http://www.latimes.com/news/science/la-sci-angioplasty27mar27,0,732814,full.story

Study questions the widespread use of angioplasty

For patients with clogged arteries who have not had a heart attack, drugs work as well as the surgery, report says.

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For patients with clogged arteries who have not had a heart attack, the widely used surgical treatment of balloon angioplasty with the insertion of a stent is no better than conventional drug treatment, researchers said Monday

In a study of more than 2,000 patients, those receiving only drug therapy had the same number of heart attacks, strokes and deaths as those who received the medication and underwent artery-opening angioplasty, researchers from the Department of Veterans Affairs told a meeting of the American College of Cardiology.

The only difference was a slight improvement in quality of life for those receiving angioplasty because of fewer chest pains, known as angina.

The findings deal a blow to the stent industry, which sells an estimated $3.2 billion worth of the devices each year in the United States. About 1 million stenting procedures are performed each year, costing about $40,000 per surgery. About 65% are performed on patients such as those in the study.

"This is good news for patients and physicians," said Dr. William E. Boden of the University of Buffalo School of Medicine, who led the study.

In the rush to perform angioplasty, the effectiveness of drug treatment "was lost in the shuffle. It was considered old-fashioned, ho-hum. Now we can say to physicians … you are not putting patients in harm's way."

Stent makers criticized the studying, saying it said nothing new and failed to look at the newest generation of drug-eluting, or medicated, stents.

Experts also cautioned that the results do not apply to patients who have suffered a heart attack because of a blockage in the coronary artery. Numerous studies have shown that angioplasty is the gold standard for such patients, and physicians urge that it be implemented as soon as possible to restore blood flow to the heart.

But in non-emergency situations, the drugs act fast enough to forestall the need for angioplasty.

The study, called the Courage Trial, enrolled 2,287 patients at 15 VA medical centers and 35 hospitals in the United States and Canada.

It was sponsored primarily by the VA and the Canadian Institutes of Health Research. Most of the researchers involved have received consulting and lecture fees from major drug companies.

All the patients had at least a 70% blockage of their coronary artery and chest pains several times per week. Most also had high cholesterol and blood pressure, and many had diabetes.

"This is a moderate- to high-risk group of patients," Boden said. "We wanted to give angioplasty the best possible chance to show a benefit."

All of the patients were placed on multiple medications, including beta-blockers, ACE (angiotensin-converting enzyme) inhibitors and diuretics to lower blood pressure, statins to decrease cholesterol and blood thinners to prevent clots. The drug treatments typically cost at least $1,500 a year, according to the American Heart Assn.

The patients were counseled about lifestyle programs for smoking cessation, increased exercise and a better diet.

Half the patients also underwent angioplasty, and most of them received a stent — a wire-mesh tube inserted into the artery to hold it open after the balloon is withdrawn. The balloon and the stent are threaded into the coronary artery through a small incision in the groin.

After an average of 4.6 years of monitoring, there were 211 deaths, heart attacks or strokes in the group receiving angioplasty and 202 in the group receiving only drug therapy — a difference the study deemed statistically insignificant.

The only difference between the two groups was that angioplasty patients had fewer symptoms of angina — although even that difference was not as large as had been expected.

After three years, 67% of those in the angioplasty group were free of angina, compared to 62% in the medication-only group.

The overall results should not be that surprising, said Dr. Valentin Fuster, director of the cardiovascular institute at Mt. Sinai Medical Center in New York.

"Today, we treat patients medically much better than we did in the past," said Fuster, who was not involved in the study. "The medications that we use are much more efficient, and more patients are compliant."

The statins, for example, were not introduced until the late 1980s. Several new drugs to control hypertension were introduced in the 1990s.

The report was also published online Monday by the New England Journal of Medicine.

In an editorial accompanying the report, Dr. Judith S. Hochman, director of the Cardiovascular Clinical Research Center at the New York University Medical Center, said narrowing of the coronary artery is a marker for more widespread disease. Atherosclerosis is a clogging and hardening of arteries throughout the body, and it is these lesions elsewhere — not the one in the coronary artery — that typically break apart to produce heart attacks and stroke.

It is not surprising, she wrote, that compressing one or a few stable blockages did not reduce the rate of heart attacks.

"Atherosclerosis is a systemic disease, and we need to treat it systemically," Boden said.

Stent makers tended to scoff at the study. Dr. Donald S. Baim of Boston Scientific Corp. said the results "don't really tell us much that we didn't already know."

Dr. David E. Kandzari, chief medical officer of Cordis Cardiology, noted that most of the patients received bare-metal stents and that the results would have been better if they received the newer drug-eluting stents, which slowly release medication to prevent reclogging.

Boden, however, said the drug-eluting stents only reduce the risk that a patient will require a second procedure to reopen the artery.

"There is not a shred of evidence to support the possibility that drug-eluting stents are superior in preventing heart attacks, strokes and death," Boden said.

Some Wall Street analysts said the study would have limited impact, but only because they don't anticipate it will depress sales any more than they've already fallen.

Sales of stents have been declining since last year over concerns that deadly clots may form around a small percentage of the most popular devices and that bypass surgery may have a significant survival advantage over stents in some patients.

The study "is less important than many people are making it out to be," said Jeff Jonas, a portfolio manager with Gamco Medical Opportunities Fund. Gamco owns shares of Johnson & Johnson, the parent company of Cordis Corp. "I think physicians are already pulling back and I don't see this accelerating that."

Boden disagreed. Most patients who agree to undergo angioplasty have "an implicit belief … that they will have a lower likelihood of heart attack, and will live longer," he said. That is not true, he said.

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(INFOBOX BELOW)

Treating clogged arteries

In a study of 2,287 patients, those receiving only drug therapy had about the same number of heart attacks, strokes and deaths as those who received drugs and underwent artery-opening angioplasty.

Using stents

Stents used in angioplasty procedures compress plaque in clogged arteries, allowing better blood flow.

A ballon catheter with a wire mesh tube, called a stent, is inserted.

Once at the narrowed section of artery, the balloon is inflated to open the artery.

The balloon is deflated and the stent is left in place to keep the vessel open.

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Using drugs

Beta blockers

Slow the heart rate and blood flow, easing the pressure of blood on artery walls.

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Nitrates

Dilate the arteries to the heart. This increases blood flow, relieving chest pain. They also dilate veins to reduce the heart's workload.

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ACE inhibitors

Narrow blood vessels occur when chemicals join with a specific enzyme. ACE inhibitors may prevent this.

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Statins

Lower LDL cholesterol by inhibiting an enzyme that controls the rate of cholesterol production. Increase the liver's ability to remove the LDL cholesterol already in the blood.

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Sources: American Heart Assn., Cordis Corp., Associated Press. Graphics reporting by Julie Sheer