

HEART OF THE MATTER

President's Message



Howard C. Herrmann,
MD, FACC, President

In my last letter, I pointed out how important I think the ACC's national Political Action Committee (PAC) will be to the future of medicine both locally and nationally. As much of the ACC's agenda has shifted to advocacy, this may be the most effective way we have to influence the campaign process by contributing to candidates who support legislation that is consistent with the mission and goals of the ACC.

Fortunately, enough of you took my message to heart to make our state number one on the list of state contributors. Unfortunately, the percentage of members who contributed remains exceedingly low. Since April 1, 2003, about \$60,000 was collected nationally and contributed to federal Representatives and Senators supportive of our agenda. If you haven't contributed yet, please consider doing so.

In Pennsylvania, our chapter finances remain strong. Although we are legally prohibited from contributing to the PAC (donations must come from individuals), we are finding useful ways to spend some of your dues. Many of you (about 85 practices) requested the medical liability reform tool kit and should have received pamphlets, posters and displays for your waiting

rooms. The Chapter paid for their printing and distribution. We are also in the process of buying automated external defibrillators (AEDs) for the state. Through a partnership with the AHA, the Chapter will buy approximately six AEDs to be placed at highway rest stops. Training for the Department of Transportation staff as well as advocacy for passage of an AED registry is underway. A "kick-off" event in Harrisburg is also planned to raise awareness of this issue and to enhance the image of cardiologists in general

and the Pennsylvania ACC Chapter in specific.

Finally, I want to welcome our new district councilors: John Doherty, MD (Philadelphia, District I) and David Lasorda, MD (Sewickley, District IV). I hope to see all of you at the Annual Scientific Session (March 7-10, 2004) in New Orleans at which time Conrad Smith, MD will begin his term as President. I hope you will also make every effort to attend the Annual Chapter Meeting/Legislative Conference in Harrisburg on May 4, 2004. ■

Annual Chapter Meeting and Legislative Conference 2004

by Steven M. Ettinger, MD, FACC

The PaACC Annual Chapter Meeting and Legislative Conference will be held at the Harrisburg Marriott on May 4, 2004. This conference provides physicians and health care related professionals with an opportunity to discuss various legislative issues that have a direct impact upon the quality and deliverability of healthcare in the State of Pennsylvania. In addition, the conference allows for an informal dialogue between physicians from various regions in the state in an effort to develop new ideas and approaches relating to practice situations.

The conference will feature several outstanding lectures from represen-

tatives of the American College of Cardiology, Society of Cardiac Angiography and Interventions and the Pennsylvania Medical Society. In addition, legislative representatives from the House and Senate will present their perspective of the current health care crisis during this one-day conference.

In keeping with the mission of the PaACC — to educate and inform physicians of critical issues, the conference will also feature a "hot topic" session. Leading physicians will discuss the performance of PCI at hospitals without on-site surgical backup;

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Fall 2003



Pennsylvania Chapter

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HGSAdministrator Update on Drug-Eluting Intracoronary Stents

by Andrew Bloschichak MD, MBA, Medical Director
Pennsylvania Medicare Part B, HGSAdministrators

Congratulations

To the Chapter's Two Newly Elected District Councilors:

John Doherty, MD, FACC
Philadelphia — District I

David Lasorda, DO, FACC
Sewickley — District IV

With Medicare's recently announced coverage of drug-eluting intracoronary stents, HGSAdministrators has received numerous claims submitted to Medicare Part B for the physician's service of placement of such stents.

Unfortunately, there has been much confusion (both in Pennsylvania and nationally) regarding the proper coding for the physician's service of transcatheter placement of drug-eluting intracoronary stents in Medicare Part B.

Physicians should continue to use the CPT codes 92980/92981 (Transcatheter placement of an intracoronary stent(s), percutaneous,

with or without other therapeutic intervention, any method; single vessel/each additional vessel) for their professional service whether the stent(s) are drug-eluting or not. HCPCS codes G0290-G0291 will deny under the Medicare Part B fee schedule as they are only to be used (and paid) in the Medicare Hospital Outpatient Prospective Payment (HOPPS) setting.

I fully understand the confusion as: (a) The HCPCS descriptor states "transcatheter placement of a drug-eluting intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method"; and (b) A recent article published in

the "Cardiology Coding Alert" erroneously leads physicians to conclude that G0290-G0291 are to be used for the physician service when inserting drug-eluting intracoronary stents.

However, The Centers for Medicare and Medicaid Services (CMS) has recently confirmed to Medicare contractors that the G0290-G0291 codes are only to be utilized in the HOPPS setting. Physicians are to use the 92980/92981 codes in Medicare Part B for placement of intracoronary stent(s), regardless of whether the stent(s) are coated drug-eluting, or not. ■

Annual Chapter Meeting

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the financial impact of drug-eluting stents; and the impact and effects of the Pennsylvania Health Care Cost Containment Council (PHC4).

The PaACC extends an open invitation to all its members along with health care professionals to attend the 2004 Chapter Meeting and Legislative Conference. **In order to make changes in our health care system we all must be involved!!**

Registration information will be mailed to all chapter members in the new year. You will also be able to access the registration form at the Website at www.pcacc.org. ■

Email Addresses— You have them, We need them

Have you changed your e-mail in the past year?

If so, we can no longer reach you with our chapter e-mail communications. Please take a few seconds to help us update our e-mail address list.

Simply send an e-mail to melias@pamedsoc.org and type your full name in the subject field.

It's that easy—we will take care of the rest and you will begin receiving only important alerts, no junk e-mail, from the PaACC.

If you've acquired an e-mail address and haven't provided it to us yet, please send us a note. Thanks!

Update for Implantation of Automatic Defibrillators

This provider education article discusses the background of the National Coverage Determination (NCD) to expand coverage of implantable automatic defibrillators for services rendered on or after October 1, 2003, coverage guidelines, billing instructions for providers who render services to managed care patients, and billing instructions for providers who render services to fee-for-service patients.

Background

The NCD will be effective on October 1, 2003, to expand coverage of implantable automatic defibrillators for Medicare managed care and fee-for-service patients. Providers will be reimbursed for services provided to managed care patients for implantable automatic defibrillators that fall under the expanded coverage indications effective October 1, 2003, according to the NCD on a fee-for-service basis until capitation rates are adjusted to account for this expanded coverage.

Coverage Guidelines

The following services are covered when rendered on or after July 1, 1991:

- Documented episode of cardiac arrest due to ventricular fibrillation (VF), not due to a transient or reversible cause;
- Documented sustained ventricular tachyarrhythmia (VT), either spontaneous or induced by an electrophysiology (EP) study, not associated with an acute myocardial infarction (MI) and not due to a transient or reversible cause;
- Documented familial or inherited indications with a high risk of life-threatening VT, such as long QT syndrome or hypertrophic cardiomyopathy;

As stated in the NCD, the following indications will be covered when rendered on or after October 1, 2003:

- Coronary artery disease with a documented prior MI, a measured left ventricular ejection fraction ≤ 0.35 , and inducible, sustained VT or VF at EP study. (The MI must have occurred more than 4 weeks prior to defibrillator insertion. The EP test must be performed more than 4 weeks after the qualifying MI.);
- Documented prior MI and a measured left ventricular ejection fraction ≤ 0.30 and a QRS duration of > 120 milliseconds. Patients must not have:
 - a) New York Heart Association classification IV;
 - b) Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm;
 - c) Had a coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) within past 3 months;

- d) Had an enzyme-positive MI within past month;
- e) Clinical symptoms or findings that would make them a candidate for coronary revascularization; or
- f) Any disease, other than cardiac disease (e.g., cancer, uremia, liver failure), associated with a likelihood of survival less than 1 year.

As stated in the NCD, effective October 1, 2003, the following additional coverage guidelines apply:

- All patients considered for implantation of a defibrillator must not have irreversible brain damage, disease, or dysfunction that precludes the ability to give informed consent;
- MIs must be documented by elevated cardiac enzymes or Q-waves on an electrocardiogram. Ejection fractions must be measured by angiography, radionuclide scanning, or echocardiography; and
- All other indications remain noncovered except in Category B IDE clinical trials (60 CFR 48417) or as a routine cost in clinical trials defined under CIM 30-1.

NOTE: Refer to Coverage Issues Manual, Section 35-85 (revisions effective October 1, 2003).

Billing Instructions for Providers Who Render Services to Managed Care Patients

The following instructions apply to providers who render expanded implantable automatic defibrillator services to managed care patients:

- Providers are encouraged not to submit claims for services rendered on or after October 1, 2003, because Medicare will not be able to process the claims until January 5, 2004.
- Physicians must use modifier KZ (new coverage not implemented by managed care) when billing for services rendered on and after October 1, 2003.
- Providers billing fiscal intermediaries on or after October 1, 2003, must use condition code 78 (payment for coverage not implemented by HMO).
- Providers who are paid under the Outpatient Prospective Payment System (OPPS) must bill all services related to this expanded coverage on one claim and for the same date of service, using condition code 78.
- Providers billing carriers and providers who are paid under the OPPS must split the bills if they overlap September 2003 and October 2003.

Patients who receive these services must pay any applicable coinsurance amounts.

For services rendered to managed care patients whose indications fall outside this expanded coverage, providers must not bill using condition code 78 or modifier KZ.

Congratulations to

Paul N. Casale, MD

Dr. Casale has been elected to a four-year term of the Pennsylvania Medical Society's Board of Trustees as one of the 13 new specialty representatives. Dr. Casale will represent 18 medical specialties along with Dr. Linda Green (Allergy).

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HGSA Carrier Advisory Committee Reports

June 2003

By Donald C. Durbeck, MD, FACC
CAC Representative

Both Dr. Scher and myself attended the June 12, 2003, Highmark Blue Shield Carrier Advisory Committee meeting. General comments included additions to their Website, some with CME credits involved, as well as a listing of HIPPA compliant vendors. There was continued discussion regarding the need for Medicare coverage of self-administered drugs. Currently, coverage is available only if a majority of the doses are administered by a health professional.

Of the Pennsylvania medical policies reviewed, the one of interest to the PaACC was that regarding the Implantable Cardioverter Defibrillator. Current coverage, since July, 1999, has only been for documented VF not due to a transient or reversible cause; VT, either spontaneous or induced, not due to a transient or reversible cause, or for familial or inherited conditions with a high risk of ventricular tachyarrhythmia such as Long QT syndrome or IHSS. In addition, if a patient had an EF less than 35%, had nonsustained VT and inducible VT via EP study, an ICD is reimbursable (MADIT I Study criteria). Revisions contained in the newest policy, include a prior MI and an EF of 30% or less. This latter indication was added in response to the MADIT II study. The policy further requires evidence of a prior MI such as Q waves, enzyme documentation, a fixed nuclear defect, or cath evidence of an area of LV akinesis and obstructive CAD (criteria for inclusion and exclusion of the study population). The EF may be obtained by cath, MUGA, or Echo. The EF determination must be less than three months old. The patient may not have had coronary revascularization within the prior three months, and an MI within the prior month, and an arrhythmia associated with a transient or reversible cause.

Considerable discussion ensued, led by Dr. Scher, and complemented by written comments from several electrophysiologists across the state in regards to the time intervals between an MI or bypass surgery and device implantation. After consultation with some EP experts on the Chapter roster, it was agreed that a one month time interval was appropriate between MI and implant. The policy was unanimously approved without the QRS duration criteria specified in the CMS decision. This indication for ICD implant has been approved by multiple private carriers and HMOs without this criterion. There was also concern that the Pennsylvania policy was more far reaching than national policy, but that the data supports it. The approval was done during this window of

uncertainty about the final outcome of the exact criteria or date of enactment of the CMS decision.

The final draft of this policy will be made available shortly. Dr. Scher and I left the meeting feeling quite impressed by the willingness of the Highmark CAC committee to respond to new clinical data in this most responsible manner. We are proud that Pennsylvania is well ahead of the curve with regards to taking proactive stands in matters such as these.

September 2003

By David L. Scher, MD, FACP, FACC
Alternate CAC Representative

The Medicare Coverage Issue Manual dated August 22, 2003 (can get via Pennsylvania Medical Society or online at CMS site) states that the new MADIT II indication for ICD implants took effect October 3, 2003. It was stated at the meeting that the PA MCAC vote for approval in July was a significant factor in expediting the starting date by CMS. Unfortunately, the CMS guideline requires a QRS duration of > 120 msec for reimbursement. This is 'written in stone', though not consistent with private carriers who have approved reimbursement for any QRS duration. The reimbursement criteria for the new indication are:

Documented prior MI and a measured EF <31% and a QRS duration of >120 msec. Patients must NOT have:

- NYHA Class IV
- Cardiogenic shock or symptomatic hypotension while in stable baseline rhythm.
- Had a CABG or PTCA within the previous three months.
- Had an enzyme positive MI within the past month.
- Clinical symptoms or findings that would make them a candidate for coronary revascularization; or
- Any disease, other than cardiac disease (e.g. cancer, uremia, liver failure), associated with a likelihood of survival less than one year.

MI's must be documented by elevated enzymes, Q waves on ECG. EF must be measured by angiography, radionuclide scanning, or echocardiography.

Absence of irreversible brain damage, disease, or dysfunction that precludes the ability to give informed consent.

Since this is a national coverage policy, the national ACC, in addition to other cardiology organizations, should, if it chooses, petition CMS to change the QRS duration criteria.

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Fellows Corner

by William H. Sauer, MD, FIT Representative to PaACC Executive Council

The Fellow's Council welcomed new members in a dinner meeting in Philadelphia in early September, where there was representation from all the major training programs in Pennsylvania. The fellow representatives for 2003-2004 are:

Sean Curran, MD, *Lankenau Hospital*

Jeffrey Friedel, MD, *Allegheny General Hospital*

Fermin Garcia, MD, *Albert Einstein Medical Center*

Tareq Khawaja, MD, *Western Pennsylvania Hospital*

Ramarao Lankipalli, MD, *Graduate Hospital*

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J.D. Menteeer, MD, *Children's Hospital of Philadelphia*

Manoj Panday, MD, *Drexel University Hospital*

Anwer Qureshi, MD, *Geisinger Medical Center*

Peter Reyes, MD, *Temple University Hospital*

Bryan Robertson, MD, *Hershey Medical Center*

William Sauer, MD, *Hospital of the University of Pennsylvania*

Steven Silver, MD, *Thomas Jefferson University Hospital*

We have already had a seminar led by chapter president, Dr. Howard C. Herrmann, on "What's New in Interventional Cardiology." The event was well attended by fellows from all programs near Philadelphia. The yearly seminar on transitioning from fellowship to the job market is planned for early December with speakers from local cardiology practices, law firms skilled at contract negotiation, and job recruiters.

Our goal of learning about new technology and topics not traditionally covered in fellowship continues with planned seminars on pregnancy and cardiovascular disease, advances in interventional electrophysiology, and the emerging role of cardiac MRI in clinical practice. In addition, social events are planned in conjunction with the national heart meetings.

Fellows continue to be enthusiastic about planning events and bringing new ideas for the council to implement. This, along with Dr. William VanDecker's leadership and support, provides for an exciting and enriching year to come. ■

HGSA CAC Reports

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Reimbursement for high sensitivity C Reactive Protein for screening with regards to coronary artery disease was presented. It was stated that the local CAC, because of the original mandate of Medicare in the original legislation, cannot approve tests done for screening in the absence of signs or symptoms of disease.

Reimbursement for body surface mapping for the diagnosis of coronary artery disease was discussed. Because of a lack of clinical utility, it was suggested to have it reimbursed as a standard 12-lead ECG.

As of the meeting date, only 25% of providers in the Commonwealth were HIPPA compliant. The importance of this with regards to the deadline which was less than 30 days away was discussed. CAC has available much in-

formation with regards to becoming HIPPA compliant. It was discussed that small practices may be HIPPA-exempt and may choose to go paperless. However, it was stated that the burden it would place on local carriers will result in major prolonged delays in reimbursement, and that it would ultimately not be worthwhile to pursue this on a mere loophole basis.

It was stated that when submitting policy proposals to the CAC regarding new and emerging technology, it would be extremely useful to the CAC to have a specialty organization submit a model policy to the CAC. The CAC would then work with the organization to finalize the proposal. This was positively received by CAC members.

The next CAC meeting is Dec. 11, 2003. ■

Update for Implantation of Automatic Defibrillators

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Billing Instructions for Providers Who Render Services to Fee-for-Service Patients

The following instructions apply to providers who render expanded implantable automatic defibrillator services to fee-for-service patients:

Claims for these services cannot be billed using modifier KZ, condition code 78, or for services outside of this expanded coverage.

Procedure Codes

- 33240
- 33245
- 33246
- 33249
- ICD-9-CM Procedure Code 37.94 (for IIX TOBs) ■

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Legislative Update

provided by the Pennsylvania Medical Society

Take Action! State Senate Vote for Caps Phase 2—November 5 to End of Legislative Session

The Pennsylvania Senate vote on a constitutional amendment to permit caps on non-economic damage awards could occur before the end of December. The Pennsylvania Medical Society is preparing an aggressive public relations and media campaign during these critical weeks, using billboards, radio and newspaper advertising. Advertisements and selected media will be deployed in targeted areas. Even though you may not see a billboard or newspaper ad in your immediate community or region, it's vital that you **engage your patients** in this campaign.

The goal is to reach every Pennsylvania patient with these message points:

- Lawsuit abuse makes it increasingly difficult for Pennsylvania doctors to provide their patients with the kind of care they need.
- Help protect your access to care and your doctor-patient relationship.
- Help stop lawsuit abuse in Pennsylvania: Ask your State Senator to support caps. ■



Cardiac Care Team Members Eligible for New ACC Associate Membership

The National ACC is now accepting applications for a new category of membership exclusively for Registered Nurses, Nurse Practitioners, Clinical Nurse Specialists, and Physician Assistants. The Cardiac Care Associate member category allows the whole team of cardiovascular professionals to benefit from the educational resources of the American College of Cardiology.

For more information or to download an application today, visit www.acc.org or contact RoseMarie McMahon at rmmahon@acc.org or (800) 253-4636 extension 675. ■

Clinical Briefs from *Journal Watch Cardiology*

Is Carvedilol Better Than Metoprolol for Chronic Heart Failure?

Though pharmacologically distinct, the beta-blockers carvedilol, metoprolol, and bisoprolol all are much more effective than placebo for treating chronic heart failure. In a randomized trial supported by the makers of carvedilol, researchers in Europe directly compared that drug (at a target dose of 25 mg twice daily) with metoprolol tartrate (at a target dose of 50 mg twice daily) in 3029 patients with chronic heart failure (mean age, 62; mean LV ejection fraction, 26%). Treatment lasted a mean of 58 months.

Estimated 5-year all-cause mortality incidence was 17% lower with carvedilol than with metoprolol (34% vs. 40%, $P=0.002$); the finding was consistent in predefined subgroups (e.g., age <65 vs. ≥ 65 and LVEF $\leq 25\%$ vs. $>25\%$). The carvedilol and metoprolol groups had the same rate of permanent study-drug withdrawal (32%) and similar rates of beta-blocker-related side effects (about 10%).

Notably, average daily doses received were 42 mg for carvedilol and 85 mg for metoprolol. By 4 months, resting heart rate had been reduced slightly — but significantly — more by carvedilol than by metoprolol (by 13.3 vs. 11.7 beats per minute, respectively); the difference remained significant until 14 months.

Comment: These findings might suggest that carvedilol (a comprehensive antiadrenergic agent) is superior to metoprolol (a β_1 -blocker) for chronic heart failure. The 17% mortality reduction and an estimated increase in life expectancy of 1.4 years with carvedilol over metoprolol are impressive. However, an editorialist notes that dosing must be considered. The mean daily dose of immediate-release metoprolol used in this trial (85 mg) was lower than the mean daily dose of controlled-release metoprolol succinate (159 mg, equivalent to 106 mg of metoprolol tartrate) used in the MERIT-HF trial (JAMA 2000; 283:1295).

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Clinical Briefs from *Journal Watch Cardiology*

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For many physicians, carvedilol will be the preferred beta-blocker for chronic heart failure, but the question remains whether carvedilol can be assumed superior to controlled-release metoprolol, particularly given carvedilol's substantially higher cost. — **Beat J. Meyer, MD**

Poole-Wilson PA et al. for the COMET Investigators. Comparison of carvedilol and metoprolol on clinical outcomes in patients with chronic heart failure in the Carvedilol Or Metoprolol European Trial (COMET): Randomised controlled trial. *Lancet* 2003 Jul 5; 362:7-13.

Dargie HJ. β blockers in heart failure. *Lancet* 2003 Jul 5; 362:2-3.

Rapid Transfer for Primary Angioplasty Beats Fibrinolysis

In a multicenter Danish trial, 1572 patients with ST-segment-elevation MI (STEMI) and symptoms for <12 hours were randomized to fibrinolysis (accelerated alteplase) or primary angioplasty. Patients in the angioplasty group who presented to the 24 hospitals that lacked angioplasty facilities (referral centers) were transferred to the nearest of 5 invasive-treatment centers. Only 4% of screened patients were excluded because they could not tolerate transport.

The fibrinolysis and angioplasty groups had similar baseline characteristics, including time from symptom onset to randomization (overall median, 135 minutes). The median distance between referral centers and invasive-treatment centers was 50 km (31 miles). The median transfer time for the 559 angioplasty patients initially seen at referral centers was 67 minutes; adverse events during transfer included atrial fibrillation (14 patients), heart block (13), and ventricular fibrillation (8).

Mostly because of a difference in reinfarction rates, incidence of the primary composite endpoint (death, clinical reinfarction, or disabling stroke at 30 days) was significantly higher with fibrinolysis than with angioplasty for all patients (13.7% vs. 8.0%), for patients seen initially at referral centers (14.2% vs. 8.5%), and for patients seen initially at invasive-treatment centers (12.3% vs. 6.7%). In the fibrinolysis group, 26 patients underwent repeat fibrinolysis, 15 underwent rescue angioplasty, and 148 (19%) underwent mechanical revascularization within 30 days.

Comment: This study documents the feasibility, safety, and efficacy of a reperfusion strategy that includes transfer of STEMI patients to invasive-treatment centers for primary angioplasty. Overall treatment delay was minimized by having 5 invasive centers, by using the same ambulance for transfer as for initial arrival, and by immediately notifying the invasive centers before transfer. The major benefit of angioplasty was in reduced reinfarction rates, suggesting that low rates of rescue angioplasty and sub-

sequent revascularization in the fibrinolysis group might have contributed to the overall observed benefit. We still need more U.S. studies comparing prehospital treatment, transfer to invasive centers, and various integrated approaches. — **Howard C. Herrmann, MD**

Andersen HR et al. for the DANAMI-2 Investigators. A comparison of coronary angioplasty with fibrinolytic therapy in acute myocardial infarction. *N Engl J Med* 2003 Aug 21; 349:733-42.

Jacobs AK. Primary angioplasty for acute myocardial infarction — Is it worth the wait? *N Engl J Med* 2003 Aug 21; 349:798-800.

Do Sirolimus-Eluting Stents Also Benefit ACS Patients?

Although sirolimus-eluting stents (SES) have reduced restenosis rates by up to 80% in randomized trials, these studies excluded acute coronary syndrome (ACS) patients. In this study of single-center registry data from the Netherlands, 198 consecutive patients with ACS (unstable angina or acute MI) received only SES and were followed for 30 days.

Procedural success was achieved in 96% of patients. The 30-day rate of major adverse cardiac events (MACE) was 6.1%, including death (3%), nonfatal MI (3%), target-vessel revascularization (1%), and stent thrombosis (0.5%).

The researchers compared the SES recipients with a control group of 301 ACS patients who received bare-metal stents in the 4 months preceding the registry. Compared with controls, the SES recipients were more likely to undergo primary angioplasty and bifurcation stenting and less likely to receive glycoprotein IIb/IIIa inhibitors, yet the 2 groups did not differ significantly in rates of procedural success or MACE. In multivariate analysis, use of SES failed to predict 30-day MACE.

Comment: This study shows that sirolimus-eluting stents may be used safely in ACS patients without increasing risk for early (30-day) adverse events. However, because serial enzymes were obtained in only 46% of SES recipients, their rate of nonfatal MI may have been underestimated. Although restenosis rates likely are lower when ACS patients receive SES rather than bare-metal stents, this study does not prove that. — **Howard C. Herrmann, MD**

Lemos PA et al. Early outcome after sirolimus-eluting stent implantation in patients with acute coronary syndromes: Insights from the Rapamycin-Eluting Stent Evaluated At Rotterdam Cardiology Hospital (RESEARCH) registry. *J Am Coll Cardiol* 2003 Jun 4; 41:2093-9.

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Clinical Briefs from *Journal Watch Cardiology*

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Two Distal-Protection Devices Compared for PCI in SVGs

Distal protection with a balloon occlusion/aspiration device can reduce complications by about 40% during percutaneous coronary intervention (PCI) in saphenous vein grafts (SVGs; *Circulation* 2002; 105; 1285). Protection with catheter-based filters offers maintained perfusion and ease of use, but does it limit complications as effectively as balloon occlusion/aspiration?

In a multicenter study, 651 patients scheduled to undergo PCI in SVGs were randomized to distal protection with either the GuardWire (GW) balloon occlusion/aspiration system or with the filter-based FilterWire EX (FW) system. About half the patients in each group received glycoprotein IIb/IIIa inhibitors before the procedure.

Device success was similar with the 2 systems (GW, 97.2%; FW, 95.5%), as were postprocedural measures of epicardial flow, angiographically detected complications, and the extent of myonecrosis. Bailout use of GPIIb/IIIa inhibitors, however, was required slightly more often with the GW than with the FW system (1.5% vs. 0%, $P=0.03$). The 2 groups did not differ significantly in the composite incidence of death, MI, or target-vessel revascularization at 30 days (GW, 11.6%; FW, 9.9%).

Comment: This first comparison of 2 FDA-approved distal microcirculatory protection devices for SVG PCI documents similar safety and efficacy with the novel, filter-based FilterWire EX and with the GuardWire balloon occlusion/aspiration system. However, periprocedural adverse outcomes occurred in about 10% of patients with either device, prompting the authors to call for “complementary device-based innovations and new pharmacologic regimens” to improve the safety of interventions in these high-risk patients.

— **Beat J. Meyer, MD**

Stone GW *et al.* for the FilterWire EX Randomized Evaluation (FIRE) Investigators. Randomized comparison of distal protection with a filter-based catheter and a balloon occlusion and aspiration system during percutaneous intervention of diseased saphenous vein aorto-coronary bypass grafts. *Circulation* 2003 Aug 5; 108:548-53. ■

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