

# Germany



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### What is the prevalence of endovascular SFA therapy as compared to surgical?

The prevalence of endovascular SFA therapy in Germany is steadily increasing. Malyar et al<sup>1</sup> analyzed all in-hospital patients with a diagnosis of peripheral artery disease based on the nationwide German diagnosis-related group system comparing the years 2005 and 2009, and they found that use of endovascular therapy increased by 46%. In contrast, open surgical revascularization procedures have decreased for two reasons: (1) the number of vascular surgeons who are performing endovascular therapy for SFA disease is rapidly increasing; and (2) more patients are looking for vascular centers that specialize in endovascular options.

### How would you describe device availability in your country, both in types of devices and different vendors within each class?

In general, with Germany being part of the European Union, all CE Mark–approved devices are commercially available, and considering that Germany is the biggest health care market in Europe, every medical device company is offering their products. As a result, users have the free choice between different vendors, resulting in an intense competition between the medical device companies. Therefore, medical devices are offered at the lowest prices in Germany compared to the rest of the European Union. Device decisions are mainly driven by price because German hospitals are exposed to serious budget restrictions. Thus, in most hospitals, administrators are responsible for choosing a particular device (eg, a drug-coated balloon [DCB]) not based on its proven clinical efficiency but on the price. At my institution, the physician decides which product is the best for the individual patient, but we are becoming the exception.

### In what ways does reimbursement (both government and private if applicable) affect device use? Which device classes are most affected?

In Germany, reimbursement is the most relevant driver of device use in numbers and classes. In particular, complex interventions are mainly performed as inpatient procedures. As long as standard therapies are used, such as plain old balloon angioplasty (POBA) with or without provisional bare-metal stent (BMS) placement, atherectomy, or thrombectomy, the so-called diagnosis-related grouping system is adequately covering the costs for the hospital. However, certain devices, such as DCBs, are currently sufficiently reimbursed by add-on payments, but others, like drug-eluting stents (DES), are not.

However, if device technologies need to be combined (eg, atherectomy plus stent placement) or more than two stents have to be implanted, those extra costs are not covered by the reimbursement system and result in a loss-making treatment for the hospital. For example, it is not cost-effective for a health care provider to treat a patient with multilevel disease (eg, an iliac artery lesion plus a femoropopliteal lesion) within one single procedure. From the cost-effectiveness perspective of the health care provider, such a procedure needs to be split into two interventions and performed in two hospital stays with a time window between both procedures of at least 1 month. The same holds true if a patient is suffering from bilateral peripheral arterial disease. It is easy to understand that certain ethical considerations—in particular critical limb ischemia patients who urge their physicians to perform complex procedures within one hospital stay—is what drives the clinic into a deficit in certain so-called centers of excellence, where the sickest patients are referred. In general, this situation is the same for publicly and privately insured patients.

### Are there any historic or cultural forces unique to your country that have affected the penetration of endovascular options?

There are no unique forces that might affect device adoption. As everywhere in the world, adoption of new technologies in Germany is driven first by adequate reimbursement and secondly by the operator's knowledge

of potential benefits of a new technology in terms of clinical effectiveness or user friendliness. One difference compared to other countries might be the more liberal access to new technologies in Germany, as long as they are officially approved for clinical use by the competent authority. As soon as a device has received CE Mark, it is left to the physicians' discretion whether to offer it to their patients.

### How do most physicians receive training in endovascular therapies in your country?

Training in endovascular therapy is provided as a part of the individual training we undergo as medical specialists, such as radiologists, vascular surgeons, or angiologists. In all of those specialties, a dedicated curriculum in endovascular therapy is part of the overall training program. In addition, physicians who are particularly interested in this therapy can attend hands-on workshops offered by highly experienced operators in collaboration with medical device companies, or they can apply for unpaid fellowships that can last from a few days to several weeks in high-volume centers.

### What is your personal strategy or algorithm for treating:

In general, my treatment algorithm depends on the vessel bed where the lesion is located (ie, the iliac, femoral, or tibial arteries).

#### • Short, focal lesions:

**Iliac:** BMS implantation is the most frequently used treatment in simple, fibrotic, common iliac artery lesions, but POBA is sufficient as well.

**Femoropopliteal:** DCBs are the treatment of choice due to the recent convincing pivotal trial data.

**Tibial:** DES, based on the three published randomized, controlled trials (YUKON, DESTINY, and ACHILLES) demonstrating the superiority of DES over the use of BMS and POBA.

#### • Long lesions:

**Iliac:** BMS, mostly self-expanding nitinol stents. The role of covered stents is still uncertain despite the data from the COBEST trial.

**Femoropopliteal:** DCB plus provisional nitinol stent placement in order to minimize the stent length. Full lesion coverage, either with DES or Viabahn endoprostheses (Gore & Associates) are the exception.

**Tibial:** POBA

#### • Calcified lesions:

**Iliac:** Balloon-expandable BMS, and the Supera nitinol stent (Abbott Vascular) for distal external iliac artery lesions.

**Femoropopliteal:** Atherectomy plus a DCB in more focal lesions, Supera stent placement in longer lesions and in small-diameter vessels combined with a DCB.

**Tibial:** Atherectomy plus POBA in more diffuse lesions; DES in focal lesions.

#### • CTOs:

**Iliac:** BMS with the choice of a balloon-expandable stent or a self-expanding stent, depending on lesion calcification.

**Femoropopliteal:** DCB if possible, in terms of intraluminal lesion passage following either mechanical thrombectomy or atherectomy plus provisional nitinol stent placement. In very long lesions, Viabahn implantation.

**Tibial:** Lesions < 10 cm are treated with DES, and those > 10 cm are treated with POBA. DCBs are reserved for clinical studies.

#### • In-stent restenosis:

**Iliac:** Stent-in-stent placement or DCBs, even though no data exist for this. Stent grafts in lesions affecting the aortic bifurcation.

**Femoropopliteal:** In-stent occlusions undergo pretreatment mostly with mechanical thrombectomy (Rotarex, Straub Medical AG) or atherectomy followed by DCB use; DES used in a stent-in-stent fashion; or Viabahn implantation, which remains an exception.

**Tibial:** DES in lesions < 10 cm, otherwise POBA.

#### • Claudicants:

In general, claudicants should be offered a definitive treatment. The treatment goal is to improve the quality of life and to avoid the need for target lesion revascularization. Thus, the most effective treatment modality should be used.

**Iliac:** BMS placement.

**Femoropopliteal:** Depends on lesion morphologies, as previously stated.

**Tibial:** DES for lesions < 10 cm, POBA for those > 10 cm, and atherectomy in dedicated lesions (bifurcation lesions, directional atherectomy; severely calcified lesions, high-speed rotational atherectomy). ■

1. Malyar N, Fürstenberg T, Wellmann J, et al. Recent trends in morbidity and in-hospital outcomes of in-patients with peripheral arterial disease: a nationwide population-based analysis. *Heart J.* 2013;34:2706-2714.