Contemporary Treatment for Critical Ischemia: The Evidence for Interventional Radiology or Surgery

Keith Hussey, MBChB, FRCS(Ed)¹ Sivanathan Chandramohan, MRCS, FRCR, EBIR²

¹Department of Vascular Surgery, Western Infirmary of Glasgow, Glasgow, Scotland, United Kingdom

²Department of Radiology, Western Infirmary of Glasgow, Glasgow, Scotland, United Kingdom

Address for correspondence Keith Hussey, MBChB, FRCS(Ed), ST8 in Vascular Surgery, Department of Vascular Surgery, Western Infirmary of Glasgow, Dumbarton Road, Glasgow, G11 6 NT, Scotland, United Kingdom (e-mail: keithhussey79@hotmail.com).

Semin Intervent Radiol 2014;31:300–306

Abstract

Keywords

- interventional radiology
- critical limb ischemia
- peripheral arterial disease
- surgery

This article is a review of the evidence regarding the management of patients with critical limb ischemia. The aim of the study is to discuss the definition, incidence, and clinical importance of critical limb ischemia, as well as the aims of treatment in terms of quality of life and limb salvage. Endovascular and surgical treatments should not be viewed as competing therapies. In fact, these are complementary techniques each with strengths and weaknesses. The authors will propose a strategy based on the available evidence for deciding the optimal approach to management of patients with critical limb ischemia.

Objectives: Upon completion of this article, the reader will be able to identify the current evidence for the treatment of critical limb ischemia, particularly the differences in indications, outcomes, and complications following endovascular versus surgical treatments.

Accreditation: This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of Tufts University School of Medicine (TUSM) and Thieme Medical Publishers, New York. TUSM is accredited by the ACCME to provide continuing medical education for physicians.

Credit: Tufts University School of Medicine designates this journal-based CME activity for a maximum of **1 AMA PRA Category 1 Credit™**. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Peripheral occlusive arterial disease (POAD) of the lower limb is a consequence of systemic atherosclerosis. The Edinburgh Artery Study reported a prevalence of 8% for asymptomatic POAD in a study population of 1,592 participants (aged 55–74 years). Symptomatic disease (intermittent claudication) was diagnosed in 4.6%.¹ Criterion for the diagnosis of critical limb ischemia (CLI) has been defined by the Second

European Consensus Document on chronic limb ischemia and includes either one of the following: more than 2 weeks of recurrent foot pain at rest that requires regular use of analgesics and is associated with an ankle systolic pressure of 50 mm Hg or less, or a toe systolic pressure of 30 mm Hg or less; or a nonhealing wound or gangrene of the foot or toes, with similar hemodynamic measurements. There is threat to limb viability and failure to intervene may result in limb loss.²

In Europe and North America, the estimated incidence of CLI is 500 to 1,000 per million population.³ At 1 year, approximately 25% of these patients will die and one-third will have a major limb amputation performed.^{3,4} It is estimated that the cost of care for a patient with a major limb amputation is approximately £30,000 in the first year and £23,500 per year thereafter.⁴

The National Institute for Health and Care Excellence (NICE) has recommended that all patients with CLI be referred to a vascular multidisciplinary team for assessment before intervention.⁴ Revascularization is advocated where possible as an alternative to major amputation. The choice of revascularization strategy (endovascular or surgical bypass) is typically left to the discretion of the treating clinicians. NICE guidance recommends that patient comorbidity, the pattern of arterial disease, the presence of a suitable conduit for bypass (autologous vein), and patient preference are considered when making these decisions.⁴

Issue Theme Peripheral Arterial Disease; Guest Editors, David Kessel, MB, BS, MA, MRCP, FRCR, EBIR and Iain Robertson, MD, MBChB, MRCP, FRCR, EBIR

Copyright © 2014 by Thieme Medical Publishers, Inc., 333 Seventh Avenue, New York, NY 10001, USA. Tel: +1(212) 584-4662.

DOI <http://dx.doi.org/10.1055/s-0034-1393965>. ISSN 0739-9529.

Historically, surgical bypass has been considered the most appropriate first-line therapeutic intervention. However, clinical practice has changed with the rapid progression of endovascular technology over the past 20 years. These changes have occurred for multiple reasons, including technical changes, such as the introduction of subintimal angioplasty, as well the development of lower profile devices, steerable hydrophilic wires, drug-eluting balloons and stents, and smaller, caliber, more flexible stents. As a consequence, there has been a paradigm shift from surgical bypass to endovascular therapy as a first-line intervention for patients with CLI.⁵⁻⁸ To date there is limited evidence from trial data to support these changes in clinical practice.

The Evidence Base

The literature contains many reports detailing the outcomes of different treatment strategies (endovascular therapy vs. surgery; angioplasty vs. stenting; drug-eluting stent/balloon vs. conventional angioplasty/stenting) in heterogeneous patient populations that frequently include a differing clinical disease severity, different levels of arterial disease, lesion morphology of varying complexity, and variable run off. As a result, it is difficult to make meaningful comparisons between studies or extrapolate these results to clinical practice.

Despite the prevalence of POAD, there have been relatively few randomized controlled trials comparing outcome between endovascular and surgical revascularization for CLI (► **Table 1**).^{7,9-11} Slow recruitment has been a feature of many of these studies, probably reflecting clinician bias with “real-world” experience. The comparison of surgery and endovascular therapy is of real interest only to a subset of patients with CLI where clinical “equipoise” regarding the outcome of intervention still exists.

The Bypass or Angioplasty in Severe Limb Ischemia (BASIL) trial is the largest prospective randomized study to date.⁹ A Delphi analysis performed before the trial defined equipoise as being present if there was clinician agreement that angioplasty or surgery would be equally effective, or if there was disagreement about which treatment would be best. There were high levels of disagreement between vascular surgeons and interventional radiologists regarding optimal treatment.¹² In other words, most clinicians exhibit strong preferences on patient management. These preferences appear to be based on specialty and local experience rather than scientific evidence.

The absence of clinical equipoise is likely to account for the difficulties in recruiting patients to randomized clinical trials. This effect can be seen within the BASIL trial. An audit of 585 patients from the six highest recruiting centers in the BASIL trial was performed. Approximately 50% of patients with CLI were potentially suitable for recruitment, of which approximately 20% were precluded as they had aortoiliac segment disease. Of the suitable patients, clinical equipoise was judged in only 30%; ultimately 70% of these patients were randomized. This suggests that fewer than 1 in 10 patients with CLI presenting to BASIL trial centers were randomized. Holm et al experienced similar difficulties with only 5% of patients with

Table 1 Summary of outcomes of studies comparing angioplasty and surgery

Author	Trial type	Arterial segment treated	Number of patients recruited (angioplasty vs. bypass)	Primary patency (angioplasty vs. bypass)	Amputation-free survival (angioplasty vs. bypass)
van der Zaag et al (2004) ¹⁰	Multicenter, randomized controlled	Femoropopliteal segment	56 (30 vs. 24)	43 vs. 82% (1 y)	–
Adam et al (2005) ⁹	Multicenter, randomized controlled	Femoropopliteal and tibial vessels	452 (224 vs. 228)	–	71 vs. 68% (1 y) 52 vs. 57% (3 y)
Kudo et al (2006) ⁷	Single-center, nonrandomized	Aortoiliac, femoropopliteal, and tibial vessels	192 (153 vs. 84)	44 vs. 28% (5 y)	–
Dick et al (2007) ¹¹	Single-center, nonrandomized	Aortoiliac, femoropopliteal, and tibial vessels	383 (207 vs. 85)	–	84.6 vs. 85.1% (1 y)

Includes all periprocedural morbidity and mortality.

CLI or claudication being considered suitable candidates for randomization to surgery or endovascular therapy.¹³

The BASIL study recruited 452 patients with CLI as a consequence of infrainguinal arterial disease from 27 hospitals across the United Kingdom over 5 years.⁹ The endpoints investigated were amputation-free survival (AFS), overall survival (OS), health-related quality of life (HRQoL), and the cost-effective use of hospital resources. Analysis was performed on an intention-to-treat basis. The short- to medium-term surgery was associated with a higher risk of morbidity (56 vs. 41%) and greater utilization of resources, although the requirement for secondary intervention was lower than in patients managed with an angioplasty-first strategy (18 vs. 26%; 95% confidence interval [CI], 0.04–15%). At 1 and 3-years, the AFS was similar between angioplasty (71 and 52%) and bypass surgery (68 and 57%). From these data, the BASIL trialists concluded that an angioplasty-first approach may be most appropriate for patients with significant medical comorbidity who are not expected to live for more than 2 years, whereas a surgical approach should be considered for patients who are relatively fit given the apparent greater durability of bypass.⁹ These conclusions have been supported by the final analysis of the BASIL trial data, which demonstrated improved OS and a trend for improved AFS in the group managed with surgical bypass.¹⁴ However, it is uncertain as to whether the results of the BASIL trial remain valid, given the improved outcomes of endovascular therapy in the femoropopliteal segment.^{15–17}

Several cohort studies of reasonable size have compared endovascular and surgical outcomes in CLI. Kudo et al reported single surgeon outcomes treating CLI in three time periods between 1993 and 2004. The proportion treated by endovascular means increased in each time period. Outcomes were similar for endovascular and surgical treatments. From this study, the authors concluded that angioplasty should be the treatment of choice for primary and secondary treatment of CLI with open surgery reserved for those unsuitable for endovascular treatment or for those in whom there was no clinical improvement following angioplasty and stenting.⁷ A prospective cohort study comparing angioplasty and surgical bypass in patients with diabetes did not demonstrate a difference in outcome between the revascularization strategies.¹¹ Al-Omran and colleagues retrospectively compared the outcomes in 11,548 patients treated by angioplasty and 15,824 patients treated by surgical bypass from Canadian National Administrative Health records between 1991 and 1999. These included a mixed cohort of patients, with intervention for both intermittent claudication and CLI. Similar OS and major AFS were found in surgical and angioplasty groups.¹⁸

Outcomes reported by other authors have demonstrated equivalent outcomes between angioplasty and surgical bypass for occlusive disease of the aortoiliac and femoro-popliteal segments.^{13,19–24} Korhonen et al²⁵ reported outcomes in 858 consecutive patients with CLI treated at a single center. OS, limb salvage, and AFS were higher in patients treated by surgery. However, patients treated by angioplasty had greater comorbidity, worse runoff, and a higher proportion had

ulceration and gangrene. Conversely, more patients with rest pain were treated with bypass grafting. When 241 more closely matched pairs of patients were compared using propensity score matching, there was still a significant benefit in terms of limb salvage in the surgical group at 5 years (77.3 vs. 88.2%, $p = 0.031$). Patients treated by angioplasty were more likely to require surgical reintervention (13.9 vs. 11.2%, $p = 0.025$), but there was no significant difference in AFS or OS. Surgical intervention for long occlusions appears to offer a durable outcome with better primary patency and AFS than angioplasty.^{15,26} A prospective cohort study of 4,288 patients (63% had CLI) undergoing bypass grafting reported a 30-day mortality rate of 2.1% and AFS at 1 and 5 years of 87 and 74%, respectively, for femoro-popliteal bypass, and 77 and 63%, respectively, for distal bypass.²⁷

Hybrid Procedures

These techniques allow revascularization of more than one arterial segment at a single intervention and are less invasive than open surgical intervention in isolation. The majority of the reported literature describes angioplasty of the aortoiliac segment with a concurrent surgical procedure of the femoropopliteal segment. The early results of these interventions seem to be good, with excellent limb salvage and reduced morbidity reported.^{28–30} Infrainguinal angioplasty (of the femoropopliteal segment) with concurrent ultradistal bypass has also been described, with the reported data demonstrating good early and 5-year outcomes (AFS 70% and OS 65%).^{31–33}

Infrapopliteal Intervention

Infrapopliteal arterial disease requires independent consideration and is associated with a poorer prognosis than arterial disease of the aortoiliac or femoropopliteal segments. This may be a reflection of the prevalence of diabetes and renal failure associated with this pattern of arterial disease.³⁴ Tibial vessel arterial disease is difficult to classify. The complexity of the Trans-Atlantic Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II) classification system limits the ability to compare outcomes between studies. The majority of reports are small, single center, and retrospective in nature. Reported primary patency rates are highly variable, but the short-/medium-term limb salvage rate following angioplasty appears to be reasonably good^{35–39} (summarized in ►Table 2). The long-term outcome data report acceptable results for endovascular recanalization in patients with isolated tibial vessel arterial disease.⁴⁰ Excellent results have also been reported by large, single-center case series describing AFS of 78 to 87% for ultradistal bypass for tibial vessel disease at 5 years.^{41,42} A meta-analysis of the available data (30 studies including 2,557 patients and 2,693 interventions) reports limb salvage rates that are comparable between angioplasty and surgical bypass (~80% at 3 years).^{43,44} Although surgery would appear to be more durable, it is associated with a higher 30-day mortality rate (2.3 vs. 1.8%)⁴⁵ and a higher rate of periprocedural complications (14 vs. 4.9%).⁴⁵

Table 2 Summary of outcomes following endovascular intervention for tibial vessel disease

Author	Study type	Patients recruited	Technical success rate	Overall complications rate ^a	Primary patency rate	Limb salvage rate
Nydahl et al (1997) ³⁶	Single-center, retrospective	27	84%	6.25%	53% (12 mo)	85% (12 mo)
Söder et al (2000) ³⁹	Single-center, retrospective	60	84%	4.2%	48% (12 mo)	80% (18 mo)
Clair et al (2005) ³⁷	Single-center, retrospective	19	95.7%	5.2%	88.5% (3 mo)	84.2% (3 mo)
Atar et al (2005) ³⁸	Single-center, retrospective	38	92.1%	7.9%	14.8% (12 mo)	74%
Iida et al (2013) ⁴⁰	Single-center, retrospective	884	95%	3%	–	85% (60 mo)
Liistro et al (2013) ⁴⁶	Single-center, prospective, randomized, controlled Balloon angioplasty Drug-eluting balloon	65 67	100% 100%	0 0	25% 73%	98.5% 100%
Spiliopoulos et al (2012) ⁴⁷	Retrospective, registry Drug-eluting stent	39	100%	–	–	84.3% (60 mo)
Rocha-Singh et al (2012) ⁴⁸	Retrospective, registry Stent	120	–	–	70.1% (12 mo)	89.6% (12 mo)

^aIncludes all periprocedural morbidity and mortality.

Advances in endovascular treatment of the femoropopliteal segment are discussed on the following page, and some of these techniques may be applicable for revascularization of the crural circulation. Provisional data from the DEBATE-BTK trial, investigating drug-eluting balloon technology, resulted in a significant reduction in restenosis (27% for drug-eluting balloon vs. 74% in the conventional angioplasty group at 1 year).⁴⁶ Conversely, the Medtronic-sponsored multicenter drug-eluting balloon BTK trial (IN.PACT DEEP) was stopped prematurely because there was no demonstrable benefit demonstrated with a trend toward more major amputation in the paclitaxel drug-eluting balloon arm. The evidence for infrapopliteal stenting is therefore limited.^{47,48}

Future Trials

Some of the limitations of the current evidence base may be addressed by the BASIL-2 trial. This will be a multicenter randomized controlled trial that aims to recruit 600 patients with severe limb ischemia as a result of atherosclerotic arterial disease of the femoropopliteal segment or tibial vessels. Patients recruited to this trial will be randomized to either “best endovascular therapy” or surgical bypass (using autologous vein), with a predefined primary endpoint of AFS. It is hoped that this trial will be powered adequately to evaluate both the health and social costs of these interventions as well as address the clinical equipoise that currently exists.

Assessment of Outcome following Intervention

Defining a clinically relevant, reproducible outcome measure is an issue that limits the ability to effectively compare the data reported in the world literature. These are frequently complex interventions, in a high-risk patient group.⁴⁹

Historically, surgeon- or lesion-orientated outcome measures such as technical success, primary patency, primary-assisted patency, secondary patency, limb salvage, AFS, and cumulative survival rates have been reported. The central advantage of these measures is that they can be clearly defined and should be reproducible. However, the number of these outcome variables, combined with reporting variation between different studies, renders meaningful comparisons difficult.

Outcome measures that have more relevance to patients, but that are more variable and difficult to assess, relate to clinical outcomes and quality of life (QoL). For an individual, a reduction or improvement in pain, wound healing, maintenance of ambulation, and functional independence are perhaps much more important than traditionally measured outcome variables.^{50,51} There is a paucity of evidence from the world literature assessing QoL following lower limb revascularization with angioplasty and OS. Different scoring systems (CLI EuroQoL⁹ and VascuQoL⁵²) have been used for this purpose, but data are limited. However, the evidence available describes an improvement in QoL following lower

limb revascularization across all domains.⁵³ It would be beneficial if future studies use QoL assessment routinely to help guide the clinician and patient in decision making.

Recommendations Based on the Evidence

It will be at least 3 years before useful data from BASIL-2 are available. In the interim, clinicians must continue to be guided by the available evidence. Despite the limitations of the current evidence base, some valid conclusions may be drawn. It must, however, be recognized that local expertise and preference should be taken into account, and that treatment plans should be based on the individual patient. The TASC II recommendations⁴ continue to recommend practice based on lesion morphology.

Aortoiliac Segment Disease

Where aortoiliac is the dominant site of disease, there is an increasing move toward endovascular therapy regardless of lesion complexity. Angioplasty can produce durable long-term results for TASC A and B lesions of the aortoiliac segment. More complex lesions (TASC C and D) may also be addressed by endovascular intervention, and outcomes seem to be comparable to open surgical revascularization. Hybrid procedures offer an alternative to surgical reconstruction of the aortoiliac and common femoral segments, although further evidence is required to evaluate the long-term durability of these techniques. The proven durability of surgery means this probably remains the first choice for younger patients with complex aortoiliac disease.

Femoropopliteal Segment Disease

TASC A, B, and C lesions of the femoropopliteal segments can be managed to good effect by angioplasty and stenting, with less procedure-related morbidity and shorter hospital stay than with surgical bypass—albeit with a potentially less durable outcome. As with aortoiliac disease, the proven durability of surgery means that it probably remains the first choice for patients requiring long-term patency. This includes patients with rest pain and younger patients with extensive femoropopliteal disease with good inflow and a suitable outflow vessel. However, outcomes of endovascular treatments are improving, so this situation is likely to change.^{3,26}

Infrapopliteal Arterial Disease

The evidence for occlusive tibial vessel disease is more uncertain, as the disease process is more difficult to classify. However, given the low morbidity associated with endovascular intervention, it seems reasonable to proceed with an “angioplasty-first” approach for even the most complex arterial lesions. This is supported by the TASC recommendation that angioplasty should be considered in patients with CLI to restore in-line flow to the foot. Similar recommendations have been made in the CIRSE standards of practice

guideline,⁵⁴ which advocates an endovascular-first revascularization strategy.

Conclusion

The current available evidence comparing angioplasty and OS in the management of POAD has many limitations. In most series, control groups are absent and data are reported for small numbers of patients. This is compounded by significant heterogeneity between patient groups in different studies. There is also variation in the categorizing and reporting of complications following intervention. These data may also be prejudiced by retrospective analysis, with short or incomplete follow-up and wide variation in the reported primary outcome measures. The potential for bias must also be considered in small trials with unconcealed methods of randomization and outcome assessment.

Clinicians need to be aware of these limitations but make the best use of the currently available evidence. In summary, it is appropriate to offer angioplasty as a first-line strategy for most patients with CLI who have POAD of any arterial segment. In particular, angioplasty has a role in the management of patients defined as being “high-risk,” those with a limited life expectancy, or for informed individuals who request a preference for angioplasty. Bypass surgery may be a more durable intervention and thus merits consideration for patients with less medical comorbidity and for long occlusions that are unattractive for angioplasty.

References

- 1 Fowkes FGR, Housley E, Cawood EHA, Macintyre CCA, Ruckley CV, Prescott RJ. Edinburgh Artery Study: prevalence of asymptomatic and symptomatic peripheral arterial disease in the general population. *Int J Epidemiol* 1991;20(2):384–392
- 2 European Working Group on Critical Limb Ischemia. Second European Consensus Document on chronic critical leg ischemia. *Eur J Vasc Surg* 1992;6(Suppl A):1–32
- 3 Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FG; TASC II Working Group. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). *J Vasc Surg* 2007;45(Suppl S):S5–S67
- 4 National Institute for Health and Clinical Excellence. Lower Limb Peripheral Arterial Disease: Diagnosis and Management. NICE clinical guideline 147; 2012. Available at: guidance.nice.org.uk/cg147
- 5 Pell JP, Whyman MR, Fowkes FGR, Gillespie I, Ruckley CV. Trends in vascular surgery since the introduction of percutaneous transluminal angioplasty. *Br J Surg* 1994;81(6):832–835
- 6 Nasr MK, McCarthy RJ, Hardman J, Chalmers A, Horrocks M. The increasing role of percutaneous transluminal angioplasty in the primary management of critical limb ischaemia. *Eur J Vasc Endovasc Surg* 2002;23(5):398–403
- 7 Kudo T, Chandra FA, Kwun WH, Haas BT, Ahn SS. Changing pattern of surgical revascularization for critical limb ischemia over 12 years: endovascular vs. open bypass surgery. *J Vasc Surg* 2006;44(2):304–313
- 8 Nowygrod R, Egorova N, Greco G, et al. Trends, complications, and mortality in peripheral vascular surgery. *J Vasc Surg* 2006;43(2):205–216
- 9 Adam DJ, Beard JD, Cleveland T, et al; BASIL trial participants. Bypass versus angioplasty in severe ischaemia of the leg (BASIL):

- multicentre, randomised controlled trial. *Lancet* 2005;366(9501):1925–1934
- 10 van der Zaag ES, Legemate DA, Prins MH, Reekers JA, Jacobs MJ. Angioplasty or bypass for superficial femoral artery disease? A randomised controlled trial. *Eur J Vasc Endovasc Surg* 2004;28(2):132–137
 - 11 Dick F, Diehm N, Galimanis A, Husmann M, Schmidli J, Baumgartner I. Surgical or endovascular revascularization in patients with critical limb ischemia: influence of diabetes mellitus on clinical outcome. *J Vasc Surg* 2007;45(4):751–761
 - 12 Bradbury A, Wilmink T, Lee AJ, et al. Bypass versus angioplasty to treat severe limb ischemia: factors that affect treatment preferences of UK surgeons and interventional radiologists. *J Vasc Surg* 2004;39(5):1026–1032
 - 13 Holm J, Arfvidsson B, Jivegård L, et al. Chronic lower limb ischaemia. A prospective randomised controlled study comparing the 1-year results of vascular surgery and percutaneous transluminal angioplasty (PTA). *Eur J Vasc Surg* 1991;5(5):517–522
 - 14 Bradbury AW, Adam DJ, Bell J, et al; BASIL trial Participants. Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial: An intention-to-treat analysis of amputation-free and overall survival in patients randomized to a bypass surgery-first or a balloon angioplasty-first revascularization strategy. *J Vasc Surg* 2010;51(5, Suppl):S5–17S
 - 15 Dearing DD, Patel KR, Compoginis JM, Kamel MA, Weaver FA, Katz SG. Primary stenting of the superficial femoral and popliteal artery. *J Vasc Surg* 2009;50(3):542–547
 - 16 Rogers JH, Laird JR. New drugs and technologies—overview of new technologies for lower extremity revascularisation. *Circulation* 2007;116:2072–2085
 - 17 Desgranges P, Boufi M, Lapeyre M, et al. Subintimal angioplasty: feasible and durable. *Eur J Vasc Endovasc Surg* 2004;28(2):138–141
 - 18 Al-Omran M, Tu JV, Johnston KW, Mamdani MM, Kucey DS. Outcome of revascularization procedures for peripheral arterial occlusive disease in Ontario between 1991 and 1998: a population-based study. *J Vasc Surg* 2003;38(2):279–288
 - 19 Wilson SE, Wolf GL, Cross AP. Percutaneous transluminal angioplasty versus operation for peripheral arteriosclerosis. Report of a prospective randomized trial in a selected group of patients. *J Vasc Surg* 1989;9(1):1–9
 - 20 Ah Chong AK, Tan CB, Wong MW, Cheng FS. Bypass surgery or percutaneous transluminal angioplasty to treat critical lower limb ischaemia due to infrainguinal arterial occlusive disease? *Hong Kong Med J* 2009;15(4):249–254
 - 21 Burke CR, Henke PK, Hernandez R, et al. A contemporary comparison of aortofemoral bypass and aortoiliac stenting in the treatment of aortoiliac occlusive disease. *Ann Vasc Surg* 2010;24(1):4–13
 - 22 McQuade K, Gable D, Pearl G, Theune B, Black S. Four-year randomized prospective comparison of percutaneous ePTFE/nitinol self-expanding stent graft versus prosthetic femoral-popliteal bypass in the treatment of superficial femoral artery occlusive disease. *J Vasc Surg* 2010;52(3):584–590, discussion 590–591, e1, e7
 - 23 Scali ST, Rzcudlo EM, Bjerke AA, et al. Long-term results of open and endovascular revascularization of superficial femoral artery occlusive disease. *J Vasc Surg* 2011;54(3):714–721
 - 24 Siracuse JJ, Giles KA, Pomposelli FB, et al. Results for primary bypass versus primary angioplasty/stent for intermittent claudication due to superficial femoral artery occlusive disease. *J Vasc Surg* 2012;55(4):1001–1007
 - 25 Korhonen M, Biancari F, Söderström M, et al. Femoropopliteal balloon angioplasty vs. bypass surgery for CLI: a propensity score analysis. *Eur J Vasc Endovasc Surg* 2011;41(3):378–384
 - 26 Ihnat DM, Duong ST, Taylor ZC, et al. Contemporary outcomes after superficial femoral artery angioplasty and stenting: the influence of TASC classification and runoff score. *J Vasc Surg* 2008;47(5):967–974
 - 27 Feinglass J, Pearce WH, Martin GJ, et al. Postoperative and amputation-free survival outcomes after femorodistal bypass grafting surgery: findings from the Department of Veterans Affairs National Surgical Quality Improvement Program. *J Vasc Surg* 2001;34(2):283–290
 - 28 Mousa A, Abdel-Hamid M, Ewida A, Saad M, Sahrabi A. Combined percutaneous endovascular iliac angioplasty and infrainguinal surgical revascularization for chronic lower extremity ischemia: preliminary result. *Vascular* 2010;18(2):71–76
 - 29 Dosluoglu HH, Lall P, Cherr GS, Harris LM, Dryjski ML. Role of simple and complex hybrid revascularization procedures for symptomatic lower extremity occlusive disease. *J Vasc Surg* 2010;51(6):1425–1435, e1
 - 30 Piazza M, Ricotta JJ II, Bower TC, et al. Iliac artery stenting combined with open femoral endarterectomy is as effective as open surgical reconstruction for severe iliac and common femoral occlusive disease. *J Vasc Surg* 2011;54(2):402–411
 - 31 Schneider PA, Caps MT, Ogawa DY, Hayman ES. Intraoperative superficial femoral artery balloon angioplasty and popliteal to distal bypass graft: an option for combined open and endovascular treatment of diabetic gangrene. *J Vasc Surg* 2001;33(5):955–962
 - 32 Schanzer A, Owens CD, Conte MS, Belkin M. Superficial femoral artery percutaneous intervention is an effective strategy to optimize inflow for distal origin bypass grafts. *J Vasc Surg* 2007;45(4):740–743
 - 33 Lantis J, Jensen M, Benvenisty A, Mendes D, Gendics C, Todd G. Outcomes of combined superficial femoral endovascular revascularization and popliteal to distal bypass for patients with tissue loss. *Ann Vasc Surg* 2008;22(3):366–371
 - 34 Gray BH, Grant AA, Kalbaugh CA, et al. The impact of isolated tibial disease on outcomes in the critical limb ischemic population. *Ann Vasc Surg* 2010;24(3):349–359
 - 35 Varty K, Bolia A, Naylor AR, Bell PRF, London NJM. Infrapopliteal percutaneous transluminal angioplasty: a safe and successful procedure. *Eur J Vasc Endovasc Surg* 1995;9(3):341–345
 - 36 Nydahl S, Hartshorne T, Bell PRF, Bolia A, London NJM. Subintimal angioplasty of infrapopliteal occlusions in critically ischaemic limbs. *Eur J Vasc Endovasc Surg* 1997;14(3):212–216
 - 37 Clair DG, Dayal R, Faries PL, et al. Tibial angioplasty as an alternative strategy in patients with limb-threatening ischemia. *Ann Vasc Surg* 2005;19(1):63–68
 - 38 Atar E, Siegel Y, Avrahami R, Bartal G, Bachar GN, Belenky A. Balloon angioplasty of popliteal and crural arteries in elderly with critical chronic limb ischemia. *Eur J Radiol* 2005;53(2):287–292
 - 39 Söder HK, Manninen HI, Jaakkola P, et al. Prospective trial of infrapopliteal artery balloon angioplasty for critical limb ischemia: angiographic and clinical results. *J Vasc Interv Radiol* 2000;11(8):1021–1031
 - 40 Iida O, Soga Y, Yamauchi Y, et al. Clinical efficacy of endovascular therapy for patients with critical limb ischemia attributable to pure isolated infrapopliteal lesions. *J Vasc Surg* 2013;57(4):974–981, e1
 - 41 Pomposelli FB Jr, Marcaccio EJ, Gibbons GW, et al. Dorsalis pedis arterial bypass: durable limb salvage for foot ischemia in patients with diabetes mellitus. *J Vasc Surg* 1995;21(3):375–384
 - 42 Kalra M, Głowiczki P, Bower TC, et al. Limb salvage after successful pedal bypass grafting is associated with improved long-term survival. *J Vasc Surg* 2001;33(1):6–16
 - 43 Romiti M, Albers M, Brochado-Neto FC, Durazzo AE, Pereira CA, De Luccia N. Meta-analysis of infrapopliteal angioplasty for chronic critical limb ischemia. *J Vasc Surg* 2008;47(5):975–981
 - 44 Schamp KB, Meerwaldt R, Reijnen MM, Geelkerken RH, Zeebregts CJ. The ongoing battle between infrapopliteal angioplasty and bypass surgery for critical limb ischemia. *Ann Vasc Surg* 2012;26(8):1145–1153

- 45 Casella IB, Brochado-Neto FC, Sandri GdeA, et al. Outcome analysis of infrapopliteal percutaneous transluminal angioplasty and bypass graft surgery with nonreversed saphenous vein for individuals with critical limb ischemia. *Vasc Endovascular Surg* 2010; 44(8):625–632
- 46 Liistro F, Porto I, Angioli P, et al. Drug-eluting balloon in peripheral intervention for below the knee angioplasty evaluation (DEBATE-BTK): a randomized trial in diabetic patients with critical limb ischemia. *Circulation* 2013;128(6):615–621
- 47 Spiliopoulos S, Fragkos G, Katsanos K, Diamantopoulos A, Karnabatidis D, Siablis D. Long-term outcomes following primary drug-eluting stenting of infrapopliteal bifurcations. *J Endovasc Ther* 2012;19(6):788–796
- 48 Rocha-Singh KJ, Jaff M, Joye J, Laird J, Ansel G, Schneider P; VIVA Physicians. Major adverse limb events and wound healing following infrapopliteal artery stent implantation in patients with critical limb ischemia: the XCELL trial. *Catheter Cardiovasc Interv* 2012;80(6):1042–1051
- 49 Landry GJ. Functional outcome of critical limb ischemia. *J Vasc Surg* 2007;45(6, Suppl A):A141–A148
- 50 Goshima KR, Mills JL Sr, Hughes JD. A new look at outcomes after infrainguinal bypass surgery: traditional reporting standards systematically underestimate the expenditure of effort required to attain limb salvage. *J Vasc Surg* 2004;39(2): 330–335
- 51 Taylor SM, Kalbaugh CA, Blackhurst DW, et al. Determinants of functional outcome after revascularization for critical limb ischemia: an analysis of 1000 consecutive vascular interventions. *J Vasc Surg* 2006;44(4):747–755, discussion 755–756
- 52 Nguyen LL, Moneta GL, Conte MS, Bandyk DF, Clowes AW, Seely BL; PREVENT III Investigators. Prospective multicenter study of quality of life before and after lower extremity vein bypass in 1404 patients with critical limb ischemia. *J Vasc Surg* 2006;44(5): 977–983, discussion 983–984
- 53 Holtzman J, Caldwell M, Walvatne C, Kane R. Long-term functional status and quality of life after lower extremity revascularization. *J Vasc Surg* 1999;29(3):395–402
- 54 van Overhagen H, Spiliopoulos S, Tsetis D. CIRSE Standards of Practice Guidelines: below the knee interventions. *Cardiovasc Intervent Radiol* 2013;36:302–311