Original Contribution

Treatment of Peripheral Artery Disease and Critical Limb Ischemia: An Observational Michigan Medicare Analysis

Jihad A. Mustapha, MD[1*]; Fadi A. Saab, MD[1]; William R. Ranger, MD[2]; Nicolas J. Mouawad, MD[3]; Bynthia M. Gates, PhD[4]; Brad J. Martinsen, PhD[4]; Larry J. Diaz-Sandoval, MD[5]; Michael Sumners, MD[6]; Carmen Heaney, RN; Thomas P. Davis, MD[7]

Abstract

Purpose. The selection of endovascular revascularization versus open surgical bypass for an individual patient involves assessment of life expectancy, vascular anatomy, comorbid risk factors, patient preference, and available local skill sets. There are conflicting data in specific situations on amputation outcomes in patients who receive open or percutaneous revascularization. We completed an observational Michigan Medicare analysis to investigate the rates of peripheral vascular intervention (PVI) via endovascular approach or surgical bypass, as well as the amputation rates for potentially informative trends. **Methods.** The Medicare 5% sample was analyzed to investigate the amputation rates and PVI rates of various endovascular techniques and surgical bypass, by hospital, in the State of Michigan over the years 2014 to 2018. To avoid confounding factors, amputation as the index procedure (primary amputation) was excluded. In addition, only patient outcomes related to PVI (endovascular or surgical bypass), rather than all institutional amputations, were included. **Results.** The PVI case count was 570,006 for the United States and 23,216 for Michigan. Over the period 2014-2018, original Medicare patients represented approximately 65% of all Medicare enrollees in Michigan. As institutional use of atherectomy increased, the numbers of patients without amputation increased in the Michigan Medicare population (averaged over five years). Hospitals that used atherectomy at least 57% of the time had amputation rates under 10%, while those that used atherectomy less than 10% of the time typically had amputation rates over 30%. Institutions with a notably high rate of amputation had a correspondingly high rate of surgical bypass and low rate of atherectomy utilization. **Conclusion.** Extreme differences in treatment preferences at institutions can have dire consequences for CLI patients, resulting in higher amputation rates. Despite the observational nature of this Michigan Medicare analysis, the data indicate that there is an opportunity to standardize the treatment of CLI patients across institutions. A more balanced PVI approach to obtain optimal limb salvage rates may help our community reach the American Heart Association policy statement goal of reducing nontraumatic lower-extremity amputations by 20% by 2030.

J CRIT LIMB ISCHEM 2023;3(2):E56-E63. Epub 2023 April 18.

Key words: peripheral artery disease; critical limb ischemia; medicare; endovascular; surgery; atherectomy

Introduction

During the summer of 2021, to counter misperceptions among health care professionals and the public, the American Heart Association (AHA) released a Scientific Statement addressing treatment of lower extremity peripheral artery disease (LE PAD). The AHA holds that practitioners typically believe the diagnosis of PAD to be insignificant, both in terms of the health of their patients and the practice in their clinics.[1] LE PAD is defined by the AHA/American College of Cardiology (ACC) as atherosclerotic disease of the arteries supplying the legs,[2] and the AHA contends that this disease is both underdiagnosed and undertreated throughout the world.[1] Many practitioners stand in agreement with this contention, along with the idea that a failure to screen at-risk populations is a major cause of the problem, and the involvement of a multi-disciplinary team to evaluate patients is a major part of the solution.[3–5] The devastating consequence of underdiagnosis and undertreatment is the progression of PAD to a more severe and lethal disease, critical limb ischemia (CLI).[6]

Twenty years ago, 15%-16% of CLI patients in the United States underwent amputation as their primary procedure, and the medical community largely accepted this approach, even though the majority of these patients had not even received a diagnostic angiogram.[3,7] A decade ago, in an analysis of Medicare beneficiaries with a CLI diagnosis, it was found that 19% received primary amputation.[8] By 2016, the AHA/ACC Guideline on the Management of Patients with PAD concluded that amputation is not an acceptable first-line therapy.[2] Yet, in the AHA 2021 Policy Statement on Reducing Nontraumatic Lower-Extremity Amputations, it was reported that there are ~150,000 of such lower extremity amputations (LEA) performed in the United States (US) every year, and 25% of patients diagnosed with CLI will have an amputation within one year of diagnosis.[9] Most patients who undergo amputation have diabetes. In these patients, the amputation rate increased by 50% from 2009 (3.07 procedures per 1000 diabetic patients) to 2015 (4.62 procedures per 1000 diabetic patients).[9] The AHA stated their goal is to reduce the rate of nontraumatic LEA by 20% by 2030. For patients with comorbidities such as congestive heart failure, cardiomyopathy, severe lung disease, and chronic kidney disease, the 2016 guidelines had recommended endovascular revascularization for CLI.[2] However, proponents of a surgical bypass-first approach suggest that endovascular interventions are ineffective,[10] despite ample, current evidence to the contrary.[11-17] Meanwhile, proponents of an endovascular-first approach claim that percutaneous interventions are superior to surgical bypass and should be considered the primary option.[18,19]

Such a disagreement, it seems, could have been resolved by the Bypass or Angioplasty in Severe Limb Ischemia (BASIL) trial[20] or the Best Endovascular vs. Best Surgical Therapy in Patients With Critical Limb Ischemia (BEST-CLI) trial.[21] Unfortunately, BASIL suffered from a lack of clinical equipoise, with less than 10% of the eligible patients ultimately being randomized. It was concluded that "most clinicians exhibit strong preferences on patient management. The results of the BEST-CLI trial were just recently published and the results are being fiercely debated. These preferences appear to be based on specialty and local experience rather than scientific evidence."[22] In order to address this bias in clinical practice and dearth of scientific evidence, we retrospectively analyzed Medicare data over the 5-year period from 2014 to 2018, to investigate the rates of peripheral vascular intervention (PVI) via endovascular approach or surgical bypass, as well as the amputation rates for potentially informative trends and correlations.

Table 1. PAD and CLI ICD-9 and ICD-10 Codes

Category	ICD-9 Code	ICD-10 Code
PAD	440.20	I70.201
		I70.202
		I70.203
		I70.208
		I70.209
PAD	440.21	I70.211
		I70.212
		I70.213
		I70.218
		I70.219
CLI with Rest Pain	440.22	I70.221
		I70.222
		I70.223
		I70.228
		I70.229
CLI with Ulceration	440.23	I70.231
		I70.232
		I70.233
		I70.234
		I70.235
		I70.238
		I70.239
		I70.241
		I70.242
		I70.243
		I70.244
		I70.245
		I70.248
		I70.249
		I70.25
CLI with Gangrene	440.24	I70.261
		I70.262
		I70.263
		I70.268
		I70.269

CLI = critical limb ischemia; ICD = International Classification of Diseases; PAD = peripheral artery disease

Methods

An observational Michigan Medicare analysis was completed to investigate the rates of peripheral vascular intervention (PVI) via endovascular approach (angioplasty, atherectomy, stent, atherectomy + stent) or surgical bypass, as well as the amputation rates for potentially informative trends. Major amputation was defined as above-the-knee (ATK) or below-the-knee (BTK) and minor amputation was defined as below-the-ankle (BTA).

Data was extracted from the 2014-2018 Medicare Inpatient & Outpatient Hospital SAFs containing inpatient & outpatient hospital claims for 100% of Medicare claims processed by

TABLE 1. PAD AND CLI ICD-9 AND ICD-10 CODES (CONT)

Category	ICD-9 Code	ICD-10 Code
PAD	440.29	I70.291
		I70.292
		I70.293
		I70.298
		I70.299
	440.4	I70.92
	440.8	I70.8
	440.9	I70.90
		I70.91
	443.9	I73.9

CLI = critical limb ischemia; ICD = International Classification of Diseases; PAD = peripheral artery disease

CMS, and from the 2014-2018 Medicare Physician/Carrier SAF containing physician claims for 5% of Medicare claims processed by CMS.[23] ICD-9 codes were utilized until October 1, 2015. ICD-10 codes were implemented on October 1, 2015 and used through 2018.

A clean period of 1 year was applied to all patients within the analysis to ensure that peripheral vascular intervention (PVI) rates were not affected by patients that have already undergone treatment. Patients were excluded if they had a diagnosis of PAD or CLI in the 2013 inpatient or outpatient SAFs. Data analyzed came from claims with an ICD-9/ICD-10 CM code indicating peripheral artery disease (PAD) or critical limb ischemia (CLI) in a primary or secondary position in order to ensure procedures were performed to treat PAD or CLI **(Table 1)**. Claims then had to include an PVI ICD-9/ICD-10 PCS code or PVI CPT[24] code indicating a peripheral vascular intervention took place **(Table 2** and **Table 3)**. Patients were excluded if they did not have at least 1 PVI with a primary or secondary diagnosis of PAD or CLI in the 2014-2018 Medicare population. This analysis includes 387,693 patients within 3,195 inpatient and outpatient hospitals utilizing 53,303 physicians from the Inpatient Hospital and Outpatient Hospital SAFs. Additionally, this analysis includes 6,124 patients utilizing 1,385 physicians within an office care setting from the 5% sample Physician/Carrier SAF. Data were then parsed for the State of Michigan only. In the results section/figures the identification of Institutions/Hospitals were masked via the use of a series of alphabetical letter codes.

Major amputation (ATK and BTK), minor amputations (BTA), and PVI cases without amputations are mutually exclusive. Cases are classified by the least to most severe, with the severity level being PVI cases without amputations > minor amputations (BTA)> major amputation (ATK or BTK). Traumatic amputations were excluded from this analysis. Additionally, to avoid confounding factors, amputation as the index procedure (primary amputation) was excluded from this dataset and from our analysis. This database specifically included only patient outcomes related to PVI (endovascular or surgical bypass), rather than all institutional amputations.

TABLE 2. PVI ICD-9 TO ICD-10 PCS CODES.

PVI CATEGORY	ICD-9 CODE	ICD-10 CODE
Major amputation (ATK)	84.16	0Y6F0ZZ to 0Y6G-0ZZ
Major amputation (ATK)	84.17	0Y6C0Z1 to 0Y6D0Z3
Major amputation (ATK)	84.18	0Y670ZZ to 0Y680ZZ
Major amputation (ATK)	84.19	0Y620ZZ to 0Y640ZZ
Major amputation (BTK)	84.10	0Y6M0Z0 to 0Y6J0Z3
Major amputation (BTK)	84.13	
Major amputation (BTK)	84.14	
Major amputation (BTK)	84.15	
Minor amputation (BTA)	84.11	0Y6P0Z0 to 0Y6Y0Z3
Minor amputation (BTA)	84.12	0Y6M0Z4 to 0Y6N0ZF
Angioplasty	39.50	047C34Z to 047Y4ZZ
Atherectomy	17.56	04CC3ZZ to 04CY4ZZ
Stent	00.55	047C34Z to 047Y44Z
Stent	00.60	047K341 to 047L44Z
Stent	39.90	047C3DZ to 047Y4DZ
Surgical bypass	38.40	
Surgical bypass	38.48	04RK07Z to 04RY4KZ
Surgical bypass	39.25	0410096 to 041J4ZK
Surgical bypass	39.29	0312096 to 041N4ZS
Surgical bypass	39.49	
Surgical bypass		041C090 to 041J4ZQ

ATK = above-the-knee, BTA = below-the-ankle, BTK = below-the-knee, ICD = International Classification of Diseases, PAD = peripheral artery disease, PVI = peripheral vascular intervention, PCS = procedure coding system

PVI categories of angioplasty, atherectomy, stent, atherectomy + stent, and surgical bypass are not mutually exclusive. A case may include more than one of these PVI categories. The

Table 3. PVI CPT Codes

Category	CPT Code
Major amputation (ATK)	27290
	27295
	27590
	27591
	27592
	27594
	27596
	27598
Major amputation (BTK)	27880
	27881
	27882
	27884
	27886
Minor amputation (BTA)	27888
	27889
	28124
	28126
	28140
	28150
	28153
	28160
	28800
	28805
	28810
	28820
	28825
Angioplasty	37220
	37222
	37224
	37228
	37232
Angioplasty + Stent	37221
	37223
	37226
	37230
	37234
Atherectomy + Angioplasty	0238T[1]
	37225
	37229
	37233
Atherectomy + Angioplasty + Stent	37227
	37231
	37235

ATK = above-the-knee, BTA = below-the-ankle, BTK = below-the-knee, CPT = current procedural terminology, PVI = peripheral vascular intervention.[1] Must also include a CPT code for angioplasty within the claim.

category of atherectomy + stent is comprised of those cases where a stent and atherectomy were used during the same stay. These cases are also be found in the separate categories of atherectomy and stent.

Within inpatient & outpatient settings, physicians, hospitals, and cities were included only if they had total intervention counts of 11 or more for all of 2014-2018. Counts within an office care setting are multiplied by 20 to account for the physician/carrier file's 5% sample size.

Results

The PVI (endovascular or surgical bypass) case count was 570,006 for the United States and 23,216 for Michigan. Over the period 2014-2018, original Medicare patients represented approximately 65% of all Medicare enrollees in Michigan. The 5% sample, therefore, represented about 3.25% of the Medicare population.

The data from the State of Michigan showed **(Figure 1)** that as institutional use of atherectomy increased, the numbers of patients without amputation increased in the Michigan Medicare population, averaged over five years. Hospitals that used atherectomy at least 57% of the time had amputation rates under 10%, while those that used atherectomy less than 10% of the

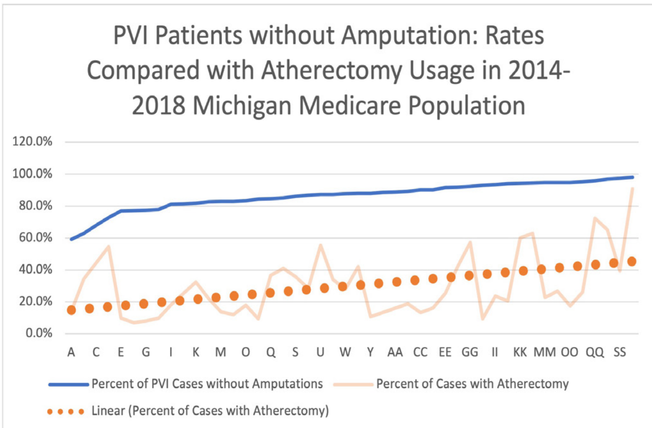

FIGURE 1. As institutional use of atherectomy increased, the number of patients without amputation also increased. Capital letter code = Masked identification of institutions/hospitals.

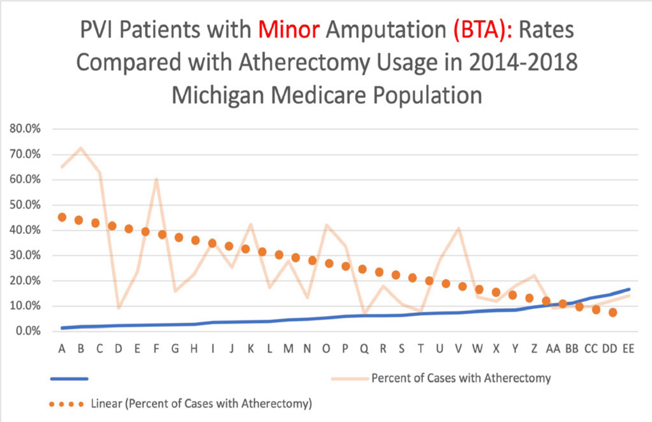

FIGURE 2. As institutional use of atherectomy decreased, minor amputation (BTA) rates increased. Capital letter code = masked identification of institutions/hospitals.

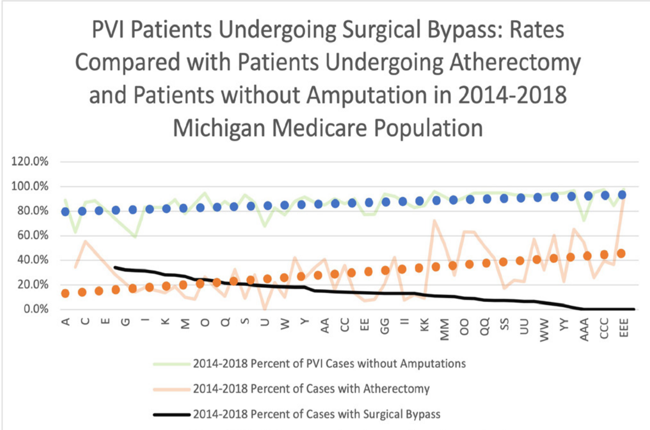

FIGURE 4. Institutions with a notably high rate of amputation had a correspondingly high rate of surgical bypass and low rate of atherectomy utilization. Capital letter code = masked identification of institutions/hospitals.

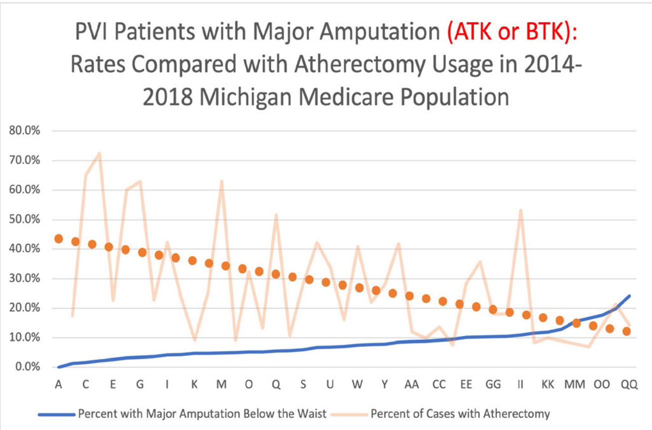

FIGURE 3. As institutional use of atherectomy decreased, major amputation (ATK or BTK) rates increased. Capital letter code = masked identification of institutions/hospitals.

time typically had amputation rates over 30%. Parsing the data further, hospital rates of minor amputation (BTA) were investigated. As shown in **Figure 2**, as institutional use of atherectomy decreased (trendline), minor amputation (BTA) rates increased. The data were then studied to compare atherectomy usage rates with rates of patients who received major amputation (ATK or BTK). The same inverse correlation was discovered **(Figure 3)**: as atherectomy use declined, the institutional rate of major amputation increased.

To compare atherectomy outcomes with those of surgical bypass, we charted institutional rates of both procedures, together with the rate of amputation at the corresponding hospital. We saw, as before, an inverse relationship between atherectomy usage and rates of amputation, but a direct correlation with surgical bypass usage **(Figure 4)**. As rates of surgical bypass increased, the rate of amputation increased. Further, the inverse relationship between amputation rates and atherectomy usage was not only generally held, as shown by the charted trendlines, but was reflected in the specific data points as well. As revealed in this figure, each institution with a notably high rate of amputation had a correspondingly low point of atherectomy usage.

Discussion

This retrospective analysis of Medicare claims data investigated the trends of PVI as they relate to the unwanted outcome of amputation from 2014 to 2018 in hospitals located in Michigan. We identified, in the state of Michigan, that as institutional usage of atherectomy increased, there was a concomitant decrease in institutional rates of subsequent amputation. This finding agrees with a previous, nationwide investigation of the Medicare claims data, which revealed that CLI patients who underwent atherectomy experienced lower rates of mortality and major amputation over four years than did patients who underwent surgical bypass.[25]

Most studies of surgical bypass versus endovascular intervention suffer from bias, a lack of equipoise. This analysis looked exclusively at patient-level outcomes based upon the type(s) of intervention received, in an attempt to circumvent the issue of selection bias. Given the nature of the data, causality cannot be determined, but rather an association can be made with lower amputation rates for those who underwent atherectomy. It is important to note that this was not a randomized, controlled trial (RCT) of surgery versus endovascular, but both were considered as a PVI option based on operator discretion. The recently published BEST-CLI trial, an RCT of endovascular versus surgical bypass,[20,21,26] has provided more information on the differences in baseline patient characteristics, as well as outcomes. At this time, however, a recent analysis of diabetic patients presenting with tissue loss showed that clinical failure was not different between patients who underwent endovascular intervention and patients who underwent surgical bypass.[4]

Vascular disease is the cause of over half of all amputations performed in the United States,[27] and nearly half of these individuals will die within five years of their amputation procedure.[28] Even a minor amputation is not a minor event: 85% of LEA are preceded by a foot ulcer.[28] Amputation is clearly a negative outcome of PVI treatment, and this Medicare database provided information both on major amputation (ATK or BTK), and minor amputation (BTA). A recent study that concluded surgical bypass to be superior to endovascular intervention for outcomes relating to amputation did not include atherectomy among their recanalization techniques.[29] In analyzing the Medicare data for hospitals in Michigan, we looked specifically at this often-excluded endovascular intervention. Atherectomy utilization has been scrutinized in recent years,[10,30] leading to a decrease in utilization, which likely led to the increase in minor amputation seen in these data. Minor amputation typically leads to progressive amputation, and it has similar mortality rates as major amputation.[31] In Type 2 diabetics, nearly 60% of patients with a toe amputation had to undergo further surgery (to revise the original amputation or to amputate a new site) and only 21% of patients had no complications at one year. The mortality rate was 7.4%, showing definitively that toe amputation is not a harmless or minor procedure.[32]

Our study fills a void in the current conversation regarding appropriate PVI treatment. In addition to the concern of equipoise, other limitations of many studies are the small, often homogenous patient populations, the limited number of institutions assessed, and the unique circumstances borne by those institutions. For example, Perlander et al reported that at two years, bypass surgery was associated with higher amputation-free survival than endovascular intervention.[29] The authors' conclusion was based on their study performed at Sahlgrenska University Hospital, Gothenburg, Sweden and two surrounding district hospitals. All three of these centers had dedicated vascular surgery units providing care for CLI patients.[29] Our study investigated real-world data from all available hospitals (58) in an entire State and was not limited to those with specialty centers that may favor one approach over the other.

Additionally, this retrospective analysis provides an objective investigation of the treatment factors that may contribute to the risk of amputation in patients with PAD. This is a critical area of study, as the consequences of amputation are severe and lethal. Unfortunately, these consequences are often underestimated and/or underreported. While risk-prediction tools exist for objectively assessing some post-amputation outcomes, they tend to assess populations as a whole rather than consider patient-level individual factors. Most focus on operative risk, exclude relevant comorbidities, and none assess quality of life as an outcome.[33,34] The authors of a novel risk-prediction model that differentiated between mortality outcomes for patients undergoing transmetatarsal, transtibial, or transfemoral amputation stated as an advantage, rather than a limitation, the fact that their study "excluded co-morbidities strongly associated with mortality and a clinical indication for a transfemoral amputation.[34]" This highlights the willful bias against inclusion of at-risk populations and subsequent reporting of amputation outcomes. For example, it is known that of patients with PAD, those who have diabetes have worse treatment outcomes than those without.[35]

However, subjects with diabetes and other comorbidities, such as older age, advanced ASA grade, and severe renal disease, are routinely excluded from studies of LEA.[36] Fortington et al showed that the very population that typically undergoes LEA, elderly patients with PAD and diabetes, generally do not meet the inclusion criteria for LEA studies. They contend that "difficulties with population sampling are frequent in amputation research and this impacts our ability to draw accurate conclusions." While investigators commonly admit this is a limitation of their research, nothing is done to actually address the biased conclusions.[36] In the study analyzed by Fortington, they noted that only 27% of all potential patients were referred to the study and included in the outcome reporting. However, in the key outcome of one-year survival, which is typically reported in amputation research, there was a significant difference between the two groups. The reported 67% survival rate was for the carefully selected, referred patient population, and differed significantly from the 40% survival rate of non-referred patients, who are more representative of the population at large which undergoes LEA.[36]

In reality, subjects with PAD and/or diabetes who undergo LEA have 1- and 5-year mortality risks (44% and 77%) that exceed those of most cancers.[31,37] In the UK, patients who also had typical comorbidities of renal dysfunction, advanced ASA grade, and older age have a 30-day mortality rate of 9%-17%.[38] Without performing a retrospective analysis, as was done in the work reported here with the Medicare sample, it is impossible to delineate the true consequences and correlations of LEA. This was done with the UK sample. When investigating the impact of just one of the comorbid factors, (physical status), it was found that the 30-day mortality rate was 23.2% for subjects with an ASA grade ≥ 4.38 The impact on amputation outcome reporting by removing such patients from the studied population is obvious and detrimental, generating falsely optimistic conclusions regarding LEA results.

Further objective investigations, such as the retrospective analysis reported herein, are critical for properly elucidating and addressing the causes, effects, and solutions of the amputation epidemic. It is imperative to look at the rest of the 49 US states and observe trends. If the national trend is consistent with the

Michigan data, we must focus on appropriate use criteria for CLI patients. It is unacceptable to have such a large range of amputation rates by institution. To achieve the AHA's goal of reducing amputation by 20% in the year 2030, institutional policies must be changed.

Limitations. There are important limitations of this study to consider. First, the type of PVI performed was identified using claims codes, so how this decision was made cannot be discerned. Although use of claims codes to define the primary exposure can result in misclassification, appropriate and accurate billing is required for reimbursement and likely reduces this risk. Second, CMS data do not include detailed procedural information, including lesion characteristics such as length and severity of disease, degree of calcification, presence of total occlusion, number of vessels affected, nor location of the lesions. Thus, any comparisons between endovascular and surgery should be viewed as observational. In addition, PVI categories of angioplasty, atherectomy, stent, atherectomy + stent, and surgical bypass are not mutually exclusive. A case may include more than one PVI category. Thus, the order of procedures in those cases (ie, endovascular prior to bypass) could not be determined, but should be noted as a potential confounder. Third, other endpoints like repeat revascularization could not be evaluated due to the ambiguity of claims codes.

This retrospective analysis focused on the state of Michigan and was observational in nature—no statistical analyses were completed to adjust for confounding factors. We are planning an additional analysis and publication that will examine the full national Medicare database, as well as the completion of statistical analysis to adjust for confounding. Adding 49 states beyond the scope of Michigan would expand the real-world nature of such an analysis. Further, our investigation ended in 2018, per the available data. Although a limitation, it also eliminated the significant, confounding influence of the Covid-19 pandemic on hospital procedures. We acknowledge that trendlines do not always reflect the realities of each data point, and we attempted to address this by ensuring specific points mirrored the stated trends; for example, see discussion of **Figure 4**.

Conclusions

This retrospective analysis of Medicare claims data investigated the trends of PVI as they relate to the unwanted outcome of amputation from 2014 to 2018 in hospitals located in Michigan. We identified, in the state of Michigan, that as institutional usage of atherectomy increased, there was a concomitant decrease in institutional rates of subsequent amputation. Despite the observational nature of this Michigan Medicare analysis, the data indicate that there is an opportunity to standardize the treatment of CLI patients across institutions. A more balanced PVI approach to obtain optimal limb salvage rates may help our community reach the American Heart Association policy statement goal of reducing nontraumatic lower-extremity amputations by 20% by 2030.

References

1. Criqui MH, Matsushita K, Aboyans V, et al, on behalf of the American Heart Association Council on Epidemiology and Prevention; Council on Arteriosclerosis, Thrombosis and Vascular Biology; Council on Cardiovascular Radiology and Intervention; Council on Lifestyle and Cardiometabolic Health; Council on Peripheral Vascular Disease; and Stroke Council. Lower Extremity Peripheral Artery Disease: Contemporary Epidemiology, Management Gaps, and Future Directions: A Scientific Statement From the American Heart Association. *Circulation [Internet].* 2021 [cited 2022 Jan 17];144. Available from: https://www.ahajournals.org/doi/10.1161/CIR.0000000000001005
2. Gerhard-Herman MD, Gornik HL, Barrett C, et al, Treat-Jacobson D, Walsh ME. 2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease: Executive Summary. *Circulation.* 2016;CIR.0000000000000470.
3. Fakorede F, Anose BM, Yost M, Harlow A, Martinsen B. Mississippi delta miracle: angiographic screening yields dramatic reduction in amputations. *Cath Lab Digest* [Internet]. 2019 [cited 2022 Jan 18];Available from: https://www.hmpgloballearningnetwork.com/site/cathlab/content/mississippi-delta-miracle-angiographic-screening-yields-dramatic-reduction-amputations
4. Deery SE, Hicks CW, Canner JK, Lum YW, Black JH, Abularrage CJ. Patient-centered clinical success after lower extremity revascularization for complex diabetic foot wounds treated in a multidisciplinary setting. *J Vasc Surg*. 2022;75(4):1377-1384.e1. Epub 2021 Dec 15 doi: 10.1016/j.jvs.2021.11.063
5. van den Berg JC, Driver VR, et al for the CLI Global Society. Modern multidisciplinary team approach is crucial in treatment for critical limb threatening ischemia. *J Cardiovasc Surg (Torino).* 2021;62(2):124-129. Epub 2021 Jan 26. doi: 10.23736/S0021-9509.21.11725-2
6. Mustapha JA, Anose BM, Martinsen BJ, et al. Lower extremity revascularization via endovascular and surgical approaches: A systematic review with emphasis on combined inflow and outflow revascularization. *SAGE Open Med.* 2020;8:2050312120929239.
7. Mustapha JA, Saab FA, Martinsen BJ, et al. Digital subtraction angiography prior to an amputation for critical limb ischemia (CLI): An Expert Recommendation Statement From the CLI Global Society to Optimize Limb Salvage. *J Endovasc Ther.* 2020;27:540-546. eCollection 2020. doi: 10.1177/2050312120929239.
8. Mustapha JA, Katzen BT, Neville RF, et al. Determinants of Long-Term Outcomes and Costs in the Management of Critical Limb Ischemia: A Population-Based Cohort Study. *J Am Heart Assoc.* 2018;7(16):e009724. doi: 10.1161/JAHA.118.009724
9. Creager MA, Matsushita K, Arya S, et al, On behalf of the American Heart Association Advocacy Coordinating Committee. Reducing Nontraumatic Lower-Extremity Amputations by 20% by 2030: Time to Get to Our Feet: A Policy Statement From the American Heart Association. *Circulation*. 2021;143(17):e875-e891. Epub 2021 Mar 25. doi: 10.1161/CIR.0000000000000967
10. Mukherjee D, Liu C, Jadali A, Lewis E, Neville R. Effects of peripheral arterial disease interventions on survival: a propensity-score matched analysis using VQI data. *Ann Vasc Surg.* 2021;S0890509621006543.
11. Lin F, Wang H, Ding W, Chen G, Zhang Z. Atherectomy plus drug-coated balloon versus drug-coated balloon only for treatment of femoropopliteal artery lesions: A systematic review and meta-analysis. *Vascular.* 2021;29(6):883-896. Epub 2021 Jan 21. doi: 10.1177/1708538120985732.
12. Rao S, Martinsen B, Higgins J, Dhandhusaria H, Patel D. Orbital atherectomy for treating calcified iliac artery disease to enable large bore device delivery: a case series report. *SAGE Open Med Case Rep.* 2020 Jul 22;8:2050313X20943068. eCollection 2020. doi: 10.1177/2050313X20943068

13. Holden A, Hill A, Walker A, et al. PRELUDE Prospective Study of the Serranator Device in the Treatment of Atherosclerotic Lesions in the Superficial Femoral and Popliteal Arteries. *J Endovasc Ther.* 2019;26(1):18-25. Epub 2018 Dec 24. doi: 10.1177/1526602818820787

14. Rocha-Singh KJ, Sachar R, DeRubertis BG, et al, The REALITY Investigators. Directional atherectomy before paclitaxel coated balloon angioplasty in complex femoropopliteal disease: The VIVA REALITY study. *Catheter Cardiovasc Interv.* 2021;98(3):549-558. Epub 2021 Jun 3. doi: 10.1002/ccd.29777

15. Iida O, Urasawa K, Shibata Y, et al. Clinical safety and efficacy of rotational atherectomy in Japanese patients with peripheral arterial disease presenting femoropopliteal lesions: The J-SUPREME and J-SUPREME II Trials. *J Endovasc Ther.* 2022;29(2):240-247. Epub 2021 Sep 13. doi: 10.1177/15266028211045700.

16. Böhme T, Noory E, Beschorner U, et al. Photoablative atherectomy followed by a paclitaxel-coated balloon to inhibit restenosis in instent femoro-popliteal obstructions (PHOTOPAC): A randomized multicentre pilot study. *Vasa.* 2021;50(5):387-393. Epub 2021 Jun 10. doi: 10.1024/0301-1526/a000959

17. Kronlage M, Werner C, Dufner M, et al. Long-term outcome upon treatment of calcified lesions of the lower limb using scoring angioplasty balloon (AngioSculpt™). *Clin Res Cardiol.* 2020 Sep;109(9):1177-1185. Epub 2020 Feb 8. doi: 10.1007/s00392-020-01610-3

18. Kerzmann A, Boesmans E, Holemans C, Quaniers J, Alexandrescu V, Defraigne JO. [Endovascular treatment of femoropopliteal arterial occlusive disease]. *Rev Med Liege*. 2020;75(11):717-723.

19. Bosiers M. Is vessel prep necessary before treating the superficial femoral artery? *J Cardiovasc Surg (Torino)*. 2019;60(5):557-566. Epub 2019 Jun 21. doi: 10.23736/S0021-9509.19.11037-3

20. Menard MT, Farber A. The BEST-CLI trial: a multidisciplinary effort to assess whether surgical or endovascular therapy is better for patients with critical limb ischemia. *Semin Vasc Surg*. 2014;27(1):82-84. Epub 2015 Jan 22. doi: 10.1053/j.semvascsurg.2015.01.003

21. Farber A, Menard MT, Conte MS, et al for the BEST-CLI Investigators. Surgery or endovascular therapy for chronic limb-threatening ischemia. *N Engl J Med*. 2022;387(25):2305-2316. Epub 2022 Nov 7 doi: 10.1056/NEJMoa2207899

22. Hussey K, Chandramohan S. Contemporary treatment for critical ischemia: the evidence for interventional radiology or surgery. *Semin Interv Radiol*. 2014;31(4):300-306. doi: 10.1055/s-0034-1393965

23. Medicare Inpatient Hospital, Outpatient Hospital, and Physician/Carrier Analytical Files 2014-2018. Center for Medicare & Medicaid Services (CMS), Baltimore, MD. www.cms.hhs.gov.

24. Current Procedural Terminology 2014-2018, American Medical Association. Chicago, IL 2014-2018. CPT is a registered trademark of the American Medical Association. Current Procedural Terminology (CPT®) is copyright 2014-2018 American Medical Association. All Rights Reserved. Applicable FARS/DFARS apply.

25. Mustapha JA, Katzen BT, Neville RF, et al. Propensity score-adjusted comparison of long-term outcomes among revascularization strategies for critical limb ischemia. *Circ Cardiovasc Interv.* 2019;12:e008097.

26. Menard MT, Farber A, Assmann SF, et al. Design and rationale of the best endovascular versus best surgical therapy for patients with critical limb ischemia (BEST-CLI) Trial. *J Am Heart Assoc.* 2016;5(7):e003219. doi: 10.1161/JAHA.116.003219

27. Ziegler-Graham K, MacKenzie EJ, Ephraim PL, Travison TG, Brookmeyer R. Estimating the prevalence of limb loss in the United States: 2005 to 2050. *Arch Phys Med Rehabil.* 2008;89(3):422-429. doi: 10.1016/j.apmr.2007.11.005

28. Robbins JM, Strauss G, Aron D, Long J, Kuba J, Kaplan Y. Mortality rates and diabetic foot ulcers. *J Am Podiatr Med Assoc.* 2008;98(6):489-493. doi: 10.7547/0980489

29. Perlander A, Jivegård L, Nordanstig J, Svensson M, Österberg K. Amputation-free survival, limb symptom alleviation, and reintervention rates after open and endovascular revascularization of femoropopliteal lesions in patients with chronic limb-threatening ischemia. *J Vasc Surg*. 2020;72(6):1987-1995. Epub 2020 Apr 8. doi: 10.1016/j.jvs.2020.03.029

30. Mukherjee D, Hashemi H, Contos B. The disproportionate growth of office-based atherectomy. *J Vasc Surg*. 2017;65(2):495-500. Epub 2016 Dec 13. doi: 10.1016/j.jvs.2016.08.112

31. Armstrong DG, Swerdlow MA, Armstrong AA, Conte MS, Padula WV, Bus SA. Five year mortality and direct costs of care for people with diabetic foot complications are comparable to cancer. *J Foot Ankle Res*. 2020;13(1):16. doi: 10.1186/s13047-020-00383-2.

32. Vassallo IM, Gatt A, Cassar K, Papanas N, Formosa C. Healing and mortality rates following toe amputation in type 2 diabetes mellitus. *Exp Clin Endocrinol Diabetes*. 2021;129(6):438-442. Epub 2019 Jun 17. doi: 10.1055/a-0942-1789

33. Preece RA, Dilaver N, Waldron C-A, et al. A systematic review and narrative synthesis of risk prediction tools used to estimate mortality, morbidity, and other outcomes following major lower limb amputation. *Eur J Vasc Endovasc Surg*. 2021;62(1):127-135. Epub 2021 Apr 24. doi: 10.1016/j.ejvs.2021.02.038

34. Norvell DC, Thompson ML, Boyko EJ, et al. Mortality prediction following non-traumatic amputation of the lower extremity. *Br J Surg*. 2019;106(7):879-888. Epub 2019 Mar 13. doi: 10.1002/bjs.11124

35. Luan J, Xu J, Zhong W, Zhou Y, Liu H, Qian K. Adverse prognosis of peripheral artery disease treatments associated with diabetes: a comprehensive meta-analysis. *Angiology*. 2022;73(4):318-330. Epub 2021 Sep 21. doi: 10.1177/00033197211042494.

36. Fortington LV, Geertzen JHB, Bosmans JC, Dijkstra PU. Bias in amputation research; impact of subjects missed from a prospective study. *PloS One.* 2012;7(8):e43629. Epub 2012 Aug 20. doi: 10.1371/journal.pone.0043629.

37. Fortington LV, Geertzen JHB, van Netten JJ, Postema K, Rommers GM, Dijkstra PU. Short and long term mortality rates after a lower limb amputation. *Eur J Vasc Endovasc Surg.* 2013;46(1):124-131. Epub 2013 Apr 28. doi: 10.1016/j.ejvs.2013.03.024 .

38. Scott SWM, Bowrey S, Clarke D, Choke E, Bown MJ, Thompson JP. Factors influencing short- and long-term mortality after lower limb amputation. *Anaesthesia*. 2014;69(3):249-258. doi: 10.1111/anae.12532.

From [1]Advanced Cardiac & Vascular Centers for Amputation Prevention, Grand Rapids, Michigan, Michigan State University College of Human Medicine, East Lansing, Michigan; [2]Western Michigan University, Homer Stryker School of Medicine, Kalamazoo, Michigan; [3]Vascular & Endovascular Surgery, McLaren Health System, Bay City, Michigan; [4]Clinical Scientific Affairs, Cardiovascular Systems Inc., St. Paul, Minnesota; [5]Borgess Heart Institute, Ascension Borgess Hospital, Kalamazoo, Michigan; [6]University of Michigan Health West - Heart and Vascular, Wyoming, Michigan; [7]East Lake Cardiovascular, P.C., St. Clair Shores, Michigan.

Disclosure: The authors have completed and returned the ICMJE Form for Disclosure of Potential Conflicts of Interest. JM has consulting relationships with Angiodynamics, Avinger, Becton Dickinson (BD), Boston Scientific (BS), Cardiovascular Systems, Inc. (CSI), Cordis, Medtronic, Micromedical Solutions, Philips, PQ Bypass, and Terumo; equity ownership in CardioFlow (CF) and Reflow Medical; and research relationships with BS, PQ Bypass, CF, and Avinger. FS has consulting relationships with BD, BS, CSI, Gore, Medtronic, Philips, PQ Bypass, and Terumo; equity ownership in CF; and research relationships with BS, PQ Bypass, Micromedical Solutions. BG and BM are employed by and own stock in CSI. NM is a consultant/speaker for BD, Bard, and an advisory board member for Medtronic and BS. TD is a consultant to Abbott, Avigner, CF, CSI, Cordis, BS, BD, Philips, Medtronic, Siemens, and has equity ownership in 2MG. MS has a consulting relationship with BD. LD received honoraria for speaking for Cook Medical. WR and CH have no conflicts of interest to declare.

Manuscript accepted March 30, 2023.

Address for correspondence: Jihad Mustapha, MD, Advanced Cardiac & Vascular Centers for Amputation Prevention, 1525 E. Beltline Ave, NE, Suite 1010, Grand Rapids, MI 49525 USA. Email: jmustapha@acvcenters.com