Can the laser light at the end of the tunnel be used to get to the end of the tunnel?

See page 1797 for the article to which this Editorial refers

Arguably, the two most important challenges facing interventional cardiology are in-stent restenosis and chronic total occlusion. The former is manifest after intervention while the latter often prevents achievement of initial success. Indeed, there are many occlusions that appear to have such a low likelihood of success that they are never even attempted; chronic total occlusion dilatation. The most common failure mode has always been inability to pass a guidewire through the occlusion into the distal lumen. This problem has resulted in success rates in most published series of selected patients of approximately 60%–65%. These series have also documented that while failure is usually uncomplicated, there are a small number of patients in whom attempts at traversing the lesion result in compromise of ipsilateral collaterals and development of myocardial infarction. Although chronic total occlusion remains a common clinical problem, which has been refractory to conventional therapy, when treatment is successful, outcome is improved and CABG avoided. Thus efforts continue to identify a ‘better way to get there’.

The TOTAL trial reported here by Serruys et al[1] is another important piece of the puzzle. An important consideration was the angiographic selection criteria. There was a mixture of favourable and unfavourable features — the former being a requirement for excellent visualization of the distal vessel and its course and lack of multiple curves in the occlusion; the latter was inclusion of patients in both treatment limbs with occlusions documented by angiography to be greater than 4 weeks in duration and inclusion of patients irrespective of major branches at the site of occlusion (38% and 55%), blunt stump to the occlusion (44% and 41%), or bridging collaterals (15% and 18%), all features associated with markedly decreased success rates in past series.

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The primary end-point was treatment success. Although crossover was allowed, it required that recanalization attempts with the randomized guidewire be 30 min of fluoroscopy in duration, thus insuring that a ‘whole hearted’ attempt had been made with the initial guidewire device. Other endpoints included measures of safety, e.g. death, myocardial infarction and also longer-term outcome such as major adverse clinical events and restenosis. One important safety end-point was perforation. An interesting strict definition was used which included leakage of contrast dye into the pericardium or tamponade requiring treatment. Smaller guidewire passages were euphemistically termed ‘laser wire exits’.

Although the laser system itself has been well studied in large numbers of patients, the laser wire is unique, as it is a 0.018 inch shapeable guidewire with 12 fibres with a 45 micron diameter. This allowed the investigators to shape the wire, ascertain that it was in contact with the chronic total occlusion and in the longitudinal plane of the artery and then activate the device. Although this process sounds straightforward, it is extremely difficult, requiring substantial time and excellent three-dimensional visualization of the course of the vessel, as well as multiple injections to document intraluminal location. Although the wire was shapeable, that is a relative term. It was also somewhat stiff.

A total of 303 patients were randomized. The procedures were difficult, requiring long fluoroscopy time at 41 min and considerable contrast, about 500 cc. Overall, there was no statistically significant difference in success rate with the initial randomized wire, at 53% for the laser wire and 47% for the mechanical wire (P=0.33). Crossover to the non-allocated wire was performed in 31% of the laser wire and 42% of the mechanical wire; the success rate of an additional attempt after crossover to the laser wire was 45%, compared with the success rate after crossover to the mechanical wire of 27% (P=0.054). This probably relates, in part, to the reason for failing with the initial wire: the most frequent reason for failure in the initial laser wire group was misalignment or false route tracking, neither of which may be helped by switching to a mechanical wire, while the most common reason for failure in a mechanical wire group was non-progression of the wire, which could be potentially solved by crossover to the laser wire. At the end of the procedure, including crossovers, there was no difference in the overall success rate, with 63% with the laser wire and 66% with the mechanical wire (P=0.61). Clinical success with achievement of a final adequate lumen was less in both groups but not statistically significantly different. Importantly, there was no difference in perforation.

The long-term clinical follow-up and angiographic endpoints were not different between the two groups, as least in terms of freedom from major adverse cardiac events and angina. As might be expected, patients with successful procedures had improved outcome compared with unsuccessful procedures with less need for coronary bypass graft surgery in the future. Despite the frequent use of stents, the rates of restenosis and subsequent occlusion were increased compared to the treatment of patients without chronic total occlusion.

What then are we to make of this technology and this approach? We can say that it is not a magic bullet — indeed industry has already concluded that, and the device is no longer commercially available.

We can say that success rates of chronic total occlusion are still substantially less than with subtotal occlusion, usually because we cannot gain access to the distal bed irrespective of whether we use a laser wire or a mechanical wire. Approaching chronic total occlusion takes time and commitment. These procedures should only be attempted if the interventional cardiologist is really committed to using the full range of guidewires available. Finally, from the patient standpoint it remains worthwhile because if recanalization is successful, it results in improved outcome, particularly avoidance of coronary bypass graft surgery. As the authors conclude, a further improvement in treatment modalities is warranted in order to make percutaneous treatment of chronic total occlusions more efficacious.

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