Journal of the Society for Cardiovascular Angiography & Interventions 1 (2022) 100374

Contents lists available at ScienceDirect

Journal of the Society for Cardiovascular Angiography & Interventions

journal homepage: www.jscai.org

Original Research

Intravascular Lithotripsy vs Atherectomy in the Treatment of Calcified Common Femoral Artery Disease

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A B S T R A C T

Background: Common femoral artery (CFA) disease is often heavily calcified and prone to low patency rates with endovascular treatment compared with surgical endarterectomy. Recent data suggest promising short-term outcomes with the adjunct use of intravascular lithotripsy; however, data on its midterm effectiveness are lacking. We compared clinically driven target lesion revascularization (CD-TLR) between patients receiving drug-coated balloon angioplasty with adjunct intravascular lithotripsy (IVL-DCB) vs adjunct atherectomy (Ath-DCB) for treatment of CFA disease.

Methods: In a single-center retrospective cohort study, patients receiving IVL-DCB vs Ath-DCB for symptomatic CFA disease from January 2015 to March 2020 were included. The primary outcome was cumulative CD-TLR with angiographic restenosis ≥50%, estimated by Kaplan-Meier analysis during 18-month follow-up and compared by log-rank test.

Results: Total of 68 CFA lesions (Ath-DCB, 35; IVL-DCB, 33) were included. Patients had a mean age (standard deviation) of 72 (8) years and were predominantly male (63.3%) and White (92%). Mean baseline angiographic stenosis was 78% (11) in the Ath-DCB group and 70% (10) in the IVL-DCB group ($P = .002$). Technical success was 100% in both groups. One flow-limiting dissection occurred in IVL-DCB requiring stent placement, whereas 2 bailout stentings were performed in the Ath-DCB group. Cumulative Kaplan-Meier freedom from CD-TLR was 91.2% (95% CI, 81.6%-100%) in the Ath-DCB group vs 79.4% (95% CI, 64.6%-94.2%) in the IVL-DCB group (Log-rank $P = .167$).

Conclusions: The safety and effectiveness of IVL-DCB were comparable to those of Ath-DCB in the treatment of calcified CFA disease during the 18-month follow-up. Further studies are required to verify these findings.

Introduction

Common femoral artery (CFA) disease frequently presents with heavily calcified atherosclerosis, associated with claudication and chronic limb-threatening ischemia (CLTI).[1] Surgical treatment with endarterectomy with or without patch angioplasty has excellent 5-year patency rates[2]; however, surgical treatment is associated with higher short-term morbidity and mortality and longer hospital stays.[3] While endovascular treatment of CFA disease with stenting and atherectomy has shown higher patency rate and lower target lesion revascularization (TLR) than conventional balloon angioplasty or drug-coated balloon (DCB) alone,[4-7] stenting has been met with caution owing to stent fracture from greater mobility at the hip joint and concern of compromising endovascular access.[8] Atherectomy on the other hand increases the risk of peripheral embolism and requires additional use of an embolic protection device which increases cost, procedure duration, and radiation exposure.[9] Endovascular treatment with intravascular lithotripsy (IVL) as an adjunct therapy has shown promising results in the treatment of calcified peripheral artery disease. IVL delivers pulsatile sonic pressure waves to the vessel wall, fracturing calcium, thereby increasing vessel wall compliance and luminal gain. It reduces acute recoil and

Abbreviations: ABI, ankle-brachial index; ath, atherectomy; CD-TLR, clinically driven target lesion revascularization; CFA, common femoral artery; CLTI, chronic limb-threatening ischemia; DCB, drug-coated balloon; IVL, intravascular lithotripsy; PFA, profunda femoris artery; SFA, superficial femoral artery.

Keywords: Atherectomy; common femoral artery; intravascular lithotripsy.

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https://doi.org/10.1016/j.jscai.2022.100374
Received 10 February 2022; Received in revised form 12 April 2022; Accepted 26 April 2022
Available online 20 May 2022

the likelihood of dissection. Its short-term effectiveness and safety have been well documented in previous studies.[10-15]

There are no data comparing the technical success and midterm outcomes of IVL and atherectomy for the treatment of calcified CFA disease. The goal of this study was to compare clinically driven target lesion revascularization (CD-TLR) during an 18-month follow-up period in patients undergoing DCB angioplasty with adjunct IVL vs adjunct atherectomy for the treatment of calcified CFA disease.

Materials and methods

Study design and patient population

This is a retrospective cohort study from a single-center university-affiliated tertiary care hospital (The Miriam Hospital, Providence, Rhode Island). Patients receiving endovascular treatment for calcified CFA disease with either combined IVL-DCB or Ath-DCB, from January 2015 to March 2020, were included. Electronic medical records were reviewed retrospectively for data extraction on baseline clinical characteristics, noninvasive imaging, and outcomes. Patients were retrospectively followed through chart review from the date they received an intervention until the completion of the 18-month follow-up or until the occurrence of an event (CD-TLR), all-cause death, or lost to follow-up, whichever happened first. Those who were lost to follow-up, died, or completed the 18-month follow-up without an event were censored. All patients undergoing treatment had clinical indications for revascularization due to lifestyle-limiting Rutherford Class III claudication or CLTI. Ankle-brachial index (ABI) before the intervention and at 1, 6, and 12 months after the procedure were performed routinely. Arterial duplex ultrasound to assess peaked systolic velocity ratios were also obtained at 6 and 12 months after the procedure on routine basis. Those with acute limb ischemia were excluded. Angiographic stenosis was quantified using "visual estimate" of stenosis severity. The degree of calcification was graded based on the arterial wall calcium deposit observed during fluoroscopy with none or mild; moderate, involving 1 side of the arterial wall; and severe, involving both sides of the arterial wall. Medina classification was used to classify bifurcation lesions with 1-0-0, involving CFA; 1-0-1, CFA and origin of profunda femoris artery (PFA); 1-1-0, CFA and origin of superficial femoral artery (SFA); and 1-1-1, involving CFA, origins of SFA and PFA.[16,17] A majority (>90%) of the interventions were performed by Dr Soukas, whereas few (<10%) were performed by Dr Hyder.

Exposure

Patients with angiographic CFA stenosis of >50% undergoing revascularization with either combined IVL-DCB or combined Ath-DCB were included. Patients in the Ath-DCB group were consecutively enrolled in the study from January 2015, and patients in the IVL-DCB group were consecutively enrolled after January 2018. CFA lesions requiring the use of stenting as a primary method for revascularization; combined use of IVL, DCB, and atherectomy; use of atherectomy alone, DCB alone, or IVL alone were excluded. Routine conventional balloon angioplasty before or after dilation was not performed as a definitive therapy in either group.

Atherectomy-DCB

Type and device of atherectomy used were at the discretion of the interventionalist. Orbital atherectomy was performed using 1.5- and/or 2.0-mm Diamondback 360 orbital atherectomy system (Cardiovascular Systems, Inc) while directional atherectomy was performed using SilverHawk (Medtronic) or HawkOne (Medtronic) systems. Distal embolic protection devices used were Emboshield NAV6 (Abbott) and SpiderFX (Medtronic). Adjunctive DCB was applied in all cases. The choice of paclitaxel-coated balloon (IN.PACT Admiral [Medtronic] or Lutonix [Bard Peripheral Vascular Inc]) was at the discretion of the interventionalist.

Intravascular lithotripsy-DCB

The peripheral IVL system (Shockwave Medical) consists of a generator, connector cable, and an IVL catheter that contains multiple lithotripsy emitters enclosed in an angioplasty balloon. Peripheral IVL catheters are available in diameters ranging from 3.5 mm to 7 mm (in 0.5-mm increments) and are 60 mm in length. The balloon is inflated to 4 atm using a solution of saline and contrast to achieve apposition to the vessel wall. The sonic impulses pass through the balloon to the vascular soft tissue, disrupting calcified plaque. Lithotripsy is administered in 30 pulse increments. Following lithotripsy treatment, balloon is inflated to 6 atm to maximize luminal gain. The cycle is then repeated as needed until desired results are obtained. Similar to the Ath-DCB group, adjunctive paclitaxel-DCB was performed in all cases, and choice of balloon used was at the discretion of the interventionalist, ie, IN.PACT Admiral, Lutonix, or Stellarex (Philips).

Outcomes

The primary outcome of interest was cumulative CD-TLR during the 18-month follow-up, which was defined as any endovascular or surgical revascularization for recurrent symptoms of lifestyle-limiting Rutherford class III claudication or CLTI with a target lesion angiographic restenosis of >50%. Secondary outcomes of interest were technical success, defined as residual angiographic stenosis <30% after the intervention, procedural complications including major dissection (National Heart, Lung, and Blood Institute C or higher) requiring stent placement, perforation, distal embolization, retained embolic protection device, or major amputation defined as amputation above the ankle.

Statistical analysis

Descriptive statistics are presented as mean (standard deviation) for continuous variables and proportion (percent) for categorical variables. Differences in demographics, comorbidities, lesion, and procedural characteristics between the 2 groups were compared using Student test and Wilcoxon rank-sum test for means and χ^2 and Fisher exact tests for proportions. Kaplan-Meier survival analysis was performed on CD-TLR during the 18-month follow-up, and Log-rank test was used to compare between-group differences in CD-TLR. Type 1 error (alpha) was set at 0.05. The research protocol was approved by the Miriam Hospital institutional review board committee. Statistical analysis was conducted using R Studio version 1.3.1073 (R Foundation for Statistical Computing) and SAS version 9.4 (SAS Institute).

Table 1. Baseline characteristics of patients by treatment type

	Ath-DCB (*n* = 30)	IVL-DCB (*n* = 30)	*P* value
Female sex	14 (46.7%)	8 (26.7%)	.108
Age, y	71.7 ± 7.49	73.2 ± 8.48	.471
Body mass index, kg/m^2	27.3 ± 6.11	29.7 ± 6.22	.146
Race			.972
White	28 (93.3%)	27 (90.0%)	
Black	2 (6.7%)	2 (6.7%)	
Smoking history	25 (83.3%)	26 (86.7%)	.717
Diabetes mellitus	11 (36.7%)	18 (60.0%)	.071
Hypertension	29 (96.7%)	29 (96.7%)	—
Coronary artery disease	20 (66.7%)	25 (83.3%)	.136
CKD stage 3	11 (36.7%)	7 (23.3%)	.259
Dyslipidemia	28 (93.3%)	28 (93.3%)	—
Stroke/TIA	7 (23.3%)	10 (33.3%)	.390
Symptoms on presentation			.541
Rutherford Class III	22 (73.3%)	24 (80.0%)	
CLTI	8 (26.7%)	6 (20.0%)	
Baseline ABI	0.65 ± 0.39	0.69 ± 0.289	.180

Values are mean ± standard deviation or *n* (%).

ABI, ankle-brachial index; Ath-DCB, atherectomy with drug-coated balloon angioplasty; CKD, chronic kidney disease; CLTI, chronic limb-threatening ischemia; IVL-DCB, intravascular lithotripsy with drug-coated balloon angioplasty; TIA, transient ischemic attack.

Table 2. Lesion and procedural characteristics

	Ath-DCB ($n = 35$)	IVL-DCB ($n = 33$)	P value
Artery intervened			
Right CFA	20 (57.1)	24 (72.7)	.284
Multivessel intervention	35 (100)	26 (78.8)	—
De novo lesions	35 (100)	25 (75.8)	—
Percent angiographic stenosis	78.4 ± 11.4	70.2 ± 10.2	.007
Chronic total occlusion	3 (8.6)	0 (0)	—
Calcification severity			.912
None/mild	6 (17.1)	7 (21.2)	
Moderate	11 (31.4)	10 (30.3)	
Severe	18 (51.4)	16 (48.5)	
Medina classification			.910
1-0-0 CFA	11 (31.4)	12 (36.4)	
1-0-1 CFA and origin of PFA	7 (20.0)	5 (15.2)	
1-1-0 CFA and origin of SFA	7 (20.0)	5 (15.2)	
1-1-1 CFA, origin of SFA and PFA	10 (28.6)	11 (33.3)	
Inflow disease requiring intervention			.639
None	14 (40.0)	15 (45.5)	
External iliac	10 (28.6)	12 (36.4)	
Common iliac	3 (8.6)	2 (6.1)	
External and common iliac	7 (20.0)	3 (9.1)	
Outflow disease requiring intervention			.002
None	4 (11.4)	6 (18.2)	
SFA	8 (22.9)	9 (27.3)	
PFA	12 (34.3)	3 (9.1)	
SFA and PFA	4 (11.4)	6 (18.2)	
SFA, PFA, and Pop	7 (20.0)	1 (3.0)	
SFA and Pop	0 (0)	7 (21.2)	
Reference CFA diameter, mm	6.07 ± 1.30	6.59 ± 1.43	.124
Lesion length, mm	29.8 ± 13.6	25.9 ± 10.3	.205
Lesion characteristic			.655
Concentric	20 (57.1)	20 (60.6)	
Eccentric	15 (42.9)	12 (36.4)	
Predilation performed	2 (5.7)	1 (3.0)	—
Lithotripsy balloon diameter, mm			
5.50		2 (6.06)	
6.00		8 (24.24)	
6.50		5 (15.15)	
7.00		18 (54.55)	
Number of IVL pulses	—	202 (111)	—
Length of DCB, mm	50.3 (17.1)	78.2 (33.2)	<.001
Diameter of DCB, mm			
5.00	2 (5.71)	0 (0)	.002
6.00	22 (62.86)	9 (27.27)	
7.00	11 (31.43)	24 (72.73)	
Embolic protection device	29 (83)	—	—
Below-the-knee runoffs			.474
1-vessel	2 (5.7)	1 (3.0)	
2-vessel	17 (48.6)	11 (33.3)	
3-vessel	15 (42.9)	17 (51.5)	
Type of atherectomy			
Orbital	8 (22.9)	—	—
Directional	10 (28.6)	—	
Combined orbital and directional	17 (48.6)	—	

Values are mean ± standard deviation or n (%).
Ath-DCB, atherectomy with drug-coated balloon angioplasty; CFA, common femoral artery; IVL-DCB, intravascular lithotripsy with drug-coated balloon angioplasty; PFA, profunda femoris artery; Pop, popliteal artery; SFA, superficial femoral artery.

Results

Baseline characteristics

A total of 68 CFA lesions in 60 patients were included. Baseline clinical characteristics of patients were similar between the 2 groups (Table 1). Most patients presented with lifestyle-limiting Rutherford class III claudication (Ath-DCB, 73%; $n = 22$ vs IVL-DCB, 80%; $n = 24$; $P = .541$). The mean baseline ABI between the 2 groups was similar (Ath-DCB, 0.65 ± 0.39 vs IVL-DCB, 0.69 ± 0.29; $P = .180$) (Table 1). All CFA lesions in the Ath-DCB group were de-novo lesions (Ath-DCB 100%, $n = 35$, vs IVL-DCB 76%, $n = 25$), and a multivessel intervention was common in both groups (Ath-DCB 100%, $n = 35$, vs IVL-DCB 79%, $n = 26$). The Ath-DCB group had a higher baseline mean angiographic stenosis (Ath-DCB, 78% stenosis vs IVL-DCB, 70%, $P = .002$) and consisted of all chronic total occlusion cases ($n = 3$). The proportion of severe calcification was similar between the 2 groups (Ath-DCB, 51%; $n = 18$ vs IVL-DCB, 49%; $n = 16$; $P = .912$), as was the distribution of bifurcation lesions according to Medina classification (Table 2). Lesion length, reference CFA diameter, and lesion characteristics along with the proportion of inflow and outflow disease requiring intervention are shown in Table 2.

Table 3. Primary and secondary outcomes

Primary outcome	Ath-DCB ($n = 35$) 18-mo KM estimate (95% CI)	IVL-DCB ($n = 33$) 18-mo KM estimate (95% CI)	Log-rank P value
KM freedom from CD-TLR	91.2% (81.6%, 100%)	79.4% (64.6%, 94.2%)	.166
Secondary outcomes	**n (%)**	**n (%)**	**Odds ratio (95% CI)**
Residual angiographic stenosis <30%	35 (100)	33 (100)	—
Procedural complications	2 (5.7)	1 (3.0)	0.52 (0.01-10.45)
Perforation	0 (0)	0 (0)	
Flow-limiting dissection requiring stent	0 (0)	1 (3.0)	
Bailout stenting	2 (5.7)	0 (0)	
Retained embolic device	0 (0)	0 (0)	

Ath-DCB, atherectomy with drug-coated balloon angioplasty; CD-TLR, clinically driven target lesion revascularization; CI, confidence interval; IVL-DCB, intravascular lithotripsy with drug-coated balloon angioplasty; KM, Kaplan-Meier.

Procedural characteristics

In the IVL-DCB group, lithotripsy balloon diameter used was 7.00 mm in 54% of cases ($n = 18$), and the length of IVL balloon was 60 mm in all cases (Table 2). Mean IVL pulses delivered were 202 ± 111. In the Ath-DCB group, combined directional and orbital atherectomy was performed in 49% ($n = 17/35$) of the CFA lesions, whereas 23% ($n = 8/35$) were orbital-only and 28% ($n = 10/35$) were directional-only atherectomies. An embolic protection device was used in 83% ($n = 29/35$) of Ath-DCB cases. The mean length of DCB used was higher in the IVL-DCB group than that in the Ath-DCB group (Ath-DCB, 50 ± 17 mm vs IVL-DCB, 78 ± 78 mm; $P < .001$) (Table 2).

Outcomes

Technical success was 100% in both groups. In the Ath-DCB group, 5.7% ($n = 2$) of CFA lesions required bailout stenting, whereas 3% ($n = 1$) of CFA lesion in the IVL-DCB group had flow-limiting dissection requiring stent placement (Table 3). Cumulative CD-TLR at the 18-month follow-up was 8.6% ($n = 3$) in the Ath-DCB group vs 18.2% ($n = 6$) in the IVL-DCB group (Table 4.) Kaplan-Meier freedom from CD-TLR (shown in Figure 1) was 91.2% (95% CI, 81.6%-100%) in the Ath-DCB group vs 79.4% (95% CI, 64.6%-94.2%) in the IVL-DCB group (log-rank $P = .167$). Two out of

Table 4. Cumulative CD-TLR at 6-, 12- and 18-month follow-up

	Ath-DCB ($n = 35$)	IVL-DCB ($n = 33$)	Overall ($N = 68$)
6 mo	1 (2.9%)	2 (6.1%)	3 (4.4%)
12 mo	2 (5.7%)	6 (18.2%)	8 (11.8%)
18 mo	3 (8.6%)	6 (18.2%)	9 (13.2%)

Ath-DCB, atherectomy with drug-coated balloon angioplasty; CD-TLR, clinically driven target lesion revascularization; IVL-DCB, intravascular lithotripsy with drug-coated balloon angioplasty.

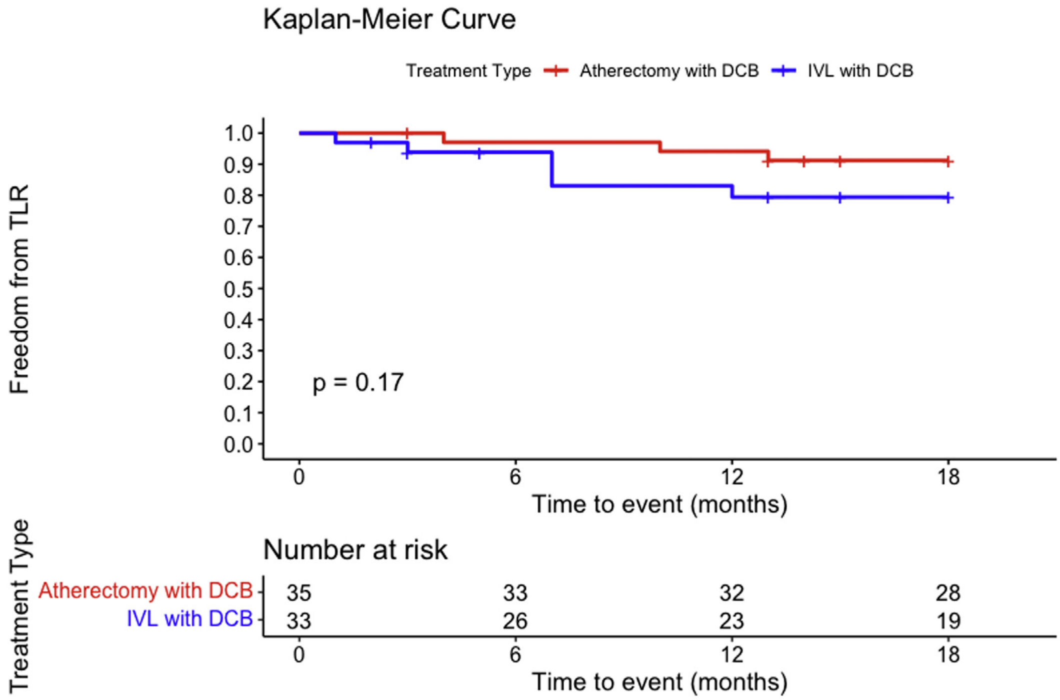


Figure 1. Freedom from clinically driven target lesion revascularization by treatment group. DCB, drug-coated balloon angioplasty; IVL, intravascular lithotripsy; TLR, target lesion revascularization.

30 patients (6.6%) died, and 2 of 30 patients (6.6%) were lost to follow-up at 18 months in the Ath-DCB group; in the IVL-DCB group, 6 of 30 patients (20%) died, and 2 of 30 patients (6.6%) were lost to follow-up (see Central Illustration). None of the deaths were related to procedural complications. Most of the deaths in the IVL-DCB group occurred within 6 months of procedure, mainly due to poor prognosis from a terminal illness. There was statistically significant improvement in mean ABI from baseline at 6 and 12 months within each group, and the improvement in ABI was found to be similar between the 2 groups (Table 5 and Figure 2). Peaked systolic velocity ratios measured by routine arterial duplex ultrasound at 6 and 12 months after the procedure were not significantly different between the 2 groups (Table 5). Among patients who did not require revascularization, 10% ($n = 3$) in each group had Rutherford class III claudication symptoms at 18 months.

Discussion

In the first study to compare DCB with adjunctive IVL vs DCB with adjunctive atherectomy for the treatment of calcified CFA disease, we found that technical success and 18-month cumulative CD-TLR were similar between the 2 groups.

CFA lesions are often heavily calcified, frequently accounting for low patency rates with percutaneous endovascular treatment.[18,19] Previous studies have investigated the effectiveness of different endovascular therapies in the treatment of CFA disease. When investigating conventional percutaneous transluminal angioplasty as a primary treatment, Bonvini et al[4] found 1-year TLR of 20%; however, stenting was performed in 37% of CFA lesions due to suboptimal results produced by angioplasty. Similarly, the primary patency with percutaneous transluminal angioplasty alone was lower than that with atherectomy (67% vs 87%; $P = .043$) at 4-year follow-up in a study by Guo et al.[6] Stavroulakis et al[7] compared DCB alone with combined Ath-DCB in CFA disease and found that freedom from TLR was 89% in the Ath-DCB group vs 75% in the DCB-only group ($P = .98$) at 1-year follow-up. In the DEFINITIVE-AR trial of femoropopliteal disease, TLR rate at 12 months was found to be 7.3% for Ath-DCB vs 8% with DCB-only ($P = .9$), while bailout stenting was 3.7% and flow-limiting dissection requiring stent placement was 19% in the DCB-only group vs only 2% in the Ath-DCB group ($P = .01$). When compared to the study by Stavroulakis et al, the relatively low TLR rate of 8% with DCB-only treatment in the DEFINITIVE-AR trial could have been due to a higher proportion of stent usage for bailout stenting and flow-limiting dissections in the DCB-only group.[7,20] Atherectomy is useful in mechanically debulking heavily calcified atherosclerotic plaques from the vessel's intimal layer and is usually combined with balloon angioplasty with the goal of minimizing plaque shift and avoiding stent placement.[21] However, in a study by

Table 5. Baseline ABI, follow-up ABI, and mean of differences in ABI from baseline

	Ath-DCB ($n = 35$)	IVL-DCB ($n = 33$)	P value[b]
Baseline ABI, n (%)	24 (69)	28 (85)	
ABI	0.65 ± 0.39	0.69 ± 0.289	.180
6-mo ABI, n (%)	25 (71)	17 (52)	
ABI	0.85 ± 0.40	0.86 ± 0.42	.581
Difference from baseline	0.17 ± 0.25	0.19 ± 0.29	.526
P value[a]	.011	.026	
12-mo ABI, n (%)	19 (54)	11 (33)	
ABI	0.81 ± 0.34	0.98 ± 0.41	.188
Difference from baseline	0.20 ± 0.28	0.20 ± 0.25	.952
P value	.014	.039	
PSVR at 6 mo after intervention, n (%)	25 (71.4)	13 (39.3)	
Mean ± standard deviation	1.29 ± 0.523	1.35 ± 0.901	.832
Median [minimum, maximum]	1.25 [0.510, 2.57]	1.10 [0.660, 4.20]	
PSVR at 12 mo after intervention, n (%)	23 (65.7)	10 (30.3)	
Mean ± standard deviation	1.65 ± 2.55	1.22 ± 0.491	.446
Median [minimum, maximum]	1.07 [0.360, 13.2]	1.20 [0.570, 2.20]	

[a] P value for difference in means within the same group.
[b] P value to compare difference in means between the two groups.
Values are mean ± standard deviation or median [minimum, maximum] unless otherwise noted.
ABI, ankle-brachial index; Ath-DCB, atherectomy with drug-coated balloon angioplasty; IVL-DCB, intravascular lithotripsy with drug-coated balloon angioplasty; PSVR, peaked systolic velocity ratio.

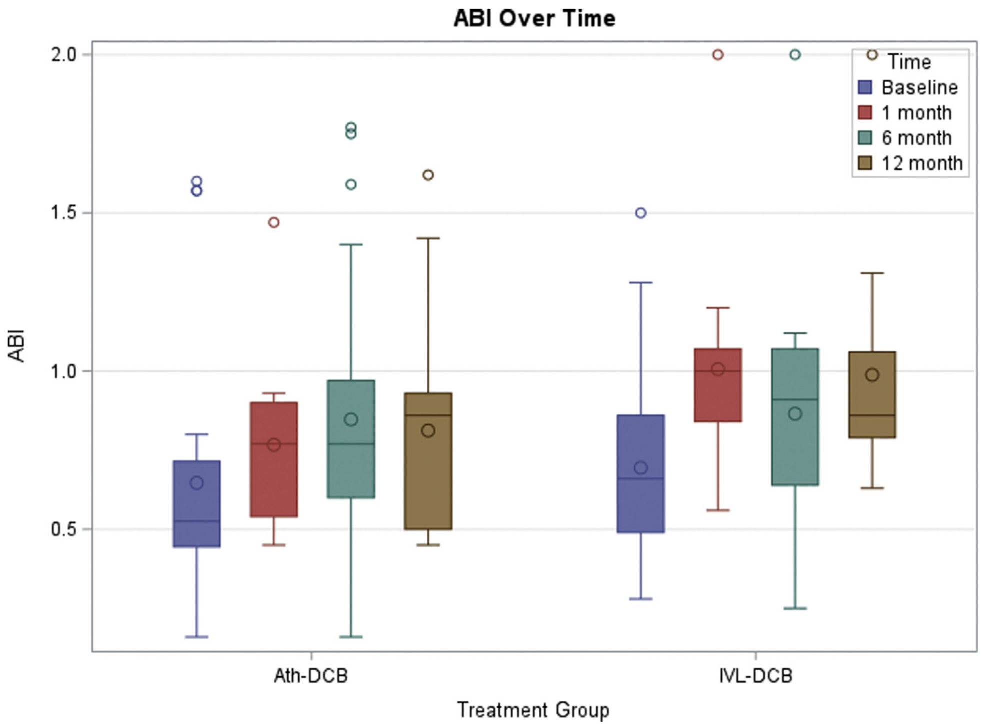
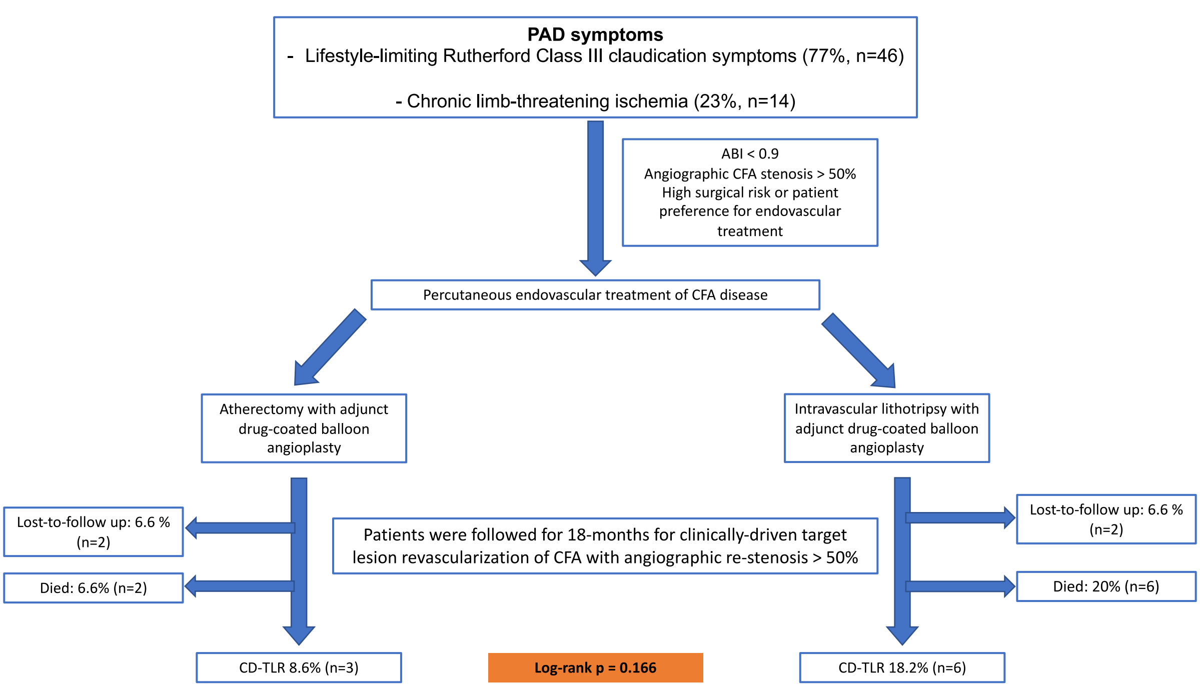


Figure 2. Ankle-brachial index (ABI) over a 12-month duration. Ath-DCB, atherectomy with drug-coated balloon angioplasty; IVL-DCB, intravascular lithotripsy with drug-coated balloon angioplasty.

Rocha-Singh et al,[22] atherectomy was associated with removal of more than 1 vessel wall layers, with tunica adventitia seen in about 39% of histological samples. While the role of DCB for the treatment of symptomatic peripheral arterial disease is well established, when used alone in heavily calcified disease, it has poor technical success and patency.[23] We found that IVL when used adjunctively with DCB has a CD-TLR similar to that of the Ath-DCB group during the 18-month follow-up, with minimal to no stent placement required in the IVL-DCB group. Cumulative CD-TLR of 18% at the 18-month follow-up in our IVL study group is comparable to the CD-TLR of 21% at 12 months in the Disrupt PAD II observational study where IVL-only intervention was performed in SFA and popliteal lesions.[12]

IVL works by fracturing calcium by delivering sonic pressure waves to the intimal and medial layers of the vessel wall, thereby increasing luminal gain while also improving drug delivery to the vessel wall when used in conjunction with DCB.[12] It is notable that IVL in this study was performed using a first-generation device capable of delivering up to 150 pulses per catheter, whereas second-generation M5 devices can deliver up to 300 pulses per catheter and has a higher luminal diameter of up to 8 mm. It is our speculation that the second-generation M5 IVL catheter



Central Illustration. Schematic presentation of study outcomes.

would have contributed to improved outcomes in vessels of higher diameter if used in our study. Technical success was 100% in both groups, considering a low stent placement rate in both groups. We found that the risk of dissection and need for bailout stenting were negligible with DCB and adjunct IVL or adjunct atherectomy use. Although the baseline angiographic stenosis and number of chronic total occlusion lesions were higher in the Ath-DCB group than those in the IVL-DCB group, calcification severity, presence of bifurcation lesions, and lesion length were similar between the 2 groups (Table 2). Lesion length, severity of calcification, and bifurcation lesions involving the origin of PFA in femoropopliteal artery disease are strong predictors of dissection, stenting, technical failure, and poor durability with endovascular therapy.[17,23-25]

Surgical treatment of symptomatic CFA disease with common femoral endarterectomy has excellent 5-year patency rates; however, it is associated with higher morbidity and mortality (>3%) and longer hospital stay.[3] While endovascular treatment with stenting for the treatment of CFA stenosis has been associated with 1-year patency rates comparable to surgical endarterectomy,[5,26,27] it is associated with stent fracture secondary to high mobility at the hip joint and risk of compromising access to downstream vessels. Recently, a TECCO randomized trial has shown promising results with the use of a self-expandable stent in CFA disease (67% self-expandable stents and 33% balloon-expandable stents were used in the study) when compared to surgical endarterectomy. Stent use was associated with relatively lower short- and long-term complications and essentially similar TLR at 24 months when compared to surgery.[27,28] It remains unclear if the combined use of atherectomy, IVL, and DCB in heavily calcified CFA disease will have similar safety and effectiveness when compared to stenting and/or surgery alone. Further studies are required to investigate the multimodality endovascular intervention in the treatment of heavily calcified CFA disease.

Limitations

Our study has some limitations. It is a single-center, retrospective observational study, and therefore, results may not be generalizable and causal inference cannot be established. Due to the small sample size, this study is likely underpowered. Lesion characteristics and procedural success were based on operator's reporting without central core lab adjudication. Atherectomy device and DCB selection were at the discretion of the operator; therefore, bias in device selection cannot be ruled out. Finally, the difference in enrollment time between the 2 groups is notable, where patients in the Ath-DCB group were enrolled earlier than those in the IVL-DCB group. This may have contributed to lead-time bias, which may explain the higher CD-TLR in the IVL-DCB group; however, it remained statistically insignificant.

Conclusion

Our study did not find statistically significant difference in short-term and midterm safety and effectiveness between IVL and atherectomy for the treatment of calcified CFA disease when used adjunctively with DCB. Future studies with a larger sample size and longer duration of follow-up are required to confirm these findings.

Declaration of competing interest

Dr Soukas is a site principal investigator for Shockwave Medical. Dr Aronow is on the data safety and monitoring board for the Philips ILLUMENATE studies. All other authors have no declaration of interests. The authors received no specific funding for this work.

Ethics statement

The research reported here has adhered to the relevant ethical guidelines.

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