Is it fiscally responsible to perform primary amputation as treatment?

BY MARY L. YOST, MBA

During the past 15 years, the number of major dysvascular amputations (defined as amputations above the ankle) performed annually has decreased. However, major amputation (MA) continues to be a primary therapy and is frequently the only treatment offered for critical limb ischemia (CLI).1,2

PATHWAY TO AMPUTATION

The treatment of CLI in the United States has been characterized as a “Pathway to Amputation,” a phrase coined by Allie et al, who found that amputation was the first procedure in 67% of Medicare patients who underwent MA.1 A 2012 study of 20,464 Medicare patients with CLI who underwent MA found strikingly similar results. Seventy-one percent had no revascularization, and 54% had no angiogram obtained before an MA.2

Approximately 65,000 to 70,000 MAs are currently performed for peripheral artery disease (PAD), and almost all of these patients suffer from the end stage of PAD, known as CLI.3,4 Between 25% and 33% of Medicare CLI patients undergo primary amputation.5,6

AMPUTATION LOTTERY AND PRACTICE HETEROGENEITY

Numerous studies have demonstrated that the probability of undergoing amputation depends on who you are and where you live: the “Amputation Lottery.”2,5-19 Minority race, lower socioeconomic status, age, sex, insurance payer, and low hospital volume have all been shown to increase the probability of MA.5,7-15 Medicare and Medicaid patients are more likely to undergo MA than privately insured patients, with Medicaid patients being the most likely.5,8

Geographic location is associated with different probabilities of amputation and variations in vascular procedures (such as lower extremity surgical bypass, endovascular revascularization, or diagnostic endovascular evaluation) offered to Medicare patients before they are referred for an amputation.1,16-18,20 Similar amputation rates are found in neighboring hospital referral regions (HRRs). Hospitals with high amputation rates are surrounded by neighboring clusters of HRRs that also have high rates of amputation.16 Geographic differences in amputation rates persist even after adjustment for regional differences in age, sex, race, comorbidities, and year of amputation.17 It is hypothesized that these differences reflect variations in the practice of medicine, or “practice heterogeneity,”2,16,20,21 which is partially due to the absence of published expert consensus or guideline documents to provide the definition of a salvageable limb and the diagnostic and therapeutic strategies necessary for adequate management.22,23

SELECTIVE ANGIOGRAPHY: THE MISSING LINK

Angiography is protective against MA; however, it is underutilized in CLI. A recent study of more than 1 million Medicare inpatients with CLI found that an angiogram reduced the odds of amputation by 90%.5 However, angiography was performed in only 27% of these hospitalized CLI patients.5 Other studies have also found low utilization of angiography before amputation.1,2,24 It has
become widely known that performance of selective angiography (defined as an angiogram obtained with a catheter placed as far as the P3 segment of the popliteal artery) reveals the presence of disease that is far less severe than that identified by abdominal angiography with runoff, CT, or MRI. This can also be complemented by retrograde angiography (performed through tibial, pedal, or digital access) or by specialized high-frequency duplex ultrasound imaging. These modalities allow the identification of therapeutic targets in the distal tibial, pedal, and even digital arteries, which have been accessed and treated by a few operators worldwide with an amazing rate of technical and clinical success.25

AMPUTATION—HIGH PERIOPERATIVE MORBIDITY AND MORTALITY

Compared with other surgical procedures, MA has high perioperative morbidity and mortality, as well as high revision rates. Above-knee amputation (AKA) and below-knee amputation (BKA) are among the top five surgical procedures with the highest perioperative mortality.26 Five percent to 10% of BKA patients and 15% to 20% of AKA patients die in the hospital before discharge.27–30 Rates of perioperative mortality for infrainguinal bypass and endovascular revascularization are 2% to 8% and 1% to 3%, respectively.31–36 The 20% to 37% major complication rate associated with amputation is considerably higher than the 16% to 17% average for vascular surgery and the average of 5% to 9% for endovascular surgery.36,33,34,37–39 Wound infection, the most frequent complication, occurs at a rate of 10% to 30% and, if not resolved, can lead to reaparation at a higher level.27,28,40,41 In-hospital amputation revision rates are 13% to 20% for BKA and 8% to 12% for AKA procedures.42,43 Other serious complications include high rates of deep vein thrombosis (13%–26%), cardiac complications (9%–10%), sepsis (9%), bleeding (8%), and renal failure (2%–3%).28,29,44–47

AMPUTATION IS COSTLY

What are the economic costs of amputation? MA is costly, ranking as the sixth most expensive surgical procedure performed in the United States.48 The macroeconomic cost of amputation is estimated at $10.6 billion.49 Medicare and Medicaid pay the majority, or almost 80% of the national bill (Figure 1).50 Inpatient hospital costs are the largest single component, representing about 45% of total annual amputation costs (Figure 2). Outpatient and physician follow-up costs account for about 20% and nursing home costs, for 12% to 16%. The rest of costs are related to rehabilitation, home health care, and durable medical equipment.42

IS AMPUTATION COST-EFFECTIVE?

Does primary amputation represent the best allocation of scarce health care resources? How do the costs and the outcomes of amputation compare with the alternative therapies for CLI: bypass surgery and endovascular revascularization?

In order to answer these questions, it is necessary to focus on costs rather than charges and to employ only United States cost studies, as costs in other countries can vary considerably due to differences in the organization of the health care system, prices, and reimbursement systems.51 Charges represent the dollar amount billed to the patient or the payer and show a poor correlation with the actual cost of care as measured by the resources consumed.52 The 2012 study by Barshes et al, which compares primary amputation with revascularization, is the only cost-effectiveness analysis of CLI therapies published in the last 15 years. This analysis was conducted from a broad socioeconomic point of view and included all inpatient and outpatient costs, except for the impact of lost wages. Amputation was found to be less cost-effective than either surgical bypass or endovascular revascularization.53 A 1999 analysis comparing amputation to surgical bypass also concluded that amputation was less cost-effective than bypass.54 Data from the US PAD cohort of the Reduction of Atherothrombosis for Continued Health (REACH) registry provide insight into cardiovascular costs, a significant component of the total bill associated with amputation and revascularization. At 2 years, mean annual hospitalization and medication costs in 2004 dollars for those who had undergone previous amputation ($11,963) exceeded costs of those who had undergone previous revascularization ($10,430).55 Because Medicare and Medicaid (which are funded by US tax payers) pay for the majority of amputations, it is informative to examine the impact of the "Pathway to Amputation" on hospital costs. Unfortunately, no recent United States studies have done this. In the late 1980s, a number of single-center, nonrandomized studies compared surgical bypass with amputation.56–58 These studies examined charges (reimbursements), rather than costs. In general, charges were similar for uncomplicated amputation and bypass. Complications and repeat procedures increased charges significantly for both procedures. However, when charges generated by higher rates of complications and revisions were taken into account, amputation was more expensive than bypass.56–59 Examination of the Healthcare Cost and Utilization Project (HCUP) data shows that average procedure costs for amputation and endovascular revascularization are similar.60,61 However, costs associated with in-hospital
mortality, morbidity, and repeat procedures increase total costs and need to be included for an accurate assessment of the financial burden.62,63

Lacking CLI-specific data, costs of in-hospital morbidity and mortality reported in the vascular and general surgical literature have been inflated to 2010 dollars. The average cost of an in-hospital death exceeds $18,000.64 Each type of complication generates additional costs. For example, the average hospital cost of a wound infection is $19,000 to $42,000, a deep vein thrombosis costs over $14,000, and so on for each complication.65 The cost of a revision procedure after a failed or complicated surgical procedure can conservatively be assumed to be at least as much as the original. When costs of mortality, morbidity, and revisions are calculated and added to the initial procedure cost, the total cost of primary amputation exceeds that of an endovascular revascularization by almost $10,000.49

COSTS REFLECT HIGH UTILIZATION OF HOSPITAL RESOURCES

Amputees are heavy users of hospital resources in the first month after the amputation, experiencing frequent readmissions.42,66 They are readmitted for amputation as well as for nonamputation reasons.42,66 Thirty-day all-cause readmissions for Medicare patients who undergo amputation exceed those of the average Medicare patient (26% vs 20%).67,68 In one study, about half of the readmissions were amputation-related, whereas 21% were due to cardiovascular or cerebrovascular disease.66

In the subsequent year or years, amputees continue to require frequent hospitalizations, with hospital utilization surpassing that of other chronic disease patients.42,66 During a mean follow-up of 3.25 years, Henry and colleagues found high rates of readmissions and lengthy stays. Amputees were readmitted 19.5 times per person-year, with a length of stay of 71.2 days per person-year.66 Length of stay exceeded that for CLI patients after revascularization with surgical bypass and far exceeded that of patients undergoing treatment for metastatic lung cancer and recurrent or refractory ovarian cancer.66

It can be concluded that in CLI patients, amputation is not the final treatment. Instead, the initial amputation is followed by revisions, more proximal amputations, contralateral amputations, and cardiovascular procedures.66 All of these add to the total economic burden.

PATIENT COSTS AND OUTCOMES

Even at almost $11 billion, the costs of amputation are understated because this estimate does not include direct patient costs and societal costs of lost productivity. Societal costs can be assessed by including lost production days (of patients and their family member caregivers), the increase in the number of disabled citizens, and the overall negative impact on society and the economy.

The inability to work, on the part of the patient and/or caregiver, results in lost wages, reduces productivity, and negatively affects economic growth. Long-term care research has shown that caregiving can be emotionally and financially costly.69 In the United States, the average lifetime income-related losses (lost wages, Social Security benefits, and pensions) associated with caregiving exceed $300,000 per caregiver.70

Unreimbursed deductibles and copayments for rehabilitation, nursing home care, and home health care, as well
as modifications required for living with a disability, also add to patient costs. These include items such as handrails, wheelchair ramps, and wheelchair transportation. In 2012, the average annual cost for nursing home care was $90,520 for a private room and $81,030 for a semiprivate room. Because Medicare limits nursing home payments to 100 days, lengthy stays represent a considerable patient cost. The purchase price of a wheelchair-accessible van is $30,000 to $40,000, while a minivan wheelchair conversion costs $13,000 to $17,000.

Patient outcomes associated with amputation are dismal and compare unfavorably to endovascular revascularization. After amputation, only 18% to 24% of patients are routinely discharged home, while the majority of patients (70%) go to another institution (a nursing home, rehabilitation facility, or other long-term care facility). Sixty percent to 80% are unable to walk. One-third or more experience depression, and in some, severe depression with suicidal ideation. The 2-year mortality rate is 30% to 50%, and contralateral amputation occurs in 36% to 50%.

In contrast, after endovascular revascularization, almost two-thirds of patients are routinely discharged home, and less than 20% are discharged to a nursing home. At 2 years, 80% are walking, and almost 90% are living independently. In recent studies, 2-year mortality is 16% to 24%. However, reintervention is required in 30% to 40%, resulting in reduced prosthetic use, as well as shorter walking distance if using a prosthetic.

Additional adverse amputation outcomes include a lengthy healing process, reduced quality of life, chronic pain, and skin problems in the stump. At 100 days, 45% of BKAs and 24% of AKAs have not healed. Amputees perceive themselves to be severely impaired in ambulation, body care, movement, and mobility. Chronic pain is experienced by almost all amputees (not just phantom limb pain—which occurs at a rate of 80%—but also residual limb pain in up to 74% of patients, and back pain in 50%–60%). Skin problems in the stump occur in 15% to 40%, resulting in reduced prosthetic use, as well as shorter walking distance if using a prosthetic.

Perler writes, "The rationale for primary amputation assumes that patients will ambulate successfully with a prosthesis..." In reality, many patients are not even successfully fitted for a prosthesis, and thus are not able to walk. A population-based study of all major lower limb amputees aged 65 and older in Olmstead County, Minnesota, found that barely more than one-third of patients were successfully fitted for a prosthesis. Forty-seven percent of BKA patients and only 15% of AKA patients were fitted. The major reason for not being fitted was death. Additional reasons included reamputation, presence of cerebrovascular disease, cognitive deficits, and skin integrity.

Referral studies have reported fitting rates of 60% to 90%. However, because of potential bias in referral studies, the assumption that the majority of elderly, diabetic vascular amputees ambulate may be incorrect. Patients referred to specialized fitting clinics tend to be younger, expected to do well, with fewer comorbidities, and more likely to have a BKA.

CONCLUSION

Although research is limited, available evidence indicates that treating CLI patients with primary amputation is not cost-effective and economically represents a misallocation of United States health care resources.

In order to obtain more accurate CLI cost estimates, additional data are needed on direct patient costs and the total hospital costs of different therapies (procedure costs plus mortality, morbidity, and revisions). Cost and additional quality-of-life data are also needed for patient groups believed to be best served with specific therapies. Several studies have concluded that primary amputation might be the best therapy in certain patient groups (those who have dementia or are institutionalized or nonambulatory, etc). However, the economic impact is unknown, because costs were not included. For example: Is it more expensive to care for a nursing home patient with an AKA than one with both limbs intact? What are the costs to the patient and family?

Finally, the cost-effectiveness of preventive care in CLI remains largely unexplored. This includes an economic analysis of costs and benefits of broader utilization of risk factor modification therapies to prevent cardiovascular morbidity and mortality, as well as the potential impact of earlier CLI diagnosis and treatment. Another important area of economic investigation relates to the cost and effect of early revascularization on survival.

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