**A new concept to help deal with dissections in peripheral angioplasty**

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**Editorial**

Peripheral Arterial Disease (PAD) affects nearly a fifth of those over the age of 60 in the Western World (1). It is the primary cause of limb amputation in the United States and the United Kingdom and remains a leading cause of major cardiovascular morbidity (2). Patients with PAD who develop symptoms typically present either with Intermittent Claudication (IC) or Chronic Limb Threatening Ischaemia (CLTI). More than half of those diagnosed with symptomatic PAD are expected to die, have an amputation or a major cardiovascular event within five years(3-5). Also, the reduced mobility, chronic pain, and leg ulceration associated with advanced PAD have a devastating impact on Quality of Life (QoL)(3,6). Percutaneous Transluminal Angioplasty (PTA) is a routine treatment for PAD and it is recommended by international guidelines(7). The aim of PTA is not only limb salvage, but also QoL improvement – i.e. improve one’s walking distance and therefore autonomy. We have recently shown in a comprehensive network meta-analysis that treating patients with IC using a combination of supervised exercise, best medical therapy as well as PTA leads to a substantial improvement of their walking distance and QoL at one year compared to strategies that do not involve PTA(8). The Femoro-Popliteal segment (F-P) is the most commonly treated site in those with PAD. The durability of PTA at this site can be challenged by parameters such as: long occlusions, vessel mobility, multilevel disease, calcified plaques, and neo-intimal hyperplasia. A variety of technologies have been developed to address these shortcomings. Drug coated balloons (DCBs) have been used for many years in coronary interventions to prevent neo-intimal hyperplasia. Following the publication of a series of randomised trials (all industry funded) regarding their use in F-P procedures, DCBs are now also widely applied in this clinical context. Exhaustive data on cost- and clinical- effectiveness though, especially in terms of amputation free survival, are still unavailable. The issue of multiple dissections, especially in long calcified lesions, following PTA cannot fully be addressed by simply using a DCB. Endovascular stents can come handy in this instance and may improve patency(9).Complications of stent implantation, however, include in-stent restenosis or occlusion, stent compression, and stent fracture(10). Initial designs of laser-cut bare nitinol stents have now evolved and stent fractures are rare with newer devices, some of which even have biomimetic properties and adapt to arterial anatomy and movement(11). Drug eluting stents (DES), which combine a stent with a cytostatic or cytotoxic drug, have been developed to prevent neo-intimal hyperplasia and in-stent stenosis. Some studies suggest superiority of paclitaxel eluting stents over bare metal stents(12-15).Using a DES, though, may be less cost-effective and paclitaxel eluting stents may also be associated with increased long-term mortality(16). Despite these newer technological advances, stenting is still burdened by the possibility of stent occlusion. This can be a “catastrophic” event, given the difficulties in treating in-stent occlusions. Using a stent to address a focal dissection may therefore be a form of over-treatment and impact on future outcomes.

The advent of the TACK device is therefore a welcome addition in the PTA armamentarium. This technology provides intraluminal focal support only at the site of a dissection after PTA. In theory at least this concept appears appealing; the “healthy” artery proximal to the focal dissection does not have to be covered by a stent, there is no absolute need to use additional drug coated devices and normal anatomy can be restored addressing flow-limiting dissections. At the same time, however, one has to consider the following potential pitfalls: i) ease of use; ii) precision of placement of the device; iii) medium and long-term longevity; iv) cost- and clinical- effectiveness compared to established modes of treatment.

Gray et al. in this issue of the Journal report an interesting prospective cohort (single arm study) using the TACK device. This is the first prospective study of this size to evaluate the use of the technology in F-P PTA. The inclusion criteria are sufficiently broad; however, extremely calcified and very long lesions were excluded. It appears that, at least in the hands of the experienced operators taking part in this series, the device can be deployed with relative ease and precision (95.8% device deployment at intended site). The procedure was feasible and successful in almost 100% of cases and it appears that it is not very time-consuming. The real issue here though is translating these findings into actual clinical practice. The IDEAL collaboration have published clear guidance on the adoption of new technologies(17). These suggestions have to be taken seriously by endovascular specialists before adopting new technologies widely, given the ever advancing nature of endovascular devices. Recent experience with endovascular grafts introduced into practice without high-quality randomised data supporting their use has led to patients suffering several major adverse events(18). The counter argument is that well-designed randomised studies evaluating actual cost- and clinical- effectiveness may delay the introduction of new beneficial technologies in routine care. Evidence in other clinical areas has shown that this is actually not true. Performing high-quality clinical effectiveness randomised trials with clinically-driven primary outcomes delays routine adoption by less than a year(19).

The publication by Gray et al. does provide some basic valuable insights into this new device relating to its safety, ease of use and precision of deployment. It is important that we now assess the technology in terms of medium and long-term longevity as well as cost- and clinical- effectiveness in a randomised trial of high quality. This will guide adoption in routine practice by addressing two key questions: what is the impact on amputation free survival and which residual lesions/dissections actually need treating with the TACK device?

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