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Dilate or debulk?

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WHAT ARE THE RELATIVE ups and downs of balloon dilatation and directional atherectomy? How effective is one compared with the other in addressing the problems of restenosis, acute closure, and chronic total occlusion?

This first installment in a new series, "Cardiology Dialogues," edited by James Thomas, MD, of the Cleveland Clinic Department of Cardiology, is an adaptation of an informal discussion between David R. Holmes Jr, MD, Director of the Cardiac Catheterization Laboratory at the Mayo Clinic, who details the advantages of balloon dilatation over atherectomy, and Eric J. Topol, MD, Chairman, Department of Cardiology, The Cleveland Clinic Foundation, who defines the current and future role of atherectomy.

DR. HOLMES: A good reason to use balloon dilatation is that it has been used in more than 1 million patients around the world, and it works. It's not perfect, but it works. In published series we have seen that, regardless of the patient subgroup, dilatation works in about 93% of cases. In well-selected single-vessel and multivessel cases, dilatation has a 93% to 95% success rate.

A second advantage is that the risks and complications of balloon dilatation are known in 1 million patients, so you will not be seeing new complications. With balloon dilatation, you know what the risks are because you've faced them before.

Other considerations in favor of balloon dilatation include the availability of a wide variety of balloon sizes and the low price and cost-effectiveness of the procedure compared with atherectomy. A single balloon costs $400 to $500. There aren't many rotational atherectomy devices available for that price.

Of course, restenosis is a problem after balloon dilatation. But on the other hand, the new atherectomy devices have not overwhelmed the world by their ability to prevent restenosis. The Rotablator is associated with a restenosis rate of 65%.[1] The restenosis rate for laser angioplasty is approximately 50%.[2] In the Coronary Angioplasty vs Excisional Atherectomy Trial (CAVEAT I), the restenosis rate for atherectomy was approximately 50%. It's far from zero. Of course, the use of stents can decrease restenosis rates, but you must keep the patient in the hospital for as long as you would for surgery. If you're eventually going to operate on the patient, why not do it first?

Another problem with balloon dilatation is acute closure, which occurs in 5% to 7% of conventional dilatation cases. Some new "bail-out" devices are now available, but it still is a problem. When you look at directional atherectomy, you'll find that its rate of acute closure is even higher. In CAVEAT I, the difference was 8% for directional atherectomy

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vs 3.9% for balloon dilatation, hardly a dramatic improvement with directional atherectomy. And the same has been true of rotational atherectomy: How many of these cases eventually go to the CCU?

Chronic total occlusion is another problem. Dilatation isn't possible if you can't cross the occlusion with a guide wire. Laser angioplasty has been proposed as a solution, but it is ironic that, to be included in any of the laser registry studies of chronic total occlusion, the lesion first had to be crossed with a wire. If you can get through with a wire, why not follow that with balloon dilatation.

In diffuse disease, surgery is not a bad option. However, balloon dilatation may be useful. Long balloons—up to 80 mm—are available and enable the dilatation of longer segments with diffuse disease, with a success rate of 90%. Laser angioplasty in diffuse disease has a success rate of about 90%, but I don't believe you need laser angioplasty for this application.

I have given the main reasons why dilatation is the preferred method of treatment for every patient with coronary artery disease. Unfortunately, use of directional atherectomy and related procedures is still based largely on anecdotal experience rather than on a critical review of the data. An important role for atherectomy technologies is in exploring the mechanisms of treatment of coronary artery disease.

WHY USE ATHERECTOMY?

DR. TOPOL: A major reason for using atherectomy devices is that we need to work on solving the problem of restenosis. Balloon dilatation has not been able to adequately manage the problem of the big plaque burden. If you image disease segments with intravascular ultrasound before and after balloon dilatation, you see very little difference. The only way to address the underlying pathophysiological problem is to debulk, or resect, the plaque, and the only way to debulk today is with the various atherectomy techniques, with directional atherectomy having been introduced first.

Now, some might say that in CAVEAT atherectomy has been associated with a number of complications, so perhaps it's not a good option. That is partly true, but atherectomy is a quickly changing technology. Ultrasound guidance is an important development. Without ultrasound, you're performing "pseudo-directional" atherectomy, not really directional atherectomy. That is, when you shave the plaque, you don't really know in a three-dimensional way where you're shaving. But if you can really shave where you want to, that is, guided by ultrasound, you can theoretically obtain optimal resection of the plaque. Recurrence is due in large part to the fact that the diseased segment is never really treated the first time.

As for the philosophy of "bigger is better," dilating the vessel as large as possible to obtain a better result over time, the plaque itself is preventing you from obtaining a maximal acute-phase response. So the philosophy should be "better channel, less restenosis."

At present, our technology is not well suited for this. We are in the midst of emerging technology, of coupling ultrasound with atherectomy and ultrasound with stenting. For example, Nakamura and Colombo[3] have used ultrasound to guide stenting and have found that they do not have to use anticoagulation. The patients go home the next morning and are only in the hospital for 24 hours. So the idea that you have to be in the hospital for a week for a stent—the same as for a bypass operation—may change over time if we can find better ways to get apposition of the entire stent mesh against the vessel wall, rather than partly against the wall, partly in the lumen, with these "lagoons" between the stent and the vessel wall which potentiate thrombosis.

We need to continue to improve the technologies we have today. One major goal must be to avoid tearing the vessel, a frequent complication of balloon dilatation. Balloon dilatation is an uncontrollable process. It's like a lottery: you blow up the balloon and you never know, the vessel might tear from stem to stern. Uncontrolled injury is a major problem. What we would rather have, and will have before the next millennium, is "controlled" injury. That is, we wouldn't have unpredictable rips in the vessel. While there would still be some injury, because manipulating a vessel without invoking some damage is almost impossible, at least we wouldn't have the kind of unpredictable tears that require conversion to emergency bypass surgery. One percent of patient deaths in the catheterization laboratory occur because of profound tears from unpredictable ripping of the vessel by balloons.

Our only hope of avoiding this trauma lies with new technologies. Other improvements are needed, such as decreasing the hospital stay and decreasing the need for anticoagulation, which increases the risk for subsequent bleeding complications.

DR. HOLMES: As Dr. Topol pointed out, dilatation is an uncontrolled event. In further support of balloon dilatation, I point out that in Gruentzig's initial series of 169 patients,[4] 133 had follow-up angiography within 6 months of their initial intervention, and the restenosis rate was 31%. That was a group of patients who underwent a very unsophisticated and very "user-unfriendly" device, and they did just fine.

Clearly, in the future, we must deal with the issue of plaque burden. At present, all we can do is blow up the balloon and hope for the best. I think in the future we'll become much smarter about balloon dilatation and the proper application of new devices. Current research is going to allow us to select new devices more intelligently. At present, however, major research institutions should not be wedded to the new technology other than to assess its relative role and to study the science involved in how to treat the patients in the best possible way.

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