

Cath Lab Digest

A product, news & clinical update for the cardiac catheterization laboratory specialist

www.cathlabdigest.com • October 2025 • vol. 33, no. 10

LASER ATHERECTOMY

Long-Term Outcomes of Excimer Laser Coronary Angioplasty in Severely Calcified De Novo Coronary Lesions: A Retrospective, Single-Center Study

Giancarla Scalone; Luca di Vito; Alessandro Aimi; Eliana Carapellucci; Luca Mariani; Anita Merani; Francesco Orazi; Simona Silenzi; Pierfrancesco Grossi

ABSTRACT

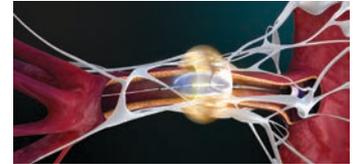
Background. Excimer laser coronary angioplasty (ELCA) is increasingly recognized as a valuable tool for treating severely calcified plaques. In this single-center, retrospective study, we sought to evaluate the efficacy and safety of ELCA in the management of severely calcified de novo coronary lesions and explore its potential long-term benefits.

Methods and Results. Between January 1, 2014 and December 22, 2024, 50 patients who underwent ELCA for angiographically confirmed, severely calcified coronary plaques or uncrossable lesions were retrospectively included. The mean patient age was 76.6 ± 8.2 years, with a male preponderance (74%). Acute coronary syndrome (ACS) was the presentation in 76% of cases. The minimum lumen diameter increased from 0.40 mm^2 (IQR 0.10-0.90) before percutaneous coronary intervention (PCI) to 1.1 mm^2 (IQR 0.40-1.8) after ELCA. Angiographic success, defined as residual stenosis <20%, was achieved in 96% of cases.

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Paradise™ Ultrasound Renal Denervation in Contemporary Practice



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A Tale of Two Agencies: Medical Device Approval and Coverage in the United States



Mehdi H. Shishehbor, DO, MPH, PhD, and Ashkan Yahyavi, MD

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QUALITY IMPROVEMENT

How Did Michigan Become the National Leader in Intracoronary Imaging-Guided PCI?

Sabina Kumar, DO; Devraj Sukul, MD, MSc; Ryan Madder, MD; Milan Seth; Jay Mohan, DO; Hitinder Gurm MD; Eric Cantey, MD; Mark Zainea, MD

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Background. Excimer laser coronary angioplasty (ELCA) is increasingly recognized as a valuable tool for treating severely calcified plaques. In this single-center, retrospective study, we sought to evaluate the efficacy and safety of ELCA in the management of severely calcified de novo coronary lesions and explore its potential long-term benefits.

Methods and results. Between January 1, 2014 and December 22, 2024, 50 patients who underwent ELCA for angiographically confirmed, severely calcified coronary plaques or uncrossable lesions were retrospectively included. The mean patient age was 76.6 ± 8.2 years, with a male preponderance (74%). Acute coronary syndrome (ACS) was the presentation in 76% of cases.

The minimum lumen diameter increased from 0.40 mm^2 (IQR 0.10-0.90) before percutaneous coronary intervention (PCI) to 1.1 mm^2 (IQR 0.40-1.8) after ELCA. Angiographic success, defined as residual stenosis $<20\%$, was achieved in 96% of cases. Intravascular ultrasound was employed in 18% of procedures, showing a median final stent expansion of 81% (IQR 70-96).

Three procedural dissections (6%) occurred and were successfully managed with stent implantation. At median follow-up of 85 months (IQR 10-130), 10 all-cause deaths (20%) were recorded. The median time to event was 64 months (IQR 24-127), with a median age at death of 86 years (IQR 69-89).

Age at the time of PCI was the only independent predictor of adverse events (OR 0.39, 95% CI 0.006-0.032, $P=.004$).

Conclusions. This retrospective real-world analysis suggests that ELCA is a safe and effective option for treating severely calcified de novo coronary lesions, with favorable long-term outcomes.

Heavily calcified coronary plaques can pose challenges during percutaneous coronary intervention (PCI) as these plaques are associated with lower rates of complete revascularization, increased peri-procedural complications, and poorer clinical outcomes.¹⁻⁴ Over the past 25 years, interest has been increasing in excimer laser coronary angioplasty (ELCA) as a valuable tool in the PCI armamentarium for the management of heavily calcified plaques, owing to its ability to modify undilatable and uncrossable coronary lesions.⁵⁻¹⁰ However, the evidence supporting the efficacy and safety of ELCA in the setting of de novo coronary lesions remains limited, consisting mostly of non-randomized studies with short-term follow-up.¹¹

In this single-center, retrospective study, we sought to investigate the efficacy and safety of ELCA in the treatment of severely calcified de novo coronary lesions, and identify any potential benefits at long-term follow-up.

Methods

This single-center, retrospective, observational study included 50 consecutive patients who underwent ELCA-assisted PCI for severely calcified de novo coronary lesions between January 1, 2014 and December 22, 2024.

ELCA was used at operator discretion in cases of angiographically confirmed, severely calcified coronary plaques or in all cases of the inability of the smallest balloon or microcatheter to cross the lesion. Severely calcified lesions

Table 1. Clinical characteristics of the study population (n=50).

Age, years, mean \pm SD	76.6 \pm 8.2
Male, n (%)	38 (76)
Cardiovascular risk factors	
DM, n (%)	34 (68)
Hypertension, n (%)	40 (80)
Dyslipidemia, n (%)	44 (88)
Current smoker, n (%)	21 (42)
LVEF, %, median (IQR)	50 (23-65)
Hemodialysis, n (%)	3 (6%)
Cardiac syndrome, n (%)	
Stable angina	12 (24)
ACS	38 (76)
Previous MI, n (%)	5 (10)
Previous PCI, n (%)	4 (8)
Previous CABG, n (%)	9 (18)

ACS = acute coronary syndrome; CABG = coronary artery bypass; DM = diabetes mellitus; n = number; IQR = interquartile range; LVEF = left ventricular ejection fraction; MI = myocardial infarction; PCI = percutaneous coronary intervention; SD = standard deviation.

were angiographically defined as radiopacities observed on fluoroscopy, without cardiac motion before contrast injection, compromising one or both sides of the lumen.¹²

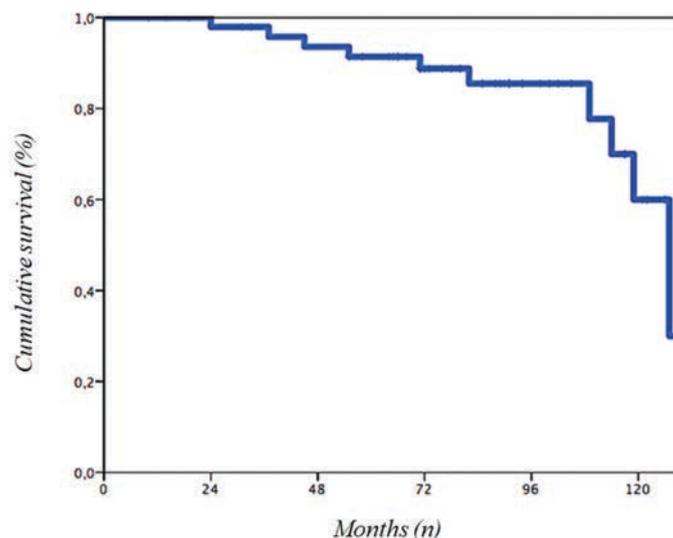
Vascular access was obtained using 6 French sheaths via the left or right radial arteries. A 0.9 mm ELCA catheter was used with a minimum fluency of 80 mJ/mm^2 . The number of laser pulses was according to operator preference.

Saline flush and “bathe technique” were used to clear the blood and dye during delivery

Table 2. Procedural data of the study population (n=50).

Target vessel, n (%)	
LAD	28 (56)
RCA	9 (18)
LM	7 (14)
LCx	6 (12)
Lesion location, n (%)	
Ostium	1 (2)
Proximal	27 (54)
Mid	21 (42)
Distal	1 (2)
Lesion length, mm median (IQR)	28 (23-42)
RVD, mm median (IQR)	2.9 (2-4)
Uncrossable lesions, n (%)	36 (72)
Tortuosity, n (%)	11 (22)
MLD, mm ² median (IQR)	
Before ELCA	0.4 (0.10-0.90)
After ELCA	1.1 (0.40-1.8)
Residual stenosis <20%	48 (96)
Stent diameter, mm median (IQR)	3 (2-4)
Stent length, mm median (IQR)	30 (14-48)
Maximum NC balloon diameter, mm median (IQR)	4 (3-4)
Number of NC balloons used, n median (IQR)	7 (5-15)
Number of scoring balloons used, n (%)	6 (12)
IVUS, n (%)	9 (18)
Time of fluoroscopy, min median (IQR)	33 (23-45)
Periprocedural complications, n (%)	
Perforation	- (0)
Type B dissection	2 (4)
Type C dissection	1 (2)
Tamponade	- (0)
Distal embolization	- (0)

ELCA = excimer laser coronary artery; IVUS = intravascular ultrasound; IQR = interquartile range; LCx = left circumflex artery; LAD = left anterior descending; LM = left main; MLD = minimal lumen diameter; n = number; NC = noncompliant; RCA = right coronary artery; RVD = reference vessel diameter.

**Figure. Cumulative survival rate of the study population during a median period of 85 months (Interquartile range: 10-130).**

of the therapy, with the catheter advanced in small increments during 10-second bursts of lasing.

Clinical characteristics of the patients were collected at the time of procedure.

Quantitative coronary angiography analysis was performed offline. Lesion length (including the stented segment plus 5 mm proximal and distal margins), reference vessel diameter (RVD), and minimal lumen diameter (MLD) before PCI and after ELCA were measured using the outer catheter diameter as the calibration standard. Angiographic success was defined as residual stenosis <20% after PCI.

Two independent researchers reviewed the angiographic sequences, and average values were used for analysis. Additional procedural characteristics were recorded: diameter and the length of the implanted stents, the number and diameter of the noncompliant (NC) balloons and their maximum diameter, and the number of scoring balloons. The choice to employ intravascular imaging was left to the operator. The fluoroscopy time was also evaluated.

The following periprocedural complications were recorded and verified: perforation, dissection, tamponade, and distal embolization. Perforation was defined as the demonstration of a persistent extravascular collection of contrast medium beyond the vessel wall. Major dissection was defined as type C or worse, and minor dissection was defined as type A or B, according to the National Heart, Lung and Blood Institute classification.¹³

Patients were followed during hospitalization and afterward through outpatient visits for up to 130 months post PCI. Major adverse cardiac events (MACE) included death for any cause, myocardial infarction (MI), cardiac death, and target lesion revascularization.

Statistical Analysis

Data distribution was assessed according to the Kolmogorov-Smirnov test. Continuous variables were analyzed using Student's t-test or Mann-Whitney U-test, as appropriate, and are reported as mean \pm standard deviation or median (interquartile range [IQR]). Categorical variables were compared using the chi-square test. Event-free survival was calculated from the procedure date to death. Kaplan-Meier analysis was used to estimate cumulative mortality. Independent predictors of survival were assessed via Cox proportional hazards regression model, and results are presented as odds ratio (OR) with 95% confidence intervals (CI). A P-value $< .05$ was established as the level of statistical significance for all tests. SPSS 17.0 statistical software (SPSS Italia, Inc.) was used for analyses.

followed by the right coronary artery (18%), left main (14%), and circumflex artery (12%). Lesions were in the proximal segment in 54% of cases, in the mid segment in 42%, and in the ostial or distal segment in 2% of cases. Lesion tortuosity was present in 22% of cases.

ECLA was used for uncrossable lesions in 72% of cases.

Intravascular ultrasound (IVUS) was employed in 9 procedures (18%), to assess final stent expansion.

Median lesion length was 28 mm (IQR 23-42), with a median RVD of 2.9 (IQR 2-4).

Median pre-PCI MLD was 0.40 mm² (IQR 0.10-0.90), increasing to 1.1 mm² (IQR 0.40-1.8) after ELCA. Angiographic success (residual stenosis $< 20\%$) was achieved in 96% of cases.

Only drug-eluting stents (DES) were implanted. The median stent diameter and length

At the univariate analysis, age at the time of PCI was the only independent predictor of death (OR 0.39, 95% CI 0.006-0.032, $P = .004$).

Discussion

The main findings of our retrospective, real-world study are as follows:

1. ELCA was associated with a high procedural success rate in the treatment of severely calcified de novo coronary lesions, even in a population predominantly composed of elderly patients presenting with ACS;
2. The lack of cardiac events at a long-term follow-up suggests that ELCA may offer durable clinical benefits in this high-risk setting;
3. Age was the only independent predictor of all-cause of mortality.

In recent years, ELCA has attracted renewed interest for the treatment of complex coronary disease, including in-stent restenosis (ISR),¹⁴ debulking of saphenous vein graft lesions,¹⁵ facilitating chronic total occlusion interventions,¹⁶ and treating thrombotic lesions¹⁷.

Despite this, the overall utilization of ELCA remains relatively low. This may partly be due to the higher complications rates reported during PCI with the use of ELCA. Complications with ELCA are significantly greater than interventions without the use of ELCA,¹⁸ although these rates vary depending on lesion complexity and anatomical characteristics. Evaluating the efficacy and safety of ELCA in specific coronary scenarios is challenging due to the predominance of retrospective studies, heterogeneity in lesion types, and small sample sizes within subgroups.¹¹

Recently, Jurado et al¹⁹ conducted the first randomized trial comparing 3 advanced plaque modification techniques: rotational atherectomy, ELCA, and intravascular lithotripsy, in the treatment of calcified coronary lesions. They concluded that all three methods demonstrated comparable efficacy and safety, emphasizing their complementary roles. The selection of plaque modification technique should therefore be individualized based on patient profile and lesion characteristics.

Our real-world data support the findings of Jurado et al in the context of ELCA and, to our knowledge, offer the longest follow-up

Read the commentary on the page 24:

Sustained Safety and Success: Long-Term Data Support the Role of Excimer Laser Atherectomy

Akiva Rosenzweig, MD; Robert S. Dieter, MD; Ayesha Nawaz, MD; Merlin Nikita, MD; Thomas Callahan, MD; Aravinda Nanjundappa, MD

Results

Patient clinical characteristics are reported in Table 1. The mean age was 76.6 \pm 8.2 years, with a male preponderance (76%). Among the included patients, 68% had diabetes, 80% had hypertension, and 88% had dyslipidemia. Thirty-eight patients (76%) presented with acute coronary syndrome (ACS), while 12 (24%) were treated electively for stable angina. Thirteen patients had received a prior revascularization with either PCI (8%) or coronary artery bypass (18%), and 5 (10%) had a history of previous MI. Median left ventricular ejection fraction (LVEF) was 50% (IQR 23-65).

Procedural characteristics are reported in Table 2. The target vessel was most often the left anterior descending artery (56%),

were 3 mm (IQR 2-4) and 30 mm (IQR 14-48 mm), respectively.

A median of 7 NC balloons were used per procedure (IQR 5-15), with a maximum balloon diameter of 4 mm (IQR 2-4). Scoring balloons were employed in 6 cases (12%).

IVUS-assessed final stent expansion showed a median value of 81% (IQR 70-96). Median fluoroscopy time was 33 minutes (IQR 23-43).

Regarding the intraprocedural complications, 3 procedural dissections (6%) were observed, all managed successfully with stent implantation. No MACE occurred during hospitalization.

At median follow-up of 85 months (IQR 10-130), there were 10 all-cause deaths (20%). The median time to event was 64 months (IQR 24-127), with a median age at death of 86 years (IQR 69-89) (Figure).

reported to date for this modality. Our cohort was older than those in prior studies,^{20,21} and 76% presented with ACS. Despite this, no stent-related adverse events were recorded during follow-up. Notably, the 20% rate of MACE was entirely due to all-cause mortality, occurring at a mean age of 86 years, with age emerging as the sole predictor of these events.

Use of IVUS was low (18%) and employed primarily to assess the final stent expansion. The limited use of IVUS likely reflects the challenging nature of these lesions, many of which were uncrossable at baseline, discouraging operators from employing imaging modalities at the initial stage. Moreover, these procedures were performed over a long period, during which the routine use of intracoronary imaging in such complex PCI was not yet widely recommended.^{22,23}

Study Limitations

Our study has several limitations. First, it is a retrospective, single-center study with a relatively small sample size. Second, the absence of intracoronary imaging at the start of procedure limited our ability to characterize the nature of the calcium and therefore identify the coronary lesions that could best benefit from ELCA use.^{22,23}

Conclusions

Our retrospective, real-world data suggest that ELCA is an effective and safe option for treating severely calcified de novo coronary lesions, even in elderly patients with multiple cardiovascular risk factors and predominant ACS presentation. The lack of cardiac events at long-term follow-up indicates a potential sustained benefit of ELCA in this setting. However, further larger prospective studies are needed to confirm these findings and better define the role of ELCA in contemporary PCI practice. ■

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Find the study by
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Disclosure: The authors declare no conflicts of interest regarding the content herein.

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COMMENTARY

Sustained Safety and Success: Long-Term Data Support the Role of Excimer Laser Atherectomy

Akiva Rosenzweig, MD; Robert S. Dieter, MD; Ayesha Nawaz, MD; Merlin Nikita, MD; Thomas Callahan, MD; Aravinda Nanjundappa, MD

Coronary artery calcification, fueled by an aging population and increasing comorbidities such as diabetes and kidney disease, presents significant hurdles for interventional cardiologists.¹ Calcified lesions impede the delivery of balloons, stents, and imaging devices while limiting optimal stent expansion, leading to poorer prognosis and worse clinical outcomes.² To overcome these challenges, plaque modification devices (PMDs) have become essential for optimizing lesion preparation.³ Excimer laser coronary angioplasty (ELCA), introduced in the 1980s, is one such PMD that, despite early setbacks, is experiencing a resurgence due to improved technology and contemporary practices like dual antiplatelet therapy and drug-eluting stents.⁴⁻⁶

In this issue of *Cath Lab Digest*, Scalone et al's study, "Long-Term Outcomes of Excimer Laser Coronary Angioplasty in Severely Calcified De Novo Coronary Lesions," adds valuable evidence to the ELCA literature. In a retrospective, single-center study of 50 patients, the authors report a 96% procedural success rate, with minimal lumen diameter improving from 0.40 mm² (IQR 0.1-0.9) to 1.1 mm² (IQR 0.4-1.8). Over a median follow-up of 85 months, all-cause mortality was 20%, with no cardiac-related deaths. Procedural complications were limited to three dissections (6%), all managed with stent placement. Notably, the cohort was older (mean age 76.6 ± 8.2 years), 76% had acute coronary syndromes (ACS), and 72% had uncrossable lesions with a median length of 28 mm (IQR 23-42). These results, despite the small sample size, underscore ELCA's durability in challenging cases.

ELCA uses ultraviolet light to ablate atherosclerotic plaque, disrupt molecular bonds, and enhance vessel compliance through acoustic and mechanical effects. A cavitation bubble further aids in debulking soft plaque or thrombus. These properties make ELCA particularly effective for complex coronary scenarios, including in-stent

restenosis, stent under-expansion, thrombotic lesions, and uncrossable lesions.

Early enthusiasm for ELCA waned after the AMRO and LAVA trials in the late 1990s, which showed no benefit over balloon angioplasty alone, and reported higher rates of dissections and periprocedural myocardial infarction.^{4,5} However, device advancements and modern interventional practices have revitalized ELCA's role. Recent observational studies highlight its efficacy. For example, Tomasello et al reported a 97% success rate and 4.7% major adverse cardiovascular events (MACE) in 320 patients over a median of 841 days, though their cohort was younger (71 ± 9 years) and primarily had chronic coronary syndrome.⁷ Similarly, Iiya et al's study of 586 ACS patients showed improved MACE and target lesion revascularization (TLR) at 2 years in the ELCA group compared to a propensity-matched non-ELCA cohort.⁸ A larger retrospective study of 448 patients reported 38% all-cause mortality and 17% TLR at nearly 10 years, with propensity-matched analyses indicating that outcomes were driven by lesion complexity rather than ELCA itself.⁹ Scalone et al's findings align with this growing evidence, reinforcing ELCA's long-term benefits.

ELCA in the Plaque Modification Device Landscape

ELCA is one of several plaque modification devices, alongside rotational atherectomy (RA), orbital atherectomy (OA), and intravascular lithotripsy (IVL). The ROLLER COASTR-EPIC22 trial, which randomized 171 patients with severe calcification to RA, ELCA, or IVL, found no differences in procedural or 1-year outcomes, including MACE, death, TLR, or stent thrombosis.¹⁰ Despite its small sample size, this trial supports the safety and efficacy of these plaque modification devices. The 2024 Society for Cardiovascular Angiography and Interventions (SCAI) Expert

Consensus Statement provides guidance on plaque modification device use for calcified lesions, but does not specify a preferred device for uncrossable or undeliverable lesions, highlighting the need for further research to define optimal strategies.¹¹

The primary limitation of Scalone et al's study is its small sample size, which constrains its statistical power. Nevertheless, its findings are consistent with broader evidence supporting ELCA's role in modern practice. Randomized, controlled trials are urgently needed to compare ELCA with stent deployment alone or other plaque modification devices, particularly in the context of advanced stents, intracoronary imaging, and dual antiplatelet therapy. Such studies will clarify ELCA's optimal indications and potential synergies with other plaque modification devices.

Scalone et al's study provides robust evidence for ELCA's role in managing severely calcified coronary lesions, offering long-term durability and a favorable safety profile. As calcified coronaries remain a formidable challenge, ELCA emerges as a vital tool in the interventionalist's arsenal. Clinicians should consider ELCA for complex lesions, while researchers must prioritize randomized trials to refine its application and enhance patient outcomes in this evolving field. ■

References are available online with the commentary:



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Disclosures: Drs. Rosenzweig, Dieter, Nawaz, and Nikita report no conflicts of interest regarding the content herein. Dr. Callahan reports serving as a consultant to Philips, Abbott, Medtronic, Shockwave, and Boston Scientific. Dr. Nanjundappa reports serving as a consultant and speaker for Philips.

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Commentary online only

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