# Society for Vascular Surgery appropriate use criteria for management of intermittent claudication

Karen Woo, MD, PhD,[a] Jeffrey J. Siracuse, MD, MBA,[c] Kyle Klingbeil, MD, MS,[b] Larry W. Kraiss, MD,[d] Nicholas H. Osborne, MD,[e] Niten Singh, MD,[f] Tze-Woei Tan, MD,[g] Shipra Arya, MD, SM,[h] Subhash Banerjee, MD,[i] Marc P. Bonaca, MD, MPH,[j] Thomas Brothers, MD,[k] Michael S. Conte, MD,[l] David L. Dawson, MD,[m] Young Erben, MD,[n] Benjamin M. Lerner, MD,[o] Judith C. Lin, MD, MBA,[p] Joseph L. Mills Sr, MD,[q] Derek Mittleider, MD,[r] Deepak G. Nair, MD, MS, MHA,[s] Leigh Ann O'Banion, MD,[t] Robert B. Patterson, MD,[u] Matthew J. Scheidt, MD,[v] *and* Jessica P. Simons, MD, MPH,[w] for the Society for Vascular Surgery Appropriateness Committee, *Los Angeles, Stanford, San Francisco, and Fresno, CA; Boston and Worcester, MA; Salt Lake City, UT; Ann Arbor and East Lansing, MI; Seattle, WA; Tucson, AZ; Dallas, Temple, and Houston, TX; Aurora, CO; Charleston, SC; Jacksonville, Melbourne, and Sarasota, FL; Louisville, KY; Providence, RI; and Milwaukee, WI*

## ABSTRACT

The Society for Vascular Surgery appropriate use criteria (AUC) for the management of intermittent claudication were created using the RAND appropriateness method, a validated and standardized method that combines the best available evidence from medical literature with expert opinion, using a modified Delphi process. These criteria serve as a framework on which individualized patient and clinician shared decision-making can grow. These criteria are not absolute. AUC should not be interpreted as a requirement to administer treatments rated as appropriate (benefit outweighs risk). Nor should AUC be interpreted as a prohibition of treatments rated as inappropriate (risk outweighs benefit). Clinical situations will occur in which moderating factors, not included in these AUC, will shift the appropriateness level of a treatment for an individual patient. Proper implementation of AUC requires a description of those moderating patient factors. For scenarios with an indeterminate rating, clinician judgement combined with the best available evidence should determine the treatment strategy. These scenarios require mechanisms to track the treatment decisions and outcomes. AUC should be revisited periodically to ensure that they remain relevant. The panelists rated 2280 unique scenarios for the treatment of intermittent claudication (IC) in the aortoiliac, common femoral, and femoropopliteal segments in the round 2 rating. Of these, only nine (0.4%) showed a disagreement using the interpercentile range adjusted for symmetry formula, indicating an exceptionally high degree of consensus among the panelists. Post hoc, the term "inappropriate" was replaced with the phrase "risk outweighs benefit." The term "appropriate" was also replaced with

From the Division of Vascular Surgery and Endovascular Therapy[a] and Division of General Surgery,[b] Department of Surgery, David Geffen School of Medicine, University of California, Los Angeles, Los Angeles; the Division of Vascular Surgery and Endovascular Surgery, Department of Surgery, Boston University School of Medicine, Boston[c]; the Department of Surgery, University of Utah, Salt Lake City[d]; the Section of Vascular Surgery, Department of Surgery, University of Michigan, Ann Arbor[e]; the Division of Vascular and Endovascular Surgery, Department of Surgery, University of Washington, Seattle[f]; the Division of Vascular and Endovascular Surgery, Department of Surgery, University of Arizona College of Medicine, Tucson[g]; the Division of Vascular Surgery, Department of Surgery, Stanford University School of Medicine, Stanford[h]; the Division of Cardiovascular Disease, Department of Internal Medicine, University of Texas Southwestern Medical Center and Veterans Affairs North Texas Health Care System, Dallas[i]; the Cardiovascular Division, Department of Medicine, University of Colorado School of Medicine, Aurora[j]; the Surgery Section, Ralph H. Johnson Department of Veterans Affairs Medical Center and Division of Vascular Surgery, Medical University of South Carolina, Charleston[k]; the Division of Vascular and Endovascular Surgery, Department of Surgery, University of California, San Francisco[l]; the Division of Vascular Surgery, Department of Surgery, Baylor Scott & White Health, Temple[m]; the Division of Vascular and Endovascular Surgery, Mayo Clinic Florida, Jacksonville[n]; the Norton Healthcare, Louisville[o]; the Division of Vascular Surgery, Department of Surgery, Michigan State University College of Human Medicine, East Lansing[p]; the Division of Vascular Surgery and Endovascular Therapy, Michael E DeBakey Department of Surgery, Baylor College of Medicine, Houston[q]; the Vascular & Interventional Physicians, Brevard Physician Associates, Melbourne[r]; the Sarasota Vascular Specialists, Sarasota[s]; the Division of Vascular Surgery, Department of Surgery, University of California, San Francisco, Fresno[t]; the Department of Surgery, Warren Alpert School of Medicine, Brown University, Providence[u]; the Division of Vascular and Interventional Radiology, Department of Radiology, Medical College of Wisconsin, Milwaukee[v]; and the Division of Vascular and Endovascular Surgery, University of Massachusetts Medical School, Worcester.[w]

This project was supported by the Society for Vascular Surgery. Data collection, analysis, and submission of the article for publication were supported by the Society for Vascular Surgery. The project was also supported by the National Center for Advancing Translational Sciences, National Institutes of Health (grants UL1TR001881 and K08DK107934), and the National Institute of Diabetes and Digestive and Kidney Diseases. The National Institutes of Health did not participate in the collection, analysis, or interpretation of the data; writing of the report; or the decision to submit the article for publication.

Author conflict of interest: see the Supplementary Table (online only).

Additional material for this article may be found online at www.jvascsurg.org.

Correspondence: Karen Woo, MD, PhD, Division of Vascular Surgery and Endovascular Therapy, Department of Surgery, David Geffen School of Medicine, University of California, Los Angeles, 200 UCLA Medical Plaza, Ste 526, Los Angeles, CA 90095 (e-mail: kwoo@mednet.ucla.edu).

Independent peer review and oversight have been provided by the members of the Society for Vascular Surgery Document Oversight Committee (Ruth Bush, chair, Marc Schermerhorn, vice-chair, Keith Calligaro, Mohammad Eslami, Raul Guzman, Ahmed Kayssi, Chris Kwolek, Gregory Landry, Katharine McGinigle, Erika Mitchell, Patrick Muck, William Robinson, Jeannie Ruddy, Evan Ryer, Palma Shaw, Chris Smolock, Britt Tonnessen, Brant Ullery, Chandu Vemuri, and Greg Westin).

0741-5214



https://doi.org/10.1016/j.jvs.2022.04.012

"benefit outweighs risk." The key principles for the management of IC reflected within these AUC are as follows. First, exercise therapy is the preferred initial management strategy for all patients with IC. Second, for patients who have not completed exercise therapy, invasive therapy might provide net a benefit for selected patients with IC who are nonsmokers, are taking optimal medical therapy, are considered to have a low physiologic and technical risk, and who are experiencing severe lifestyle limitations and/or a short walking distance. Third, considering the long-term durability of the currently available technology, invasive interventions for femoropopliteal disease should be reserved for patients with severe lifestyle limitations and a short walking distance. Fourth, in the common femoral segment, open common femoral endarterectomy will provide greater net benefit than endovascular intervention for the treatment of IC. Finally, in the infrapopliteal segment, invasive intervention for the treatment of IC is of unclear benefit and could be harmful. (J Vasc Surg 2022;76:3-22.)

**Keywords:** Appropriate use criteria; Intermittent claudication; Peripheral artery disease; RAND appropriateness method

## PREFACE

The RAND appropriateness method was developed in the 1980s and has been widely used in North America and Europe. The original RAND terms "appropriate," "indeterminate," and "inappropriate" were used by the committee during its deliberations as prescribed by the process. The Society for Vascular Surgery determined that these terms, in particular, "appropriate" and "inappropriate," carry many different and often highly charged social connotations in the 21st century, especially when considered outside the strict context of the RAND appropriateness methodology definitions. After careful deliberation, the Society for Vascular Surgery decided post hoc to replace "appropriate" with benefit outweighs risk (B>R) and "inappropriate" with risk outweighs benefit (R>B) because these represent the definitions used by the panelists. These changes removed the positive and negative semantic connotations and strictly align with the RAND appropriateness methodology definitions. This change is methodologically sound and retains the scientific integrity of the work.

## EXECUTIVE SUMMARY

The Society for Vascular Surgery Appropriate Use Criteria (AUC) for the management of intermittent claudication (IC) were created by adhering as closely as possible to the RAND appropriateness method.[1] The RAND appropriateness method is the only validated method for developing AUC and is a standardized method that combines the best available evidence from medical literature with expert opinion, using a modified Delphi process.

**Implementation of AUC.** These AUC serve as a baseline framework on which individualized patient and clinician shared decision-making can grow. These criteria have numerous limitations. A mutually agreed on care plan must consider each patient's goals and values, factors impossible to categorize and rate.

It is important to recognize that these criteria are not absolute. The AUC should not be interpreted as requiring one to administer treatment rated as appropriate (benefit outweighs risk). Nor should the AUC be interpreted as a prohibition to treatments rated as inappropriate (risk outweighs benefit). An important attribute of AUC is that "they should be flexible" and "should not limit physician freedom, but should impede arbitrary decisions."[1] "Freedom" refers to that which "permits decisions different from those recommended by the criteria, but requires that such decisions be justified" vs "arbitrariness," which means that the AUC are "not followed but no attempt is made to explain why."[1] Accordingly, clinical situations will undoubtedly exist in which moderating patient factors, not included in the scenarios addressed in these AUC, will shift the appropriateness level of a treatment for an individual patient. However, proper implementation of the AUC requires a description of those moderating patient factors.

For scenarios with an indeterminate rating, clinician judgment, combined with the best available evidence, should be the primary determinant of the optimal course of treatment. For scenarios with an indeterminate rating, an ongoing need exists for mechanisms to track treatment decisions and the resulting outcomes. As medical technology, drug therapies, and strategies are anticipated to improve and progress over time, the AUC should be revisited periodically to ensure that these criteria remain relevant.

**Summary of recommendations.** The panelists rated 2280 unique scenarios for the treatment of IC in the aortoiliac, common femoral, and femoropopliteal segments in their round 2 rating. Of the 2280 scenarios, only 9 (0.4%) had disagreement using the interpercentile range adjusted for symmetry formula, indicating an exceptionally high degree of consensus among the panelists. The appropriateness level of each scenario has been presented in the Results section. Post hoc, the term "inappropriate" was replaced with the phrase "risk outweighs benefit" (R>B). The term "appropriate" was also replaced with the phrase "benefit outweighs risk" (B>R). The key principles for the management of IC reflected within these AUC are as follows:

- Exercise therapy is a preferred initial management strategy for all patients with IC.
- For patients who have not completed exercise therapy, invasive therapy might provide a net benefit for selected patients with IC who are nonsmokers, are

taking optimal medical therapy, are considered to have a low physiologic and technical risk, and are experiencing severe lifestyle limitations and/or a short walking distance.
- Considering the long-term durability of currently available technology, invasive interventions for femoropopliteal disease should be reserved for patients with severe lifestyle limitations and a short walking distance.
- In the common femoral segment, open common femoral endarterectomy will provide greater net benefit than endovascular intervention for the treatment of IC.
- In the infrapopliteal segment, invasive intervention for the treatment of IC is of unclear benefit and could be harmful.

## DISCLAIMER

The Society for Vascular Surgery develops evidenced-based documents as a resource to assist members in the practice of vascular surgery. These appropriate use criteria (AUC) contain guidance on intermittent claudication and were determined from a recent review of the reported evidence and expert opinion. These AUC reflect the available body of evidence, and their applicability reflects the limitations of those data and are subject to reassessment and revision as new knowledge emerges. Given these limitations, AUC do not represent a statement of the standard of care, nor can they substitute for clinician judgment or supplant patient preference or shared decision-making. The Society for Vascular Surgery recognizes that departure from the AUC could be warranted when, in the reasonable judgment of the treating clinician, such a course of action is indicated by the clinical presentation of the patient, limitations of the available resources, advances in knowledge or technology, and/or patient preference. Readers must rely solely on their own judgment to determine which practices and procedures, whether included in this document, are appropriate for them, their patient, their institution, or their practice.

## INTRODUCTION

Peripheral artery disease (PAD) of the lower extremities affects >200 million people worldwide. Among patients with PAD who are symptomatic, intermittent claudication (IC) is the most common manifestation.[2] The prevalence of PAD is expected to increase for the foreseeable future, highlighting PAD as a major public health problem.[3] In addition to being highly prevalent, PAD is a costly disease to treat. A study reported in 2008 estimated the total annual costs associated with vascular-related hospitalizations for patients with PAD were >$21 billion in the United States alone.[4,5] The number of interventions for PAD in the United States has increased dramatically in recent years, correlating with increased costs to the healthcare system.[6-8]

In recognition of these issues, the Society for Vascular Surgery (SVS) has developed clinical practice guidelines for the management of IC.[9] Clinical practice guidelines provide clinicians with summaries of the evidence for or against specific treatments using the GRADE (grading of recommendations assessment, development, evaluation) system for evaluating the strength of the evidence.[10] However, the clinical practice guideline writing process is not designed to address patient-specific decision-making, and clinical practice guidelines cannot account for multidimensional clinical situations. In contrast, appropriate use criteria (AUC) are designed to inform the appropriateness of an intervention in a particular clinical scenario given specific patient characteristics. Furthermore, the Centers for Medicare and Medicaid Services and other payors have taken notice of AUC, primarily for their role in reducing overuse of healthcare items such as diagnostic testing and invasive interventions. The Centers for Medicare and Medicaid Services has previously mandated the use of AUC for certain advanced imaging studies, with imaging studies that do not align with AUC requiring prior authorization.[11]

Accordingly, the SVS leadership has identified "appropriateness" as a critical component of efforts to enhance the quality of care and sought to define AUC for the treatment of IC. The ultimate objective of the development and implementation of AUC is to promote the use of appropriate interventions and minimize overuse of potentially inappropriate procedures that could be associated with downstream negative consequences to patients and the healthcare system.

## METHODS

These AUC were created by adhering as closely as possible to the RAND appropriateness method (RAM).[1] The RAM is a validated, standardized method that combines the best available evidence from the medical literature with expert opinion, using a modified Delphi process.

### Writing panel

Under the leadership of the SVS Quality Council and the SVS Appropriateness Committee, a writing panel was convened with five members (N.H.O., J.P.S., N.S., J.J.S., T.W.T.) guided by the writing panel chair (K.W.). As prescribed by the RAM, the writing panel chair was formally trained in the RAM, with experience leading and moderating prior AUC development projects. All members of the writing panel declared they were free from conflicts of interest relevant to these AUC at their appointment to the committee. During the course of the project period, one member (N.S.) had performed consulting work on the topic of atherosclerotic disease (PAD) that fell within the SVS standards (Supplementary Table, online only). The SVS has a clearly

defined policy and set of standards for determining conflicts, which were applied to this work.[12]

## Systematic review

As prescribed by the RAM, the first step in the execution of the project was a systematic literature review. The literature review was designed to inform what the writing panel agreed were the most fundamental questions with respect to appropriateness in the care of IC patients: (1) what is appropriate as initial management of IC; and (2) what is appropriate as management of IC after a trial of exercise therapy that failed to adequately treat symptoms? These were the areas for which the panel determined a clear statement was necessary to define the basis of appropriate care for IC. Although several other questions were considered, including the appropriateness of various types of endovascular interventions, these questions were deemed separate from, and subsequent to, the chosen questions.

The writing panel identified specific questions the systematic review would address to inform the determination of appropriateness:

1. For patients with IC who were receiving optimal medical therapy (OMT; antiplatelet and/or statin), what were the outcomes of initial treatment with exercise therapy (supervised or nonsupervised) compared with invasive interventions?
2. For patients with IC, what were the outcomes of endovascular vs open revascularization?

The writing panel identified and defined 21 covariates, eight interventions, and seven outcomes of interest that commonly affect decision-making for IC. The Mayo Clinic Evidence Practice Center conducted a systematic review and meta-analysis that evaluated the literature between 2000 and 2020 for evidence associated with each of these factors (Saadi et al., Unpublished data). The Mayo Clinic Evidence Practice Center systematic review identified 36 studies (10 comparative observational, 13 noncomparative observational, and 13 randomized controlled trials) that met the extensive Evidence Practice Center criteria for inclusion (eg, single-arm studies must have had ≥50 patients).

The included literature was not adequate to perform a meta-analysis. All studies were found to have a risk of bias in at least one category. Considering the inadequate evidence from the systematic review and the exclusion of some studies that the writing panel believed were important and relevant, the writing panel compiled a supplemental literature review, which summarized the findings of these studies.

## Assumptions and definitions

The writing panel determined several baseline assumptions and defined each term used in the clinical scenarios to be presented to the rating panelists. For the purposes of this project, the RAND definition of "appropriate" was used: "The expected health benefit (eg, increased life expectancy, relief of pain, reduction in anxiety, improved functional capacity) exceeds the expected negative consequences (eg, mortality, morbidity, anxiety, pain, time lost from work) by a sufficiently wide margin that the procedure is worth doing, exclusive of cost."[1] "Inappropriate" was defined as the converse; the risks clearly exceed the benefits by a wide margin. Post hoc, the term "inappropriate" was replaced throughout with the phrase "the risk outweighs the benefit" (R>B). In addition, the term "appropriate" was replaced with "the benefit outweighs the risk" (B>R). The assumptions and definitions were ultimately discussed and modified by the rating panel in the second round of rating to generate the final assumptions and definitions (presented in the Results section).

## Scenarios

The writing panel next generated a set of clinical scenarios to be rated by the rating panelists for appropriateness. The scenarios were designed to mimic clinical decision-making. Because of the paucity of relevant high-quality evidence, many of the original covariates used in the systematic review (eg, depression, quality of life) were not included in the scenarios. The scenarios were dichotomized into patients receiving initial therapy and those who had completed exercise therapy but remained significantly disabled by IC. The scenarios were further grouped according to the anatomic level of disease; a basic assumption was hemodynamically significant single-level disease. For the scenarios involving initial treatment, the treatment options considered were exercise therapy, open in-line surgical revascularization, extra-anatomic surgical revascularization, and endovascular revascularization. For scenarios involving patients who had completed exercise therapy, the treatment options were specific to the anatomic location and included open in-line surgical revascularization, extra-anatomic surgical revascularization, endovascular revascularization, and common femoral endarterectomy (CFEA). Each scenario was designed to include the clinical characteristics the writing panel agreed were relevant to determining the most appropriate treatment for a given patient.

## Rating panel

The SVS executive board selected a multidisciplinary rating panel consisting of 15 volunteers from three professional societies (two from the American College of Cardiology [ACC; 13%], two from the Society of Interventional Radiology [SIR; 13%], and 11 from the SVS [(73%]; Table I). Of the 11 SVS members, 6 (55%) had self-reported as a member of an academic practice, 4 (36%) as being in private practice with or without a teaching component, and 1 as being in a hospital-employed

**Table I.** Members of rating panel

| Name | Professional society | Affiliation | Location | Self-reported practice type |
|---|---|---|---|---|
| Shipra Arya, MD, SM | SVS | Stanford University School of Medicine | Stanford, CA | Academic |
| Subhash Banerjee, MD | ACC | University of Texas Southwestern Medical School | Dallas, TX | Academic |
| Marc Bonaca, MD, MPH | ACC | University of Colorado School of Medicine | Aurora, CO | Academic |
| Thomas Brothers, MD | SVS | Medical University of South Carolina | Charleston, SC | Academic |
| Michael Conte, MD | SVS | University of California, San Francisco | San Francisco, CA | Academic |
| David Dawson, MD | SVS | Baylor Scott and White Health | Temple, TX | Hospital employed |
| Young Erben, MD | SVS | Mayo Clinic, Jacksonville | Jacksonville, FL | Academic |
| Benjamin Lerner, MD | SVS | Norton Vascular Associates | Louisville, KY | Private practice, nonteaching |
| Judith Lin, MD, MBA | SVS | Michigan State University | East Lansing, MI | Academic |
| Joseph Mills, MD | SVS | Baylor College of Medicine | Houston, TX | Academic |
| Derek Mittleider, MD | SIR | Brevard Physician Associates | Melbourne, FL | Private practice, nonteaching |
| Deepak Nair, MD | SVS | Sarasota Vascular Specialists | Sarasota, FL | Private practice, nonteaching |
| Leigh Ann O'Banion, MD | SVS | University of California, San Francisco, Fresno | Fresno, CA | Private practice, teaching program |
| Robert Patterson, MD | SVS | Brown University | Providence, RI | Private practice, teaching program |
| Matthew Scheidt, MD | SIR | Medical College of Wisconsin | Milwaukee, WI | Academic |

*ACC*, American College of Cardiology; *SIR*, Society for Interventional Radiology; *SVS*, Society for Vascular Surgery.

practice. A total of 81 SVS members volunteered to serve as panelists, 68% of whom identified as being in academic practice. The ACC and SIR members were nominated by their respective organizations. The panelists represented various geographic areas across the United States and a wide range of duration in practice. Fourteen rating panel members declared no relevant conflicts of interest at their appointment to the panel, as defined by the SVS policy.[12] One rating panel member (D.M.) had a potential conflict of interest as a member of an advisory board and speaker's panels for companies that make devices that can be used in the treatment of IC (Supplementary Table, online only). During the course of the project, one other rating panel member (M.P.B.) acquired modest stock holdings in two companies that make devices and medications that can be used in the treatment of IC. Other industry-associated research and institutional relationships are noted in the Supplementary Table (online only).

## Rating and classifying appropriateness

The rating panelists rated the scenarios in two rounds using REDCap (Research Electronic Data Capture) tools hosted at the University of California Los Angeles.[13] REDCap is a secure, web-based software platform designed to support data capture for research studies.

**Round one rating.** In round one, the rating panelists were provided with the assumptions and definitions created by the writing panel, the results of the systematic review and supplemental review, and the full text of all cited references. The panelists each independently rated 1512 scenarios. The identities of the rating panelists were concealed from each other until round one had been completed to ensure that the ratings were performed independently. In accordance with the RAM, the panelists were instructed to rate the appropriateness level of each scenario on a scale of 1 to 9: 1, the risks clearly exceed the benefits by a wide margin; to 9, the benefits clearly exceed the risks by a wide margin. A score of 5

**Table II.** Classification of appropriateness stratified by rating and disagreement

| Variable | R>B | IND | IND | B>R |
|---|---|---|---|---|
| Median rating | 1-3 | Any | 4-6 | 7-9 |
| Disagreement[a] | No | Yes | No | No |

*B>R,* Benefit outweighs risk; *IND,* indeterminate; *R>B,* risk outweighs benefit.
[a]As defined using the interpercentile range adjusted for symmetry formula.

meant the scenario is of uncertain or equivocal appropriateness.

On completion of the round one rating, the scenarios were classified into three levels of appropriateness: (1) B>R, panel median score of 7 to 9 without disagreement; (2) indeterminate, panel median score of 4 to 6 or any median score with disagreement; and (3) R>B, panel median of 1 to 3 without disagreement (Table II). According to the RAM, disagreement is a binary outcome; either there is disagreement or there is not. The presence of disagreement was determined using the interpercentile range adjusted for symmetry (IPRAS) formula.[1] The round one ratings were used only to inform round two. Only the ratings from round two were used in the final classification of appropriateness.

**Round two rating.** Although the RAM recommends that round two ratings be conducted in person, given the ongoing COVID-19 (coronavirus disease 2019) pandemic, round two was conducted virtually using the Ring Central Meetings platform (Ring Central, Inc, Belmont, CA) over 2 days, totaling 15 hours. All members of the rating panel attended the entirety of the virtual meeting. In accordance with the RAM, an experienced moderator (K.W.) led the entirety of round two. The rating panelists were provided with individualized results from round one, indicating the median score for each scenario rated in round one and a reminder of how the individual panelist had rated each scenario in round one.

In accordance with the RAM, the rating panelists discussed and revised the assumptions and definitions and reached a consensus (Tables III and IV). The panelists assumed single-level, hemodynamically significant disease in all cases, except as explicitly noted (Table IV). They participated in extensive discussion regarding the definition of "prior intervention," including the variety of possible prior interventions for an anatomic segment, and the variable methods in which the different interventions would sway their judgment. The panelists agreed that "prior intervention" was a marker for a more complex scenario with a decreased likelihood of short- and long-term success. The panelists agreed that a failed prior intervention would potentially raise their threshold for deeming revascularization appropriate but that each scenario would be interpreted in conjunction with the described anatomic complexity. The panelists debated whether the details of prior interventions and the specific number of interventions were important enough to (1) expand the number of scenarios markedly; (2) remove the term and defer to a separate AUC project; or (3) develop a more generalized definition of prior intervention. Ultimately, the panelists decided to retain "prior interventions" as a variable, categorized as prior open and prior endovascular interventions. The panelists agreed that the term should be broadly interpreted as any number or type of prior open or endovascular intervention, implying a decrease in the likelihood of long-term success.

The panelists further deliberated extensively on the optimal term to capture an aggregate assessment of life expectancy, functional status, and physiologic fitness for surgery. The panelists ultimately classified this variable as low, medium, and high risk for an intervention. This term was intended to allow the clinician to incorporate age, burden of comorbid disease, and frailty into the decision, without having to set rigid thresholds such as chronologic age.

The definition of, and assumptions about, OMT (defined as any dose and any type of both a lipid-lowering agent and an antiplatelet agent) were also discussed at length. The rating panel decided that one assumption should be that OMT was prescribed in all cases; thus, scenarios of nonadherence or an inability to take OMT as prescribed could be rated. Although the panelists discussed nuances of the distinction between a patient choosing not to take OMT, having an allergy to or intolerance of OMT, and an inability to take OMT for other reasons, the panelists ultimately determined that the variable should be classified as taking vs not taking OMT. An additional assumption was that clinicians could offer cilostazol or pentoxifylline at the clinician's discretion. They did not choose to assess the appropriateness of cilostazol in these AUC.

The panelists discussed exercise therapy extensively. The panelists noted that marked variability exists in the availability of supervised exercise therapy programs in the United States, making it reasonable to accept home- or technology-based exercise therapy as sufficient for completion of exercise therapy.[14] The panelists agreed to assume that a good faith effort was made by the clinician to thoroughly counsel the patient regarding how to properly perform exercise therapy. The panelists also agreed to assume that, in the scenarios in which the patient had completed exercise therapy, the physician had verified that the patient had made a good faith

**Table III.** Final assumptions

| |
|---|
| The hypothetical patient has symptoms most consistent with vasculogenic claudication (not musculoskeletal or neurogenic) that are reproducible with physical exertion; the symptoms are in a major muscle group in a distribution corresponding to the designated anatomic segment |
| The symptoms have been present for ≥90 days |
| The hypothetical patient has hemodynamically significant atherosclerotic disease isolated to the specified anatomic location; some specific variations allowed, depending on the anatomic level (see the Femoropopliteal and Infrapopliteal sections) |
| The hypothetical patient does not have symptoms of chronic limb threatening ischemia (rest pain and/or tissue loss) in either leg |
| At the discretion of the clinician, the hypothetical patient has been offered a trial of cilostazol |
| The hypothetical patient has been prescribed OMT (see Table IV) |
| The hypothetical patient has continued taking OMT after the intervention |

*OMT,* Optimal medical therapy.

attempt at exercise therapy for a minimum of 12 weeks. The key components of supervised- or home-based exercise therapy were described in the SVS IC clinical practice guidelines as (1) a duration of >6 months, (2) at least three sessions per week, and (3) a session duration of ≥30 minutes; the desired end point for patients to achieve is a nearly maximal claudication pain, and walking is the preferred form of exercise.[9] In contrast, the American Heart Association/ACC guidelines have recommended a trial of exercise for 12 weeks.[15] The rating panel chose to use the 12-week duration for their definition of a good faith effort.

The panelists discussed and revised the scenarios to arrive at those they determined were reasonable representations of clinical situations encountered in practice. One scenario that the panelists debated was the combination of severe lifestyle limitations and a long walking distance. Although this combination is likely to have a low prevalence in practice, the panelists elected to include it. The panelists wished to address scenarios in which a patient who routinely participated in long-distance activities, such as marathon running (an example specifically discussed by the panelists), might report severe lifestyle limitation due to IC.

In the process of revising the scenarios, the panelists dramatically expanded the total number of scenarios from the original 1512 in round one. During round two, the panelists each rated 2280 scenarios. In accordance with the RAM, consensus was required for the content of the scenarios but not for the level of appropriateness. Areas of disagreement with respect to appropriateness were discussed; however, consensus was never forced. The revised scenarios were then rated by all rating panelists.

### Statistical analysis

The appropriateness of each scenario was determined using round two ratings as described. All analyses were conducted using SAS, version 9.4 (SAS Institute, Cary, NC).

## RESULTS

### Aortoiliac disease

The rating panel agreed that the Trans-Atlantic Inter-Society Consensus II (TASC II) is the most common and widely accepted system to categorize anatomic complexity for aortoiliac disease.[16] Thus, the distribution of disease was categorized as straightforward or complex using the TASC II classification (Table IV). The panelists discussed distinguishing between the types of open inline (eg, aortofemoral, iliofemoral) and types of extra-anatomic (eg, axillobifemoral bypass, femorofemoral bypass) surgical revascularization (Table IV). Ultimately, they decided that subcategorizing within "inline" and within "extra-anatomic" was not worthwhile; procedures within each group had outcomes that could reasonably be considered as one group in the clinical decision-making process. Disease of the internal iliac artery was not included in aortoiliac disease. Internal iliac disease was thought to represent an uncommon presentation for IC, and limited data are available regarding the outcomes of internal iliac artery interventions for IC to serve as guidance. Laterality was not considered for aortoiliac interventions because treatment is often bilateral for open and endovascular interventions.

**Straightforward aortoiliac disease.**

***Initial therapy.*** For initial therapy for patients with IC with straightforward aortoiliac disease, exercise therapy was rated as B>R in all included scenarios (Table V). There were no described scenarios in which an open inline surgical revascularization was rated as B>R as initial treatment. Extra-anatomic surgical revascularization was rated as R>B in the included scenarios as initial therapy.

For current nicotine users with severe lifestyle limitations, open inline surgical revascularization was indeterminate for patients who were low risk, taking OMT, or with a short walking distance; otherwise, it was R>B. For nonsmokers with severe lifestyle limitations and high risk or a long walking distance, open inline surgical revascularization was deemed R>B; otherwise, it was deemed indeterminate.

For current nicotine users, endovascular intervention was only B>R as the initial therapy in the case of severe lifestyle limitations with a short walking distance. For non-nicotine users, initial endovascular therapy was B>R for patients with severe lifestyle limitations, who were low or medium risk, were taking OMT, or had short walking distances. Other initial endovascular intervention scenarios were either R>B or indeterminate, with

**Table IV.** Final variable definitions

| Variable | Definition |
|---|---|
| **Anatomic location of disease** | |
| Aortoiliac | Atherosclerotic stenotic or occlusive disease involving the aorta, common iliac, or external iliac arteries (excludes internal iliac) |
| Common femoral | Atherosclerotic stenotic or occlusive disease involving the common femoral artery and its bifurcation to include the profunda femoris |
| Femoropopliteal | Atherosclerotic stenotic or occlusive disease involving the superficial femoral and popliteal arteries |
| Infrapopliteal | Atherosclerotic stenotic or occlusive disease involving the anterior tibial arteries, tibioperoneal trunk, peroneal artery, posterior tibial artery, and/or pedal arteries |
| **Complexity of disease** | |
| Aortoiliac | |
| Straightforward | TASC II A/B, not heavily calcified |
| Complex | TASC II C/D and/or heavily calcified |
| Common femoral | |
| Straightforward | Focal stenosis or occlusion or multiple focal stenoses, not heavily calcified, patent bifurcation |
| Complex | Diffuse stenoses or occlusion, extension into profunda and/or heavily calcified |
| Femoropopliteal | |
| Straightforward | TASC II A/B, not heavily calcified, can perform bypass above the knee only, ≥2 tibial vessel (anterior tibial, peroneal, posterior tibial artery) runoff |
| Complex | TASC II C/D, heavily calcified, requires bypass to a distal target in below the knee popliteal or proximal infrapopliteal vessels, and/or single tibial vessel (anterior tibial, peroneal, posterior tibial artery) runoff |
| **OMT** | |
| Yes | Patient is taking lipid-lowering and antiplatelet medications |
| No | Patient is not taking both lipid-lowering and antiplatelet medications for any reason, including allergy, intolerance, and/or medical contraindications |
| Lifestyle limitation secondary to vasculogenic claudication[a] | |
| Mild | Although unable to perform some activities, everyday activities are not limited. Rutherford class 0-1 |
| Moderate | Rutherford class 2 |
| Severe | Refrains from routine errands that require walking; Rutherford class 3 |
| Operative risk status: frailty, functional status, life expectancy[b] | |
| Low risk | Robust, independently functional, >5-year life expectancy |
| Medium risk | Prefrail, partially dependent: vulnerable patients could cycle back to robust with interventions or become frail if subjected to stressors, 2- to 5-year life expectancy |
| High risk | Frail, completely dependent, <2-year life expectancy |
| **Total walking distance**[c] | |
| Short distance | <2 Blocks |
| Medium distance | 2-4 Blocks |
| Long distance | >4 Blocks |
| **Prior intervention** | |
| Failed endovascular | Any prior endovascular intervention for peripheral arterial disease in same anatomic distribution as current disease that has become occluded |
| Failed open | Any prior open intervention for peripheral arterial disease in same anatomic distribution as current disease that has become occluded |

**Table IV.** Continued.

| Variable | Definition |
|---|---|
| **Conduit** | |
| SSGSV | Only pertains to femoropopliteal scenarios |
| Non-SSGSV | Any conduit other than SSGSV (only pertains to femoropopliteal scenarios) |
| **Nicotine use** | |
| Yes | Cigarette smoking, electronic cigarette use, or chewing tobacco within 30 days before intervention |
| No | No cigarette smoking, electronic cigarette use, or chewing tobacco within 30 days before intervention |
| **Treatment** | |
| Exercise therapy | Including both supervised and unsupervised exercise therapy—unsupervised exercise therapy: clinician has explained in depth or referred the patient to one of the following and believes the patient has made a good faith effort to perform 1 of the following for ≥12 weeks: community walking program, unsupervised walking program, unsupervised exercise therapy, walking prescription, group-mediated cognitive behavioral walking intervention, or home-based exercise therapy; supervised exercise therapy: a structured and supervised exercise regimen with the intent of improving the walking distance or for cardiac rehabilitation; these typically have at least a 30-minute session duration, 3 times/wk for 12 weeks |
| Open in-line surgical revascularization | Open surgical bypass that is anatomic, including aortoiliac, and aortofemoral (only pertains to aortoiliac scenarios) |
| Open extra-anatomic surgical revascularization | Axillary to femoral or femoral to femoral bypass (only pertains to aortoiliac scenarios) |
| Endovascular revascularization | Isolated endovascular intervention, including angioplasty, stenting, and/or atherectomy, at the treating provider's discretion of best available intervention |
| Common femoral endarterectomy | Open surgical revascularization of common femoral artery with endarterectomy and patch angioplasty |

*OMT,* Optimal medical therapy; *SSGSV,* single-segment greater saphenous vein; *TASC II,* Trans-Atlantic Inter-Society Consensus II.
[a]"Disabling" refers to disabling in everyday life; although reported by the patient, the assumption was also that a thorough discussion had occurred and that the clinician agreed with the patient regarding the degree of lifestyle limitation. Thus, the clinician must have explained, in detail, the rationale that the limitation must be severe enough to justify the risks associated with treatment to help guide patients in reporting their limitations accurately.
[b]Assessment of physiologic reserve determined by the presence of severe comorbidities; poor functional, cognitive, or nutritional status; and associated expected life expectancy.
[c]One block equals 300 ft or 100 meters; these distance categories are meant to serve as a proxy for what the panelist would consider to be short, medium, and long distances, rather than strict literal interpretations of the patient's walking distance.

mild or moderate lifestyle limitation categories more often rated as R>B.

***Completed exercise therapy.*** For current nicotine users who were low risk or had a short walking distance and had straightforward aortoiliac disease and had completed a trial of exercise therapy, open inline surgical revascularization for severe lifestyle limitations was rated B>R (Table V). For the described scenarios for non-nicotine users, open inline surgical revascularization for severe lifestyle limitation was B>R, except when patients were high risk or had a long walking distance. Extra-anatomic surgical revascularization was B>R for only one of the included scenarios: non-nicotine users with severe lifestyle limitations with failed endovascular interventions. Otherwise, extra-anatomic surgical revascularization was deemed R>B for most scenarios.

Endovascular intervention for a patient who had completed exercise therapy was B>R for those with severe lifestyle limitation if they were any risk, were taking OMT, had a short walking distance or no previous intervention, regardless of nicotine status. Endovascular intervention for non-nicotine users, those not taking OMT, those with a medium walking distance, and those with failed endovascular or open revascularization was also deemed B>R. Most other scenarios for endovascular interventions, after completion of exercise therapy, were indeterminate, with some R>B scenarios, such as patients with a long walking distance, not taking OMT, and with previously failed endovascular interventions in the mild and moderate lifestyle limitation groups.

**Complex aortoiliac disease.**

***Initial therapy.*** For patients with complex aortoiliac disease, exercise therapy was deemed B>R in the described scenarios (Table V). There were no included scenarios in which open inline surgical revascularization was deemed B>R. Open inline surgical revascularization was R>B for initial therapy in most scenarios; some scenarios were rated as indeterminate, primarily for non-nicotine users with severe lifestyle limitations.

Extra-anatomic surgical revascularization was R>B in the described scenarios as initial therapy. Endovascular intervention as initial therapy was B>R for complex

**Table V.** Aortoiliac disease

| | | | Straightforward Aortoiliac Disease | | | | | | | Complex Aortoiliac Disease | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Initial Therapy | | | | Completed Exercise Therapy | | | Initial Therapy | | | | Completed Exercise Therapy | | |
| **Nicotine Use** | **Lifestyle Limitation** | **Additional Factor** | Exercise Therapy | Open inline surgical revascularization | Open extra-anatomic surgical revascularization | Endovascular revascularization | Open inline surgical revascularization | Open extra-anatomic surgical revascularization | Endovascular revascularization | Exercise Therapy | Open inline surgical revascularization | Open extra-anatomic surgical revascularization | Endovascular revascularization | Open inline surgical revascularization | Open extra-anatomic surgical revascularization | Endovascular revascularization |
| Current nicotine user | Mild | low risk | B>R | R>B | R>B | R>B | - | R>B | - | B>R | R>B | R>B | R>B | R>B | R>B | - |
| | | medium risk | B>R | R>B | R>B | R>B | - | R>B | - | B>R | R>B | R>B | R>B | R>B | R>B | R>B |
| | | high risk | B>R | R>B | R>B | R>B | R>B | R>B | - | B>R | R>B | R>B | R>B | R>B | R>B | R>B |
| | | taking OMT | B>R | R>B | R>B | R>B | - | R>B | - | B>R | R>B | R>B | R>B | R>B | R>B | - |
| | | not taking OMT | B>R | R>B | R>B | R>B | R>B | R>B | - | B>R | R>B | R>B | R>B | R>B | R>B | R>B |
| | | short walking distance | B>R | R>B | R>B | - | - | R>B | - | B>R | R>B | R>B | R>B | - | R>B | - |
| | | medium walking distance | B>R | R>B | R>B | R>B | - | R>B | - | B>R | R>B | R>B | R>B | R>B | R>B | - |
| | | long walking distance | B>R | R>B | R>B | R>B | R>B | R>B | R>B | B>R | R>B | R>B | R>B | R>B | R>B | R>B |
| | | failed endovascular | | | | | - | R>B | R>B | | | | | R>B | R>B | R>B |
| | | failed open intervention | | | | | R>B | R>B | - | | | | | R>B | R>B | - |
| | | no previous intervention | | | | | - | R>B | - | | | | | R>B | R>B | - |
| | Moderate | low risk | B>R | R>B | R>B | - | - | R>B | - | B>R | R>B | R>B | R>B | R>B | R>B | - |
| | | medium risk | B>R | R>B | R>B | R>B | - | R>B | - | B>R | R>B | R>B | R>B | R>B | R>B | - |
| | | high risk | B>R | R>B | R>B | R>B | R>B | R>B | - | B>R | R>B | R>B | R>B | R>B | R>B | R>B |
| | | taking OMT | B>R | R>B | R>B | R>B | - | R>B | - | B>R | R>B | R>B | R>B | - | R>B | - |
| | | not taking OMT | B>R | R>B | R>B | R>B | R>B | R>B | R>B | B>R | R>B | R>B | R>B | R>B | R>B | R>B |
| | | short walking distance | B>R | R>B | R>B | - | - | R>B | - | B>R | R>B | R>B | - | - | R>B | - |
| | | medium walking distance | B>R | R>B | R>B | - | - | R>B | - | B>R | R>B | R>B | R>B | R>B | R>B | - |
| | | long walking distance | B>R | R>B | R>B | R>B | R>B | R>B | R>B | B>R | R>B | R>B | R>B | R>B | R>B | R>B |
| | | failed endovascular | | | | | - | R>B | R>B | | | | | R>B | R>B | R>B |
| | | failed open | | | | | R>B | R>B | - | | | | | R>B | R>B | - |
| | | no previous intervention | | | | | - | R>B | - | | | | | R>B | R>B | - |
| | Severe | low risk | B>R | - | R>B | - | B>R | R>B | B>R | B>R | - | R>B | - | - | R>B | B>R |
| | | medium risk | B>R | R>B | R>B | - | - | R>B | B>R | B>R | R>B | R>B | - | - | R>B | - |
| | | high risk | B>R | R>B | R>B | - | - | R>B | B>R | B>R | R>B | R>B | - | - | R>B | - |
| | | taking OMT | B>R | - | R>B | - | - | - | B>R | B>R | - | R>B | - | - | - | B>R |
| | | not taking OMT | B>R | R>B | R>B | R>B | - | R>B | - | B>R | R>B | R>B | - | - | R>B | - |
| | | short walking distance | B>R | - | R>B | B>R | B>R | - | B>R | B>R | - | R>B | - | - | R>B | - |
| | | medium walking distance | B>R | R>B | R>B | - | - | R>B | - | B>R | R>B | R>B | - | - | R>B | - |
| | | long walking distance | B>R | R>B | R>B | R>B | - | R>B | - | B>R | R>B | R>B | R>B | - | R>B | - |
| | | failed endovascular | | | | | - | - | - | | | | | - | R>B | - |
| | | failed open | | | | | - | - | - | | | | | - | R>B | - |
| | | no previous intervention | | | | | - | R>B | B>R | | | | | - | R>B | - |
| Non-nicotine user | Mild | low risk | B>R | R>B | R>B | R>B | - | R>B | - | B>R | R>B | R>B | R>B | - | R>B | - |
| | | medium risk | B>R | R>B | R>B | R>B | R>B | R>B | - | B>R | R>B | R>B | R>B | - | R>B | - |
| | | high risk | B>R | R>B | R>B | R>B | R>B | R>B | - | B>R | R>B | R>B | R>B | R>B | R>B | - |
| | | taking OMT | B>R | R>B | R>B | R>B | - | R>B | - | B>R | R>B | R>B | R>B | - | R>B | - |
| | | not taking OMT | B>R | R>B | R>B | R>B | R>B | R>B | R>B | B>R | R>B | R>B | R>B | R>B | R>B | R>B |
| | | short walking distance | B>R | R>B | R>B | - | - | R>B | B>R | B>R | R>B | R>B | - | - | R>B | - |
| | | medium walking distance | B>R | R>B | R>B | R>B | - | R>B | - | B>R | R>B | R>B | R>B | - | R>B | - |
| | | long walking distance | B>R | R>B | R>B | R>B | R>B | R>B | - | B>R | R>B | R>B | R>B | R>B | R>B | - |
| | | failed endovascular | | | | | - | R>B | - | | | | | - | R>B | - |
| | | failed open | | | | | R>B | R>B | - | | | | | - | R>B | - |
| | | no previous intervention | | | | | - | R>B | - | | | | | - | R>B | - |
| | Moderate | low risk | B>R | R>B | R>B | - | - | R>B | - | B>R | - | R>B | - | - | R>B | - |
| | | medium risk | B>R | R>B | R>B | - | - | R>B | - | B>R | R>B | R>B | - | - | R>B | - |
| | | high risk | B>R | R>B | R>B | R>B | R>B | R>B | - | B>R | R>B | R>B | R>B | R>B | R>B | - |
| | | taking OMT | B>R | R>B | R>B | - | - | R>B | - | B>R | R>B | R>B | - | - | R>B | - |
| | | not taking OMT | B>R | R>B | R>B | R>B | R>B | R>B | - | B>R | R>B | R>B | R>B | - | R>B | - |
| | | short walking distance | B>R | R>B | R>B | - | - | R>B | B>R | B>R | - | R>B | - | - | R>B | - |
| | | medium walking distance | B>R | R>B | R>B | - | - | R>B | - | B>R | R>B | R>B | - | - | R>B | - |
| | | long walking distance | B>R | R>B | R>B | R>B | R>B | R>B | - | B>R | R>B | R>B | R>B | R>B | R>B | - |
| | | failed endovascular | | | | | - | - | - | | | | | - | R>B | - |
| | | failed open | | | | | - | R>B | - | | | | | - | R>B | - |
| | | no previous intervention | | | | | - | - | - | | | | | - | R>B | - |
| | Severe | low risk | B>R | - | R>B | B>R | B>R | - | B>R | B>R | - | R>B | - | B>R | - | B>R |
| | | medium risk | B>R | - | R>B | B>R | B>R | - | B>R | B>R | - | R>B | - | B>R | - | B>R |
| | | high risk | B>R | R>B | R>B | - | - | - | B>R | B>R | - | R>B | - | - | - | B>R |
| | | taking OMT | B>R | - | R>B | B>R | B>R | - | B>R | B>R | - | R>B | - | B>R | - | B>R |
| | | not taking OMT | B>R | - | R>B | - | B>R | - | B>R | B>R | - | R>B | - | B>R | - | B>R |
| | | short walking distance | B>R | - | R>B | B>R | B>R | - | B>R | B>R | - | R>B | B>R | B>R | B>R | B>R |
| | | medium walking distance | B>R | - | R>B | - | B>R | - | B>R | B>R | - | R>B | - | B>R | - | B>R |
| | | long walking distance | B>R | R>B | R>B | - | - | - | - | B>R | R>B | R>B | - | - | - | - |
| | | failed endovascular | | | | | B>R | B>R | B>R | | | | | B>R | - | B>R |
| | | failed open | | | | | B>R | - | B>R | | | | | - | - | B>R |
| | | no previous intervention | | | | | B>R | - | B>R | | | | | B>R | - | B>R |

*B>R,* Benefit outweighs risk; *R>B,* risk outweighs benefit; - Indeterminate; OMT Optimal Medical Therapy.

disease less often than for straightforward disease. The only included scenario in which endovascular intervention was deemed B>R as initial therapy was in the case of non-nicotine users with severe lifestyle limitations and a short walking distance. Other scenarios with endovascular intervention as the initial treatment were R>B or indeterminate, with patients with mild or moderate lifestyle limitation more often being R>B.

***Completed exercise therapy.*** For those with complex aortoiliac disease who completed exercise therapy, open inline surgical revascularization was B>R for non-nicotine users with severe lifestyle limitations, except for those scenarios with a high-risk patient, a long walking distance, or failed prior open intervention (Table V). Otherwise, open inline surgical revascularization was R>B or indeterminate, with current nicotine use more often resulting in a rating of R>B.

Extra-anatomic surgical revascularization was B>R for only one of the included scenarios: non-nicotine users with severe lifestyle limitations and a short walking distance. Otherwise, extra-anatomic surgical revascularization was indeterminate for the remainder of the described scenarios with non-nicotine use; it was R>B for the described scenarios of current nicotine use, except for severe lifestyle limitations and taking OMT, which was deemed indeterminate.

Endovascular intervention for complex disease after a patient had completed exercise therapy was B>R for current nicotine users with severe lifestyle limitation if they were low risk or taking OMT. Endovascular intervention was B>R for the included cases of non-nicotine users with severe lifestyle limitation, except for those with a long walking distance. Otherwise, endovascular intervention was deemed R>B or indeterminate.

## Common femoral disease

Common femoral disease was defined as atherosclerotic stenotic or occlusive disease involving the common femoral artery (CFA) and its bifurcation to include the profunda femoris. The superficial femoral artery was assumed to be patent because one basic assumption was the presence of single-level disease. Because no consensus classification exists for common femoral disease, the panelists created definitions of straightforward and complex common femoral disease (Table IV). The panelists discussed the inclusion of disease laterality and ultimately decided to omit laterality for the common femoral segment because simultaneous treatment of bilateral common femoral disease was perceived as uncommon.

**Straightforward common femoral disease.**

***Initial therapy.*** For straightforward common femoral disease, exercise therapy was rated as B>R for the included scenarios (Table VI). Endovascular therapy as initial therapy was R>B for the included scenarios. For current nicotine users, CFEA was R>B as initial therapy for the described scenarios with mild and moderate lifestyle limitations except for those with a short walking distance, for which it was indeterminate. For current nicotine users with severe lifestyle limitation, CFEA was B>R as initial therapy only for patients who were low risk or with a short walking distance; otherwise, it was indeterminate.

Among non-nicotine users, CFEA as initial therapy was indeterminate in scenarios with mild lifestyle limitations when also taking OMT or also with short distance limitation or low surgical risk. For non-nicotine users with moderate lifestyle limitations, CFEA was rated as indeterminate as initial therapy in the included scenarios, except for those with long walking distance, for which it was deemed R>B. For non-nicotine users with severe lifestyle limitations, CFEA was B>R as initial therapy for patients who were low or medium risk, those who were taking OMT, and those with short walking distance.

***Completed exercise therapy.*** After a trial of exercise therapy, CFEA was B>R for current nicotine users with mild or moderate lifestyle limitations who also had short walking distance and for patients with moderate lifestyle limitation with no previous intervention (Table VI). For current nicotine users with severe lifestyle limitation, CFEA was B>R for low- or medium-risk patients, those taking OMT, those with short walking distance, and those with a history of prior failed endovascular intervention or no previous intervention.

Among the non-nicotine users with severe lifestyle limitation, CFEA was B>R for the described scenarios but not for those not taking OMT, for which CFEA was indeterminate. CFEA was B>R for patients who were non-nicotine users with moderate lifestyle limitations and short walking distance, with the remainder of scenarios rated as indeterminate or R>B.

Endovascular revascularization of the CFA was not rated as B>R in the included scenarios, reflecting a strong consensus across the rating panel regarding the risks and benefits of endovascular intervention for IC in the CFA. This was based in large part on limited data on long-term patency and clinical effectiveness and concerns about the potential use of stents in the CFA (either by design or as bail-out), which could have serious negative implications (including the limitation of surgical options) for the patient in the future.

Endovascular revascularization was R>B for both nicotine and non-nicotine users in all scenarios with mild or moderate lifestyle limitation. It was also R>B for scenarios of severe lifestyle limitation except among non-nicotine users when the patient was low or medium risk, was taking OMT, had a short or medium walking distance, or no prior intervention or failed open intervention, where endovascular revascularization was indeterminate.

**Table VI.** Common femoral disease

| | | | Straightforward Common Femoral Disease | | | | | Complex Common Femoral Disease | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Initial Therapy | | | Completed Exercise Therapy | | Initial Therapy | | | Completed Exercise Therapy | |
| **Nicotine Use** | **Lifestyle Limitation** | **Additional Factor** | Exercise Therapy | Common Femoral Endarterectomy | Endovascular revascularization | Common Femoral Endarterectomy | Endovascular revascularization | Exercise Therapy | Common Femoral Endarterectomy | Endovascular revascularization | Common Femoral Endarterectomy | Endovascular revascularization |
| Current Nicotine User | Mild | low risk | B>R | R>B | R>B | - | R>B | B>R | R>B | R>B | - | R>B |
| | | medium risk | B>R | R>B | R>B | - | R>B | B>R | R>B | R>B | - | R>B |
| | | high risk | B>R | R>B | R>B | - | R>B | B>R | R>B | R>B | R>B | R>B |
| | | taking OMT | B>R | R>B | R>B | - | R>B | B>R | R>B | R>B | - | R>B |
| | | not taking OMT | B>R | R>B | R>B | R>B | R>B | B>R | R>B | R>B | R>B | R>B |
| | | short walking distance | B>R | - | R>B | B>R | R>B | B>R | - | R>B | - | R>B |
| | | medium walking distance | B>R | R>B | R>B | - | R>B | B>R | R>B | R>B | - | R>B |
| | | long walking distance | B>R | R>B | R>B | - | R>B | B>R | R>B | R>B | R>B | R>B |
| | | failed endovascular intervention | | | | - | R>B | | | | - | R>B |
| | | failed open intervention | | | | - | R>B | | | | - | R>B |
| | | no previous intervention | | | | - | R>B | | | | - | R>B |
| | Moderate | low risk | B>R | R>B | R>B | - | R>B | B>R | R>B | R>B | - | R>B |
| | | medium risk | B>R | R>B | R>B | - | R>B | B>R | R>B | R>B | - | R>B |
| | | high risk | B>R | R>B | R>B | - | R>B | B>R | R>B | R>B | - | R>B |
| | | taking OMT | B>R | R>B | R>B | - | R>B | B>R | R>B | R>B | - | R>B |
| | | not taking OMT | B>R | R>B | R>B | - | R>B | B>R | R>B | R>B | - | R>B |
| | | short walking distance | B>R | - | R>B | B>R | R>B | B>R | - | R>B | - | R>B |
| | | medium walking distance | B>R | R>B | R>B | - | R>B | B>R | R>B | R>B | - | R>B |
| | | long walking distance | B>R | R>B | R>B | - | R>B | B>R | R>B | R>B | R>B | R>B |
| | | failed endovascular intervention | | | | - | R>B | | | | - | R>B |
| | | failed open intervention | | | | - | R>B | | | | - | R>B |
| | | no previous intervention | | | | B>R | R>B | | | | - | R>B |
| | Severe | low risk | B>R | B>R | R>B | B>R | R>B | B>R | - | R>B | B>R | R>B |
| | | medium risk | B>R | - | R>B | B>R | R>B | B>R | - | R>B | B>R | R>B |
| | | high risk | B>R | - | R>B | - | R>B | B>R | - | R>B | - | R>B |
| | | taking OMT | B>R | - | R>B | B>R | R>B | B>R | - | R>B | B>R | R>B |
| | | not taking OMT | B>R | - | R>B | - | R>B | B>R | - | R>B | - | R>B |
| | | short walking distance | B>R | B>R | R>B | B>R | R>B | B>R | - | R>B | B>R | R>B |
| | | medium walking distance | B>R | - | R>B | - | R>B | B>R | - | R>B | B>R | R>B |
| | | long walking distance | B>R | - | R>B | - | R>B | B>R | - | R>B | - | R>B |
| | | failed endovascular intervention | | | | B>R | R>B | | | | B>R | R>B |
| | | failed open intervention | | | | - | - | | | | - | R>B |
| | | no previous intervention | | | | B>R | R>B | | | | B>R | R>B |
| Non-nicotine user | Mild | low risk | B>R | - | R>B | - | R>B | B>R | - | R>B | - | R>B |
| | | medium risk | B>R | R>B | R>B | - | R>B | B>R | R>B | R>B | - | R>B |
| | | high risk | B>R | R>B | R>B | R>B | R>B | B>R | R>B | R>B | - | R>B |
| | | taking OMT | B>R | - | R>B | - | R>B | B>R | - | R>B | - | R>B |
| | | not taking OMT | B>R | R>B | R>B | R>B | R>B | B>R | R>B | R>B | R>B | R>B |
| | | short walking distance | B>R | - | R>B | - | R>B | B>R | - | R>B | - | R>B |
| | | medium walking distance | B>R | R>B | R>B | - | R>B | B>R | R>B | R>B | - | R>B |
| | | long walking distance | B>R | R>B | R>B | R>B | R>B | B>R | R>B | R>B | R>B | R>B |
| | | failed endovascular intervention | | | | - | R>B | | | | - | R>B |
| | | failed open intervention | | | | R>B | R>B | | | | R>B | R>B |
| | | no previous intervention | | | | - | R>B | | | | - | R>B |
| | Moderate | low risk | B>R | - | R>B | - | R>B | B>R | - | R>B | - | R>B |
| | | medium risk | B>R | - | R>B | - | R>B | B>R | - | R>B | - | R>B |
| | | high risk | B>R | - | R>B | - | R>B | B>R | R>B | R>B | - | R>B |
| | | taking OMT | B>R | - | R>B | - | R>B | B>R | - | R>B | - | R>B |
| | | not taking OMT | B>R | - | R>B | - | R>B | B>R | R>B | R>B | - | R>B |
| | | short walking distance | B>R | - | R>B | B>R | R>B | B>R | - | R>B | - | R>B |
| | | medium walking distance | B>R | - | R>B | - | R>B | B>R | - | R>B | - | R>B |
| | | long walking distance | B>R | R>B | R>B | - | R>B | B>R | R>B | R>B | R>B | R>B |
| | | failed endovascular intervention | | | | - | R>B | | | | - | R>B |
| | | failed open intervention | | | | - | R>B | | | | - | R>B |
| | | no previous intervention | | | | - | R>B | | | | - | R>B |
| | Severe | low risk | B>R | B>R | R>B | B>R | - | B>R | B>R | R>B | B>R | R>B |
| | | medium risk | B>R | B>R | R>B | B>R | - | B>R | B>R | R>B | B>R | R>B |
| | | high risk | B>R | - | R>B | B>R | R>B | B>R | - | R>B | B>R | R>B |
| | | taking OMT | B>R | B>R | R>B | B>R | - | B>R | B>R | R>B | B>R | R>B |
| | | not taking OMT | B>R | - | R>B | - | R>B | B>R | - | R>B | B>R | R>B |
| | | short walking distance | B>R | B>R | R>B | B>R | - | B>R | B>R | R>B | B>R | R>B |
| | | medium walking distance | B>R | - | R>B | B>R | - | B>R | - | R>B | B>R | R>B |
| | | long walking distance | B>R | - | R>B | B>R | R>B | B>R | - | R>B | B>R | R>B |
| | | failed endovascular intervention | | | | B>R | R>B | | | | B>R | R>B |
| | | failed open intervention | | | | B>R | - | | | | - | R>B |
| | | no previous intervention | | | | B>R | - | | | | B>R | R>B |

*B>R,* Benefit outweighs risk; *CET,* completed exercise therapy; *ET,* exercise therapy; *EVR,* endovascular revascularization; *IND,* indeterminate; *NA,* not applicable; *OMT,* optimal medical therapy; *R>B,* risk outweighs benefit.

**Complex common femoral disease.**

***Initial therapy.*** For patients with complex common femoral disease, exercise therapy was B>R for the described scenarios (Table VI). CFEA was R>B or indeterminate as the initial therapy in the included scenarios with current nicotine users. For non-nicotine users, CFEA was B>R as initial therapy for patients with severe lifestyle limitations with low or medium risk, taking OMT, or with short walking distance. Endovascular intervention was R>B for all scenarios.

***Completed exercise therapy.*** CFEA was deemed indeterminate or R>B for the described scenarios with mild and moderate lifestyle limitation (Table VI). For nicotine users with severe lifestyle limitation, CFEA was B>R, except for those who were high risk, those not taking OMT, those with long walking distance, and those with a failed open intervention, for which it was indeterminate. For non-nicotine users with severe lifestyle limitation, CFEA was B>R for the included scenarios, except for those with failed open intervention, for which it was deemed indeterminate. Endovascular intervention for complex common femoral disease was rated as R>B in the included scenarios.

## Femoropopliteal disease

Given that a baseline assumption for all included scenarios was that all patients had single-level hemodynamically significant disease, the panelists had an extensive discussion regarding the status of runoff distal to the femoropopliteal segment for the purpose of the scenarios. The panelists emphasized the importance of considering the relationship between anatomic complexity and durability when determining appropriateness rather than the likelihood of procedural technical success. The panelists agreed that the status of the infrapopliteal segment is significantly associated with the durability of femoropopliteal interventions. Therefore, the rating panel agreed to include the status of the infrapopliteal vessels in the complexity of femoropopliteal disease.

With respect to the number of patent infrapopliteal arteries, straightforward disease was defined as anatomy with two or more patent infrapopliteal runoff vessels (Table IV). Disease was considered complex for cases with single- or zero-vessel runoff. Consistent with the overall definitions, the panelists also included the TASC II classification and degree of calcification in the definition of disease complexity. TASC II A/B, noncalcified lesions were defined as straightforward femoropopliteal disease, and TASC II C/D and/or heavily calcified lesions were considered complex femoropopliteal disease. If the anatomy was considered complex for any of these reasons (ie, runoff, TASC II classification, or degree of calcification) the overall classification was complex disease.

The rating panel further discussed the differences in durability between an above-the-knee and a below-the-knee popliteal bypass graft target and the importance of this consideration in determining durability and appropriateness. Thus, the panelists determined that disease requiring a below-the-knee popliteal bypass target would be categorized as complex disease, and disease allowing for an above-the-knee bypass target was deemed straightforward. Additionally, the panelists discussed whether below-the-knee popliteal lesions might require the hood of a bypass to be placed onto the tibioperoneal trunk for technical reasons, leading to categorization as infrapopliteal bypass. Although the panelists agreed this situation was relatively rare, they determined it was important to consider it within the AUC. Therefore, the scenario of performing the distal anastomosis of a bypass to the proximal infrapopliteal vessels was represented as complex disease in scenarios involving bypass only.

The panelists determined that in the femoropopliteal segment, open surgical revascularization should be stratified based on the availability of conduit into bypass with single-segment great saphenous vein (SSGSV) or bypass with non-SSGSV (to include prosthetic graft, arm vein, and spliced conduits). The rating panel further determined that the distinction between unilateral and bilateral symptomatic disease was relevant to the femoropopliteal segment because unilateral revascularization in cases with bilateral disease might have a lower likelihood of significant, durable lifestyle benefit. The panelists noted that durability and freedom from reintervention are lower in femoropopliteal disease compared with aortoiliac and common femoral interventions. When this risk is multiplied over two affected limbs, the risk/benefit ratio of intervention is affected, and, therefore, the appropriateness will also be affected.

The rating panel emphasized that treatment of femoropopliteal disease, in particular, can be very nuanced. It is exceptionally challenging to capture all the nuances in scenarios and simultaneously maintain a reasonable number of scenarios. Therefore, it is important to recognize that, especially with treatment of femoropopliteal disease, these AUC are intended to represent general statements about common cases seen in clinical practice and should not be considered as absolutes.

**Straightforward femoropopliteal disease.**

***Initial therapy.*** Exercise therapy was B>R as initial therapy in the described scenarios (Table VII). Any intervention (endovascular or open) was rated as R>B for the included scenarios with mild to moderate lifestyle limitations. For severe lifestyle limitation among current nicotine users, open revascularization with non-SSGSV was R>B in all scenarios, and open surgical revascularization with SSGSV was R>B or indeterminate, depending on factors such as risk status. For cases of severe lifestyle limitations among non-nicotine

**Table VII.** Femoropopliteal disease

| | | | Straightforward Femoropopliteal Disease | | | | | | | Complex Femoropopliteal Disease | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Initial Therapy | | | | Completed Exercise Therapy | | | Initial Therapy | | | | Completed Exercise Therapy | | |
| **Nicotine Use** | **Lifestyle Limitation** | **Additional Factor** | Exercise Therapy | Open surgical revascularization with SSGSV | Open surgical revascularization with non-SSGSV | Endovascular revascularization | Open surgical revascularization with SSGSV | Open surgical revascularization with non-SSGSV | Endovascular revascularization | Exercise Therapy | Open surgical revascularization with SSGSV | Open surgical revascularization with non-SSGSV | Endovascular revascularization | Open surgical revascularization with SSGSV | Open surgical revascularization with non-SSGSV | Endovascular revascularization |
| Current Nicotine User | Mild | low/medium/high risk | B>R | R>B | R>B | R>B | R>B | R>B | R>B | B>R | R>B | R>B | R>B | R>B | R>B | R>B |
| | | taking/ not taking OMT | B>R | R>B | R>B | R>B | R>B | R>B | R>B | B>R | R>B | R>B | R>B | R>B | R>B | R>B |
| | | short/medium/long walking distance | B>R | R>B | R>B | R>B | R>B | R>B | R>B | B>R | R>B | R>B | R>B | R>B | R>B | R>B |
| | | unilateral/bilateral symptoms | B>R | R>B | R>B | R>B | R>B | R>B | R>B | B>R | R>B | R>B | R>B | R>B | R>B | R>B |
| | | failed endovascular/open intervention | | | | | R>B | R>B | R>B | | | | | R>B | R>B | R>B |
| | | no previous intervention | | | | | R>B | R>B | R>B | | | | | R>B | R>B | R>B |
| | Moderate | low/medium/high risk | B>R | R>B | R>B | R>B | R>B | R>B | R>B | B>R | R>B | R>B | R>B | R>B | R>B | R>B |
| | | taking/ not taking OMT | B>R | R>B | R>B | R>B | R>B | R>B | R>B | B>R | R>B | R>B | R>B | R>B | R>B | R>B |
| | | short/medium/long walking distance | B>R | R>B | R>B | R>B | R>B | R>B | R>B | B>R | R>B | R>B | R>B | R>B | R>B | R>B |
| | | unilateral/bilateral symptoms | B>R | R>B | R>B | R>B | R>B | R>B | R>B | B>R | R>B | R>B | R>B | R>B | R>B | R>B |
| | | failed endovascular/open intervention | | | | | R>B | R>B | R>B | | | | | R>B | R>B | R>B |
| | | no previous intervention | | | | | R>B | R>B | R>B | | | | | R>B | R>B | R>B |
| | Severe | low risk | B>R | - | R>B | - | - | - | - | B>R | - | R>B | - | - | - | - |
| | | medium risk | B>R | - | R>B | - | - | - | - | B>R | - | R>B | - | - | - | - |
| | | high risk | B>R | R>B | R>B | R>B | - | R>B | - | B>R | R>B | R>B | - | - | R>B | - |
| | | taking OMT | B>R | - | R>B | - | - | - | - | B>R | - | R>B | - | - | - | - |
| | | not taking OMT | B>R | R>B | R>B | R>B | - | R>B | - | B>R | R>B | R>B | R>B | - | - | - |
| | | short walking distance | B>R | - | R>B | - | - | - | B>R | B>R | - | R>B | - | - | - | B>R |
| | | medium walking distance | B>R | R>B | R>B | - | - | - | - | B>R | R>B | R>B | - | - | - | - |
| | | long walking distance | B>R | R>B | R>B | R>B | - | R>B | - | B>R | R>B | R>B | R>B | - | R>B | - |
| | | unilateral symptoms | B>R | - | R>B | - | - | - | - | B>R | - | R>B | - | - | - | - |
| | | bilateral symptoms | B>R | R>B | R>B | R>B | - | R>B | - | B>R | R>B | R>B | R>B | - | - | - |
| | | failed endovascular intervention | | | | | - | - | - | | | | | - | - | - |
| | | failed open intervention | | | | | - | R>B | - | | | | | - | - | - |
| | | no previous intervention | | | | | - | - | - | | | | | - | - | - |
| Non-nicotine user | Mild | low/medium/high risk | B>R | R>B | R>B | R>B | R>B | R>B | R>B | B>R | R>B | R>B | R>B | R>B | R>B | R>B |
| | | taking/ not taking OMT | B>R | R>B | R>B | R>B | R>B | R>B | R>B | B>R | R>B | R>B | R>B | R>B | R>B | R>B |
| | | short/medium/long walking distance | B>R | R>B | R>B | R>B | R>B | R>B | R>B | B>R | R>B | R>B | R>B | R>B | R>B | R>B |
| | | unilateral/bilateral symptoms | B>R | R>B | R>B | R>B | R>B | R>B | R>B | B>R | R>B | R>B | R>B | R>B | R>B | R>B |
| | | failed endovascular/open intervention | | | | | R>B | R>B | R>B | | | | | R>B | R>B | R>B |
| | | no previous intervention | | | | | R>B | R>B | R>B | | | | | R>B | R>B | R>B |
| | Moderate | low/medium/high risk | B>R | R>B | R>B | R>B | R>B | R>B | R>B | B>R | R>B | R>B | R>B | R>B | R>B | R>B |
| | | taking/ not taking OMT | B>R | R>B | R>B | R>B | R>B | R>B | R>B | B>R | R>B | R>B | R>B | R>B | R>B | R>B |
| | | short/medium/long walking distance | B>R | R>B | R>B | R>B | R>B | R>B | R>B | B>R | R>B | R>B | R>B | R>B | R>B | R>B |
| | | unilateral/bilateral symptoms | B>R | R>B | R>B | R>B | R>B | R>B | R>B | B>R | R>B | R>B | R>B | R>B | R>B | R>B |
| | | failed endovascular/open intervention | | | | | R>B | R>B | R>B | | | | | R>B | R>B | R>B |
| | | no previous intervention | | | | | R>B | R>B | R>B | | | | | R>B | R>B | R>B |
| | Severe | low risk | B>R | - | - | - | B>R | - | B>R | B>R | - | - | - | B>R | - | B>R |
| | | medium risk | B>R | - | R>B | - | B>R | - | B>R | B>R | - | R>B | - | B>R | - | B>R |
| | | high risk | B>R | - | R>B | - | - | - | B>R | B>R | - | R>B | - | - | R>B | B>R |
| | | taking OMT | B>R | - | - | - | B>R | - | B>R | B>R | - | - | - | B>R | - | B>R |
| | | not taking OMT | B>R | - | R>B | - | - | - | B>R | B>R | - | R>B | - | - | - | - |
| | | short walking distance | B>R | - | - | - | B>R | B>R | B>R | B>R | - | - | B>R | B>R | - | B>R |
| | | medium walking distance | B>R | - | R>B | - | B>R | - | B>R | B>R | - | R>B | - | B>R | - | B>R |
| | | long walking distance | B>R | - | R>B | - | - | - | B>R | B>R | - | R>B | - | - | R>B | - |
| | | unilateral symptoms | B>R | - | - | - | B>R | - | B>R | B>R | - | - | - | B>R | - | B>R |
| | | bilateral symptoms | B>R | - | R>B | - | B>R | - | B>R | B>R | - | R>B | - | B>R | - | B>R |
| | | failed endovascular intervention | | | | | B>R | - | B>R | | | | | B>R | - | - |
| | | failed open intervention | | | | | - | - | B>R | | | | | - | - | - |
| | | no previous intervention | | | | | B>R | - | B>R | | | | | B>R | - | B>R |

*B>R*, Benefit outweighs risk; *CET*, complete exercise therapy; *IND*, indeterminate; *NA*, not applicable; *OMT*, optimal medical therapy; *R>B*, risk outweighs benefit; *SSGSV*, single segment great saphenous vein.

users, open revascularization with SSGSV and endovascular revascularization were both indeterminate as initial treatment in all scenarios. Open revascularization with non-SSGSV was rated as indeterminate as initial therapy for non-nicotine users who were low risk, were taking OMT, had a short walking distance, or had unilateral disease.

***Completed exercise therapy.*** Intervention (endovascular or open) was R>B in the included scenarios with mild or moderate lifestyle limitations (Table VII). For severe lifestyle limitation, endovascular intervention was B>R for current nicotine users with short walking distance. Open surgical revascularization with SSGSV was considered indeterminate for the described cases of current nicotine users with severe lifestyle limitations. Open revascularization with non-SSGSV was R>B for current nicotine users who were high risk, not taking OMT, had long walking distance, had bilateral symptoms, or had failed open intervention.

For scenarios with severe lifestyle limitation among non-nicotine users, endovascular revascularization was B>R in the described scenarios. However, open revascularization with non-SSGSV was rated as indeterminate in the included scenarios, except for a short walking distance, for which it was rated B>R. Among non-nicotine users who had completed exercise therapy but continued to have severe lifestyle limitation, open revascularization with SSGSV was B>R, except for patients who were high risk, those not taking OMT, those with long walking distance, and those with a failed open intervention, for which it was indeterminate.

**Complex femoropopliteal disease.**

***Initial therapy.*** As with straightforward disease, exercise therapy was B>R as initial therapy for all described scenarios with complex femoropopliteal disease (Table VII). Revascularization (endovascular or open) was R>B for the included scenarios with mild and moderate lifestyle limitations.

For scenarios with severe lifestyle limitation among current nicotine users, open revascularization with non-SSGSV was always rated as R>B as initial therapy. Open revascularization with SSGSV and endovascular revascularization were indeterminate or R>B depending on the risk, walking distance, and presence of unilateral or bilateral disease.

For scenarios with severe lifestyle limitations among non-nicotine users, open revascularization with SSGSV and endovascular revascularization was always indeterminate, except for scenarios with short walking distance, for which endovascular intervention was rated as B>R. Open revascularization with non-SSGSV was R>B for low risk, taking OMT, short walking distance, and bilateral disease; otherwise, it was indeterminate.

***Completed exercise therapy.*** Revascularization (endovascular or open) was again rated R>B for the included scenarios with mild and moderate lifestyle limitation (Table VII). For severe lifestyle limitation in current nicotine users, the included methods of revascularization were indeterminate for the described scenarios with three exceptions. Endovascular revascularization for those with a short walking distance was rated as B>R. Open surgical revascularization with non-SSGSV for high-risk patients and for those with a long walking distance was rated as R>B.

For scenarios with severe lifestyle limitation among non-nicotine users, endovascular revascularization and open revascularization with SSGSV were mostly rated as B>R. Scenarios were indeterminate when OMT was not being taken, when the walking distance was long, and when there was a failed open intervention. For scenarios with severe lifestyle limitation among non-nicotine users, open revascularization with non-SSGSV was R>B for high-risk patients and those with a long walking distance; otherwise, it was indeterminate.

### Infrapopliteal disease

After discussion, the rating panel unanimously agreed that scenarios involving open or endovascular revascularization of infrapopliteal disease for patients with symptoms limited to IC were R>B. The panelists unanimously agreed not to individually rate any infrapopliteal scenarios. The panelists also unanimously agreed that isolated infrapopliteal lesions do not result in disabling claudication and, therefore, are R>B to treat for an indication of IC.

The rating panel discussion included "downstream" infrapopliteal interventions, defined as any endovascular intervention in the setting of concomitant proximal intervention (open and/or endovascular). The panelists unanimously agreed that "total" revascularization (performing an infrapopliteal intervention to improve runoff distal to a femoropopliteal revascularization) is R>B for IC. This was a notable and intentional deviation from the assumption of single-level disease used in the other anatomic segments.

**Initial therapy.** For all infrapopliteal scenarios, exercise therapy was deemed B>R as initial therapy. All open and endovascular revascularizations were deemed R>B as initial therapy for IC.

**Completed exercise therapy.** After completion of exercise therapy, all infrapopliteal interventions, open or endovascular, were unanimously deemed R>B for the treatment of IC.

## DISCUSSION

These AUC define several key principles of appropriate care of IC due to PAD using a rigorous, scientific, and validated method. Importantly, exercise therapy was always rated as a B>R management strategy for the initial treatment of IC. In contrast, revascularization (both open and endovascular) was frequently rated as R>B, with some

important exceptions, primarily patients with persistent severe lifestyle limitations after a good faith effort at exercise therapy. In considering invasive interventions as treatment of IC, the rating panel agreed on the guiding principle of weighing the durability of symptom relief and procedural risk.

Other professional societies (ie, the ACC and Society for Cardiovascular Angiography and Interventions [SCAI]) have published AUC for peripheral artery interventions.[17,18] Although the ACC AUC for PAD, published in 2018, were endorsed by several other professional societies, the SVS did not formally endorse the ACC AUC. Both the ACC and SCAI used a method similar to that prescribed by the RAM. However, they did not strictly adhere to the RAM. The ACC deviated enough from the RAM to term their method the "ACC appropriate use criteria methodology."[19]

The SVS committed to creating these AUC by adhering to the RAM with the greatest degree of integrity possible. The RAM is the only validated method for development of AUC and has been used to develop AUC for numerous procedures across a broad spectrum of disciplines. A Pubmed.gov search of the term returned nearly 1200 results (as of August 14, 2021). The RAM has also been shown to have a high degree of retest reliability.[20] Furthermore, when AUC are created using the RAM, investigators have repeatedly demonstrated that procedures performed according to appropriate indications have superior outcomes compared with procedures performed for inappropriate indications (eg, hip replacement and coronary revascularization).[21,22]

Similar to the SVS AUC, the ACC AUC for PAD were developed by a writing group and a rating panel. The ACC writing group consisted of six members: three from the ACC, one from the SIR, one from the Society for Vascular Medicine (SVM), and one from the SCAI. The ACC rating panel included one SVS member and five from the ACC, one from the SIR, two from the SVM, one from the SCAI, one from the Society for Vascular Ultrasound, and one from the American College of Radiology. For the SCAI AUC, the rating panel consisted of "experts within the SCAI peripheral vascular disease committee."[18] The SVS strove for multidisciplinary representation on the rating panel for these AUC by including 4 of 15 of the members (27%) as non-vascular surgeons. This amount of representation allowed for the detection of significant disagreement between vascular surgeons and non-vascular surgeons, when the IPRAS formula was applied as prescribed by the RAM.

Although the SVS AUC writing panel included only SVS members, the content of these final AUC was driven nearly entirely by the rating panel. Despite the baseline assumptions, definitions, and scenarios that were created initially by the writing panel, the rating panel significantly modified all of these during round two of rating, as described. The content and results of the round two rating are represented in this AUC document. Furthermore, all rating panelists were offered the opportunity to review and edit this report and be included as authors.

Both the ACC and the SCAI addressed PAD broadly in their AUC by incorporating multiple manifestations of atherosclerotic vascular disease, including renal artery stenosis, IC, and chronic limb threatening ischemia.[17,23] The SVS chose to focus these AUC on IC for several reasons. First, the SVS sought to assemble writing and rating panelists with specific expertise in lower extremity PAD because expertise in one arterial bed does not necessarily translate to expertise in other arterial beds. Second, focusing on IC allowed for addressing the topic as thoroughly as possible by including thousands of permutations of variables that are relevant to clinical decision-making. Thus, the scenarios in these AUC are multifactorial, such as "open surgical revascularization with SSGSV as initial therapy for a patient with complex femoropopliteal disease, severe lifestyle limitations, current nicotine use, and short walking distance." In contrast, a representative scenario from the ACC AUC is as follows: "endovascular treatment for aortoiliac disease in intermittent claudication despite guideline-directed medical therapy-stenotic lesions."[17] A representative scenario from the SCAI AUC is "percutaneous transluminal angioplasty in Rutherford class 4-6, femoropopliteal chronic total occlusion."[18] The multifactorial nature of the scenarios in these AUC allows for insight into which factors the panelists believed were most influential in determining appropriateness.

Clinical practice guidelines and AUC are both intended to guide clinical decision-making. However, the distinctions between clinical practice guidelines and AUC must be remembered.[24] Both clinical practice guidelines and AUC start with synthesis of the evidence through systematic reviews and meta-analyses. However, the clinical practice guideline process includes the development of consensus statements for recommendations that typically address a single aspect of care, such as, the use of statin therapy for patients with symptomatic PAD.[9] Clinical practice guideline recommendations are graded according to the quality of evidence used to develop the recommendation. In contrast, the AUC method allows for addressing permutations of multiple aspects of clinical care without the goal of achieving consensus. The AUC method allows for disagreement among rating panelists, which results in an indeterminate rating and signifies an area in which more research and higher quality evidence are needed. AUC are primarily aimed at clinical decision-making with respect to interventions and determining whether the benefit exceeds the risk for a specific patient profile. Clinical practice guidelines, however, are often developed to address the entire spectrum of care, from medical management to preoperative evaluation and optimization, to operative interventions, to postoperative management.

In general, the rating panel leaned toward a noninvasive approach for the treatment of most patients with IC. Although IC can significantly affect health-related quality of life, the risk of a major amputation for patients with IC is exceedingly low at <1% annually.[25] Unsurprisingly, and importantly, exercise therapy was deemed appropriate for every scenario in which it was included. This is consistent with the SVS clinical practice guidelines for IC, which recommend a supervised exercise program (if available) as first-line therapy (grade 1A) and home-based exercise when a supervised exercise program is unavailable (grade 1B).[9] Exercise therapy is noninvasive and has been shown repeatedly through case series, randomized trials, and meta-analyses to be effective for patients with IC. Exercise therapy increases both the walking distance to the onset of claudication and the walking distance to the maximum claudication pain.[26-29] The evidence presented in the clinical practice guidelines and now coupled with the strong endorsement for exercise therapy in these AUC emphasizes the need for expanding the funding for, and availability of, exercise programs for the treatment of IC.

The balance of risk of an invasive procedure and benefit to quality of life (heavily influenced by durability considerations by the rating panelists) is reflected in the overall trend of invasive interventions being more likely to be rated as R>B or indeterminate in scenarios with mild or moderate lifestyle limitations or long walking distance. The trend toward favoring interventions in non-nicotine users also deserves comment. The definition we used did not differentiate a current smoker who has made no effort to quit from one who has markedly decreased their nicotine use. The clinical benefit of this latter scenario is unclear; however, the importance of counseling for smoking cessation cannot be overstated.

The rating panel repeatedly emphasized the importance of considering durability with respect to symptom relief in determining the appropriateness of an invasive intervention for IC. This is consistent with the SVS clinical practice guidelines for IC, which recommend that the modality offered should "provide a reasonable likelihood of sustained benefit to the patient (>50% likelihood of clinical efficacy for at least 2 years (grade 1C)."[9] The durability of interventions varies by the type of intervention and the arterial bed treated. Inline open bypass in the aortoiliac segment, aortoiliac endovascular interventions, and CFEA typically have excellent long-term results, with 5-year primary patency nearing or exceeding 90%.[30,31] In contrast, extra-anatomic bypass (eg, axillary–bifemoral) in the aortoiliac segment, bypass performed with a vein or prosthetic graft in the femoropopliteal segment, and endovascular interventions in the femoropopliteal segment have less reliable and wide-ranging long-term results.[32-34] Accordingly, all invasive interventions for femoropopliteal disease for mild to moderate lifestyle limitation, regardless of all other factors, were deemed R>B compared with a wider variation for the other segments. This largely reflects the importance the panelists placed on durability in accordance with the recommendations from the SVS clinical practice guidelines for IC.

Notably, for infrapopliteal disease, the panelists unanimously agreed that open or endovascular intervention in the infrapopliteal segment is of unclear benefit, with increased risk in all included scenarios for the treatment of IC, consistent with the SVS clinical practice guidelines. The SVS guidelines state that "treatment of isolated infrapopliteal disease for relief of claudication is not advised."[9] The clinical practice guidelines further state that "in patients with multi-segment disease, the more proximal disease should be treated first and usually results in improvement in symptoms without extending treatment to the more distal arteries." This sentiment is reflected in the panelists' unanimous agreement that infrapopliteal interventions downstream from a more proximal intervention, including those performed with the intention of improving patency of a more proximal intervention, are considered to pose a greater risk than benefit for patients with IC. The panelists' rationale centered on the extremely low likelihood that infrapopliteal disease would contribute to symptoms of claudication and that failure of tibial interventions is both more common and potentially more deleterious to the patient compared with treatment of proximal arterial segments.

In contrast, the ACC AUC rated endovascular treatment for "below the knee disease, for intermittent claudication despite guideline-directed medical therapy (stenotic lesions and chronic total occlusion)" as "may be appropriate" and surgical treatment to be "rarely appropriate."[17] Similarly, the SCAI AUC rated treatment of Rutherford class 2 to 3 infrapopliteal disease using percutaneous transluminal angioplasty, drug-eluting stent, rotational atherectomy, and cutting balloon as "appropriate" in a number of scenarios.[18] In addition, bare metal stenting, drug-coated balloons, and laser atherectomy were rated as "may be appropriate" in the infrapopliteal distribution in numerous other scenarios in the SCAI AUC.

The panelists, as a group, expressed a strong aversion to endovascular intervention for IC in the CFA. This was reflected by an R>B rating for virtually all the included scenarios for endovascular intervention in the CFA, except for eight, which were rated as indeterminate. These ratings are in accordance with the SVS clinical practice guidelines for IC, which state that "common femoral artery disease should be treated surgically."[9]

Remarkably, of the 2280 scenarios in the aortoiliac, common femoral, and femoropopliteal segments that were rated in round two, only 9 (0.4%) had disagreement according to the IPRAS formula. This reflects the success of the second round of the rating process, when conducted exactly as prescribed by the RAM. When the

rating panelists met to discuss the assumptions, definitions, and scenarios, they modified them in a way that facilitated agreement about the appropriateness ratings, despite the lack of any encouragement to reach a consensus regarding appropriateness. Thus, most of the scenarios that were ultimately classified as indeterminate represent areas of uncertain or equivocal appropriateness, rather than disagreement, and should be the subject of future research.

**Study limitations.** The number of scenarios that would be required to address every possible clinical situation that could be encountered in clinical practice would be many-fold greater than contained in these AUC. It would be unreasonable to ask panelists to rate more scenarios than the amount they rated in this project. The RAM recommends limiting the number of scenarios to <2000, which was exceeded in these AUC.

The objective of these AUC is to address the situations most often encountered in clinical practice. The included variables were those that the writing and rating panelists agreed are most relevant to clinical decision-making and simultaneously have some level of evidence to support the appropriateness rating beyond expert opinion. The number of variables and potential scenarios that were omitted are too numerous to count. Many have already been mentioned, including nuances of prior interventions, the reasons for not taking OMT, the distinction between supervised and nonsupervised exercise therapy, and a more granular breakdown of intervention types than inline vs extra-anatomic. Although "prior intervention" was included in these AUC, the rating panel noted that the potential variability was extensive and could affect the scenarios in various ways, which led to largely indeterminate ratings. No trend was noted (neither a trend toward more B>R designations nor toward more R>B designations) for scenarios with this variable compared with other scenarios in the same anatomic segment. This is consistent with the panel's discussion that the effects of a prior intervention on determining the appropriateness of a current intervention after failed exercise therapy were so varied that no effect could be discerned.

Patients who refuse to perform exercise therapy (regardless of the reason; ie, pain, time constraints, access) was a scenario that was not addressed. The issue of patient engagement in their own healthcare is an important one that should be considered in every clinician–patient encounter. Several barriers to patient participation in supervised exercise therapy have been documented, including lack of access, inconvenience, and lack of interest.[35,36] Although home-based exercise therapy can overcome some of these barriers, its efficacy might be limited to certain types of programs that incorporate behavioral techniques.[37] The issues surrounding the level of patient engagement can be quite complex and could not be adequately captured without significantly increasing the number of scenarios.

As stated, a basic assumption of these AUC was the presence of single-level disease, apart from the statement regarding downstream infrapopliteal interventions. Therefore, multilevel disease was not included in these AUC. The number of permutations required to incorporate all the combinations of multilevel disease would be unmanageable and would far exceed the RAM-recommended limit. Intuitively, multilevel disease settings are anatomically more complex and thus require considerable clinical judgment and risk assessment for any invasive strategy. Similarly, specific types of endovascular interventions (eg, angioplasty, stenting, atherectomy) were not included in these AUC owing to the large number of additional scenarios that would be required. Furthermore, the amount and quality of data available regarding the outcomes of interventions for multilevel disease and specific types of endovascular interventions are limited. Thus, if included, the ratings would have relied primarily on expert opinion.

Finally, although a great effort was made to have a diverse rating panel, not all specialty and professional society groups could be equally represented in a panel of 15 members. The RAM recommends a nine-member panel. This was expanded to 15 to accommodate a more diverse representation. Among the SVS members, there was diversity in age, gender, geographic region, and practice type; however, this was ultimately limited by the composition of the SVS volunteers for the panel. In addition, only one nonproceduralist was included in the rating panel (M.P.B.). It is possible that had the rating panel been composed of different proportions of specialties, practice types, and proceduralists, the results would be different. Nevertheless, the exceptionally high degree of agreement among panelists has provided strong support for the validity of these results.

## CONCLUSIONS

These AUC provide the fundamentals for determining the appropriateness of treatment in the management of IC. Exercise was deemed B>R as the initial therapy for all patients with IC. Revascularization was rated as B>R for selected patients with severe lifestyle-limiting IC symptoms despite treatment with OMT and an adequate trial of exercise. Revascularization of infrapopliteal disease for IC was rated as R>B for all scenarios. Future AUC efforts are needed to address the variables and scenarios that we could not incorporate in this project. Scenarios rated as indeterminate highlight areas that should be targets of further research. The modern treatment of PAD is rapidly evolving, with innovations in devices and techniques being introduced constantly. As innovations occur and the body of literature increases, these AUC will require regular reassessments and revisions to reflect the rapidly advancing field. Ultimately,

treatment of IC must be individualized to each patient in partnership with the clinician, with consideration of the patient's goals and values. These AUC can serve as a basis from which shared decision-making can occur.

## AUTHOR CONTRIBUTIONS

Conception and design: KW, JPS
Analysis and interpretation: KW, JPS
Data collection: KW, JJS, KK, LK, NO, NS, TT, SA, SB, MB, TB, MC, DD, YE, BL, JL, JM, DM, DN, LO, RP, MS, JPS
Writing the article: KW, JJS, NO, NS, TT, JPS
Critical revision of the article: KW, JJS, KK, LK, NO, NS, TT, SA, SB, MB, TB, MC, DD, YE, BL, JL, JM, DM, DN, LO, RP, MS, JPS
Final approval of the article: KW, JJS, KK, LK, NO, NS, TT, SA, SB, MB, TB, MC, DD, YE, BL, JL, JM, DM, DN, LO, RP, MS, JPS
Statistical analysis: KW, KK
Obtained funding: KW
Overall responsibility: KW

## REFERENCES

1. Fitch KB, Aguilar SJ, Burnand B, LaCalle JR, Lazaro P, van het Loo M, et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation; 2001.
2. Fowkes FG, Aboyans V, Fowkes FJ, McDermott MM, Sampson UK, Criqui MH. Peripheral artery disease: epidemiology and global perspectives. Nat Rev Cardiol 2017;14:156-70.
3. Song P, Rudan D, Zhu Y, Fowkes FJI, Rahimi K, Fowkes FGR, et al. Global, regional, and national prevalence and risk factors for peripheral artery disease in 2015: an updated systematic review and analysis. Lancet Glob Health 2019;7:e1020-30.
4. Mahoney EM, Wang K, Cohen DJ, Hirsch AT, Alberts MJ, Eagle K, et al. One-year costs in patients with a history of or at risk for atherothrombosis in the United States. Circ Cardiovasc Qual Outcomes 2008;1:38-45.
5. Mahoney EM, Wang K, Keo HH, Duval S, Smolderen KG, Cohen DJ, et al. Vascular hospitalization rates and costs in patients with peripheral artery disease in the United States. Circ Cardiovasc Qual Outcomes 2010;3:642-51.
6. Hicks CW, Holscher CM, Wang P, Black JH III, Abularrage CJ, Makary MA. Overuse of early peripheral vascular interventions for claudication. J Vasc Surg 2020;71:121-30.e1.
7. Desai U, Kharat A, Hess CN, Milentijevic D, Laliberté F, Zuckerman P, et al. Incidence of major atherothrombotic vascular events among patients with peripheral artery disease after revascularization. Ann Vasc Surg 2021;75:217-26.
8. Hess CN, Fu JW, Gundrum J, Allen LaPointe NM, Wang TY, Rogers RK, et al. Diabetes mellitus and risk stratification after peripheral artery revascularization. J Am Coll Cardiol 2021;77:2867-9.
9. Conte MS, Pomposelli FB, Clair DG, Geraghty PJ, McKinsey JF, Mills JL, et al. Society for Vascular Surgery practice guidelines for atherosclerotic occlusive disease of the lower extremities: management of asymptomatic disease and claudication. J Vasc Surg 2015;61(Suppl): 2s-41s.
10. Brozek JL, Akl EA, Alonso-Coello P, Lang D, Jaeschke R, Williams JW, et al. Grading quality of evidence and strength of recommendations in clinical practice guidelines. Part 1 of 3. An overview of the GRADE approach and grading quality of evidence about interventions. Allergy 2009;64:669-77.
11. Protecting access to Medicare act 2014. H.R. 4302 — 113th congress (2013-2014). Available at: https://www.congress.gov/bill/113th-congress/house-bill/4302. Accessed August 14, 2021.
12. Society for vascular Surgery conflict of interest. Available at: https://online.vascular.org/svsssa/f?p=700:110:14106955809939::::P110_COLLECTION_ID:CONFLICT_OF_INTEREST_2021. Accessed September 21.
13. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009;42:377-81.
14. Divakaran S, Carroll BJ, Chen S, Shen C, Bonaca MP, Secemsky EA. Supervised exercise therapy for symptomatic peripheral artery disease among Medicare beneficiaries between 2017 and 2018: participation rates and outcomes. Circ Cardiovasc Qual Outcomes 2021;14: e007953.
15. Gerhard-Herman MD, Gornik HL, Barrett C, Barshes NR, Corriere MA, Drachman DE, et al. 2016 AHA/ACC guideline on the management of patients with lower extremity peripheral artery disease: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation 2017;135:e726-79.
16. Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FG, et al. Inter-society consensus for the management of peripheral arterial disease (TASC II). Eur J Vasc Endovasc Surg 2007;33(Suppl 1): S1-75.
17. Bailey SR, Beckman JA, Dao TD, Misra S, Sobieszczyk PS, White CJ, et al. ACC/AHA/SCAI/SIR/SVM 2018 appropriate use criteria for peripheral artery intervention: a report of the American College of Cardiology appropriate use criteria task force, American Heart association, society for cardiovascular Angiography and interventions, society of interventional Radiology, and society for vascular medicine. J Am Coll Cardiol 2019;73:214-37.
18. Klein AJ, Jaff MR, Gray BH, Aronow HD, Bersin RM, Diaz-Sandoval LJ, et al. SCAI appropriate use criteria for peripheral arterial interventions: an update. Catheter Cardiovasc Interv 2017;90:E90-110.
19. Hendel RC, Lindsay BD, Allen JM, Brindis RG, Patel MR, White L, et al. ACC appropriate use criteria methodology: 2018 update: a report of the American College of Cardiology appropriate use criteria task force. J Am Coll Cardiol 2018;71:935-48.
20. Lawson EH, Gibbons MM, Ko CY, Shekelle PG. The appropriateness method has acceptable reliability and validity for assessing overuse and underuse of surgical procedures. J Clin Epidemiol 2012;65: 1133-43.
21. Fitch K, Lázaro P, Aguilar MD, Kahan JP, van het Loo M, Bernstein SJ. European criteria for the appropriateness and necessity of coronary revascularization procedures. Eur J Cardiothorac Surg 2000;18:380-7.
22. Quintana JM, Aróstegui I, Azkarate J, Goenaga JI, Elexpe X, Letona J, et al. Evaluation of explicit criteria for total hip joint replacement. J Clin Epidemiol 2000;53:1200-8.
23. Parikh SA, Shishehbor MH, Gray BH, White CJ, Jaff MR. SCAI expert consensus statement for renal artery stenting appropriate use. Catheter Cardiovasc Interv 2014;84:1163-71.
24. Murad MH, Montori VM, Sidawy AN, Ascher E, Meissner MH, Chaikof EL, et al. Guideline methodology of the Society for Vascular Surgery including the experience with the GRADE framework. J Vasc Surg 2011;53:1375-80.
25. Criqui MH, Langer RD, Fronek A, Feigelson HS, Klauber MR, McCann TJ, et al. Mortality over a period of 10 years in patients with peripheral arterial disease. N Engl J Med 1992;326:381-6.
26. Gardner AW, Parker DE, Montgomery PS, Blevins SM. Step-monitored home exercise improves ambulation, vascular function, and inflammation in symptomatic patients with peripheral artery disease: a randomized controlled trial. J Am Heart Assoc 2014;3: e001107.
27. Gardner AW, Parker DE, Montgomery PS, Scott KJ, Blevins SM. Efficacy of quantified home-based exercise and supervised exercise in patients with intermittent claudication: a randomized controlled trial. Circulation 2011;123:491-8.
28. McDermott MM, Ades P, Guralnik JM, Dyer A, Ferrucci L, Liu K, et al. Treadmill exercise and resistance training in patients with peripheral arterial disease with and without intermittent claudication: a randomized controlled trial. JAMA 2009;301:165-74.
29. McDermott MM, Liu K, Guralnik JM, Criqui MH, Spring B, Tian L, et al. Home-based walking exercise intervention in peripheral artery disease: a randomized clinical trial. JAMA 2013;310:57-65.
30. Boufi M, Ejargue M, Gaye M, Boyer L, Alimi Y, Loundou AD. Systematic review and meta-analysis of endovascular versus open repair for common femoral artery atherosclerosis treatment. J Vasc Surg 2021;73:1445-55.
31. Sharma G, Scully RE, Shah SK, Madenci AL, Arnaoutakis DJ, Menard MT, et al. Thirty-year trends in aortofemoral bypass

for aortoiliac occlusive disease. J Vasc Surg 2018; 68:1796-804.e2.
32. Bath J, Lawrence PF, Neal D, Zhao Y, Smith JB, Beck AW, et al. Endovascular interventions for claudication do not meet minimum standards for the Society for Vascular Surgery efficacy guidelines. J Vasc Surg 2021;73:1693-700.e3.
33. Igari K, Kudo T, Katsui S, Nishizawa M, Uetake H. The comparison of long-term results between aortofemoral and axillofemoral bypass for patients with aortoiliac occlusive disease. Ann Thorac Cardiovasc Surg 2020;26:352-8.
34. Pereira CE, Albers M, Romiti M, Brochado-Neto FC, Pereira CA. Meta-analysis of femoropopliteal bypass grafts for lower extremity arterial insufficiency. J Vasc Surg 2006;44:510-7.
35. Dua A, Gologorsky R, Savage D, Rens N, Gandhi N, Brooke B, et al. National assessment of availability, awareness, and utilization of supervised exercise therapy for peripheral artery disease patients with intermittent claudication. J Vasc Surg 2020;71:1702-7.
36. Harwood AE, Smith GE, Cayton T, Broadbent E, Chetter IC. A systematic review of the uptake and adherence rates to supervised exercise programs in patients with intermittent claudication. Ann Vasc Surg 2016;34:280-9.
37. Polonsky TS, McDermott MM. Lower extremity peripheral artery disease without chronic limb-threatening ischemia: a review. JAMA 2021;325:2188-98.

Submitted Mar 31, 2022; accepted Apr 9, 2022.

*Additional material for this article may be found online at www.jvascsurg.org.*

**Supplementary Table (online only).** Relationships with industry and other entities related to atherosclerotic peripheral arterial disease

| Participant | Consultant | Speaker's bureau | Ownership, partnership, principal | Personal research | Institutional, organizational, or other financial benefit | Expert witness |
|---|---|---|---|---|---|---|
| Writing panel | | | | | | |
| Karen Woo, MD PhD | None | None | None | None | None | None |
| Jeffrey J. Siracuse, MD MBA | None | None | None | None | None | None |
| Kyle Klingbeil, MD MS | None | None | None | None | None | None |
| Larry W. Kraiss, MD | None | None | None | None | None | None |
| Nicholas H. Osborne, MD | None | None | None | None | None | None |
| Niten Singh, MD | Cook Medical | None | None | None | None | None |
| Jessica P Simons, MD MPH | None | None | None | None | None | None |
| Tze-Woei Tan MD | None | None | None | None | None | None |
| Rating panel | | | | | | |
| Shipra Arya, MD SM | None | None | None | None | None | None |
| Subhash Banerjee, MD | None | None | None | None | Boston Scientific (research grant) | None |
| Marc P. Bonaca, MD, MPH | None | None | Pfizer, Medtronic (modest stock holdings) | None | See footnote[a] | None |
| Thomas Brothers, MD | None | None | None | None | None | None |
| Michael S. Conte, MD | None | None | None | Abbot Vascular (DSMB) | None | None |
| David L. Dawson, MD | None | None | None | None | None | None |
| Young Erben, MD | None | None | None | None | None | None |
| Benjamin M. Lerner, MD | None | None | None | None | None | None |
| Judith C. Lin, MD, MBA | None | None | None | None | None | None |
| Joseph L. Mills, Sr, MD | None | None | None | None | None | None |
| Derek Mittleider, MD | Boston Scientific and Inari (advisory boards) | Boston Scientific and Inari | None | None | None | None |
| Deepak G. Nair, MD, MS, MHA | None | None | None | None | None | None |
| Leigh Ann O'Banion, MD | None | None | None | None | Abbott, Medtronic, Shockwave | None |
| Robert B. Patterson, MD | None | None | None | None | None | None |
| Matthew J. Scheidt, MD | None | None | None | None | None | None |

[a]M.P.B. is the executive director of CPC, a nonprofit academic research organization affiliated with the University of Colorado that receives research grants and consulting funding from Abbott, Agios, Alexion Pharma, Alnylam, American Heart Association, Amgen, Angionetics, Anthos Therapeutics, ARCA Biopharma, Array, AstraZeneca, Atentiv, Audentes, Bayer, Better Therapeutics, Brigham and Women's Hospital, Bristol-Myers Squibb, Cardiol Therapeutics, Cell Research, Cook Medical, Cook Regentec, CSL Behring, Eidos Therapeutics, EP Trading Co, EPG Communications, Epizon Pharma, Esperion Therapeutics, EverlyWell, Faraday, Fortress Biotech, HDL Therapeutics, Heartflow, Hummingbird Bioscience, Insmed, Janssen, Kowa Research, Lexicon, Medtronic, Merck, Moderna, NIH, Novate Medical, NovoNordisk, Pfizer, PhaseBio, PPD Development, Prairie Education and Research, Prothena Biosciences, Regeneron, Regio Biosciences, Sanifit Therapeutics, Sanofi, Silence Therapeutics, Stealth BioTherapeutics, University of Colorado, University of Pittsburgh, VarmX, Worldwide Clinical Trials, Wraser, Yale Cardiovascular Research Group.