically harvested vein grafts had more adverse cardiac events was that these grafts were significantly more prone to failure, either by developing severe stenosis or total occlusion.

Although the pathophysiologic process linking endoscopic vein harvesting and graft failure is unknown, Dr. Lopes hypothesized that the blame lies with the increased trauma that occurs to a blood vessel that is removed endoscopically. Endoscopic extraction involves substantial folding and pulling on the vessel, he noted. In contrast, vein grafts that are removed by open surgery are generally carefully excised with little bending, pulling, or other manipulation, said Dr. Lopes, a cardiologist at Duke University, Durham, N.C.

About 400,000 CABG surgeries are done each year in the United States, and probably more than half of the vein grafts used are currently harvested endoscopically, affecting more than 200,000 patients. Because endoscopic vein-graft harvesting was linked with a greater that 1% absolute excess in patient death during 3 years of follow-up, endoscopic graft harvesting may potentially be resulting in hundreds or even thousands of excess deaths each year.

The study used data collected in the Project of Ex-Vivo Vein Graft Engineering via Transfection (PREVENT)—IV trial. That study, done during August 2002—October 2003 at 107 centers in the United States, was designed to test the efficacy of a new agent, edifoligide, to treat vein grafts prior to grafting in an effort to improve graft patency. The study's primary results failed to show that the treatment was effective (JAMA 2005;294:2446-54).

Surgeons who participated in the study were allowed to harvest a patient's saphenous veins by whichever method they preferred, either endoscopy or open surgery. Outcome data were available for 1,247 patients (42%) whose vein grafts were harvested without using endoscopy, and 1,753 patients (58%) whose vein grafts were either partially or completely harvested using endoscopy. The average age of the patients was 64, and 79% were men.

The 58% rate of endoscopic vein-graft harvesting seen at the 107 participating centers is probably representative of current, routine U.S. practice, Dr. Lopes said in an interview. This rate jibes with the

rates reported in national registries. In general, surgeons either use endoscopic harvesting for most or all of their patients, or don't use the method at all. No guidelines currently exist on endoscopic vein-graft harvesting, he said. Because endoscopic harvesting leads to less wound infection and better wound healing, compared with open-surgery harvesting, surgeons might particularly tend to use endoscopic harvesting on patients who are obese, have diabetes, have pe-

ripheral artery disease, or are women.

During 3 years of follow-up, the rates of death; death and myocardial infarction; and death, myocardial infarction, and need for revascularization were all higher in patients who received at least one endoscopically harvested vein. In a multivariate analysis that controlled for differences among the patients, including gender, age, body mass index, hypertension, renal function, and severity of heart failure, the patients who received at least one vein graft

obtained by endoscopy were significantly more like to have worse cardiac outcomes and worse survival. (See box.)

A second analysis looked at the link between graft-harvesting method and graft failure, which was defined as the development of either stenosis of 75% or greater or complete occlusion 12-18 months after CABG. The failure rate on a per-patient basis was about 47% of patients who received at least one endoscopically harvested vein and about 38% of





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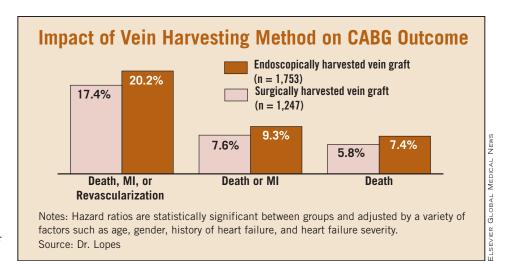
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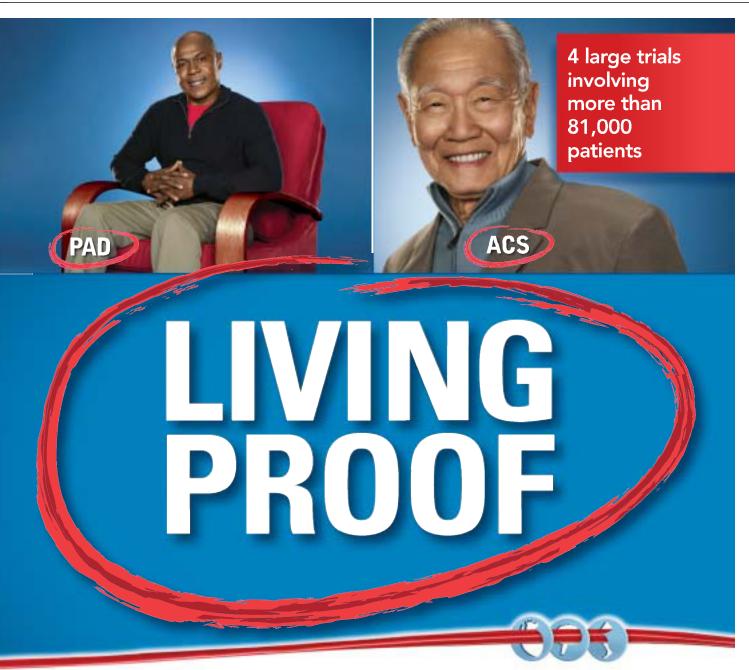
[†]For patients with non–ST-segment elevation acute coronary syndrome (unstable angina/non–Q-wave MI), including patients who are to be managed medically and those who are to be managed with percutaneous coronary intervention (with or without stent) or CABG, PLAVIX has been shown to decrease the rate of a combined end point of cardiovascular death, MI, or stroke as well as the rate of a combined end point of cardiovascular death, MI, stroke, or refractory ischemia.

[‡]For patients with ST-segment elevation acute myocardial infarction, PLAVIX has been shown to reduce the rate of death from any cause and the rate of a combined end point of death, reinfarction, or stroke. This benefit is not known to pertain to patients who receive primary angioplasty. those who did not receive an endoscopically harvested vein. The per-graft failure rate was about 28% for veins obtained by endoscopy and about 23% in grafts not harvested endoscopically.

Dr. Lopes and his associates called for a randomized, controlled study to confirm the poor performance of vein grafts obtained by endoscopy, compared with those harvested surgically. He noted that although the analyses controlled for baseline differences, it is possible that additional clinical factors confounded the results. But a randomized trial would probably take 2-3 years to run and it is unclear if any organization would be willing to fund it. Absent trial results, Dr. Lopes said that other CABG data sets could also be analyzed.

Although the reduced infection rate, quicker wound healing, and improved cosmesis provided by endoscopic vein harvesting might be attractive for some patients, it is unlikely that many patients or surgeons would be willing to choose these benefits at the expense of significantly worse survival, he said. "Until more data are available, surgeons and patients should carefully weigh the demonstrated short-term benefits [of endoscopic harvest] against the possibility of long-term harm.





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In clinical trials, the most common clinically important side effects were pruritus, purpura, diarrhea, and rash; infrequent events included intracranial hemorrhage (0.4%) and severe neutropenia (0.05%). (See ADVERSE REACTIONS.§)

§PLEASE SEE BRIEF SUMMARY OF **FULL PRESCRIBING INFORMATION** ON ADJACENT PAGE.



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