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Medical Policy Manual Surgery, Policy No. 233

Coronary Intravascular Lithotripsy

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Next Review: December 2024
Last Review: December 2023

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

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

MEDICAL POLICY CRITERIA

Notes: This policy only applies to coronary intravascular lithotripsy.

Coronary 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

Coronary artery calcification (CAC) can interfere with percutaneous coronary intervention (PCI)

due to inadequate stent expansion, difficulty transiting the catheter through a calcified lesion, coated drug separation from a stent, proclivity for in-stent restenosis and stent thrombosis, and a change to the underlying pharmacokinetics.

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]

EVIDENCE SUMMARY

CORONARY INTRAVASCULAR LITHOTRIPSY (IVL)

The evidence summary includes systematic reviews and randomized clinical trials not included in the systematic reviews.

Systematic Reviews

Caminiti (2023) published a systematic review with meta-analysis to investigate the success rate of IVL for the treatment of stent underexpression (SU) because of coronary calcified plaque.[4] 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.[5]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.[6-8]

Satter (2022) published a meta-analysis for IVL outcomes in severely calcified coronary lesions.[6] 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. The definition of sever calcification was not uniform likely due to a lack of consistency of imaging type (ultrasound or optical coherence tomography). 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.[7] 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).[8]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.

Sheikh (2021) published a systematic review assessing the efficacy and feasibility of IVL in treating severe coronary calcification.[9] The review included a total of 62 studies with 1389 patients (1414 lesions; 74.7% male patients with a mean age of 72.03 years) with significant coronary calcification or under-expanded stents underwent IVL. Significant improvement was demonstrated in acute and sustained vessel patency with a procedural success rate of 78.2 – 100% in hospital. The authors conclude that recent studies have highlighted that the use of IVL with adjuvant intracoronary imaging has revolutionized the way of treating heavily calcified, non-dilatable coronary lesions and is likely to succeed the conventional ways of treating these complex lesions. And that further studies are needed to gauge the long-term efficacy and safety of IVL against techniques currently available for calcium modification including conventional balloons, cutting or scoring balloons, rotational atherectomy and laser atherectomy.

Randomized Controlled Trials

Two studies published in 2023 reported the results of the ROTA shock trial.[10, 11] 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.[10] 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.[11]

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.[12] 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. The evidence reviewed includes six systematic reviews (SR) and two recent randomized clinical trials. All SRs are based on single armed studies and in mostly male subjects. 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), which predisposes to publication bias. Two randomized trials were recently published including a prospective non-inferiority trial (n = 70) comparing outcomes of IVL or rotational atherectomy (RA) and a prospective study (n = 40) comparing pretreatment with IVL to predilatation with conventional and/or speciality balloon strategy. Both studies suggested IVL is not inferior to the comparator procedures. The RCTs have limitations such as small sample size, mostly male participants, heterogeneity of baseline lumen diameters. Adequately powered randomized controlled trails comparing IVL to currently used procedures are needed to assess the safety and efficacy of IVL.

PRACTICE GUIDELINE SUMMARY

None

SUMMARY

There is not enough research to support the use of coronary intravascular lithotripsy in any indication. No clinical guidelines based on research recommend coronary intravascular lithotripsy. Therefore, coronary intravascular lithotripsy is considered investigational for all indications.

REFERENCES

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CODES

Codes	Number	Description
CPT	92972	Percutaneous transluminal coronary lithotripsy (List separately in addition to code for primary procedure)
HCPCS	C1761	Catheter, transluminal intravascular lithotripsy, coronary

Date of Origin: *December 2023*