National trends in lower extremity bypass surgery, endovascular interventions, and major amputations

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Introduction: **Advances in endovascular interventions have expanded the options available for the invasive treatment of lower extremity peripheral arterial disease (PAD). Whether endovascular interventions substitute for conventional bypass surgery or are simply additive has not been investigated, and their effect on amputation rates is unknown.**

Methods: **We sought to analyze trends in lower extremity endovascular interventions (angioplasty and atherectomy), lower extremity bypass surgery, and major amputation (above and below-knee) in Medicare beneficiaries between 1996 and 2006. We used 100% samples of Medicare Part B claims to calculate annual procedure rates of lower extremity bypass surgery, endovascular interventions (angioplasty and atherectomy), and major amputation between 1996 and 2006. Using physician specialty identifiers, we also examined trends in the specialty performing the primary procedure.**

Results: **Between 1996 and 2006, the rate of major lower extremity amputation declined significantly (263 to 188 per 100,000; risk ratio [RR] 0.71, 95% confidence interval [CI] 0.6-0.8). Endovascular interventions increased more than threefold (from 138 to 455 per 100,000; RR = 3.30; 95% CI: 2.9-3.7) while bypass surgery decreased by 42% (219 to 126 per 100,000; RR = 0.58; 95% CI: 0.5-0.7). The increase in endovascular interventions consisted both of a growth in peripheral angioplasty (from 135 to 337 procedures per 100,000; RR = 2.49; 95% CI: 2.2-2.8) and the advent of percutaneous atherectomy (from 3 to 118 per 100,000; RR = 43.12; 95% CI: 34.8-52.0). While radiologists performed the majority of endovascular interventions in 1996, more than 80% were performed by cardiologists and vascular surgeons by 2006. Overall, the total number of all lower extremity vascular procedures almost doubled over the decade (from 357 to 581 per 100,000; RR = 1.63; 95% CI: 1.5-1.8).**

Conclusion: **Endovascular interventions are now performed much more commonly than bypass surgery in the treatment of lower extremity PAD. These changes far exceed simple substitution, as more than three additional endovascular interventions were performed for every one procedure declined in lower extremity bypass surgery. During this same time period, major lower extremity amputation rates have fallen by more than 25%. However, further study is needed before any causal link can be established between lower extremity vascular procedures and improved rates of limb salvage in patients with PAD. (J Vasc Surg 2009;50:54-60.)**

Lower extremity peripheral arterial disease (PAD) affects over 8 million Americans, with significant associated morbidity and mortality.[1-5] Until recently, the treatment of these patients primarily consisted of peripheral arterial bypass surgery, such as femoral-popliteal bypass.[3] However, advances in catheter-based technology have made endovascular interventions, such as balloon angioplasty or percutaneous atherectomy (removal of intra-arterial plaque using catheter-based devices) a commonly utilized alternative.[3,6] In fact, many physicians now advocate an "endovascular first" strategy.[7-9]

This change has occurred in the setting of limited and often conflicting evidence. For example, in the early 1990s, population-based data from Maryland led many vascular surgeons to argue that the use of angioplasty was not effective, and instead resulted in even higher utilization of peripheral bypass surgery.[10] In contrast, the only randomized trial prospectively comparing the effectiveness of endovascular interventions with open surgery reported similar short-term outcomes between the two treatments.[7] Nonetheless, while many believe a shift towards endovascular interventions has occurred, two uncertainties remain. First, it is not yet known if endovascular interventions are performed as a substitute for bypass surgery, or in addition to bypass surgery. Second, it is unknown if these temporal changes in the use of lower extremity revascularization (both open and endovascular) have also been associated with changes in the incidence of major lower extremity amputation.

To further examine changes in utilization of endovascular interventions, as well as its relationship to rates of bypass surgery and major amputation, we examined recent trends in lower extremity vascular procedures in the United States using the national Medicare claims database.

METHODS

Database and subjects. We studied all Medicare claims from the Centers for Medicare and Medicaid Services between 1996 and 2006, using the Medicare Physician/Supplier Pro-

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Competition of interest: none.

Presented at the New England Society for Vascular Surgery, Newport, RI, October 3-5, 2008.

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0741-5214/$36.00

doi:10.1016/j.jvs.2009.01.035

cedure Summary Master File.[11] This is a 100% sample of all Part B claims from all insurance carriers. Codes including a −50 modifier represented a procedure done on both sides of the body; therefore, any code with this modifier was multiplied by two in order to account for each limb. Given that the absolute size of the Medicare population remained stable over the study period, (31.7 million beneficiaries in 1996, 31.9 million beneficiaries in 2006, absolute change = 0.4%), as well as our limited ability to adjust for patient co-morbidity burden, we presented only unadjusted data in our current analysis reported per 100,000 beneficiaries. We obtained permission from the Institutional Review Board at Dartmouth Medical School's Center for the Protection of Human Subjects to perform our analyses.

The unit of analysis in this study was the procedure. A single patient may undergo multiple procedures (endovascular interventions, open bypass surgery, or amputation) over the years in our analysis, on their right or left lower extremity. However, only one procedure per patient per day was entered into our analysis dataset. Data from our regional quality improvement initiative, the Vascular Study Group of Northern New England (VSGNNE), suggests that approximately 10% of patients will undergo more than one revascularization procedure during a time period similar to this interval.[12]

Analysis of lower extremity revascularization rates. Rates of lower extremity revascularization procedures were examined between 1996 and 2006, according to Current Procedural Terminology (CPT) codes[13] listed in Table I. To allow for comparison over time, annual rates were normalized to reflect incidence rates per 100,000 Medicare beneficiaries. To examine changes over time, we calculated risk ratios (RRs) and 95% confidence intervals (CIs), using 1996 as the referent year. All analyses were performed using Microsoft Excel (Redmond, Wash) and STATA (College Station, Tex).

These procedures were further categorized as either lower extremity bypass surgery or endovascular interventions. Bypass procedures included in our analysis were aortobifemoral bypass, femoral-femoral crossover grafts, as well as lower extremity bypass operations such as femoral-popliteal bypass or femoral-tibial bypass, with both native or prosthetic conduit. Because fewer than 1000 axillary-femoral procedures were done in any year, these were not included in the analysis. Patients who underwent combined or hybrid procedures, such as a femoral-popliteal bypass with an iliac angioplasty above the bypass, were coded as open procedures. We did not include endovascular interventions consisting only of stent placement without angioplasty, as procedural codes for stent placement alone are not specific for the site where the stent was placed (ie, upper extremity, lower extremity, or visceral).

Analysis of major amputations. Rates of major amputations, defined as above-knee or below-knee amputation, (coded according to current procedural terminology [CPT] codes listed in Table I) were examined over the study period. Given that lesser amputations at the metatarsal or single toe level are not generally considered failures of limb salvage, amputations at lesser levels were not included in this analysis. To allow for comparison over time, annual rates were again normalized to reflect incidence rates per 100,000 Medicare beneficiaries, and RRs were calculated similarly as above. We assumed that the proportion of major lower extremity amputation due to peripheral vascular disease remained constant over the study period, as prior analyses have demonstrated that fewer than 15% of major lower extremity amputations are traumatic in nature, and little change has occurred in the incidence of traumatic amputation in recent years.[14,15]

Specialty designation analysis. Specialty designation of the physicians performing the procedures during the study period was taken from the Medicare Part B file. It is important to note that this designation represents a self-reported label, and does not necessarily imply subspecialty board certification or practice patterns. For endovascular interventions, we also considered the four most commonly occurring specialties: vascular surgery, general surgery, cardiology, and radiology (both diagnostic and interventional). We reasoned that most general surgeons who per-

Table I. CPT codes used to define procedures studied in our analysis

Procedure	*CPT code*	*Number (total)*
Open revascularization		
Iliac bypass		
Aortobifemoral bypass	35646	59,797
Femoral-femoral bypass	35661	55,328
Femoral-popliteal bypass:		
Vein	35556	88,278
In situ	35583	40,322
Other than vein	35656	20,948
Femoral-tibial bypass:		
Vein	35566	85,765
In situ	35585	64,799
Other than vein	35666	34,662
Major amputation		
Above knee		
Thigh, through femur, any level	27590	282,067
Thigh, through femur, with immediate prosthetic	27591	1,820
Thigh, through femur, any level guillotine	27592	4,748
Below knee		
Leg, through tibia and fibula	27880	235,222
Leg, through tibia and fibula with immediate prosthetic	27881	12,436
Leg, through tibia and fibula, guillotine	27882	12,820
Endovascular revascularization		
Atherectomy:		
Iliac	35492	2,472
Femoral-popliteal	35493	55,693
Tibioperoneal trunk and branches	35495	25,946
Balloon angioplasty:		
Iliac	35473	252,464
Femoral-popliteal	35474	359,162
Tibioperoneal trunk and branches	35470	89,528

CPT, Current Procedural Terminology.

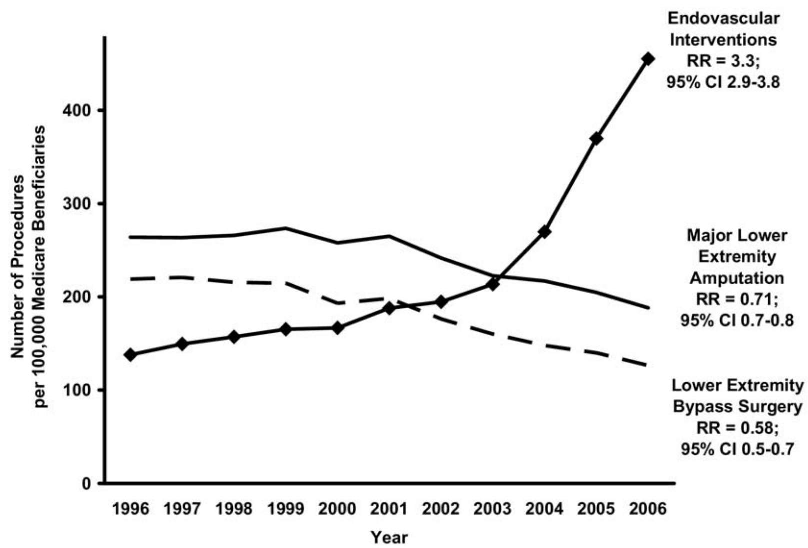

Fig 1. Trends in endovascular interventions, major amputation, and lower extremity bypass surgery, 1996-2006. *RR,* Risk ratio; *CI,* confidence interval.

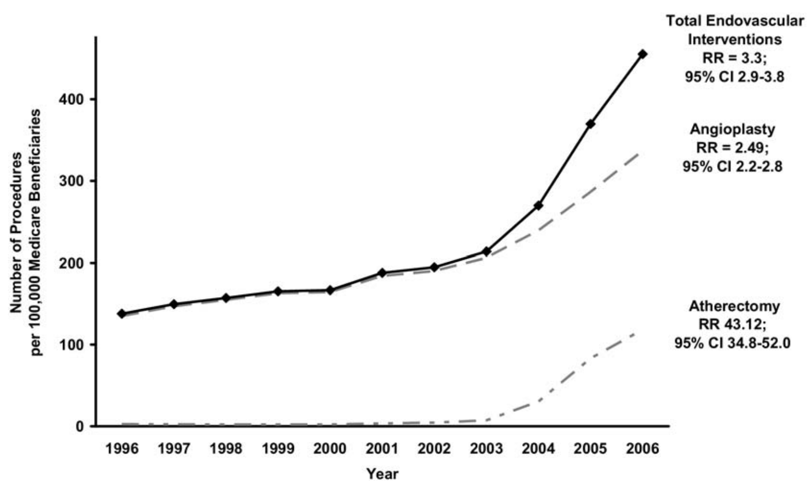

Fig 2. Trends in endovascular interventions (peripheral angioplasty and percutaneous atherectomy), 1996-2006. *RR,* Risk ratio; *CI,* confidence interval.

formed peripheral angioplasty likely practiced vascular surgery as well, and therefore we analyzed both general and vascular surgeons collectively.

RESULTS

Lower extremity revascularization. The use of endovascular interventions grew substantially between 1996 and 2006 (138 to 455 procedures per 100,000, RR = 3.30; 95% CI: 2.9-3.7), while bypass surgery decreased by 42% (219 to 126 per 100,000; RR = 0.58; 95% CI: 0.5-0.7) (Fig 1). The concomitant rise of 317 per 100,000 endovascular interventions and decline of 93 per 100,000 bypass surgeries suggest that more than three new endovascular interventions replaced each bypass surgery. Overall, the total number of all lower extremity vascular procedures almost doubled over the decade (from 357 to 581 per 100,000; RR = 1.63; 95% CI: 1.5-1.8).

In addition to an overall rise in the rate of endovascular interventions, the characteristics of these procedures changed as well. Peripheral angioplasty was the most commonly performed endovascular intervention, increasing from 135 to 337 interventions per 100,000 (RR = 2.49; 95% CI: 2.2-2.8). However, in addition to angioplasty, percutaneous atherectomy increased over the 10-year study period by 43-fold (3 to 118 interventions per 100,000; RR = 43.12; 95% CI: 34.8-52.0). As shown in Fig 2, percutaneous atherectomy was performed in addition to, not as a substitute for, peripheral angioplasty, as rates of both procedures rose steadily between

Table II. Distribution of endovascular procedures, by year and anatomic location, per 100,000 Medicare beneficiaries

Procedure	*1996*	*1997*	*1998*	*1999*	*2000*	*2001*	*2002*	*2003*	*2004*	*2005*	*2006*
Angioplasty											
Iliac	52	58	64	69	71	78	76	75	78	87	91
Femoral-popliteal	69	74	76	78	78	88	93	107	129	154	184
Tibial	15	15	16	16	16	19	21	25	32	45	62
Atherectomy											
Iliac	0	0	0	0	0	0	1	0	1	2	2
Femoral-popliteal	2	2	1	2	1	2	3	5	21	56	78
Tibial	1	1	1	0	1	1	1	2	8	25	39

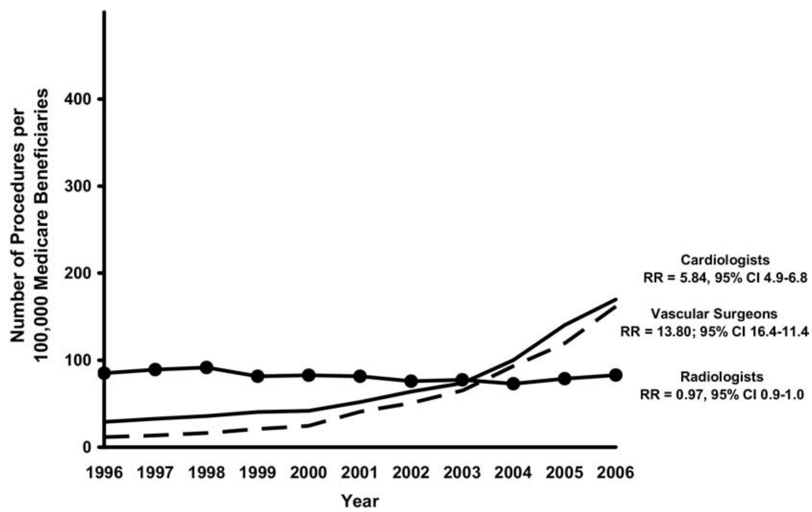

Fig 3. Trends in endovascular interventions, by specialty, 1996-2006. *RR,* Risk ratio; *CI,* confidence interval.

2002 and 2006. Lastly, the vascular beds treated with endovascular interventions changed over time as well, with fewer iliac and more tibial interventions performed later in the study period (Table II).

Major amputation. A distinct decline in the population-based rates of major lower extremity amputation occurred between 1996 and 2006 (Fig 1). Overall, the rate of below- and above-knee amputation decreased from 263 to 188 amputations per 100,000 Medicare beneficiaries, a 29% decline (RR 0.71, 95% CI 0.6-0.8). This decline began in 2000, and remains progressive throughout the next 6 years. Results were not different if above-knee amputations were studied distinctly from below-knee amputations as both decreased in similar magnitude.

Changes in provider specialty. Lastly, we examined changes in the operating physician across endovascular interventions in our study. The number of endovascular interventions performed by cardiologists (29 to 170 interventions per 100,000 Medicare beneficiaries, RR 5.84, 95% CI 4.9-6.80) and vascular surgeons (12 to 162 interventions per 100,000 Medicare beneficiaries, RR 13.80, 95% CI 16.4-11.4) increased over the study period, whereas the number of interventions performed by radiologists remained relatively constant (85 to 82 interventions per 100,000 Medicare beneficiaries, RR 0.97, 95% CI 0.94-1.01) (Fig 3). Because the growth in endovascular interventions occurred exclusively among cardiologists and vascular surgeons, the proportion of all endovascular interventions performed by radiologists declined over time (Fig 4). As shown in Fig 4, radiologists performed nearly 70% of all endovascular interventions in 1998. However, by 2006, they performed less than 20% of all endovascular interventions.

DISCUSSION

In our national analysis of major lower extremity amputation and revascularization rates in Medicare beneficiaries with PAD, we found a large decline in amputations that is paralleled by major changes that the location, techniques, and providers of lower extremity revascularization have changed significantly in the last decade. Bypass surgery was utilized less often, while endovascular interventions flourished. Cardiologists and vascular surgeons have become the specialists most commonly providing endovascular interventions. But, perhaps most importantly, the rate of increase in endovascular interventions far outpaced the decline in bypass surgery. More than three endovascular interventions were performed for every one fewer bypass surgery during the study period, and overall, the total number of lower extremity revascularization procedures

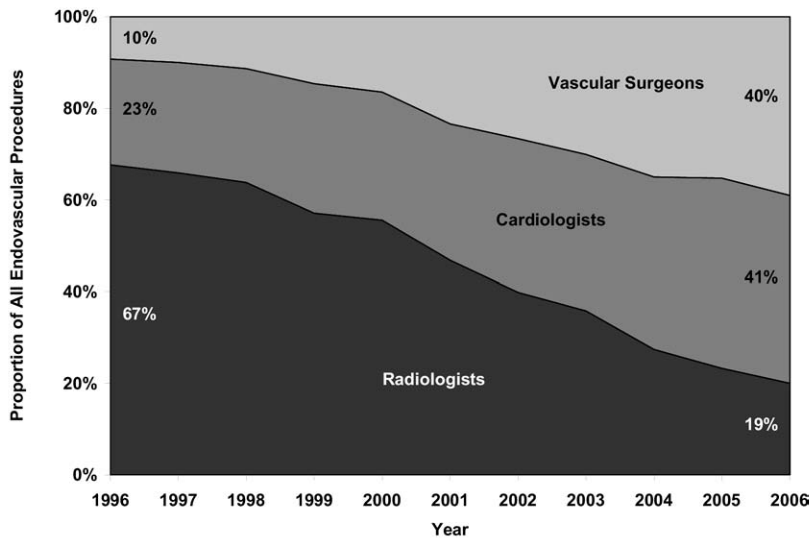

Fig 4. Proportion of endovascular interventions performed by specialty, 1996-2006.

almost doubled over the last decade. Whether or not this is causally related to the change in amputation rates remains unknown.

Why have endovascular interventions grown so rapidly? Several explanations are possible. First, given the less invasive nature of these newer techniques, a group of patients previously untreated with surgical bypass may now be receiving endovascular interventions. Patients with severe PAD judged too ill for surgical bypass, who in the time period prior to aggressive utilization of endovascular technology would have undergone either no treatment or amputation, now likely undergo at least one, if not several, episodes of endovascular intervention before resorting to surgical therapy or amputation. Similarly, patients whose symptoms are limited to claudication, whom in the past may have deferred surgery because of its associated morbidity, may now be eligible for endovascular intervention because "it is only a needle puncture."[16] A decrease in the threshold for intervention, both in claudicants and in patients with critical limb ischemia, likely represents a major contribution to the increase in utilization.[9,17,18] Similarly, many suspect that rising awareness of PAD[19] has contributed to the increase in utilization of lower extremity revascularization.

Second, it is possible that endovascular interventions are less durable, requiring patients to have several "maintenance" endovascular procedures as opposed to one lower extremity bypass. Bypass graft and stent patency rates in the treatment of superficial femoral artery disease would support this idea, as often results of angioplasty and stenting[9,17] are less durable than surgical bypass.[20] Therefore, repeat procedures may be necessary for endovascular interventions to achieve a similar result when compared to surgical bypass. However, as with the coronary circulation, given the less invasive nature of endovascular interventions, patients may perceive this as an acceptable tradeoff.[21]

Third, provider profiles among physicians treating PAD of the lower extremity have changed. Vascular surgeons who once provided only surgical therapy, now almost universally offer endovascular interventions and bypass surgery.[22,23] Invasive cardiologists effective in translating lessons learned in the coronaries to the periphery,[24] have identified the treatment of PAD as an important element of cardiovascular care. Lastly, competition and variation between treatment providers has also likely played a role in the expansion of endovascular interventions.[25]

Is more common use of the invasive treatments of PAD making the care of patients with PAD better? The answer remains unknown, and for several reasons, it will be difficult to determine. First, in contrast to coronary care, where mortality is an important, easily measured, and broadly applicable outcome, the outcome measures of interest in PAD vary according to the indication for intervention. For example, among claudicants, walking distance and freedom from recurrence are the outcomes of interest.[26] However, in patients with critical limb ischemia, amputation-free survival is an important outcome, as are other functional measures such as ambulatory status and independent living.[27]

Some may conclude that the data presented here suggests that the increase in utilization of endovascular interventions has improved the care of patients with lower extremity PAD, by decreasing amputation rates. However, this conclusion cannot be directly established, and is overly simplistic in nature. In patients with PAD, invasive therapy alone is not the sole determinant of the success of an intervention. Critical evaluation of interventions and their outcome must also consider the treatment of comorbidities, such as hyperlipidemia, diabetes, heart disease, and tobacco abuse,[19,28] as well as the influence of podiatric care. Many have demonstrated that successful management of these conditions is associated with improvements in the results of both open[29,30] and endovascular interventions.[31,32] Therefore, we must take into consideration the influence of these covariates when deciding if and why the care of PAD is improving. Between 1996 and 2006, we found that Medicare patients receive more diabetics podiatric visits (increased by 360%), as well as more testing for glycosylated hemoglobin (increased by 319%) and hyperlipidemia (increased by 168%). These changes are on a time course and magnitude similar to that of endovascular interventions. Therefore, it is overly simplistic, and likely incorrect, to attribute all the improvement in vascular care to the increase in use of endovascular interventions.

Therefore, what is making amputation rates fall? The answer remains elusive, but several investigators have begun to examine these relationships. Al-Omran, in a population-based cohort study of nearly 16,000 patients in Ontario, examined survival and amputation-free survival in patients undergoing open and endovascular lower extremity revascularization, and found lower odds of amputation or death in those undergoing angioplasty, although the authors admit limitations in adjustment for patient characteristics and the specifics of the procedures.[33] In a regional analysis using instrumental variables analysis, an econometric measure designed to measure the impact of new treatments while accounting for patient characteristics and treatment selection bias, Ho et al suggests that increasing use of angioplasty in a region may be related to lower amputation rates.[34] But wide-spread agreement on the effect of angioplasty on amputation rates is not uniform; Anderson et al, using the Nationwide Inpatient Sample, found little change in amputation rates between 1980 and 2000, while the use of endovascular interventions increased 10-fold.[6] It is important to note, however, that this particular analysis leaves out the years after 2000, the time period in our work that demonstrated the greatest decline in amputation rates.

Our future work aims to explore the relationships among all of these treatments to allow us to learn just how much of the decrease in amputation rates can be attributed to each therapy. Even though it will be challenging, the effectiveness of endovascular interventions must be critically evaluated. Few trials comparing bypass and endovascular interventions have been performed in patients with claudication,[35,36] and only a single trial has been performed in patients with critical limb ischemia.[7] Certainly larger and broader clinical trials, as well as risk-adjusted population-based studies, are needed to critically examine the result of lower extremity revascularization and determine which patient characteristics, invasive procedures, and medical adjuncts result in the best functional outcomes in patients with PAD.

Our analysis has several limitations. First, precise details about the indication for surgery lie deeper within our administrative dataset than our current work describes. We presume that approximately one-quarter of patients have undergone open revascularization for claudication and three-quarters for critical ischemia, given results from previous large clinical datasets.[12,37] Testing this assumption will require algorithms to discern clinical detail from administrative data, because defining a patient as having claudication or critical ischemia can be accomplished by a variety of coding options; our future work will pursue this task. Second, the unit of analysis in our study is the procedure, not the patient; it is likely that many patients have undergone multiple procedures. Estimates from our regional vascular surgery registry[12] suggest that repeat procedures occur in approximately 10% of patients, and our future work on national data will address this issue more directly in both open and endovascular interventions. And lastly, the nature of this analysis is a descriptive depiction of national, "real-world" use of revascularization procedures obtained from billing data. The weaknesses of administrative data, especially in the use of risk adjustment for determining outcomes, have been well described.[38,39] However, many have questioned the relative importance of these weaknesses[40] and described analytic methods to defer the impact of these difficulties.[41] Therefore, our future work aims to use many of these strategies to gain insight into the nature and causes of changes in revascularization and amputation in the national Medicare population.

In the current era, cost and efficacy play an ever-increasing role in the design and implementation of our national health care system for patients over age 65. In a time period when medical errors and unexplained variations in care dominate the medical and lay literature, reduction in major limb amputations means that a greater proportion of our seniors with peripheral vascular disease are staying out of nursing homes and continuing to live independent, mobile lives. While a direct causative link between peripheral intervention and limb salvage remains elusive, accurate elucidation of this relationship will help patients, providers, payers, and policymakers evaluate the effectiveness of the use of open and endovascular therapy in patients with PAD.

AUTHOR CONTRIBUTIONS

Conception and design: PG, RZ
Analysis and interpretation: PG, HW, RZ
Data collection: PG, AB, JN, RZ
Writing the article: PG, AB, HW, RZ
Critical revision of the article: PG, HW, RZ
Final approval of the article: PG, AB, JN, HW, RZ
Statistical analysis: PG, JN, HW
Obtained funding: PG, RZ
Overall responsibility: PG

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Submitted Nov 5, 2008; accepted Jan 9, 2009.