Regence

Medical Policy Manual Surgery, Policy No. 233

Intravascular Lithotripsy

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Intravascular lithotripsy is used to prepare stenotic, calcified vessels for stent placement. Ultrasound waves are applied intravascularly to selectively break-up calcium deposits to aid with stent placement.

MEDICAL POLICY CRITERIA

Intravascular lithotripsy is considered **investigational** for all indications.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. New and Emerging Medical Technologies and Procedures, Medicine, Policy No. 149

BACKGROUND

Shockwave intravascular lithotripsy (IVL) utilizes a percutaneous catheter device to produce acoustic pressure waves to break superficial and deep calcium deposits and aid with the subsequent deployment of a vascular stent. Guidance with an intravascular imaging device either with intravascular ultrasound or optical coherence tomography (OCT) is used to define calcium density and to aid in choosing the lesion modification strategy. There are several adjunctive therapies to aid in the modification of calcified plaques in order to facilitate stent delivery. These include rotational atherectomy (RA), scoring, cutting and super high-pressure balloons, orbital atherectomy (OR), laser atherectomy (LA) and IVL.[1]

REGULATORY STATUS

In 2021, The US Food and Drug administration (FDA) granted Premarket Approval (PMA) for the Shockwave Intravascular Lithotripsy (IVL) System with Shockwave C2 Coronary Intravascular Lithotripsy (IVL) Catheter (Product code QMG, PMA number P200039).[2]

The Shockwave Intravascular Lithotripsy (IVL) System with Shockwave C2 Coronary IVL Catheter is indicated for lithotripsy-enabled, low-pressure balloon dilatation of severely calcified, stenotic *de novo* coronary arteries prior to stenting.[3]

The Peripheral IVL System (M5+) Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave L6 Peripheral IVL Catheter received FDA clearance on April 22, 2021. This device is intended for lithotripsy-enhanced balloon dilatation of lesions, including calcified lesions, in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries. Not for use in the coronary or cerebral vasculature. (K221852)

The Shockwave E8 Peripheral IVL Catheter received FDA clearance on September 2024 for treating calcified femoropopliteal and below-the-knee peripheral artery disease and chronic limb-threatening ischemia (CLTI).

EVIDENCE SUMMARY

CORONARY INTRAVASCULAR LITHOTRIPSY (IVL)

Systematic Reviews

Lingamsetty (2025) published a systematic review and meta-analysis examining the safety and efficacy of intravascular lithotripsy (IVL) during percutaneous coronary intervention (PCI) of calcified left main coronary artery disease.[4] The analysis included 10 studies with 435 patients (mean age 73.1 years, 73.1% males). The pooled procedural success rate was 98.8% (95% CI 95.58-100). Procedural complications included perforation 0.02% (95% CI 0.00-0.87), major dissection 0.87% (95% CI 0.00-3.97), slow-flow/no-reflow 0.27% (95% CI 0.00-1.47), and abrupt vessel closure 0.01% (95% CI 0.00-1.01). In-hospital cardiovascular events included major adverse cardiovascular events (MACE) 2.14% (95% CI 0.64-4.21), death 0.96% (95% CI 0.00-2.98), cardiovascular death 0.46% (95% CI 0.00-2.17), myocardial infarction (MI) 0.94% (95% CI 0.04-2.56), stent thrombosis 0.99% (95% CI 0.00-6.14), and target vessel revascularization 0% (95% CI 0.00-0.32). Thirty-day outcomes were MACE 4.79% (95% CI 1.51-9.35), mortality 3.09% (95% CI 0.00-9.69), and MI 2.25% (95% CI 0.45-4.95).

Sagris (2025) published a systematic review and meta-analysis evaluating the efficacy and safety of IVL in managing under expanded stents.[5] The analysis comprised 23 studies including 819 patients and 837 treated lesions (mean age 71.7 ± 8.8 years). The overall IVL procedural success rate was 92% (95% CI: 88%-95%, I2 = 35%). In-hospital-30-day mortality was 1% (95% CI: 1%-3%, I2 = 0%) and long-term mortality was 4% (95% CI: 2%-6%, I2 = 0). The 30-day rates of acute myocardial infarction and stroke were each 1% (95% CI: 0%-1%, I^2 = 0% and 95% CI: 0%-2%, I2 = 0%, respectively). No short-term target lesion revascularization

(TLR) was observed, while long-term rates were 6% (95% CI: 3%-10%, I2 = 48%). Angiographic and imaging data showed significant improvement: stent diameter stenosis decreased (SMD: -3.57, 95% CI: -4.64 to -2.44%, I2 = 94%), minimal stent area increased (SMD: +1.98, 95% CI: 0.86-3.09, I2 = 93%), minimal lumen diameter increased (SMD: +2.68, 95% CI: 1.94-3.41, I2 = 90%), and minimal lumen area increased (SMD: +1.92, 95% CI: 1.46-2.38, I2 = 69%). Major procedural and device-related complications were 2% (95% CI: 1%-5%, I2 = 0%) and 1% (95% CI: 0%-2%, I2 = 80%), respectively. Rates of stent thrombosis, dissections, and perforations were each 1%, with no-reflow at 0%.

Eri (2025) published a systematic review and meta-analysis assessing the immediate and midterm efficacy and safety of IVL for calcified in-stent restenosis (ISR).[6] The analysis included 5 studies with 207 patients and 212 treated lesions. Acute procedural success was 85% (95% CI 0.76-0.91, I^2 = 42.0%). At 1-year follow-up, major adverse cardiac events included myocardial infarction in 6% of patients (95% CI 0.02-0.16, I^2 = 52.5%), target lesion revascularization in 13% (95% CI 0.08-0.20, I^2 = 45.8%), and cardiac death in 4% (95% CI 0.02-0.08, I^2 = 0.0%). The rate of periprocedural MI was 1.5% (95% CI 0.01-0.05, I2 = 0.0%), while no-reflow phenomenon occurred in 0.5% (95% CI 0.01-0.06, I2 = 0.0%), with no other procedural complications reported. The overall incidence of MACE was 16% (95% CI 0.07-0.33, I^2 = 69.8%). Limitations included the small number of studies, relatively short follow-up period, and high heterogeneity in MACE outcomes.

Suruagy-Motta (2025) published a systematic review and meta-analysis comparing intravascular lithotripsy (IVL) with rotational atherectomy (RA) for calcified coronary lesions.[7] The study included 11 studies with 2120 patients. Intravascular lithotripsy demonstrated reduced contrast use (mean difference -17.45 mL), shorter procedural time (mean difference -27.90 minutes), and lower rates of complications. While luminal gain showed no significant differences between groups (mean difference -0.07 mm^2), IVL provided higher rates of stent deployment success and lower target lesion revascularization. The meta-analysis for mortality showed a pooled odds ratio of 0.55 under the common-effect model and 0.70 under the random-effects model, with negligible heterogeneity.

Moghadam (2025) published a systematic review and meta-analysis comparing IVL with RA in calcific coronary lesions.[8] The study included 14 studies (two randomized controlled trials and 12 observational studies) with 2056 IVL patients and 3099 RA patients. Intravascular lithotripsy and RA showed comparable risk of major adverse cardiovascular events (odds ratio 0.81) and similar risks of all-cause mortality, myocardial infarction, stroke, and repeat revascularization. However, IVL was associated with a lower risk of coronary perforation (odds ratio 0.43) and slow or no-reflow (odds ratio 0.34). Additionally, IVL resulted in shorter procedure duration and fluoroscopy time. Post-procedural minimum stent area was similar between IVL and RA.

Sagris (2024) published a SR with meta-analysis evaluating the safety and efficacy of intravascular lithotripsy (IVL) for lesion preparation in severely calcified coronary arteries before stenting. [9]The study included 38 studies with 2977 patients, with a mean age of 72.2 years. The mean age was 72.2 ± 9.1 years, with an overall IVL clinical success of 93% (95% confidence interval [CI]: 91%-95%, I2 = 0%) and procedural success rate of 97% (95% CI: 95%-98%, I2 = 73.7%), while the in-hospital and 30-days incidence of MACE, myocardial infarction (MI), and death were 8% (95% CI: 6%-11%, I2 = 84.5%), 5% (95% CI: 2%-8%, I2 = 85.6%), and 2% (95% CI: 1%-3%, I2 = 69.3%), respectively. There was a significant increase in the vessel diameter (standardized mean difference [SMD]: 2.47, 95% CI: 1.77 3.17, I2 = 96%) and a decrease in diameter stenosis (SMD: -3.44, 95% CI: -4.36 to -2.52, I2 = 97.5%) immediately after IVL application, while it was observed further reduction in diameter stenosis (SMD: -6.57, 95% CI: -7.43 to -5.72, I2 = 95.8%) and increase in the vessel diameter (SMD: 4.37, 95% CI: 3.63-5.12, I2 = 96.7%) and the calculated lumen area (SMD: 3.23, 95% CI: 2.10-4.37, I2 = 98%), after stent implantation. The mean acute luminal gain following IVL and stent implantation was estimated to be 1.27 ± 0.6 and 1.94 ± 1.1 mm, respectively. Limitations include high heterogeneity in the results (I2 values ranging from 69.3% to 98%), retrospective studies that lacked direct comparisons with other lesion preparation strategies.

Sheikh (2023) published a systematic review evaluating the efficacy and feasibility of intravascular lithotripsy (IVL) in treating severe coronary calcification.[10] The study included 62 publications with 1389 patients (1414 lesions) who underwent IVL. The results showed significant improvements in vessel patency, with a mean minimal lumen diameter of 2.78±0.46 mm and an acute gain of 1.72±0.51 mm. The acute procedural success rate ranged from 78.2% to 100%, with an in-hospital complication rate of 5.6% to 7.0%. The 30-day major adverse cardiovascular events (MACE) rate ranged from 2.2% to 7.8%. The authors conclude that there is a need to evaluate the long-term efficacy and safety of IVL compared to other calcium modification techniques, such as conventional balloons, cutting or scoring balloons, rotational atherectomy, and laser atherectomy.

Caminiti (2023) published a systematic review with meta-analysis to investigate the success rate of IVL for the treatment of stent under expression (SU) because of coronary calcified plaque.[11] The meta-analysis included 13 studies with 354 patients, majority male (77%). The mean follow-up time was 2.6 months (95% CI 1 to 15.3). Strategy success was seen in 88.7% (95% CI 82.3 to 95.1) of patients. The mean minimal stent area was reported in 6 studies, the pre-IVL value was 3.4 mm2 (95% CI 3 to 3.8), and the post-IVL value was 6.9 mm2 (95% CI 6.5 to 7.4). The mean diameter stenosis (percentage) was reported in seven studies, the pre-IVL value was 69.4% (95% CI 60.7 to 78.2), and the post-IVL value was 14.6% (95% CI 11.1 to 18). The rate of intraprocedural complications was 1.6% (95% CI 0.3 to 2.9). The authors concluded that the “stent through” technique was safe to treat SU.

Mhanna (2022) published a systematic review evaluating the utility of adjunctive IVL.[12]The study included a total of eight single-arm observational studies, including 980 patients (1011 lesions), were included. 48.8% of the patients presented with acute coronary syndrome. Severe calcifications were present in 97% of lesions. Clinical success was achieved in 95.4% of patients (95%CI:92.9%-97.9%). Angiographic success was achieved in 97% of patients (95%CI:95%-99%). There was an overall increase in postprocedural lumen area as well as significant reduction of calcium angle and maximum calcium thickness.

Most of the evidence of safety and effectiveness of Coronary IVL extends from the four prospective, nonrandomized, single arm, manufacturer sponsored, multisite DISRUPT CAD studies: Disrupt CAD I (NCT02650128); Disrupt CAD II (NCT03328949); Disrupt CAD III; and Disrupt CAD IV (NCT04151628). The following publications (systematic review with meta-analysis, meta-analysis, and a pooled analysis) discuss the results of these, as well as retrospective registry studies.[13-15]

Satter (2022) published a meta-analysis for IVL outcomes in severely calcified coronary lesions.[13] The primary outcomes included clinical and angiographic success event ratios. The secondary outcomes included minimal lumen diameter (MLD), diameter stenosis (DS), lumen area, maximum calcium thickness, and calcium angle at minimal lumen area (MLA) and final minimal stent area (MSA). A total of seven studies (n = 760) were included. The DISRUPT CAD I – IV, a subgroup analysis of the DISRUPT CAD I study, and two registry (retrospective cohort analysis) studies. The primary outcomes: pooled clinical and angiographic success event ratio parentage of IVL was 94.4 % and 94.8 %, respectively. On a random effect model for standard inverse variance for secondary outcomes showed: minimal lumen diameter increase with IVL was 4.68 mm ($p < 0.0001$, 95 % CI: 1.69 to 5.32); diameter decrease in the stenotic area after IVL session was -5.23 mm (95 % CI: -22.6 to 12.8). At the MLA and final MSA sites, MLA gain was 1.42 mm2 (95 % CI: 1.06 to 1.63; $p < 0.00001$) and 1.34 mm2 (95 % CI: 0.71 to 1.43; $p < 0.00001$), respectively. IVL reduced calcium thickness at the MLA site (SMD -0.22; 95 % CI: -0.40 to 0.04; $p = 0.02$); calcium angle was not affected at the MLA site. The tertiary outcomes: most common complication was MACEs (n = 48/669), and least common complication was abrupt closure of the vessel (n = 1/669). The analysis was limited by inclusion of only single-arm observational studies. Only two studies reported diameter stenosis data. The post procedural outcomes did not include any form of adjunctive treatment (atherectomy or specialty cutting balloons). The authors suggest that more studies, including randomized, double-blind trials, are needed to study safety and efficacy in a head-to-head comparison with other debulking procedures.

Kereiakes (2021) published a pooled safety and effectiveness results from the four DISRUPT CAD I-IV studies.[14] Data was included from patients (n = 628) enrolled in 72 sites from 12 countries. The primary safety endpoint was a composite score of cardiac death, all myocardial infarction, or target vessel revascularization at 30 days. Procedural success was defined as stent delivery with a residual stenosis of >= 30% assessed by quantitative coronary angiography and without in-hospital major adverse CV events. The primary safety and effectiveness endpoints were achieved in 92.7% and 92.4% of patients, respectively. The rate of in-hospital major adverse cardiovascular events was 6.5% (4.7% to 8.8%), driven by non-Q-wave myocardial infarction (5.7%, 4.1% to 7.9%). The rate of 30-day major adverse cardiovascular events was 7.3% (5.4% to 9.7%), also driven by non-Q-wave myocardial infarction (5.9%, 4.2% to 8.1%). At 30 days, the rates of target lesion failure, cardiac death, and stent thrombosis were 7.2%, 0.5%, and 0.8%, and rates of postprocedure and final serious angiographic complications were 2.1% and 0.3%, respectively, with no procedure associated perforations, abrupt closure, or episodes of no reflow, suggesting procedural success in treating both eccentric and concentric calcified lesions. Results of multivariate logistic regression show that treatment of bifurcation lesion ($p = 0.006$), prior myocardial infarction ($p = 0.04$), and lesion length ≥ 25 mm ($p = 0.049$) were independent predictors of 30-day major adverse cardiovascular events. Prior myocardial infarction ($p = .016$) and treatment of bifurcation lesion ($P = .015$) were predictors of lack of procedural success. Several of the authors of this analysis have professional affiliations with the device manufacture.

Sattar (2021) published a SR with meta-analysis examining the safety and efficacy of coronary IVL for left coronary calcified disease (LCAD).[15]They included four studies in their analysis (n = 282 patients) including results from the Disrupt CAD I and CAD II trials. In LCAD, ICL can yield lumen gain of up to 4.16 mm. The overall post-procedure lumen diameter was significantly higher than the pre-procedure diameter. The authors concluded that IVL offer a significant improvement in the vessel lumen to facilitate coronary stent delivery and deployments in severely calcified coronary arteries. They also indicated recommended that there is a need for randomized controlled trials and longer-term follow-up before recommending the routine use of Coronary Intravascular Lithotripsy.

Randomized Controlled Trials

Jurado-Román (2025) published a randomized controlled trial comparing RA, IVL, and excimer laser coronary angioplasty for treating calcified coronary stenosis.[16] The study enrolled 171 patients (77.2% male, mean age 70.9 years) with moderate to severe calcified coronary lesions, randomizing 57 patients to each treatment arm. The primary endpoint was percentage of stent expansion measured by optical coherence tomography. Intravascular lithotripsy was noninferior to rotational atherectomy in stent expansion (85.6% vs 86.4%, p = 0.77), while excimer laser coronary angioplasty did not reach the noninferiority margin in intention-to-treat analysis. Final minimum stent area was similar across all three groups (rotational atherectomy 5.5 mm², intravascular lithotripsy 5.4 mm², excimer laser coronary angioplasty 5.1 mm²), with procedural success rates comparable among arms. Complication rates were low across all groups with no significant differences.

Pleva (2025) published a prospective randomized study comparing IVL to RA as adjunctive therapy before drug-eluting stent implantation in calcified coronary lesions.[17] The study enrolled 50 patients with 52 calcified lesions, randomized 1:1 to IVL or RA followed by drug-eluting stent implantation. The primary endpoint was procedural success, with secondary endpoints including 12-month late lumen loss, binary in-stent restenosis, major adverse cardiac events, and target lesion failure. Procedural success was achieved in 84.0% of the intravascular lithotripsy group and 96% of the rotational atherectomy group (p = 0.349). At 12 months, late lumen loss was 0.12 mm in the intravascular lithotripsy group versus 0.61 mm in the rotational atherectomy group (p = 0.084), with no significant differences in binary in-stent restenosis (11.1% vs 8.0%), major adverse cardiac events (18.5% vs 8.0%), target lesion revascularization (14.8% vs 8.0%), or target lesion failure (18.5% vs 8.0%).

Basile (2025) published a one-year follow-up analysis of the ROLLER COASTER-EPIC22 randomized trial comparing RA, IVL, and excimer laser coronary angioplasty for calcified coronary stenosis.[18] The study included 171 patients (77.2% male, mean age 70.9 years) with angiographic moderate to severe calcified coronary lesions, with 57 patients randomized to each treatment arm. The primary endpoint was major adverse cardiovascular events (MACE) at one year, defined as cardiac death, target vessel myocardial infarction, target lesion revascularization, target vessel revascularization, and stent thrombosis. At one year, there were no significant differences in MACE among the three arms (rotational atherectomy 5.3%, intravascular lithotripsy 5.3%, excimer laser coronary angioplasty 3.5%, p = 0.88). All-cause death showed no significant differences between groups (p=0.22), with no events in the intravascular lithotripsy group (rotational atherectomy 5.3%, intravascular lithotripsy 0%, excimer laser coronary angioplasty 5.3%). No significant differences were observed among the three arms for target vessel myocardial infarction (p = 0.61), target vessel revascularization (p = 0.59), target lesion revascularization (p = 1.00), or stent thrombosis (p = 0.61).

Wong (2025) published a randomized controlled trial comparing balloon angioplasty versus IVL for pretreatment of severely calcified coronary lesions prior to drug-eluting stent implantation.[19] The study included 60 patients randomly assigned 1:1 to conventional balloon angioplasty (n=27) or intravascular lithotripsy (n=33) groups. Procedural success was achieved in 55.6% of the balloon angioplasty group versus 72.7% of the intravascular lithotripsy group (p=0.165), with no significant difference in in-hospital major adverse cardiovascular events (96.3% vs 90.9%, P=.405). However, the balloon angioplasty group required significantly more bailout calcium modification devices (22.2% vs 0.0%, p=0.004).

Blatchutzik (2024) published a randomized, prospective, double-arm multi-center non-inferiority trial that compared the use of intravascular lithotripsy (IVL) and rotational atherectomy (RA) in treating coronary calcified nodules (CNs) using optical coherence tomography (OCT).[20] The sub analysis of the ROTA shock trail (described below) included 19 patients with CNs detected by OCT in the target lesion, who were treated with either IVL or RA. The results showed that both IVL and RA were unable to reduce the volume of the calcified plaque, with no significant difference in nodule volume between native and final OCT scans (RA: 0.66 ± 0.12 mm3 vs. 0.61 ± 0.33 mm3, p = 0.68; IVL: 0.64 ± 0.19 mm3 vs. 0.68 ± 0.22 mm3, p = 0.74). However, the study found that the angle and thickness of the CNs were significantly reduced after both IVL and RA treatment, with a mean angle of CNs increasing from 68 ± 7° to 92 ± 17° after RA (p = 0.01) and from 60 ± 10° to 89 ± 18° after IVL (p = 0.03). The thickness of CNs also decreased significantly after both treatments, from 38.6 ± 13.1 mm to 17.8 ± 7.8 mm after RA (p = 0.02) and from 37.2 ± 14.3 mm to 16.5 ± 9.0 mm after IVL (p = 0.02). The authors conclude that RA or IVL are unable to reduce the volume of the calcified plaque. Calcified nodule modulation seems to be mainly induced by the stent implantation and not by RA or IVL.

Two studies published in 2023 reported the results of the ROTA shock trial.[21, 22] The ROTA shock study is a randomized, prospective, non-blinded, double-arm, multicenter non-inferiority trial. Patients (n=70) were randomly (1:1) assigned to undergo either IVL or rotational atherectomy (RA) before percutaneous coronary intervention of severely calcified coronary lesions. The mean patient age was 73.3 ± 7.2 years, and the majority were male (75.4%). The primary endpoint minimal stent area (MSA) was lower but non-inferior after IVL (mean: 6.10 mm^2 , 95% confidence interval [95% CI]: 5.32-6.87 mm^2) versus RA (6.60 mm^2 , 95% CI: 5.66-7.54 mm^2 ; difference in MSA: -0.50 mm^2 , 95% CI: -1.52-0.52 mm^2 ; non-inferiority margin: -1.60 mm^2). Stent expansion was similar (RA: 0.83 ± 0.10 vs. IVL: 0.82 ± 0.11; p = 0.79). There were no significant differences regarding contrast media consumption (RA: 183.1 ± 68.8 vs. IVL: 163.3 ± 55.0 mL; p = 0.47), radiation dose (RA: 7269 ± 11288 vs. IVL: 5010 ± 4140 cGy cm^2; p = 0.68), and procedure time (RA: 79.5 ± 34.5 vs. IVL: 66.0 ± 19.4 min; p = 0.18). Two patients randomized to IVL were required to crossover to the RA group. In addition to small sample size and gender bias, limitations included a lower threshold for non-inferiority than originally predicted and the baseline vessel dimensions and reference vessel area in final OCT scans were larger in the RA than in the IVL group, leading to a bias for the comparison of MSA between these two groups.[21] An additional evaluation of the ROTA shock trial compared plaque modification of severely calcified lesions by coronary intravascular lithotripsy (IVL) with that of rotational atherectomy (RA) using optical coherence tomography (OCT). They concluded that RA leads to a greater acute lumen gain, IVL induces more and longer fractures of the calcified plaque.[22]

A 2023 prospective single center randomized study to investigate if pre-treatment with IVL in severely calcified lesions increases stent expansion, assessed by optical coherence tomography (OCT), when compared to predilatation with conventional and/or specialty balloon strategy.[23] A total of 40 patients were included. The minimal stent expansion in the IVL-group (n = 19) was 83.9 ± 10.3% and 82.2 ± 11.5% in the conventional group (n = 21) (p = 0.630). Minimal stent area was 6.6 ± 1.5 mm^2 and 6.2 ± 1.8 mm^2, respectively (p = 0.406). No peri-procedural, in-hospital and 30-day follow-up major adverse cardiac event (MACE) were reported. The authors concluded that in severely calcified coronary lesions there were no significant difference in stent expansion measured by OCT when comparing IVL, as plaque modification, with conventional and/or specialty angioplasty balloons.

Section Summary

Coronary intravascular lithotripsy (IVL) is a relatively new technology for treating calcified coronary lesions, with an evolving evidence including recent randomized controlled trials and systematic reviews. Early evidence primarily derived from four prospective, nonrandomized, single-arm, manufacturer-sponsored DISRUPT CAD studies, included predominantly male subjects. Recent randomized controlled trials have demonstrated that IVL is noninferior to rotational atherectomy (RA) in stent expansion, procedural success, and clinical outcomes, with comparable rates of major adverse cardiovascular events at one year. Multiple meta-analyses have demonstrated that IVL and RA have similar efficacy in terms of luminal gain and major adverse cardiovascular events. IVL offers potential advantages including lower rates of coronary perforation and slow/no-reflow**,** reduced contrast use, shorter procedural times, and high procedural success rates (92-98.8%) across various clinical scenarios including left main disease and in-stent restenosis. Limitations include predominantly male study populations, relatively small sample sizes in RCTs, need for longer-term follow-up data, and the need for additional adequately powered randomized controlled trials comparing IVL to other calcium modification techniques such as conventional balloons, cutting or scoring balloons, and laser atherectomy to further clarify optimal treatment strategies for different patient populations and lesion characteristics.

NON-CORONARY INTRAVASCULAR LITHOTRIPSY

Systematic Reviews and Meta-Analyses

Bouchareine (2025) conducted a systematic review with meta-analysis of 16 studies (13 on atherectomy with 960 limbs; 3 on IVL with 66 limbs) for symptomatic common femoral artery atherosclerosis.[24] Both atherectomy and IVL demonstrated comparable outcomes: technical success (96% vs 97%), bailout stenting (6% vs 8%), freedom from TLR (90% vs 91%), and limb salvage (97% vs 95%). IVL showed a trend toward more perioperative complications than atherectomy (16% vs 10%). Risk of bias assessment using MMAT showed 5 atherectomy and 2 IVL studies met all 7 criteria. Limitations include the need for longer follow-up studies to formulate clinical recommendations.

Yiu (2025) performed a systematic review and network meta-analysis of four randomized controlled trials comprising 549 patients comparing atherectomy, IVL, and plain balloon angioplasty before drug-coated balloon application for femoropopliteal disease.[25] Weighted mean lesion length was 103.4±6.67 mm. No significant differences were found in freedom from target lesion revascularisation TLR (GRADE: high), major amputation (GRADE: low), or mortality (GRADE: moderate). Bailout stenting rates were significantly reduced with IVL and atherectomy compared to plain balloon angioplasty (RR 0.25, 95% CI: 0.07-0.89; GRADE: moderate). Limitations include the moderate certainty of evidence and the need for longer-term outcome data.

Evans (2025) conducted a systematic literature review of seven articles documenting 11 patients (aged 56-82 years) who underwent carotid artery stenting with IVL for calcific carotid stenosis.[26] Preoperative stenosis ranged from 60% to 95%, with postoperative vessel patency described in all cases. Postoperative complications included one case of transient right eye blindness secondary to central retinal artery occlusion and one left hemispheric transient ischemic attack. All patients exhibited good clinical outcomes with no new permanent deficits.

Limitations include the small sample size and off-label use of IVL, warranting further research on safety and efficacy.

Sagris (2024) published a systematic review and meta-analysis which evaluated the safety and efficacy of Intravascular Lithotripsy (IVL) in treating heavily calcified peripheral artery lesions, analyzing 20 studies with 1,223 patients (mean age 70.6 ± 17.4 years).[27] The study demonstrated 100% successful IVL delivery (95% CI: 100%-100%, I2 = 0%), with significant improvements in luminal diameter (SMD: 4.66, 95% CI: 3.41-5.92) and reduction in diameter stenosis (SMD: -4.15, 95% CI: -4.75 to -3.55). Complications were minimal, with 97% of procedures free from dissection, though 6% experienced dissections of any type. In TAVI-specific cases, there was 100% successful implantation with only 4% experiencing dissections. Limitations included the retrospective nature of included studies and the need for future prospective validation of results.

Wong (2022) performed a systematic review and meta-analysis of nine studies encompassing 681 patients (769 lesions) with IVL for lower extremity PAD.[28] Severe calcification was present in 75.53% (95% CI: 66.08%-83.03%) of lesions. Diameter stenosis reduction was 59.3% (95% CI: 53.30%-65.31%) comparing pre-IVL to post-IVL measurements. Flow-limiting or type D/E/F dissection occurred in only 1.25% (95% CI: 0.60%-2.61%) of cases. Stent placement occurred in 15.89% (95% CI: 5.22%-39.34%) of procedures. Limitations include heterogeneity in study designs and the need for high-quality evidence comparing IVL with other treatment modalities such as atherectomy across different lesion characteristics.

Madhavan (2020) performed an individual pooled meta-analysis of five prospective studies including 336 patients who underwent endovascular revascularization using IVL for peripheral artery disease (PAD).[29] The analysis utilized individual patient-level data to assess IVL efficacy. Over 12% of patients received adjunctive device therapy, making it difficult to isolate IVL benefits. Limitations include the lack of comparators in single-arm studies preventing proper safety and efficacy comparisons with other endovascular PAD treatments, and limited patient numbers in key subgroups necessitating larger future cohorts.

Randomized Controlled Trials

Tepe (2022) published a randomized controlled trial evaluating mid-term outcomes of intravascular lithotripsy (IVL) versus percutaneous transluminal angioplasty (PTA) in 306 patients with moderately-to-severely calcified femoropopliteal arteries, with 153 patients in each treatment arm receiving either IVL or PTA prior to drug-coated balloon treatment or stenting. The powered secondary effectiveness endpoint was primary patency at one year, defined as freedom from clinically driven target lesion revascularization plus freedom from restenosis determined by duplex ultrasound, with acute PTA failure requiring stent placement during the index procedure prespecified as a loss of primary patency. Primary patency at one year was significantly greater in the IVL arm (80.5% vs 68.0%, p=0.017), with significantly lower requirement for provisional stenting in the IVL group (4.6% vs 18.3%, p<0.0001), while freedom from clinically driven target lesion revascularization (IVL: 95.7% vs PTA: 98.3%, p= .94) and restenosis rates (IVL: 90.0% vs PTA: 88.8%, p=0.48) were similar between groups at one year, and at two years, primary patency remained significantly greater in the IVL arm (70.3% vs 51.3%, p=0.003). The study demonstrated superior 1-year primary patency with IVL followed by drug-coated balloon treatment, confirming consistent safety and effectiveness for patients with heavily calcified femoropopliteal arteries with minimal stent requirement.

Tepe (2021) reported 30-day results of the Disrupt PAD III randomized controlled trial.[30] A total of 153 patients with moderate or severe calcification in a femoropopliteal artery were randomized to each group, receiving either vessel preparation with IVL or PTA prior to drug-coated balloon (DCB) or stenting. Better outcomes were reported in the IVL group for procedural success (65.8% vs. 50.4%; p = 0.01), percentage of lesions with residual stenosis (≤30%; 66.4% vs. 51.9%; p = 0.02), flow-limiting dissections (1.4% vs. 6.8%; p = 0.03), post-dilatation (5.2% vs. 17.0%; p = 0.001), and stent placement (4.6% vs. 18.3%; p < 0.001). The rates of major adverse events (IVL: 0% vs. PTA: 1.3%; p = 0.16) and clinically driven target lesion revascularization (IVL: 0.7% vs. PTA: 0.7%; p = 1.0) at 30 days were not significantly different between groups.

Non-Randomized Studies

Shammas (2024) published a prospective, multicenter observational study evaluating intravascular lithotripsy (IVL) for treating severely calcified common femoral artery (CFA) disease in 177 patients (163 analyzable) across 23 sites.[31] The study assessed 164 treated lesions with moderate-severe calcification (95.1%), mean diameter stenosis of 74.8±17.7%, and mean lesion length of 53.6±53.1 mm, with concomitant calcium-modifying therapy used in 32.3% of cases and final treatment including drug-coated balloons (68.9%) and stenting (16.5%). Post-IVL residual stenosis was 29.2±16.5% and final residual stenosis was 23.6±11.5%, with no vascular complications (flow-limiting dissections, perforations, embolization, slow/no reflow, or abrupt closure) present at procedure end by core-laboratory assessment, except for one flow-limiting dissection (0.8%) occurring immediately following IVL treatment. Limitations include observational study design without a control group, lack of long-term follow-up data, operator discretion in concomitant treatments which may have influenced outcomes, and potential selection bias inherent in registry studies.

Armstrong (2024) published an observational study evaluating the real-world acute performance of intravascular lithotripsy (IVL) in the treatment of calcified peripheral artery disease.[32] The Disrupt PAD III Observational Study was a prospective, multicenter, single-arm study that enrolled 1373 patients with 1677 lesions (1531, 91.3% core lab evaluable) across 30 global sites between November 2017 and June 2021. The study population included patients with claudication or critical limb-threatening ischemia and at least moderate calcification. Treated lesions had a mean diameter stenosis of 80.6±17.6% and mean lesion length of 93.5±74.3 mm, with target vessels including femoropopliteal (61%), iliac (15.8%), common femoral (10.7%), and infrapopliteal arteries (12.8%). Lesion characteristics included 31.1% chronic total occlusions and 19.3% long lesions (≥15 cm or greater). At final assessment, residual stenosis was 23.8±11.3%, with 0.9% serious angiographic complications and no abrupt closures, distal embolization, no flow, or thrombotic events. Multivariable analysis identified independent predictors of ≤30% residual stenosis as lesion length ≥15 cm (odds ratio 0.384), female sex (odds ratio 1.850), age ≤75 years (odds ratio 1.625), IVL balloon to artery ratio ≥1.0 (odds ratio 1.538), and chronic total occlusion lesions (odds ratio 0.638). Lesion length ≥15 cm (odds ratio 16.076) was an independent predictor of procedural complications. The study was limited by its observational design without randomization or control group, focus on acute procedural outcomes without long-term follow-up data, potential selection bias in patient enrollment, and lack of standardized adjunctive therapy protocols across sites.

Chandra (2024) published a prospective, multicenter, single-arm study evaluating intravascular lithotripsy (IVL) for treating calcified below-the-knee (BTK) peripheral arterial disease. The study enrolled 250 subjects with moderate to severely calcified infrapopliteal lesions (Rutherford category 3-5) from 38 sites in the United States and Europe, treating 305 lesions with mean length of 76 ± 65 mm and 78% ± 18% diameter stenosis. The primary effectiveness endpoint of procedural success (≤50% residual stenosis without serious angiographic complications) was achieved in 97.9% of cases, with residual stenosis reduced from 78% to 29% after IVL and to 26% after optional post dilatation and/or stenting. At 30 days, the major adverse limb event rate was 0.8% with no deaths, mean Vascular Quality of Life scores improved by 4.0 ± 5.0 ($P < .0001$), and among patients with baseline wounds, 15.8% healed and 53.4% improved. Study limitations include the single-arm design without a control group, short-term follow-up at 30 days, and potential selection bias from excluding patients without moderate or severe calcification.

Nagpal (2023) published a secondary analysis of the multicenter Disrupt PAD III Observational Study examining sex-specific outcomes of intravascular lithotripsy (IVL) for treating calcified peripheral artery disease in the lower extremities.[33] The study included 1262 patients (29.9% women) with over 85% having moderate to severe lesion calcification. Women were older (74 vs 71 years, $p<0.001$), had lower ankle-brachial index (0.7 vs 0.8, $p=0.003$), smaller reference vessel size (5.3 vs 5.6 mm, $p=0.009$), and more severe baseline stenosis (82.3% vs 79.8%, $p=0.012$) compared with men. Residual stenosis after IVL alone was significantly reduced in both groups, with final residual stenosis of 21.9% in women and 24.7% in men ($p=0.001$). Serious angiographic complications were infrequent and similar between groups (1.4% vs 0.6%, $p=0.21$), with no abrupt vessel closure, distal embolization, or thrombotic events during any procedure. Limitations include the observational study design, short-term follow-up focused on acute procedural outcomes, and the relatively small proportion of women enrolled in the study (29.9%).

Adams (2022) published an observational study evaluating the safety and effectiveness of the Shockwave S4 intravascular lithotripsy (IVL) catheter for treating calcified infrapopliteal lesions in an all-comers cohort.[34] The Disrupt PAD III observational study was a prospective, nonrandomized, multicenter single-arm study that enrolled 101 patients with 114 calcified infrapopliteal arteries treated with the S4 IVL catheter. The study population included patients with claudication or critical limb ischemia (CLI), with CLI present in 69.3% of patients, and at least moderate calcification as assessed by angiography. The treated vessels had a mean reference vessel diameter of 3.1±0.8 mm, minimum lumen diameter of 0.5±0.6 mm, diameter stenosis of 83.4%±15.8%, and mean lesion length of 64.7±54.7 mm, with moderate to severe calcification in 69.3% of lesions by Peripheral Academic Research Consortium (PARC) criteria. Results demonstrated an average acute gain of 2.0±0.7 mm at the end of the procedure, with residual stenosis less than 50% achieved in 99.0% of lesions and a mean residual stenosis of 23.3±12.5%. Adjunctive calcium-modifying technology was used in 22.7% of procedures. There were no flow-limiting dissections, embolization, slow flow/no-reflow, or abrupt closure events at the end of the procedure. The study was limited by its observational design, lack of randomization and control group, short-term follow-up focused on acute outcomes, and potential selection bias.

Armstrong (2020) reported a cohort analysis from the Disrupt PAD III Study focusing on IVL for calcified, stenotic iliac arteries in 200 lesions across 20 sites.[35] Among 118 patients, 101 sought treatment for claudication or critical limb ischemia, while 17 required optimization 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.

An initial analysis of the prospective, non-randomized, single-arm, registry study component of the Disrupt PAD III study was published by Adams (2020).[36] This included data from 200 patients with 220 target lesions. Intravascular Lithotripsy was used with additional balloon-based technologies in 54% of target lesions, with concomitant atherectomy in 19.8% and stenting in 29.9% of cases. The authors reported a 3.4mm average acute gain and residual stenosis rate of 23.6% post-procedure. There were two type D dissections reported, as well as a perforation that was unrelated to the IVL procedure.There was no abrupt closure, distal embolization, no reflow, or thrombotic event.

Brodman (2019) evaluated the safety and feasibility of treating calcified, stenotic common femoral arteries (CFAs) using peripheral IVL. The analysis was completed for 21 patients who underwent IVL for calcified, stenotic lesions of the common femoral arteries, which reported mean residual stenosis of 21.3% and five Grade B dissections.[37] Access to the target lesion and delivery of treatment by the IVL catheter were successful in all 21 patients. Post treatment mean diameter stenosis was 21.3%, representing an acute mean lumen gain of 3.1±1.3 mm (range 0.7-5.2). Vascular complications were minimal, with only five type B (non-flowing-limiting) dissections reported. The profunda femoris artery was patent in all patients following IVL, and none of the subjects experienced a perforation, distal embolization, thrombus, no reflow, or abrupt closure.

Brodmann (2019) reported outcomes of the Disrupt PAD II post-market registry study, a non-randomized, multi-center study that enrolled 60 subjects with complex, calcified peripheral arterial stenosis.[38] The primary efficacy endpoint for this study was patency of the target lesion at 12 months, and the primary safety endpoint was major adverse events (MAE) within 30 days, which was defined as “emergency surgical revascularization of the target limb, unplanned target limb major amputation, symptomatic thrombus or distal emboli, and perforations or grade D or greater dissections requiring an intervention.” A composite patency endpoint was also assessed, which was defined as freedom from ≥50% restenosis or clinically driven target lesion revascularization (TLR). The IVL procedure was successful in all 60 patients, and the residual stenosis was 24.2% post-procedure. At 12 months, target lesion patency was 69.8% (30/43, patients with TLR [20.7%] were excluded) and the composite patency outcome (freedom from TLR or ≥50% restenosis) was achieved in 54.5% (30/55). The MAE rate within 30 days was 1.7%, and there was one cardiac-related death that was not due to the study device.

Brodman (2018) published the Disrupt Below the Knee (BTK) study, a nonrandomized safety study that evaluated the use of IVL in 20 patients with moderate to severe BTK arterial calcification.[39] The IVL procedure was successful in 19 of these patients. All patients had a residual stenosis of 50% or less, two had stent placements, and there was one Grade B dissection. The composite of major adverse events at 30 days was 0%. The acute reduction in percent diameter stenosis of target lesions was 46.5%. All patients achieved residual diameter stenosis ≤50%. Vascular complications were minimal with only 1 type B dissection reported and 2 stents placed. None of the subjects experienced thrombus formation, abrupt closure, distal embolization, or perforation. There were no device-related complications.

Section Summary

Non-coronary intravascular lithotripsy (IVL) evidence comprises systematic reviews, meta-analyses, randomized controlled trials, and observational studies evaluating its use across various peripheral arterial territories including femoropopliteal, common femoral, iliac, carotid, and below-the-knee arteries. Systematic reviews and meta-analyses report that IVL achieves comparable outcomes to atherectomy in terms of freedom from target lesion revascularization, limb salvage, and mortality, while showing reduced bailout stenting rates compared to plain balloon angioplasty. A randomized controlled trail with over 300 patients demonstrated that IVL followed by drug-coated balloon treatment achieved greater primary patency at one year (80.5% vs 68.0%) and two years (70.3% vs 51.3%) compared to percutaneous transluminal angioplasty, with lower rates of provisional stenting (4.6% vs 18.3%) and flow-limiting dissections (1.4% vs 6.8%). Multiple prospective observational studies across diverse anatomical locations and patient populations have shown procedural success, minimal serious angiographic complications, reductions in residual stenosis, and rare occurrences of flow-limiting dissections, perforations, or embolic events. Limitations include the predominance of single-arm observational studies without control groups or randomization, relatively short-term follow-up periods (often 30 days to 1 year) limiting assessment of long-term durability, small sample sizes in certain anatomical territories (particularly carotid arteries with only 11 patients documented), heterogeneity in study designs and adjunctive therapy protocols, potential selection bias in registry studies, off-label use in some applications, lack of standardized comparisons with other calcium modification techniques across different lesion characteristics. Future research priorities should include adequately powered head-to-head randomized trials comparing IVL with established vessel preparation techniques, extended follow-up studies to assess long-term durability and patency, and prospective investigations of optimal patient selection criteria and lesion characteristics most amenable to IVL treatment.

PRACTICE GUIDELINE SUMMARY

AMERICAN COLLEGE OF CARDIOLOGY/AMERICAN HEART ASSOCIATION JOINT COMMITTEE ON CLINICAL PRACTICE GUIDELINES

The 2024 joint guideline for the management of lower extremity peripheral disease recognize lithotripsy as an endovascular technique for claudication:[40] " Endovascular therapy typically involves the displacement or removal of stenotic or occlusive atherosclerotic disease using catheter-based techniques. Endovascular techniques for claudication include PTA (sometimes referred to as "plain-old balloon angioplasty"); drug coated balloon angioplasty; bare-metal, drug-eluting, and covered stents; lithotripsy; and atherectomy. Endovascular tools are selected based upon lesion characteristics (e.g., anatomic location, lesion length, degree of calcification), operator experience, and the range of available technologies. The appropriateness of particular endovascular therapies for the treatment of claudication is beyond the scope of this document."

SOCIETY FOR INTERVENTIONAL RADIOLOGY

The 2020 Society for Interventional Radiology published guidelines on device selection in aorto-iliac arterial interventions.[41] These guidelines indicate that early studies with IVL have demonstrated feasibility for the management of severely calcified arterial stenosis in coronary and peripheral and that further RCTs for an AO-I indication are required.

SUMMARY

There is not enough research to show that intravascular lithotripsy (IVL) improves health outcomes for patients with peripheral artery disease or coronary artery disease. Evidence from randomized controlled trials and prospective studies with longer-term follow-up is necessary to determine the effectiveness of this procedure. In addition, current clinical practice guidelines do not recommend this procedure. Therefore, IVL is considered investigational.

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CODES

Codes	Number	Description
CPT	37262	Intravascular lithotripsy(ies), iliac vascular territory, including all imaging guidance and radiological supervision and interpretation necessary to perform the intravascular lithotripsy(ies) within the same artery (List separately in addition to code for primary procedure)
	37279	Intravascular lithotripsy(ies), femoral and popliteal vascular territory, including all imaging guidance and radiological supervision and interpretation necessary to perform the intravascular lithotripsy(ies) within the same artery (List separately in addition to code for primary procedure)
	92972	Percutaneous transluminal coronary lithotripsy (List separately in addition to code for primary procedure)
HCPCS	C1761	Catheter, transluminal intravascular lithotripsy, coronary
	C7571	Percutaneous transluminal coronary angioplasty, single major coronary artery or branch with percutaneous transluminal coronary lithotripsy
	C9764	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed
	C9765	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed
	C9766	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel(s), when performed
	C9767	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed
	C9772	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies), with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed
	C9773	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed
	C9774	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed
	C9775	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel (s), when performed

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