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Intravascular Lithotripsy for Treatment of Calcified, Stenotic Iliac Arteries: A Cohort Analysis From the Disrupt PAD III Study

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ABSTRACT

Purpose: The presence of calcification in the iliac arteries is associated with decreased procedural success and increased complication risk during endovascular intervention. The objective of this study was to evaluate the safety and efficacy of peripheral intravascular lithotripsy (IVL) during endovascular treatment of iliac arterial peripheral artery disease (PAD).

Methods: The Disrupt PAD III Observational Study is a prospective, non-randomized, multi-center single-arm study to assess the 'real-world' safety and effectiveness of the Shockwave Peripheral IVL System for the treatment of de novo calcified lesions in the peripheral arteries, with a goal of treating 1500 patients. This is an analysis of consecutive patients enrolled for treatment of an iliac artery, a specified sub-group, with at least moderate calcification and a minimum length of 20 mm.

Results: Between December 2017 and July 2019, 118 patients with a total of 200 lesions were enrolled across 20 sites. 101 patients were treated primarily for claudication or critical limb ischemia, while 17 patients were treated to optimize the iliac vasculature for large-bore access. All 118 patients had successful IVL catheter delivery. The average reference vessel diameter was 7.3 mm ± 1.9 mm, with an average diameter stenosis of 83.1% ± 13.4% and an average lesion length of 58.3 mm ± 57.6 mm. Severe calcification was present in 82.0% of overall cases. Stent placement was performed in 72.9% of the overall cases. As expected, the access group received less adjunctive therapies including stents (41.2%, $p < 0.001$). Angiographic complications were minimal with no flow-limiting dissections and a final mean residual stenosis of 12.0% ± 12.1% with no differences between the groups.

Conclusions: Acute results with IVL in calcified iliac lesions suggest that it is a safe and effective option for calcified, stenotic iliac disease. IVL can be used successfully both for treatment of PAD symptoms and to optimize access for large-bore procedures.

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1. Introduction

Endovascular treatment of peripheral artery disease (PAD) due to iliac occlusive disease accounts for a quarter of all endovascular procedures [1–3]. Calcification is very common in the iliac arteries, and is associated with decreased procedural success with standard endovascular techniques. Complications during iliac artery endovascular intervention can be especially problematic due to the potential catastrophic complications of bleeding if an iliac artery is ruptured or precipitating acute limb ischemia with significant dissection.

As a result, the standard of care for endovascular treatment of calcified iliac artery disease is often direct or primary stenting, with bare metal or

Abbreviation list: PAD, peripheral artery disease; PTA, percutaneous transluminal angioplasty; CLI, critical limb ischemia; TAVR, trans-aortic valve replacement; EVAR, endovascular repair of abdominal aorta; TEVAR, endovascular repair of thoracic aorta; IVL, intravascular lithotripsy; EC, Ethics Committee; IRB, investigational review board; RVD, reference vessel diameter; TF, trans-femoral.

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covered stents [4–7]. Other endovascular treatments exist but are limited and include percutaneous transluminal angioplasty (PTA), specialty balloons, atherectomy, and surgical bypass. PTA is limited by the force necessary to modify calcium without increasing risk of perforation or dissection. Specialty balloons, such as scoring or cutting, have no data supporting use in iliac arteries, and atherectomy is limited due to safety concerns arising from the mechanism of action [8,9]. Surgical bypass remains an alternative to endovascular treatment but is used less frequently.

Consistent with this, a meta-analysis reviewed safety and effectiveness of endovascular interventions used to treat claudication or critical limb ischemia (CLI) in extensive iliac disease and found high technical success in most studies and a clear benefit compared to surgery with reduction in morbidity and mortality. The majority of complications during endovascular intervention were largely found to be related to iliac artery injury, distal embolization and access site complications [8]. For these reasons, a new treatment modality that can effectively and safely dilate calcified iliac arteries would have significant clinical benefit.

In addition to treating patients with PAD and lifestyle limiting claudication or CLI, there are an increasing number of procedures that require ilio-femoral access for large bore sheath delivery including transaortic valve replacement (TAVR), endovascular repair of abdominal (EVAR), thoracic aortic (TEVAR) disease, or percutaneous mechanical circulatory support (Impella). A subset of those patients have calcified stenotic iliac disease that may alter or prohibit standard transfemoral access approaches. Alternative access procedures and/or additional interventions are options but tend to be associated with an increase in morbidity and mortality [10–13].

More recently, Intravascular Lithotripsy (IVL) has emerged as a potential treatment option for calcified, stenotic iliac artery disease. This technology uses sonic pressure waves, with principles similar to urologic lithotripsy, that pass harmlessly through soft tissues and fracture calcium. IVL has been previously studied as stand-alone treatment in the Disrupt PAD I/II and BTK studies [14–16] demonstrating safety and effectiveness along with registry data and case reports on its use in the iliac artery [17–25]. The objective of the Disrupt PAD III Observational Study was to evaluate the performance of peripheral IVL in the 'real-world' setting with multi-level calcified PAD where it may be used in combination with adjunctive devices. The objective of this analysis is to evaluate the safety and effectiveness when IVL is used in the iliac artery.

2. Methods

2.1. Study device

The Peripheral IVL system is indicated for lithotripsy-enhanced, low-pressure balloon dilatation of calcified, stenotic peripheral arteries, including the iliac artery. The system consists of a generator, a connector cable, and an IVL catheter that houses an array of lithotripsy emitters enclosed in an integrated balloon. Peripheral IVL catheters are 60 mm in length and are available in multiple diameter sizes ranging from 3.5–7.0 mm in 0.5 mm increments. Once a calcified arterial lesion is crossed with a 0.014 in. guidewire, the IVL catheter is advanced across the lesion and is positioned using radio-opaque marker bands. The generator produces 3 kV of energy that travels through the connector cable and catheter to the lithotripsy emitters at one pulse per second. With the integrated balloon expanded to 4 atm (to achieve balloon-vessel wall apposition) by a mixed saline and contrast solution, a small electrical discharge at the emitters vaporizes the fluid and creates a rapidly expanding bubble within the balloon. This bubble generates a series of sonic pressure waves that travel through the fluid-filled balloon and pass through soft vascular tissue, selectively cracking hardened intimal and/or medial calcified plaque. The emitters positioned along the length of the device create a localized field effect within the vessel. Low pressure (4 atm) balloon inflation decreases risk of barotrauma with lithotripsy. When the balloon is inflated to 4 atm, lithotripsy is administered in 30-pulse increments. Following calcium disruption, the balloon is then inflated to nominal pressure (6 atm) to maximize luminal gain. This cycle is then repeated as often as needed until the desired diameter is obtained. The IVL catheter can then be moved to other lesion locations to deliver lithotripsy up to the defined maximum number of pulses per catheter. During the course of the study, software updates were made to increase the maximum number of pulses per catheter from 180 to 300 total pulses.

2.2. Study design and patient enrollment

The Disrupt PAD III Observational Study is a prospective, non-randomized, multi-center single-arm study conducted to assess the 'real-world' acute safety and effectiveness of the Shockwave Peripheral IVL System for the treatment of de novo calcified, stenotic peripheral arteries, with a goal of treating 1500 patients. This publication consists of a cohort analysis of consecutive patients enrolled with treatment of the iliac artery.

Patients were eligible for enrolment if they had at least moderate calcification as assessed by angiography defined as fluoroscopic evidence of (1) calcification on parallel sides of the vessel, and (2) extending >50% the lesion length if lesion length was ≥50 mm or extending for a minimum of 20 mm if the lesion length was <50 mm.

The Ethics Committee (EC) or Institutional Review Board (IRB) for each site approved the study protocol and informed consent form, which was signed by all patients prior to study enrolment. The study was conducted in accordance with the Declaration of Helsinki, ISO 14155:2011 Guidelines, and Good Clinical Practices. The study was registered on the National Institutes of Health website (ClinicalTrials.gov; identifier NCT02923193).

2.3. Study procedures

A patient was considered enrolled once IVL catheter insertion was attempted. All investigators were trained on the Instructions for Use for the Peripheral IVL System. Adjunctive technologies, including drug-eluting therapy, atherectomy and stenting were allowable per physician discretion to optimize treatment and outcomes. Vascular access, anticoagulation, introduction of guidewires and catheter use were conducted using each institution's standard of care for endovascular procedures. Final angiography (including run-off views) was performed to assess the final procedural result. Follow-up for the observational study consisted of intraprocedural and in-hospital data, but not long-term outcomes, as the registry was designed to assess procedural safety and acute procedural success.

2.4. Statistical analysis

Continuous variables are expressed as mean and standard deviation. Categorical variables are described as percentage and count. All statistical analyses were performed using the software R version 3.5.2. The function t.test, wilcox.test, and shapiro.test from the package stats were used for the unequal variances *t*-test (Welch's test), the Mann–Whitney *U* test and the normality Shapiro–Wilk test, respectively. A p-value <0.05 was considered as significant. All tests were two-sided.

3. Results

Between December 2017 and July 2019, 118 patients with a total of 200 lesions were consecutively enrolled across 20 sites (19 US and 1 German site). Study results are presented for the entire cohort, as well as those treated for claudication/CLI vs. those treated primarily for access during large bore procedures. Baseline characteristics represent a complex patient population, consistent with risk factors for calcification, including increased age, diabetes, renal insufficiency and current or former use of tobacco (smoking). There were no baseline differences between groups. Baseline patient characteristics are summarized in Table 1.

Table 1
Baseline characteristics.

	Overall (N = 118)	Claudication/CLI (n = 101)	Access (n = 17)	p-Value
Age, years	70.4 ± 8.3	70.0 ± 8.3	72.5 ± 8.3	0.262
Male gender	78 (66.1)	69 (68.3)	9 (52.9)	0.270
Diabetes	44 (37.3)	40 (39.6)	4 (23.5)	0.281
Hypertension	109 (92.4)	95 (94.1)	14 (82.4)	0.090
Hyperlipidemia	104 (88.1)	88 (87.1)	16 (94.1)	0.689
Current or former smoker	106 (89.8)	89 (88.1)	17 (100.0)	0.211
Coronary artery disease	66 (55.9)	55 (54.5)	11 (64.7)	0.599
Renal insufficiency	29 (24.6)	25 (24.8)	4 (23.5)	1.0
On dialysis	6 (5.1)	6 (5.9)	0 (0.0)	0.591
ABI	0.7 ± 0.3	0.7 ± 0.4	0.7 ± 0.3	0.364
Rutherford classification				0.281
RC 0	0 (0.0)	0 (0.0)	0 (0.0)	
RC 1	0 (0.0)	0 (0.0)	0 (0.0)	
RC 2	15 (12.8)	12 (12.0)	3 (17.6)	
RC 3	67 (57.3)	60 (60.0)	7 (41.2)	
RC 4	19 (16.2)	14 (14.0)	5 (29.4)	
RC 5	12 (10.3)	11 (11.0)	1 (5.9)	
RC 6	4 (3.4)	3 (3.0)	1 (5.9)	

Values are mean ± SD or n (%).

Table 3
Adjunctive therapy.

	Overall (N = 118)	Claudication/CLI (n = 101)	Access (n = 17)	p-Value
PTA	76 (64.4)	68 (67.3)	8 (47.1)	0.169
DCB	20 (16.9)	20 (19.8)	0 (0.0)	0.073
Specialty balloon	10 (8.5)	9 (8.9)	1 (5.9)	1.0
Stent	86 (72.9)	79 (78.2)	7 (41.2)	*0.003*
DES	11 (9.3)	11 (10.9)	0 (0.0)	0.362
BMS	49 (41.5)	43 (42.6)	6 (35.3)	0.608
Covered	39 (33.1)	36 (35.6)	3 (17.6)	0.173
Atherectomy	5 (4.2)	5 (5.0)	0 (0.0)	1.0
Embolic filter	2 (1.7)	2 (2.0)	0 (0.0)	1.0
With atherectomy	1 (0.8)	1 (1.0)	0 (0.0)	1.0
Without atherectomy	1 (0.8)	1 (1.0)	0 (0.0)	1.0

Values are n (%).

3.1. Procedural details and acute outcomes

All 118 patients had successful IVL catheter delivery and received lithotripsy treatment with a mean number of pulses of 214.4 ± 136.5. The average reference vessel diameter (RVD) was 7.3 mm ± 1.9 mm, with an average diameter stenosis of 83.1% ± 13.4% and an average lesion length of 58.3 mm ± 57.6 mm. Site-reported severe calcification was present in 82.0% of cases overall. The majority of patients (N = 101) patients were treated primarily for claudication or critical limb ischemia, while 17 patients were treated to optimize the iliac vasculature for large-bore access (N = 4 for TAVR, N = 13 for EVAR). The access group had a significantly larger RVD than the claudicant/CLI group (8.4 mm ± 2.5 mm versus 7.1 mm ± 1.7 mm, p < 0.001). The access group tended to have shorter lesions (42.5 mm ± 22.0 mm) compared to the claudicant/CLI group (60.9 mm ± 61.1 mm) and a higher rate of severe calcification (89.3% v 80.8%). In the claudicant/CLI group, 31.4% of the patients had multi-level treatment and 21.6% underwent bilateral iliac treatment.

The majority of patients were treated with IVL catheters ranging in diameter between 6.0 and 7.0 mm. In the access the group, no catheters smaller than 6.0 mm were utilized, whereas in the claudicant/CLI group, a low number of smaller catheters were used. Baseline lesion and procedural characteristics are summarized in Table 2.

Adjunctive therapies were used frequently in both groups. Stent placement was performed in 72.9% of the overall cases. As expected, the access group received less adjunctive therapies including stents (41.2%). A summary of adjunctive therapy utilization is shown in Table 3. The final mean residual stenosis was 12.0% ± 12.1% with no differences between the groups.

Angiographic complications were minimal with no flow-limiting dissections in either group. Final results and angiographic complications are summarized in Table 4. Adverse events were reported in 8 patients, all of which were reported as not related to the study device. There were three reported anemia events requiring blood transfusion and one access site bleeding following an attempt to remove a closure device requiring a thrombin patch and VIABAHN stent placement. There were no reported perforations of the iliac or common femoral arteries. One

Table 2
Lesion and procedural characteristics.

	Overall (N = 200)	Claudication/CLI (n = 172)	Access (n = 28)	p-Value
RVD, mm	7.3 ± 1.9	7.1 ± 1.7	8.4 ± 2.5	*<0.001*
Diameter stenosis, %	83.1 ± 13.4	83.6 ± 12.3	79.7 ± 18.7	0.449
Lesion length, mm	58.3 ± 57.6	60.9 ± 61.1	42.5 ± 22.0	0.080
Calcification				0.505
Mild	1 (0.5)	1 (0.6)	0 (0.0)	
Moderate	35 (17.5)	32 (18.6)	3 (10.7)	
Severe	164 (82.0)	139 (80.8)	25 (89.3)	
IVL catheter size, mm[a]				
7.0	128 (61.8)	102 (58.0)	26 (83.9)	
6.5	27 (13.0)	26 (14.8)	1 (3.2)	
6.0	38 (18.4)	34 (19.3)	4 (12.9)	
5.5	3 (1.4)	3 (1.7)	0 (0.0)	
5.0	5 (2.4)	5 (2.8)	0 (0.0)	
<5.0	6 (2.8)	6 (3.4)	0 (0.0)	

	Overall (N = 118)	Claudication/CLI (n = 101)	Access (n = 17)	p-Value
Multi-level treatment	31 (26.3)	32 (31.4)	0 (0.0)	*0.006*
Bilateral treatment	30 (25.4)	22 (21.6)	7 (41.2)	0.133
IVL pulses, n	214.4 ± 136.5	210.7 ± 135.6	234.3 ± 144.2	0.407

Values are mean ± SD or n (%).
Lesion characteristics are 'by lesion analysis' and Procedural Details are 'by patient analysis'.
[a] Multiple catheters were used per patient (Overall = 207, Claudicant/CLI = 176 and Access = 31).

Table 4
Final results after intravascular lithotripsy.

Final angiographic results	Overall (N = 200)	Claudicant/CLI (*n* = 169)	Access (n = 28)	p-Value
Diameter stenosis, %	12.0 ± 12.1	11.7 ± 11.9	13.4 ± 13.3	0.573
Dissections, type D–F	0 (0.0)	0 (0.0)	0 (0.0)	N/A
Perforation	0 (0.0)	0 (0.0)	0 (0.0)	N/A
Slow flow/no reflow	0 (0.0)	0 (0.0)	0 (0.0)	N/A

Values are mean ± SD or n (%).
Final results are 'by lesion analysis' and complications are 'by patient analysis'.

perforation was noted due to wire advancement attempt through a left SFA occlusion and was not related to the IVL treatment performed previously on the right common iliac artery. Other complications included heart block in two patients during the placement of the aortic valve during the TAVR procedure and one patient with both occlusive and aneurysmal disease of the abdominal aorta who developed distal embolization during placement of the EVAR graft (which was successful managed with a thrombectomy), all of which was unrelated to iliac treatment or gaining or removing access. There were no deaths reported or surgical interventions required. Complications are summarized in Table 5.

4. Discussion

This is the largest report of IVL used in the treatment of severely calcified iliac arteries. The major findings are: (1) IVL is safe and effective to treat symptomatic occlusive disease and to enable large bore sheath advancement through calcified iliac arteries, (2) acute results including low residual stenosis with minimal complications, are similar to those previously reported in clinical studies despite a 'real-world' population and a high rate of severe calcification, (3) IVL provides safe vessel preparation for severely calcified iliac lesions prior to stent placement, and (4) IVL enables large bore transfemoral access over alternative access sites, thereby simplifying the approach to complex procedures.

It is well established that stent implantation (bare-metal or covered) is the most common treatment strategy for endovascular treatment of iliac artery disease. The use of IVL as the primary adjunctive therapy prior to stent placement in severely calcified iliac arteries is growing. The successful application of IVL in iliac arteries for modification of calcium prior to stent placement was first published in a small, single-center study in which IVL was used to facilitate stent placement in seven patients. Those early core lab adjudicated results demonstrated safety and feasibility with full stent expansion in all cases [23]. In this study, 72.9% of patients had stents placed. However, the majority of the stents placed were not balloon-expandable covered stents as would be anticipated in this type of lesion. This is presumably because of the unique mechanism of action of IVL, using sonic pressure waves to modify calcium and not static pressure from a balloon, whereby the risk of trauma to soft tissue and risk of dissection or perforation is low. This is consistent with previously reported IVL studies with a low rate of flow-limiting dissections and no perforations and was replicated in this study, with no flow-limiting dissections or perforations despite 82.0% of lesions being severely calcified. Likewise, atherectomy has not been widely adopted for use in the iliac arteries, due to concerns around safety and risk of perforation and dissection. In this group it was utilized only in a small number of patients. The outcomes reported in the sub-group analysis of the CONFIRM registries excluded multi-level treatment and included a lower rate of severe calcification with shorter lesion length compared to this study and demonstrated a 1.5% rate of perforation and vessel closure [9]. See Fig. 1 for a representative case example.

The use of IVL to facilitate trans-femoral (TF) access for large bore procedures was initially reported in case reports [18–20], and more recently a multi-center registry [17] was published demonstrating the safety and effectiveness prior to TAVR procedures. Avoiding alternative access during large sheath procedures has a benefit to both patient outcomes and cost-effectiveness. While there are no large head-to-head studies evaluating TF access versus alternatives, available literature demonstrate an increase in complications, including stroke, with alternative access strategies [12,26]. Surgical techniques, such as pave and crack or creation of conduits are also an option but are associated with increased cost and increased complications [13,27,28]. Using IVL to facilitate TF access is becoming a necessary part of the treatment algorithm for large bore procedures with a goal to maintain the safety profile of traditional TF access, although more research needs to be done to improve the understanding on patient selection for IVL in these patients.

Another benefit of using IVL to enable access is the possibility that stenting is rarely performed. With low risk of dissections and perforations and the ability to both increase luminal size and improve vessel compliance, large sheaths can pass safely. The Pre-TAVR Registry [17] showed only one stent placement and that was at the access site to assist with closure due to prolonged bleeding; however, in this study there was a higher rate of stent utilization despite no dissections or perforations. It will be interesting to see over time as physicians become more comfortable with IVL if the rate of stent use in access cases decreases even further. The present study was limited to inclusion for iliac access for EVAR and TAVR procedures, but the benefits could be applied to other large bore procedures including TEVAR and Impella procedures. Case reports have been published using IVL in these procedures, and further research is underway [22,24,25]. See Fig. 2 for a representative case example.

Table 5
Complications.

Timing	Event (N = 118)				
	Bleeding	Anemia	Perforation	Embolization	Heart block
IVL intervention Included: access, closure and IVL procedure to target vessel(s)	1 (0.8)	3 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)
TAVR/EVAR procedure Included complication related to definitive procedure (ie TAVR and EVAR placement)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	2 (1.6)
Other Included complication reported during same treatment, but not involving access, closure or target treatment area for IVL	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)

Values are n (%).
Complications are 'by patient analysis'.

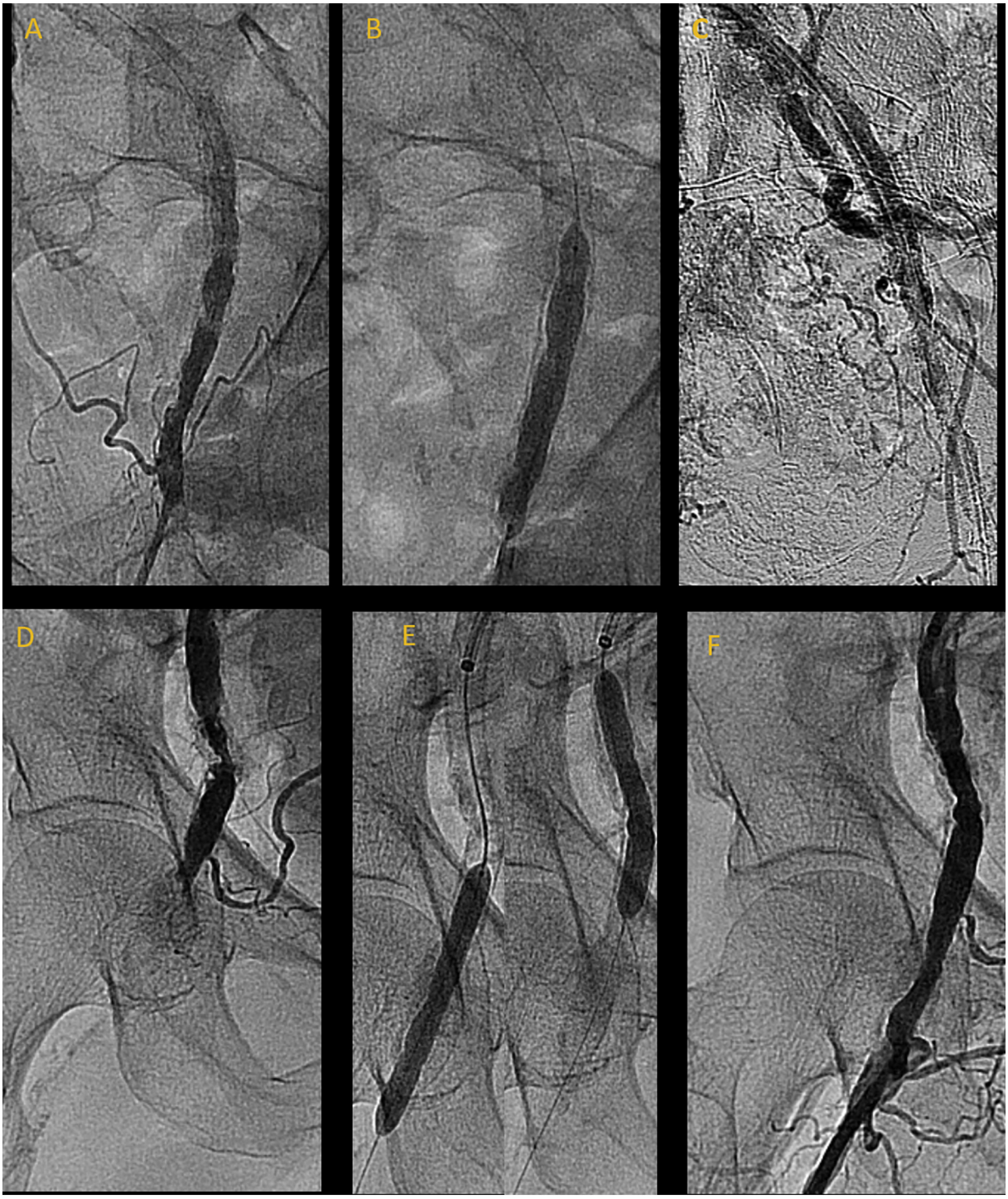

Fig. 1. Case example: 75 year old male, hemodialysis dependent and Rutherford Classification 4, with bilateral, multi-level disease with severe calcification where IVL was used as definitive treatment. A. Baseline left iliac artery: 7.0 mm and 99% diameter stenosis. B. IVL treatment left iliac artery: 6.5 × 60 mm IVL catheter, 60 pulses utilized. C. Final result left iliac artery: 10% residual stenosis bilaterally with 0 dissections, perforations or stent placement. D. Baseline right iliac and CFA arteries: Iliac - 7.0 mm and 80% diameter stenosis and CFA – 6.0 mm RVD with 100% stenosis. E. IVL treatment the right iliac and CFA arteries: 6.5 × 60 mm IVL catheter, 60 pulses utilized in each location. F. Final result right iliac and CFA arteries: 10% residual stenosis bilaterally with 0 dissections, perforations or stent placement.

4.1. Limitations

While this is a large, multi-center study, several limitations should be acknowledged. The Disrupt PAD III observational study is a single-arm study without a control arm. Additionally, this analysis includes site reported data only. There are no direct comparisons available in the literature, as the inclusion of similar severely calcified lesions has been excluded from other prospective studies.

5. Conclusions

Acute results with the Peripheral Intravascular Lithotripsy System in calcified iliac lesions confirm a consistent reduction in stenosis with few complications, similar to findings in other peripheral arteries. IVL-assisted large bore access facilitates endovascular procedures that result in reduced morbidity and mortality. The outcomes suggest that IVL is a safe and effective option for calcified, stenotic iliac disease.

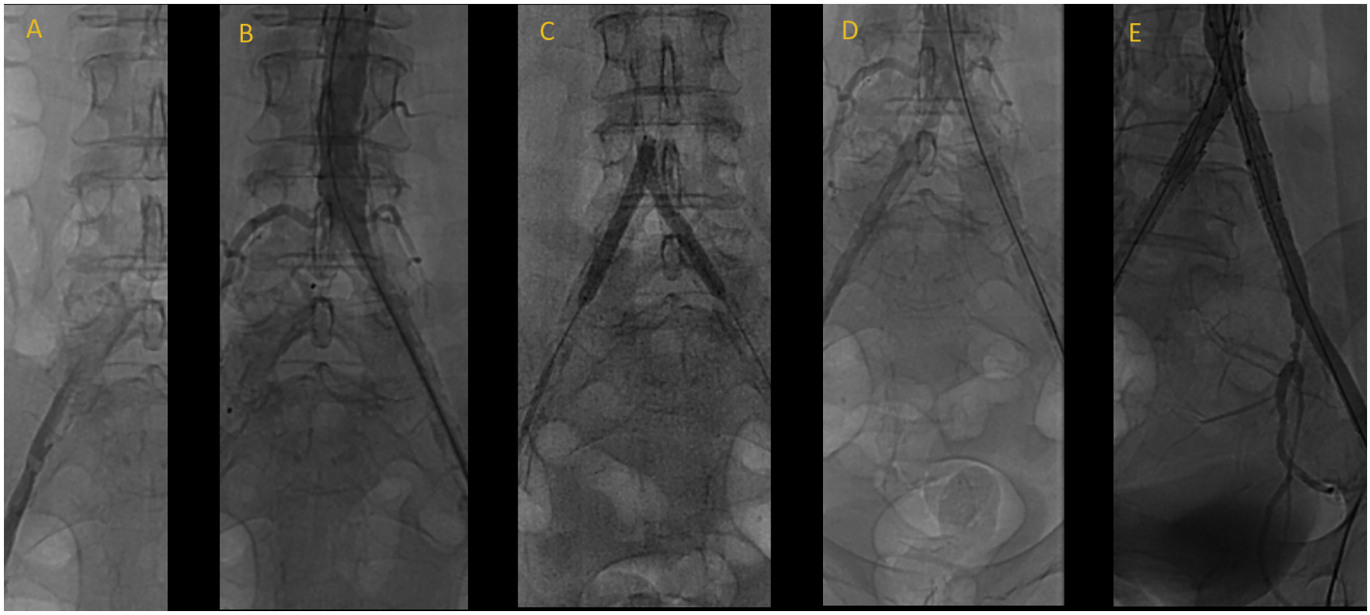

Fig. 2. Case Example: 54 year old female, Rutherford Classification 4, with abdominal aortic aneurysm undergoing EVAR procedure with bilateral, severe calcification of iliac arteries. A. Baseline right iliac artery: 8.0 mm RVD and 100% diameter stenosis. B. Baseline left iliac artery: 8.0 mm RVD and 40% diameter stenosis. C. IVL treatment: Two 7.0 × 60 mm IVL catheters utilized for a total of 270 pulses. D. Post IVL treatment: 0% Residual stenosis and 0 dissections or perforations. E. Final result following EVAR procedure which was placed without complication: Bilateral bare-metal stents placed in iliac arteries.

Previous presentation of this data

This data has not previously been presented.

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Declaration of competing interest

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