Peer reviewed version

University of Bristol - Explore Bristol Research
General rights

Systematic review and narrative synthesis of surveillance practices following endovascular intervention for lower limb peripheral arterial disease.

SHORT TITLE:

Surveillance following peripheral endovascular intervention

AUTHORS:

Kitty HF Wong[1,2], Benjamin E Zucker[1,3], Bethany G Wardle[2], Patrick A Coughlin[4], Katherine Chaplin[1], Hung-Yuan Cheng[1], Robert J Hinchliffe[1,2], Christopher P Twine[1,2], Graeme K Ambler[1,2]

1. Bristol Centre for Surgical Research, Bristol Medical School, University of Bristol, Bristol, UK.
2. North Bristol NHS Trust, Bristol, UK.
3. University Hospitals Bristol and Weston NHS Foundation Trust, Bristol, UK.
4. Cambridge University Hospitals NHS Foundation Trust, Cambridge, UK.

CORRESPONDING AUTHOR: Graeme K. Ambler

Email: graeme.ambler@bristol.ac.uk

Phone: +44 117 331 3929

CATEGORY: Systematic review

DECLARATION OF INTERESTS: None

WORD COUNT: 3200

ABSTRACT

Objectives

The optimal timing and modality of surveillance after endovascular intervention for peripheral arterial disease is controversial, and no randomised trial to assess the value of peripheral endovascular intervention has ever been performed. The aim of this systematic review was to examine the practice of surveillance following peripheral endovascular intervention in randomised trials.

Data Sources

Medline, Embase, Cochrane Library, and WHO trial registry databases.

Methods

Systematic review of the literature was performed to capture surveillance strategies used in randomised trials comparing endovascular interventions. Surveillance protocols were assessed for completeness, modalities used, duration, and intensity.

Results

Ninety-six different surveillance protocols were reported in 103 trials comparing endovascular interventions. Protocol specification was incomplete in 32% of trials.

The majority of trials used multiple surveillance modalities (mean 3.46 modalities), most commonly clinical examination (96%), ankle-brachial index (80%), duplex ultrasound (75%),

and digital subtraction angiography (51%). Trials involving infrapopliteal lesions used more angiographic surveillance than trials with femoropopliteal lesions (p=0.006).

The median number of surveillance visits in the first 12 months after intervention was three and the mean surveillance duration was 21 months. Trials treating infrapopliteal vessels had a higher surveillance intensity compared to those treating femoropopliteal lesions in the first 12 months after endovascular intervention (mean 5 vs. 3 surveillance visits; p=0.017). Trials with drug-eluting devices had longer surveillance duration compared to those without (mean 26 vs. 19 months; p=0.020).

Conclusions

There is a high level of variation in the modality, duration, and intensity of surveillance protocols used in randomised trials comparing different types of peripheral endovascular arterial intervention. Further research is required to determine the value and impact of post-procedural surveillance on patient outcomes.

KEY WORDS

Systematic review; Peripheral arterial disease; endovascular procedures

Introduction

Lower limb peripheral arterial disease (PAD) affects 5.6% of the population worldwide aged 25 or older.(1) Percutaneous endovascular interventions are the most common revascularisation strategy used to treat PAD although this commonly encompasses a heterogeneous group of treatment modalities.(2) Early patency rates following endovascular interventions are generally good yet, the "Achilles heel" of such interventions is that of re-stenosis or occlusion which limits longer term efficacy.(3)

The ability to reintervene before progression to vessel occlusion forms the argument for ongoing surveillance after endovascular intervention with the overall aim of preventing significant limb events such as acute limb ischaemia and amputation. Currently, there is however a lack of data to confirm benefit from surveillance with justification for surveillance in the endovascular setting modelled on surveillance following lower limb vein bypass, even though the evidence for the usefulness of this to prevent amputation is conflicted (4). Further, it is well recognised that loss of endovascular patency is not always associated with severe limb events and there is potential morbidity associated with reintervention. Finally, the natural history of asymptomatic restenosis is still not fully understood. There is therefore still a question mark around whether surveillance has a role to play in improving patient outcomes.

Where surveillance is performed, there is no guidance on the required composition of a standard surveillance pathway, specifically, the optimal duration and frequency of surveillance. As a result, surveillance frequency and intervals are largely based on personal preference and resource availability,(4,5) resulting in wide variations in practice. The majority of the peripheral

endovascular literature on surveillance is from randomised-controlled trials (RCTs) comparing endovascular devices. These trials appear to have influenced antiplatelet prescribing practice internationally,(6,7) and may also have influenced practice around surveillance. Surveillance strategies within RCTs are largely driven by patency-based outcome measures and are not powered for limb outcomes, limiting the extrapolation of surveillance effect on limb outcomes.

The aim of this systematic review is to understand post-intervention surveillance following peripheral endovascular intervention. In order to do this, we initially had two objectives. The first was to evaluate the impact of surveillance on outcomes following peripheral endovascular lower limb intervention in randomised trials specifically assessing surveillance modalities. The second was to examine the surveillance protocols used in randomised trials for peripheral endovascular intervention to understand how these were designed and utilised. Systematic review of the literature revealed that there were no randomised trials assessing the impact of surveillance on outcomes following peripheral endovascular lower limb intervention (Supplementary Figure 1). We therefore report here on the surveillance protocols used in randomised trials for peripheral endovascular intervention.

Methods

A systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) standards.(8) MEDLINE, EMBASE, and the Cochrane Library databases were searched via Ovid from inception for RCTs including participants with peripheral arterial disease undergoing any endovascular arterial intervention

(search initially performed in January 2019, updated in June 2020). Trial registry databases

including ClinicalTrials.gov, ICTRP, and ISRCTN were searched separately. All reports

regardless of publication type, publication date, and language were searched. The full search

strategy is shown in Supplementary Table 1. The study protocol was registered on PROSPERO

on 06/08/2019 (URL:

https://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42019143452).

Screening and selection

RCTs examining patients with chronic atherosclerotic disease who underwent primary

endovascular intervention in any peripheral territory in the lower limbs were separately searched

for narrative synthesis. Non-randomised trials were excluded. Trials including open surgery,

conservative treatment, non-atherosclerotic lower limb disease, aneurysms, and acute disease

presentations were excluded. Study selection was performed by screening titles and abstracts

(KC and 50% of excluded studies checked by HC). Full texts of potentially eligible studies in the

initial search (performed in January 2019) were screened by two authors (KC and HC)

independently, and disagreements were resolved by discussion or consulting a third author (RJH

and GKA shared this role). The search was updated in June 2020 and independently screened by

two authors (KW and BZ), with disagreements again resolved by discussion or consulting a third

author (GKA).

Data extraction

Data was extracted by one reviewer directly from published reference papers (KW) and 20% cross-checked by another reviewer (BZ), with disagreements resolved by discussion or by a third researcher (GKA). The following data were extracted using a pre-specified proforma:

- Study characteristics;

- Baseline demographics, clinical (Rutherford classification) and anatomical (divided into "iliac", "femoropopliteal", "infrapopliteal", and "mixed" if more than one region involved) information of the study populations;

- Primary and secondary outcomes, including primary patency, target vessel restenosis and re-intervention, freedom from amputation, all-cause mortality.

Details of surveillance protocols were also extracted:

- Surveillance modality;

- Surveillance duration;

- Surveillance intensity in the first 12 months following intervention, and also longer-term (beyond 12 months).

- Surveillance protocol completeness ("fully specified" if all three of modality, duration, and intensity were stated; "incomplete" if only some of the criteria were met; and "unspecified" if no protocol was mentioned);

Trials were further divided into subgroups according to anatomical location of the lesion (defined above) and the endovascular interventions they studied, which were grouped into: Primary stenting (combination of bare metal stent (BMS) or covered stent); Drug-coated balloon (DCB); Drug-eluting stents (DES); Atherectomy (AT); and Other. Any trials including DCB and

DES were categorized as such irrespective of the comparator arm. Plain balloon angioplasty was not listed as an individual category as it was largely used as the control arm against more complex interventions.

Quality assessment

Included trials were assessed for quality and bias using the Cochrane risk of bias tool(9).

Data synthesis

A narrative synthesis was performed for all trial surveillance protocols from RCTs of peripheral endovascular intervention. Trial protocols were grouped as percentages of total number of trials in any pre-specified group. Subgroup analyses were performed by type of endovascular intervention and anatomical location.

Statistical analysis

Statistical analysis was performed using SPSS (version 26.0, SPSS, Chicago, Illinois). Differences between categorical variables were assessed using the Fisher's exact test; and continuous variables with the t-test. Logistic regression analysis was used to examine trends in DUS use over time. All statistical tests were 2-sided with a P-value of 0.05 regarded as evidence of significance.

Results

A total of 8227 publications were identified, and 491 were assessed as full text. The PRISMA flow diagram is shown in Figure 1. One-hundred-and-three randomised trials were included for narrative synthesis of surveillance protocols.

Study demographics

A summary of study characteristics of trials is detailed in Supplementary Table 2. Forty-five trials (44%) were company sponsored. Fifty-five (53%) trials treated patients with claudication (Rutherford 1-3); and 27 (26%) included patients with chronic limb threatening ischaemia (Rutherford 4-6). Ten (10%) could not be assessed accurately as they only gave a mean or median Rutherford score, and eleven (11%) gave no information on the degree of ischaemia or symptoms.

The most frequent primary outcome measure in the trials was primary patency (32 trials, 31%). The majority of included trials treated atherosclerotic disease in the femoropopliteal arteries (78, 76%), with 19 (18%) treating infrapopliteal disease. Four trials (4%) treated any lesion in the lower limb irrespective of anatomical location. Primary stenting was used in 27 trials (26%); 34 (33%) used drug-coated balloons; 10 (10%) used drug-eluting stents; 6 used atherectomy (6%); and 26 trials (25%) used other interventions including cutting-balloon angioplasty, brachytherapy, radiotherapy, laser-assisted angioplasty, cryoplasty, and ultrasound-guided paclitaxel delivery.

Quality of included studies

The overall quality of studies was low, with 91% of studies having a high risk of bias in at least one domain, most commonly due to a lack of personnel blinding due to the interventional nature of the trials (Figure 2, Supplementary Figure 2). Allocation concealment was unclear in 73% of trials and blinding of outcome assessment was unclear in 72% of trials. There were also significant risks for attrition and reporting bias (34% and 29% respectively).

Surveillance protocol completeness

Of the 103 included trials, there were 96 different post-procedural surveillance protocols (Supplementary Table 3). Two trials (2%) specified a different protocol for each intervention arm; and another two (2%) used different surveillance modalities based on anatomical lesion location. These were analysed separately (see 'Trials with multiple surveillance strategies' below).

Of the remaining 99 trials, 67 (68%) fully specified their surveillance protocols, and 32 (32%) had incomplete protocols (Table 1). Incomplete specifications were typically minor. The most common reasons for an incomplete surveillance protocol were lack of clear surveillance duration or frequency of surveillance episodes (15 trials, 15%).

Surveillance modalities

The majority of trials used multiple surveillance modalities (mean 3.46 modalities), most commonly involving clinical examination (96%), ankle-brachial index (ABI) (80%), duplex ultrasound (DUS) (75%), and angiography (51%) (Table 1). Thirty-three different surveillance modality combinations were found in 99 trials (Supplementary Table 4), with 21 trials (21%)

using clinical examination plus ABI plus DUS; and the addition of DSA in 12 trials (12%) (Figure 3).

Plain X-ray was used in trials with stents, particularly in the DES group (44%). Trials involving infrapopliteal lesions used more angiographic surveillance than femoropopliteal lesions (80% vs 44%, p=0.006). There was a significant increase in use of DUS over time (odds of DUS being used increased by a ratio of 1.097 per year, 95% CI 1.034 to 1.171, p=0.003) (Figure 4).

Four trials included some form of evaluation of different surveillance modalities, though in all cases this was done informally, without any quantitative analysis or statistical testing:

- "ABI was unreliable especially for diabetic patients with calcified arteries."(10)
- "Results from DUS and angiographic imaging were comparable."(11)
- "Excellent agreement between results of DUS and those of angiography."(12)
- "Late luminal loss was not assessed angiographically given the excellent results achieved by duplex ultrasound in the evaluation of femoropopliteal arterial obstructions." (13)

Further to these comments, 7 other trials allowed DUS to be used instead of DSA (and vice versa) when one modality was deemed unsuitable for clinical reasons or withdrawal of consent.

Surveillance duration

Overall, the most common length of surveillance was 12 months (42%), with 46 trials (47%) conducting surveillance beyond 12 months (mean 22.1 months, range 6-60 months) (Table 1). Two trials did not specify the surveillance duration. Trials involving drug-eluting technologies

(DES and DCB) had a longer average surveillance duration when compared to studies which did not involve drug-eluting technology (26.2 vs 19.0 months: mean difference (MD) 7.18, 95% confidence interval (CI) 1.17 - 13.19, p=0.020). There was no significant difference in the length of surveillance between trials treating femoropopliteal and infrapopliteal lesions (22.6 vs 20.4 months; MD 2.23, 95% CI -5.53 – 9.99, p=0.570).

Surveillance intensity

Mid-term (up to 12 months post-intervention)

The median number of surveillance visits in the first 12 months after endovascular intervention was three (mean 3.43) (Table 1). Two trials did not specify surveillance intervals. There were no significant differences in surveillance intensity between trials with different intervention arms (primary stenting 3.58, DCB 3.96, DES 2.89, AT 3.17; p=0.913). Trials involving intervention to infrapopliteal vessels had a higher surveillance intensity compared to those treating femoropopliteal lesions in the first 12 months after endovascular intervention (mean 5 vs. 3.08 surveillance visits: MD 1.92, 95% CI 0.35 – 3.49, p=0.017).

Longer-term (beyond 12 months post-intervention)

Forty-six (47%) trials continued surveillance beyond 12 months post-intervention. The majority of these were annual episodes (26 trials, 26%) and the mean number of surveillance visits beyond 12 months was 1.85. Six trials (6%) did not fully specify longer-term surveillance intervals. Trials treating infrapopliteal lesions had a larger average number of longer-term surveillance appointments compared to trials treating femoropopliteal disease (2.75 vs 1.75 times: MD 1.00, 95% CI 0.52 – 1.48, p<0.001).

Trials with multiple surveillance strategies

According to intervention arm

Rastan *et al.* (14,15) compared plain balloon angioplasty against BMS for treatment of popliteal lesions. Clinical examination, ABI measurements, and DUS were performed for both intervention arms at 6 and 12 months; but only the BMS group received angiographic assessment at 12 months. Dake *et al.* (16–18) compared PBA with or without secondary BMS against DES for femoropopliteal lesions. All patients were assessed clinically, by ABI, and using patient-reported outcome measures (PROMs) at 6, 12, 24, 36, 48, and 60 months, and by plain X-ray at 12, 36, and 60 months. DUS was performed for all patients at 6 and 12 months, then only for stented patients at 24, 36, 48, and 60 months.

According to anatomical lesion location

Debing *et al*. (19) compared PBA against DCB, with surveillance at 30 days and 6 months post-intervention. Both groups were examined clinically, and patients with lesions in the superficial femoral artery received DUS surveillance; whilst patients with infrapopliteal lesions received angiographic surveillance. Fanelli *et al.* (20,21) compared PBA against DCB, with surveillance at 6, 12, and 24 months. Both arms received clinical and ABI examination, and once again patients with superficial femoral artery lesions had DUS surveillance, whilst DSA was used for infrapopliteal lesions. This is similar to the common surveillance strategies in trials where interventions to only a single anatomical location were included (see 'Surveillance modalities' above).

Discussion

No randomised trials directly comparing different surveillance strategies following endovascular intervention in the lower limbs have ever been performed. There is a high level of variation in the modality, duration, and intensity of surveillance protocols used in randomised trials of peripheral endovascular intervention, with significant differences according to both the type of endovascular intervention performed and the anatomical lesion location.

We found that duplex ultrasound is the mainstay of surveillance following endovascular intervention, particularly for trials involving the use of stents. There is very little literature on the utility of DUS surveillance after peripheral endovascular intervention. As previously mentioned, there are no randomized studies. In addition, there are very few case series or cohort studies which examine this question. There is one study which reports that DUS surveillance can predict severe in-stent restenosis with >90% specificity.(22) One further cohort study found that a DUS-based surveillance protocol at 3, 6, and 12 months after femoropopliteal angioplasty with or without stenting only had a sensitivity and specificity of 88% and 60% to predict occlusion over 2 years following intervention.(23) However in this study half of the patients who required re-intervention for restenosis presented with ischaemic symptoms regardless of DUS findings. This calls into question whether systematic DUS surveillance actually provides a clinically meaningful benefit. Even in surgical vein bypass, where graft surveillance is routine (and recommended by the Global Vascular Guidelines),(24) intensive DUS surveillance did not show any additional clinical benefits in a moderate-sized randomized trial.(25) Furthermore, there is uncertainty surrounding the psychosocial stress associated with periodic surveillance. Although there is a lack of research into this topic in vascular surgery, anxiety symptoms have been

demonstrated in active surveillance for other chronic progressive diseases, such as prostate cancer in a longitudinal study by Ruane-McAteer *et al*.(26) It is therefore not clear that routine surveillance imaging after endovascular intervention has benefit, and there may indeed be associated harms.

For patients with tibial disease, angiography may offer more precise imaging than duplex, and this is reflected in the fact that we found angiography to be a more common mode of surveillance in patients undergoing infrapopliteal intervention, however it carries significant procedural risks.(27) A recent consensus document from the European Society for Vascular Surgery recommended that angiography assessment should be limited to patients who are likely to need re-intervention; however over half of the included trials in this systematic review used it routinely for all participants, reflecting the "artificial environment" of a clinical trial as compared to daily clinical practice.(28) There may also be a higher risk of excessive re-intervention when angiography is used as a surveillance modality, as it is easy to reintervene within the same session, possibly leading practitioners to treat more minor re-stenoses, though many of these studies reported high rates of primary patency, so it is possible that this concern is not warranted.

Current recommendation from the recent Global Vascular Guidelines in the form of a good practice statement suggest "Observe patients who have undergone infrainguinal endovascular interventions for CLTI in a surveillance program that includes clinical visits, pulse examination, and non-invasive testing (resting APs and TPs)".(24) Yet the guidelines recognise that there are inadequate data demonstrating clinical benefit of an ultrasound surveillance program after endovascular intervention, only suggesting that there may be subgroups of patient who may gain

more benefit than others. Given the expanding use of an "endovascular first" strategy for lower limb revascularisation such an evidence gap needs filling.

Current post-procedural surveillance in peripheral endovascular intervention may have been modelled on the practice of serial follow-up and imaging following surgical revascularisation, though the evidence for the benefit for surveillance after surgical revascularisation is conflicting.(25) However, to date, the actual efficacy of post-procedural surveillance remains unclear due to the lack of randomised trials directly comparing routine surveillance versus no surveillance as a control group.(5,29) One retrospective study by Todaran *et al.* (30) found that in the setting of close clinical surveillance, there was no difference in primary and secondary patency between percutaneous superficial femoral artery interventions for critical limb ischaemia or claudication; concluding that it was the close clinical surveillance which enabled them to deliver comparable outcomes for both conditions, despite the absence of a control group. Other case series with shorter surveillance duration (less than 12 months) demonstrated better outcomes for patients with intermittent claudication, lending some indirect weight to this hypothesis.(31,32)

The high degree of heterogeneity in published protocols make it clear that more must be done to clarify the merits of routine surveillance after lower extremity peripheral endovascular intervention. Restenosis/reocclusion is the Achilles heel of peripheral endovascular intervention, so it is critical to identify optimal follow-up strategies to ameliorate the clinical impact of these events. While a randomised trial comparing different strategies would be welcome, it is difficult to see what the appropriate comparator arms would be at this stage. Given that over 90% of the

trials we identified incorporated some form of routine post-procedural imaging surveillance, practitioners may feel uncomfortable recruiting patients into a trial where one arm did not perform post-procedural imaging surveillance. It may be more appropriate therefore to examine the benefit of intensive surveillance when compared to less intensive surveillance on limb rather than patency outcomes, with careful documentation of symptoms to assess how many patients in the less intensive surveillance arm underwent re-intervention for symptomatic recurrent disease. If the study showed a lack of benefit for intensive surveillance but the majority of patients in the less intensive surveillance arm who underwent reintervention had recurrent or persistent symptoms, a further study could then be performed to determine whether any form of routine imaging was necessary in the absence of symptoms.

Strengths of this systematic review include the thorough search protocol and detailed reporting of results. The heterogeneity of surveillance protocols is concerning given the potential impact meticulous surveillance may have on post-intervention outcomes in different patient demographics and different endovascular procedures.

This review has some limitations. Surveillance strategies can be limited by infrastructure, availability of healthcare resources and the condition of patients, which were not presented or discussed in the literature. As there are no RCTs comparing different surveillance strategies, it is impossible to directly assess the impact of surveillance on post-procedural outcomes.

Conclusion

We found a high level of variation in the modality, duration, and intensity of surveillance protocols used in randomised trials of peripheral endovascular arterial interventions. Further research is required to determine the impact of surveillance on patient outcomes following endovascular intervention, as well as the optimal intensity and most appropriate modalities.

Conflicts of interest:

None to declare.

Figure 1. PRISMA flow diagram for included studies.

Figure 2. Cochrane risk of bias graph for included studies.

Figure 3. Venn diagram of commonly used surveillance modalities in included studies.

Figure 4. Trials using duplex ultrasound and angiography surveillance over time.

Table 1. Surveillance protocols in randomised trials of lower limb endovascular intervention, stratified by type of endovascular intervention and anatomical location.

REFERENCES

1. 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(8):e1020–30.

2. National Vascular Registry. 2019 Annual Report. [Internet]. [cited 2020 Apr 24]. Available from: https://www.vsqip.org.uk/content/uploads/2019/12/NVR-2019-Annual-Report.pdf

3. Gur I, Lee W, Akopian G, Rowe VL, Weaver FA, Katz SG. Clinical outcomes and implications of failed infrainguinal endovascular stents. J Vasc Surg. 2011;53(3):658–67.

4. Sobieszczyk Piotr, Eisenhauer Andrew. Management of Patients After Endovascular Interventions for Peripheral Artery Disease. Circulation. 2013;128(7):749–57.

5. Thukkani AK, Kinlay S. Endovascular Intervention for Peripheral Artery Disease. Circ Res. 2015;116(9):1599–613.

6. Wong K, Bosanquet D, Ambler G, Qureshi M, Hinchliffe R, Twine C, et al. The CLEAR (Considering Leading Experts' Antithrombotic Regimes around peripheral angioplasty) survey: an international perspective on antiplatelet and anticoagulant practice for peripheral arterial endovascular intervention. CVIR Endovasc. 2019 Dec 1;2.

7. Qureshi MI, Li HL, Ambler GK, Wong KHF, Dawson S, Chaplin K, et al. Antiplatelet and Anticoagulant Use in Randomised Trials of Patients Undergoing Endovascular Intervention for Peripheral Arterial Disease: Systematic Review and Narrative Synthesis. Eur J Vasc Endovasc Surg Off J Eur Soc Vasc Surg. 2020;60(1):77–87.

8. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gøtzsche PC, Ioannidis JPA, et al. The

    PRISMA Statement for Reporting Systematic Reviews and Meta-Analyses of Studies That

    Evaluate Health Care Interventions: Explanation and Elaboration. PLOS Med.

    2009;6(7):e1000100.

9. Savović J, Weeks L, Sterne JA, Turner L, Altman DG, Moher D, et al. Evaluation of the

    Cochrane Collaboration's tool for assessing the risk of bias in randomized trials: focus

    groups, online survey, proposed recommendations and their implementation. Syst Rev.

    2014;3:37.

10. Laird J, Katzen B, Scheinert D, Lammer J, Carpenter J, Buchbinder M, et al. Nitinol stent

    implantation versus balloon angioplasty for lesions in the superficial femoral artery and

    proximal popliteal artery: twelve-month results from the RESILIENT randomized trial. Circ

    Cardiovasc Interv. 2010;3(3):267-276.

11. Dick P, Wallner H, Sabeti S, Loewe C, Mlekusch W, Lammer J, et al. Balloon angioplasty

    versus stenting with nitinol stents in intermediate length superficial femoral artery lesions.

    Catheter Cardiovasc Interv. 2009;74(7):1090-1095.

12. Schillinger M, Sabeti S, Loewe C, Dick P, Amighi J, Mlekusch W, et al. Balloon angioplasty

    versus implantation of nitinol stents in the superficial femoral artery. N Engl J Med.

    2006;354(18):1879-1888.

13. Gallino A, Do D, Alerci M, Baumgartner I, Cozzi L, Segatto J, et al. Effects of probucol

    versus aspirin and versus brachytherapy on restenosis after femoropopliteal angioplasty: the

    PAB randomized multicenter trial. J Endovasc Ther. 2004;11(6):595-604.

14. Rastan A, Krankenberg H, Baumgartner I, Blessing E, Müller-Hülsbeck S, Pilger E, et al. Stent placement versus balloon angioplasty for the treatment of obstructive lesions of the popliteal artery: a prospective, multicenter, randomized trial. Circulation. 2013;127(25):2535-2541.

15. Rastan A, Krankenberg H, Baumgartner I, Blessing E, Müller-Hülsbeck S, Pilger E, et al. Stent placement vs. balloon angioplasty for popliteal artery treatment: two-year results of a prospective, multicenter, randomized trial. J Endovasc Ther. 2015;22(1):22-27.

16. Dake M, Ansel G, Jaff M, Ohki T, Saxon R, Smouse H, et al. Paclitaxel-eluting stents show superiority to balloon angioplasty and bare metal stents in femoropopliteal disease: twelve-month Zilver PTX randomized study results. Circ Cardiovasc Interv. 2011;4(5):495-504.

17. Dake M, Ansel G, Jaff M, Ohki T, Saxon R, Smouse H, et al. Sustained safety and effectiveness of paclitaxel-eluting stents for femoropopliteal lesions: 2-year follow-up from the zilver PTX randomized and single-arm clinical studies. J Am Coll Cardiol. 2013;(24):2417–27.

18. Dake M, Ansel G, Jaff M, Ohki T, Saxon R, Smouse H, et al. Durable Clinical Effectiveness with Paclitaxel-Eluting Stents in the Femoropopliteal Artery: 5-Year Results of the Zilver PTX Randomized Trial. Circulation. 2016;(15):1472–83.

19. Debing E, Aerden D, Vanhulle A, Gallala S, von Kemp K. Paclitaxel-coated versus plain old balloon angioplasty for the treatment of infrainguinal arterial disease in diabetic patients: the Belgian diabetic IN.PACT Trial. J Cardiovasc Surg (Torino). 2017;58(4):528-534.

20. Fanelli F, Cannavale A, Boatta E, Corona M, Lucatelli P, Wlderk A, et al. Lower limb multilevel treatment with drug-Eluting balloons: 6-Month results from the DEBELLUM randomized trial. J Endovasc Ther. 2012;(5):571–80.

21. Fanelli F, Cannavale A, Corona M, Lucatelli P, Wlderk A, Salvatori F. The 'DEBELLUM' - Lower limb multilevel treatment with drug eluting balloon - Randomized trial: 1-Year results. J Cardiovasc Surg (Torino). 2014;(2):207–16.

22. Baril DT, Rhee RY, Kim J, Makaroun MS, Chaer RA, Marone LK. Duplex criteria for determination of in-stent stenosis after angioplasty and stenting of the superficial femoral artery. J Vasc Surg. 2009;49(1):133–8; discussion 139.

23. Bui TD, Mills JL, Ihnat DM, Gruessner AC, Goshima KR, Hughes JD. The natural history of duplex-detected stenosis after femoropopliteal endovascular therapy suggests questionable clinical utility of routine duplex surveillance. J Vasc Surg. 2012;55(2):346–52.

24. Conte MS, Bradbury AW, Kolh P, White JV, Dick F, Fitridge R, et al. Global vascular guidelines on the management of chronic limb-threatening ischemia. J Vasc Surg. 2019;69(6):3S-125S.e40.

25. Davies A, Hawdon A, Sydes M, Thompson S, VGST P. Is duplex surveillance of value after leg vein bypass grafting? Principal results of the Vein Graft Surveillance Randomised Trial (VGST). Circulation. 2005;112(13):1985-1991.

26. Ruane-McAteer E, Porter S, O'Sullivan J, Dempster M, Prue G. Investigating the psychological impact of active surveillance or active treatment in newly diagnosed

favorable-risk prostate cancer patients: A 9-month longitudinal study. Psychooncology. 2019;28(8):1743–52.

27. Michalska M, Kazimierczak W, Leszczyński W, Nadolska K, Bryl Ł. Contemporary follow-up imaging after endovascular repair of lower extremity atherosclerotic lesions. Pol J Radiol. 2018;83:e634–42.

28. Venermo M, Sprynger M, Desormais I, Björck M, Brodmann M, Cohnert T, et al. Follow-up of patients after revascularisation for peripheral arterial diseases: a consensus document from the European Society of Cardiology Working Group on Aorta and Peripheral Vascular Diseases and the European Society for Vascular Surgery. Eur J Prev Cardiol. 2019;26(18):1971–84.

29. Bandyk DF, Chauvapun JP. Duplex Ultrasound Surveillance Can Be Worthwhile After Arterial Intervention: Perspect Vasc Surg Endovasc Ther [Internet]. 2016 [cited 2020 Apr 21]; Available from: https://journals.sagepub.com/doi/10.1177/1531003507311681

30. Todoran TM, Connors G, Engelson BA, Sobieszczyk PS, Eisenhauer AC, Kinlay S. Femoral artery percutaneous revascularization for patients with critical limb ischemia: Outcomes compared to patients with claudication over 2.5 years. Vasc Med. 2012;17(3):138–44.

31. Kalbaugh CA, Taylor SM, Blackhurst DW, Dellinger MB, Trent EA, Youkey JR. One-year prospective quality-of-life outcomes in patients treated with angioplasty for symptomatic peripheral arterial disease. J Vasc Surg. 2006 Aug;44(2):296–302; discussion 302-303.

32. Scott EC, Biuckians A, Light RE, Burgess J, Meier GH, Panneton JM. Subintimal angioplasty: Our experience in the treatment of 506 infrainguinal arterial occlusions. J Vasc Surg. 2008 Oct 1;48(4):878–84.