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Editorial Comment

Procedural Efficacy and Complications of X-Sizer Thrombectomy in De Novo and Stented Lesions

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Sometimes curious things happen during randomized controlled trials (RCT). Occasionally there are unexpected results, undermining preconceived bias, for example the results from the Women's Health Initiative demonstrating that hormone replacement therapy had no beneficial effect on coronary artery disease, but indeed, had several detrimental side effects with an increase in myocardial infarctions and some cancers. On the other hand, sometimes there is a "Beta error," a negative RCT result for a device that is clinically useful. Despite the concerns of this accompanying article, I believe the X-Sizer falls into this category.

The X-Sizer is a mechanical Archimedes screw catheter 1.5 or 2.0 mm in diameter that cuts up thrombus and removes it very effectively with a low incidence of arterial damage or distal embolization. When used during an acute MI or to treat coronary lesions with a large thrombus burden, it is the most effective thrombectomy device I have seen. Yet the X-Sizer did not pass FDA approval after its RCT in the United States. Why?

When the RCT to assess the X-Sizer was being developed, decisions had to be made concerning trial design that would appropriately test the device's ability and safety. Although it was known that the X-Sizer worked remarkably well to remove thrombus, it was decided that to study the device in acute MI would be difficult and perhaps yield negative results because the measure of its effectiveness, CPK level, would be dominated by the size of the original infarct damage. It was felt that the comparative benefit, as measured by peak CPK or ejection fraction, would be dwarfed and would yield a negative study even though, when used in appropriate situations, individual patients might have significant benefit. So a decision was made to design the RCT to test the device in saphenous vein graft lesions (75%) or native arteries with angiographic thrombus (25%). The result of the Xtract trial was unimpressive for the device: there was no significant difference between groups for periprocedural MI or overall MACE, however there was a significant reduction (45%) in the incidence of large MIs (CPK $>$ 8 times normal, $p = 0.04$).

Although this result was disappointing, it was not completely surprising. During our participation in this trial, we performed intravascular ultrasound imaging (IVUS) prior to and following the use of the X-Sizer in the vein grafts. We found that not all vein grafts are filled with thrombus or "friable gruel." About one third of vein grafts, even 10-15 years old, have dense fibrotic material creating the stenosis. In these cases, a thrombectomy device is not necessary; even a distal protection device is not necessary. These lesions respond well to balloon dilatation and placement of a stent. In addition to diluting the power of the Xtract Trial, perhaps the X-Sizer is not primarily effective for saphenous vein grafts. On the other hand, in acute MI cases, when IVUS shows enormous thrombus burden, the X-Sizer was very efficient in removing thrombus and soft plaque. It may be difficult to demonstrate this in an RCT, but in selected cases, the use of an efficient and safe thrombectomy device can be extremely helpful.

The accompanying article by Pate and co-authors is certainly disconcerting for those of us who have been impressed with the efficacy of the X-Sizer. Their description of complications that they experienced, highlight the necessity to be cautious with this device. As with other extraction devices, it cannot be forced and is likely to traumatize the arterial wall when passed through a tortuous segment with a sharp radius of curvature. Perhaps we experienced less complications because we used intravascular ultrasound guidance.

Despite this report of complications with the device, there are still situations where the X-Sizer would be useful. Similar to rotational and directional atherectomy, we have to use this device carefully in selected cases.

I am hopeful that future trials with the X-Sizer will demonstrate clinical utility so that we can have access to this device for patients who demonstrate a large thrombus burden.

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