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SYSTEMATIC REVIEWS

Use of intravascular lithotripsy in non-coronary artery lesions

Chukwuemeka Anthony Umeh, Ashley Stratton, Tifani Wagner, Shipra Saigal, Krystal Sood, Raghav Dhawan, Cory Wagner, Jessica Obi, Sabina Kumar, Tsung Han Scottie Ching, Rahul Gupta

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Abstract

BACKGROUND

Intravascular lithotripsy (IVL) is a novel technique increasingly used for plaque modification and endovascular revascularization in patients with severe calcification and peripheral artery disease. However, much of the available literature on IVL is focused on its use in coronary arteries, with relatively limited data on non-coronary artery use.

AIM

To analyze the safety and efficacy of current IVL use in non-coronary artery lesions, as reported in case reports and case series.

METHODS

We searched EMBASE, PubMed, and *Reference Citation Analysis* databases for case reports and case series on IVL use in peripheral artery disease. We then extracted variables of interest and calculated the mean and proportions of these variables.

RESULTS

We included 60 patients from 33 case reports/case series. Ninety-eight percent of the cases had IVL usage in only one blood vessel, while four had the IVL used in two vessels (2.0%), resulting in 64 Lesions treated with IVL. The mean age of the patients was 73.7 (SD 10.9). IVL was successfully used in severe iliofemoral artery stenosis (51.6%), severe innominate, subclavian, and carotid artery stenosis (26.7% combined), and severe mesenteric vessel stenosis (9.4%). Additionally, IVL was successfully used in severe renal (7.8%) and aortic artery (4.7%) stenosis. There were complications in 12% of the cases, with dissection being the commonest.

CONCLUSION
IVL has successfully used in plaque modification and endovascular revascularization in severely calcified and challenging lesions in the iliofemoral, carotid, subclavian, aorta, renal, and mesenteric vessels. The most severe but transient complications were with IVL use in the aortic arch and neck arteries.

Key Words: Intravascular lithotripsy; Peripheral artery disease; Non-coronary artery

Core Tip: Intravascular lithotripsy (IVL) has emerged as a novel endovascular therapy for treating severe vascular calcifications. In this review of case reports, we assessed the efficacy and safety of IVL in treating calcified lesions in non-coronary artery vessels and the various situations in which IVL was used in these vessels. We found that IVL has successfully facilitated treating severely calcified and challenging lesions in the iliofemoral, carotid, subclavian, aorta, renal, and mesenteric vessels.

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INTRODUCTION

The global prevalence of peripheral artery disease (PAD) is estimated to be over 230 million[1]. This prevalence was higher in high-income countries than in low- and middle-income countries (LMICs). As per data published in 2021, approximately 6.5 million people in the United States aged 40 and above suffer from PAD[2]. A vast majority of these conditions are due to atherosclerosis.

Intravascular lithotripsy (IVL) is a novel technique successfully used for plaque modification and endovascular revascularization in patients with severe calcification and PAD. Severe vascular calcifications are statistically correlated with poor clinical outcomes and increased mortality rates. In addition, they present technical challenges during the revascularization process and increase complications like stent thrombosis or stent fracture following endovascular revascularization[3-6]. Atherectomy, a treatment modality for debulking calcifications, has been reported as not being selective to the calcified plaque lesions and disrupting the vessel's intimal healthy soft tissue[7]. In addition, this procedure has been associated with higher complications. During the EASE trial, the dissection and perforation rate was estimated at around 6%[8], while the DEFINITIVE Ca++ trial reported a major adverse event rate of 6.9%[9].

IVL is based on a similar concept of shockwave lithotripsy deployed to treat nephrolithiasis. The selected single-use balloon catheter's diameter is 1.1 times that of the reference vessel diameter, embedded with lithotripsy emitters, capable of disrupting both superficial and embedded calcification with the advantage of controlled dilatation[10]. After the successful apposition of the balloon with the vessel wall, pulses are first generated at 50 atmospheres. Once calcification has been disrupted, the balloon is inflated to fully expand the vessel at 6 atmospheres, reducing stenosis rates and procedural complications[11,12]. Much of the available literature on IVL is focused on its use in coronary arteries, with relatively limited data on non-coronary artery use. This systematic review of case reports of IVL in non-coronary artery lesions aims to analyze the safety and efficacy of current IVL use in non-coronary artery lesions.

MATERIALS AND METHODS

Articles were obtained by searching PubMed, EMBASE, and *Reference Citation Analysis* databases with the keywords peripheral artery intravascular lithotripsy. We exclusively selected case reports or case series. Two authors independently reviewed the titles and abstracts to determine the studies that met our inclusion criteria. Our inclusion criteria include: (1) The study must be a case report or case series; and (2) the study must be regarding intravascular lithotripsy on non-coronary arteries. In addition, we excluded studies that were not written in English. The next phase was reviewing the full text of the studies that met the inclusion criteria and data extraction into a data spreadsheet. The extracted data included the country of publication, the age and gender of patients, the vessels in which IVL was used, and the complications reported. We assessed the quality of the studies using The Joanna Briggs Institute Critical Appraisal Checklist for Case Reports. The checklist evaluates the quality of case reports using an eight items list[13,14].

We did a qualitative and quantitative analysis. In the qualitative analysis, we summarized the use of IVL in different vessel groups in the body, such as the mesenteric, lower extremity, upper trunk, and neck, *etc*. In the quantitative analysis, we used means, standard deviations, and percentages to describe the statistics of the patients in the study, the vessels in which IVL was used, and the complications reported.

RESULTS

Identification of relevant studies

Our search identified 185 articles, of which 114 were unique after removing duplicate publications. Two researchers independently reviewed the abstracts to assess if they met our study's inclusion and exclusion criteria. Articles excluded include a description of IVL (25), coronary artery IVL (42), and review articles (n = 15). We included 60 patients from 33 case reports/case series (Figure 1; Table 1).

Quality of studies assessment

Our assessment showed that ninety-seven percent of the case reports (32 of 33) were high quality and well-written. They included pertinent information about the patient's demographics, clinical symptoms, procedures performed, and outcomes. One of the case reports (3%) did not include patients' demographic information and history, although it was a conference abstract. However, it had information about the procedure outcomes and complications. Twenty-one percent of the studies (7 of 33) did not comment on the presence or absence of adverse events or complications from the procedure (Supplementary Table 1).

Quantitative result

Most patients had the IVL used in only one vessel (98%), while four had the IVL used in two vessels (2%), resulting in 64 lesions treated with IVL. The mean age of the included population was 73.7 (SD 10.9), with 56% males. The majority of the published cases were from the United States (54%), followed by Italy (18.8%) and France (12.5%). The baseline demographic and procedural characteristics are shown in Table 2. IVL was successfully used in severe iliofemoral artery stenosis (51.6%), severe innominate, subclavian, and carotid artery stenosis (26.7% combined), and severe mesenteric vessel stenosis (9.4%) (Table 3). Additionally, IVL was successfully used in severe renal (7.8%) and aortic arteries (4.7%) stenosis. There were complications in 12% of the cases. The reported complications include dissections, perforation, a transient ischemic attack, an acute blindness post-carotid artery IVL successfully treated with tissue plasminogen activator (TPA), and transient hypotension, which improved with fluids and inotropes.

DISCUSSION

IVL use in the iliofemoral artery

IVL use in iliofemoral arteries was mainly for treating heavily calcified and symptomatic peripheral artery disease[15,16] and providing large-bore vascular access for cardiovascular procedures such as transcatheter aortic valve replacement in patients with heavily calcified lesions[17,18].

IVL was used to improve vessel compliance and predilection before stent placement[16]. Several authors reported the use of IVL for severely calcified vessels before stent placement[16,19] or before treatment with drug-coated balloon angioplasty[20]. IVL was also used in severely calcified vessels as a stand-alone treatment without stent placement. Nasiri reported IVL use in the distal right anterior tibial artery as a stand-alone therapy with resolution of the slow blood flow [16].

Furthermore, IVL was used in treating patients with heavily calcified iliofemoral artery in-stent restenosis. Honton *et al* [15] described the use of IVL in treating severe common iliac artery stent restenosis caused by underlying eccentric severely calcified stenosis. This led to the device under expansion and inadequate stent deployment. An intrastent IVL was successfully deployed to disrupt the calcified lesion resulting in stent expansion.

In summary, IVL was successfully used without complication in heavily calcified iliofemoral arteries before stent placement, as a stand-alone treatment without stent placement, and in in-stent restenosis.

IVL use in the aortic arch and necks arteries

The use of IVL was also reported in the aortic arch vessels, including the carotid, subclavian and innominate vessels. Though IVL is not yet approved for use in these vessels, Case *et al*[21] reported the use of IVL in two cases of heavily calcified carotid artery lesions in patients who were not candidates for carotid endarterectomy. Both patients had post-radiation necks and were determined by the vascular surgeons to be non-surgical candidates. IVL was successfully used before the placement of stents. Unfortunately, despite using distal embolic protection, one of the patients developed temporary right eye blindness, likely secondary to emboli to the central retinal artery. The patient was treated with non-selective delivery of tPA at the ostium of the right ophthalmic artery and intravenous heparin for 48 h with the resolution of the blindness[21].

IVL was also successfully used in two patients with severe calcified subclavian artery stenosis[21]. One of the cases was *de-novo* totally occluded left subclavian artery at the ostium. The patient was symptomatic, and the decision was made to open up the artery for symptomatic relief. IVL was used for the severely calcified lesion, and a stent was successfully placed with no significant residual stenosis. The second case was a left subclavian artery in-stent restenosis in which IVL was successfully used. In both cases, no complications were reported, and the patients did well at one year of follow-up.

In summary, although IVL is not approved for use in patients with heavily calcified aortic arch arteries, IVL was successfully used to treat de-novo calcified arteries and in-stent restenosis. However, it is essential to ensure that distal embolic protections are used with aortic arch arteries IVL to prevent emboli to the brain.

Table 1 Studies included in the review

Ref.	Country	Age	Sex	Iliac-femoral	Popliteal and infra-popliteal	Carotid, subclavian, innominate	Celiac, superior mesenteric	Renal	Radial	Aorta
Honton *et al*[15], 2020	France	75	M	1						
Nasiri *et al*[16], 2022		82	M	1						
Nasiri *et al*[16], 2022		70	M	1						
Nasiri *et al*[16], 2022		75	M	1						
Nasiri *et al*[16], 2022		59	F							1
Nasiri *et al*[16], 2022		74	F		1					
Tayal *et al*[17], 2021	United States	78	F	1						
Riley *et al*[18], 2019		78	F	1						
Rosseel *et al*[19], 2020	Denmark	69	F	1						
Golamari *et al*[20], 2019	United States	66	M	1	1					
Case *et al*[21], 2020	United States	56	M			1				
Case *et al*[21], 2020	United States	72	M			1				
Case *et al*[21], 2020	United States	73	M			1				
Case *et al*[21], 2020	United States	82	M			1				
Case *et al*[21], 2020	United States	54	M			1				
Cheng *et al*[23], 2021	United States	79	F				1			
Khan *et al*[24], 2020	United States	73	F				1			
Khan *et al*[24], 2020	United States	65	F				1			
Schnupp *et al*[28], 2020	Germany	76	M					1		
Lee *et al*[29], 2020	United States	85	F					1		
Chag *et al*[32], 2021	India	67	F							1
Bellini *et al*[33], 2019	Italy	65	M			1				
Donas *et al*[34], 2022		74	M	1						
Napoli *et al*[35], 2023		37							1	
Yousif *et al*[36], 2021	Bahrain	72	F					1		
Cereda *et al*[37], 2020	Italy	86	M	1						
Kumar *et al*[38], 2022		76	M	1						

Kumar *et al*[38], 2022		75	F	1				
Price *et al*[39], 2021	United States	97	M	1				
Price *et al*[39], 2021	United States	71	M	1				
Price *et al*[39], 2021	United States	82	M	1				
Price *et al*[39], 2021	United States	75	F	1				
Price *et al*[39], 2021	United States	83	F	1				
Price *et al*[39], 2021	United States	83	F	1				
Price *et al*[39], 2021	United States	59	M	1				
Price *et al*[39], 2021	United States	81	M	1				
Price *et al*[39], 2021	United States	83	F	1				
Ahsan *et al*[40], 2022	United States	74	F				1	
Amor *et al*[41], 2022	France				1			
Amor *et al*[41], 2022	France				1			
Amor *et al*[41], 2022	France				1			
Amor *et al*[41], 2022	France				1			
Amor *et al*[41], 2022	France				1			
Harada *et al*[42], 2022	United States	86	F				1	
Shah *et al*[43], 2022	India	80	F	1				1
Fazzini *et al*[44], 2022	Italy			1				
Fazzini *et al*[44], 2022	Italy			1				
Fazzini *et al*[44], 2022	Italy			1				
Fazzini *et al*[44], 2022	Italy			1				
Fazzini *et al*[44], 2022	Italy			1				
Balboa *et al*[45], 2021		67	M			1		
Kiron *et al*[46], 2021	India	75	M		1			
Varotto *et al*[47], 2022	Italy	83	M		1			
Henry *et al*[48], 2021	United States	73	M		1			
Henry *et al*[48], 2021	United States	81	M		1			
Misztal *et al*[49], 2020	Poland	82	M		1			

Spaccarotella *et al* [50], 2020	Italy	82	M	1					
Hamandi *et al*[51], 2020	United States	42	F	1					
Rehman *et al*[52], 2020	United States	80	M	1					
Sogomonian *et al* [53], 2021		75	F						1

Table 2 Descriptive statistics of study participants

	Number	Percentage
Age (yr)	73.7 (SD 10.9)	
Gender		
Male	28	56%
Female	21	44%
Country		
Bahrain	1	2.1%
Denmark	1	2.1%
France	6	12.5%
Germany	1	2.1%
India	3	6.3%
Italy	9	18.8%
Poland	1	2.1%
United States	26	54.2%

Table 3 Vessels where intravascular lithotripsy was used and complications reported

Artery	Percentage	Complication reported
Iliofemoral, popliteal, and tibial	51.6% (33/64)	Dissection (3/33), perforation (1/33)
Carotid, subclavian, and innominate arteries	25.0% (16/64)	Transient ischemic attack (1/16), acute blindness that resolved with TPA (1/16), transient hypotension, which improved with fluids and inotropes (1/16)
Mesenteric vessels, including celiac and superior mesenteric artery	9.4% (6/64)	None
Renal	7.8% (5/64)	None
Aorta	4.7% (3/64)	None
Radial	1.6% (1/64)	None

TPA: Tissue plasminogen activator.

IVL use in mesenteric arteries

IVL was successfully used to treat heavily calcified lesions in the splanchnic circulation. Endovascular revascularization has become an alternative to open surgical repair of stenotic splanchnic lesions, especially in elderly patients and patients with comorbidities[22]. Endovascular revascularization results in lower short-term mortality compared to surgical intervention but have decreased long-term primary patency compared to surgical repair[22]. One major limitation of endovascular revascularization is the presence of heavily calcified lesions, resulting in under-expanded stents[23]. Cheng *et al*[23] reported the use of IVL in a symptomatic elderly patient with a heavily calcified celiac artery that failed prior percutaneous endovascular intervention. IVL was safely used to modify the calcified lesion allowing a stent to be successfully deployed. Khan *et al*[24] also reported IVL use in treating severely calcified *de novo* superior mesenteric artery stenosis and celiac artery in-stent restenosis. In both cases, IVL was successfully used without complications. In

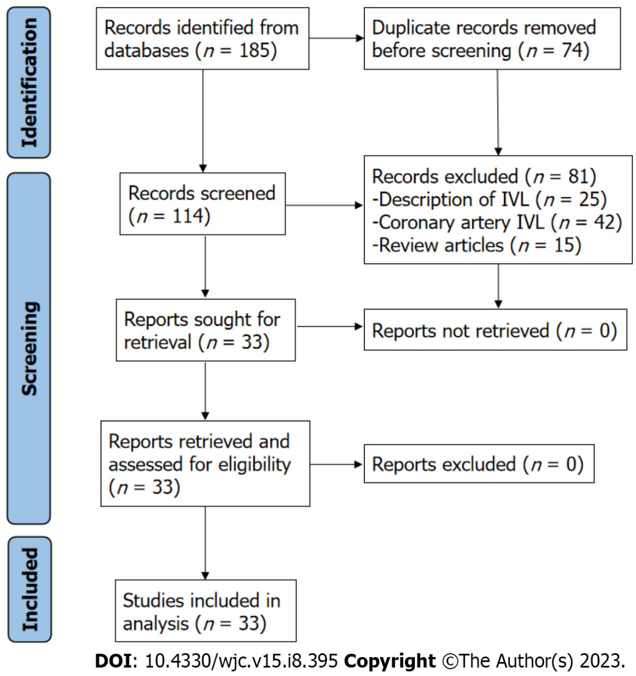

Figure 1 Preferred reporting items for systematic review and meta-analyses guidelines flowchart of the selection process. IVL: Intravascular lithotripsy.

summary, IVL has been used without complications in treating *de novo* stenosis and in-stent restenosis of heavily calcified mesenteric arteries.

IVL use in renal arteries and aorta

Angioplasty of renal arteries with or without stent placement has not been found to be superior to medical therapy in patients with atherosclerotic renal artery stenosis[25,26]. However, revascularization is a reasonable option in patients with hemodynamically significant atherosclerotic renal artery stenosis with flash pulmonary edema, recurrent unexplained congestive heart failure, progressive chronic kidney disease, and resistant hypertension[27]. Angioplasty of the renal artery could be challenging due to the large diameter, and heavily calcified plaques make it more challenging [28]. Lee *et al*[29] reported a heavily calcified bilateral renal artery stenosis successfully treated with IVL and stenting. The initial attempt at percutaneous transluminal renal angioplasty was unsuccessful due to severely calcified lesions. Schnupp *et al*[28] also reported safely using IVL in heavily calcified renal artery stenosis with successful stent placement. In summary, IVL has been successfully used in heavily calcified renal artery stenosis.

Efficacy of IVL procedures

We found 100% clinical and angiographic success in patients with heavily calcified non-coronary artery lesions treated with IVL. While we cannot rule out a publication bias because authors are more likely to publish successful IVL cases, previous systematic reviews of IVL in lower extremity peripheral artery disease have reported high success rates. A systematic review and meta-analysis involving nine studies with 681 patients showed a diameter stenosis reduction of 59.3% in lower extremity lesions post-IVL[30]. Similarly, another study of 336 patients who underwent endovascular revascularization of lower extremity peripheral artery lesions with IVL demonstrated a significant diameter stenosis reduction of 55.1% post-IVL[31].

Complications of IVL procedures

In our study, complications were reported in 12% of the cases. The reported complications include dissections (4.7%), perforation (1.6%), a transient ischemic attack (1.6%), an acute blindness post-carotid artery IVL (1.6%) that was successfully treated with TPA and transient hypotension (1.6%), which improved with fluids and inotropes. In the subgroup analysis, complications were more likely to occur in the IVL involving the aortic arch and necks arteries (18.7%), followed by IVL of lower extremity arteries (12.1%). However, none of the complications was associated with permanent disability or in-hospital mortality.

The reported complication rates in the lower extremities in our sub-group analysis are similar to those reported in previous systematic reviews of IVL use in lower extremity peripheral artery disease. For example, Madhavan *et al*[31] reported dissection with IVL in 14.5% of the procedures, but the flow-limiting dissection or type D/E/F dissection was in only 0.9% of the 328 cases. Similarly, Wong *et al*[12] reported flow-limiting dissection of the lower extremity vessels in 1.25% of the 681 patients in their meta-analysis.

Limitations of the study

One major limitation of the study is the small sample sizes provided by case reports. Additionally, authors might be more likely to publish cases with successful outcomes leading to publication bias. Therefore, there is a need for more extensive studies to evaluate the safety and efficacy of these procedures in different non-coronary artery vessels.

CONCLUSION

Heavily calcified lesions present a challenge in endovascular procedures, and IVL has been shown to safely and effectively address the calcified lesions and improve vessel compliance[16]. One advantage of IVL is that it does not typically lead to distal emboli like many atherectomy procedures, and distal protection is usually unnecessary[16,24]. An exception is the atherectomy of the carotid arteries, where distal protection is still necessary due to the severe consequences of an embolus[21]. Furthermore, compared to atherectomy of a calcified lesion, IVL is a relatively quicker procedure, easy to learn, has a lower risk of vascular injuries such as vessel rupture or dissection, and more uniform plaque disruption[16,24]. In summary, we found that IVL was safely and successfully used in plaque modification and endovascular revascularization in severely calcified and challenging lesions in the iliofemoral, carotid, subclavian, aorta, renal, and mesenteric vessels. The most severe but transient complications were with IVL use in the aortic arch and neck arteries.

ARTICLE HIGHLIGHTS

Research background

Peripheral arterial disease (PAD) is a common manifestation of atherosclerotic disease globally, and heavy calcifications in peripheral artery diseases reduce the success of endovascular therapy for PAD. Intravascular lithotripsy (IVL) has emerged as a technique for plaque modification of severely calcified artery lesions.

Research motivation

Most of the focus of IVL has been on treating coronary artery diseases, and its use in peripheral arteries has not been extensively studied.

Research objectives

To analyze the use of IVL in the peripheral arteries, its safety, and efficacy, as reported in case reports.

Research methods

We searched and extracted cases from PubMed, EMBASE, and *Reference Citation Analysis* databases. Then, we did a quantitative and qualitative analysis of case reports on IVL use in peripheral artery diseases.

Research results

IVL was successfully and safely used in heavily calcified lesions in the iliofemoral artery, aortic arch and necks arteries, mesenteric arteries, renal arteries, and aorta, with the iliofemoral artery being the commonest site reported. Adverse effects were minimal, but the most severe was reported in IVL use in the neck arteries.

Research conclusions

IVL has been safely used in a broadening array of complex, severely calcified peripheral artery disease lesions.

Research perspectives

More extensive studies are needed to assess the safety of IVL in peripheral artery vessels, such as the aortic arch and necks arteries, where it is not currently approved for use.

FOOTNOTES

Author contributions: All authors conceptualized and revised the study design; Stratton A, Wagner T, Saigal S, Sood K, Dhawan R, and Wagner C extracted the data; Umeh CA analyzed the data; Umeh CA and Gupta R wrote the first draft of the paper; Ching THS, Kumar S, Obi J, Gupta R, and Umeh CA reviewed and revised the paper; Stratton A led and coordinated the research and writing of the manuscript; Scottie C, Gupta R, and Umeh CA supervised the project; and all authors have read and approved the final manuscript.

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