

# Nationwide Trends of Hospital Admission and Outcomes Among Critical Limb Ischemia Patients



From 2003–2011

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## ABSTRACT

**BACKGROUND** Critical limb ischemia (CLI) continues to be a major cause of vascular-related morbidity and mortality in the United States.

**OBJECTIVES** The study sought to characterize the trends in hospitalization of U.S. patients with CLI from 2003 to 2011, using the Nationwide Inpatient Sample. We compared the cost utilization and in-hospital outcomes of endovascular and surgical revascularization procedures for CLI.

**METHODS** CLI and revascularization procedures were identified using International Classification of Diseases-Ninth Edition-Clinical Modification codes. In-hospital mortality and amputation were coprimary outcomes. Length of stay (LOS) and cost of hospitalization were secondary outcomes.

**RESULTS** We included a total of 642,433 admissions with CLI across 2003 to 2011. The annual rate of CLI admissions has been relatively constant across 2003 to 2011 (~150 per 100,000 people in the United States). There has been a significant reduction in the proportion of patients undergoing surgical revascularization from 13.9% in 2003 to 8.8% in 2011, while endovascular revascularization has increased from 5.1% to 11.0% during the same time period. This was accompanied by a steady reduction in the incidence of in-hospital mortality and major amputation. Compared to surgical revascularization, endovascular revascularization was associated with reduced in-hospital mortality (2.34% vs. 2.73%,  $p < 0.001$ ), mean LOS (8.7 days vs. 10.7 days,  $p < 0.001$ ), and mean cost of hospitalization (\$31,679 vs. \$32,485,  $p < 0.001$ ) despite similar rates of major amputation (6.5% vs. 5.7%,  $p = 0.75$ ).

**CONCLUSIONS** While CLI admission rates have remained constant from 2003 to 2011, rates of surgical revascularization have significantly declined and endovascular revascularization procedures have increased. This has been associated with decreasing rates of in-hospital death and major amputation rates in the United States. Despite multiple adjustments, endovascular revascularization was associated with reduced in-hospital mortality compared to surgical revascularization during 2003 to 2011. (*J Am Coll Cardiol* 2016;67:1901-13)

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It has been estimated that 10 million individuals are currently suffering from critical limb ischemia (CLI) in the United States (1,2). In addition to pain, decreased quality of life, and immobility, amputation and death are major adverse effects of CLI (3). Previous data from the Nationwide Inpatient Sample (NIS) demonstrated a marked rise in endovascular revascularization during 1996 to 2005 and was temporally associated with a reduction in the rates

of major amputation (4). However, this relationship is not causal and may be related to better medical and overall wound care. Importantly, the rise of endovascular procedures, in general, has raised some concerns (5). We conducted a comprehensive analysis using the large nationwide registry from 2003 to 2011 to expand on these previous findings and examine the overall CLI hospital admissions, cost utilization, and outcomes (mortality and major



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Manuscript received January 30, 2016; revised manuscript received February 9, 2016, accepted February 11, 2016.

## ABBREVIATIONS AND ACRONYMS

**CI** = confidence interval

**CLI** = critical limb ischemia

**HCUP** = Healthcare Cost and Utilization Project

**ICD-9-CM** = International Classification of Diseases-Ninth Edition-Clinical Modification

**LOS** = length of stay

**NIS** = Nationwide Inpatient Sample

**OR** = odds ratio

**PAD** = peripheral artery disease

**SES** = socioeconomic status

amputations) between surgical and endovascular procedures for CLI.

## METHODS

**DATA SOURCE.** Data were obtained from the NIS from 2003 to 2011, which is sponsored by the Agency for Healthcare Research and Quality as a part of the Healthcare Cost and Utilization Project (HCUP). The NIS across 2003 to 2011 contains discharge level data from approximately 8 million hospitalizations annually from about 1,000 U.S. hospitals. The NIS is designed to represent a 20% stratified sample of all hospitals in the country. Criteria used for stratified sampling of hospitals into the NIS include location

(urban or rural), teaching status, geographic region, patient volume and hospital ownership. Every hospital has been classified into small, medium, and large size on the basis of the number of beds available for in-hospital admissions. The cutpoints for classification differ according to geographic location of the hospital and the teaching status (6).

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**STUDY POPULATION.** The NIS provides up to 15 diagnoses and 15 procedures for each hospitalization record for the years 2003 to 2009. The number of diagnoses coded in the database was expanded to 25 for the years 2010 to 2011. All these have been coded using the standard International Classification of Diseases-Ninth Edition-Clinical Modification (ICD-9-CM) codes. All adult hospitalizations (>18 years of age) with a diagnosis code corresponding to CLI were included in our study. The list of diagnosis codes used to identify patients with CLI and peripheral artery disease (PAD) is shown in [Online Table 1](#). The first diagnosis in the database is referred to as the principal diagnosis and is considered the primary reason for admission to the hospital. The ICD-9-CM codes for surgical and endovascular procedures performed during the hospitalization are shown in [Online Table 2](#). Sequential revascularization was defined as both endovascular and surgical revascularization performed during a single hospital admission. We used the Charlson Comorbidity Score to quantitate the comorbidity of each admitted patient on the basis of 17 categories of diagnoses (7). In addition, the NIS database provides 29 Elixhauser comorbidities on each hospital admission, on the basis of standard ICD-9-CM codes (8). These were used to derive the prevalence of hypertension, diabetes, obesity, and chronic kidney disease in our population.

**STUDY OUTCOMES.** Our study aimed to evaluate the trend in the CLI hospitalization of adults across 2003 to 2011. To calculate the annual rate of admissions among CLI patients, we divided the total of number of hospitalizations in a given year by the U.S. census population for that year and expressed it as a rate per 100,000 U.S. population. This methodology has been described and validated by HCUP and other recent studies (9,10). We also evaluated the changes in the distribution of demographic and clinical characteristics among these patients. In-hospital mortality and major amputation (amputation above the ankle) were coprimary endpoints of our study. Secondary endpoints included resource utilization, which was assessed by evaluating the trends in revascularization procedures, length of stay (LOS), and total cost of hospitalization across the study period. The NIS database provides the total charges associated with each hospital stay that was claimed by the respective hospital. The total charges of each hospital stay were converted to cost estimates using the group average all-payer in-hospital cost and charge information from the detailed reports by hospitals to the Centers for Medicare and Medicaid Services. All costs and charges were then converted to projected estimates for the year 2015, after accounting for annual inflation rates on the basis of consumer price index data available from the Bureau of Labor Statistics (11). Furthermore, we compared the primary and secondary outcomes between the endovascular, surgical and sequential revascularization in the study cohort, across 2003 to 2011.

**STATISTICAL ANALYSIS.** Survey statistics traditionally used to analyze complex semi-random survey designs were employed to analyze these data (12,13). Because the data from NIS represent a collection of scattered hospital clusters, analysis was structured to account for a complex, multistage, probability sampling. NIS recommends the use of “strata” for constructing analysis clusters, which include geographic census region, hospital ownership, teaching status, urban/rural location and bed size. Furthermore, the analysis is further stratified into individual hospitals, which serve as primary sampling units for the analysis. In the NIS, each hospital admission is linked to a “discharge weight” that can be utilized to calculate projected national estimates for all hospital-related outcomes, after accounting for the hierarchical structure of the dataset. To facilitate analysis of trends across multiple years, the Agency for Healthcare Research and Quality has developed new discharge trend weights (TRENDWT) for NIS data to create national estimates for trends analysis (14). Although TRENDWT was developed for trends analysis, it can be

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