United States

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

As is the trend in many places around the world, the prevalence of endovascular SFA therapy is high and is clearly rising. The less invasive nature of endovascular therapies as well as the improvements in equipment and techniques has shifted the balance toward the endovascular approach. The practice patterns around the United States are widely variable, and the approach to SFA disease is quite heterogeneous. This is reflected in data from the Vascular Quality Initiative, which demonstrates a wide-ranging percentage of patients with SFA disease treated with surgical bypass within participating institutions. The fact that vascular surgery training programs now incorporate (and emphasize) endovascular therapies means that many of the younger vascular practitioners are favoring the endovascular-first approach.

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

Although the United States tends to lag behind Europe and other regions of the world with regard to early availability of new technologies, there is no shortage of devices and vendors for SFA treatment modalities. Endovascular specialists in the United States are often frustrated by the cautious nature of the US Food and Drug Administration (FDA) and the slow pace of FDA approval of new devices. Nonetheless, we are fortunate that we are not limited by cost restraints with regard to treatment options. Most institutions have wide availability of the full spectrum of balloons, stents, atherectomy devices, chronic total occlusion technologies, embolic protection, etc. The problem is usually not whether the desired device is available, but whether it is the best treatment option (among the many treatment options) for a given patient's SFA disease.

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

Reimbursement for outpatient procedures, particularly in physician-owned, office-based endovascular suites, has had an important impact on device use. Strong reimbursement for atherectomy procedures has greatly impacted the use of these devices in the outpatient setting. Jones and colleagues published an interesting overview of this trend in the *Journal of the American College of Cardiology* earlier this year.[1] They reported that from 2006 to 2011, the use of atherectomy increased twofold in outpatient hospital settings and 50-fold in office-based clinics due to changes in the outpatient prospective payment system. Recent improvements in reimbursement for DCB angioplasty, with the pass-through code, will also likely impact the use of these devices and make the economics more favorable for hospitals.

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

Historically, physicians have been reluctant to treat SFA disease in claudicants with surgical bypass due to the concern about worsening a patient's symptoms if the bypass fails or if the graft becomes infected. This is particularly true since the natural history of intermittent claudication is relatively benign (as least as far as limb outcomes) and patients can do well with medical therapy and an exercise program. This reluctance to intervene on patients with claudication has carried over to endovascular therapies to some extent. There continues to be strong emphasis on wanting to avoid worsening a patient's symptoms or accelerating the natural history of peripheral artery disease. As the results of endovascular therapies continue to improve, particularly for more complex SFA disease, the reluctance to intervene on SFA disease in claudicants will gradually decrease.

Map of The United States – Single Color by FreeVectorMaps.com

UNITED STATES DCB REIMBURSEMENT UPDATE

By Ryan Graver, President, MedAxiom Ventures

The Centers for Medicare & Medicaid Services (CMS) recently examined the LEVANT 2 and IN.PACT SFA I and IN.PACT SFA II clinical trials and adjusted the reimbursement of DCB use in the SFA, removing the device offset in the outpatient hospital setting and, more recently, granting a hospital inpatient DCB a new technology add-on payment. A few key points about these payment programs are listed here.

OUTPATIENT

- In February 2015, CMS approved a transitional pass-through payment for DCB use under the Medicare hospital outpatient prospective payment system.
- This reimbursement provision became effective on April 1, 2015, with a Healthcare Common Procedure Coding System code of C2623 (catheter, transluminal angioplasty, drug-coated, non-laser).
- In June, CMS further improved the pass-through payment by awarding the code without a device offset, which makes the device fully reimbursable.
- This reimbursement determination was made retroactive to April 1, 2015.

INPATIENT

- For a new technology to qualify for an add-on payment in the inpatient setting, it must demonstrate a substantial clinical improvement relative to predecessor technology and meet specific cost thresholds. The NTAP payment will provide hospitals with a payment, in addition to the DRG reimbursement, of up to 50% of the cost of the DCB, and is expected to last for a period of 2 to 3 years.
- CMS determined the amount of the add-on payment to be a maximum of $1,036 when DCBs are used for inpatient peripheral procedures and the total device costs exceed the allowance for existing diagnosis-related group reimbursement.
- The add-on payment is effective October 1, 2015.

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

The days of on-the-job training or going to a few hands-on courses and then doing cases with the help of the local device representative are largely gone. Most vascular specialists within the various disciplines who treat peripheral vascular disease receive their training as part of a formal fellowship/residency program. Vascular surgery fellowships have now fully embraced endovascular training as part of the dedicated training program. Interventional cardiologists frequently receive formal training in endovascular therapies during a 1- or 2-year interventional fellowship. Most radiologists who perform endovascular procedures have received training as part of a dedicated interventional radiology fellowship.

What is your personal strategy or algorithm for treating (in brief):

I must preface my comments by saying that the recent approval of DCBs has changed my practice and affected my algorithm for the treatment of SFA disease. Things are in evolution from the standpoint of how I treat femoropopliteal disease.

- **Short, focal lesions:** POBA for the most focal lesions, but DCB angioplasty for everything else.
- **Long lesions:** DCB angioplasty followed by provisional stenting if an adequate angiographic or hemodynamic result is not achieved with a DCB.
- **Calcified lesions:** I favor the Supera stent (Abbott Vascular) for heavily calcified lesions. Lesion preparation is important prior to Supera stent deployment, so this may include high-pressure PTA or scoring balloon angioplasty. In addition, I will sometimes perform orbital atherectomy for heavily calcified lesions.
- **CTOs:** My algorithm has evolved since the approval of DCBs (as I suspect it has for others). For short- to medium-length CTOs, I use DCB with provisional stenting. For long CTOs, I will consider a DES or covered stent (Viabahn, Gore & Associates).
- **In-stent restenosis:** Atherectomy (usually excimer laser) followed by DCB angioplasty.
- **Claudicants:** I think it is still very important to attempt medical therapy and a walking program for patients with claudication. Smoking cessation is aggressively pursued. I commonly prescribe ramipril and cilostazol for claudicant patients. If medical therapy does not provide satisfactory results, then endovascular therapy is a very reasonable option. As has already been discussed, we now have very many good options, including DCBs, DES, and better atherectomy devices. ■

1. Jones WS, Mi X, Qualls LG, et al. Trends in settings for peripheral vascular intervention and the effect of changes in the outpatient prospective payment system. J Am Coll Cardiol. 2015;65:920-927.