Prevalence, Incidence, and Outcomes of Critical Limb Ischemia in the US Medicare Population

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ABSTRACT: Objective. This study aimed to assess annual prevalence and incidence of critical limb ischemia (CLI) and associated outcomes (amputation, leg revascularization, death) in elderly persons in the United States. Method. Medicare beneficiaries ages 65 and older were retrospectively analyzed and compared for demographic and clinical characteristics from January 2007 to December 2008. Using the direct standardization method, year, age, gender, and race, as well as diabetes-specific prevalence and incidence rates were estimated for the CLI burden in the United States. Potential risk factors for CLI outcomes, events, and mortality were selected using Cox proportional hazard regression models. CLI prevalence and incidence was 0.23% and 0.20% respectively. Similar to prevalence, incidence increased sharply among beneficiaries ages 65 to 69 (0.13%) to 85 and older (0.31%). Results. Among black patients, 0.41% had CLI, compared to 0.18% among white patients. Diabetes caused 7.6 times increased CLI risk compared to nondiabetic patients. In the multivariate analysis, younger, male, diabetic (HR 1.21), or proliferative retinopathy (HR 1.112) patients were significantly associated with nontraumatic amputation, while hypertension (HR 1.043), angina pectoris (HR 1.074), myocardial infarction (HR 1.08), or hyperlipidemia (HR 1.1) were significantly related to leg revascularization. Black patients had a lower revascularization probability and a higher amputation probability than white patients (after adjustment for age, gender, CLI severity, comorbidities), and displayed a longer time to first revascularization and shorter time to amputation. Older, male and black patients had higher CLI prevalence. Conclusion. CLI management differs among the US population according to ethnicity, leading to varying outcomes (revascularization, amputation). Since outcome event risk varies, patients should be examined individually.

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Key words: critical limb ischemia, prevalence, incidence, revascularization, amputation

Critical limb ischemia (CLI) is a severe obstruction of the arteries that seriously decreases blood flow to the extremities.[1] Although the hallmark of peripheral arterial occlusive disease is an inadequate blood flow to supply vital oxygen demanded by the limb, CLI occurs after a chronic lack of blood supply resulting in a cascade of pathophysiologic events that ultimately leads to severe pain in the feet or toes, even while resting,[2] and at a later stage sores and wounds that will not heal on the legs and feet. Thus, these patients would be classified as stage III or IV in the Fontaine classification, given that CLI is considered the "end stage" of peripheral arterial disease (PAD).[3,4] If left untreated, CLI will lead to amputation of the affected limb.[5]

Although CLI continues to be a significantly morbid disease process for the aging population, the epidemiology of CLI remains sparse in the US population. To date, the number of US patients suffering from CLI has been estimated indirectly, from the estimated number of amputations,[6] CLI incidence in the United Kingdom and Ireland based on a 1995 survey of vascular surgeons,[7,8] estimated progression from intermittent claudication (IC) or a combination of amputations, revascularizations, and progression from IC in Italy.[9]

The estimations from these indirect calculations vary widely. Although CLI incidence of 300 per million per year has been calculated by Weitz et al, who estimated that 1% of Americans over age 50 years may ultimately acquire chronic CLI,[10] Goodney et al. claims that diagnosed CLI currently affects roughly 1 million Americans.[11] Recently published analysis by The Sage Group concluded that an estimated 2 million people in the United States have CLI, including undiagnosed patients.[12] Reflecting the aging population, this number is projected to grow to almost 2.8 million by 2020. However, if the prevalence of diabetes continues to increase, there could be over 3.5 million cases of CLI by 2020.[12]

Prompt medical care is crucial in all patients with CLI to immediately improve blood flow and prevent nontraumatic lower-extremity amputation (LEA). LEA is often an expensive and catastrophic complication leading to permanent disability and a reduction in functional status, which thereby decreases quality of life.[13] The Centers for Disease Control and Prevention reported in 1997 that, in the United States, the LEA rate among those with diabetes was 28 times that of those without diabetes.[14] In another report by Bertele et al[15] in 1999, a 6-month amputation rate of 12% and a 1-year mortality rate of 19.1% were observed in CLI patients. In a study of Medicare patients who underwent lower extremity amputation from 2003 to 2006, variation was evident in the intensity of vascular care given before amputation, which was likely due to regional practice patterns.[11] Up to 80% of patients in various regions throughout the United States received a vascular procedure within 1 year of amputation, and less than 12% of patients in other regions underwent a vascular procedure 1 year before amputation.

In addition, patients with CLI have an increased risk of sustaining cardiovascular ischemic events. Approximately 1% of patients with PAD are diagnosed with CLI, of which 50% will have died 5 years after diagnosis, and 70% 10 years after diagnosis.[16] The recent trial by Conte et al observed a 2.7% perioperative mortality rate, 5.2% graft occlusion rate, 16% mortality rate at 1 year, 80% secondary patency rate at 1 year, and an 88% limb salvage rate at 1 year.[17]

Although previous studies have shed some light on the burden of CLI, there has been no large, retrospective population-based study of the direct estimation of incidence and prevalence, which is the primary purpose of this paper. Using the United States national Medicare dataset, we estimated the prevalence and incidence of CLI for the overall population and for different segments in terms of age, gender, race, and diabetic status. We also estimated factors associated with the high likelihood of nontraumatic amputation, leg revascularization and mortality among the CLI population. The study examined the significance of difference of the following comparisons: non-CLI vs new CLI patients, non-CLI vs CLI stage III patients, and non-CLI vs CLI stage IV patients, in terms of demographic variables and comorbidities.

Method

Data Sources and Study Population

We used the 100% Medicare inpatient, outpatient, and denominator file, which includes final action claims data submitted by inpatient hospital providers and institutional outpatient providers. Data available for each encounter included selected demographic variables (age, gender, geographic location) and information on variables related to hospitalizations or outpatient facilities. Because 98% of all US patients over age 65 have health insurance coverage through Medicare, using Medicare claims data reflects the most complete information about the real-world burden of CLI.

Patients with CLI were identified using International Classification of Diseases 9th Revision Clinical Modification (ICD-9-CM) diagnosis codes (440.22: rest pain, 440.23: ulceration, 440.24: gangrene) recorded in inpatient and outpatient claims files for Medicare beneficiaries age 65 years and older from January 2007 to December 2008. Moreover, for sensitivity analysis, we combined Current Procedural Terminology (CPT) codes (37205, 37206, 37207, 37208, 37215, 37216, C1874, C1875, C1876, C1877, C2617, C2625, 355xx, 356xx, 35700, 2788x, 27590, 27591,27592, 27594, 27596, 27598, 27599, 28800, 28805, 28810, 28820, 28825) and ICD-9-CM codes to determine incidence, a measure of the risk of developing a new condition within a specified period of time as well as prevalence, a measure of the total number of cases of disease in a population. Medicare managed-care patients were excluded because previous services provided were not consistently captured by Medicare during the time of this study.

To compare baseline characteristics of CLI patients versus non-CLI patients and examine the association between baseline characteristic and death, as well as outcome events such as nontraumatic amputation (ICD-9-CM codes: 84.11-84.19, 997.60, 997.61, 997.62, 997.69, V497.x, and V521.x) and leg revascularization (ICD-9-CM codes: 38.04, 38.06, 38.08, 38.14, 38.16, 38.18, 38.44, 38.46, 38.48, 39.25, 39.26, 39.29, 39.49, 39.57, 39.58, 39.59, 39.90, and 00.55), a minimum of 1 year of continuous Medicare enrollment before and after the date of diagnosis of CLI was required, patients who did not meet this requirement were excluded. Presence of comorbidities such as but not limited to diabetes, hypertension, renal disease, chronic heart failure, stroke, angina pectoris, myocardial infarction, renal failure, cancer, hyperlipidemia, and proliferative retinopathy were also identified from the Medicare claims database.

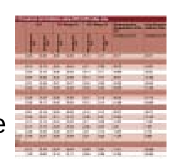
Statistical Methodology

Year, age, gender, ethnic, and diabetes-specific annual population prevalence and incidence rates of CLI were estimated using the direct standardization method.[18] In addition, age, gender, ethnic, and diabetes-specific incidence rates of nontraumatic amputation and leg revascularization following CLI were also estimated.

Descriptive statistics were calculated as means ± standard deviation (SD) and percentages. Differences between the cohorts were analyzed using the *t* test, Mann-Whitney *U* test, and chi-square test. The Cox proportional hazards model was applied, using the same variables, to examine the risk factors for mortality and outcome events. Statistical analyses were performed using SAS v9.2 software.

No patient identity or medical records were disclosed for the purposes of this study except in compliance with applicable law. Because the core study did not involve the collection, use, or transmittal of individual identifiable data, Institutional Review Board (IRB) approval to conduct this study was not required. Both the data set and the security of the data meet the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

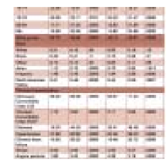
Results



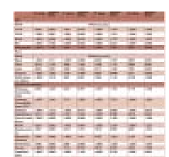
[4]Table 1 shows the year, age, gender, ethnicity, and diabetes-specific annual prevalence and incidence rates of CLI in the United States. In patients over the age of 65, the overall prevalence and incidence of CLI were 0.23% and 0.20% respectively and remained constant in each year. When considering the age-specific annual rates, a progressive rise in prevalence and incidence was observed in patients from 65 years to 69 years of age (prevalence: 0.15%, incidence: 0.13%) to patients aged 85+ (prevalence: 0.36%, incidence: 0.31%). The overall rates among males surpassed those of females by approximately 8 cases per 10,000 persons/year in prevalence and 6 cases per 10,000 persons/year in incidence.

Trends in race-specific prevalence and incidence exhibited that black patients had the highest rate of claims for CLI (prevalence: 0.49%, incidence: 0.41%), while Asian patients had the lowest (prevalence: 0.12%, incidence: 0.10%). After adjustment for age, gender and diabetes status, CLI incidence and prevalence rates in black patients were approximately 2.3 times higher than in white patients. Overall, the annual CLI prevalence and incidence rates were remarkably higher in patients who had diabetes (prevalence: 1.03%, incidence: 0.86%), which were approximately 9 times higher than those of patients who did not. Similar trends in prevalence and incidence were detected for CLI stages III and IV.

In terms of nontraumatic amputation events and leg revascularization events after CLI, the overall incidence rates of these events in new CLI patients were 25.17% and 29.71% respectively, with 29.34% and 31.10% in males and 21.09% and 28.36% in females. The incidence in the age stratum 65-69 was 28.76% and 34.95% respectively, which decreased with each successive age stratum. This is probably due to a healthy survivor effect. Trends in ethnic-specific incidence exhibited different patterns: black patients had the highest incidence of nontraumatic amputation (27.84%), whereas white patients had the highest incidence of leg revascularization (32.77%). Compared to patients without diabetes, diabetic patients had higher incidence of nontraumatic amputation but a comparable incidence of leg revascularization.

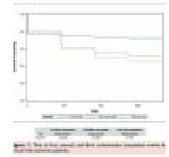


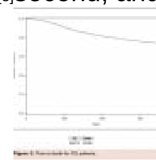
[5]A total of 68,074 new patients with CLI in 2007 were identified: 16,724 in CLI Fontaine stage III (ICD-9-CM code: 440.22) and 51,350 in CLI Fontaine stage IV (ICD-9-CM codes: 440.23, 440.24) (Table 2). In comparison with patients without CLI, those with CLI were more likely to be male, to be black, to be in a higher age stratum, and to have higher Elixhauser index scores (based on 30 ICD-9-CM comorbidity flags and diagnosis-related groups to differentiate secondary diagnosis from comorbidities), and Charlson comorbidity index scores (an assigned weight ranging from 1 to 6 according to disease severity for 19 conditions) (2.65 vs 1.10, $P<.0001$) and other comorbid diseases such as diabetes (44.53% vs 19.25%, $P<.0001$), hypertension (65.95% vs 47.98%, $P<.0001$) and renal failure (25.75% vs 7.13%, $P<.0001$). A similar trend was observed with disease severity in comparison between CLI patients. Even though patients in CLI stage IV were less likely to have angina pectoris, cancer, and hyperlipidemia, they were more likely to be male, to be black, to be in a higher age stratum, to suffer from diabetes before the index date (48.48% vs 32.41%, $P<.0001$), and to have renal failure (29.04% vs 15.66%, $P<.0001$).

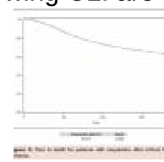


[6]In multivariate Cox proportional hazard regression models adjusted for age, gender, ethnicity, and baseline comorbidities, risk factors significantly associated with the occurrence of nontraumatic amputation and leg revascularization were found (Table 3). Patients in a higher age stratum and who were female were less likely to have nontraumatic amputation and leg revascularization events in 1 year after CLI among patients newly diagnosed with CLI. Black patients had a hazard ratio (HR) of 1.311 for the development of amputation but only 0.869 for the development of leg revascularization in comparison with white patients. Indeed, in the year following CLI diagnosis, white patients had the highest incidence of revascularization (32.8%), and black patients the highest incidence of amputation (27.8%). Various relationship patterns between baseline comorbidities and follow-up events were observed. Patients with higher Charlson comorbidity index scores (HR 1.034) and diabetes (HR 1.21) were significantly associated with an increased risk of 1-year nontraumatic amputation events, whereas patients with myocardial infarction (HR 1.08) and hyperlipidemia (HR 1.1) were significantly related to a higher risk of 1-year leg revascularization events. In addition, patients in a more severe stage of CLI had a higher risk of nontraumatic amputation (HR 3.044) but a lower risk of leg revascularization (HR 0.715).

Table 3 also presents a multivariable Cox model that simultaneously relates these baseline predictors to the risk of 1-year death after CLI and after nontraumatic amputation following CLI. Compared with patients ages 65 to 69, a clear monotonic increase in mortality hazard with increasing age was observed. Male patients (HR 1.087) were also associated with a pronounced increase in hazard of death after CLI. Although there was no evidence of a statistical interaction between baseline cancer ($P=.39$), baseline angina pectoris ($P=.18$), or baseline myocardial infarction ($P=.27$) and mortality risk in patients with CLI, there was a significant link between CLI stage IV and baseline comorbidities, such as the Charlson and Elixhauser comorbidity indexes; chronic heart failure, stroke, and renal failure; and increased mortality risk. In addition, black patients had a lower probability of revascularization and a higher probability of amputation compared to white patients (after adjustment for age, gender, CLI severity, and comorbidities), and displayed a longer time to first revascularization and a shorter time to amputation.



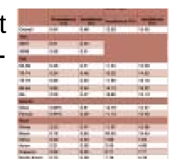




[7]Of the 68,074 patients who were newly diagnosed with CLI in 2007, a clear trend for recurrence of nontraumatic amputation was observed: 22,810 (33.51%) patients received the first nontraumatic amputation in 1 year after CLI, 14,534 (21.35%) patients received the second, and 9,756 (14.33%) patients received the third (Figure 1). The trend, however, was not persistent for all outcome events. When considering leg revascularization, only 23,240 (34.14%) patients received the first leg revascularization, 4,445 (6.53%) patients received the [8]second, and 901 (1.32%) received the third (Figure 2). In contrast with nontraumatic amputation, leg revascularizations were less likely to be recurrent in CLI patients.

One-year survival rates and curves after CLI and nontraumatic amputations following CLI are presented in Figure 3. 20,618 (30.29%) out of 68,074 [9]patients died within 1 year after CLI diagnosis, and 8,296 (40.42%) out of 20,527 patients with an amputation in the same year after CLI diagnosis, in 2007, died within 1 year after their first nontraumatic amputation.

Sensitivity Analysis



[10]Sensitivity analysis (Table 4) explores whether prevalence and incidence of CLI are different between the use of different coding methods, namely between ICD-9-CM codes only and ICD-9-CM codes together with CPT codes. Compared with ICD-9-CM codes only, the estimated overall prevalence and incidence significantly increased after incorporating CPT codes, from 0.23% to 0.54% and 0.20% to 0.48% respectively. A progressive rise by year in the overall population was observed, with 0.51% in 2007 and 0.58% in 2008 for prevalence, and 0.45% in 2007 and 0.51% in 2008 for incidence.

When considering the age-specific rates, there was a significant increase of prevalence and incidence from the age 65-69 stratum to the age 80-84 stratum. Once above age 85, the trend of increase no longer persisted. Similar to the pattern when using ICD-9-CM codes only, ethnic-specific prevalence and incidence using both ICD-9-CM and CPT codes attained its highest value in black patients and lowest in Asian patients. Approximately a five-fold pronounced increase in rates also demonstrated a significant association between diabetes and the development of CLI. As depicted in Table 4, the incidence of nontraumatic amputation and leg revascularization events following CLI showed a significant decrease in overall and age, gender, ethnic, and diabetes-specific rates, with an overall rate of 12.53% for nontraumatic amputation and 15.42% for leg revascularization, which is most likely due to the increase in the number of patients identified with CLI using both ICD-9-CM and CPT codes.

Discussion

Researchers employed mostly disease progression-based approaches to previously estimate prevalence and incidence of CLI in the United States. CLI prevalence was derived from the PAD population or from specific high-risk populations, such as diabetic or chronic kidney disease patients.[19] To our knowledge, this is the first nationwide study on the direct estimates of incidence and prevalence of CLI development. Results from this analysis show that the prevalence and incidence of CLI increase with age and are higher in males than in females. After incorporating CPT codes, the prevalence and incidence rates were also higher in each successive age group, except for those who were older than 85. Similar to a previous study of PAD reported by Allison et al,[20] the difference in ethnic groups leads to a difference in prevalence, which is significantly higher in the black population. This was also reported by the Trans-Atlantic Inter-Society Consensus (TASC II) for the Management of Peripheral Arterial Disease working group, explaining that this increased risk in the black population was not explained by the higher levels of other risk factors such as diabetes, hypertension, or obesity.[3]

In addition, differences in CLI patient management among the US population, according to ethnic origin, leading to different outcomes (revascularization or amputation) also was recently shown by Vogel et al[21] and Goodney et al[11] Vogel et al observed an increased probability of 30-day amputation after tibioperoneal percutaneous transluminal angioplasty in black patients compared to white patients. Higher levels of incidence rates of dysvascular amputations in black patients were already demonstrated in one study done by Dillingham et al. using hospital discharges involving dysvascular amputation data in Maryland between 1986 and 1997.[22] They concluded that African-Americans were 2 to 4 times more likely to lose a lower limb than white persons of similar age and gender. This confirms our findings in such differences according to ethnicity. In our study, black patients had a lower probability of revascularization and a higher probability of amputation compared to white patients (after adjustment on age, gender, CLI severity, comorbidities) and displayed a longer time to first revascularization and a shorter time to amputation.

This analysis also demonstrated that although the diagnosis of CLI is straightforward, the care of many patients with CLI, a disease process with tremendous cardiovascular burden, is not straightforward. Given that CLI patients have complex comorbidities, including diabetes, hypertension, renal disease, and advanced age that vary from patient to patient, determining which patient should be offered surgical intervention for nontraumatic amputation or leg revascularization is difficult.

The “ideal” CLI treatment pathway recommended by the Society for Vascular Surgery and the European Society for Vascular Surgery suggests that 70% of patients should be revascularized, and that the remaining 30% undergo primary amputation (15%) or palliative therapy (15%). The reality is quite different. The UK BASIL study found that less than 30% of patients were considered suitable for revascularization (bypass or angioplasty).[23] Our study indicates that as many as 33% of new CLI patients may undergo primary amputation within 1 year after diagnosis.

As a retrospective analysis using a claims database, our study contained some limitations. First, it is based on retrospective records, which cannot provide full information on how physicians decide whether to code CLI. While a determination of CLI was based on the clinicians’ heightened awareness of and the ability to diagnose these conditions of PAD, it is possible that inappropriate documentation may result from other factors or from ineffective diagnostic tests. Among PCPs, it has been demonstrated that knowledge of PAD, and presumably also CLI, is quite low.

Even if patients with rest pain are identified at the primary care level, they may frequently be referred to the wrong specialist group. This may explain why patients with rest pain “only” are not well-diagnosed compared to patients with ulcers/gangrene, and that could be a possible explanation for the fact that in the dataset using ICD-9-CM codes, we found one-quarter of patients with CLI stage III and three-quarters with CLI stage IV codes. A Michigan Cardiovascular Institute survey found that only 15% of doctors referred their patients to vascular surgeons. Orthopedic specialists (suspected osteoarthritis) and neurologists (suspected neuropathy) are likely two important incorrect referral sources for patients with rest pain.[24]

This ratio (CLI stage III vs CLI stage IV) may also be explained by the fact that our dataset included only inpatient or outpatient hospital data. Nonetheless, it is unlikely that a patient is not captured in the Medicare files used for the study over the 3-year period (3 years of data from January 2007 to December 2008 with a minimum of 1-year continuous Medicare enrollment before and after the date of diagnosis of CLI) by having at least one visit in an inpatient or outpatient hospital setting within our data period, due to the severity of the disease and the need for hospital management (even higher for stage IV patients).

Lastly, because we had only quarter information for events in our dataset, our time-to-event analysis is less precise than what it would have been if we had the exact dates for the events of interest.

However, the Medicare database was validated and has been used for many retrospective studies. While claims data are extremely valuable for treatment patterns, health care resource utilization, and costs, these data are collected for the purpose of payment rather than research. Absence of a diagnosis code on a medical claim is not necessarily proof of the absence of disease, as diagnoses may be incorrectly coded or included as rule-out criteria rather than actual disease. However, we applied sensitivity analysis to this study in order to explore the effect of these problems, showing us a more than two-fold increase of the CLI prevalence and incidence rates, and a more than two-fold decrease in the prevalence/incidence rates of events after CLI diagnosis. Finally, the difference in amputation rates between diabetic and nondiabetic patients showed that diabetes should be an important factor in the decision whether to amputate or not. We did not find any significant differences between revascularization by diabetes status.

Conclusion

The overall prevalence (0.23%) and incidence (0.20%) of CLI in a population-based elderly cohort in the United States increased with age, increased with diabetes status, and was higher in male and black patients. In addition, CLI patient management seems to differ among the US population according to ethnic origin, leading to different outcomes (revascularization or amputation). Therefore, understanding the risk of clinical CLI among the at-risk population would serve as a guide for proper treatment.

References

1. O'Hare AM, Glidden DV, Fox CS, Hsu CY. High prevalence of peripheral arterial disease in persons with renal insufficiency: results from the National Health and Nutrition Examination Survey 1999-2000. *Circulation.* 2004;109(3):320-323.
2. Hernando FJS, Conejero AM. Peripheral artery disease: patheophysiology, diagnosis and treatment. *Rev Esp Cardiol.* 2007;60(9):969-982.
3. Norgren L, Hiatt WR, Dormandy JA, et al. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). *Eur J Vasc Endovasc Surg.* 2007;33:S1-S75.
4. Hirsch AT, Haskal ZJ, Hertzer NR, et al. ACC/AHA 2005 Practice Guidelines for the Management of Patients with Peripheral Arterial Disease (Lower Extremity, Renal, Mesenteric, and Abdominal Aortic): A Collaborative Report from the American Association. *Circulation.* 2006;113(11):e463-e654.
5. Sanders LJ. Johns Hopkins Guides: Gangrene and critical limb ischemia. Updated November 11, 2011. http://www.hopkinsguides.com/hopkins/ub/view/Johns_Hopkins_Diabetes_Guid... [11]
6. Abela GS, ed. *Peripheral Vascular Disease: Basic Diagnostic And Therapeutic Approaches.* Philadelphia, PA: Lippincott Williams & Wilkins; 2004.
7. Varty K, Nydahl S, Butterworth P, et al. Changes in the management of critical limb ischaemia. *Br J Surg.* 1996;83(7):953-956.
8. Rothwell PM, Coull AJ, Silver LE, et al.; for the Oxford Vascular Study. Population-based study of event-rate, incidence, case fatality, and mortality for all acute vascular events in all arterial territories. *Lancet.* 2005;366(9499):1773–1783.
9. Cimminiello C. PAD: Epidemiology and pathophysiology. *Thromb Res.* 2002;106(6):V295-V301.
10. Weitz JI, Byrne J, Clagett GP, et al. Diagnosis and treatment of chronic arterial insufficiency of the lower extremities: a critical review. *Circulation.* 1996;94(11):3026–3049.
11. Goodney PP, Travis LL, Nallamothu BK, et al. Variation in the use of lower extremity vascular procedures for critical limb ischemia. *Circ Cardiovasc Qual Outcomes.* 2012;5(1):94-102.
12. The SAGE Group reports that in 2007 approximately 2.8 million people in Western Europe suffered from critical limb ischemia [press release]. Atlanta, GA: SAGE Group. Oct. 20, 2008. http://thesagegroup.us/press%20releases/PressReleaseCLI%20W%20Eu08.html [12]
13. Peters EJ, Childs MR, Wunderlich RP, Harkless LB, Armstrong DG, Lavery LA. Functional status of persons with diabetes-related lower-extremity amputations. *Diabetes Care.* 2001;24(10):1799-1804.
14. Centers for Disease Control and Prevention (CDC). Hospital discharge rates for non traumatic lower extremity amputation by diabetes status--United States, 1997. *MMWR Morb Mortal Wkly Rep.* 2001;50 (43):954-958.
15. Bertelè V, Roncaglioni MC, Pangrazzi J, Terzian E, Tognoni EG. Clinical outcome and its predictors in 1560 patients with critical leg ischaemia. Chronic Critical Leg Ischemia Group. *Eur J Vasc Endovasc Surg.* 1999;18(5):401-410.
16. Watelet J, Soury P, Menard JF, et al. Femoropopliteal bypass: in situ or reversed vein grafts? Ten-year results of a randomized prospective study. *Ann Vasc Surg.* 1997;11(5):510-519.
17. Conte MS, Bandyk DF, Clowes AW, et al; PREVENT III Investigators. Results of PREVENT III: a multicenter, randomized trial of edifoligide for the prevention of vein graft failure in lower extremity bypass surgery. *J Vasc Surg.* 2006;43(4):742-751; discussion 751.
18. Fleiss JL. *Statistical Methods for Rates and Proportions.* 2nd ed. New York, NY: John Wiley and Sons; 1981:244-246.
19. Critical limb ischemia volume I: Prevalence, market opportunities and analysis of the two most common comorbidities: Diabetes and chronic kidney disease. Atlanta, GA: SAGE Group; 2010. http://thesagegroup.us/pages/reports/cliepiusreprt.php [13]
20. Allison MA, Ho E, Denenberg JO, et al. Ethnic-specific prevalence of peripheral arterial disease in the United States. *Am J Prev Med.* 2007;32(4):328-333.
21. Vogel TR, Dombrovskiy VY, Carson JL, Graham AM. In-hospital and 30-day outcomes after tibioperoneal interventions in the US Medicare population with critical limb ischemia. *J Vasc Surg.* 2011;54(1):109-115.

22. Dillingham TR, Pezzin LE, MacKenzie EJ. Racial differences in the incidence of limb loss secondary to peripheral vascular disease: a population-based study. *Arch Phys Med Rehabil.* 2002;83(9):1252-1257.
23. Adam DJ, Beard JD, Cleveland T, et al; BASIL trial participants. Bypass versus angioplasty in severe ischaemia of the leg (BASIL): Multicentre, randomised controlled trial. *Lancet.* 2005;366(9501):1925-1934.
24. Hirsch AT, Criqui MH, Treat-Jacobson D, et al. Peripheral arterial disease detection, awareness, and treatment in primary care. *JAMA.* 2001;286(11):1317-1324.

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