Editorial

Endovascular Interventions for Infrainguinal Arterial Disease: Collecting Evidence to Expand Indications

In their paper, the authors followed a highly refined algorithm in order to obtain methodological robustness. This is made clear when one pays attention to the presence of 1) a priori inclusion criteria, limiting the analysis to randomized controlled trials (RCTs) where DEB and DES were evaluated for femoro-popliteal and/or infrapopliteal PAD treatment in humans with, at least, one of the following outcomes: binary restenosis (reduction in percent diameter of 50% or greater), target lesion revascularization (TLR; repeat percutaneous or surgical revascularization), late lumen loss (LLL; difference in minimum lumen diameter at procedure completion and at follow-up), amputation rates, or mortality rates; 2) a thorough assessment of possible biases, including publication bias and possible interference from industries (the so-called corporative bias); and 3) a complex, yet elegant, statistical analysis of the selected data. Noteworthy to mention that no study evaluating DEB or DES in the treatment of restenosis was included in this analysis.

After evaluating the available trials, eight randomized trials were found for DEB angioplasty in the treatment of PAD. Analyzing the compelled data, the authors demonstrated statistically significant superiority of DEB over non-pharmacological balloon angioplasty of femoral-popliteal disease for LLL, restenosis, and TLR, without benefit in major amputation or mortality. For infrapopliteal disease, superiority of DEB over percutaneous transluminal angioplasty (PTA) was statistically significant for restenosis and TLR. Twelve trials evaluating the use of DES implantation in peripheral arterial disease were included in this meta-analysis. Drug-eluting stents were significantly superior over bare metal stents (BMSs) for late lumen loss and restenosis in femoral-popliteal disease, with no benefit in mortality or amputation. Evaluating the use of DES for infrapopliteal PAD, DES showed statistically significant superiority over BMSs for both restenosis and TLR; again, no benefit in amputation or mortality was seen.

According to recent AHA/ACC Guidelines for management of patients with PAD [13], the following interventions received a Class I recommendation: use of statins, use of antihypertensive medications - including beta-blockers - to achieve BP control, proper frott care in diabetic patients, smoking cessation - with the use of specific medications, if no contraindication - , use of aspirin (or clopidogrel, as an alternative to it), use of exercise as an initial treatment and use of cilostazol in patients without heart failure. The same guidelines also give a Class I recommendation for endovascular procedures in the following circumstances: 1) those who have lifestyle-limiting claudication with reasonable likelihood of improvement and, at least, 1 of these: inadequate response to exercise/medical therapy and/or
a very favorable risk-benefit ratio (eg. focal aortoiliac disease); 2) it is the preferred technique for TASC (Transatlantic Intersociety Consensus) type A iliac and femoropopliteal lesions; 3) provisional stent is indicated as salvage therapy in the iliac arteries; 4) stenting as the primary therapy for common and external iliac artery stenosis and occlusions. When one takes a look into the recommendations for stenting in femoral, popliteal and tibial arteries, it is seen that the guidelines go with a Class IIa for stenting as salvage therapy, and a III for stenting as primary therapy. On the other hand, surgical interventions received a Class I recommendation, regardless of arterial territory.

In summary, endovascular interventions are an option in the treatment of PAD as long as an adequate evaluation regarding location and extent of disease is performed. Direct stenting is still a class III recommendation for treatment of infra-inguinal PAD, and no statement is made in favor of DES over BMS. The same guidelines do not explicit any preference for DEB over plain angioplasty with non-pharmacological balloons in any arterial territory. Although more randomized trials are needed to better evaluate the role of these new technologies in the treatment of PAD in a broader range, their safety (compared to surgery) and benefits (compared to BMS or PTA) are being demonstrated and, hopefully, in the future we will have a larger number of class I recommendations for endovascular interventions.

References