From the Society for Vascular Surgery

Mid-term outcomes of Shockwave intravascular lithotripsy in the IVLIAC Registry for the treatment of calcified iliac occlusive disease

Stefano Fazzini, MD, PhD,[a] Valerio Turriziani, MD,[a] Chiara Lomazzi, MD,[b] Edoardo Forcella, MD,[c] Ludovica Grazioli, MD,[d] Sara Allievi, MD,[d] Davide Mastrorilli, MD,[c] Alberto Maria Settembrini, MD, FEBVS, FACS,[e] Eugenio Martelli, MD,[a] Santi Trimarchi, MD, PhD,[b] Luca Garriboli, MD,[c] *and* Stefano Bonvini, MD, PhD,[d] *Rome, Milan, Negrar, Trento, and Rovereto, Italy*

ABSTRACT

Objective: The aim of this study was to evaluate safety and efficacy of intravascular lithotripsy (IVL) treatment in calcified iliac arteries and explore a new approach to determining whether to stent or not to stent calcific iliac vessels.

Methods: All consecutive patients who underwent IVL (Shockwave Medical) for calcified iliac arteries from February 2021 to May 2024 at four centers were included. Indication for IVL was Rutherford category ≥3 in iliac lesions with moderate-to-severe calcification and was based on a new algorithm: IVL as stand-alone therapy ± provisional stenting in case of stenosis, or IVL as vessel preparation for planned stenting in cases of chronic total occlusion. The primary endpoint was primary patency; assisted primary patency, secondary patency, and freedom from iliac complications were also analyzed. Clinical and procedural data were compared between two groups: IVL stand-alone therapy (IVL ONLY) vs IVL with adjunctive stenting (IVL + STENT). Indication for IVL ONLY was based on adjunctive completion assessments (extravascular ultrasound and translesional gradient pressure). A Cox regression univariate analysis between cases with or without target lesion revascularization was performed.

Results: In total, 100 iliac arteries were treated in 86 patients (52 male; mean age, 74 ± 9 years). Median follow-up was 20 months (range, 1-45 months). Critical limb ischemia was present in 55% of the patients, the majority of whom (75%) had severe calcifications (180°-360°). The mean target lesion length was 40.95 ± 29.25 mm with a mean stenosis of 84% ± 10% (12 chronic total occlusions). Technical success was 99%. The target lesions were treated with IVL ONLY in 77% of cases, whereas IVL + STENT was employed in the remaining 23% of the cases (provisional stenting, 11%; planned stenting, 12%). Mean residual stenosis was 14.95% ± 14% at final angiogram. Extravascular ultrasound with improved imaging (bi-triphasic in place of monophasic/blunted ipsilateral common femoral artery waveform), and/or decreased translesional gradient pressure (mean, −71%) were detected in all IVL ONLY cases. Primary patency and assisted primary patency at 24 months were 95% (95% confidence interval, 85.1%-98.1%) and 98% (95% confidence interval, 92%-99.5%), respectively, whereas secondary patency was 100%. Primary patency showed no statistically significant difference ($P = 24$) between the IVL ONLY and IVL + STENT groups. There was one iliac rupture and no distal embolization. Longer target lesions ($P = 24$) were significantly related to target lesion revascularization.

Conclusions: IVL is a safe and effective treatment option for calcific iliac occlusive disease. This multicenter experience shows promising mid-term results in terms of primary patency despite the very low stenting rate, preserving future treatment options. Further studies are needed to confirm these findings. (J Vasc Surg 2025;■:1-9.)

Keywords: Arterial occlusive disease; Iliac artery; Lithotripsy; Stent; Ultrasound imaging

Peripheral artery disease (PAD) is a global health concern that significantly affects the quality of life for millions of people worldwide and imposes a high economic burden. One-third of all PAD cases in the United States are due to aortoiliac occlusive disease (AIOD).[1,2]

From the Unit of Vascular and Endovascular Surgery, Department of Biomedicine and Prevention, Tor Vergata University, Rome[a]; the Section of Vascular Surgery, Cardio Thoracic Vascular Department, Fondazione IRCCS Cà Granda Ospedale Maggiore Policlinico, Milan[b]; the Department of Vascular Surgery, IRCCS Sacro Cuore-Don Calabria, Negrar[c]; the Department of Vascular and Endovascular Surgery, Santa Chiara Hospital, Trento[d]; and the Department of Vascular Surgery, IRCCS MultiMedica, Sesto San Giovanni, Milan.[f]

Presented at the Fifty-first Veith Symposium of the Society for Vascular Surgery, New York, New York, November 19-23, 2024.

Additional material for this article may be found online at www.jvascsurg.org.

Correspondence: Stefano Fazzini, MD, PhD, Unit of Vascular and Endovascular Surgery, Department of Biomedicine and Prevention, Tor Vergata University, Via Cracovia, 90, Rome 00133, Italy (e-mail: stefano.fazzini@uniroma2.it).

The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214

https://doi.org/10.1016/j.jvs.2025.04.025

Recent evidence and advancements in stent technology support endovascular treatment for most AIOD, challenging the TransAtlantic Inter-Society Consensus II (TASC II) that previously recommended surgery for TASC II C and D lesions.[3]

The American and European Societies of Vascular Surgery now recommend selective or primary stenting for iliac artery stenosis or occlusions, respectively, in patients with claudication.[4-6]

Intravascular lithotripsy (IVL) has been proposed to address calcific lesions and improve the safety and efficacy of AIOD stenting. The Disrupt PAD III study,[7-9] with nearly 100 patients with a 30-day follow-up, shows that in calcific AIOD, IVL with adjunctive stenting is preferred over the "leave nothing behind" approach commonly used in the femoro-popliteal segment.[10,11] The primary indication for IVL in these studies was vessel preparation, as no studies currently support its use as a stand-alone therapy.

Stenting in the calcified iliac arteries presents unique challenges due to anatomical complexities. The necessity for bilateral "kissing" stents at the aortic bifurcation, often required in cases of extensive disease, adds procedural complexity and may inhibit future procedures (up-and-over access technique). The exclusion of collateral branches during stent placement can compromise collateral circulation. Furthermore, severe bending in the distal iliac segment could lead to future stent fractures and occlusions. These factors, in addition to the risk of stent recoil and/or suboptimal stent expansion, underscore the importance of exploring alternative or adjunctive therapies to optimize treatment strategies for AIOD.

This study aimed to evaluate the mid-term outcomes of patients with calcified iliac lesions treated with IVL, with or without adjunctive stenting, and to propose a new algorithm guiding these different treatment strategies.

ARTICLE HIGHLIGHTS

- **Type of Research:** A multicenter retrospective study of prospectively collected data
- **Key Findings:** A total of 100 calcified iliac lesions in 86 patients were treated with intravascular lithotripsy (IVL) alone in 77% of cases and IVL with adjunctive stenting in 23%. At 24 months (median follow-up, 20 months), primary and assisted primary patency rates were 95% and 98%, respectively, whereas secondary patency was 100%.
- **Take Home Message:** With promising mid-term outcomes, high primary patency, and a minimal stenting rate, IVL expands endovascular strategies for iliac occlusive disease and enables a "leave nothing behind" approach even in this anatomical region.

METHODS

Study design and patient selection. The IVLIAC (IVL in ILIAC arteries) registry is a multi-center, retrospective analysis of prospectively collected data. All consecutive patients treated with the M5/M5^{+} IVL catheter (Shockwave Medical) for calcified iliac arteries between February 2021 and May 2024 at four centers (>15 patients per site) were included.

IVL was indicated for clinically relevant iliac occlusive disease (Rutherford category ≥3) in patients with calcified iliac lesions (stenosis ≥70% or chronic total occlusion [CTO]), confirmed through baseline clinical examination and duplex ultrasound (DUS).

All target iliac lesions were further characterized using computed tomography angiography (CTA) to assess the complexity of calcium burden and to allow for accurate preoperative planning. Patients with in-stent restenosis, concomitant iliac aneurysms, prior aortoiliac surgery, use of iliac IVL to facilitate aortic endograft delivery, or use of other calcium modification tools (eg, atherectomy), were excluded. However, those with concomitant PAD of the infrainguinal vessels were included. Decisions regarding infrainguinal treatment indication, the choice of endovascular or surgical approach, and perioperative management were made at the discretion of each participating center following international PAD guidelines.[4-6]

Follow-up assessments, including clinical examination, ankle-brachial index, and DUS, were scheduled at 1, 6, and 12 months, and annually thereafter, with earlier assessment in cases of clinical worsening. A second CTA was not mandatory to plan target lesion revascularization (TLR). Dual antiplatelet therapy was prescribed for at least 2 months, then continued with lifelong aspirin (100 mg) or clopidogrel (75 mg). Patients on oral anticoagulation received a single additional antiplatelet agent for at least 2 months post-procedure.

A single antiplatelet therapy was prescribed in the IVL ONLY group in cases of high bleeding risk. Clinical, demographic, and imaging data were prospectively collected and retrospectively analyzed in accordance with local ethics committee requirements and the Declaration of Helsinki. All patients provided informed consent before the intervention.

Procedural protocol. All procedures were performed by experienced vascular surgeons in either an angiographic suite or a hybrid theatre. A consultant vascular anesthetist evaluated each patient preoperatively, tailoring anesthesia based on the planned procedure, institutional protocols, and patient comorbidities. General anesthesia was preferred for open surgery (eg, common femoral artery [CFA] endarterectomy), whereas local anesthesia was preferred for endovascular procedures. A 6Fr or 7Fr percutaneous access (single or double femoral, or brachial) was selected based on the need

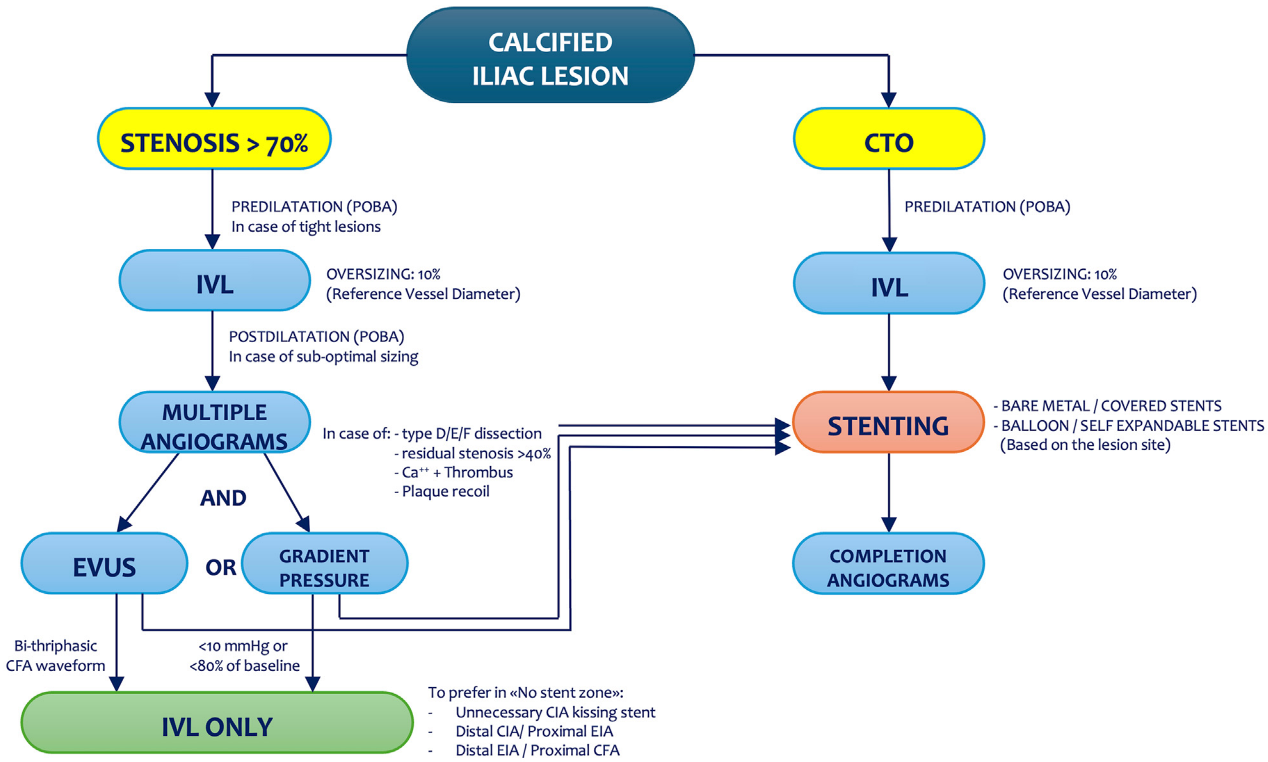


Fig. Algorithm showing intravascular lithotripsy (*IVL*) indication in case of calcified iliac stenosis and chronic total occlusion (*CTO*). *CFA*, Common femoral artery; *CIA*, common iliac artery; *EIA*, external iliac artery; *EVUS*, extravascular ultrasound; *POBA*, plain old balloon angioplasty.

for multiple access points, the type of CTO recanalization (antegrade or retrograde), and the location of the target lesion.

The Shockwave Medical Peripheral IVL System has been previously described.[8,12] The M5/M5$^+$ IVL catheters are 60 mm in length and are available in diameters ranging from 3.5 to 8.0 mm (M5$^+$ up to 8 mm, available since October 2021).

Both intraluminal and subintimal CTO crossing were considered suitable for IVL. In cases of tight stenosis or CTOs, predilatation with a 3 to 3.5 mm plain old balloon angioplasty was performed to facilitate IVL delivery. In multiple lesions, at least one-half of the 300 available pulses were typically delivered to the main lesion. In cases of aortic bifurcation and bilateral common iliac disease, a kissing balloon technique was used, either with IVL and plain old balloon angioplasty (switching sides after one-half of the pulses) or double IVL. The number of pulses delivered for each lesion was adjusted based on whether stenting was intended as a provisional or planned option. In general, most pulses were delivered to the target lesions, whereas IVL stand-alone treatment was considered in selected cases (Fig).

Algorithm: to stent or not stent. The Fig shows the algorithm for using IVL in iliac lesions.

(1) Calcified iliac stenosis: IVL is indicated as either a *stand-alone therapy or as vessel preparation prior to provisional stenting.*

The decision is guided by angiographic findings, extravascular ultrasound (EVUS) and translesional gradient pressure measurements.[3,13,14] If, after IVL treatment, the duplex waveform improves (eg, from monophasic/blunted to biphasic/triphasic at the level of the CFA) and/or the translesional gradient pressure at rest decreases to <10 mm Hg or <80% of baseline, then IVL standalone therapy may be appropriate. This strategy is particularly indicated where stenting would be suboptimal, such as at the iliac bifurcation, in the distal external iliac artery (EIA), or when attempting to avoid unnecessary kissing stents in the presence of a healthy contralateral common iliac artery (CIA). However, residual stenosis >40%, post-IVL flow limiting dissection, plaque recoil, or the presence of thrombus indicates the need for provisional stenting.[4,5,15]

(2) Calcified iliac CTO: IVL is indicated as *vessel preparation prior to planned stenting.*[4,5]

The number of pulses delivered depends on the calcium burden and target lesion location, with the aim of facilitating stent expansion and preventing recoil.

Stent selection (balloon-expandable vs self-expandable) is based on lesion location (CIA vs EIA) and plaque morphology. Covered stents are preferred in the presence of thrombotic plaque components, which pose a higher embolization risk. Conversely, bare metal stents are favored to preserve collateral circulation (eg, hypogastric artery) and minimize procedural costs.

Outcomes. The primary endpoint of this study was primary patency, defined as freedom from significant restenosis or occlusion without the need for reintervention. Secondary endpoints included assisted primary patency and secondary patency, freedom from iliac complications (rupture, embolization, and flow-limiting dissection), freedom from major amputation, incidence of major adverse events, and overall survival.

Definitions. The target lesions were divided into two groups based on the final treatment (Fig and Supplementary Fig 1, online only).

(1) IVL ONLY group received IVL stand-alone therapy.
(2) IVL + STENT group received IVL with adjunctive stenting (provisional or planned).

Technical success was defined as residual stenosis of less than 30% (IVL + STENT) or less than 40% (IVL ONLY) in the absence of arterial perforation at the target site. Procedural success was defined as technical success with freedom from device- or procedure-related serious adverse events. Clinical success was defined as an improvement of one or more Rutherford classes at 1-, 6-, 12-, and 24-month follow-up compared with baseline. Amputation-free survival was defined as the time until major amputation of the index limb or all-cause death, whichever occurred first. The target lesions were divided into six segments, three for the CIA (CIA1: proximal; CIA2: middle; CIA3: distal) and three for the EIA (EIA1: proximal; EIA2: middle; EIA3: distal). The distal aorta and CFA were considered adjunctive treatment areas and not primary targets.

The calcification burden was graded based on arterial wall calcium measured on preoperative CTA, using three different classifications: 360° calcification grade (mild [0°-90°], moderate [90°-180°], severe [180°-270°], concentric [270°- 360°]),[16] Peripheral Arterial Calcium Scoring Scale (PACSS) (I, unilateral calcification <5 cm; II, unilateral calcification ≥5 cm; III bilateral calcification <5 cm; IV, bilateral calcification ≥5 cm[17]), and Peripheral Academic Research Consortium (PARC) (I, <180° [1 side of vessel] and less than one-half of the total lesion length; II, <180° [1 side of vessel] and greater than one-half of the total lesion length; III, ≥180° [both sides of vessel at the same location] and less than one-half of the total lesion length; IV, >180° [both sides of the vessel at the same location] and greater than one-half of the total lesion length).[18]

Target vessel dissections were categorized in six types (A-F) based on the National Heart, Lung, and Blood Institute (NHLBI) classification. Flow-limiting dissections were classified as follows: C, contrast outside vessel lumen (persistent staining), D, spiral dissection, E, persistent filling defects, F, impaired flow to total occlusion.[19,20]

Significant restenosis was defined as a peak systolic velocity ratio >2.0 on DUS within the target lesion. Secondary patency was defined as restored flow in the treated segment after occlusion or restenosis. Major amputation was defined as any above-ankle amputation. Major adverse events were defined as any clinical event leading to persistent or significant disability, requiring surgical or percutaneous intervention, or resulting in prolonged hospitalization.

Statistical analysis. Continuous variables are presented as mean ± standard deviation or median (interquartile range), whereas categorical data are reported as counts. Comparisons between subgroups were performed using the Student *t*-test or Mann-Whitney *U* test according to the distribution of continuous variables, and the Fisher exact test for categorical variables. Cumulative primary and assisted primary patency were estimated by Kaplan-Meier curves. Univariate analysis was performed comparing cases with TLR vs cases without TLR to identify statistically significant differences between groups. The significant variables were included in Cox regression analyses to determine risk factors for TLR. The subgroups of IVL with or without adjunctive stenting were analyzed.

A *P* value ≤ .05 was considered statistically significant. All analyses were conducted using R (version 3.6.1 R Foundation for Statistical Computing, 2020; available at: https://www.R-project.org).

RESULTS

Baseline characteristics. A total of 86 patients with 100 calcified iliac arteries were included in the study. Demographic data are summarized in Table I. The majority of patients were male (61%) and smokers (66%), with a mean age of 74 ± 9 years. Most had arterial hypertension and dyslipidemia. Most patients had critical limb ischemia (CLI) (55%) and TASC C/D lesions (83%). Target lesion characteristics are outlined in Table II. Most lesions (88%) were stenotic with a mean stenosis of 84% ± 10%, whereas 12% were CTOs. The mean lesion length was 41 ± 29 mm.

Calcium burden was severe according to three different classifications: 75% of lesions had a 180° to 360° arc calcification; 68% were classified as PACCS 3 to 4, and 72% as PARC 3 to 4. Additionally, 31% were concentric calcific lesions. Most target lesions (72%) were located in either the proximal or distal CIA or EIA. One-quarter of lesions (26%) involved both the CIA and EIA, whereas 56% extended across at least two iliac segments.

Journal of Vascular Surgery
Volume ■, Number ■

Table I. Baseline demographics, risk factors, and clinical presentation

Variable	Data
Patient treated	86
Iliac arteries treated	100
Bilateral arteries	14
Age, years	74 ± 8.6
Male	52 (61)
Hypertension	78 (91)
Dyslipidemia	71 (83)
Active smoking	57 (66)
Diabetes	28 (33)
CAD	38 (44)
COPD	31 (36)
CKD	18 (21)
Claudication	45 (45)
CLI	55 (55)
Rutherford category	
Stage 3	45 (45)
Stage 4	22 (22)
Stage 5	29 (29)
Stage 6	4 (4.0)
ABI	0.47 ± 0.16

ABI, Ankle-brachial index; *CAD,* coronary artery disease; *CKD,* chronic kidney failure; *CLI,* critical limb ischemia; *COPD,* chronic obstructive pulmonary disease.
Continuous data are presented as the mean ± standard deviation; categorical data are presented as number (%).

Table II. Target lesion characteristics

Variable	Data
Stenosis, %	84 ± 10
Length, mm	41 ± 29
RVD, mm	7.8 ± 1.4
MLD, mm	2.3 ± 1.2
Target lesion location[a]	
CIA + EIA	26 (26)
Proximal CIA	59 (30)
Middle CIA	32 (16)
Distal CIA	30 (15)
Proximal EIA	31 (15)
Middle EIA	25 (12)
Distal EIA	23 (11)
At least two iliac segments	56 (56)
Adjunctive distal abdominal aorta	6 (6)
Adjunctive common femoral artery	11 (11)
TASC II class	
A	2 (2)
B	15 (15)
C	37 (37)
D	46 (46)
PACSS grade	
1	17 (17)
2	15 (15)
3	49 (49)
4	19 (19)
Circumferential calcium grade	
Mild (0°-90°)	0 (0)
Moderate (90°-180°)	25 (25)
Severe (180°-270°)	44 (44)
Concentric (270°-360°)	31 (31)
PARC grade	
1	8 (8)
2	20 (20)
3	37 (37)
4	35 (35)

CIA, Common iliac artery; *EIA,* external iliac artery; *MLD,* minimum lumen diameter; *PACSS,* Peripheral Arterial Calcium Scoring Scale; *PARC,* Peripheral Academic Research Consortium; *RVD,* reference vessel diameter; *TASC,* Transatlantic Inter-Society Consensus.
Continuous data are presented as the mean ± standard deviation; categorical data are presented as number (%).
[a]Target lesion located in single/multiple iliac segments based on the length.

Procedural and 30-day outcomes. Clinical and procedural characteristics are described in Table III. The target lesions were treated with IVL ONLY in 77% of cases and IVL + STENT in 23% (provisional stenting, 11%; planned stenting, 12%; bare metal stents, 13%; covered stents, 10%). Predilatation was performed in 45% of cases.

Technical and procedural success rates were 99% and 98%, respectively. The mean residual stenosis at the final angiogram was 15% ± 14%. The completion functional assessment was conducted in all IVL ONLY cases and was determined by an improved EVUS signal (bi- or triphasic waveform at the level of the ipsilateral CFA) and/or significant reduction in translesional pressure gradient (mean decrease, 71%).

No significant differences were observed between the IVL ONLY and IVL + STENT groups in terms of intraprocedural outcomes, including residual stenosis and gradient pressure (Table IV).

A single IVL catheter was used in 89% of cases, with a mean oversizing of 0.92 ± 0.16 and very low inflation pressure (3.6 ± 0.3 ATM). No embolic protection devices were used. Twelve patients had bilateral CIA1 target lesions, with only one (8.3%) receiving kissing stents. Complications were minimal: one iliac rupture, no distal embolization, five flow-limiting dissections, and one recoil, all of which were successfully treated with additional stenting. The iliac rupture occurred in one of the earliest cases, with a tight concentric stenosis treated without predilatation, with an IVL nominal pressure of 4 ATM, and suboptimal IVL sizing (target lesion located at iliac bifurcation with a wide mismatch of iliac diameter). A covered stent (Viabahn VBX; W. L. Gore & Associates)

Table III. Clinical and procedural characteristics

Variable	Data
Clinical follow-up, months (range)	21 ± 11 (1-45)
Technical success	99 (99)
Procedural success	98 (98)
Device success[a]	100 (100)
5/5.5/6/6.5 mm IVL, %	32
7 mm IVL, %	29
8 mm IVL, %	39
IVL oversizing (range)	0.92 ± 0.16 (0.6-1.4)
IVL pulses/iliac axis	224 ± 84
IVL ATM/cycle	3.6 ± 0.3
Kissing stent	1 (8.3)
Bare metal stents	13 (13)
Covered stents	10 (10)
Balloon-expandable stents	13 (13)
Self-expandable stents[b]	10 (10)
Predilatation	45 (45)
TL residual stenosis at completion angiogram, %	14 ± 13
Pre-treatment monophasic waveform at ipsilateral CFA (EVUS), %	95
Bi-triphasic waveform at ipsilateral CFA (EVUS) at completion angiogram, %	95
Pre-treatment translesional gradient pressure, mmHg	31 ± 12
Translesional gradient pressure at completion angiogram, mmHg	9.6 ± 6.5
Femoral access	88 (88)
Brachial access	12 (12)
Percutaneous access	59 (59)
Adjunctive procedures	
CFA IVL	11 (11)
CFA endarterectomy	32 (32)
SFA IVL	2 (2)
Femoro-popliteal bypass[c]	4 (4)
Complications	
Percutanous access site complication	1 (1.7)
Flow-limiting dissection	5 (5)
Distal embolization	0 (0)
Iliac rupture	1 (1)

CFA, Common femoral artery; *EVUS*, extravascular ultrasound; *IVL*, intravascular lithotripsy; *SFA*, superficial femoral artery; *TL*, target lesion. Continuous data are presented as the mean ± standard deviation; categorical data are presented as number (%).
[a]Device success is defined as successful device delivery.
[b]Double self-expandable stent in one case.
[c]All with associated CFA endarterectomy.

was placed between the CIA and EIA to control the bleeding, resulting in hypogastric artery occlusion. No claudicant patients received adjunctive infrainguinal procedures. Most of the patients with CLI (81%) received surgical or endovascular femoro-popliteal treatment (Table III). One case of access-site bleeding required reintervention. No major adverse events or deaths were reported within the first 30 days (Table III).

Mid-term outcomes. The median follow-up time was 20 months (range, 1-45 months). Primary patency and assisted primary patency at 24 months were 95% (95% confidence interval [CI], 85%-98%) and 98% (95% CI, 92%-99.5%), respectively, whereas secondary patency was 100%. There were no statistically significant differences between the IVL ONLY and IVL + STENT groups in terms of primary patency ($P = .24$) or any other clinical outcomes, including assisted primary patency ($P = .43$), amputation-free survival ($P = .68$), and overall survival ($P = .30$) (Supplementary Fig 2, online only).

Two target vessel occlusions (2%) and two significant restenoses (2%) were revascularized, resulting in freedom from TLR of 95% (95% CI, 85%-98%) at 45 months. No additional occlusions or restenoses with clinical worsening occurred. The occlusions were treated with primary stenting, whereas the restenosis cases were managed with appropriately sized IVL stand-alone therapy. The Supplementary Table (online only) describes preoperative, procedural, and post-procedural characteristics of TLRs.

Clinical success was achieved in 100%, with most patients experiencing a two-class improvement in Rutherford classification from baseline throughout follow-up (Supplementary Fig 3, online only). Complete wound healing was achieved in all patients within 12 months, except for one case (1%) that resulted in major amputation after 6 months. Amputation-free survival and overall survival rates at 24 months was 90% (95% CI, 82%-94%) and 91% (95% CI, 83%-95%), respectively. Univariate analysis comparing cases with and without TLR was performed (Table V). Longer target lesion length (hazard ratio, 1.02; 95% CI, 1.00-1.04; $P = .024$,) and greater residual stenosis (hazard ratio, 1.06; 95% CI, 1.01-1.11; $P = .024$) were significantly associated with TLR.

DISCUSSION

The IVLIAC registry represents the first multicenter evaluation of IVL in severely calcified iliac arteries, reporting mid-term outcomes. The key findings are:[1] IVL can be used as a stand-alone therapy or as vessel preparation for stenting, following a structured algorithm[2]; IVL is safe and effective for symptomatic, complex iliac occlusive disease[3]; mid-term outcomes are comparable to previous studies that explored alternative treatment strategies, despite the high prevalence of severe calcifications and CLI in our cohort.[21-23]

Calcium remains a major challenge in the endovascular treatment of iliac artery disease, affecting both procedural and long-term outcomes.[24] A debate regarding the use of covered stents vs bare metal stents has

Table IV. Clinical presentation, anatomical and procedural factors in the intravascular lithotripsy (*IVL*) ONLY and IVL + STENT groups

	IVL + STENT	IVL ONLY	*P*
Age, years	72 (68-82)	74 (68-79)	.98
CLI	11 (48)	44 (57)	.43
Total lesion length, mm	29 (21-50)	30 (20-58)	.81
PACSS 3-4	18 (78)	50 (65)	.23
TASC C-D	18 (78)	65 (84)	.49
Reference vessel diameter, mm	7 (6.8-8)	8 (6.92-9)	.23
Minimum lumen diameter, mm	2 (0-2.6)	2.2 (1.9-3.1)	**.010**
TL stenosis, %	85 (80-90)	80 (75-90)	**.008**
TL CTO	12 (52)	0 (0)	**<.001**
TL residual stenosis, %	5 (0-20)	15 (5-25)	.08
Preoperative ABI	0.5 (0.4-0.6)	0.4 (0.3-0.6)	.32
ABI at discharge	0.9 (0.7-1)	0.7 (0.7-0.9)	**.019**
Preoperative gradient pressure, mmHg	50 (45-55)	25 (23-35)	**.047**
Postoperative gradient pressure, mmHg	0 (0-5)	10 (5-15)	.17
Adjunctive infrainguinal surgical repair	5 (22)	27 (35)	.23
Adjunctive infrainguinal endovascular repair	5 (22)	8 (10)	.15
IVL oversizing	0.87 (0.84-1)	0.89 (0.85-1)	.86

ABI, Ankle-brachial index; *CLI*, chronic limb ischemia; *CTO*, chronic total occlusion; *PACSS*, Peripheral Arterial Calcium Scoring Scale; *TL*, target lesion.
Continuous data are presented as the median (interquartile ranges); categorical data are presented as number (%).
Boldface *P* values indicate statistical significance ($P < .05$).

Table V. Cox regression analysis for target lesion recanalization

	NO TLR	TLR	*P*	HR	95% CI
Age, years	74 (68-79)	76 (70-80)	.70		
CKD	18	0	.53		
Diabetes	27	1	.79		
Total lesion length, mm	30 (20-52)	78 (69-92)	**.024**	1.02	1.00-1.04
Reference vessel diameter, mm	8 (7-9)	7 (6.4-9)	.64		
Target lesion stenosis, %	80 (80-90)	90 (85-91)	.65		
Residual stenosis, %	10 (0-21)	32.5 (23-40)	**.024**	1.06	1.01-1.11
Preoperative ABI	0.5 (0.3-0.6)	0.42 (0.3-0.5)	.42		
Preoperative gradient pressure, mmHg	27.5 (25-35)	25 (22.5-27.5)	.46		
Postoperative gradient pressure, mmHg	10 (5-10)	20 (15-20)	.05		
IVL oversizing	0.89 (0.86-1)	0.94 (0.84-1.08)	.32		

ABI, Ankle-brachial index; *CKD*, chronic kidney disease; *IVL*, intravascular lithotripsy; *TLR*, target lesion revascularization.
Continuous data are presented as median (interquartile ranges).
Boldface *P* values indicate statistical significance ($P < .05$).

emerged, based not only on the lesion extent but also on the presence of calcium.[4]

Covered stents are recommended to prevent complications, although the DISCOVER trial showed no superiority over bare metal stents in common iliac arteries.[25,26]

The introduction of IVL has led to a re-evaluation of standard approaches such as primary stenting, which, although effective, is susceptible to stent recoil and underexpansion in heavily calcified vessels.[8] Furthermore, extensive calcifications increase the risk of life-threatening ruptures, especially when high-pressure balloons are used.

Stent selection (ballon-expandable vs self-expandable, bare metal vs covered) usually depends on lesion location, each with inherent trade-offs (radial force vs flexibility).

However, no single stent is ideal for all calcified iliac lesions, and unnecessary stenting, especially at bifurcation or when covering key branches (eg, internal iliac artery), should be avoided. Compared with thrombotic and fibrotic plaques, calcified lesions tend to be more stable over time, making a "leave nothing behind" approach feasible with IVL.[27,28]

In the IVLIAC registry, only 23% of cases required stenting after IVL, a significant reduction compared with the 78% reported by Armstrong et al.[8] The high safety profile of IVL reinforces its advantage over other approaches. Importantly, mid-term primary patency (95%) was excellent in both the IVL ONLY and IVL + STENT groups.

Previous research supported the versatility of IVL as a vessel preparation tool, but the decision-making process for adjunctive stenting remains understudied. We propose a structured algorithm based on lesion type (stenosis vs CTO) and intraoperative functional assessments (EVUS and pressure gradient) to determine whether stenting is necessary.[3,12] The impact of sonic pressure waves improves vessel compliance and luminal gain, but such modifications may not always be evident on digital subtraction angiography alone. Intraoperative functional assessments play a crucial role in determining whether IVL alone is enough.

Avoiding unnecessary iliac stenting preserves future treatment options, such as sparing unwarranted scaffolding of non-diseased arteries (eg, kissing stents in a healthy contralateral iliac artery) or stenting in suboptimal locations (diameter mismatch among multilevel segments or high-flexible regions such as inguinal ligaments). This is extremely important, given that 72% of target lesions in this study were located at the proximal or distal portion of each iliac segment.

IVL as a vessel preparation strategy enhances the safety and efficacy of iliac stenting in challenging cases (calcific CTOs, extensive disease) and expands treatment options by allowing for the use of spot stenting, single stents, or bare metal stents instead of kissing stents, multiple stents, or covered stents, respectively.

These advantages benefit both younger and older patients, whether claudicants or those with CLI, as future interventions are often required in this population. This new protocol could simplify the treatment of calcified AIOD, minimizing unnecessary stenting while maintaining strong patency rates.

Mid-term comparisons of a "leave nothing behind" approach remain scarce in the literature, especially because severely calcified lesions are often excluded from these studies. Moreover, a unified classification system for calcific lesions is lacking, despite the two scoring systems that were recently proposed for complex access in aortic endografting and transcatheter aortic valve repair.[29,30]

The clinical and procedural outcomes in this study might have been further improved if 10% IVL oversizing, as recommended by Shockwave's instructions for use, had been consistently achieved.[9,31] However, this was often not possible, as M5/M5+ catheters are limited to a maximum diameter of 8 mm. Many cases involved long diseased segments with significant diameter mismatch between the proximal CIA and distal EIA, leading to suboptimal IVL sizing. This may explain why shorter calcified lesions had the best outcomes in the IVLIAC registry. The recent introduction of the new Shockwave L6 catheter, available in 8 to 12 mm diameters, could help overcome this limitation, optimizing energy delivery and pulse utilization for the most challenging lesions. This device could further refine a customized "leave nothing behind" approach whenever feasible.

Future research should focus on larger and prospective trials to validate these findings and to refine the algorithm for adjunctive stenting after IVL, further solidifying IVL's role in treating calcified AIOD.

Limitations. Although this study presents promising mid-term outcomes, several limitations should be acknowledged. The IVLIAC study is a multicenter, retrospective single-arm study with no control arm. Data were site-reported; imaging evaluation (CTA, angiogram, EVUS) was not reviewed by a core laboratory. Additionally, all consecutive cases were included without accounting for learning curve or excluding the earliest cases from each center (eg, the single case of iliac rupture) to provide raw unfiltered data. Lastly, the retrospective design and the involvement of multiple operators introduce variability in protocol compliance.

CONCLUSIONS

IVL is a safe and effective option for calcified iliac occlusive disease. When combined with a standardized algorithm for intraoperative assessment, IVL may serve not only as a vessel preparation technique but also as a stand-alone therapy. As in other vascular regions, iliac IVL helps preserve future treatment options, especially in cases where iliac stent placement may be suboptimal.

IVL as a first-line strategy in iliac interventions allows for avoidance of unnecessary stenting or optimizing stent expansion, both of which contribute to favorable mid-term outcomes. This multicenter experience demonstrates promising primary patency rates despite a low stenting rate. However, further prospective studies are needed to confirm these findings and refine treatment strategies.

The authors thank Judy Greengard (consultant for Shockwave Medical) for support in language editing.

AUTHOR CONTRIBUTIONS

Conception and design: SF, VT, CL, EM, ST, LGa, SB
Analysis and interpretation: ST, VT, CL, EF, SA, LGa, SB
Data collection: VT, CL, EF, LGr, DM, AS
Writing the article: SF
Critical revision of the article: SF, VT, CL, EF, LGr, SA, DM, AS, EM, ST, LGa, SB

Final approval of the article: SF, VT, CL, EF, LR, SA, DM, AS, EM, ST, LGa, SB
Statistical analysis: VT
Obtained funding: Not applicable
Overall responsibility: SF

FUNDING

None.

DISCLOSURES

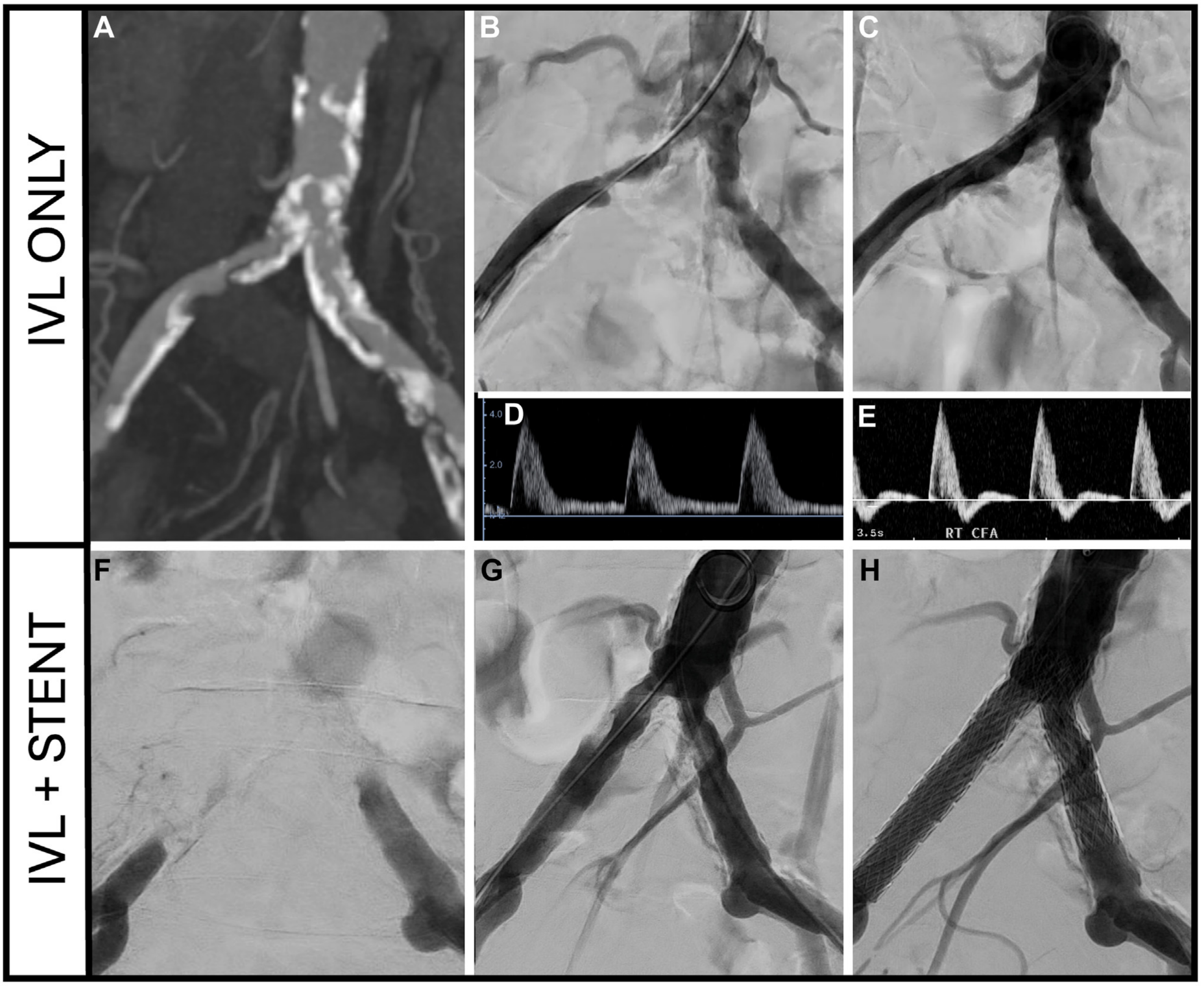
S.F., L.G., and S.B. are consultants for Shockwave Medical.

REFERENCES

1. Panneton JM, Bismuth J, Gray BH, Holden A. Three-year follow-up of patients with iliac occlusive disease treated with the Viabahn balloon- expandable Endoprosthesis. *J Endovasc Ther*. 2020;27: 728−736.
2. Bismuth J, Gray BH, Holden A, Metzger C, Panneton J. Pivotal study of a next-generation balloon-expandable stent-graft for treatment of iliac occlusive disease. *J Endovasc Ther*. 2017;24:629−637.
3. Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FGR. Inter-society consensus for the management of peripheral arterial disease (TASC II). *J Vasc Surg*. 2007;45:S5−S67.
4. Nordanstig J, Behrendt CA, Baumgartner I, et al. Editor's choice – European Society for Vascular Surgery (ESVS) 2024 clinical practice guidelines on the management of asymptomatic lower limb peripheral arterial disease and Intermittent claudication. *Eur J Vasc Endovasc Surg*. 2024;67:9−96.
5. Conte MS, Bradbury AW, Kolh P, et al. Global vascular guidelines on the management of chronic limb-threatening ischemia. *Eur J Vasc Endovasc Surg*. 2019;58:S1−S109.e33.
6. Conte MS, Pomposelli FB, Clair DG, et al. Society for Vascular Surgery practice guidelines for atherosclerotic occlusive disease of the lower extremities: management of asymptomatic disease and claudication. *J Vasc Surg*. 2015;61:2S−41S.e1.
7. Adams G, Shammas N, Mangalmurti S, et al. Intravascular lithotripsy for treatment of calcified lower extremity arterial stenosis: initial analysis of the disrupt PAD III study. *J Endovasc Ther*. 2020;27: 473−480.
8. Armstrong EJ, Soukas PA, Shammas N, et al. Intravascular lithotripsy for treatment of calcified, stenotic iliac arteries: a cohort analysis from the disrupt PAD III study. *Cardiovasc Revasc Med*. 2020;21: 1262−1268.
9. Armstrong EJ, Adams G, Soukas PA, et al. Intravascular lithotripsy for peripheral artery calcification: 30-day outcomes from the disrupt PAD III observational study. *J Endovasc Ther*. 2024. https://doi.org/10.1177/15266028241283716.
10. Bosiers M. Leaving nothing behind. *JACC Cardiovasc Interv*. 2013;6: 1294.
11. Keefe N, Shull T, Botea L, McGinigle K. Drug-coated balloon versus drug-eluting stent: the debate of leave nothing behind. *Semin Intervent Radiol*. 2023;40:161−166.
12. Stavroulakis K, Bisdas T, Torsello G, Tsilimparis N, Damerau S, Argyriou A. Intravascular lithotripsy and drug-coated balloon angioplasty for severely calcified femoropopliteal arterial disease. *J Endovasc Ther*. 2023;30:106−113.
13. Fazzini S, Pennetta FF, Turriziani V, Vona S, Ascoli Marchetti A, Ippoliti A. Extravascular ultrasound (EVUS) to assess the results of peripheral endovascular procedures. *Diagnostics*. 2023;13:1356.
14. Tepe G, Brodmann M, Bachinsky W, et al. Intravascular lithotripsy for peripheral artery calcification: mid-term outcomes from the randomized disrupt PAD III trial. *J Soc Cardiovasc Angiogr Interv*. 2022;1: 100341.
15. Baumann F, Fust J, Engelberger RP, et al. Early recoil after balloon angioplasty of tibial artery obstructions in patients with critical limb ischemia. *J Endovasc Ther*. 2014;21:44−51.
16. Dattilo R, Himmelstein SI, Cuff RF. The COMPLIANCE 360° Trial: a randomized, prospective, multicenter, pilot study comparing acute and long-term results of orbital atherectomy to balloon angioplasty for calcified femoropopliteal disease. *J Invasive Cardiol*. 2014;26: 355−360.
17. Rocha-Singh KJ, Zeller T, Jaff MR. Peripheral arterial calcification: prevalence, mechanism, detection, and clinical implications. *Catheter Cardiovasc Interv*. 2014;83:E212−E220.
18. Patel MR, Conte MS, Cutlip DE, et al. Evaluation and treatment of patients with lower extremity peripheral artery disease: consensus definitions from peripheral academic research consortium (PARC). *J Am Coll Cardiol*. 2015;65:931−941.
19. National Heart Lung and Blood Institute. Coronary artery angiographic changes after PTCA. In: *Manual of operations: NHLBI PTCA registry*. National Heart, Lung, and Blood Institute; 1985:6−9.
20. Kobayashi N, Hirano K, Yamawaki M, et al. Simple classification and clinical outcomes of angiographic dissection after balloon angioplasty for femoropopliteal disease. *J Vasc Surg*. 2018;67:1151−1158.
21. Mwipatayi BP, Sharma S, Daneshmand A, et al. Durability of the balloon-expandable covered versus bare-metal stents in the covered versus balloon expandable stent trial (COBEST) for the treatment of aortoiliac occlusive disease. *J Vasc Surg*. 2016;64:83−94.e1.
22. De Donato G, Bosiers M, Setacci F, et al. 24-Month data from the BRAVISSIMO: a large-scale prospective registry on iliac stenting for TASC A & B and TASC C & D lesions. *Ann Vasc Surg*. 2015;29:738−750.
23. Holden A, Takele E, Hill A, et al. Long-term follow-up of Subjects with iliac occlusive disease treated with the Viabahn VBX balloon-expandable endoprosthesis. *J Endovasc Ther*. 2025;32:68−76.
24. Kriens M, Jayet J, Gallien Y, et al. Influence of perioperative factors on patency after endovascular and hybrid treatments of TASC II D aortoiliac occlusive lesions. *Ann Vasc Surg*. 2024;99:252−261.
25. Bekken JA, Vroegindeweij D, Vos JA, et al. Editor's choice − Two year results of the Randomised DISCOVER trial comparing covered versus bare metal stents in the common iliac artery. *Eur J Vasc Endovasc Surg*. 2023;65:359−368.
26. Li J, Zhang Y, Fang J, Qu C, Teng L, Shen C. Outcomes of covered vs bare metal stents for the treatment of aortoiliac occlusive disease. *J Vasc Surg*. 2024;79:330−338.
27. Nandalur KR, Hardie AD, Raghavan P, Schipper MJ, Baskurt E, Kramer CM. Composition of the stable carotid plaque: insights from a multidetector computed tomography study of plaque volume. *Stroke*. 2007;38:935−940.
28. Jinnouchi H, Sato Y, Sakamoto A, et al. Calcium deposition within coronary atherosclerotic lesion: implications for plaque stability. *Atherosclerosis*. 2020 Aug;306:85−95.
29. Fazzini S, Pennetta FF, Torsello G, et al. Intravascular iliac artery lithotripsy to facilitate aortic endograft delivery: midterm results of a dual-center experience. *J Endovasc Ther*. 2024. https://doi.org/10.1177/15266028241241246.
30. Palmerini T, Saia F, Kim WK, et al. Vascular access in patients with peripheral arterial disease undergoing TAVR: the hostile registry. *JACC Cardiovasc Interv*. 2023;16:396−411.
31. Brodmann M, Werner M, Holden A, et al. Primary outcomes and mechanism of action of intravascular lithotripsy in calcified, femoropopliteal lesions: results of Disrupt PAD II. *Catheter Cardiovasc Interv*. 2019;93:335−342.

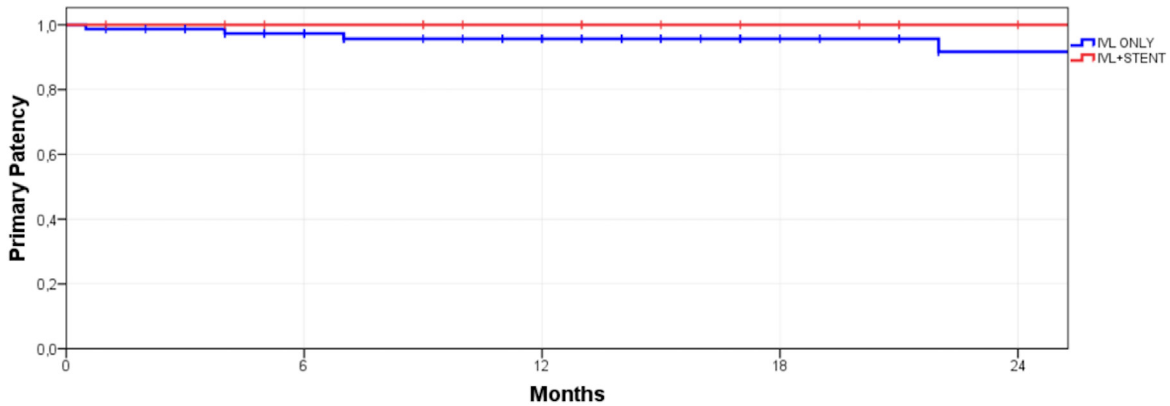
Submitted Feb 23, 2025; accepted Apr 12, 2025.

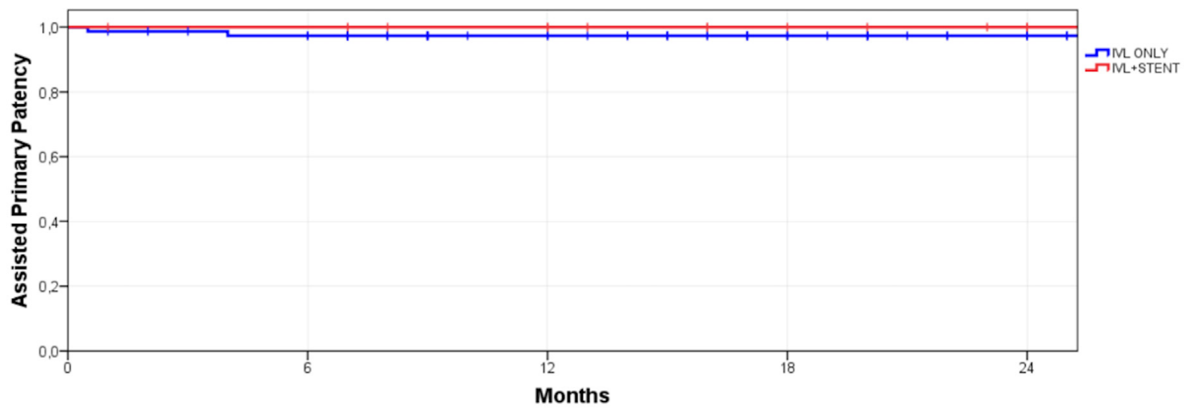
Additional material for this article may be found online at www.jvascsurg.org.



Supplementary Fig 1 (online only). Example case of intravascular lithotripsy (*IVL*) ONLY and IVL + STENT. **(A-B)** Preoperative computed tomography angiography (CTA) and angiogram showing a calcified stenosis of the proximal common right iliac artery; **(B-C)** Pre- and postoperative angiograms after IVL stand-alone therapy without the need of a kissing stent; **(D-E)** Extravascular ultrasound (EVUS) showing preoperative (monophasic) and postoperative (triphasic) right common femoral artery (CFA) waveforms in patient with left palpable femoral and distal pulses. **(F)** Preoperative angiogram showing a bilateral calcified chronic total occlusion (CTO) of the common iliac arteries (CIAs); **(G-H)** post bilateral IVL (5 cycles per side) and post kissing stent angiogram.

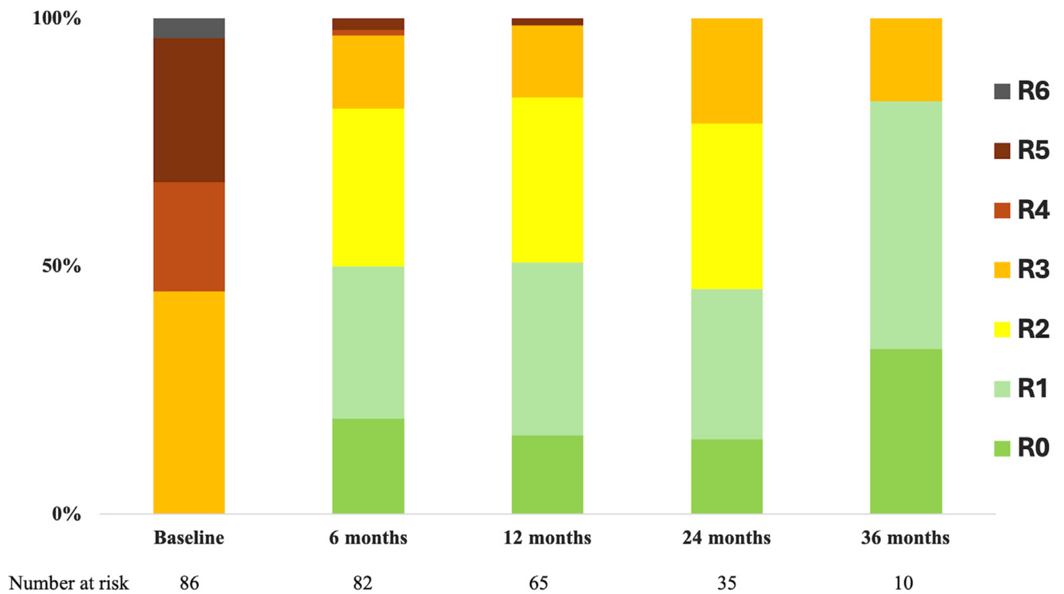
Journal of Vascular Surgery
Volume ■, Number ■





	6 MONTHS	12 MONTHS	18 MONTHS	24 MONTS	IVL ONLY vs IVL + STENT
	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	*p*
PRIMARY PATENCY	98% (92%-99.5%)	96.9% (90.7%-99%)	96.9% (90.7%-99%)	94.6% (85%-98%)	.24
Number at risk	94	74	53	38	
ASSISTED PRIMARY PATENCY	98% (92%-99.5%)	98% (92%-99.5%)	98% (92%-99.5%)	98% (92%-99.5%)	.43
Number at risk	94	75	55	40	

Supplementary Fig 2 (online only). Kaplan-Meier curves showing primary and assisted primary patency of the two groups (intravascular lithotripsy [IVL] ONLY, IVL + STENT). *CI*, Confidence interval.



Supplementary Fig 3 (online only). Distribution of Rutherford categories from baseline to 3 years follow-up.

Supplementary Table (online only). Preoperative, procedural, and post-procedural characteristics of target lesion revascularization (*TLR*)

		Target lesion anatomic characteristics						Intraoperative characteristics					Completion assessment			
Type of lesion	Follow-up, months	PACCS	PARC	Calcium grade	Total lesion length, mm	RVD, mm	MLD, mm	IVL ONLY	IVL + STENT	IVL sizing	IVL cycles	Treated segments: type of treatment	Residual stenosis at angiogram	Pressure gradient, mmHg	EVUS	TLR
Occlusion	1	2	2	90°-180°	115	11	3.1	Yes	No	−17%	8	CIA: IVL EIA: IVL	40%	20	–	Stenting
Occlusion	4	2	2	180°-270°	71	5.8	1.2	Yes	No	+38%	8	CIA: IVL	20%	20	–	Stenting
Restenosis	7	2	3	180°-270°	63	7	1.7	Yes	No	0%	10	CIA: IVL CFA: open repair	25%	10	–	Properly sized IVL
Restenosis	23	2	2	180°-270°	71	6.8	1.2	Yes	No	−12%	5	CIA: IVL EIA: IVL	40%	–	–	Properly sized IVL

CFA, Common femoral artery; *CIA,* common iliac artery; *EIA,* external iliac artery; *EVUS,* extravascular ultrasound; *IVL,* intravascular lithotripsy; *MLD,* minimum lumen diameter; *PACSS,* Peripheral Arterial Calcium Scoring Scale; *PARC,* Peripheral Academic Research Consortium; *RVD,* reference vessel diameter.