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INSIDE

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Special Report: PVS options

Which is best way to go for PVS: Compress, suture, or seal?

Leanings vary, but devices decrease length of stay for the surgery

Your options for closing the femoral artery access site following catheterization procedures such as diagnostic angiography, angioplasty, stenting, and atherectomy are broadening. In addition to the traditional method of manual compression for percutaneous vascular surgery (PVS), with or without clamping, there are three FDA-approved means available now — two of which rely on collagen plugs, the other on suturing. **(See story containing basic information on the three methods, p. 77.)** A fourth arterial closure device, not yet approved, also looks promising.

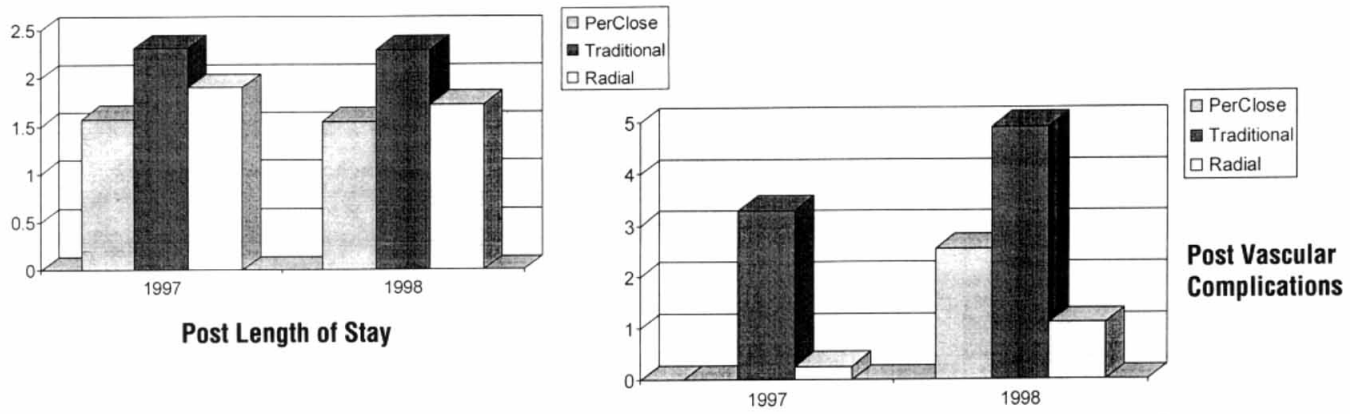
This article is intended to help you compare the suturing and plug methods. It seems clear that any one of those products is more effective and efficient than the manual compression techniques, but which one is best for your facility — and saves your facility money and time — should be based on independent testing and experience. We offer here the opinions of various clinicians and administrators across the country who have tried at least one of the devices.

One is **Cheryl M. Morgan**, RN, a nurse data abstractor at Morton Plant Hospital in Clearwater, FL. She says they either use the Perclose suturing device following their femoral catheterization interventions, or compress the site manually or with a clamp. Even though using the suturing device costs more than using manual compression, she says. "It has saved us money because our lengths of stay are definitely shorter and our vascular complications have decreased." **(See charts showing those data, p. 74.)**

Morgan says patients respond better to the suturing method. "They can get up faster — they hate to lie down for six to eight hours waiting for a clot to form and strengthen at the arterial puncture site."

In addition, her facility's cardiologists increasingly have been using radial access for caths, and that option is an alternative as well. **(See related article on radial access, p. 79.)**

Morton Plant Hospital Data
Interventional Cardiology Patients



Source: Cheryl Morgan, RN, Morton Plant Hospital, Clearwater, FL.

"We don't use VasoSeal or AngioSeal, but plan to run a pilot study on those products soon," Morgan says. "The physicians are happy with the suturing system that we use now, but they want to review other options as well."

This past May, the Food and Drug Administration (FDA) approved a labeling claim of reduced time to discharge for the two new PVS products — both made by the same company — that feature suturing rather than collagen plugs. To comply with FDA regulations, the devices have to be used for patients who have no other medical conditions requiring hospital observation.

The suturing products, Techstar 6F (six French) and Prostar 8F (eight French), manufactured by Menlo Park, CA-based Perclose, are the only PVS-suturing products on the market approved for that labeling claim. Both have also been granted permission to use the labeling claims of reduced time to hemostasis and ambulation.

The reduced time-to-discharge claims were granted based on two clinical studies, STAND I and STAND II, which showed that patients treated with the Perclose devices left the hospital earlier than patients treated with conventional compression methods.[1] Time to hemostasis for Perclose patients was 0.3 hours, and time to ambulation was 3.9 hours.

Once a diagnostic or interventional cath is completed and the anticoagulation level normalizes, unless one of the new PVS devices — AngioStat, VasoStat, or the Perclose system — is chosen, the traditional method of stopping blood flow at the groin site is for a nurse or technician to press down on the wound for 20 to 30 minutes or resort to mechanical compression devices such as Femostop or Clamp Ease to create the seal and then monitor for continued hemostasis.

If you use compression, patients have to stay under observation for several hours — sometimes overnight if the procedure is done late in the day. Walking is out of the question until a substantial clot has stabilized. Recovery takes longer if the patient was given anticoagulants.

In the interventional setting, the introducer sheath remains in the patient's artery, and the compression process can be delayed for up to 12 hours until normal coagulation levels apply.

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The duration of the recovery period can range from 12 to 30 times the duration of the original procedure, and it is often considered the most difficult component of the procedure for both patient and caregiver. The access leg is kept in a fully extended position, and the head cannot flex for at least six hours. Patients must ask for assistance with feeding and urinating, sometimes have to be restrained, and often complain of leg cramps and back and shoulder pain. Those precautions are taken to prevent complications such as bleeding from the puncture site, hematoma, pseudoaneurysm, and arterial-venous fistula.

Saving on admission and nursing labor

Linda Hicks, the coordinator of the cath lab at OSF St. Francis Medical Center in Peoria, IL, says the staff at St. Francis started using the suturing devices in December 1998.

"We've absolutely seen a reduced time to discharge with this," she says. "Since 80% of our patients are outpatients — before we had Perclose — if we did them at three in the afternoon, they would have had to be admitted and either stay overnight or be released after three to four hours of bed rest. Now we do them with Perclose, and in an hour they're home. They don't have to be admitted to the hospital, and the hospital doesn't have that admission charge and labor-intensive nursing for no reason other than for the patient to lay there until they can get up and walk."

She says that they have used VasoSeal as well, but "the suturing is more reliable."

John Stewart, the administrative director at Sacred Heart Regional Heart Institute in Pensacola, FL, agrees.

"We use some vascular device [rather than manual arterial compression] on 85% of our cath patients," he says, "and for 75% of those we use the suturing system because our physicians are more comfortable with that, and they can discharge their patients earlier."

Stewart says the cardiovascular staff at his facility has experienced some delays and complications with the collagen plug devices.

"There is some hold time after the procedure because the plugs can be coughed out," he says.

Coughing or sneezing can increase vascular pressure and dislodge the clot, causing bleeding. Also the plugs leave a foreign body beneath the skin for a time, and typically, in the words of **Edwin W. Rogers Jr.**, MD, a cardiologist at Sacred Heart, "the body doesn't like that." The sutures dissolve over time.

Stewart and Rogers conducted a retrospective analysis measuring LOS and hospital resource utilization following use of the suture-based hemostasis system. In both diagnostic and interventional groups, the duration, nursing intensity, and average cost decreased while patient satisfaction was enhanced.

"Taking into account the cost of the device, we've enjoyed an annual savings of $298,000 using the suturing device," says Stewart. That was accomplished because 60% of Sacred Heart's cath patients are now able to be done on an outpatient basis.

"Our outpatient cath lab costs decreased by 13%, and our inpatients costs decreased by 3%," he adds. "For inpatients, we utilize critical care and progressive care a lot less than we used to. Nearly all our patients go to the floors now without sheaths. Our mean length of stay is one day."

"We don't intend to eliminate VasoSeal and AngioSeal entirely," Stewart explains. "We don't utilize them as much as Perclose, but there are situations where they have to be used because

For More Information

- **AngioSeal**, The Kendall Co., 15 Hampshire St., Mansfield, MA 02048. Telephone: (888) 864-7444. Web site: www.angio-seal.com/contact.htm. E-mail: tordella@kendallhq.com.
- **Duett**, Vascular Solutions Inc., 2495 Xenium Lane N., Minneapolis, MN 55441. Telephone: (612) 553-2970. Fax: (612) 553-2089. Web site: www.vascularsolutions.com.
- **Hemoband**, TZ Medical, 15858 S.W. Upper Boones Ferry Road, Lake Oswego, OR 97035. Telephone: (503) 639-0282; (800) 944-0218.
- **Perclose Inc.**, 400 Saginaw Drive, Redwood City, CA 94063. Telephone: (650) 473-3100. Web site: www.perclose.com. E-mail: info@perclose.com.
- **VasoSeal**, Datascope Corp., 14 Philips Pkwy., Montvale, NJ 07645. Telephone: (201) 391-8100. Web site: www.vasoseal.com.

suturing isn't feasible. If a patient presents with a tortuous stick site or a bifurcation of the vessel, the way Perclose deploys, you can't use it. Also, if there's a rock-hard calcification, Perclose cannot be used. Rather than use nothing and compress manually, we use VasoSeal or AngioSeal; on those patients, they tend to work well."

Kevin Barnes, RN, clinical nurse in the cardiac cath lab at Scripps Mercy Hospital in San Diego, reports that they use both VasoSeal and AngioSeal, but find that VasoSeal meets their needs more often.

"AngioSeal provides a collagen mechanism to close the artery, but it requires a dissolvable intra-arterial anchor," he explains, "and that can cause problems with patients with peripheral vascular disease. The disk goes on the inside of the artery and opens up to form a seal at the puncture site, and on top of that you tamp a collagen plug. The artery wall is sandwiched between the disk and a collagen plug."

AngioSeal forms a good seal on the artery, Barnes adds, but the disk has to fit exactly flat against the inside of the artery. If there are calcifications and the artery wall is rough, the disk may not fit right and there will be leaking around it."

VasoSeal is entirely extra-arterial and can be used with such patients. "You apply the collagen plug to the top of the artery — a sort of tire patch," he says.

Another reason the cath lab at Scripps uses VasoSeal more than the other collagen sealer is because AngioSeal requires a physician to insert the intra-arterial component. With the VasoSeal, once the case is finished, the physician leaves the care of the groin area to the nurse-tech teams.

"Our nurse-tech team can apply the extra-arterial sealer," Barnes says. They have been inserviced and have gone through a training program. "Our techs do so many — 2,500 cases a year — they have the competency and experience to get good results. While the physician is talking to the family and writing orders, our techs can relieve him of that task."

Patients like quicker mobility with collagen

Barnes says patients are happy with both of the collagen devices because they can get up sooner than with the manual compression. "The diagnostics get up in two or three hours and move around. They are much more comfortable with improved mobility and ambulation."

Cost Management in Cardiac Care asked Barnes if he's ever experienced a collagen plug being coughed out. He replies that it does happen but very rarely: "Anytime you apply pressure to an artery from the inside, there can be a problem. The patient has to be warned that if they are going to cough or sneeze, apply a little pressure over the area."

He says if a cough-out happens, the patient might get a small hematoma over the area, "but I don't see it as a major problem."

Scripps has had no experience with the Perclose systems, but Barnes points out that they require a physician to suture. "Our physicians have decided not to go that way," he says. "I have heard others say that if you are going to use it, the physician has to be very skilled or you can get into problems with it."

CMCC asked others if anyone but a physician

Medicare may pay a part . . . or may not

Is any post-cath percutaneous vascular surgery procedure reimbursable? Because the arterial closing is not the principal procedure, and because it has no existing code, for inpatient services the DRG classification of diagnostic or interventional cath procedures will not change as a result of the closure. A miscellaneous ICD-9-CM procedure code, for example, 39.99 (other operations on vessels), or another payer-specific miscellaneous code may be used to document the closure.

For outpatient services, arterial closure devices most likely would be considered a general supply or device under the ancillary services category. General revenue codes for medical surgical supplies and devices are 270, 272, and 279; or 621 and 622. Payment for the devices depends on the payer. Current Medicare policy in the outpatient environment will usually pay some portion. Private insurance normally allows reimbursement for the devices. ■

could do the suturing. Hicks says the suturing system carries with it a somewhat lengthy training period — about 10 cases — but "once the doctors are proficient, the suturing takes five minutes or less."

The doctors at St. Francis do the suturing now, but, says Hicks, "we can train staff to do it too, if we want to."

Sacred Heart has also opted not to cross-train its nurses or technicians to suture with Perclose. "Sacred Heart is not a teaching facility, and our physicians prefer to do it themselves," says Stewart.

The suturing systems are also more expensive, Barnes points out. "Our physician director of the cardiovascular department has said that if you look at charges, not cost, there's an $800 savings when we use a collagen product."

Kevin Wolschleger, MD, at St. Joseph's Hospital and Marshfield Heart Care Clinic in Marshfield, WI, says they haven't tried Perclose yet, but have it in mind. "AngioSeal and VasoSeal are equivalent. They have their pluses and minuses, but perform about the same." Marshfield Heart Care performs more than 2,000 cardiac cath procedures and more than 700 interventional procedures each year.

Sandy Charlton, a nurse practitioner who works with the cardiologists at Arkansas Heart Hospital in Little Rock, says they have been using the suturing system for over a year. "We Perclose every single case we do on a daily basis, as long as the patient is a candidate."

Reference

1. Baim D, Pinkerton C, Schatz R, et al. Acute results of the STAND II percutaneous vascular surgical device trial. *Circulation* 1997; 96-98:I-443 (2,468).

Suggested reading

Shrake KL, Mayer SA. A cost analysis of complications associated with arterial closure following diagnostic and therapeutic cardiac catheterization. *J Cardiovasc Mgmt* 1998; 6:26-33.

Shrake KL. Vascular sealing devices: Are the advantages sustainable? *J Cardiovasc Mgmt* 1999; 1:16-19.

Sanborn TA, Gibbs HH, Brinker JA, et al. A multicenter randomized trial comparing a percutaneous collagen hemostasis device with conventional manual compression after diagnostic angiography and angioplasty. *J Am Coll Cardiol* 1993; 22:1,273-1,279. ■

Three new arterial closure devices are FDA-approved

Two employ collagen; the other sutures the site

Now, with three new devices, closing the femoral access site following diagnostic and interventional catheterizations can be done in three FDA-approved ways:

1. VasoSeal, manufactured by Datascope of Montvale, NJ, fills the tunnel with two successive plugs of purified cow collagen, which has been used in surgery since 1960 to help stop bleeding. The collagen overlays, but does not intrude into, the punctured artery. At the site of puncture, collagen biochemically stimulates clot formation while it mechanically blocks the hole. The device received FDA approval for sale in this country in September 1995.

2. AngioSeal, manufactured by Kensey-Nash of Exton, PA, uses collagen plus an internal plastic cork. The cardiologist uses a tube to insert a bit of plastic, shaped like a hat, into the artery. He pulls a string looped through the hat, drawing the hat up to its brim in the puncture. A biochemical seal is added by discharging collagen from the installation tube as it is backed out. The procedure takes two minutes. The hat and string, as well as the collagen seal, are degraded by the body within 90 days. The device was approved last August.

3. Perclose's Prostar and Techstar systems fit into the femoral artery through a sheath, where the physician causes them to deploy the points of flexible needles. With a tug on the device handle, the needles penetrate the artery wall adjacent to the puncture. Outside the artery, a cylinder captures the needlepoints. The cardiologist pulls them out, each one trailing a suture, cuts away the needles, ties two square knots, and pushes the knots down to the surface of the artery, sewing the hole shut. The devices provide immediate post-cath hemostasis without relying on the formation of a blood clot at the arterial access site. **(See article, p. 78.)**

The Prostar device deploys four needles and pulls two suture loops through the artery wall. The Techstar device deploys two needles and pulls one suture loop. The devices received approval in 1997 and have just acquired additional claims approval this spring.

The list price of VasoSeal is $195 and AngioSeal is $205. Prostar costs $325 and Techstar costs $225.

In addition, Vascular Solutions in Minneapolis has developed the Duett sealing device which takes a dual approach to arterial access site closure: A balloon catheter initiates hemostasis of the access site, then a natural procoagulant is delivered to form a permanent seal.

The Duett sealing device is currently distributed in international markets while undergoing studies and awaiting FDA approval. Presently, Duett can only be used for clinical investigations. ■

How the suturing device works

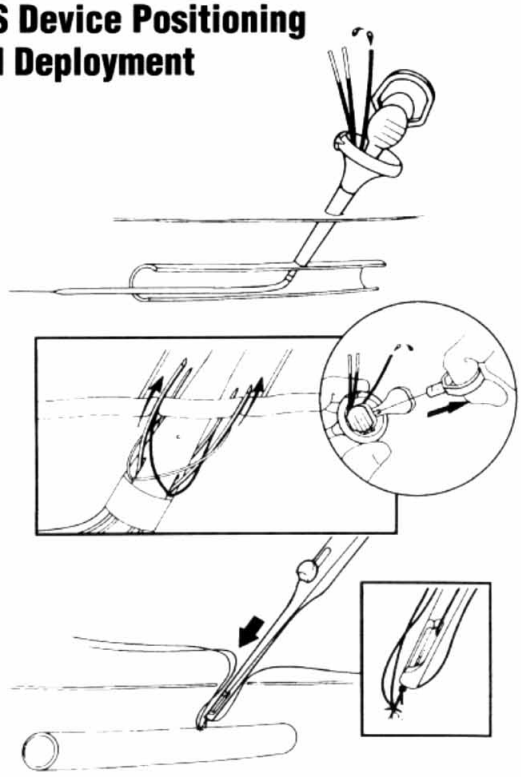
Percutaneous vascular surgery (PVS) device positioning, needle and suture deployment, and knot advancement. (See picture, top right.)

At the end of the diagnostic or interventional catheterization procedure, the artery sheath is removed and the PVS device is introduced into the femoral artery over a guidewire. The barrel of the device, which receives needles after deployment, rotates, facilitating introduction of the device.

Appropriate positioning is indicated by a pulsatile flash of blood from the marker lumen exiting the proximal section of the device. The lumen communicates with a small port which, when positioned intraluminally, permits backbleeding through the lumen. Needle tips are located distal to the marker port; thus, the flash of blood from the marker lumen indicates the needle tips are intraluminal and correctly positioned to capture arterial tissue. Needles and sutures are deployed by unlocking and pulling the ring handle.

Once deployed, the needles are removed from the device and cut from the sutures. A square knot is tied and then advanced with a knot pusher to the surface of the artery while the device is simultaneously removed. Guidewire access may be maintained until hemostasis is confirmed. Once hemostasis is achieved, overhand throws are advanced to secure the position of the square knot. The sutures are then trimmed below the skin and a sterile dressing is applied to cover the access site. ■

PVS Device Positioning and Deployment



Source: Perclose Inc., Menlo Park, CA.

Radial Access: Patients' Lengths of Stay

Post LOS (Mean days)	1997	1998
PerClose Device	1.57	1.55
Traditional (Femoral/ No PerClose)	2.31	2.29
Radial Access	1.90	1.72

Vascular Comps	1997	1998
PerClose Device	0/62 0%	5/196 2.55%
Traditional (Femoral/ No PerClose)	44/1335 3.3%	60/1223 4.91%
Radial Access	1/386 0.26%	6/243 1.10%

Source: Cheryl Morgan, RN, Morton Plant Hospital, Clearwater, FL.

Then there's radial access

Those lengths of stay are short

Cheryl Morgan, a nurse data abstractor at Morton Plant Hospital in Clearwater, FL, says the cardiologists there are increasingly using radial access for their catheterizations, placing hemobands immediately after the procedure.

Morgan's department has kept retrospective comparative data for three years on length of stay (LOS) and complications for three categories: "Femoral access, no Perclose," "Femoral access, Perclose," and "Radial access." **(See chart, p. 78.)**

"Our lengths of stay are definitely shorter with the 'Femoral access, Perclose' patients than with the 'Femoral access, no Perclose' patients. Radial access patients don't create much of a cost differential except for the hemobands," she says. **(See article "Radial access for stents: Fewer complications, shortened LOS" in *Cost Management in Cardiac Care,* November 1998, for information on other facilities using radial access for caths.)**

But the radial access patients' lengths of stay are short as well. "Four or five physicians here do radial access because of our favorable complications and length of stay data for radial," Morgan says. "The method is also a powerful patient satisfier, significantly decreasing mandatory bed rest time." Contraindications to radial access include an absence of perfusion through the ulnar and radial arteries and arterial spasms. ■

Take plaque's temperature to predict heart attack

Elevated artery temps may identify patients at risk

A new procedure that measures the temperature of blood vessels may hold potential as a way to identify people at risk for an impending heart attack, a new study has found.[1]

A simple, inexpensive test, thermography may prove useful also for diagnosing conditions such as myocarditis and aortitis, and predicting which plaque-obstructed arteries, already opened by balloon angioplasty, have a high risk of narrowing again. Thermography could also monitor the effects of antibiotics or other drugs.

The investigators used a tiny thermometer attached to the tip of a catheter to measure the temperature at selected sites on the interior lining of the coronary arteries of 90 people, of whom half were without disease and half had atherosclerosis. The researchers divided the heart-disease patients into three groups: 15 with stable angina, 15 with unstable angina, and 15 who had experienced a heart attack.

Five readings were taken at sites along a section of healthy artery wall. Another five were taken at sites on the plaque in the patients with atherosclerotic arteries. Among 45 disease-free people, the temperature was steady throughout the coronary artery — an average of 0.65° C above oral temperature. Among the 45 with hardening of the arteries, plaque temperatures were lowest in the stable-angina group and highest in the heart-attack group.

The temperature difference between plaque and healthy vessel wall was progressively greater in patients with more severe clinical conditions. The average difference was:

— 0.106° C among patients with stable angina;

— 0.683° C among patients with unstable angina;

— 1.472° C among infarction patients.

No correlation was found between the amount of narrowing in blood vessels and plaque temperature. "This explains the observation that the internal diameter of the blood vessel is not critical — both wide and narrow blood vessels could lead to acute heart attacks," wrote the lead author.

Because it can identify vulnerable plaque — that is, plaque that may rupture and cause a heart attack — thermography can be used to

KEY POINTS

- Thermography may provide a new clue to patients' AMI risk.
- The theory is that bacterial infections and inflammation may play a significant role in the development of atherosclerosis.

help predict which individuals are most likely to have a heart attack, commented **Valentin Fuster**, MD, president of the American Heart Association: "The technology fits into a growing number of methods — invasive and noninvasive — being developed that are based on the new knowledge that plaque rupture is one of the major triggers of a heart attack."

The researchers undertook the study because of growing evidence that bacterial infections and inflammation may play a significant role in the development of atherosclerosis. Temperature elevations, they reasoned, could provide an easy method to detect infections or inflammation.

Levels of C-reactive protein, a strong indication of infection, increased as the plaque temperatures rose, supporting the theory that temperature elevation is due to acute inflammation.

"According to the theory of inflammation as a factor in the development of atherosclerosis, local increase of temperature could be detected in plaques," the lead author wrote. "Our finding supports, but does not prove, the theory that bacterial infection is a factor contributing to atherosclerotic plaque development."

Reference

1. Stefanadis C, Diamantopoulos L, Vlachopoulos C, et al. Thermal heterogeneity within human atherosclerotic coronary arteries detected in vivo: A new method of detection by application of a special thermography catheter. *Circulation* 1999; 99:1,965-1,971. ■

T-graft technique promises longer-lasting bypasses

New configuration may avoid or delay re-CABGs

A new surgical technique for coronary artery bypass grafts has been shown to be safe, effective, and an economic improvement on surgical methods currently used for such operations. A study describing T-graft configuration was presented at the annual meeting of the Chicago-based Southern Thoracic Surgical Association in St. Louis earlier this year and will be published in a few months in the *Annals of Thoracic Surgery*. Investigators found that their technique results in longer-lasting bypasses with reduced chances for postoperative infections.

KEY POINTS

- A new technique uses arteries from both the arm and chest to form a T-shaped conduit for CABG procedures.
- Traditional bypasses that use a leg vein as the conduit work well, but for a limited time because the vein doesn't "like" being part of the arterial system.

Researchers examined 650 patients who had undergone bypasses using T-graft configuration. They tracked operative survival, wound infection, and incidences of such conditions as stroke and found the operation to be safe and "a better alternative to current techniques used for bypasses," stated senior study author **Hendrick B. Barner**, MD, professor of cardiothoracic surgery at Washington University School of Medicine in St. Louis.

The mortality rate for patients in the study was 0.2% — one person out of 650 died within 30 days of the operation. "That's an incredibly low rate," said Barner. "For low-risk patients, the rate for the standard procedures ranges from about 1% to 3%."

The T-graft configuration technique uses arteries from both the arm and chest to form a T-shaped conduit around the diseased portions of the heart. The study's authors say the method, while complicated to master, offers surgeons a longer, wider conduit to work with as they revascularize the heart compared with using both internal thoracic arteries.

Traditional bypasses that use a leg vein as the conduit work well, but for a limited time, commented Barner, because the vein doesn't "like" being part of the arterial system. What's more, he said, veins used in bypass operations harden — about half close within 10 years, leaving patients back where they started.

Within 15 years of a bypass operation, some 75% of all veins develop atherosclerotic plaque, and patients "end up needing another bypass 10 years after the first one," he said. Over the last 20 years, surgeons have been substituting internal thoracic arteries for the leg veins because arteries outpace veins and remain disease-free at least twice as long.

The Washington University study examined the effectiveness of using one artery from the chest, the left internal thoracic artery, and one from the forearm, the radial artery. The primary

benefit, stated Barner, is that the radial artery is longer than the right internal thoracic artery, offering surgeons more flexibility when fashioning the alternate conduit. Using the radial artery also lowers the risk of chest wound problems. When surgeons use both internal thoracic mammary arteries, they run the risk of sternal infections because that artery provides blood to the sternum. Breastbone infection was experienced by only four patients, or 0.6% of the study group.

What's unique about Barner's technique, though, is the configuration, which uses fewer arteries without reducing blood flow. The body hosts seven potential arterial conduits, two in the chest, two in the arm, one in the abdomen, and two in the lower abdominal wall, though the latter may be quite short and are of limited usefulness. With the T-graft technique, only two conduits are utilized instead of three, four, or five.

"If you use four arterial conduits in one operation, there's only three left," said Barner, "and that could be a problem if you needed another operation at a future date."

Some surgeons were concerned that the T-graft may not provide enough blood flow to the heart muscle. Not so, said the investigator. Only 2%, or 14 patients, experienced temporary low-output syndrome, meaning that the heart still functioned below expected levels despite the surgery. Compared with 2% to 5% incidence of low cardiac output after coronary grafting, Barner said, "that number was gratifyingly low." ■

Electrophysiology test may predict SCD risk

Investigators induce VT in CAD patients

Electrophysiology studies can help predict who is at risk for sudden cardiac death (SCD) and guide treatment to prevent a significant number of those deaths, researchers report. Information on their study was presented in May at the 20th annual scientific session of the North American Society of Pacing and Electrophysiology (NASPE) in Toronto.

Investigators for the Multicenter Unsustained Tachycardia Trial (MUSTT) evaluated more than 2,200 patients believed to be at high risk for SCD. Electrophysiology studies were conducted to determine whether sustained ventricular tachycardia (VT) could be induced in certain patients with coronary artery disease (CAD). Key results:

- **Patients in whom VT could be induced were 1.4 times more likely to subsequently die than those in whom VT could not be induced.**
- **Among patients in whom VT could be induced, deaths were reduced by 27% in those who received therapy compared with those who received no therapy.**
- **Among patients who received therapy, deaths were reduced by 74% in patients treated with a defibrillator compared with patients treated with antiarrhythmic drugs.**
- **At five years, 32% of patients in whom sustained VT could be induced had died, compared with 24% of those who could not be induced.**

Patients evaluated in MUSTT had a history of CAD combined with depressed function of the left ventricle of the heart and a history of spontaneous nonsustained VT. In patients in whom sustained VT could be induced, half were initially treated with antiarrhythmic drugs and half received no therapy. If electrophysiology studies showed that the initial drug therapy was not effective in preventing VT, patients received other drug therapies or were given a defibrillator. Of 2,202 patients enrolled in the study, sustained VT was induced in 767. Of these, a total of 704 were randomized, with 353 receiving standard drug therapy and 351 receiving no therapy. A total of 161 patients went on to receive defibrillator therapy.

Azimilide shows promise for PSVT and SCD

At the same meeting, a study was presented that showed that azimilide, an investigational antiarrhythmic drug manufactured by Procter & Gamble Pharmaceuticals, significantly reduced the risk of recurrence in patients with symptomatic paroxysmal supraventricular tachycardia (PSVT).

"For years, radio frequency ablation has been the standard of care. However, noninvasive drug therapy is preferred by many physicians and patients," said **Richard Page**, MD, a lead study investigator from the University of Texas Southwestern Medical Center in Dallas. "Azimilide showed potential as a valuable addition to the range of drug therapies currently available to treat PSVT." **(See the news brief on ablation in *Cost Management in Cardiac Care*, June 1999, p. 70.)**

The studies showed that patients on placebo had a 135% greater risk of a symptomatic arrhythmia recurrence vs. patients treated with azimilide. On average, patients on azimilide were 60% more likely to be free of a symptomatic occurrence on any given day as compared to patients on placebo.

More than 130 patients were treated with once-daily oral doses of 100 mg, 75 mg, or 35 mg of azimilide or placebo and tracked over six to nine months. The 100 mg dose was found to have statistically significant and clinically important antiarrhythmic effects.

Azimilide is generally well tolerated, the most commonly reported side effect being headache. It is the first antiarrhythmic agent found to effectively block both the slow and fast potassium channels in the heart, and it significantly prolongs the symptomatic recurrence of atrial fibrillation.

The drug is also being studied to understand its potential role in the prevention of SCD in high-risk patients after a heart attack. ■

Early heart repair for Marfan's syndrome critical

People with Marfan's syndrome should be carefully monitored for development of an aortic aneurysm and should be treated early, according to a large international study led by physicians at the Johns Hopkins Hospital in Baltimore.[1]

The risk of death for Marfan's syndrome patients is eight times higher when they wait until they require emergency surgery for the aneurysms. Results of the study showed that death rates from surgical repair of the aneurysm were only 1.5% when done early, compared to 12% among patients who underwent emergency repair.

In Marfan's, a connective tissue disorder, the aorta is weakened and prone to enlargement. Without proper monitoring and medications to reduce stress on the aorta, it could tear, resulting in sudden death. Surgery to repair an aortic aneurysm is no longer a high-risk procedure when done early, stated lead study author **Vincent L. Gott**, MD. Results are similar to those from bypass operations.

"The frightening thing for Marfan's syndrome patients is that often the aneurysm has no symptoms until it becomes life-threatening, at which point they have terrible chest pain," Gott said. Aneurysms frequently are not seen on chest X-rays, so, he said, physicians need to pay close attention to their patients and check for aneurysms by echocardiogram.

For the study, researchers examined the records of 675 Marfan's syndrome patients who underwent replacement of the aortic root at 10 surgical centers. The average size of their aneurysms was 6.5 cm. Among 455 patients who underwent elective surgery to repair the aneurysm, the death rate was 1.5%. By contrast, the mortality rate was 2.6% among the 117 patients who underwent urgent repair within seven days of surgical consultation and 12% among the 103 patients who underwent

Clarification

The June issue of *Cost Management in Cardiac Care* contained an article on portable finger-stick coagulation testing devices and included detailed information about CoaguChek (Boehringer Mannheim / Roche, Indianapolis) and the ProTime Microcoagulation System (International Technidyne Corp., Edison, NJ).

The following information regarding ProTime provides further clarification: In 1997 ProTime received categorization as a waived device by the Centers for Disease Control and Prevention in Atlanta. This encompassed use by patients to self-test their PT / INR at home and by the professional for patient anticoagulation management.

In the professional setting, the system has a list price of approximately $1,500; the cost per test is $5. International Technidyne Corp. also manufactures a device, the Hemochron Signature, cleared by the FDA to monitor heparin therapy. That device lists at $3,750 and tests all ranges of the ACT, the APTT, and the PT. The per-test cost is under $3. ■

emergency repair within 24 hours. While all patients had a high risk of death for approximately 60 days following surgery, 93% of patients were still alive a year later, and 59% were still alive 20 years later.

Reference

1. Gott VL, Greene PS, Alejo DE, et al. Replacement of the aortic root in patients with Marfan's syndrome. *N Engl J Med* 1999; 340:1,307-1,313. ▼

FDA gives Fragmin nod for angina, MI

Late in May, the Food and Drug Administration (FDA) approved dalteparin sodium injection (Pharmacia & Upjohn's Fragmin) for the treatment of unstable angina and non-Q-wave myocardial infarction for patients on concurrent aspirin therapy. A low molecular weight heparin, Fragmin provides the cardiologist an opportunity to stabilize a patient awaiting additional testing and treatment of underlying causes during the acute phase, decreasing the risk of unexpected heart attack.

The FDA approval of Fragmin was based on the results of two large, international clinical studies that showed use of Fragmin significantly lowers the risk of heart attack and death when administered twice-daily concurrently with aspirin to patients during the acute phase of treatment — five to eight days — of unstable angina and non-Q-wave myocardial infarction. Fragmin has a predictable anti-thrombotic effect, eliminating the need for laboratory monitoring. First approved in the United States in 1995 for prevention of deep-vein thrombosis in patients undergoing abdominal surgery who are at risk for thromboembolic complications, it is also indicated for patients undergoing hip replacement surgery. Fragmin injection is available in packs of 10 single-dose prefilled syringes in two strengths, 2500 IU and 5000 IU, as well as a 95,000 IU multi-dose vial. Fragmin should not be given to patients undergoing regional anesthesia or patients with active major bleeding, and it should be used with caution in patients receiving neuroaxial anesthesia or spinal puncture, and in those with a history of heparin-induced thrombocytopenia. ▼

$ß_2$-agonists may increase MI risk

The use of $ß_2$-agonist metered-dose inhalers increases the risk of myocardial infarction (MI) by more than threefold in patients with a history of cardiovascular disease, according to a recent study presented at the American Lung Association / American Thoracic Society International Conference in San Diego in April.

Investigators reviewed the records of nearly 1,500 patients hospitalized for a first MI and more than 4,000 matched controls. Patients who had received one $ß_2$-agonist inhaler during the three months prior to hospitalization were 67% more likely than others to have a first MI.

The investigators said that $ß_2$-agonists prescribed for airflow limitation may themselves increase the risk of MI via a biologic mechanism, or the therapy might be coincident in that it is prescribed for nonspecific chest discomfort, which could be the result of angina.

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Editor: **Dorothy Pennachio**, (201) 760-8700, (dorothy.pennachio@medec.com).
Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@medec.com).
Executive Editor: **Susan Hasty**, (404) 262-5456, (susan.hasty@medec.com).
Managing Editor: **Paula Stephens**, (404) 262-5521, (paula.stephens@medec.com).
Production Editor: **Nancy McCreary**.

Editorial Questions

For questions or comments, call **Dorothy Pennachio** at (201) 760-8700.

"Regardless," stated the lead researcher, "physicians should use caution when prescribing ß$_2$-agonists for the first time in patients with cardiovascular disease." He recommended that physicians consider alternative diagnoses, such as angina, in patients with a history of cardiovascular disease or several cardiovascular risk factors and present with symptoms of airway inflammation, particularly if symptoms do not resolve with ß$_2$-agonist therapy.

However, he stressed that ß$_2$-agonists are relatively safe and remain the first-line therapy for airflow limitation caused by asthma and chronic obstructive pulmonary disease. ▼

Nearby hospital may not be best choice

Patients with chest pain are typically taken by ambulance to the nearest hospital approved to take emergency cases; but your patients are getting the message through the popular press that the hospital closest to their home (or closest to the site of their infarction) may not be the best place to go if they get a heart attack.

Media such as *The New York Times* had front-page stories in late May announcing findings of Johns Hopkins investigators who compared 30-day and one-year mortality rates of 100,000 infarction patients who were treated at 4,000 hospitals — high-volume and low-volume facilities closest to their homes.[1]

The investigators found that after they adjusted for differences in severity, the patients treated at the lowest-volume hospitals were 17% more likely to die within 30 days after admission than were those treated at the highest-volume hospitals. High-volume hospitals were those that averaged at least 4.4 heart attack patients a week, and low-volume sites treated 1.4 or fewer. Also, the investigators found that the use of aspirin, beta-blockers, and other treatments accounted for about one-third of the survival benefit at the high-volume hospitals. The rest is chalked up to experience of doctors, nursing staff, and technicians.

Reference

1. Thiemann DR, Coresh J, Oetgen WJ, et al. The association between hospital volume and survival after acute myocardial infarction in elderly patients. *N Engl J Med* 1999; 340:1,640-1,648. ■

Kevin Barnes, RN, clinical nurse, cardiac cath lab, Scripps Mercy Hospital, San Diego. Telephone: (619) 260-7001.

Sandy Charlton, nurse practitioner, Arkansas Heart Hospital, Little Rock, AR. Telephone: (501) 219-7360.

Cheryl Morgan, RN, nurse data abstractor, Morton Plant Hospital, Clearwater, FL. Telephone: (727) 462-7760.

Linda Hicks, coordinator, cath lab, OSF St. Francis Medical Center, Peoria, IL. Telephone: (309) 655-2231.

John Stewart, administrative director, Sacred Heart Regional Heart Institute, Pensacola, FL. Telephone: (850) 416-7888.

Kevin Wolschleger, MD, St. Joseph's Hospital and Marshfield Clinic, Marshfield, WI. Telephone: (715) 387-1713. ■