The New Ropanasuri Journal of Surgery

Volume 7 | Number 1 Article 8

6-23-2022

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Recommended Citation

Suhartono, Raden and Wijaya, Ghany H. (2022) "Revascularization Techniques for Infra-popliteal Peripheral Artery Disease in Diabetic Foot: A Literature Review," *The New Ropanasuri Journal of Surgery*: Vol. 7: No. 1, Article 8.
DOI: 10.7454/nrjs.v7i1.1119
Available at: https://scholarhub.ui.ac.id/nrjs/vol7/iss1/8

The New Ropanasuri Journal of Surgery
OPEN ACCESS
Published by Department of Surgery
Faculty of Medicine, Universitas Indonesia

Revascularization Techniques for Infra-popliteal Peripheral Artery Disease in Diabetic Foot: A Literature Review

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Corresponding author: ghanyhendwij@gmail.com Received: 2/Mar/2022 Accepted: 15/Jun/2022 Published: 22/Jun/2022
Website: https://scholarhub.ui.ac.id/nrjs/ DOI:10.7454/nrjs.v7i1.1119

Abstract

Foot ulcers are one of the problems that are often encountered in uncontrolled diabetes mellitus. With diabetic peripheral neuropathy, the typical clinical symptoms of PAD (peripheral arterial disease) may be obscured, leading to critical limb ischemia (CLTI). Diabetes may accelerate atherosclerosis that diminishes blood flow in PAD—further, diabetic patients with PAD often enfaces infra-popliteal lesions and require revascularization. However, studies on revascularization techniques in infra-popliteal PAD remain minimal. We reviewed the literature on EBSCO, and PubMed focused on the revascularization techniques in PAD, namely: expanded polytetrafluoroethylene (ePTFE), saphenous vein graft (SVG), atherectomy, surgical revascularization first, revascularization with endovascular bypass, direct and indirect angiosome revascularization, open surgery, direct bypass, indirect bypass, PTA, drug-eluting stent, pedal artery angioplasty, non-drug balloon angioplasty, DCB balloon angioplasty, infra-popliteal angioplasty, and cryoplasty. The methods of cryoplasty, atherectomy, direct bypass, balloon angioplasty, and eluting drug stent showed a better outcome in infra-popliteal CLTI.

Keywords: Revascularization, infra-popliteal peripheral arterial disease, diabetic foot, chronic limb-threatening ischemia

Introduction

Foot ulcers are the most common problems with diabetic foot. Further, it is known that fifty percent of patients with diabetes and foot ulcers encounter peripheral artery disease.[1,2] Rathariwibowo (2014) shows that at dr. Cipto Mangunkusumo general hospital (CMGH), there were 56.39% of peripheral arterial disease (PAD) patients with critical limb-threatening ischemia (CLTI), 61.3% with diabetes, and 33% underwent major amputation.[3] In Indonesia, the number of diabetic patients continues to increase and is estimated to reach 21.3 million people by 2030 and is ranked fourth with the highest number of diabetes worldwide.[3,4]

In a person with diabetes, peripheral neuropathy may obscure the typical clinical symptoms of PAD, namely, claudication and pain at rest, leading PAD to continue to CLTI, the most severe manifestation of PAD. In addition, diabetes in PAD may accelerate atherosclerosis, worsening the impaired blood flow. To this problem, treatment of revascularization and non-revascularization is needed. Revascularization measures such as endovascular and open surgery are required. However, the different characteristics of PAD with diabetes than non-diabetes make revascularization more challenging. This is because multisegmented and bilateral lesions characterize PAD with diabetes with a more distal predilection for lesions, especially in the infra–popliteal area/below the knee. The arteries in infra–popliteal region have a smaller diameter than those in the above-knee region. Thus, arterial calcification is more common, particularly in the medial region. In addition, the poor quality of the collateral arteries and the rapid progression of atherosclerosis leads diabetic patients to be at high risk for CLTI and amputation.[4]

Studies on infra–popliteal PAD revascularization methods remain relatively minimal, although diabetic patients with PAD often encounter lesions in the infra-popliteal. In addition, the increasing number of diabetic patients indicates that there will be an increase in diabetic ulcers with PAD requiring revascularization.

The procedures of revascularization, particularly those of endovascular performed in CMGH since 2012.[3] Unfortunately, no study on the revascularization of infra-popliteal PAD in the diabetic foot has been conducted in the hospital. The authors proceeded with a literature search to find high-quality evidence. The literature is required as the rational basis for deciding on revascularization.

Method

The authors proceeded with literature searching on some online databases (EBSCO and PubMed) provided by the library of Universitas Indonesia. The author chooses these two online databases because other databases have many duplications of the same journals. The keywords used were: (peripheral arterial disease OR peripheral artery disease OR PAD) AND (critical limb ischemia OR critical limb ischemia OR CLTI OR critical limb-threatening ischemia OR critical limb-threatening ischemia OR CLTI) AND (diabetic foot OR diabetic foot OR diabetic ulcer * OR diabetic foot ulcer OR diabetes *) AND (below the knee OR knee OR BTK OR infra-popliteal) AND (angioplasty OR stent * OR drug-eluting OR drug coating OR atherectomy OR balloon OR bypass OR open OR surgical OR surgery OR endovascular OR EVR OR multi-vessel * OR pedal arch OR angiosome * OR cryoplasty).

The inclusion criteria were those published within the last 20 years, studies in patients with the diabetic foot with infra-popliteal PAD below the knee, and revascularization measures such as open or endovascular surgery, one of the outcomes was a reduction in restenosis, decreased amputation, and mortality rates, healing of lesions, and the patency of revascularization, and, definitely, available in *full text*. Furthermore, the articles were reviewed for the quality of evidence and critically appraised. A specific critical appraisal tool for cohort studies (prognostic studies) was used according to the Center of Evidence-Based Medicine Critical Appraisal of Cohort Studies University of Oxford, 2015.

Results

Search using keywords on online databases, namely, EBSCO and PubMed, according to the diagram based on PRISMA 2020 flow diagram. Ten articles were included in this study, described in Tables 1, 2, and 3.

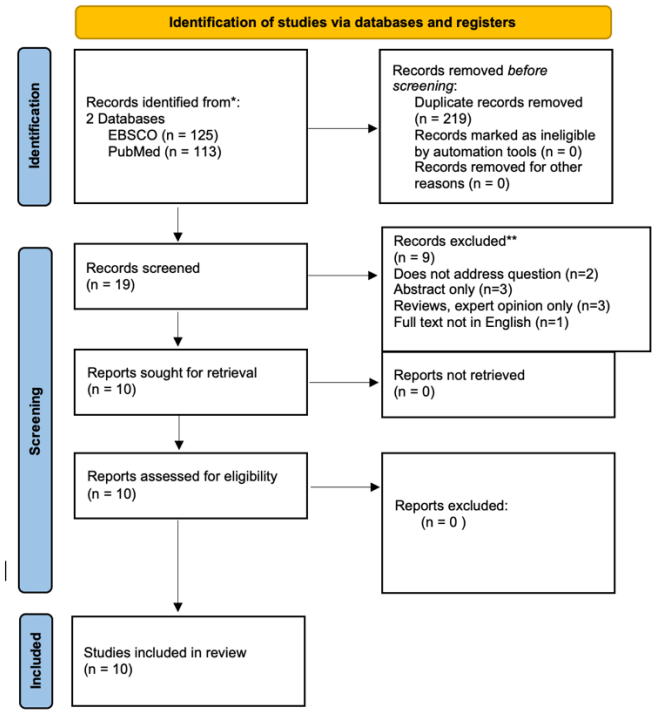

Figure 1. Literature searching following PRISMA protocol found ten eligible articles.

Of the eight cohort studies found, two studies (Neville et al. and Spillerova et al.) met all the criteria (table 2). The study of Dayama et al. did not meet the outcome criteria over time. They did not proceed with Kaplan-Meier analysis, while the other five study groups did not meet the criteria for accuracy in prognostic estimates because none discussed the number of confidence intervals in the results. However, some studies produced statistically significant results.

Neville et al. analyzed the outcomes of two groups of patients with similar demographic characteristics. They proceeded with postoperative follow-up and follow-up over 1 to 12 months to observe differences in outcomes of tibial artery bypass with heparin-bonded expanded polytetrafluoroethylene (HePTFE) and quality of the saphenous vein. The safety reported over time using Kaplan-Meier charts showed that saphenous vein grafting (86%) had a better outcome than the HePTFE (75%) and significant results with 95% confidence intervals. The study is a retrospective cohort study using the medical records of patients undergoing tibial artery bypass, referred to as a study with level 2b in the hierarchy of evidence according to the Oxford Center of Evidence-Based Medicine (OCEBM).

In the study of Das et al., patients with a diagnosis of CLTI from 16 sites were pooled to investigate the use of cryoplasty in managing patients with a below-knee occlusive disease and CLTI. The subjects were monitored postoperatively at one, three, six, and twelve months. Kaplan-Meier analysis showed an amputation-free rate of 89.3% on day 180. The study is a non-RCT but retrospective cohort; according to the OCEBM, it is categorized as a study with level 2b in the hierarchy of evidence.

Palena et al. investigated 21 diabetic patients with CLTI and analyzed the outcome of endovascular revascularization using Lutonix drug-coated balloons (LDCB). They proceeded with follow-up for 390 days, and Kaplan-Meier analysis showed 83.8% freedom of revascularization of the target lesion at day 390. This retrospective study was categorized as a study with level 2b in the hierarchy of evidence.

Troisi et al. investigated male-dominant patients with diabetic foot lesions below the knee following direct-angiosome revascularization (DAR). Follow-up was performed over one to 16 months. In addition, they performed a Kaplan-Meier analysis for freedom from minor amputations, limb salvage, and safety by comparing DAR with non-DAR examinations and comparing the same based on the shape of the leg curve. This retrospective cohort was categorized as a study with level 2b in the hierarchy of evidence

Spillerova et al. investigated 545 diabetic patients with CLTI and defects to evaluate the effect of angiosome–based revascularization. Patients were monitored for one to twelve months postoperatively, and a Kaplan-Meier analysis was performed to assess limb salvage and the progression of wound healing. The study showed that 60.3% of ischemic wounds healed at a one-year follow-up with a 95% confidence interval. At the number of affected angiosome below 3, the wound healing rate was worst, while direct bypass resulted in the best wound healing. While an amputation rate of 25.1% at one-year follow-up of patients with atrial fibrillation, hemodialysis, C-reactive protein level $\geq$10 mg/dL, and angiosome count affected >3 could be significantly associated with poor limb salvage. This retrospective cohort was categorized as a study with level 2b in the hierarchy of evidence

Dayama et al. investigated 1355 patients with CLTI below the genicular artery. Two treatments, namely, endovascular-first and bypass-first revascularization, were compared in the study. Monitoring was carried out for 30 days, and the results were then adjusted according to the factors in each subgroup and analyzed statistically with a 95% confidence interval. This retrospective cohort study using data from "The American College of Surgeons National Surgical Quality Improvement Program" was categorized as a study with level 2b in the hierarchy of evidence.

Brizzi et al. included 282 CLTI patients undergoing endovascular treatment to find out the survival rate, amputation–free, primary – and secondary patency. The subjects were grouped into STENT, POBA, nitinol, BES, and POBA sub-groups for comparison. Follow-up was performed at 0 to 35 months, and the Kaplan-Meier analysis showed 94% amputation-free, 64.9% survival, 74.9% primary patency, and 84.9% secondary patency. This retrospective cohort study using data on European medical centers is categorized as a study with level 2b in the hierarchy of evidence.

Commeau et al. investigated the efficacy and safety of sacrolimus-eluting stents (SESs) as a treatment for CLTI with lesions below the knee unstable for surgery were reviewed by improvement survival, amputation-free rate, and patency. Follow-up was performed in 2-24 months and found clinical improvement in 100% of patients. Kaplan-Meier analysis found 92.5% survival and 82.5% amputation-free survival. This prospective cohort study is categorized as a study with level 2b in the hierarchy of evidence.

The two remaining studies conducted by Teymen et al. (2017) [24] and Rastan et al. (2015)[23] was categorized as a study with levels 1b and 2b in the hierarchy of evidence, respectively.
In their study, Rastan et al. (2015),[23] proceed with no blinding method to the treatment group. However, the outcome is reliable with a 95% confidence interval. They reported the loss to follow-up in 7 patients. While in the study of Das et al. (2007),[21] three patients were reported to a loss to follow-up. Somehow, Teymen et al. (2017) [24] and Rastan et al. (2015)[23] reported p-value was not statistically significant.

Table 1. List of articles obtained from literature searching

No	Author	Year	Sample Size	Study Design	Intervention	*Outcome*	LOE
1	Commeau et al.[20]	2006	30	Prospective cohort	Drug-eluted balloon angioplasty, plain old balloon angioplasty	Clinical improvement and wound healing	2b
2	Das et al.[21]	2007	108	Nonrandomized, controlled trial	cryoplasty	Technical success, mortality, amputation rates	2b
3	Neville et al.[22]	2012	112	Retrospective cohort	Expanded fluoropolyethylene and vein graft	Number of amputations, patency, mortality, morbidity	2b
4	Rastan et al.[23]	2015	189	Prospective cohort	Directional atherectomy	Primary patency rate, procedural success, freedom of amputation rate	2b
5	Teymen et al.[24]	2017	48	Prospective cohort	Open-cell stent; closed-cell stent	Freedom of amputation rate in one year, MALE revascularization rate,	1b
6	Palena et al.[25]	2017	21	Retrospective cohort	Drug-coated balloon angioplasty and POBA	survival rates, limb salvage	2b
7	Spillerova et al.[27]	2017	24	Retrospective cohort	Angiosome targeted PTA, endovascular revascularization	primary patency rate assisted patency rate	2b
8	Troisi et al.[26]	2017	93	Retrospective cohort	Complete pedal arch, incomplete pedal arch	Freedom of amputation, limb salvage, wound healing	2b
9	Brizzi et al.[29]	2018	282	Retrospective cohort	Drug-eluted balloon angioplasty, plain old balloon angioplasty,	Primary and secondary patency, wound healing, target lesion revascularisation	2b
10	Dayama et al.[28]	2018	1354	Retrospective cohort	Bypass first and endovascular first	MALE, MACE, amputation rate, patency, mortality	2b

LOE: Level of evidence

Table 1. A critical review of cohort studies (prognostic studies) according to the Center of Evidence-Based Medicine Critical Appraisal of Cohort Studies University of Oxford 2015

Criteria	Studies							
	Neville et al.	Das et al.	Palena et al.	Troisi et al.	Spillová et al.	Dayama et al.	Brizzi et al.	Commeau et al.
Internal validity								
A certain representative sample of patients is collected at the same point early in the course of the disease	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
The follow-up is quite long and done	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Outcome criteria are objective or applied covertly	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
If there are subgroups with different prognoses, were adjustments made for important prognostic factors?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Outcomes over time [+]	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
Prognostic estimation accurac [*]	Yes	No	Not	No	Yes	Yes	No	Not
Applicability								
Can the important valid evidence from this study be applied to my patient	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

[+]Outcomes over time are presented in each article in the form of a Kaplan-Meier curve (attached). [*]Prognostic estimation accuracy is expressed in confidence interval figure.

Table 2. Critical review for randomized control trial studies according to the Center of Evidence-Based Medicine Critical Appraisal of Cohort Studies University of Oxford 2015

Criteria	Studies	
	Teymen et al.[24]	Rastan et al.[23]
Were the patients in each treatment group randomized?	Yes	No
Were the groups consistent from the start of the experiment?	Yes	Yes
Is the treatment of each group the same?	Yes	Yes
Is there *blinding* from the beginning to the end of the study	Yes	No
Have any patients *lost to follow*- up?	Yes	Yes
Does the article report overall side effects?	Not	Yes
Are there significant differences in each group?	Exist	No
Are the results reliable?	Yes	Yes
Applicability		
Is there a difference between my patient's condition and the study?	Yes	Yes

[+]Outcomes over time are presented in each article in the form of a Kaplan-Meier curve (attached). [*]Prognostic estimation accuracy is expressed in confidence interval figure.

Discussion

The basic revascularization techniques to treat infra-popliteal PAD in diabetic foot patients are important to determine the best option for the population. In this review, ten studies were included as references; they used different techniques with different outcomes. For instance, Neville et al. (2009)[22] found that the expanded polytetrafluoroethylene (ePTFE) method bound to heparin had no statistically significant difference compared with the saphenous vein graft (SVG) in the distribution of the target tibial artery in the anterior tibia (15 vs. 17 in ePTFE and SVG), posterior tibial (22 vs. 16), dorsal pedis (4 vs. 5), and peroneal (21 vs. 12). Regarding survival, Neville et al. (2009)[22] found that the primary patency of the ePTFE method was 75%, and the primary patency of the SVG method was 86.4%. In addition, *end-stage renal disease* contributed to decreased function and had an 86% higher risk of death (95% CI, 64%-245%). On the other hand, when compared with the two methods, SVG had a lower risk of occlusion or death (95% CI, 14.2%-94.5%, p >0.05).

Rastan et al. (2015) [23] showed that the direct atherectomy resulted in a primary patent of 84% for a year. The risk of amputation was reduced by 97.1%. Whereas Dayama et al. (2018)[28] who compared endovascular–first revascularization with the bypass–first revascularization, found that wound complications in the bypass–first were 9.7%, while wound complications in the endovascular–first were 3.7% and were statistically significant (p <0.01). However, from the perspective of 30 days mortality, these two methods have no significant difference. The mortality revascularization with the bypass–first was 3.2%. and surgical revascularization–first was 1.8% (p = 0.1).

Some studies have also compared direct and indirect revascularization methods. Spillerova et al. (2017)[27] compared direct bypass, open surgical methods, and PTA. This study found that in a 1-year *follow-up*, the cure rates for the *direct bypass method* were 77%, 68.5% for the *indirect bypass* method, 52.4% for the direct PTA method, and 52% for the direct the indirect PTA method. For survival, it was found that the best wound healing resulted from *direct bypass* (p = 0.003), while the one-year survival rates of the three PTA, *direct bypass*, and *indirect bypass methods* were 25.5%, 21.4%, and 32.3%, respectively. Troisi et al. (2017)[26] compared direct and indirect revascularization methods. They found that direct and indirect angiosome revascularization had no statistically significant difference in the healing process after three months (direct = 23.6% vs. indirect = 23.7%, p = 1). From the perspective of free amputations (in one year), the direct revascularization method showed a success of 74.4% and the indirect revascularization method of 76.8%.

Commeau et al. (2006)[20] reviewed the drug-eluting stent method. They found that only two patients required amputation, one toe in one patient and one in the other: 100% of the subject were free from the risk of amputation. However, the mortality reported were two cardiac-related and one stroke with hemiparesis, one early reperfusion syndrome, one contralateral CLTI, and three cases of recurrent homolateral claudication. All survivors had medium-term clinical improvement with 97% of primary patents (56 patent arteries in 58 arteries).

The drug-eluted *stent* method was also compared with other methods. Teymen et al. (2017),[24] compared the drug-eluted stent method with the same method with the addition of pedal artery angioplasty. In this study, the mortality in the two methods was not statistically significant (in angioplasty of 5% and without angioplasty of 8%, p = 1). The total amputated patients were 15% in angioplasty and 24% without angioplasty (p = 0.291).

Meanwhile, another study by Brizzi et al. (2018)[29] compared the drug eluted method and stent with non-medicated balloon angioplasty and showed that complete wound healing was found in187 patients (82.7%), the overall limb salvage rate was 94.0% with a survival rate of 89.2%. Primary and secondary patency rates were 84.5% and 91.7%, respectively, with significantly lower primary patency rates after stent placement (80.6% vs 87.6% after POBA; p = 0.043). The rate of freedom from target lesion revascularization (TLR) was 86.3% with a significantly lower rate after stent placement (81.8% vs 89.9% after POBA; p = 0.01). Subgroup analysis showed no significant difference between nitinol stents, BESs, and POBA in limb salvage and survival rates. However, primary and secondary patency rates were significantly lower after BESs (primary and secondary patency rates 84.0% after nitinol stents). vs. 77.4% after BESs vs. 87.6% after POBA; p = 0.012 and 93.0% vs. 77.4% vs. 87.6%; p = 0.003, respectively), as well as freedom from TLR levels (82.3% vs. 81.2% vs. 89.9%; p = 0.04). The finding shows that the presence or absence of angioplasty has no significant difference even though the morbidity and mortality rates are slightly lower in the drug-eluted stent method with angioplasty.

Palena et al. (2017)[25] compared angioplasty with a drug-coated balloon (DCB angioplasty with the infra-popliteal method). They found that the survival rate of DCB angioplasty was 90%, while that of infra-popliteal was 80% (p = 0.047). The survival rate from amputation in the DCB method was 100%, and infra-popliteal was 84% (p = 0.0003).

Das et al. (2007)[21] reviewed one method only, namely the cryoplasty. A balloon angioplasty inflated using NO fluid showed the advantage of reducing vascular of being injured. They found that the success rate achieved was 97.3%, the free of amputation rate was 93.4%, and there was a mortality of 4.6%.

In summary, various revascularization techniques that are used to treat PAD have been compared, namely: ePTFE, SVG, atherectomy, surgical revascularization–first, endovascular bypass revascularization, direct and indirect angiosome revascularization, open surgery, direct bypass, indirect bypass, PTA, drug-eluting stent, pedal artery angioplasty, non-drug balloon angioplasty, DCB balloon angioplasty, infra-popliteal angioplasty, and cryoplasty. Several methods may be preferred depending on the patient's condition and the risks involved because studies have shown a better prognosis, including atherectomy, direct bypass, drug-eluting stent, balloon angioplasty, and cryoplasty.

However, remember that this literature was conducted in developed countries with different demographic conditions and more adequate health facilities. Therefore, adjustments are required before applying in Indonesia, which has other case characteristics. In addition, there are several studies with small samples, namely the study conducted by Commeau et al. (2006),[20] by Teymen et al. (2017),[24] and Palena et al. (2017)[25] that may contribute to a bias factor that affects the outcome.

Conclusions

Ten studies of high-quality evidence showed that endovascular surgery such as cryoplasty, atherectomy, direct bypass, balloon angioplasty, and drug-eluting stent is best to treat PAD with infra-popliteal CLTI with revascularization.

Disclosure

The authors declare no conflict of interest

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