Early Results of the European SFA Treatment Registry: What Method of Treatment Appears Best?

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Background
Randomized trials are often considered the method that generates the most valid data for conclusion on controversial issues in clinical medicine. Randomized trials demonstrate the effect of treatment under optimal conditions ("efficacy"), whereas its effect in routine care under average conditions ("effectiveness") often demands population-based clinical studies. Randomized trials and other scientific data are mostly presented by centers of excellence with better results than those generally achieved in most hospitals. The outcomes of everyday practice are better represented by population-based registries of medical procedures with outcome data, including complications and adverse results. Such clinical registration suits vascular medicine well because most vascular procedures are well defined and the outcomes can easily be assessed within a short period of time. Vascular registries may be used to evaluate the results of everyday practice, to map vascular activity and its changes, and to achieve goals like quality assurance, good scientific work, better education, proper resource allocation, and optimal health care planning.

Purpose
Peripheral arterial disease is a significant cause of morbidity because it leads to functional limitations that reduce walking ability, impair quality of life, and at times threaten limb viability. Revascularization has changed dramatically over the last two decades, with the use of percutaneous interventional techniques both replacing much of what was done with open surgery and increasing the number of patients with non-coronary atherosclerotic disease who are treated. Despite major advances, many questions remain, partly because of the continuing evolution of tools and techniques and partly because of the paucity of large prospective randomized trials.

In the femoropopliteal segment, data regarding long-term patency with surgical bypass are relatively good. The data for angioplasty are somewhat controversial but suggest a long-term primary patency of ? 70% at 4 to 5 years for PTA of focal stenotic lesions. For occlusions and lesions > 4 to 6 cm, angioplasty has generally had very low patency rates. Studies examining the efficacy of stents in the femoropopliteal segment suggest that long-term patency is similar to and possibly worse than with PTA alone. This may be due to extensive disease and poor distal runoff. Studies of brachytherapy have been encouraging, but the number of patients reported to date is small. Other percutaneous technologies such as endarterectomy or application of cryotherapy have been proposed; multiple stent designs have been developed. Given the relatively poor long-term patency in the female population system with most percutaneous approaches and the small size of most prospective trials to date, it is imperative, perhaps more than in other arterial segments, that multicenter trials of promising approaches be performed.

Surprising variation continues to be found in the management of individual patients with identical conditions. Variations arise not only from country to country but often from one hospital to another in the same city. The specialty of cardiology has unilaterally declared the management of peripheral vascular diseases within their sphere of competence. At present, in many cardiology training programs, vascular disease is an "add on." Attempts to question the legitimacy of cardiologists' involvement in peripheral vascular care have been singularly ineffective.

Such data for selected trials leading to the benefit of medical treatment can only be collected in appropriate registries with all disciplines involved. This was the basic thought of working on a registry concerning the most attractive vascular region at time for all: the superficial femoral artery (SFA). The collected data should support and emphasize studies and trials of unique interest, for the benefit of our patients and vascular science.

Objectives
The SFA is widely treated by angiologists, cardiologists, interventional radiologists, and vascular surgeons. Experience in handling SFA lesions varies from expertise to poor performance. But the question in general is that we do not know who does what, where, why, how often, and with which results. This lack of qualified information in combination with the vast amount of studies using different approaches with no comparable data gave reason for a multidisciplinary registry. Mission strategy was an open international data bank, unlimited participating units, with participation on one's own basis, free of charge. The databank would be Internet based, with electronic data submission, together with a permanent, safe, and easy approach. General requirements were establishing a registry with follow-up on an intention-to-treat basis with the SFA as target vessel for de novo lesions ("groin to knee") enrolling only claudicants, differentiating all technologies within three therapy groups (conservative, interventional, vascular surgery) and to submit solid data for future studies and trials. The European Superficial Femoral Artery Registry (ESFAR) was launched. It provides baseline, procedural, and follow-up data on an intention-to-treat basis.

Method
Using the Internet (www.esfar.org), prospective patient enrollment is 12 months from July 1, 2005, to June 30, 2006. Follow-up is 3, 6, 12, and 24 months postprocedure. For all three therapy groups (conservative, interventional, and vascular surgery), patients have to meet inclusion criteria (planned treatment of de novo lesion/occlusion in the SFA on intention-to treat basis, patent iliac–common femoral–deep femoral artery as continuously patent proximal run-in, patent below-knee popliteal artery with minimum one patent runoff vessel, Rutherford classifications 1–3, Fontaine classification (2) as well as exclusion criteria (previous interventional

and/or vascular surgery treatment of the de novo lesion, acute previous thromboembolic occlusion, ASA classification score 4 or 5, previous contralateral major amputation). Besides demographic data in pretreatment evaluation, ESFAR attracts attention to risk factors and comorbidities (LDL level, smoking history, hypertension, diabetes, hyperhomocysteinemia, renal insufficiency, coronary artery disease history, cerebrovascular disease, PAOD onset, renovascular disease, family history, and concomitant medication), measures of disease severity (stenosis of the treated site as well as runoff grade), ankle brachial indices (ABI), treadmill evaluation (pain-free and absolute walking distances), functional status, clinical evaluation (Rutherford and Fontaine classifications), and morphology (TransAtlantic Inter-Society Consensus [TASC] criteria, runoff vessels, lesion characteristics) information on diagnostic imaging.

Main reporting requirements are based on treatment descriptions:

1. Conservative treatment: supervised/nonsupervised training, in- or outpatient treatment, pharmacologic medication (ASA, clopidogrel, ACI/AT1, CSE, ?-blocker, statins, oral anticoagulants, vitamin B6/B12/folic acid, calcium antagonist, and vascular active drugs), prostanoid therapy
2. Interventional treatment: procedure character (endoluminal, subintimal, mixed), balloon characteristics, stent characteristics, adjuvant procedures (brachytherapy, laser, lysis, and atherectomy), angiographic post-procedure results, postprocedure runoff, and procedure related complications
3. Vascular surgery: patch angioplasty, patch characteristics, above/below knee graft reconstruction, graft characteristics (details on vein, PTFE, Dacron, Biograft, and composite graft), adjuvant procedures, operating time, postprocedure results, and postprocedure runoff, complications

Discharge and follow-up data include treadmill, color duplex sonography, functional testing, information on adverse events since discharge or last examination, changes in Rutherford category and Fontaine classification, possible reinterventions, changes in medication, as well as a disease specific questionnaire for the assessment of quality of life in patients suffering from intermittent claudication.

Results

ESFAR intends to include 1,000 patients per therapy group within 1 year of patient enrollment by a minimum of 100 centers/units. All data are monitored by independent data manager to ensure correct data submission as well as in-time follow-up examinations. Data reports are provided in 6-month intervals. All participating units have permanent access to their submitted data.

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