

ALLIANCE

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Cardiology: New Devices, New Directions



United to Improve America's Health

Cardiology Explores New Devices, New Directions



Newman feels the rush of terror; it's the same fear and anxiety she faced four years ago when heart problems flared into life-or-death. The answer then was quadruple bypass surgery. Today, Newman finds help from what she calls "the Roto-rooter," a new device actually called the Rotablator. It's shaped like a high-powered dentist's drill attached to an arterial catheter. It's one of four interventional cardiac devices—the Rotablator, TEC extraction atherectomy, coronary stent and excimer laser—approved by the Food and Drug Administration. But today, more than a year later, health care organizations are re-examining the technologies' progress, potential and application.

"These technologies just haven't yet proven their long-term effectiveness," said Robert Safian, M.D., director of interventional cardiology at William Beaumont Hospital in Royal Oak, Mich.

"We do know the Rotablator is important for calcified and non-dilatable lesions and helps when balloon angioplasty doesn't," he said. "The extraction atherectomy (TEC device) may provide us with a tool to avoid or postpone repeat bypass surgery because of its ability to clean out old grafts, whereas coronary stents have proved their greatest value and make their greatest contribution during that critical moment when an artery abruptly closes during angioplasty. Implanting a stent prevents the need for emergency open-heart surgery." Safian says the excimer laser has limited application.

Beyond lasers, stents, rotational and extraction atherectomy devices—and any new technology—is the reality of the high price of cardiac care. It gobbles up 25 percent of hospital care expenditures, or \$47 billion a year. And new technologies—with their research, development, acquisition and application—add to that cost. Proponents, however, say technology cost is relative, since it only accounts for 10 percent to 20 percent of total costs per procedure.

"Yes, costs are higher using something like the Rotablator, but without it, we couldn't begin to treat some patients because of the nature of

ROTABLATOR

The Rotablator is a rotational atherectomy device with hundreds of microscopic diamond chips on its tip that spin and chew their way through fat, cholesterol and other artery-blocking deposits. The diamond chips spin within an artery at 180,000 revolutions per minute.

"This atherectomy device shaves or sands the plaque in arteries and is especially helpful when a balloon won't crack the plaque," said Azam Anwar, M.D., interventional cardiologist with the Baylor Cardiovascular Institute in Dallas.

TEC

The TEC, or transluminal extraction catheter, continuously cuts the blockage from the arterial wall while simultaneously removing debris and blood clots using vacuum extraction.

The TEC has been particularly successful in removing the usually delicate and fragile blockage material encountered in older bypass grafts.

CORONARY STENT

Coronary stents are a major development that help patients avoid emergency bypass surgery because of abrupt vessel closure or other trauma to the artery that may occur during angioplasty.

"Stents definitely save lives, but they're certainly not perfect since they are metal and foreign to the body," said Robert Safian. The stent is a thumb-long, spring-like piece of stainless steel that acts like a section of scaffolding when inserted into an artery. Each stent, about one-inch long

with the diameter of a spaghetti strand, wraps around an angioplasty balloon, which weaves its way through the artery to the point of blockage. The balloon expands and retreats, leaving the stent in place to bridge the artery. "I used to say patients had a 96 percent success rate using balloon angioplasty with a 4 percent risk of facing emergency bypass," said one cardiologist. "With coronary stents, the risk is reduced to 1 percent or 1.5 percent." Yet stents have their problems, said Safian.

"The biggest drawback is the rigorous anticoagulant regimen, which means an extended hospital stay to regulate blood coagulation to avoid clotting," he said. "However, specially coated stents and better techniques for stent implantation may reduce these problems."

EXCIMER LASER

The excimer laser, also known as a cold laser, uses a high-energy wavelength to vaporize the fat from arterial walls. However, most experts do not favor the device.

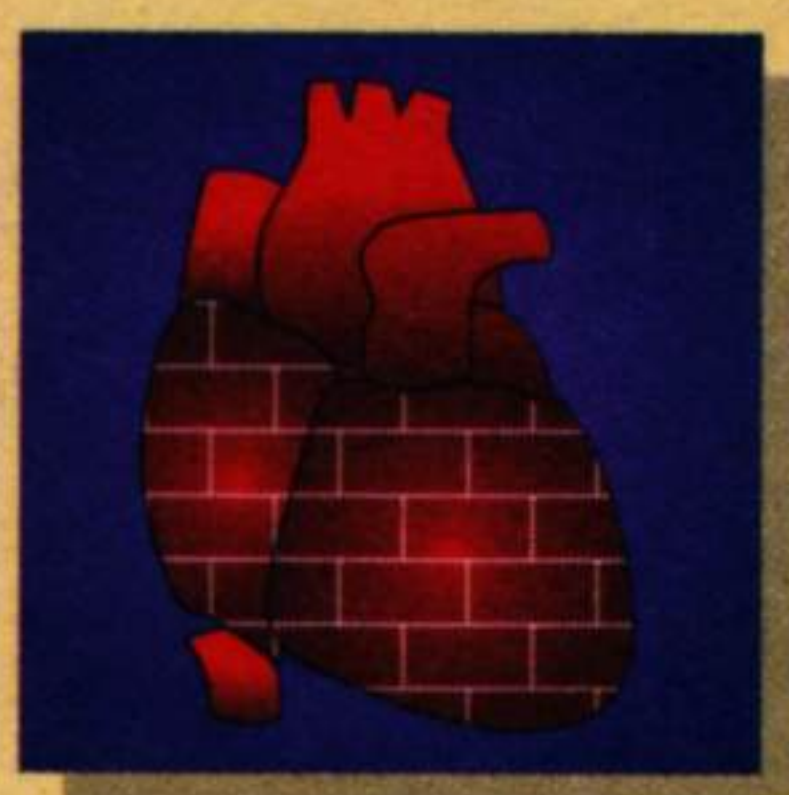
"Use of the excimer laser may grow as new designs of the device progress," said Anwar.

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VHA'S CARDIOLOGY COMMITMENT

VHA's cardiology initiative began in December 1993. Led by Ed Schrader, the cardiology program helps VHA health care organizations save at least 15 percent on cardiology products. Upcoming program developments include potential contracts for heart valves and additional electrophysiology and interventional products.

VHA health care organization participation in the cardiology program has increased 114 percent since its beginning in 1993, based on participation levels and new agreements.



VHA CARDIOLOGY CONTRACTS

- ♥ angioplasty products and accessories
- ♥ tiered-therapy implantable defibrillators and accessories
- ♥ pacemakers and accessories

VHA CARDIOLOGY VENDORS

Advanced Cardiovascular Systems Inc.
Medtronic Inc.
USCI/C.R. Bard
Ventritex

For more information about VHA's cardiology program, call Ed Schrader at (214) 830-6898.

arterial blockages they have," said Safian. "The only choice would be more open-heart surgery, which is more expensive. In that respect, we're actually reducing costs and improving patient survival."

Equally important are how new technologies affect outcomes—matters like patient mortality, satisfaction and length of stay.

"We know that interventional approaches such as angioplasty and atherectomy are initially less expensive and have fewer complications than bypass surgery," said Jill Ramsey, director of the Memorial Heart Institute at Memorial Hospitals Association in Modesto, Calif. "However, complications and hospital readmissions after these approaches are substantial. Because of the need for repeat procedures, costs are approximately equal at two years for patients who underwent interventional procedures as compared to those patients who had bypass surgery on the first admission.

"As we continue to use interventional devices, we will need to carefully evaluate patients and their disease process, and only select those most amenable for the procedure."

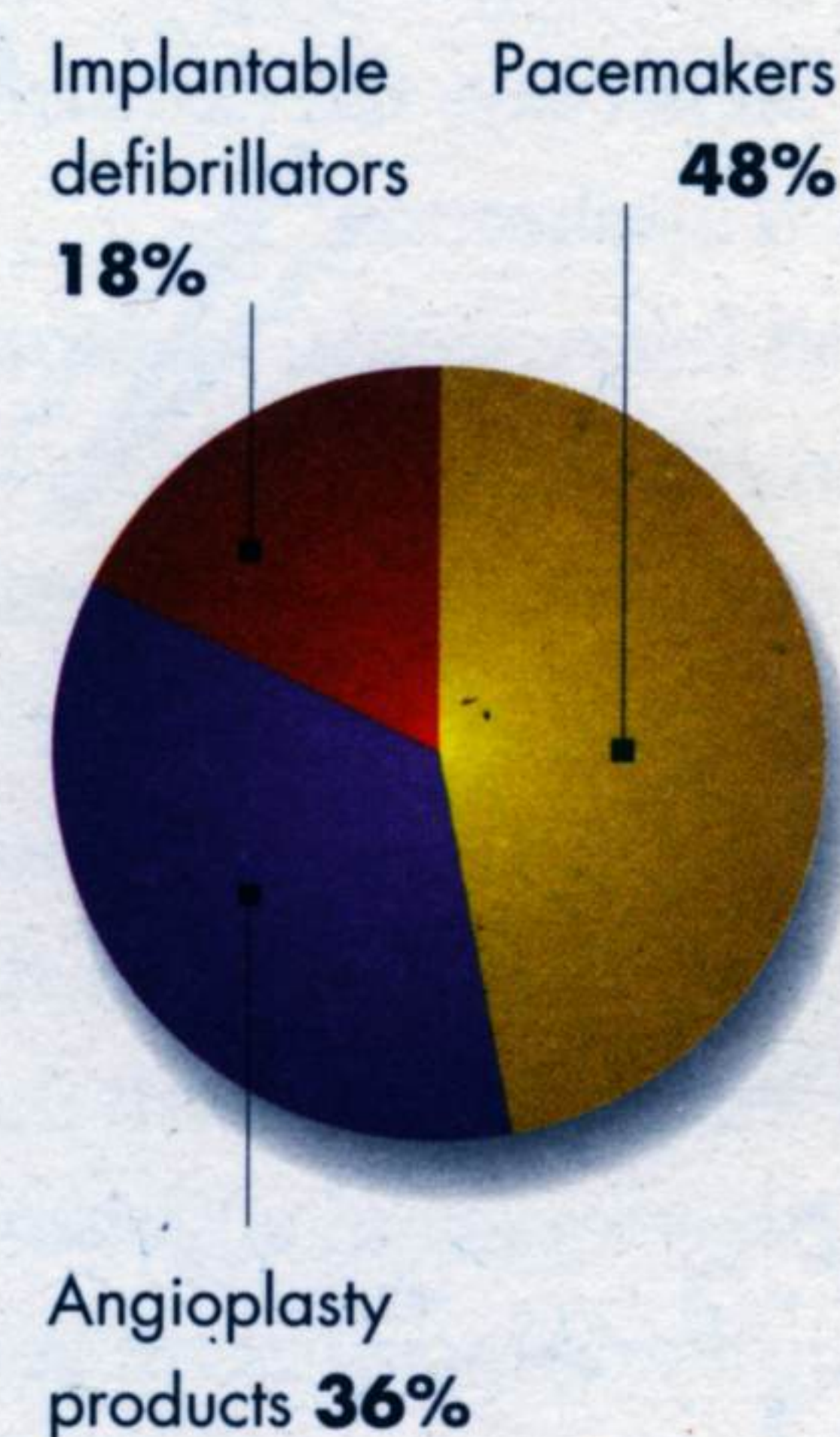
While cardiovascular services professionals evaluate the benefits of new technologies, they are also responding to market demands. Prompted by patients, payers and providers clamoring for change, cardiovascular services are re-inventing their business. For example, in recent weeks, three fiercely competitive cardiology groups in Dallas merged into HeartPlace, a centralized, consolidated megacenter of cardiac

care, while in a separate, unrelated move, 15 Texas hospitals formed a statewide health services alliance called The Heart Network of Texas.

The network, which includes nine VHA health care organizations, is a prelude to managed care, said Bruce Hoffman, executive director of the newly formed alliance.

"Managed care calls for one-stop shopping, multiple points of care and greater efficiencies and outcomes. That's why we formed this alliance and began by concentrating on cardiovascular services," said Hoffman.

CARDIOLOGY PROGRAM COMPONENTS BY VHA HCO PARTICIPATION LEVEL



The alliance of not-for-profit hospitals is developing ways to share resources and data on outcomes, volume, physician groups and payer populations.

"Our challenge is to review our costs specific to cardiovascular services,

develop ways to standardize costs and procedures, and establish outcomes reporting capabilities," said Hoffman. Alliance members have assembled a group purchasing committee to assess and inventory all cardiovascular supplies and products. Within 60 to 90 days, Hoffman hopes the alliance will have established baselines.

"These baselines will be our starting point in terms of solidifying our cost and outcomes strategies," he said.

Ramsey of the Memorial Heart Institute is also exploring new approaches to cardiovascular services and purchasing. She formed a multidisciplinary group of health professionals—including interventional cardiologists—to evaluate and recommend technologies and supplies. Changes, said Ramsey, include:

- increasing vendor negotiations and relationships that emphasize equipment standardization with decreased costs
- regularly reviewing patient outcomes data on quality of care, mortality and length of stay to determine efficacy and effectiveness of treatment
- establishing and inviting capitated groups to use Memorial for cardiovascular services
- developing and providing cardiac disease prevention programs

THE FUTURE

Technology will continue its high-profile role in interventional cardiology, said Ed Schrader, VHA cardiology senior product manager, who sees new and improved stents, genetically-engineered products and site-specific drug delivery systems.

"Already in development are next-generation stents that are being made with new materials and designs," said Schrader. "Microsurgical dilatation and site-specific drug delivery are some of the device technologies being developed to meet upcoming needs." Keith Harville, VHA vice president of technology and market research, said other future possibilities include diagnostic tools, gene therapy and biologicals.

"From the diagnostic side, we'll see more intravascular ultrasound to assess the success of interventional procedures," he said. "Gene therapy may have some potential, although it's 10 to 15 years down the road. It's likely to intervene against any genetic abnormalities that contribute to arterial disease. In the next five to 10 years, I expect to see promising, new biologicals that will be used in conjunction with interventional procedures, primarily to prevent restenosis. They are genetically engineered molecules that defend the artery from any potential damage created by the balloon, atherectomy device or laser." Beyond technology, Harville says to expect more emphasis on disease prevention.

"Health care organizations will continue grouping and merging into concentrated centers of excellence," said Harville. "VHA will continue to help institutions improve their clinical practices and to identify pharmaceuticals, supplies and devices required to produce best practices."

AT THE HEART OF CARDIAC CARE

VHA health care organizations represent a significant portion of cardiology procedures nationwide. The following chart represents VHA organizations' portion of U.S. market share.

