The True Prevalence of PAD and the Economics of Major Amputation

Mary L. Yost, MBA, presents an evidence-based approach to amputation, sharing her estimate of the current prevalence of peripheral artery disease, the impact of amputation on health care costs, and potential reimbursement changes.

What are the best estimates of the current prevalence of peripheral artery disease (PAD) in the United States (US)? What are the sources for these data, and what is known about their current accuracy and applicability?

The best estimate for the prevalence of PAD in the US in 2020 is 19 to 21 million. PAD continues to be underestimated.[1] The most commonly quoted number of 8 to 12 million was published in the PARTNERS study.[2] However, these numbers were not based on the PARTNERS results; the source of the estimate was the prevalence percentage found in a 1985 study in San Diego, California, by Criqui et al.[3]

Because of its design, the San Diego study understates PAD prevalence. It was conducted in 613 white, upper-middle–class patients aged 38 to 82 years residing in Southern California. Because PAD is significantly more prevalent in African Americans (11% of the US population aged ≥ 45 years), the study understates PAD.[4-6] Furthermore, PAD was defined in the study as an ankle-brachial index (ABI) < 0.80 rather than the standard ABI definition of < 0.90.[3,7-9]

The 8 to 12 million number was a good estimate for the US population in and around 1995.[1] Since then, the population has aged and become considerably more diabetic—two key risk factors for PAD.[1] If we apply the Criqui study's prevalence by age group to the 2020 US population, the result is 12 to 19 million.[1,3] Similarly, calculating PAD based on the prevalence in a study by Nehler et al yields 19 million.[10] Both are similar to the 21 million calculated by the Diabetes Method, which is a population-based method that calculates PAD according to age and glucose status.[1,10]

What impact does amputation have on health care costs compared with other treatment methods and/or early screening, both for the patient and the physician? Who ultimately bears the cost?

Major amputation (MA) is the most expensive treatment for critical limb ischemia (CLI), and treatment with primary MA rather than revascularization is an important factor that increases CLI costs.[11,12]

Numerous studies of hospital costs in different countries covering varying time periods all show that MA costs more than revascularization with either endovascular or surgical bypass.[13-16] Although initial procedure costs are similar for MA, surgical bypass, and endovascular revascularization, the total costs of amputation are considerably higher due to the increased frequency of procedural morbidity, mortality, and revision amputations.[12]

In 2020, the direct medical costs of MA were $13.4 billion.[17] The majority of these costs are inpatient. Because the Centers for Medicare & Medicaid Services pay almost 80% of the amputation bill, MA is financed by our tax dollars.[18] In addition to initial treatment costs, numerous medical and nonmedical expenses are incurred over an amputee's lifetime. Many of these are not reimbursed and are paid for by the patient or family. The annual cost of follow-up care for

MA exceeds $160,400 per patient; lifetime costs add approximately $11.1 billion, for a total cost of $24.5 billion.[17]

MA as a primary treatment for CLI misallocates resources and wastes taxpayer dollars.[17] Amputation also creates tremendous financial, physical, and psychologic burdens for the patient and the patient's family.[12,17]

What possible changes to reimbursement might help reduce the prevalence of amputations performed without exploring other options first, and how would this affect the global costs of PAD care?

Two reimbursement changes could significantly reduce the number of amputations performed as a treatment for CLI: (1) reimbursement for screening in high-risk populations, and (2) denial of reimbursement for amputation if appropriate diagnostic arterial testing is not performed prior to the procedure. Early diagnosis and appropriate treatment could reduce costs and the number of amputations.[17]

Screening groups with a high prevalence of PAD, such as those with diabetes who are aged > 50 years, diabetic foot ulcers, prior cardiac or cerebrovascular events, and chronic kidney disease in those aged > 65 years would yield 30% to 50% positive results.[17,19] A significant proportion of these patients would have undiagnosed disease severe enough to require revascularization.[17,19] Treating PAD when the disease is less severe would reduce costs. This reflects the fact that it costs less to treat intermittent claudication than CLI.[20] Within CLI, costs increase with Rutherford classification.[11,21,22]

Although all patients with PAD should be treated with cardiovascular risk factor modification therapies, risk factors in both intermittent claudication and CLI patients remain undertreated.[23,24] One study found that suboptimal medical management in CLI increases the risk of amputation and/or death by eightfold.[24]

An angiogram reduces the odds of undergoing amputation by 90%.[25] Despite this, 54% to 67% of CLI patients have no angiogram performed prior to MA.[26,27] Consequently, requiring an angiogram prior to MA and denying reimbursement if one is not performed should significantly reduce amputations.

The Amputation Reduction and Compassion Act (HR 8615) has been introduced to change reimbursements in the manner we have described. In addition, HR 8615 would establish a PAD education program to inform health care professionals and the public about PAD and methods to reduce amputations.[28] ■

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