INVITED COMMENTARY

Real World Iliofemoral Arterial Revascularisation: Time for the Great Hybrid Reset?

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Hybrid revascularisation of extensive iliofemoral occlusive arterial disease (TASC II C/D) has become an established treatment, but there is a paucity of good quality evidence comparing clinical and technical outcomes of open surgical reconstruction (OR) and hybrid repair (HR). A well conducted randomised controlled trial (RCT) has been long awaited and Starodubtsev and colleagues have partly closed this gap.[1]

The 2017 European Society of Cardiology and the European Society for Vascular Surgery joint guidelines suggest a hybrid procedure as first line treatment for claudicants with iliofemoral occlusive lesions (Class IIa; Level C).[2] More recently, the 2019 Global Vascular Guidelines have extended the recommendation to patients with chronic limb-threatening ischaemia (CLTI) presenting with GLASS stage IB inflow disease (Grade 2, Level C).[3] The level of evidence remains low and the grade of recommendation weak being based on observational, mostly outdated, case series studies.

Starodubtsev *et al.* randomised 202 patients between October 2015 and August 2017 to either OR or HR, providing contemporary Level B evidence on the safety and efficacy of both revascularisation modalities. Unsurprisingly, the length of stay and short term clinical outcomes favoured HR (hazard ratio 2.47; 95% confidence interval 1.13 — 5.40; $p = .20$) confirming HR non-inferiority for primary endpoints, with comparable cumulative primary patency (91% HR *vs*. 89% OR), limb salvage (98% HR *vs.* 97% OR) and mortality rates (3% HR *vs*. 7% OR) at 36 months (secondary endpoints).

The study has significant limitations. Firstly, it is a single centre trial carrying an intrinsic risk of selection bias. Secondly, most of the randomised patients were claudicants (Rutherford stage 2 — 3: 86% HR, 85% OR); this may undermine the significance of the clinical findings. An underpowered subanalysis, comparing CLTI and claudicants in the HR cohort, showed no statistically significant difference in three-year amputation-free survival (94% and 95%, respectively). However, patients with claudication and CLTI are clinically heterogeneous and are not comparable; for patients with claudication "the correlation between quantitative and qualitative measures of disease severity remains difficult to reconcile".[3] Furthermore, a structured walking exercise programme was not offered to claudicants prior to revascularisation. Finally, the eligibility for recruitment into the RCT was restrained by excluding "severe aortic calcification and iliac arteries intolerant of balloon angioplasty". In real world practice, arterial wall calcification, although a potential operative risk and a technical challenge, does not pose an absolute contraindication to endovascular recanalisation. Intravascular lithotripsy has extended the indications for treatment of severely calcified iliac arteries and may prove to be an effective vessel preparation strategy to improve luminal gain and to reduce the risk of dissection and bail out procedures.[4]

Overall, Starodubtsev *et al.* have contributed to strengthening the current evidence and reinforced our current practice to favour one-step hybrid procedures, especially for CLTI patients in the context of the ongoing SARS-CoV-2 pandemic and worldwide reorganisation of vascular services.[5]

While awaiting the long term results of this trial, we advocate the need for further large, multicentre RCTs powered to differentiate between treatment indications, designed to include up to date revascularisation modalities and focusing on pragmatic outcomes (i.e., quality of life, lower limb functional outcomes) with the aim of capturing potential benefits of hybrid revascularisation in a real practice setting.

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