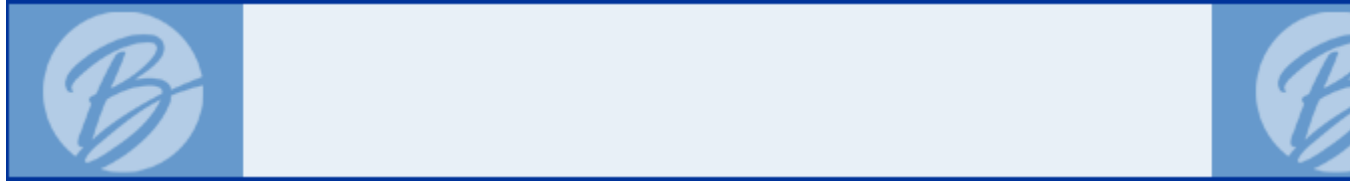




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*From the Baltimore Sun*

## Doubt cast on stents' value

### Study finds drugs just as effective for treatment of clogged arteries

From Staff and Wire Reports

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

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

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

The findings deal a blow to the stent industry, which sells an estimated \$3.2 billion worth of stents each year in the United States. As many as 65 percent of the estimated 1 million stent procedures performed each year occur in patients who have not had heart attacks, at a cost of about \$40,000 per surgery.

"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," he said. "It was considered old-fashioned, ho-hum. Now we can say to physicians you are not putting patients in harm's way. That is something we didn't know before."

Experts cautioned that the results do not apply to patients who have had heart attacks because of a blockage in the coronary artery. Numerous studies have found that angioplasty is the gold standard for

such patients, and physicians urge that it be used as soon as possible to reopen the artery and restore blood flow to the heart.

In nonemergency situations, the drugs have been found to act fast enough to forestall the need for angioplasty.

### **'A huge deal'**

"It's a huge deal," Dr. Mandeep R. Mehra, head of cardiology at the University of Maryland Medical Center, said of the study. "It's going to plummet the elective use of stents in the U.S. dramatically."

Mehra, who attended the New Orleans conference, said it was particularly striking that stents failed to relieve chest pain in the long run.

"We've always sold the notion of stenting on the basis of relieving symptoms," he said. "If we are being told drugs work just as well, there will be a hot debate on whether we are performing way too many procedures."

Mehra said stents are more commonly used in the United States than in Canada and European countries, and that outcomes here are no better than in those countries.

"If you start putting this in context," he said, "we are going to have no option but to rethink the current national guidelines."

Dr. Richard A. Lange, chief of clinical cardiology at the Johns Hopkins University School of Medicine, agreed that the study is important. "This is a terrific study and it's well done," said Lange, who also attended the conference. "Hopefully, it will change the way we practice medicine."

The study suggests that people with mild symptoms of coronary artery disease are better treated with medical therapies such as cholesterol-lowering drugs, aspirin and lifestyle changes such as improved diet and exercise.

Lange noted, however, that patients with intense chest pain improved in the first few years after angioplasty. "Stents have a place in relieving symptoms," he said.

He said angina often returns because stents clear only one major blockage.

"Even though you treat one of the blockages, it doesn't prevent people from developing others," he said. "Oftentimes people die from a minimal blockage that ruptures and causes a blood clot. This study suggests drug therapies and lifestyle changes are better at preventing that."

Stent makers criticized the study yesterday, saying it provided little new information, did not include the newest generation of drug-eluting stents and did not address the key issue of whether stents eliminate the need for further angioplasties.

They also argued that the device's greatest benefit is improving quality of life.

The new study is the first large analysis examining stents' value for those with what is known as stable disease.

The study, which enrolled 2,287 patients at 15 VA medical centers and 35 other hospitals in the United

States and Canada, 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 studied had at least a 70 percent blockage of their coronary arteries and had chest pains several times a week. Most also had high cholesterol and high 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."

## Multiple medications

All of the patients were placed on multiple medications, including beta blockers, ACE inhibitors and diuretics to lower blood pressure, statins to decrease cholesterol and blood thinners to prevent clots. The drug treatments typically cost about \$1,500 a year, according to the American Heart Association.

The patients were also counseled about smoking cessation, increased exercise and a better diet.

Half of the patients also underwent angioplasty, and most of them received stents, wire-mesh tubes 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.

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

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

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

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

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

Sales of stents have been declining since last year over concerns that deadly clots might form around a small percentage of the most popular devices after they are implanted and that bypass surgery might have a significant survival advantage over stents in some patients. Analysts say cardiologists have become more reticent about recommending the procedure.

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