Femoro-popliteal endovascular interventions

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Abstract

Peripheral artery disease (PAD) is a worldwide major health challenge, and it is a strong predictor of mortality and morbidity. The advances in PAD treatment have resulted in many therapeutic options or endovascular interventions (EVIs) for endovascular revascularization if drug therapy does not lead to substantial improvement. Randomized controlled trials (RCTs) have reported the efficacy of various EVIs such as atherectomy, stents, and medicated balloons over the traditional transluminal angioplasty; however, the standard treatment for PAD remains unclear due to the lack of head-to-head comparative studies between different EVIs. Additionally, the variable outcomes between clinical trials regarding the functional capacity and quality of life (QoL) make it difficult to ascertain the superiority of one particular EVI over another. Therefore, the latest PAD clinical trials should include head-to-head comparisons between different EVIs, and this review aimed to highlight the femoro-popliteal EVIs, evidence supporting each intervention and why those EVIs are used.

Key words: *endovascular, femoro-popliteal, interventions.*

Introduction

Peripheral artery disease (PAD) is a worldwide major health challenge, and it is a strong predictor of mortality and morbidity [1]. PAD is partial or complete obstruction of one or more peripheral arteries following atherosclerotic or occlusive disease [2].

Peripheral vascular disease and peripheral occlusive disease are similar terms to PAD. PAD can be asymptomatic or can present with life-threatening symptoms. Intermittent claudication (IC) is a common presenting symptom of PAD and manifests as ischemic leg pain during walking which disappears after rest.

The Rose [3] and San Diego Claudication Questionnaires were developed to identify IC and its severity [4].

The ankle-brachial index (ABI) is the diagnostic test used to identify patients with PAD, and it in-

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volves the ratio of the systolic blood pressure at the patient's ankle versus at the patient's arm (ABI of < 0.90 is sensitive and specific for the diagnosis of PAD) [5].

The risk factors of PAD include cigarette smoking (smoking doubles the odds of PAD) [1], diabetes mellitus type 2 (diabetic PAD patients had 5-fold higher odds of amputation compared with non-diabetic patients) [5], hypertension, dyslipidemia, and obesity [1, 5].

The femoro-popliteal segment is the most affected segment and includes the superficial femoral and popliteal arteries of the lower limbs [6, 7].

Multi-level and extensive or severe femoro-popliteal occlusion is frequently observed in patients presenting with severe IC or critical limb ischemia (CLI) [6].

The superficial femoral artery (SFA) is the longest vessel in the human body. It is exposed to compression by the surrounding muscles and when it passes through the adductor canal [8].

About 50% of patients who have undergone femoro-popliteal endovascular intervention (EVI) have chronic and total femoro-popliteal occlusion [5].

The treatment of femoro-popliteal vascular disease is usually aimed at relieving the patient's symptoms, improving the limb function, and avoiding limb amputation [9].

The treatment of femoro-popliteal vascular disease includes lifestyle modification such as smoking cessation, proper glycemic, cholesterol and blood pressure control, structured exercises, antiplatelets and anticoagulants [9].

When the PAD is refractory to lifestyle modification and medical therapy, supportive therapy such as wound care should be started followed by EVI to improve the lower limb's perfusion [9].

Endovascular interventions

The advances of EVIs and technology over the last years have resulted in increased EVIs for PAD and reduced open vascular interventions to improve the lower limb's perfusion [10].

The EVIs for PAD allow quick recovery and reduced risk of complications compared with open vascular interventions [11, 12].

The femoro-popliteal EVI begins after obtaining retrograde vascular access, through the contralateral femoral artery [13].

A contralateral femoral artery inserted catheter is used to steer the guidewire to the contralateral common iliac artery, then to the abdominal aorta, followed by a baseline angiogram to detect the femoro-popliteal lesion's extent and severity [14].

Before any endovascular treatment modality or EVI (i.e., balloon angioplasty, stenting, and atherectomy), an intraluminal guidewire should traverse the femoro-popliteal lesion. Sub-intimal crossing technique can used in chronic and total femoro-popliteal occlusion [6].

After crossing the femoro-popliteal target lesion, the endovascular surgeon uses either balloon angioplasty or atherectomy as an initial EVI [15].

Most of the PAD studies compare an endovascular treatment modality against either the standard endovascular treatment or another treatment modality.

With the development of many EVIs, and observational studies evaluating each endovascular device, it is difficult to determine the standard endovascular treatment [16] and provide strong evidence supporting each endovascular treatment or intervention. The low strength of evidence when evaluating EVIs can be explained by the observational studies that suffer from a bias risk following either a biased treatment decision or patients' inclusion criteria [16].

Therefore, this review aimed to highlight the femoro-popliteal EVIs, evidence supporting each intervention and why those EVIs are used.

Aim

This review aimed to highlight the femoro-popliteal EVIs, evidence supporting each intervention and why those EVIs are used.

Methods

A PubMed, Scopus, and Google search was performed to retrieve published randomized controlled trials (RCTs) of SFA-popliteal EVIs (i.e., drug-coated balloons (DCBs), SFA-popliteal stents, and atherectomy) published in English language between 2005 and 2020 using the following keywords: femoro-popliteal, vascular, and endovascular intervention.

The retrieved RCTs were reviewed regarding the nature of the EVI, number of participants, duration of each trial, and its outcome including QoL (quality of life), WIQ (Walking Impairment Questionnaire), and 6-min walking test (6-MWT) changes, CD-TLR

(clinically driven target lesion revascularization), primary patency and safety outcome, to highlight the femoro-popliteal EVIs, evidence supporting each intervention and why those EVIs are used.

Discussion

Endovascular therapeutic options or endovascular interventions

Standard balloon angioplasty

The balloon-tipped catheter was used to open a stenosed femoral lesion for the first time in 1974 by the German-physician Andreas Grüntzig. This procedure is known as percutaneous transluminal angioplasty (PTA) [17].

PTA has been established as the standard EVI or treatment since 2005. PTA includes a balloon inflation in the target vessel to compress the atheroma into and against the vessel wall [18].

PTA can restore the blood flow across the target lesion temporarily, but it is associated with risk of complications.

PTA complications include sudden vessel closure and/or dissection, which can occur after removal of the balloon, especially when chronic and/or total occlusions are treated [8]. Target lesion restenosis can occur after PTA, especially when severe calcified and long lesions are treated.

A Cochrane review reported insufficient evidence to reach a conclusion regarding the effects of PTA versus primary endovascular stenting for stenotic iliac arteries lesions, and only one study has reported lower distal embolization rates following primary stenting in iliac occlusion [19].

No comparative trials have been carried out to establish PTA as the standard EVI; however, it is used as the standard comparative technique to compare other endovascular treatment modalities or EVIs against it.

Drug-coated balloons

The drug-coated balloon (DCB) technique for treating PAD combines conventional PTA and anti-proliferative technology. A balloon is advanced to the target lesion, coated with an excipient and the anti-proliferative drug paclitaxel. After inflation of the balloon, the excipient helps the desired drug's (anti-proliferative) diffusion into the artery wall, which subsequently inhibits cell proliferation.

There are three different types of DCBs.

1. IN.PACT Admiral DCB (Medtronic Inc., Minnesota, USA) coated with paclitaxel (3.5 µg/mm^2 in urea excipient) [20].
2. Lutonix DCB (CR Bard Inc., New Jersey, USA) is a paclitaxel DCB (2.0 µg/mm^2 in a polysorbate/sorbitol excipient) [21].
3. Stellarex DCB (Spectranetics Corp., Colorado, USA) is coated with paclitaxel (2.0 µg/mm^2 in a polyethylene glycol excipient) [22].

The DCBs have been compared against PTA in many trials, with significant results (Table I). A significant difference was reported in target lesion revascularization and target lesion patency when the paclitaxel DCB was compared to PTA in the THUNDER trial [23].

The THUNDER trial findings were supported by the PACIFIER [24], LEVANT-II [25], BIOLUX P-I [26], AcoArt-I [27], IN.PACT [20], and ILLUMENATE trials [22].

A significant difference in the QoL and walking distance using the Walking Impairment Questionnaire (WIQ) was reported in the LEVANT-II trial when the Lutonix DCB was compared to PTA [25].

No significant differences in QoL, walking distance, and 6-min walking test (6-MWT) were reported in the ILLUMENATE [22] and IN.PACT trials [20], when the Stellarex-DCB and Medtronic Admiral DCBs were compared to PTA.

A review of records for patients who underwent EVIs showed that 65% of them underwent PTA and 31% underwent DCBs. PTA and DCBs had similar results (with no significant difference), and 90% of the participants had 12-month amputation-free intervals after both the PTA and DCBs [28].

The DCB produces homogeneous anti-proliferative drug delivery to the target lesion when compared to the conventional PTA. Moreover, the DCB can be combined with endovascular stenting during the EVI for a target lesion [29].

The advantages of DCB compared to endovascular stenting include homogeneous anti-proliferative drug delivery to the target lesion, reduced rates of restenosis and thrombosis and prolonged antiplatelet therapy [30].

Moreover, the DCB can be used when the endovascular stenting is not visible (i.e., across knee joints) [31]. Additionally, DCB is not associated with subsequent vessel recoil or residual vessel dissection when compared to endovascular stenting [31].

Table I. Drug-coated balloon (DCB) trials versus percutaneous angioplasty (PTA)

Variable	Trial name						
	THUNDER	IN.PACT	LEVANT II	PACIFIER	ILLUMENATE	AcoArt-1	BIOLUX P-1
Treatment	Paclitaxel-coated balloon versus PTA	Medtronic admiral DCB versus PTA	Lutonix PCB versus PTA	Medtronic pacific DCB versus PTA	Stellarex DCB versus PTA	Acotec Scientific Orchid DCB versus PTA	Biotronik AG Passeo-18 Lux DCB versus PTA
Number of studied patients	154	331	476	85	300	200	60
Duration of the study	5 years	2 years	1 year	1 year	1 year	1 year	1 year
QoL's change	NR	0.096 ±0.216 versus 0.055 ±0.229 (p = 0.15)	Difference between -groups: 0.01 ±0.20	NR	Similarly improved. 0.10 ±0.23 versus 0.04 ±0.2 (p = 0.2006)	NR	NR
Change in WIQ score	NR	Similarly improved from baseline	Walking-distance Score between-groups: similarly improved	NR	20.1 ±9.4 versus 22.5 ±28 (p = 0.5508)	NR	NR
Change in 6-min walking test	NR	30.9 ±87.7 versus 60.5 ±97.6 (p = 0.117)	NR	NR	70 ±114 versus 73 ±178 (p = 0.817)	NR	NR
CD-TLR	21% versus 56% (p = 0.0005)	9.1% versus 28.3% (p < 0.001)	12.3% versus 16.8% (p = 0.21)	7.1% versus 27.9% (p = 0.02)	7.9% versus 16.8% (p = 0.023)	7.2% versus 39.6% (p < 0.001)	15.4% versus 41.7% (p = 0.064)
Primary patency	Restenosis: 17% versus 54% (p = 0.04)	78.9% versus 50.1 (p < 0.00)	65.2% versus 52.6% (p = 0.02)	Restenosis: 8.6% versus 32.4% (p = 0.01)	76.3% versus 57.6% (p = 0.003)	76.1% versus 33.7% (p < 0.001)	Restenosis: 11.5% versus 34.6% (p = 0.048)
Safety outcome	Non-significant	87.4% versus 69.8% (p < 0.001)	83.9% versus 79.0% p = 0.005 for non-inferiority	7.1% versus 34.9% (p < 0.01)	92.1% versus 83.2% p = 0.025 for superiority	2% versus 3% (p = 1.00)	NR

CD-TLR – clinically driven target lesion revascularization, DCB – drug-coated balloon, NR – not reported. Primary patency = free from CD-TLR or restenosis. PTA – percutaneous transluminal angioplasty. QoL – quality of life. Safety outcome: free from 30-day device- and procedure-related complications, death, and/or major limb amputation. WIQ – Walking Impairment Questionnaire.

Self-expanding nitinol stents

Nitinol (formed of nickel/titanium) metal, self-expanding stents are metal stents frequently used during EVI for femoro-popliteal lesions due to their easy distensibility and radial force.

Stents are inserted over a guidewire into the arterial lumen, then advanced to the target femoro-popliteal lesion, and deployed to the target lesion by retracting a sheath to allow expansion of the vessel lumen by the stent.

The stent will act as a scaffold to keep the vessel wall open and to maintain the blood flow across the target lesion. Table II shows the result of femoro-popliteal endovascular stenting trials.

The bare metal stent (BMS) was compared to PTA in a femoral artery stenting trial (FAST) for stenting superficial femoral and popliteal arteries. The FAST trial did not report any significant benefit for short SFA (< 10 cm) lesions [32].

The ABSOLUTE trial compared the BMS versus PTA in SFA lesions more than 10 cm and reported beneficial efficacy of the BMS over PTA regarding the target vessel restenosis and maximal walking distance [33].

The BMS efficacy is further increased with increased target lesion length, which was subsequently supported in the RESILIENT trial [34].

The risk of femoro-popliteal stenting includes stent fracture, because the femoro-popliteal region is subjected to a wide range of movement [11].

In addition to BMSs, there are two other categories of stents used in the SFA-popliteal region: covered stents (endo-prosthesis) and drug-eluting stents (DES).

1. Covered stents (endo-prosthesis): BMSs covered by expandable polytetrafluoroethylene (PTFE) on the inner and outer surfaces.

The Viabahn trial found that the Viabahn endo-prosthesis is safe and produces significant improvement in primary patency when compared to PTA [35].

The VIBRANT trial failed to report any significant difference for the Viabahn endo-prosthesis when compared head-to-head to the nitinol BMS [36].

Moreover, the VIASTAR trial did not detect any significant difference for the endo-prosthesis when compared to BMSs [37].

The inability of the atheroma to invade through the covered stents (endo-prosthesis) is considered a theoretical advantage of covered stents (endo-prosthesis) over BMSs.

Acute limb ischemia is the presenting feature after covered stent (endo-prosthesis) thrombosis, which requires an urgent EVI.

2. Drug-eluting stents (DES): self-expanding nitinol BMSs covered with a slowly released anti-proliferative drug.

The Zilver-PTX (Cook Med., Limerick, Ireland) releases paclitaxel from a polymer-free scaffold 72 h after insertion. Paclitaxel acts as an anti-proliferative agent on the treated arterial wall.

One month after Zilver-PTX insertion, the intimal layer of the treated vessel creeps over the Zilver-PTX, which subsequently reduces thrombus formation risk [38].

The 5 years' result of the Zilver-PTX trial comparing DES (primary and provisional) versus standard EVI (defined as PTA with provisional Zilver-BMS) showed significant improvement affecting the clinically driven target lesion revascularization (CD-TLR), and primary patency following DES [38].

Atherectomy

The mechanism of atherectomy devices is based on removal of an atheromatous plaque rather than compressing it against the arterial wall, to increase the luminal diameter without leaving a stent (i.e., foreign body) in the treated vessel lumen.

Atherectomy technique can be classified into directional, rotational, orbital, and/or laser. Each one of these techniques had its advantages and disadvantages with the overall objective of atheromatous plaque removal. Table III shows atherectomy trials versus other EVIs.

1. Directional atherectomy: During directional atherectomy, a catheter contains a cutting device directed to the target lesion. The cutting device shears the target atheroma in a longitudinal direction once activated. The sheared atheroma is then collected in a nosecone.

To achieve maximum atheroma debulking, the directional atherectomy needs multiple passes across the target lesion.

Advantages of directional atherectomy include its efficacy for eccentric and calcified atheromatous plaque and its ability to treat non-stented targeted vessel segments (i.e., common femoral or popliteal).

Table II. Femoro-popliteal stent trials versus other endovascular interventions (EVIs)

Variable	Trial name						
	ZILVER-PTX	ABSOLUTE	FAST	RESILIENT	VIABAHN	VIBRANT	VIASTAR
Treatment	Zilver-PTX Overall DES (primary and provisional) versus standard treatment (PTA and provisional Zilver-BMS)	Absolute self-expanding nitinol stent (BMS) versus PTA	Bard Luminexx 3 stent (BMS) versus PTA	LifeStent self-expanding stent (BMS) versus PTA	Viabahn covered stent versus PTA	Viabahn covered stent versus nitinol BMS	Viabahn covered stent versus LifeStent/Protégé EverFlex Stent/ SMART-Control Stent (BMS)
Number of participants	104	104	244	206	197	148	141
Duration of the study	5 years	1 year	1 year	1 year	1 year	3 years	1 year
QoL's change	NR	NR	NR	Short form health survey: Similarly improved	NR	NR	NR
Change in WIQ score	Both groups significantly improved ($p < 0.05$)	Maximal distance on treadmill (m): 363 versus 270 ($p = 0.04$)	Maximal distance on treadmill (m): 185 versus 150 ($p = 0.028$)	More claudication pain in PTA group ($p = 0.009$)	NR	NR	Walking distance (m): 785.8 versus 565.9 ($p = 0.17$)
Change in 6-min walking test	NR	NR	NR	NR	NR	NR	NR
CD-TLR	16.9% versus 32.4% ($p < 0.01$)	NR	14.9% versus 18.3% ($p = 0.595$)	12.7% versus 54.8 ($p < 0.0001$)	NR	Non-significant	13.4% versus 23.0% ($p = 0.37$)
Primary patency	66.4% versus 43.4% ($p < 0.01$)	Restenosis rate: 37% versus 63% ($p < 0.01$)	Restenosis rate: 31.7% versus 38.6% ($p = 0.377$)	81.5% versus 36.7% ($p < 0.0001$)	65% versus 40% ($p = 0.003$)	24.2% versus 25.9% ($p = 0.392$)	70.9% versus 55.1% ($p = 0.11$)
Safety outcome	Free from persistent ischemic symptoms: 79.8% versus 59.3% ($p < 0.01$)	Non-significant difference	Non-significant difference	Non-significant difference	CLI 15% further improved for stent-graft group ($p = 0.003$)	Non-significant difference	Non-significant difference

BMS – bare metal stent, CD-TLR – clinically driven target lesion revascularization, CMS – covered metal stent, NR – not reported. Primary patency = free from CD-TLR or restenosis. PTA – percutaneous transluminal angioplasty. QoL – quality of life. Safety outcome: free from 30-day device- and procedure-related complications, death, and/or major limb amputation. WIQ – Walking Impairment Questionnaire

Table III. Atherectomy trials versus other endovascular techniques/interventions

Variable	Trial name			
	Shammas *et al.* trial 2011	COMPLIANCE 360 2014	EXCITE-ISR 2015	DEFINITIVE AR 2017
Treatment	Medtronic SilverHawk Directional atherectomy versus PTA	Orbital atherectomy versus PTA	Spectranetics Turbo Tandem laser catheter versus PTA	Medtronic SilverHawk/ TurboHawk directional atherectomy + Medtronic Cotavance paclitaxel coated balloon versus paclitaxel coated balloon alone
Number of participants	46	65 lesions	250	102
Duration of the study	1 year	1 year	6 months	1 year
QoL's change	NR	NR	NR	QoL index at 1 year: 0.87 ±0.2 versus 0.87 ±0.19 (p = 0.72)
Change in WIQ score	NR	NR	NR	Improved
Change in 6-min walking test	NR	NR	NR	NR
CD-TLR	8% versus 22.2% (p was not significant)	NR	26.5% versus 48.2% (p < 0.005)	7.3% versus 8.0% (p = 0.90)
Primary patency	NR	81.2% versus 78.3% (p > 0.99)	Maintained superiority throughout the follow-up (p < 0.005)	84.6% versus 81.3% (p = 0.78)
Safety outcome	Non-significant	NR	5.8% versus 20.5% (p < 0.001)	89.3% versus 90.0% (p = 0.86)

CD-TLR – clinically driven target lesion revascularization, NR – not reported. Primary patency = free from CD-TLR or restenosis. PTA – percutaneous transluminal angioplasty. QoL – quality of life. Safety outcome: free from 30-day device- and procedure-related complications, death, and/or major limb amputation. WIQ – Walking Impairment Questionnaire.

The disadvantages of directional atherectomy include risk of vessel trauma, distal embolization which necessitates embolic protection, and a long procedure time due to multiple passes across the target lesion.

No significant difference was reported in the CD-TLR when directional atherectomy (Medtronic SilverHawk) was compared to PTA [39].

Additionally, no significant difference was reported in the CD-TLR or QoL when atherectomy plus DCB was compared to DCB alone in the DEFINITIVE AR study [40].

2. Rotational atherectomy: During rotational atherectomy, a diamond-tipped and rotating burr is directed to the target lesion. The rotating burr passes through the atheromatous plaque once activated. The rotating burr grinds the atheromatous plaque into small particles that can be safely and easily eliminated by the body or aspirated during the rotational atherectomy technique.

The rotational atherectomy technique is simple, easy, takes a short time and can be used in severe calcified atheromatous lesions.

The disadvantages of rotational atherectomy include inability to detect the depth of the atheromatous plaque during the rotational atherectomy technique and spread of the grinded atheromatous plaque as an embolic particle [41].

Latacz *et al*. [42] studied 51 patients with acute thrombotic femoro-popliteal PAD or chronic critical ischemia and found that femoro-popliteal rotational atherectomy followed by DCB was an effective EVI for long-lasting revascularization.

3. Orbital atherectomy: During orbital atherectomy, rotating shafts with high speed and a debulking crown are advanced through the target lesion for debulking of the atheromatous plaque.

During orbital atherectomy, the debulking area (i.e., orbit) increased with increasing speed of the crown, and the luminal gain after orbital atherectomy matched the atheromatous plaque depth.

The advantages of orbital atherectomy include the short procedure time and improved luminal gain which matches the atheromatous depth.

The disadvantages of orbital atherectomy include inability to treat in-stent restenosis and risk for barotrauma if rotational speed is not used properly [41].

Li *et al*. [43], in a retrospective study including 80 Chinese participants with femoro-popliteal class III in-stent restenosis, found that debulking plus DCB had better outcomes in 1-year primary patency compared to DCB alone.

No significant difference in effect on primary patency was found when orbital atherectomy was compared to PTA in the COMPLIANCE 360 trial [44].

4. Laser atherectomy: During laser atherectomy the excimer laser is used to abate the atheromatous plaque using ultraviolet radiation and it was approved by the FDA for in-stent restenosis [5].

The current laser technology can ablate/treat an atheromatous plaque with 10-µm depth with each energy pulse without affecting the treated vessel wall.

Laser atherectomy was safe with a significant difference in effect on the CD-TLR and primary patency when compared to PTA in the EXCITE-ISR trial [45].

The advantages of laser atherectomy include its ability to treat the atheromatous long SFA-popliteal segment.

The disadvantages of laser atherectomy include the long procedure time caused by the slow energy pulse [18].

Current limitations

SFA-popliteal EVIs such as atherectomy devices, stents, and DCBs have been studied in many trials. This review aimed to highlight the femoro-popliteal EVIs, evidence supporting each intervention and why those EVIs are used.

However, the current SFA-popliteal therapeutic interventions contain some limitations. The limitations include lack of head-to-head trials/studies (i.e., between atherectomy techniques), which limit the endovascular surgeon to choose the appropriate EVI for their patients with SFA-popliteal disease.

A meta-analysis attempted to compare different EVIs; however, it was limited by the heterogeneity of studied populations, SFA-popliteal severity and treatment options [46].

Although DCBs were compared to the standard PTA previously, future studies comparing different DCBs are needed [5].

The lack of consensus and/or definitions which measure the clinical outcome after SFA-popliteal EVIs is another limitation of the current SFA-popliteal therapeutic options. Many studies have consistently reported CD-TLR and primary patency outcomes and ignored the patients' QoL and walking distance after

EVIs for SFA-popliteal disease. Standard clinical and functional definitions were developed to allow better evaluation of PAD and the outcome of SFA-popliteal EVIs [47, 48].

The standard clinical definitions for PAD were developed to separate patients suffering from IC and exertional limb ischemic symptoms from patients suffering from CLI. The standard functional definitions for clinical outcomes and IC include the 6-MWT, WIQ to measure walking/functional ability, and QoL. The Peripheral Artery Questionnaire (PAQ) to measure the patient's physical limitations, social function, and treatment satisfaction was also developed [47].

Future studies/research

Although the stent technology and DCBs were superior to PTA for treating SFA-popliteal lesions, the atherectomy technique requires more research [5].

It is important for RCTs to focus on head-to-head comparisons (i.e., laser versus directional atherectomy), treatment strategy (i.e., DCB/stent versus atherectomy/DCB), and standardized patients' outcome, to establish a gold standard EVI.

A review of clinicaltrials.gov showed several ongoing EVI comparative studies. For example, a randomized comparative trial of Ranger DCB versus IN.PACT DCB reported an 83% primary patency for Ranger DCB versus 81.5% for IN.PACT as the 1-year primary endpoint result. The same study reported a 17.3% CD-TRL for Ranger DCB versus 13% for IN-.PACT (p = 0.3) [49].

The TRANSCEND study, comparing SurVeil-coated DCB (Surmodics, Inc., Minnesota, USA) to high-dose DCB (IN.PACT, Medtronic Inc., Minnesota, USA) reported statistically comparable secondary outcomes for SurVeil versus IN.PACT, including target vessel patency (63.0% versus 63.1%, respectively) (p = 1.000), major target limb amputation (TLA) (0.0% versus 0.5%, respectively), (p = 1.000), and thrombosis at the target lesion (0.6% versus 0.0%, respectively) (p = 0.47) [50].

The DISRUPT PAD-III study comparing shockwave intravascular lithotripsy (IVL) to PTA showed favorable primary patency for IVL over PTA (80.5% versus 68%, respectively), (p = 0.017) after 1 year, which also remained favorable after 2 years (74.4% versus 57.7%, respectively) (p = 0.005) [51].

The FOREST trial, comparing DCB and provisional BMS to primary DES stenting, aimed to detect freedom from restenosis, CD-TLR, ABI and QoL changes [52].

Conclusions

PAD is a worldwide major health challenge, and it is a strong predictor of mortality and morbidity. EVIs became a more popular therapy over the past years. However, the standard EVI remains unclear due to a lack of head-to-head comparisons between EVIs (i.e., lack of head-to-head trials/studies between atherectomy techniques), which hinders the endovascular surgeon when choosing the appropriate EVI for their patients.

It is important for RCTs to focus on head-to-head comparisons (i.e., laser versus directional atherectomy), treatment strategy (i.e., DCB/stent versus atherectomy/DCB), and standardized patients' outcome, to establish a gold standard EVI.

This review aimed to compare different femoro-popliteal EVIs; however, the heterogeneity of the studied population and of the treated SFA-popliteal lesions were the limitations faced during this review.

Additionally, many studies have reported CD-TLR and primary patency outcomes and ignored the patients' QoL and walking distance after SFA-popliteal EVIs. Although DCBs were compared to the standard PTA previously, future studies comparing different DCBs are needed.

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Ethical approval

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Conflict of interest

The authors declare no conflict of interest.

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