Session 5

# How will financial considerations affect future decisions?

## Open Surgery Versus Endovascular Revascularization

Will cost play a role in the decision?

BY MICHAEL STONER, MD

Vascular care in the United States is largely supply-driven care that is not supported by robust science. This is because most randomized controlled trials fail to have external validity and are therefore not useful for science-based decision making. Thus, in the absence of quality science, advances in vascular care are driven by technological improvements and the lateral diffusion of technology. Patients, however, expect their surgeon to guide them to the safest and most effective procedure possible. Most patients do not care about the cost of the procedure because they are typically not the ones paying for it, so therefore their decision making is not driven by cost.

At first glance, an endovascular-first strategy appears to be a cost-saving approach to the treatment of peripheral artery disease (PAD). Moreover, many surgeons who use an endovascular-first strategy do so based upon the belief that a failed endovascular approach can be easily followed with surgical bypass. In actuality, a subset of patients who experience early failure with endovascular therapy develop more complex lesions (Figure 1). The patients then have a higher TASC grade and more distal targets. There are conflicting data about the outcomes for such patients, a group that is composed of more complex cases after failed endovascular therapy. Studies have attempted to determine if the more complicated cases reflect disease progression or are directly caused by endovascular therapy. A comparison of the subset of patients who received primary surgical revascularization versus those who received secondary surgical revascularization revealed that with regard to primary assisted patency, patients who underwent primary surgical revascularization had 75% primary assisted patency, whereas patients who underwent secondary surgery had 53% primary assisted patency. Limb salvage and tissue loss were also inferior in patients with critical limb ischemia who had a failed endovascular procedure and then went on to receive a surgical bypass.

The economic burden of reintervention may also provide a context for the creation of an endovascular treatment paradigm that reimburses based on patient value. An ideal organization for delivering such cost-efficient treatment would emphasize tighter collaboration between hospitals and providers and would create constant performance reporting and payment realignment for value. This has been proposed for the Centers for Medicare & Medicaid Services percutaneous coronary intervention pilot sites.

### SUMMARY

Patients' lack of financial stake in the therapy is a weakness in current health care reform. Patients who have a financial stake in their therapy will place an increased value on durability, patency, and quality of life. Until the system has changed to incorporate patients as payors, surgeons must make pragmatic choices to use medication and technology, and to select patients for the appropriate therapy. ■

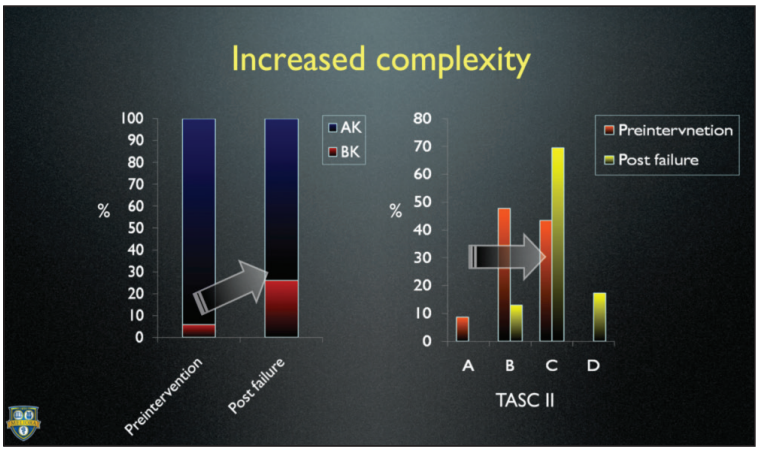


**Figure 1. Increased incidence of below-knee target and more severe TASC grade lesions in patients undergoing bypass after failed endovascular therapy.**

*Michael Stoner, MD, is from University of Rochester in Rochester, New York. He has disclosed that he has received compensation from Gore for participating in the Summit and has received honoraria from Gore for writing this article. Dr. Stoner may be reached at michael_stoner@urmc.rochester.edu.*

## Prevalence of Amputation

### Can we make an impact?

**BY ALEJANDRO FABIANI, MD**

Peripheral arterial disease (PAD) affects more than 200 million people (2.85% of the population) around the world.[1] It is the pandemic of the 21st century, affecting more people than cholera in the 19th century and AIDS in the 20th century. Unfortunately in Mexico, PAD is primarily treated by amputation.

From 1970 to 1975, the average male life expectancy in Mexico was 62.57 years. From 1990 to 1995, the average male life expectancy had increased to 71.81 years; and from 2010 to 2015, it increased further to 76.26 years.[2] Despite the increases in life expectancy, Mexico has one of the highest per capita consumptions of cigarettes, as well as a high rate of hypertension and diabetes (Figure 1). Mexico leads the world in childhood obesity and is second in the world for adult obesity. Consequently, there are almost three million people in Mexico who have had amputations (estimation based on newspapers publications and expert opinion). The cost of a prosthetic is approximately $10,000, which only 10% of patients in Mexico can afford. Of these patients, only 30% will be able to use a prosthetic. Thus, if 100 patients are sent for primary amputation, only three of them (at most) will walk again. Statistics like these provide a great deal of room for improvement; therefore, most people in the vascular industry consider Mexico to be a "sleeping giant" for the potential of endovascular surgery to change the lives of its citizens.

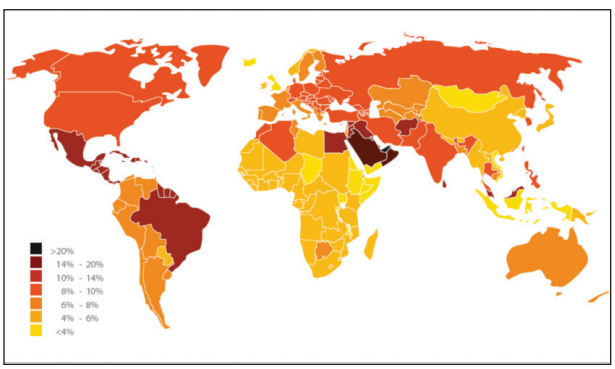


**Figure 1. Mexico leads the United States in expected prevalence of diabetes for 2025. Reprinted with permission from International Diabetes Federation. IDF Diabetes Atlas, 6th edn. Brussels, Belgium: International Diabetes Federation, 2013. http://www.idf.org/diabetesatlas.**

In the early 1990s, the requirements for saving an ischemic limb were threefold: a viable limb, a runoff vessel, and a conduit. Angiography was used to identify the presence of a runoff vessel and was thus an important first step in patient treatment. Today, the only real requirement for saving an ischemic limb is the presence of a viable limb. This change needs to be communicated to primary care physicians, vascular specialists, and patients. Only then will patients have improved access to therapeutic options other than amputation.

The School of Medicine at the Monterrey Institute of Technology (Instituto Tecnológico de Monterrey) is making an effort to change the amputation-first attitude that persists in Mexico. The main message for all stakeholders is that a diabetic foot does not necessarily have to be treated with amputation. Education grants for physicians have included courses for different specialties, education about abdominal aortic aneurysms and thoracic aortic aneurysms, carotid artery disease, PAD, and pelvic venous congestion. This education should help physicians diagnose PAD and encourage them to consider therapeutic options beyond amputation.

### SUMMARY

While surgical bypass and new devices can save limbs and improve quality of life for patients, the most important factor for decreasing the amputation rate in Mexico is education. As physicians and patients become more educated about alternatives to amputation, an increasing number of patients will receive successful bypasses. Each of these patients will then inspire other patients and physicians to consider treatment alternatives to amputation. ■

*Alejandro Fabiani, MD, is from the School of Medicine, Tecnológico de Monterrey, Mexico. He has disclosed that he has received compensation from Gore for participating in the Summit and has received honoraria from Gore for writing this article. Dr. Fabiani may be reached at dr.alejandrofabiani@tecsalud.mx.*

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2. Global health observatory. http://www.who.int/gho/mortality_burden_disease/life_tables/situation_trends/en. Accessed October 20, 2014.

# TAKE HOME POINTS

## MICHAEL STONER, MD

US health care expenditure has continued to grow over the past three decades, despite the promise that improved resource allocation, biomedical research, and technology would improve both efficiency and outcomes. Current estimates from the US Congressional Budget Office estimate that 4% of the 2007 Gross Domestic Product was allocated to Medicare and Medicaid. This amount is estimated to increase to 20% of the federal budget by 2050 if current projections remain true. Thus, health care expenditure is quickly becoming the most significant factor in the already strained US federal budget. Payment for the treatment of PAD represents a significant amount of health care resource allocation. In 2007, the United States spent $151 billion in direct and indirect costs for the treatment of 12 million beneficiaries with PAD.

It is clear that these current trends are untenable within the constraints of the economic system. Vascular care is likely to become increasingly important as the overall population ages. It will become paramount to evaluate the appropriate treatment of each patient with vascular disease within the overall context of the national health care system.

Comparative effectiveness research must provide the scientific basis for this process. Simply put, comparative effectiveness is the study of two or more treatment options to address a given medical condition. Within the domain of vascular disease, there is an ever-increasing array of options and modalities to address our patients' disease processes. Many of these new modalities compete with either nonoperative management or traditional operative techniques, and have not been fully evaluated with respect to efficacy and health care economics. The implementation of comparative effectiveness research may be ideally suited for mechanisms such as Accountable Care Organizations. Within this construct, patients and providers use evidence-based medicine to decide on clinically and financially treatment courses, and both benefit from maximizing these factors. Within the limb salvage disease space, this is accomplished by choosing the safest, most efficacious, and durable procedure. These factors have begun to translate into the federal regulatory process, as the Food and Drug Administration is now considering patient-centric outcomes for new device approvals.

## ALEJANDRO FABIANI, MD

PAD is a critical 21st century pandemic affecting 3% of the world population. In low or middle-income countries, the incidence of PAD has increased 30% between 2000 and 2010. The amputation rate seems to be 10 times higher in poor diabetic patients than wealthy diabetic patients.

In Mexico, primary amputation is the most frequent approach to patients with diabetic foot. As a consequence, there are more than 3 million amputees. Just 10% of these amputees can afford the cost of a prosthesis and, of those patients, only 30% are able to walk. Therefore, just 3% of the patients with major amputation will walk again.

In the early 1990s, my team in Argentina attempted revascularization in all patients with critical limb ischemia. We only needed a viable limb, an autologous conduit, and a runoff vessel. The 3-year limb salvage rate was up to 70%, whether or not the patient was diabetic.

Nowadays, the only requirement is to have a viable limb. In most cases, a runoff vessel can be endovascularly built and the conduit can be done in the same way, or a heparin-bonded graft can be used with long-term results comparable to those obtained with autologous veins.

A limitation in Mexico seems to be patient referral. Most physicians believe that there is no better option for diabetic patients with PAD than major amputation. The goal is to improve education on this field through efforts directed at general physicians, patients, and the community.