Perspectives:
Does Care Drive Reimbursement or Vice Versa?

A United States perspective on the factors that affect clinical decision making and how long-term data and reimbursement affect device selection.

BY TONY S. DAS, MD, FACP, FACC

Clinical decision making for endovascular procedures involves a complex analysis of multiple factors. Coexisting and sometimes competing input drive physicians' procedural decisions. Clinical data and patient outcomes are always weighed first by interventionalists, and in the past, outcomes and reimbursement were somewhat separated. However, in the current health care environment and with an increase in United States physicians, particularly interventionalists employed by hospital systems, there is greater pressure to realize the cost/benefit ratio associated with expensive devices when performing peripheral vascular procedures. In addition, the increase in outpatient procedural centers such as ambulatory surgery centers (ASCs), vascular centers, and office-based labs (OBLs) has heightened physician awareness of device cost and the true clinical impact on outcomes.

The following sections describe the factors that should be considered when selecting a device for peripheral vascular procedures, such as lesion and patient characteristics, type and cost of the device, available data, costs, and experience of the physician.

(Continued on page 61)

A look at factors that affect treatment decisions for superficial femoral artery disease in France.

BY YANN GOUËFFIC, MD, PHD

Which came first, the care we give or the reimbursement we receive? This causality dilemma comes from the observation that it is not clear which of these two events should be considered the cause and which should be considered the effect. To make matters more complicated, both care and reimbursement can be influenced by several factors.

FACTORS THAT AFFECT CARE DECISIONS

First, physicians are increasingly sensitive to clinical study results and, consequently, those results affect their choices in care. Data on superficial femoral artery (SFA) treatment have been collected for more than 20 years. Trials are designed to compare strategies, devices, and/or cost-effectiveness to make it easier for physicians to choose between therapeutic options. For example, during the 2000s, bare nitinol stents emerged as the treatment of choice for SFA disease because studies showed the superiority of bare nitinol stents over balloon-expandable stents and balloon angioplasty. Many studies have shown convincing data regarding the use of drug-eluting therapies for SFA repair.[1-4] However, clinical studies also can make the physician's choice of care

(Continued on page 60)

(Prof. Gouëffic, continued from page 58)

more complicated due to poor methodology, a bad primary endpoint, and/or the absence of clinical improvement. Moreover, the lack of direct comparisons between devices makes it confusing and difficult for physicians who must choose between available therapeutic options with limited robust data.

Obviously, industry also drives treatment choice with sales and marketing programs that may be effective despite a lack of robust data. Companies are increasingly funding clinical studies to obtain data and receive or extend device reimbursements. Conferences and media releases also influence physicians' care choices by highlighting trial results and broadcasting techniques. A physician's specialty also could also be an influencing factor. For example, a vascular interventionalist could be a vascular surgeon, angiologist, radiologist, cardiologist, or cardiac surgeon, and each has undergone different training, experience, and sensitivity that could affect their care choices.

REIMBURSEMENT IN FRANCE

In France, the most powerful factor that can influence SFA treatment is probably reimbursement. Indeed, for cardiovascular diseases, all hospitalization fees, including stay, care, devices, and physicians fees, are reimbursed by the government. Consequently, although all CE Mark–approved devices can be used in France, only reimbursed devices are used in routine practice. Until 2016, only implantable devices such as stents were eligible for reimbursement. For nonimplantable devices (eg, catheters, balloon catheters, guidewires, closure devices, drug-coated balloons, debulking devices), their costs are typically covered by the diagnosis-related group funds. As a result, most expensive nonimplantable devices, such as debulking catheters and drug-coated balloons, were not routinely used. Currently, nonimplantable (and innovative) devices also may be eligible for reimbursement.

To apply for device reimbursement in France, companies have to submit a dossier to CNEDIMTS (commission nationale d'évaluation des dispositifs médicaux et des techniques de santé). To apply, companies must provide safety and efficacy evidence related to their product. The final determination of device application and evaluation is dependent on the quality of the dossier, as well as internal and external expert advisors. Finally, devices are ranked in categories from 1 to 5, called "service attendu" (SA), and defined by the clinical improvement provided by the device compared to the reference treatment, where SA 1 = major improvement; SA 2 = important improvement; SA 3 = moderate improvement; SA 4 = minor improvement; and SA 5 = no improvement.

Based on the recommendations from the CNEMIDTS, the Ministry of Health delivers an authorization of reimbursement. After this authorization, the dossier is sent to the commission d'évaluation des produits et des prestations (CEPP) to determine the device price. A price negotiation based on SA ranking is then conducted between the CEPP and the company.

In France, the reimbursement system is similar for public and private hospitals. When reimbursement is lacking, it is still possible to conduct clinical research. For instance, a university hospital can receive grants from their institution to use nonreimbursed CE Mark–approved devices during the initial 1 to 2 years and assess their outcomes. In addition, a physician can apply for a national research grant called "programme hospitalier de recherche Clinique" (PHRC) or "programme de recherche médico-économique national" (PRME) that allows for the evaluation of safety, feasibility, tolerance, efficacy, and/or cost-effectiveness of health technologies. Finally, physicians can also get support for clinical research from companies by applying to an investigator-sponsored research program.

SUMMARY

It seems clear that reimbursement strongly influences choices in routine treatment for SFA disease. However, clinical data are now mandatory to obtain reimbursement on the French market, and thus, the dilemma still exists. ■

1. Schroeder H, Werner M, Meyer DR, et al. Low-dose paclitaxel-coated versus uncoated percutaneous transluminal balloon angioplasty for femoropopliteal peripheral artery disease: one-year results of the ILLUMENATE European randomized clinical trial (randomized trial of a novel paclitaxel-coated percutaneous angioplasty balloon). Circulation. 2017;135:2227-2236.
2. Laird JR, Schneider PA, Tepe G, et al. Durability of treatment effect using a drug-coated balloon for femoropopliteal lesions: 24-month results of IN.PACT SFA. J Am Coll Cardiol. 2015;66:2329-2338.
3. Dake MD, Ansel GM, Jaff MR, et al. Durable clinical effectiveness with paclitaxel-eluting stents in the femoropopliteal artery: 5-year results of the Zilver PTX randomized trial. Circulation. 2016;133:1472-1483.
4. Müller-Hülsbeck S, Keirse K, Zeller T, et al. Twelve-month results from the MAJESTIC trial of the Eluvia paclitaxel-eluting stent for treatment of obstructive femoropopliteal disease. J Endovasc Ther. 2016;23:701-707.

Yann Gouëffic, MD, PhD
Professor and Chief
Department of Vascular Surgery
CHU Nantes, l'Institut du Thorax, Service de Chirurgie Vasculaire
Nantes, France
yann.goueffic@chu-nantes.fr
Disclosures: Consultant to Abbott, Bard, Biotronik, Boston Scientific, Medtronic, Perouse Medical, Spectranetics Corporation, and WL Gore; research grants from Bard, Terumo, and WL Gore.

(Dr. Das, continued from page 58)

DECISION MAKING IN PERIPHERAL VASCULAR DISEASE TREATMENT

Patient- and Disease-Related Factors

Lesion-specific factors to consider include location (eg, joint space, tibial, bifurcation) and morphology (eg, calcified, diffuse, thrombotic). Patient-related factors that are typically weighed in the mental risk/benefit analysis of complex interventions include the frailty of the patient, renal insufficiency, access options, the patient's ability to cooperate, anticoagulation bleeding risk, and follow-up compliance. Experienced interventionalists weigh these elements to justify and implement clinical decisions for each individual patient, thereby making it difficult to implement generic treatment algorithms in the vascular space where it seems no two patient presentations are exactly alike.

Device-Specific Considerations

In addition to the lesion- and patient-based issues, one must weigh device-related factors, including ease of use, setup, staff familiarity, and acute technical success (eg, crossability, device deliverability, risk). Furthermore, device cost, appropriate size and availability, procedural time, and clinical support are all decision points. The least-discussed decision factors are those that are less likely to be quantified, such as competing interests for physicians' time, recent memory of device performance (good or poor), and need for extrapolation of data from clinical research trials that have narrow inclusion criteria compared to the complex real-world cases encountered in daily practice.

Achieving Procedural Success

When deciding on an access route, one must assess the likelihood of procedural success coupled with the risk of complications, as well as physician experience. For example, ultrasound-guided vascular access with micropuncture needles has lowered groin complication rates and downstream costs of prolonged hospitalization by reducing hematoma rates and bleeding complication costs (eg, CT for retroperitoneal hemorrhage and transfusion). These up-front decisions are based on sound

clinical judgment and increase the cost/benefit ratio in ways that are not always easily calculated. In the outpatient setting, this is more commonly the norm than the exception, as safety and reduction of complications are paramount for maintaining an outpatient-only experience for patients.

Long-Term Data and Costs

All available long-term data affect decision making for superficial femoral artery (SFA) and other vascular procedures, although adequate, randomized, double-blind clinical trials are limited in the peripheral space. More recently, stakeholders (patients, physicians, hospital administrators, payors) are demanding adjudicated data on the procedural success and outcomes of these devices. The decision to use costly but clinically tested devices, such as various forms of atherectomy, has been the source of some controversy. Use of laser atherectomy for in-stent restenosis based on the EXCITE ISR trial results or the use of orbital atherectomy based on data from the CONFIRM study continue to intrigue the interventional community. The DEFINITIVE LE data set on the SilverHawk device (Medtronic) helps justify clinical decision making in the setting of diffuse and somewhat calcified disease without significant concern for irresponsible spending.

Alternatively, the decision to use a specialty balloon with plaque-modifying elements, such as the AngioSculpt scoring balloon catheter (Spectranetics Corporation), Chocolate PTA balloon catheter (Medtronic), which has a nitinol cage, or even a cutting balloon, are based on registry data that are extrapolated to specific lesion types with diffuse disease in areas where stents are not as favorable. The choice of these balloons is often driven by clinical experience and the performance of plain angioplasty balloons, which may have an increased risk of dissection. The cost/benefit ratio can be difficult to calculate, as no head-to-head clinical trials exist. However, without increased reimbursement in either the hospital or outpatient setting, use of these balloons is more difficult to justify despite their clear benefit in certain clinical situations.

In the peripheral vascular space, and particularly the SFA, nitinol stents have been the most well-tested device subset, and more recently, drug-eluting stents (DESs) and drug-coated balloons (DCBs) are following this path. Clinical decisions for stent use based on lesion length and outcomes up to 5 years can be made by extrapolating data from various stent trials, which include nitinol and woven nitinol stents (Supera, Abbott Vascular) as well as DESs that have long-term data (Zilver PTX, Cook Medical). Unfortunately, much of our stent use in the United States is based on data from randomized trials that included shorter lesions and registries in which more real-world cases are compared. Recently, DCBs have been shown to improve patency up to 3 years in the IN.PACT SFA and LEVANT trials. In light of these findings, the Centers for Medicare & Medicaid Services made a decision to allow a "pass-through" cost to hospital outpatient centers for the actual cost of the balloon. However, this decision is being challenged by the vascular community and may soon be repealed and perhaps not replaced.

Procedure Location: Inpatient vs Outpatient

The fundamental question one may ask is: Does care drive reimbursement or vice versa? I would argue that the complexity of the procedures in the outpatient ASCs and OBLs are often commensurate with hospital-based procedures, particularly the hospital outpatient departments. However, the current state of reimbursement, including the lack of a DCB pass-through in the ASC or OBL, does not seem equitable. The use of complex devices in sophisticated outpatient ASCs or OBLs continues to outpace the reimbursement afforded to these centers with higher patient satisfaction and lower costs when compared to even the hospital outpatient department and certainly the hospital inpatient department.

CONCLUSION

The use of atherectomy catheters, chronic total occlusion devices, DESs, and DCBs continues to follow patient- and lesion-specific indications. Reimbursement for hospital-employed interventionalists and ASC/OBL proceduralists seem to have converged on the same economic pressures. The cost of devices weighed against their long-term data-driven outcomes and procedural success is part of the decision tree for all interventionalists in the current era, regardless of where the procedure is performed. ■

Tony S. Das, MD, FACP, FACC
Interventional Cardiologist
Cardiology and Interventional Vascular Associates
Dallas, Texas
tdas@civadallas.com
Disclosures: Consultant to Abbott Vascular, Boston Scientific Corporation, Cordis, a Cardinal Health company, and National Cardiovascular Partners.