



Endovascular-first strategy for all patients with peripheral arterial disease?

“...endovascular interventions are low-risk procedures in skilled hands with a high success rate even in complex lesions and an acceptable patency rate. Therefore, many high-volume centers have adopted an ‘endovascular-first’ approach whenever technically possible.”

KEYWORDS: balloon angioplasty ■ endovascular therapy ■ peripheral arterial disease ■ restenosis ■ revascularization

Different treatment options are available for patients with intermittent claudication, depending on patients' symptoms and their reduction in quality of life. While supervised exercise training has tremendous effects in certain subgroups of these patients, it otherwise frequently fails in those with severely limited walking capacity. Furthermore, vasoactive drugs are of only limited benefit. Therefore, patients with very short pain-free walking distance are candidates for revascularization despite the fact that evidence of any long-term benefit of revascularization treatment compared with supervised exercise and best medical treatment is lacking. Otherwise, in patients with critical limb ischemia, revascularization is obligatory for limb salvage, whenever technically possible [1].

It is well known that patients with peripheral arterial disease mostly suffer from generalized atherosclerotic disease with a consecutively increased risk concerning cardiovascular morbidity and mortality. The reported prevalence of coronary heart disease in patients with peripheral arterial disease varies between 14 and 90%, depending on the sensitivity of the diagnostic test [2]. This high comorbidity is responsible for the poor long-term prognosis in many of these patients. The annual mortality rate derived from epidemiological studies is 4–6% and is highest in those with the most severe disease. The 1-year mortality rate in patients with critical limb ischemia is approximately 25% and may be as high as 45% in those who have undergone amputation.

Independent of this long-term risk for cardiovascular events, patients undergoing an intervention for their vascular disease have an acutely increased peri-interventional risk. This is well established for patients undergoing vascular surgery. Although the overall peri-operative

event rate has declined over the past decades, the 30-day cardiovascular mortality still remains as high as 2–5% [3]. Myocardial infarction accounts for up to 40% of postoperative fatalities and can therefore be considered the major determinant of peri-operative mortality associated with vascular surgery.

It is generally assumed that endovascular treatment is associated with a reduced risk of cardiovascular complications compared with open surgery. Furthermore, for most interventions there seems to be a significant mortality advantage for endovascular compared with traditional surgery [1]. Therefore, proponents of endovascular treatment always stress these most important advantages – especially from the patient's point of view – of low procedural morbidity and mortality. This reduced peri-interventional cardiovascular morbidity and mortality is also the main reason for the dramatic shift in revascularization management during the last few years [4]. Owing to the reduced invasiveness and definitely lower complication rate compared with open vascular surgery, endovascular surgery has gained increased acceptance by physicians and especially by patients. Therefore, an increasing number of centers favor an endovascular-first approach. The most significant change in the treatment of critical limb ischemia during recent years has been the increasing tendency to shift from bypass surgery to less-invasive endovascular procedures as the preferred first approach, with bypass surgery reserved as a back-up option if necessary.

The other main reason for this shift – besides the lower complication rate – is the fact that technology and techniques of endovascular revascularization have rapidly evolved during the last decade and there is now a rapidly growing



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body of experience in the treatment of even complex cases [5].

In general, three major factors determine the decision to opt for endovascular therapy or open vascular surgery: technical success, procedural complications and patency rates. Major advances have been made in recent years in the improvement of technical success and avoidance of complications. In the early days of endovascular therapy, when it mainly consisted of plain balloon angioplasty, treatment was offered exclusively for short and easy lesions, whereas more complex and longer lesions were generally considered indications for open vascular surgery. However, with increasing experience and confidence in the minimally invasive approach, and with advanced technologies, the treatment of more complex lesions was becoming clinical routine. Recent advances to improve lesion crossing include novel recanalization wire technology as well as the development of dedicated chronic total-occlusion crossing catheters and re-entry devices, enabling successful recanalization, even of long-segment and heavily calcified lesions.

Finally, addressing the issue of patency of endovascular and surgical approaches, restenosis still has to be considered the Achilles heel of endovascular procedures [6]. However, significant progress has not only been made in improving recanalization, but also in patency, at least in the midterm. The two primary phenomena that contribute to restenosis after successful angioplasty are chronic vessel constriction (negative remodeling) and neointimal hyperplasia by means of cell proliferation. While stents can reduce the acute recoil and constricting effect of vascular remodeling, they otherwise even enhance neointimal proliferation within the stent, leading to in-stent restenosis. Therefore despite some improvements compared with angioplasty, the patency rates with the bare Nitinol stents are still suboptimal [7]. However, according to recent data, the concept of combining the advantages of the mechanical scaffolding properties of Nitinol stents with the antiproliferative action of drugs looks very promising, also in peripheral arteries [8]. A potential future improvement of local drug application for the necessary time span without the disadvantages of permanent stent implantation may be the development of bioabsorbable stents. Another new, very promising concept is the local drug application by drug-eluting balloons, particularly the paclitaxel-eluting balloons [9].

The progress in techniques and tools was not accompanied by a high volume or quality of data,

and, therefore, the optimal treatment strategy concerning endovascular versus surgical intervention is often debated due to the paucity of randomized and mostly underpowered studies. Furthermore, vascular interventions are practiced by physicians from different medical, surgical and radiologic specialty training backgrounds.

Owing to the rapid development, a thorough evaluation of new endovascular treatment options within adequately designed clinical studies is difficult. Another problem is the lack of uniform end-point definitions, which make a direct comparison among studies difficult [10]. Therefore, recently, there were large difficulties in updating the TransAtlantic Inter-Society Consensus (TASC) lesion classification and to reach a consensus in the absence of high-grade scientific evidence [11]. It was reported that the principal conclusion of the planned TASC IIb document was an endovascular-first approach. However, surgical societies saw this conclusion as being weighted too much in favor of endovascular therapies, and finally they did not endorse such an 'endovascular-first' approach.

The selection of the most appropriate revascularization strategy should currently be determined on a case-by-case basis in a specialized vascular center in close cooperation with an endovascular specialist and a vascular surgeon. The main issues to be considered are the anatomical suitability, comorbidities, local availability and expertise, and the patient's preference [4]. Advances in the endovascular treatment of peripheral arterial disease have prompted many physicians to consider more liberal indications for percutaneous intervention. Endovascular revascularization is therefore also recommended in patients with lifestyle-limiting claudication, when clinical features suggest a reasonable likelihood of symptomatic improvement and there has been an inadequate response to conservative therapy. In aortoiliac lesions, endovascular revascularization can even be considered without initial extensive conservative treatment [4]. However, the endovascular-first approach is justified only as long as low rates of complications are encountered and the surgical landing zone for the distal anastomosis of a potential secondary bypass remains unaffected by the interventional procedure.

In conclusion, endovascular interventions are low-risk procedures in skilled hands with a high success rate even in complex lesions and an acceptable patency rate. Therefore, many high-volume centers have adopted an 'endovascular-first' approach whenever technically possible.

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