

The Safety and Efficacy of Intravascular Lithotripsy in Treating Calcified Peripheral Arterial Disease

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Abstract

Calcified peripheral arterial disease (PAD) is a common health condition associated with increased morbidity and mortality. Endovascular procedures have become more common in treating these lesions, and plain balloon angioplasty (PBA) is often used for vessels with mild-to-moderate calcification. However, decreased vascular compliance in heavily calcified vessels leads to poorer outcomes and higher complication risk.

Intravascular shockwave lithotripsy is a more novel endovascular management option. It uses a specially designed balloon catheter to create shockwaves in an attempt to modify and increase compliance of the calcified plaque. This review aims to assess the safety profile and efficacy of intravascular lithotripsy (IVL).

The currently available literature shows that use of IVL for calcified PAD has a good safety profile and low complication rate. Intravascular lithotripsy has also been shown to be more effective in treating patients with calcified PAD as compared to PBA alone. Whilst short-term and mid-term results are promising, there is a scarcity of published long-term data. Hence, further long-term data is required before a definitive conclusion can be drawn.

Categories: Radiology

Keywords: angioplasty, calcified, endovascular, intervention, lithotripsy, peripheral arterial disease, radiology, shockwave

Introduction And Background

Calcified peripheral arterial disease (PAD) affects more than 200 million people globally and has a high morbidity burden and mortality rate [1-3]. It is a well-known entity and has been the focus of research for many years [4]. The underlying mechanism for PAD and atherosclerosis includes lipid accumulation and mineral deposition within the intima (innermost layer of the blood vessel) and media (middle layer of the blood vessel). Although the process is not completely understood, it is mediated by a slow chronic inflammatory process over the course of several years. It has been thought that an initial toxic stimulus (such as metabolic products and local inflammatory mediators) leads to an inflammatory response and accumulation of leukocytes, causing injury to the endothelial layer of the vessel wall (Figure 1). Over time, chronic inflammation predominantly driven by macrophage accumulation leads to atherosclerotic plaque formation within the tunica intima layer of the vessel wall, with cycles of repeated plaque rupture and inflammation. Ultimately, as cells die, extracellular calcium gets deposited between the tunica media and the atheromatous plaque. These plaques interfere with normal regulation of the calcium deposition, leading to abnormal calcium accumulation and crystallisation. While many risk factors have been recognised, chronic kidney disease (CKD), hypertension, diabetes mellitus (DM), advanced age, and atherosclerosis are among the most reported in patients with PAD [2,5-9].

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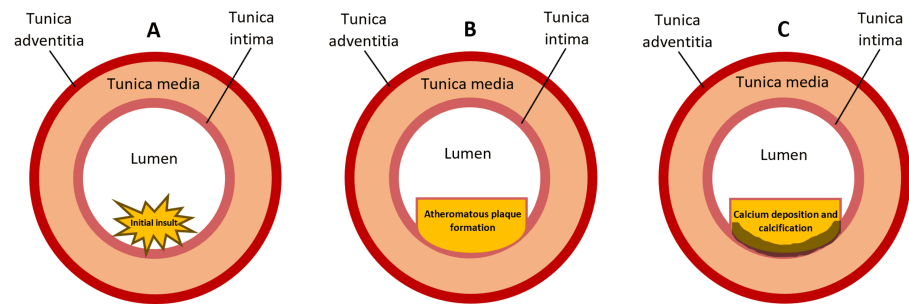


FIGURE 1: Pathophysiology of vascular calcification

A: Demonstrates the initial insult to the endothelium, triggering an inflammatory response; B: Shows the subsequent atherosclerotic plaque formation following prolonged inflammation; C: Demonstrates calcium deposition and crystallisation adjacent to the atheromatous plaque

Illustration created by the authors using Microsoft Office PowerPoint (Microsoft Corp., Redmond, WA, USA)

As management of PAD has evolved, endovascular procedures have become the mainstay of treatment [8]. Patients with calcified PAD are usually more complex to treat and represent up to 21% of those undergoing revascularisation procedures [10]. The issue with intraluminal vascular calcification is that it decreases vascular compliance, with a resultant increase in risk of developing acute complications. Furthermore, the presence of calcified plaques reduces the effectiveness of endovascular treatment, which in turn affects the success rate and results in a higher risk of developing intra/post-operative complications [3,7].

Conventional plain balloon angioplasty (PBA) is often used to dilate vessels with mild-to-moderate stenosis/calcification. However, treating a severely calcified plaque can be challenging. Although this usually results in suboptimal dilatation, more serious complications can be encountered, such as dissection, vessel perforation, restenosis, and distal embolisation [1]. This not only influences success rate and long-term outcomes, but it also limits the scope of further treatment options (such as stenting) [1,11].

Other options have been described in the literature for treatment of heavily calcified vessels, including high-pressure balloon angioplasty and atherectomy (a minimally invasive procedure to physically excise, or debulk, vascular atherosclerotic plaque). However, the effectiveness of these measures is limited and has not shown efficacy in altering the morphology of deeply seated calcium deposits [1,12].

More recently, intravascular lithotripsy (IVL) has been described in the literature to address cases of PAD with severe calcification. This is comparatively a novel treatment option and has been licensed for use in Europe and the United States since 2018 [13,14]. The IVL acts to modify and increase the compliance of both intimal and more deeply seated medial calcified deposits [15]. To achieve this, a specially designed catheter delivers pulsatile shock waves through lithotripsy emitters embedded into an angioplasty balloon [8,13]. This concept was adopted from renal lithotripsy routinely used for managing renal calculi [16]. Since then, it has been adapted and modified to be used in vascular calcification in PAD and coronary artery disease.

The aim of this review article is to summarise the principles behind IVL and to evaluate the currently available evidence around the efficacy of IVL for treating calcified PAD. A comprehensive literature search was conducted using the following keywords: peripheral arterial disease, calcified, shockwave, lithotripsy, angioplasty, intervention, radiology, and endovascular. Different electronic databases were used to retrieve the relevant literature, including Web of Science, PubMed, ScienceDirect, and Google Scholar. Relevant studies published between 2010 and 2026 were included in the search. Deploying this search strategy revealed 13 relevant studies: one review with meta-analysis, one randomised controlled trial (RCT), 10 prospective cohorts/retrospective/case series, and one review article (Table 1). Articles were reviewed following the PRISMA flow diagram (Figure 2).

No.	Authors	Paper title
1	Tepe et al., 2021 [1]	IVL for peripheral artery calcification: 30-day outcomes from the randomized Disrupt PAD III trial. Cardiovascular Interventions
2	Rocha-Singh et al., 2014 [2]	Peripheral arterial calcification: prevalence, mechanism, detection, and clinical implications
3	Madhavan et al., 2020 [3]	Efficacy and safety of IVL for the treatment of PAD: an individual patient-level pooled data analysis
4	Brodmann et al., 2019 [10]	Primary outcomes and mechanism of action of IVL in calcified, femoropopliteal lesions: results of Disrupt PAD II
5	Brodmann et al., 2019 [15]	Safety and feasibility of IVL for treatment of common femoral artery stenoses
6	Salihi et al., 2025 [17]	Intravascular shockwave lithotripsy for the treatment of severe PAD: a single-centre experience
7	Brodmann et al., 2018 [18]	Safety and feasibility of IVL for treatment of below-the-knee arterial stenoses
8	Adams et al., 2020 [19]	IVL for treatment of calcified lower extremity arterial stenosis: initial analysis of the Disrupt PAD III study
9	Armstrong et al., 2020 [20]	IVL for treatment of calcified, stenotic iliac arteries: a cohort analysis from the Disrupt PAD III study
10	Radaideh et al., 2021 [21]	Shockwave lithoplasty in combination with atherectomy in treating severe calcified femoropopliteal and iliac artery disease: a single-center experience
11	Armstrong et al., 2024 [22]	IVL for peripheral artery calcification: 30-day outcomes from the Disrupt PAD III observational study
12	Nugteren et al., 2025 [23]	Twelve-month outcomes of IVL for treatment of calcified popliteal and infrapopliteal lesions in patients with chronic limb-threatening ischemia
13	Shammas et al., 2026 [24]	IVL for treatment of severely calcified common femoral artery disease: results from the Disrupt PAD III observational study

TABLE 1: Studies included in the review

IVL: Intravascular lithotripsy, PAD: Peripheral arterial disease

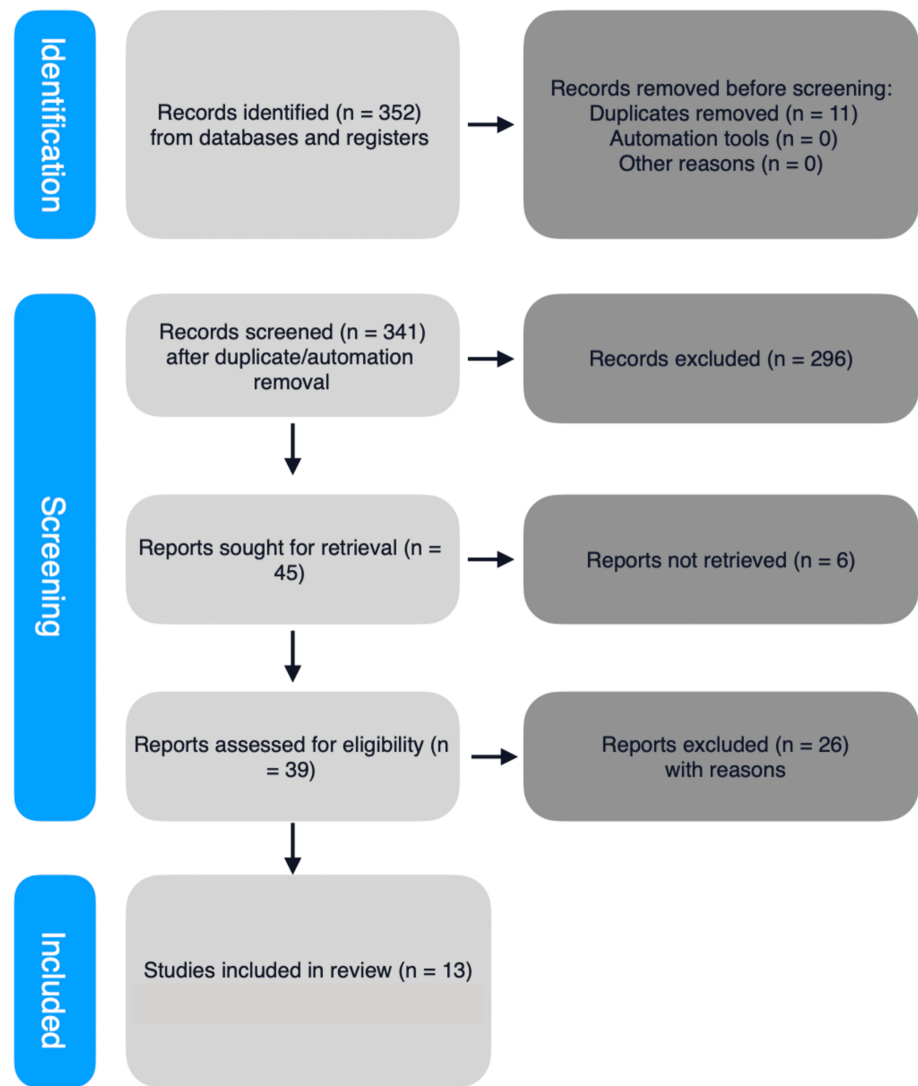


FIGURE 2: PRISMA flow chart

Diagram created using Apple Pages version 14.5 (Apple Inc., Cupertino, CA, USA)

Review

Principles of IVL

Intravascular lithotripsy utilises the concepts of extracorporeal shockwave lithotripsy (ECSL), which is widely used for fragmentation of renal calculi [25]. An IVL balloon catheter is different from a plain angioplasty balloon, as it contains multiple electrodes placed across the balloon. The IVL balloon is inflated, then a spark is emitted from the electrodes, leading to vaporisation of liquid in the balloon and formation of rapidly expanding and collapsing bubbles, known as cavitation bubbles. The formation of cavitation bubbles generates sonic pressure, known as shockwaves. These shockwaves create micro-cracks within the calcified lesion, making it more pliable and improving the success of subsequent PBA or stent deployment. Whilst the shockwaves interact with and modify the hardened calcific plaque, they do not damage healthy soft tissue. The IVL also modifies deeply seated plaque within the media of the vessel, which is not treated by atherectomy or PBA alone [7,17,26,27].

The effects of treatment with shockwaves may not be limited to their ability to modify vascular wall calcium. A systematic review suggested that extracorporeal shockwave therapy (ESWT) can influence the level of vascular endothelial growth factor (VEGF) and endothelial nitric oxide synthase (eNOS). These angiogenic factors are associated with reduction in vessel stenosis, promotion of angiogenesis, and improvement of overall perfusion [28]. However, this systemic review evaluated the effects of extracorporeal shockwave and has included studies done on animal subjects, as well as human studies. Whether these effects would also be seen in patients who had IVL for PAD is yet to be determined by future research.

During IVL, the balloon should be oversized by 10% (1.1x the diameter of the target vessel) to allow good opposition with the vessel wall and increase transmission of the shock wave into the calcified plaque (Figure 3). Initially, the balloon is inflated under low pressure to allow contact with the vessel wall only. Once shock waves have been delivered to the calcified lesions, the balloon can be inflated to a higher pressure to allow dilation of the stenosis [13].

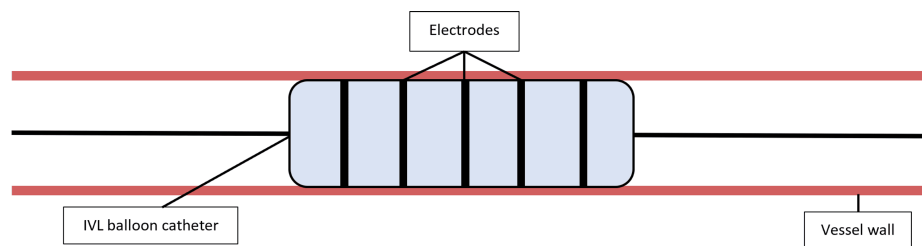


FIGURE 3: Illustration of an IVL balloon catheter with good opposition with the vessel walls

The electrodes create sparks, vaporising fluid within the balloon, causing rapidly expanding and collapsing bubbles to form and create shock waves.

Illustration created by the authors using Microsoft Office PowerPoint.

Safety and efficacy of IVL

Over the last few years, few studies have evaluated the outcomes of IVL for patients with calcified PAD. In 2018, a prospective, non-randomised, multicentre study evaluated the outcomes of 20 patients who underwent IVL treatment for moderate-to-severe infra-popliteal stenosis [18]. Post-treatment follow-up at 30 days showed a 46.5% reduction in vessel stenosis and a mean gain of 1.5 mm in lumen. Only one patient was reported to have dissection. Relatively similar results were published a year later from a retrospective study that assessed the practicality and safety of IVL in 21 patients with calcified common femoral artery (CFA) stenosis [15]. Results showed a 51% reduction in vessel stenosis and 3.1 mm lumen gain. Post-treatment vascular complications were only reported in five cases, all in the form of non-flow-limiting dissections with severe complications reported. Although these studies [15,18] are promising, both had relatively small sample sizes and a short follow-up of 30 days.

The limitations from the previous two studies were addressed to some extent by a retrospective study published in 2019 [10]. The outcomes of 60 patients with superficial femoral artery (SFA) and popliteal artery disease were evaluated at the 12th month follow-up post-procedure. Following IVL, there was a 54% reduction in pretreatment stenosis with 3 mm mean lumen gain. Only one major adverse event was reported where a patient required a stent for a grade D dissection. The 12-month primary patency rate was 54.5% across all patients, and the target lesion revascularisation (TLR) rate was only 20.7%. This study showed a reasonably good safety profile with good efficacy of IVL in treating calcified PAD, and the longer 12-month follow-up has improved the validity of the results. However, one of the potential limitations of this study is the absence of a control group. This could make it challenging to draw a solid conclusion regarding the efficacy of IVL in this cohort of patients compared to other potential treatment options (such as PBA).

A prospective, non-randomised, multicentre study with a larger sample size (200 patients) with moderate-to-severe lower limb ischaemia was published by Adams et al. 2020 [19]. They evaluated the outcomes of IVL to treat iliac, CFA, SFA, popliteal, and infra-popliteal stenoses (with/without other adjunct treatments, such as further balloon angioplasty or atherectomy). The results demonstrated a stenosis reduction of 57.6%. A mean luminal gain of 3.4 mm. There were only two dissections and a single perforation reported in this study. The larger sample size has improved the accuracy of the results; however, the short follow-up duration (up until discharge) is one of the main limitations of this study. Furthermore, the lack of a comparator group makes it difficult to draw conclusions on the safety and efficacy of IVL compared to other treatment options.

Within the same context, similar results were reported from another prospective, non-randomised multicentre study which investigated the outcomes of 200 iliac artery lesions treated with IVL [20]. Following treatment, mean stenosis reduction was 71.9%, with minimal post-intervention complications reported and no flow-limiting dissections. No long-term follow-up was available, as the patients were only followed up until discharge.

An individual, patient-level data pooled analysis from five prospective studies to evaluate the outcomes of IVL for patients with severe calcified PAD was conducted by Madhavan et al. 2020 [3]. Data from 336 patients were analysed, showing 55.1% reduction in vessel stenosis after the procedure. Significant

complications such as flow-limiting dissection (type D-F), perforation, distal embolisation, thrombus, and abrupt closure were reported in only four patients (1.22%). Overall, the study concluded that treatment with IVL for severely calcified PAD was both safe and effective. The authors of the study, however, acknowledged a few limitations, such as the lack of a control group and that 12% of patients received adjuvant therapy such as atherectomy, which could have affected the final outcomes.

To investigate procedural success of combined IVL and atherectomy, a retrospective study was conducted to analyse the outcomes of 24 patients operated on at a single centre by the same operator [21]. Pre-treatment stenosis was 57.1% (SD: 18.9), which was reduced to 36.4% (SD: 17.5) following atherectomy alone and to 21.1% (15.7) following combined treatment. This demonstrates a 20.7% gain with atherectomy alone and a 36% gain when combined with IVL. Concerning complications, a type C dissection was reported in 2 patients. The TLR was reported in another two patients at 12 months and in seven patients at 18 months. A good safety profile was demonstrated, and IVL was shown to improve results compared to atherectomy alone. Nevertheless, there are a few limitations of this study, such as the small sample size and lack of an IVL-only treatment arm. As such, it is probably impossible to judge whether the improvement in the combined therapy group was solely due to the combined therapy or mainly attributed to the use of IVL.

In 2024, the Disrupt PAD II observational study published data from a prospective multicentre single-arm study which recruited 1,373 patients (1677 total lesions) across 30 sites globally [22]. A combination of iliac, CFA, femoropopliteal and infra-popliteal artery lesions were included. Around 31.3% of the lesions were chronic total occlusions, and 19.3% were long-length lesions (>15 cm). This study demonstrated a post-procedure stenosis of 23.8% (SD: 11.3) compared to a pre-procedural stenosis of 80.8% (SD: 17.9), resulting in a stenosis reduction of 57%. Reduction in stenoses was shown across all stenosis locations, and the average acute lumen gain was 3.3 mm (SD: 1.4 mm). The incidence of severe complications was only 0.9%, with 10 dissections of type D or greater and two perforations. Overall, findings from this study substantiate the good safety profile of IVL and demonstrate its efficacy in treating calcified PAD. However, there are currently no analyses of long-term outcomes, and no results from comparison with alternative treatment options have been reported.

To date, there has only been one RCT (Disrupt PAD III) evaluating the efficacy of IVL for calcified PAD [1]. Between 2017 and 2020, 306 patients with moderate-to-severe femoropopliteal calcification were recruited across 45 centres in Austria, Germany, New Zealand and the United States. Half of the patients (n=153) were treated with PBA, and the other half were treated with IVL. All patients across both arms were subsequently treated with drug-coated balloon or stent deployment, if required. The primary outcome measure was procedural success, defined as residual stenosis <30% without flow-limiting dissection. The IVL group had a significantly higher rate of procedural success compared to the PBA group (65.8% vs 50.5%; $p=0.01$). The mean residual stenosis diameter in the IVL arm was also lower at 27.3%, compared to 30.5% in the PBA group ($p=0.02$). The risk of flow-limiting dissection was higher in the PBA group compared with the IVL group (6.8% vs 1.4%; $p<0.001$). Secondary outcomes were measured at 30 days post-procedure. Changes in ankle-brachial pressure index (ABPI), Rutherford classification, European Quality of Life (EuroQol) -5D questionnaire results, EuroQol-5D visual analogue score, and walking impairment questionnaire results were analysed. Both groups reported improvement in ABPI, Rutherford class, and questionnaire results. However, the only statistically significant difference between the two arms was an improved change in visual analogue score in the IVL group. This randomised study demonstrated statistically improved procedural outcomes with IVL and improved visual analogue score at 30 days post-procedure.

Mid-term analysis results from this study were published in 2022 [29], showing that the IVL arm had significantly greater primary patency both at one year post-procedure (80.5% vs 68.0%; $p=0.17$) and two years post-procedure (70.3% vs 51.3%; $p=0.003$). Primary patency was defined as freedom from clinically driven reintervention and restenosis on duplex ultrasound. Follow-up from this study shows an improved efficacy and safety profile of IVL compared to PBA alone. However, as of yet, no longer-term analysis has been published from this trial.

The outcomes of IVL for patients with calcified popliteal and infra-popliteal PAD at 12 months follow-up were evaluated in a prospective multicentre cohort study that included 29 patients (32 treated lesions) [23]. The primary safety endpoint assessed the presence of major adverse events at 30 days post-procedure. The primary efficacy endpoint included vessel patency, limb salvage, and absence of amputation at 12 months of follow-up. Secondary endpoints included primary assisted patency and absence of TLR. Authors reported four major adverse events within the first 30 days, none of which were related to the device being studied. At 12 months, the primary vessel patency was 68.8%, primary assisted patency was 90.0%, lack of the need for TLR was reported in 93.3%, the limb salvage rate was 83.9%, and amputation-free survival was 57.1%. Nevertheless, similar to other studies, small sample size and lack of control groups are the main limitations.

A retrospective study included 38 patients (47 treated arteries) and assessed the outcomes of IVL for calcified lower limb PAD with three months follow-up, including both clinical and duplex vascular assessment [17]. Outcome measures included amputation-free survival and the presence of potential complications. At the third-month follow-up, 37% of cases showed reasonable clinical improvement; as such, no images were acquired. Another 58% of cases showed an improvement on a duplex scan. Eleven patients needed revascularisation after the index procedure. Amputation-free survival rate was

79%. In terms of complications, distal embolisation was reported in 10.53% of patients. No perforation or flow-limiting dissection was reported.

It has been well established that surgical endarterectomy is the treatment of choice for calcified CFA stenosis [30]. In 2024, the Disrupt PAD III observational study was published to assess the effectiveness of IVL for calcified CFA stenosis [24]. This was a prospective, multicentre study which assessed the outcomes of 163 patients (164 lesions) who were enrolled across 23 sites. Adjuvant treatment (in addition to IVL) was utilised in some cases as follows: calcium-modifying treatment, drug-coated balloon, and stenting in 32.3%, 68.9%, and 16.5% of cases, respectively. Pre-procedural diameter stenosis was 74.8 $\pm$ 17.7%, which was reduced to 29.2 $\pm$ 16.5% after the initial IVL and down to 23.6 $\pm$ 11.5% at the end of the procedure. The authors reported only one flow-limiting dissection immediately after IVL (0.8%), with no significant vascular complications at the end of the procedure. This study showed promising results when treating calcified CFA stenosis utilising an interventional technique without surgical intervention, with a good safety profile. Few limitations were evident in this study, such as the lack of a control group, lack of long-term follow-up, and the use of adjuvant therapy in addition to IVL. Yet, this study has described a technique which can be used to treat calcified CFA disease, and further studies with longer follow-up and a controlled arm would be desirable to provide solid evidence.

Most of the published studies are retrospective or prospective cohorts, with only one RCT to date. These data have demonstrated the safety profile of IVL, its ability to treat calcified PAD lesions across a range of locations, and its improved efficacy compared to PBA in the mid-term. However, there is a lack of long-term data reporting patient outcomes.

Conclusions

Peripheral arterial disease is a common health condition that has been challenging to treat using PBA and atherectomy alone. It has many health-related sequelae that have a significant impact on patients' quality of life and increase overall healthcare burden. The IVL is a relatively new treatment option that can be used for treating PAD.

Current literature shows that use of IVL for calcified PAD has a good safety profile and low complication rate. Most of the studies to date have not included a control arm to allow IVL to be compared to other treatment options. Only one RCT was available at the time of the search, which demonstrated that IVLs had a significantly lower complication rate and improved effectiveness in treating calcified PAD compared to PBA. Whilst short- and mid-term results are promising, there is currently no reported long-term data on patient outcomes.

In summary, this review highlights that IVL is a promising treatment option for calcified plaques. Available studies show a good safety profile with a low complication rate and proven increased mid-term primary patency compared to PBA. However, there is a lack of published long-term data, with only one RCT identified in the literature; hence, further long-term data and randomised trials are required, and this is a potential scope for further studies to evaluate.

Additional Information

Author Contributions

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

Concept and design: Ahmed Aljawadi, Saqib Ashraf

Acquisition, analysis, or interpretation of data: Ahmed Aljawadi

Drafting of the manuscript: Ahmed Aljawadi, Saqib Ashraf

Critical review of the manuscript for important intellectual content: Ahmed Aljawadi, Saqib Ashraf

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