Session IV: Joint Venture session
mit der CLI Global Society (USA)

CLI Global Society: Need for awareness to safe limbs and lifes

Thomas Zeller On behalf of the CLI Global Society Board

Jihad A. Mustapha, MD; Barry T. Katzen, MD; Richard F. Neville, MD, Robert A. Lookstein, MD; Thomas Zeller, MD; Larry E. Miller, PhD; Vickie R. Driver, DPM; and Michael R. Jaff, DO

CLI GLOBAL SOCIETY

Faculty Disclosure: Thomas Zeller, MD

For the 12 months preceding this presentation, I disclose the following types of financial relationships:

- **Honoraria received from:** Abbott Vascular, Veryan, Biotronik, Boston Scientific Corp., Cook Medical, Gore & Associates, Medtronic, Philips-Spectranetics, Shockwave
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- **Common stock:** QT Medical

CLI GLOBAL SOCIETY

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The CLI Global Society's mission is to improve quality of life by preventing amputations and death due to critical limb ischemia.

#CLI Fighters

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CLI Global Society Board Members

Barry T. Katzen, MD, FACR, FACC, FSIR (President)
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CLI GLOBAL SOCIETY

The Critical Limb Ischemia (CLI) Global Society was formed by passionate leaders to address the unmet need of CLI. It was incorporated on January 11, 2016 and received 501(c)(6) status on June 20, 2016.

The CLI Global Society is the only organization that is solely dedicated to patients and the public health aspect of CLI.

The intent of the Society is to work toward a coalition of multiple organizations that share an interest in CLI to facilitate implementation of goals that would lead to ideal management of this impactful problem. The best way to improve awareness and enhance the way CLI is treated is through a coalition of like-minded organizations that can address clinical, coding, and reimbursement points of view. The Society will also work with like-minded organizations around the world to globally improve treatment and outcomes in patients with CLI.

CLI GLOBAL SOCIETY

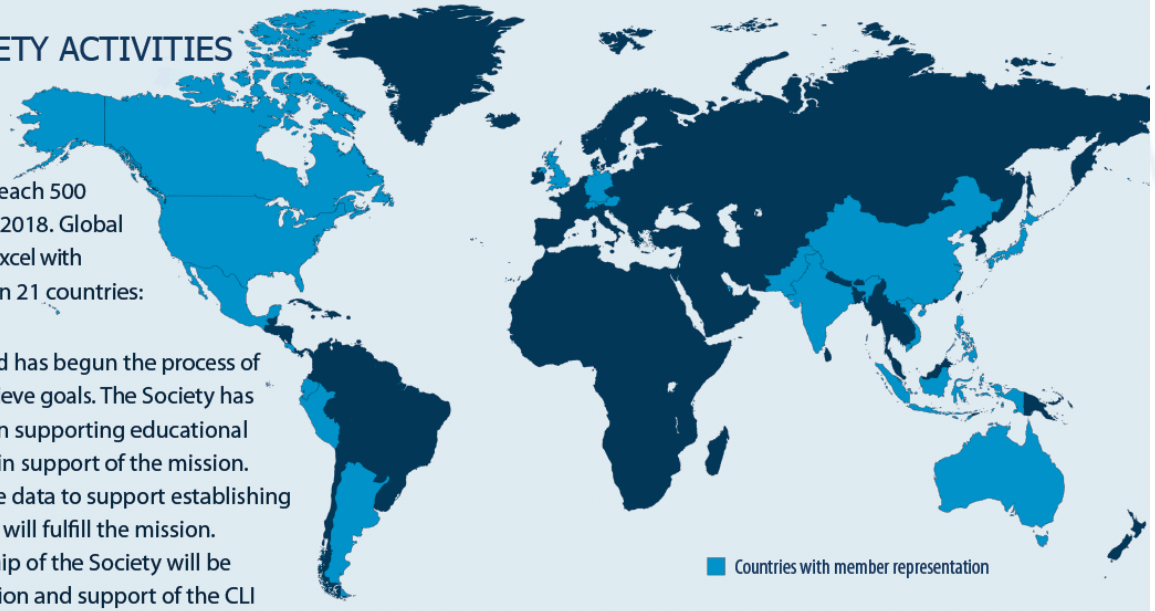
The Society has developed committees tasked with working on issues that include development of a unified definition of CLI; supporting the public health urgency of this disease by addressing CLI population health issues; analyzing technical alternatives to CLI revascularization procedures by supporting uniform quality metrics; and developing resource based algorithms based on proven clinical practice and education for patients, referring physicians, treating physicians, and third party payers.

CLI GLOBAL SOCIETY

CLI Global Society Eager to Collaborate on a Global Level

CURRENT SOCIETY ACTIVITIES

Membership has grown significantly with a firm benchmark in place to reach 500 members by the end of 2018. Global presence continues to excel with member representation in 21 countries:



An active advisory board has begun the process of creating alliances to achieve goals. The Society has been actively involved in supporting educational content focused on CLI in support of the mission. A priority is to create the data to support establishing public health goals that will fulfill the mission. The growing membership of the Society will be enhanced by collaboration and support of the CLI components of educational meetings.

Consensus activities with partnering organizations now include society educational sessions and/or member discounts at:

1st National Interdisciplinary Congress on Critical Limb Ischemia Treatment
American Professional Wound Care Association (APWCA) National Clinical Conference
Amputation Prevention Symposium (AMP)
Cardiovascular and Interventional Radiological Society of Europe (CIRSE)
International Symposium on Endovascular Therapy (ISET)
New Cardiovascular Horizons (NCVH)
Symposium on Advanced Wound Care (SAWC) Spring and Fall
Visionary Endovascular & Vascular Education (VERVE)

Founding Board Members:

Alan T. Hirsch, MD
Michael R. Jaff, DO
Barry T. Katzen, MD
Jihad A. Mustapha, MD
Dierk Scheinert, MD
Frank J. Veith, MD

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ORIGINAL RESEARCH

American Heart Association | American Stroke Association

Determinants of Long-Term Outcomes and Costs in the Management of Critical Limb Ischemia: A Population-Based Cohort Study

Jihad A. Mustapha, MD; Barry T. Katzen, MD; Richard F. Neville, MD; Robert A. Lookstein, MD; Thomas Zeller, MD; Larry E. Miller, PhD; Michael R. Jaff, DO

Background—The optimal treatment for critical limb ischemia remains controversial owing to conflicting conclusions from previous studies.

Methods and Results—We obtained administrative claims on Medicare beneficiaries with initial critical limb ischemia diagnosis in 2011. Clinical outcomes and healthcare costs over 4 years were estimated among all patients and by first treatment (endovascular revascularization, surgical revascularization, or major amputation) in unmatched and propensity-score–matched samples. Among 72 199 patients with initial primary critical limb ischemia diagnosis in 2011, survival was 46% (median survival, 3.5 years) and freedom from major amputation was 87%. Among 9942 propensity-score–matched patients (8% rest pain, 26% ulcer, and 66% gangrene), survival was 38% with endovascular revascularization (median survival, 2.7 years), 40% with surgical revascularization (median survival, 2.9 years), and 23% with major amputation (median survival, 1.3 years; $P<0.001$ for each revascularization procedure versus major amputation). Corresponding major amputation rates were 6.5%, 9.6%, and 10.6%, respectively ($P<0.001$ for all pair-wise comparisons). The cost per patient year during follow-up was $49 700, $49 200, and $55 700, respectively ($P<0.001$ for each revascularization procedure versus major amputation).

Conclusions—Long-term survival and cost in critical limb ischemia management is comparable between revascularization techniques, with lower major amputation rates following endovascular revascularization. Primary major amputation results in shorter survival, higher risk of subsequent major amputation, and higher healthcare costs versus revascularization. Results from this observational research may be susceptible to bias because of the influence of unmeasured confounders. **(*J Am Heart Assoc.* 2018;7:e009724. DOI: 10.1161/JAHA.118.009724.)**

Key Words: amputation • cost • critical limb ischemia • Medicare • peripheral artery disease • revascularization

Critical limb ischemia (CLI) represents the most advanced manifestation of peripheral artery disease and is categorized as ischemic rest pain, nonhealing ischemic ulceration, or gangrene. Patients with CLI often present with multilevel peripheral artery disease that prevents the arterial supply from meeting the metabolic demands of tissue at rest. Prompt revascularization by endovascular or open surgical procedures is indicated following the diagnosis of CLI diagnosis to preserve the limb and maintain limb function.[1] However, management of CLI remains highly controversial, particularly when selecting an initial revascularization strategy. In an analysis of 7900 CLI patients from the Vascular Quality Initiative, 3-year survival was lower with endovascular versus surgical revascularization strategies (70% versus 78%).[2] In the First-Line Treatments in Patients With Critical Limb Ischemia (CRITISCH) registry of 1200 CLI patients, there was no difference in 1-year mortality or major amputation between revascularization methods.[3] The randomized BASIL (Bypass versus Angioplasty in Severe Ischaemia of the Leg) study also found no differences in long-term mortality or major amputation when comparing endovascular versus surgical revascularization.[4] Although primary major amputation for CLI is associated with impaired mobility, high cost, high risk of contralateral limb amputation, and poor prognosis,[5,6] this procedure may be indicated in some patients with cognitive impairment, nonambulatory status,

From the Advanced Cardiac & Vascular Amputation Prevention Centers, Grand Rapids, MI (J.A.M.); Division of Interventional Radiology, Miami Cardiac and Vascular Institute, Miami, FL (B.T.K.); Division of Vascular Surgery, Department of Surgery, Inova Heart and Vascular Institute, Inova Fairfax Medical Campus, Falls Church, VA (R.F.N.); Department of Radiology, Icahn School of Medicine at Mount Sinai, New York, NY (R.A.L.); Department of Angiology, Universitäts-Herzzentrum Freiburg-Bad Krozingen, Bad Krozingen, Germany (T.Z.); Miller Scientific Consulting, Asheville, NC (L.E.M.); Newton-Wellesley Hospital, Newton, MA (M.R.J.).

Accompanying Tables S1, S2 and Figures S1 through S4 are available at https://www.ahajournals.org/doi/suppl/10.1161/JAHA.118.009724

Correspondence to: Jihad A. Mustapha, MD, Advanced Cardiac & Vascular Amputation Prevention Centers, 1525 E Beltline, NE, Ste 101, Grand Rapids, MI 49525. E-mail: jihadmustapha@aol.com

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FINDINGS FROM RECENT STUDY BY THE CLI GLOBAL SOCIETY

- CLI is a serious problem that threatens both life and limb. Patients with CLI suffer poor long-term prognosis and generate high healthcare costs.
- Revascularization and attempts to salvage the limb are effective in saving both limbs and reducing mortality.
- Considerable efforts are needed to raise disease awareness and implement coding to better define and identify the disease.

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CLI is an underdiagnosed and undertreated deadly disease that requires proper diagnostic imaging and increased awareness.

CLI GLOBAL SOCIETY

Critical Limb Ischemia: A Threat to Life and Limb

CLI is an underdiagnosed and undertreated deadly disease that requires proper diagnostic imaging and increased awareness.

BY JIHAD A. MUSTAPHA, MD; BARRY T. KATZEN, MD; RICHARD F. NEVILLE, MD, FACS; ROBERT A. LOOKSTEIN, MD; THOMAS ZELLER, MD, PHD; LARRY E. MILLER, PHD; VICKIE R. DRIVER, DPM; AND MICHAEL R. JAFF, DO

Peripheral artery disease (PAD) of the lower extremities is a global pandemic of growing proportions. Between 2000 and 2010, the world's population increased by 12.6%, and the prevalence of PAD has increased twice as much over this period.[1] The Global Burden of Disease study reported that 202 million adults worldwide have PAD, a higher prevalence than ischemic heart disease (154 million), heart failure (64 million), Alzheimer's disease/dementia (44 million), cancer (43 million), HIV/AIDS (36 million), and opioid addiction (27 million).[2] Although most patients with PAD are asymptomatic, the disease increases the risk for cardiovascular morbidity and symptomatic disease progression. Patient prognosis after PAD diagnosis is poor because the disease often progresses to the extent that distal perfusion is insufficient to meet metabolic demands. This advanced PAD is commonly described as critical limb ischemia (CLI) and represents the end stage of the disease, mostly characterized by occlusive disease of the tibial and foot arteries in which patients suffer from rest pain, ischemic ulceration, and/or gangrenous tissue loss.

CLI IS COMMON BUT UNDERDIAGNOSED

Among the 9 million to 20 million adults with PAD in the United States, a reported 11% suffer from CLI.[3,4] However, this likely represents a considerable underestimation. CLI prevalence is typically estimated from administrative claims databases using International Classification of Diseases (ICD) clinical diagnosis codes. Although use of administrative diagnosis codes yields high sensitivity when patients with a CLI diagnosis code likely have the disease, there is a corresponding loss of specificity when patients without a CLI diagnosis code may actually have the disease. Previous CLI studies utilizing administrative claims databases have used ICD-9-CM clinical diagnosis codes of 440.22 (rest pain), 440.23 (ulceration), and 440.24 (gangrene).[5] Yet there are numerous complex CLI presentations possible that would be excluded from simplistic CLI diagnosis algorithms (eg, a patient diagnosed with PAD and diabetes who undergoes above-the-ankle amputation). Validation studies suggest that use of administrative codes for CLI diagnosis may underestimate the true prevalence by 25%.[6] Given these factors, it can be estimated that between 1 million and 3 million Americans have CLI.

CLI MORTALITY IN CONTEXT

When an individual first receives a diagnosis of CLI, the mortality risk is 24% over 1 year, and 60% over 5 years.[7] Few diseases connote a higher mortality rate. Among 22 different types of malignancy, only six have a 5-year mortality rate higher than that of CLI.[8] Yet CLI is even more deadly than this statistic suggests. When viewed in isolation, 5-year mortality rates fail to convey the disease-specific mortality burden from a population perspective. For example, many cancers with high mortality rates are relatively rare, so the overall mortality burden to the population is modest; conversely, the mortality burden associated with some of the most common cancers is blunted due to relatively low mortality rates.

CLI GLOBAL SOCIETY

Peripheral Artery Disease (PAD)

- PAD of the lower extremities is a global pandemic of growing proportions.
- World population has increased by 12.6% between 2000-2010
- PAD has increased twice as much during the same period[1]

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1: Fowkes FG et al. Lancet 201

The Global Burden of Disease Study[2]

- 202 million adults worldwide have PAD
- PAD has a higher prevalence than:
  - Ischemic heart disease (154 million)
  - Heart failure (64 million)
  - Alzheimer's disease/dementia (44 million)
  - Cancer (43 million)
  - HIV/AIDS (36 million)
  - Opioid addiction (27 million)

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2: Lancet 2017;390:1211-125

Prognosis after PAD Diagnosis

- Prognosis is poor because disease often progresses to the extent that distal perfusion is insufficient to meet metabolic demands.
- This advanced PAD is commonly described as critical limb ischemia (CLI) and represents the end stage of the disease, mostly characterized by occlusive disease of the tibial and foot arteries in which patients suffer from one or more:
  - Rest pain
  - Ischemic ulceration
  - Gangrenous tissue loss

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CLI is Common but Underdiagnosed

- Among 9-20 million adults with PAD in the US, 11% suffer from CLI[3,4]
- This is likely a considerable underestimation.
- CLI prevalence is typically estimated from administrative claims databases using ICD clinical diagnosis codes.
- Although use of administrative diagnosis codes yields high sensitivity when patients with a CLI diagnosis code likely have the disease, there is a corresponding loss of specificity when patients without a CLI diagnosis code may actually have the disease.

3: Pande RL, Creager M. Circ Cardiovasc Qual Outcomes 2014

4: Yost M. Critical Limb Ischemia Volume I, United States Epidemiology 2016, The Sage Grou

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CLI is Common but Underdiagnosed

- Previous CLI studies utilizing administrative claims databases have used ICD-9-CM clinical diagnosis codes of:[5]
  - 440.22 (rest pain)
  - 440.23 (ulceration)
  - 440.24 (gangrene)
- Yet there are numerous complex CLI presentations possible that would be excluded from simplistic CLI diagnosis algorithms, for example:
  - A patient diagnosed with PAD and diabetes who undergoes above-the-ankle amputation.

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5: Mustapha JA et al. J Am Heart Assoc. 2018

CLI is Common but Underdiagnosed

- Validation studies suggest that use of administrative codes for CLI diagnosis may underestimate the true prevalence by 25%[6]
- Given these factors, it can be estimated that between 1 million and 3 million Americans have CLI.

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6: Bekwelem W et al. Vasc Med 2014

CLI Mortality in Context

- When an individual receives a first diagnosis of CLI, the mortality risk is 24% of 1 year and 60% over 5 years.[7]
- Few diseases connote a higher mortality rate.
- Among 22 different types of malignancy, only six have a 5-year mortality rate higher than that of CLI.[8]
- Yet CLI is even more deadly than this statistic suggests.
- When viewed in isolation, 5-year mortality rates fail to convey the disease-specific mortality burden from a population perspective.

7: Mustapha JA et al JACC CI 2018

8: American Cancer Society Cancer Statistics Center 2018

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CLI Mortality in Context

- For example, many cancers with high mortality rates are relatively rare, so the overall mortality burden to the population is modest.
- Conversely, the. Mortality burden associated with some of the most common cancers is blunted due to relative low mortality rates.
- Consequently, several deadly cancers, such as melanoma or ovarian cancer, are actually less common and less deadly than CLI.

7: Mustapha JA et al JACC CI 2018

8: American Cancer Society Cancer Statistics Center 2018

CLI Mortality in Context

- A helpful metric for quantifying the overall mortality burden of a disease is the 5-year incident mortality.
- That is, among all patients who receive a first-time disease diagnosis in a year, how many will die over the next 5 years?
- The annual incidence and 5-year mortality rates for CLI was derived from a Medicare claims analysis.[5]
- Values were compared to those 22 different types of cancer derived form the Cancer Statistics Center of the American Cancer Society.[8]

5: Mustapha JA et al. J Am Heart Assoc. 2018

8: American Cancer Society Cancer Statistics Center 2018

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CLI Mortality in Context

- Because CLI is both common and deadly, more incident cases die over 5 years after a CLI diagnosis than with any type of cancer, except for lung cancer (Figure 1)

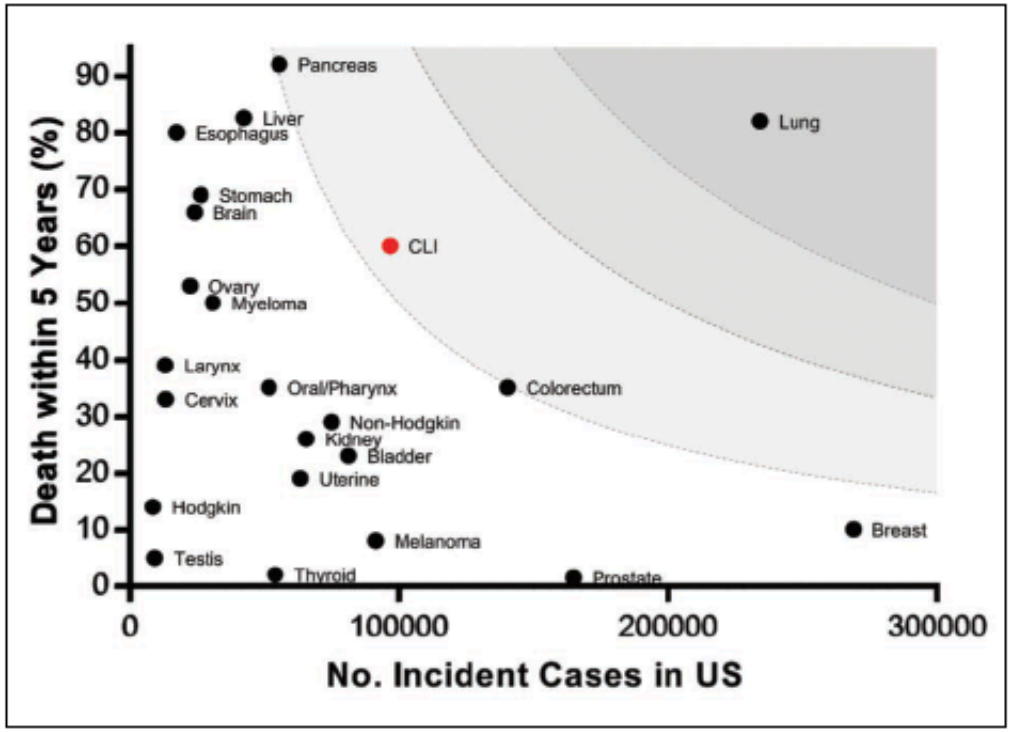

Figure 1. The relationship of 5-year mortality rate and annual incident cases of CLI and 22 common cancers. Plotted is the absolute number of deaths within 5 years among patients in the United States who received their first diagnosis during a 1-year period. The number of deaths is > 150,000 for diagnoses plotted in the dark gray background, > 100,000 in the gray background, > 50,000 in the light gray background, and < 50,000 in the white background.

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CLI Mortality in Context

- When comparing incident cases of CLI and 22 types of cancer, the diseases responsible for the most deaths over 5 years in the US are:
  - Lung cancer (192,000)
  - CLI (58,000)
  - Pancreatic cancer (51,000)
  - Colorectal cancer (49,000)
  - Liver cancer (35,000)

5: Mustapha JA et al. J Am Heart Assoc. 2018

8: American Cancer Society Cancer Statistics Center 2018

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CLI Mortality in Context

Overall, the high incidence of CLI in combination with its highly fatal course make this disease an underrecognized major threat to public health.

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CLI is Undertreated

- Adding to the poor prognosis after diagnosis of CLI, patients with this disease remain underserved with regard to diagnostic evaluation, medical therapy, and utilization of revascularization.
- Societal guidelines recommend that all individuals diagnosed with CLI undergo an imaging study to assess the viability of endovascular or surgical revascularization.

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CLI is Undertreated

Yet angiography is only performed in approximately one of four patients, despite the fact that patients who undergo angiography have a 90% lower risk of major amputation than patients who do not undergo angiography.[9]

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9: Henry AJ et al. J Vasc Surg 2011

CLI is Undertreated

- Additionally, because patients with CLI typically present with extensive atherosclerosis and multiple systemic comorbidities, optimal medical therapy focused on diabetic control, antihypertensive medications, and anti-lipids is crucial to lowering the risk of cardiovascular complications, major amputation, and mortality.
- However, less than one-third of patients with CLI are prescribed optimal medical therapy.[10]

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10: Chung J et al. J Vasc Surg 2013

CLI is Undertreated

- Limb amputation is too often the primary treatment for CLI, without first considering whether revascularization is feasible, which is a concerning disservice to these patients.
- Among patients with CLI who underwent revascularization or major amputation in a study by Mustapha et al,[7] 8.5% were subjected to above-the-ankle amputation as their initial treatment.
- Even more perplexing, 30% of patients who underwent major amputation presented with rest pain or ischemic ulcer but not gangrene.

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7: Mustapha JA et al JACC CI 2018

CLI is Undertreated

- Compared to vascularization, amputation doubles the risk of death over the next year, even after controlling for important confounders such as age, disease severity, diabetes, and chronic kidney disease.
- Furthermore, in patients with gangrene in whom many health care providers may believe major amputation is the only viable first-line therapy, endovascular and surgical revascularization double patient survival compared to amputation.

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CLI is Undertreated

These results support the view that diagnostic imaging should be performed in all patients for whom interventional treatment is being considered and that major amputation should only be attempted if revascularization has failed or is deemed futile.

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CLI Awareness Must be Raised

- In 2013, the Recalcitrant Cancer Research Act was signed into law by President Barack Obama to develop nationwide strategic plans to address the nation's deadliest cancers.
- This is defined as those with 5-year mortality rates >50%, which includes cancers of the pancreas, lung, brain, esophagus, liver, ovary and stomach.

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CLI Awareness Must be Raised

- This legislation authorized governmental research agencies to develop a comprehensive plan of action to coordinate prevention, early detection, and treatment research to lower mortality rates associated with these cancers.
- Unfortunately, no such legislation is pending for CLI, even though the 5-year mortality of CLI is >50%.
- The annual incidence of LCI is greater than that of esophageal cancer, stomach cancer, brain cancer and ovarian cancer combined.

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CLI Awareness Must be Raised

More people die from CLI each year than cancers considered to be among the deadliest.

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CLI Awareness Must be Raised

- The CLI Global Society encourages collaboration among the major vascular, interventional, medical, and podiatric societies to continue raising public and health professional CLI awareness.
- Further, the Society advocates for the formation of alliances composed of multidisciplinary health care providers who will petition lawmakers in a focused, concerted effort to designate CLI as a national public health priority in the same way as the deadliest caners.

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CMS STRATEGY

The CLI Global Society has done expansive work leading up to this publication and recognizes the many challenges that CLI places upon patients, healthcare providers, and payers. In an effort to address these challenges, the Society is working on strategies to engage the government payer system to enact reform to improve care of patients suffering from this devastating disease.

Issue	Strategy
CLI is not sufficiently recognized as the growing public health concern that it is.	Improve clinical outcomes and economic impact of CLI for Medicare beneficiaries via policy and payment strategies.
No diagnosis codes exists for CLI	Create a definitive set of diagnosis codes that define CLI in acceptable granularity (by stage, disease severity, etc.) already recognized in clinical practice.
Costs for the treatment of CLI are among the greatest health care expenditure challenges today.	Develop consensus on critical costs for tracking and analysis purposes to inform potential care improvement/economic value propositions of new care models.
Amputation often remains a first line treatment and results in major disability, loss of work productivity and burdens to family and colleagues.	Develop cost models that include disability, loss of work productivity, caregiver costs, etc., to highlight the magnitude and impact of CLI as a vehicle for awareness and change.

The Society is working to tactically implement strategies by seeking CMS' proactive engagement to define, identify CLI clinical consequences, patient outcomes and economic impact. The Society has intent to pursue ICD-10 codes within the prescribed CMS/NCHS process. Engagement with CMS will be sought to evaluate possible payment models to align payment with CLI care that follows best clinical practices. Leveraging existing research and publications and the engagement of health economists, data analytic experts, employer, and actuarial health data analytics experts is essential to model non-CMS-related costs of CLI.

CLI Global Society Organizes Coalition

A coalition of cardiovascular medical and interventional specialty societies support the CLI Global Society's initiative to improve tracking and reporting of CLI disease, starting with refining the ICD-10 Diagnosis Code Set.

The Society for Vascular Surgery (SVS), Society for Cardiovascular Angiography and Interventions (SCAI), Society of Interventional Radiology (SIR), and Society for Vascular Medicine (SVM) have appointed representatives to CLI Global Society's multispecialty Workgroup with the goal of a consensus-based proposal to the ICD-10 Coordination & Management Committee for Medicare's 2021 Fiscal Year, starting in October 2020 for inpatient admissions and January 2021 for outpatient and other services.

This effort is a first step to build awareness of the complexity associated with caring for patients who experience critical limb ischemia – both among public payers such as CMS and commercial payers. ■

Coalition to improve tracking and reporting of critical limb ischemia includes representatives from

SVS Society for Vascular Surgery

SCAI Society for Cardiovascular Angiography & Interventions

Society of Interventional Radiology

Society for Vascular Medicine

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Building awareness starts with our collaboration

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CLI Awareness Must be Raised

Only with a coordinated and comprehensive national plan to address all aspects of CLI, including diagnosis, treatment, and education of patients and health care providers, cant he ever-growing impact of this deadly disease be controlled.

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