Proceedings from the Society of Interventional Radiology Research Consensus Panel on Critical Limb Ischemia

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ABBREVIATIONS

CA = contrast arteriography, CLI = critical limb ischemia, PAD = peripheral arterial disease, RCP = research consensus panel, RCT = randomized controlled trial

BACKGROUND

In the United States, it is estimated that 5–12 million people have peripheral arterial disease (PAD) (1). The prevalence of PAD increases with age and is estimated to afflict 4.3% of the population > 40 years of age and 14.5% of those > 70 (2). Depending on the severity and extent of the disease, patients may be asymptomatic or present with clinical symptoms including atypical leg pain, classic intermittent claudication, acute limb ischemia, or chronic critical limb ischemia (CLI). The incidence of CLI is 500–1,000 patients per 1 million in the Western world (2). The natural history of patients with CLI is poor (25% mortality and 30% amputation rate at 1 year) (3–5). Patients with CLI have advanced atherosclerosis involving all cardiovascular beds and thus have greater 5-year mortality than patients with symptomatic coronary artery disease. Although the precise mechanisms associated with

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This meeting was funded by the SIR Foundation.

S.M. received funding from NIH (HL098967, HL109192, HL 88476). He is on the data safety monitoring board for Arteriocyte and Flexstent. R.L. is a consultant for Bayer Interventional, Cordis, and Boston Scientific. J.R. is a consultant for Covidien/ev3, Biotronik, St. Jude, EKOS, Simbionix, and CSI, is a speaker for Boston Scientific, Terumo, and Cook, and received research support from Covidien/ev3, NHLBI/Washington University, SIRtex, Abbott, EKOS, Flexmedics, Aastrom, and CeloNova. A.T.H. received research grants from Abbott Vascular, Aastrom Biosciences, Sanofi-aventis Partnership, Cytokinetics, and Viromed, is on the advisory board of AstraZeneca and Merck, and is a consultant for Novartis, Pozen, Summit Doppler, and Shire HGT. W.R.H. received grant income for trials in peripheral artery disease structured as a contract between the sponsor and CPC Clinical Research (a nonprofit research center affiliated with the University of Colorado) from Aastrom, AstraZeneca, DNAVEC, Pluristem, Takeda, ReNeuron, Tarix and Theravasc. M.R.J. is a consultant for Abbott Vascular (noncompensated), Becker Venture Services Group, Bluegrass Vascular Therapies, Cordis Corporation (noncompensated), Covidien (noncompensated), Hansen Medical, Medtronic (noncompensated), Micell Incorporated, Primacea, Trivascular Inc., and Vortex, and has equity in Access Closure Inc., Embolitech Inc., Hotspur Inc., Icon Interventional Inc., I.C. Sciences Inc., Janacare Inc., Northwind Medical Inc., PQ Bypass Inc., Primacea, Sadra Medical, TMI/Trireme Inc., and Vascular Therapies Inc., is a board member of VIVA Physicians (not for profit), and is a 501(c) 3 Organization member (www.vivapvd.com). C.J.W. is a consultant for Baxter Cellular Therapies and is a member of the PAD Guidelines Task Force (ACC/AHA). He is the CARE Steering committee chair (NCDR/ACC) and president of the Society of Cardiovascular Angiography and Interventions (SCAI). M.C. is on the advisory board of Aastrom Biosciences and Humacyte Inc. P.G. is a scientific advisory board member of Bard/Lutonix and Bayer/Medrad. He is an equity holder and has stock options with Pulse Therapeutics. M.P. has research grants with NHBLI, Johnson and Johnson, Astra Zeneca, Baxter Healthcare, and AHRQ and is a consultant and is on the advisory board of Bayer Healthcare, Baxter, Genzyme, Otsuka, and Cardiostem. K.R. is a consultant for Abbott Vascular, Accelmed, Becker Ventures, Micell, Complete Conference Management, Vortex/AngioDynamics, Endospan, Medicines Company, Shockwave Medical, and VuMedi. He has equity in CardioMEMs, Contego, Endospan, Embolitech, Icon, JanaCare, Medical Simulation Corporation, Micell, Primacea, PQ Bypass, Shockwave Medical, and Vortex. He received research or fellowship support from Abbott Vascular, Cordis, Lutonix/Bard, Atrium, and IDEV Technologies. He is a board member of VIVA Physicians (www.vivapvd.com).

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J Vasc Interv Radiol 2013; 24:451–458

http://dx.doi.org/10.1016/j.jvir.2012.10.028

these high mortality and amputation rates is not known, individuals with CLI are known to suffer from increased rates of comorbidities, including poorly controlled atherosclerosis risk factors (eg, smoking, diabetes, hypertension, and hypercholesterolemia), advanced chronic kidney disease, and coronary artery disease (6).

Increasingly, endovascular therapy (eg, angioplasty, atherectomy, or stent placement) for patients with CLI has become the first line of treatment, whereas open surgical revascularization is reserved for patients who are unsuitable for endovascular management, whose anticipated life span is > 2 years, or whose limb symptoms progress despite prior endovascular intervention (3,7–10). Recently, the BASIL (Bypass versus Angioplasty in Severe Ischaemia of the Leg) trial compared endovascular treatment to surgical bypass and demonstrated that endovascular revascularization may confer advantages compared to surgery for patients whose life expectancy is < 2 years (11). The surgical technique is well developed; however, the same cannot be said for endovascular therapies, which are often more varied (8,12–16). The introduction of new disruptive technologies such as drug-eluting stents, drug-coated balloons, bioabsorbable stents, atherectomy, cell based therapies, therapeutic angiogenesis, and nanotechnologies has made the selection of individual therapies more challenging, as the current CLI comparative effectiveness evidence base is weak (17–26). In addition, new percutaneous techniques are being developed such as transpedal access, subintimal antegrade flossing using antegrade and retrograde intervention (SAFARI), and below the ankle (pedal) and plantar-pedal loop angioplasty (12,15,16). The goal of this paper is to discuss the proceedings from the Society of Interventional Radiology (SIR) Foundation Research Consensus Panel (RCP) for the development of a research agenda for CLI.

METHODS

Panel Membership

On May 7, 2012, the SIR Foundation assembled a RCP for the development of a research agenda for CLI. The panel membership included (*i*) a multidisciplinary group of expert panelists, (*ii*) representatives from governmental agencies, and (*iii*) representatives from industries involved in the peripheral arterial field. There were 11 expert panelists including 3 interventional radiologists, 3 vascular medicine internists, 3 interventional cardiologists, and 2 vascular surgeons. Government agencies included the Food and Drug Administration and the Agency for Healthcare Research and Quality. Industry representatives came from major companies involved in the production and/or distribution in the United States of products for peripheral vascular therapies.

Agenda Methodology

Unlike prior SIR RCPs, a prior topic was selected to help focus the discussion. The topic for this RCP was the development of a registry for the endovascular management of patients with CLI. This topic was chosen based on input from the SIR peripheral artery disease service line and the SIR-sponsored LEARN (Lower Extremity Arterial RevascularizatioN) meeting in September 2011. Six focused topics were selected prior to the meeting for presentation by selected RCP faculty. Presentation topics are shown in **Table 1**. Panelists were also asked to include in their presentations a discussion of gaps in the current knowledge base and recommendations for basic science and clinical research questions or projects that need further study. Specifically, panelists were asked to (*i*) define the most important clinical questions that could realistically be answered through pivotal multiinstitutional clinical trials or registries, (*ii*) describe the most promising future directions that merit preclinical or early clinical exploration in the endovascular registry for CLI, and (*iii*) outline the critical alliances that must be developed to advance the prioritized research and how the SIR Foundation can best support these initiatives. Afterwards, a round-robin discussion was held to examine important research questions and trial design, to explore potential opportunities for future research studies or substudies within a CLI registry, and to consolidate similar or redundant ideas into succinct focused topics relevant for a CLI registry. Thereafter, invited comments from government and industry representatives were heard.

What Endovascular Therapies Should Be Included in a CLI Registry?

Extensive discussion focused on which endovascular technologies should be included in a CLI registry. All currently available technologies in the United States such as chronic total occlusion recanalization wires and catheters, reentry devices, drug-eluting stents, bare metal stents, covered stent grafts, atherectomy, and embolic protection devices were recommended for inclusion in the registry. The panel favored creation of a "real world registry" that would allow for evaluation of all available technologies to capture baseline and outcome status of the widest group of patients with CLI and to evaluate the variable device-based preferences of the endovascular physicians.

Table 1. Selected Presentation Topics

What endovascular therapies should be included in a CLI registry?
What can we learn from coronary registries?
What disruptive endovascular technologies are coming?
What should the primary and secondary outcomes be?
What is the best medical therapy for the patient with CLI?
What frequency of visits should the patient after an endovascular treatment have to assess patency?

CLI = critical limb ischemia.

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