Peripheral Arterial Disease Backgrounder

Peripheral arterial disease (PAD) is a consequence of atherosclerosis. It presents as pain or weakness in the lower limbs, due to decreased blood flow. It is estimated that 12–14% of the general population have the condition, rising to up to 20% of patients over the age of 75 [Hiatt 1995]. The risk factors for developing PAD are similar to those for cardiovascular disease and include smoking, diabetes mellitus, dyslipidaemia, and hypertension.

Critical limb ischaemia is the most advanced form of PAD. Approximately 1 in 20 patients diagnosed with PAD will progress to critical limb ischaemia during the course of their illness [Schanzer and Conte, 2010]. Approximately 2 out of 5 of these patients will lose their leg within 6 months and 1 in 5 will lose their life [Norgren 2007]. Traditionally, open surgical bypass of the affected vessel was the only effective treatment strategy to restore the circulation. However, in the last 10 years, the development of catheter-based devices has opened up the opportunity to treat more patients. Between 1996 and 2006 in the United States, the number of lower-extremity endovascular interventions for Medicare[1] beneficiaries rose by over 3-fold and are now more common than bypass surgery [Goodney, 2009]. Endovascular interventions are seen as preferable to bypass surgery and considerably more beneficial than amputation, which can cost double the amount for angioplasty with respect to the procedure itself.

The application of drug-eluting balloon (DEB) technology for the treatment of critical limb ischaemia offers several advantages over other techniques. DEBs deliver drugs that prevent vascular growth directly to the site of trauma and have been shown to significantly reduce late lumen loss and target-lesion revascularisation [Tepe 2008]. Preclinical studies with FREEWAY™, a paclitaxel-eluting over-the-wire peripheral transluminal angioplasty balloon catheter, have shown promising results for the prevention of neointimal injury and phase III studies are underway to evaluate their potential to inhibit restenosis following treatment for occluded or stenotic superficial femoral or popliteal arteries.

References

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Tepe G, Zeller T, Albrecht T et al. Local delivery of paclitaxel to inhibit restenosis during angioplasty of the leg. *N Engl J Med* 2008; 358: 689–699.

[1] Medicare is a social insurance programme administered by the United States Government. It provides health coverage for people aged 65 years and over. Other health care providers exist in the United States.