Contemporary Use of Laser During Percutaneous Coronary Interventions: Insights from the Laser Veterans Affairs (LAVA) Multicenter Registry

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ABSTRACT: Background. The contemporary use and outcomes of excimer laser coronary atherectomy (ELCA) in percutaneous coronary intervention (PCI) are not well described. **Methods.** We examined the baseline clinical and angiographic characteristics and procedural outcomes of 130 target lesions in 121 consecutive PCIs (n = 116 patients) in which ELCA was performed at three United States Department of Veterans Affairs (VA) medical centers between 2008 and 2016. **Results.** Mean age was 68.5 ± 9 years and 97% of the patients were men. Patients had high prevalence of diabetes mellitus (63%), prior coronary artery bypass graft surgery (41%), and prior myocardial infarction (60%). The most common target vessel was the left anterior descending (32%), followed by the right coronary artery (30%), circumflex artery (20%), and saphenous vein graft (12%). The target lesions were highly complex, with moderate/severe calcification in 62% and in-stent restenosis in 37%. The most common indication for ELCA was balloon-uncrossable lesions (43.8%), followed by balloon-undilatable lesions (40.8%) and thrombotic lesions (12.3%). Use of ELCA was associated with high technical success rate (90.0%) and procedural success rate (88.8%), and low major adverse cardiac event (MACE) rate (3.45%). Mean procedure time was 120 min (interquartile range [IQR], 81-191 min), air kerma radiation dose was 2.76 Gy (IQR, 1.32-5.01 Gy), and contrast volume was 273 mL (IQR, 201-362 mL). **Conclusion.** In a contemporary multicenter United States registry, ELCA was commonly used in highly complex lesions and was associated with high technical and procedural success rates and low incidence of MACE.

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Excimer laser coronary atherectomy (ELCA) uses a xenon-chloride excimer laser to produce bursts of ultraviolet light at 308 nm with pulse frequency of 25-80 Hz and fluence of 30-80 mJ/mm^2.[1] ELCA was initially approved by the United States Food and Drug Administration for percutaneous coronary intervention (PCI) in 1992 for multiple indications, including occluded saphenous vein bypass graft (SVG), ostial lesions, long lesions (>20 mm in length), moderately calcified lesions, eccentric lesions, chronic total occlusions (CTOs) crossable with a guidewire, balloon refractory lesions, and in-stent restenosis (ISR).[2] In recent years, laser use has increased concomitantly with the performance of increasingly complex PCIs.[3] However, few contemporary data exist on the real-world procedural indications and outcomes of ELCA. We therefore developed a multicenter registry to examine the contemporary indications and outcomes of ELCA-assisted PCI.

Methods

Patient population. We analyzed baseline clinical and angiographic characteristics and outcomes of 130 target lesions in 121 consecutive laser-assisted PCIs performed in 116 patients between 2008 and 2016 at three United States Department of Veterans Affairs (VA) medical centers.

Enrollment was performed only during part of the study period at some centers due to participation in other studies. Consecutive patients who were undergoing laser-assisted PCI at each participating VA center were identified via the clinical database of the cardiac catheterization laboratories. Data collection was performed both prospectively and retrospectively and was recorded in a dedicated online database (LAVA: Laser VA Registry) (Clinicaltrials.gov identifier: NCT02789462). Informed consent was waived for the retrospective component of the study, but was obtained from patients enrolled prospectively. The study was approved by the Institutional Review Board of each site.

Study investigation sites, electronic data capture system description, and study definitions are listed in Supplemental Appendix S1 (available at www.invasivecardiology.com).

Statistical analysis. Continuous variables were presented as mean ± standard deviation or median (interquartile range [IQR]). Categorical data were reported as frequencies or percentages. All statistical analyses were performed with JMP 11.0 (SAS Institute).

Table 1. Baseline clinical characteristics of the study patients.	
Variable	**Overall (n = 116)**
Age (years)	68.5 ± 9
Men	97%
Body mass index (kg/m²)	31.6 ± 8
Diabetes mellitus	63%
Hypertension	95%
Dyslipidemia	91%
Smoking (current)	28%
Left ventricular ejection fraction (%)	48.8 ± 15.4
Family history of coronary artery disease	30%
Congestive heart failure	37%
Prior myocardial infarction	60%
Prior coronary artery bypass grafting	41%
Prior cerebrovascular disease	16%
Prior peripheral vascular disease	17%
Baseline creatinine (mg/dL)	1.1 (0.9-1.3)

Data provided as mean ± standard deviation, percentage, or median (interquartile range).

Results

During the study period, a total of 116 patients underwent 121 laser-assisted PCIs at the three participating centers. The baseline clinical characteristics of the study patients are shown in Table 1. Mean age was 68.5 ± 9 years and 97% of the patients were men. Patients had high prevalence of diabetes mellitus (63%), prior coronary artery bypass graft (CABG) surgery (41%), and prior myocardial infarction (MI) (60%).

The angiographic characteristics of the study population are summarized in Table 2. During the study period, a total of 130 lesions were treated with ELCA. The most common target vessel was the left anterior descending artery (32%), followed by the right coronary artery (30%), circumflex (20%), SVG (12%), and left main artery (0.05%). Moderate to severe calcification and moderate to severe proximal vessel tortuosity were present in 62% and 24%, respectively. The target lesions were highly complex; 28% involved a bifurcation and 37% were due to in-stent restenosis. Intravascular ultrasound was used in 50% and optical coherence tomography in 11% of target lesions.

The most common indication for ELCA was balloon-uncrossable lesions (43.8%), followed by balloon-undilatable lesions (40.8%) and thrombotic lesions (12.3%). Other indications for laser included treatment of a complication (wire entrapment) and SVG lesions (Figure 1). Most lesions (91.4%) were treated with 0.9 mm laser catheters, 73.3% with rapid-exchange catheters, and 18.1% with over-the-wire catheters. The mean number of laser runs was 4.48 ± 2.9 per lesion, with 40 sec (IQR, 28-64 sec) lasing time.

The procedural outcomes are shown in Table 3 and Figure 1. Use of laser was associated with high technical success rate

Table 2. Procedural strategy, angiographic characteristics, and laser-assisted PCI techniques of the study lesions.	
Variable	**Overall (n = 130)**
Angiographic characteristics	
Target vessel	
Right coronary artery	30.0%
Left coronary artery	32.0%
Left circumflex artery	20.0%
Left main coronary artery	0.05%
Saphenous vein graft	12.0%
Calcification (moderate/severe)	62.0%
Tortuosity (moderate/severe)	24.0%
In-stent restenosis	37.0%
Bifurcation	28.0%
Vessel diameter (mm)	3.0 (2.5-3.5)
Lesion length (mm)	22 (15-44)
Procedural strategy	
Intravascular ultrasound	50.0%
Optical coherence tomography	11.0%
Rotational atherectomy	7.7%
Orbital atherectomy	2.3%
Cutting balloon	10.0%
Angiosculpt	40.0%
Tornus	6.2%
Threader	5.4%
Glider	2.3%
Crosser	1.5%
Indication for laser	
Balloon-uncrossable lesion	43.8%
Balloon-undilatable lesion	40.8%
Thrombus	12.3%
Other*	3.1%
Number of stents used	1.95 ± 1.5
Laser-assisted PCI techniques	
Laser type	
1.7 mm rapid-exchange catheter	1.7%
1.4 mm rapid-exchange catheter	6.9%
0.9 mm rapid-exchange catheter	73.3%
0.9 mm over-the-wire catheter	18.1%
Starting fluence (mJ/mm²)	60 (42.5-80)
Maximum fluence (mJ/mm²)	80 (60-80)
Starting frequency (Hz)	60 (40-80)
Maximum frequency (Hz)	80 (40-80)
Number of lasing passes (n)	4.48 ± 2.9
Total lasing time (sec)	40 (28-64)

Data provided as mean ± standard deviation, percentage, or median (interquartile range). *Other indications for laser included complications (lodged wire in the vessel) and saphenous vein graft lesions.

Table 3. Procedural outcomes of the study patients, classified according to the laser indication.

Variable	Overall	Balloon Uncrossable	Balloon Undilatable	Thrombus	Other*
Technical success	90.0%	87.8%	94.3%	81.3%	100%
Procedural success	88.8%	83.7%	93.8%	87.5%	100%
Laser success	84.4%	74.5%	94.3%	81.3%	100%
Procedural time (min)	120 (81-191)	128 (70-224)	120 (90-162)	99 (52-173)	69 (62-163)
Fluoroscopy time (min)	32 (20-57)	40 (19-76)	30 (23-41)	25 (17-41)	13 (9-51)
Air kerma radiation dose (Gy)	2.76 (1.32-5.01)	3.44 (1.51-5.92)	2.81 (1.34-5.03)	2.30 (1.32-2.90)	1.49 (0.66-5.19)
Contrast volume	273 (201-362)	274 (188-382)	290 (225-361)	285 (213-369)	149 (87-225)
LV assist device used	9.6%	10.4%	10.4%	0.0%	25.0%
Major adverse cardiac events	3.45%	4.08%	2.08%	6.25%	0.0%
Death	1.72%	2.04%	0.0%	6.25%	0.0%
Acute Q-wave MI	0.0%	0.0%	0.0%	0.0%	0.0%
Acute myocardial infarction	0.86%	2.04%	0.0%	0.0%	0.0%
Re-PCI	2.59%	4.08%	2.08%	0.0%	0.0%
Stroke	0.0%	0.0%	0.0%	0.0%	0.0%
Emergency CABG	0.0%	0.0%	0.0%	0.0%	0.0%
Equipment loss	0.86%	0.0%	0.0%	0.0%	25.0%
Perforation	1.72%	4.08%	0.0%	0.0%	0.0%
Vascular access complication	0.86%	0.0%	2.08%	0.0%	0.0%
Dissection/thrombus	4.31%	2.04%	8.33%	0.0%	0.0%
Pericardiocentesis	0.0%	0.0%	0.0%	0.0%	0.0%

Data provided as percentage or median (interquartile range).
LV = left ventricular; PCI = percutaneous coronary intervention; CABG = coronary artery bypass grafting.
*Other indications for laser included complications (lodged wire in the vessel) and saphenous vein graft lesion.

(90.0%), procedural success rate (88.8%), and laser success rate (84.4%). Overall, the MACE rate was low (3.45%). However, in patients with thrombotic lesions, the MACE rate was 6.25%. Two patients died after the laser procedure. One of them developed acute ST-segment elevation after the procedure, but the study lesion in which laser was used was found to be patent and a different lesion was stented; however, the patient developed pulseless electrical activity overnight and died. The other patient died 2 days after an unsuccessful procedure due to cardiogenic shock. There was no stroke, emergency CABG, or pericardiocentesis. Perforation occurred in 2 lesions, both of which were severely calcified. Both perforations were Ellis class 2, occurred after stenting, and resolved after prolonged balloon inflation, without requiring pericardiocentesis.

Median procedure time was 120 min (IQR, 81-191 min), median fluoroscopy time was 32 min (IQR, 20-57 min), median air kerma radiation dose was 2.76 Gy (IQR, 1.32-5.01 Gy), and median contrast volume was 273 mL (IQR, 201-362 mL).

Discussion

The main findings of our study are that ELCA was used in highly complex lesions (mainly balloon-uncrossable and balloon-undilatable lesions), and was associated with high technical success rate (90.0%) and procedural success rate (88.8%), and low MACE rate (3.45%).

Early studies compared ELCA with balloon angioplasty. The AMRO (AMsterdam-ROtterdam) trial did not show superiority of laser over balloon angioplasty for long-term clinical and angiographic outcomes after treatment of coronary occlusions.[4] The ERBAC (Excimer laser, Rotational atherectomy, and Balloon Angioplasty Comparison) study resulted in better procedural success with rotational atherectomy (RA), but the incidence of restenosis was equally high with atherectomy techniques.[5] These studies used an old laser catheter type without saline infusion, and stenting was not used in all cases. After the introduction of drug-eluting stents, use of ELCA decreased until recently. Fernandez et al used ELCA in 0.84% of balloon failure PCI cases over a 4-year period, with nearly one-third of these cases being CTOs.[6] In a single-center study of CTO-PCI, Patel et al reported ELCA use in 8.4% of balloon-uncrossable lesions.[7]

As reflected in our study, ELCA use has increased in recent years as a result of the growth of complex PCI, such as PCI of CTOs and calcified and thrombotic lesions. The most common use of laser was for balloon-uncrossable lesions (43.8%) (Figure 2; Supplemental Appendix S1). Balloon-uncrossable lesions cannot be crossed with a balloon after successful guidewire crossing.[7] Use of ELCA for such lesions in our study was

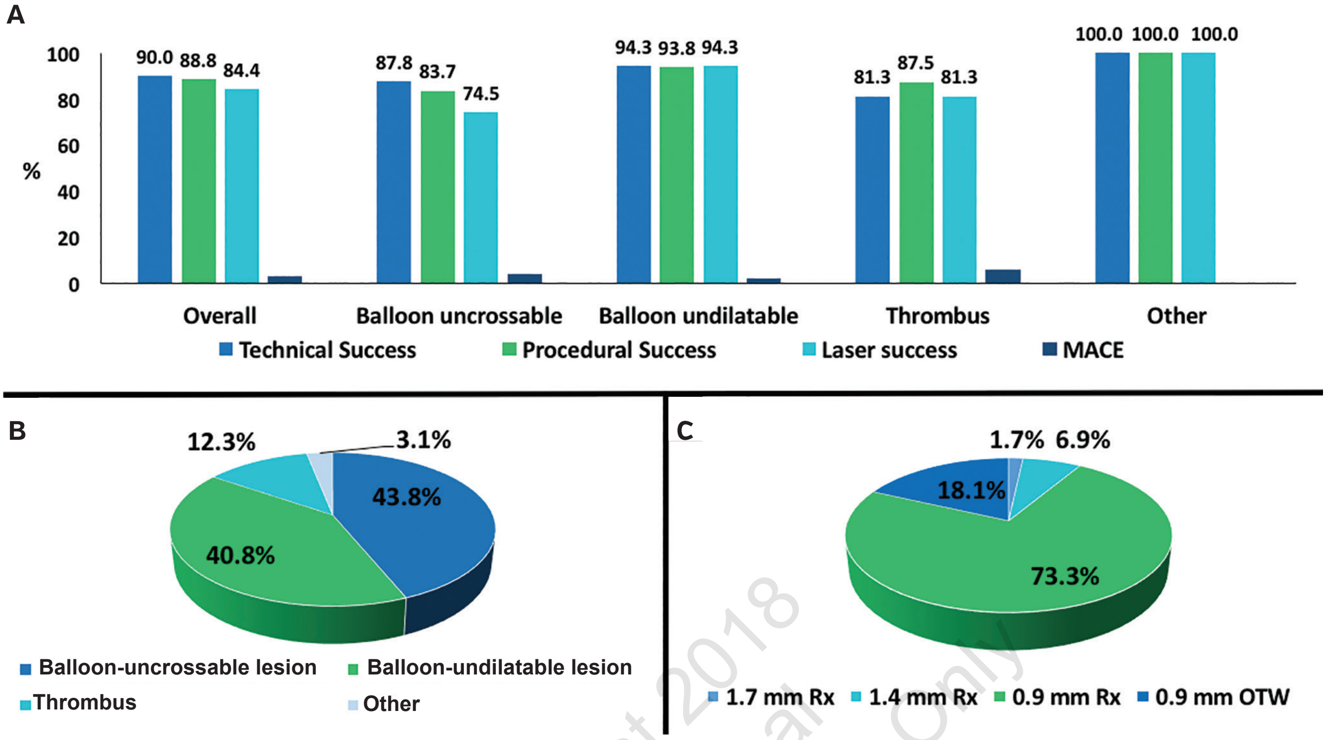

FIGURE 1. Procedural characteristics of laser-assisted percutaneous coronary intervention (PCI). (A) Technical and procedural outcomes of study patients overall and according to indication for use of laser. (B) Indications for use of laser during PCI in contemporary practice. (C) Types of laser catheters used in the present study. MACE = major adverse cardiac events; Rx = rapid-exchange excimer laser catheter; OTW = over-the-wire excimer laser catheter. Other indications for laser included complications (guidewire entrapment) and saphenous vein graft lesions.

associated with 87.8% technical success, 74.5% laser success, and 83.7% procedural success rates. Laser is a powerful option for treating balloon-uncrossable lesions since it can be used over any standard 0.014″ guidewire, in contrast to rotational and orbital atherectomy, which require insertion of specialized guidewires.[8] Shen et al reported using ELCA in 33 patients, of whom 21 had balloon-uncrossable lesions, with success achieved in 19 patients (90%) and no complications related to laser use.[9] In a contemporary multicenter CTO-PCI registry (PROGRESS CTO: Prospective Global Registry for the Study of Chronic Total Occlusion Intervention[10]) 9% of all attempted CTOs were balloon uncrossable; ELCA was used in 18% of these cases with high technical and procedural success rates (both 95%) and no associated complications.[11]

Fernandez et al used ELCA in 36 balloon-uncrossable lesions, of which 20 were lesions with TIMI 3 flow and 16 were in the setting of a CTO. Among CTO lesions, procedural success was achieved in 13 cases (81%) with laser alone. One case required combined ELCA and RA: laser was used first to allow passage of the RotaWire (Boston Scientific Corporation), which allowed RA and successful completion of the procedure (the "RASER" technique). In lesions with TIMI 3 flow (20 cases), ELCA alone led to procedural success in 10 cases and ELCA combined with RA led to procedural success in 7 cases, with 85% overall procedural success.[6]

The second-most common indication for ELCA in our study was balloon-undilatable lesions (40.8%), which are lesions that cannot be expanded after high-pressure balloon inflations. In our study, such lesions were associated with the highest technical success rate (94.3%) and procedural success rate (93.8%). Fernandez et al reported use of ELCA in 22 patients with balloon-undilatable lesions, 2 (9%) of whom were in the setting of CTO-PCI (these 2 cases were successfully treated with ELCA alone). Of the remaining 20 cases with baseline TIMI 3 flow, a total of 18 were treated successfully with laser alone, 1 was treated successfully with laser combined with RA, and 1 was treated successfully with RA alone.[6]

In the LEONARDO (early outcome of high energy Laser [Excimer]-facilitated coronary angioplasty ON hARD and complex calcified and ballOon-resistant coronary lesions) registry, which enrolled 80 patients, ELCA was successful in 30 of 32 balloon failure cases (93.7%) without any major complications.[12] Another registry examining balloon-undilatable lesions, the ELLEMENT (Excimer Laser LEsion Modification to Expand Non-dilatable sTents) registry, reported success after laser-assisted stent dilation in 27 of 28 cases (96.4%). Periprocedural MI occurred in 7.1%, transient slow-flow in 3.6%, and transient ST-segment elevation in 3.6% of the patients.[13] In some patients, contrast-enhanced laser therapy was used to modify balloon-undilatable lesions.[13-15] The recently

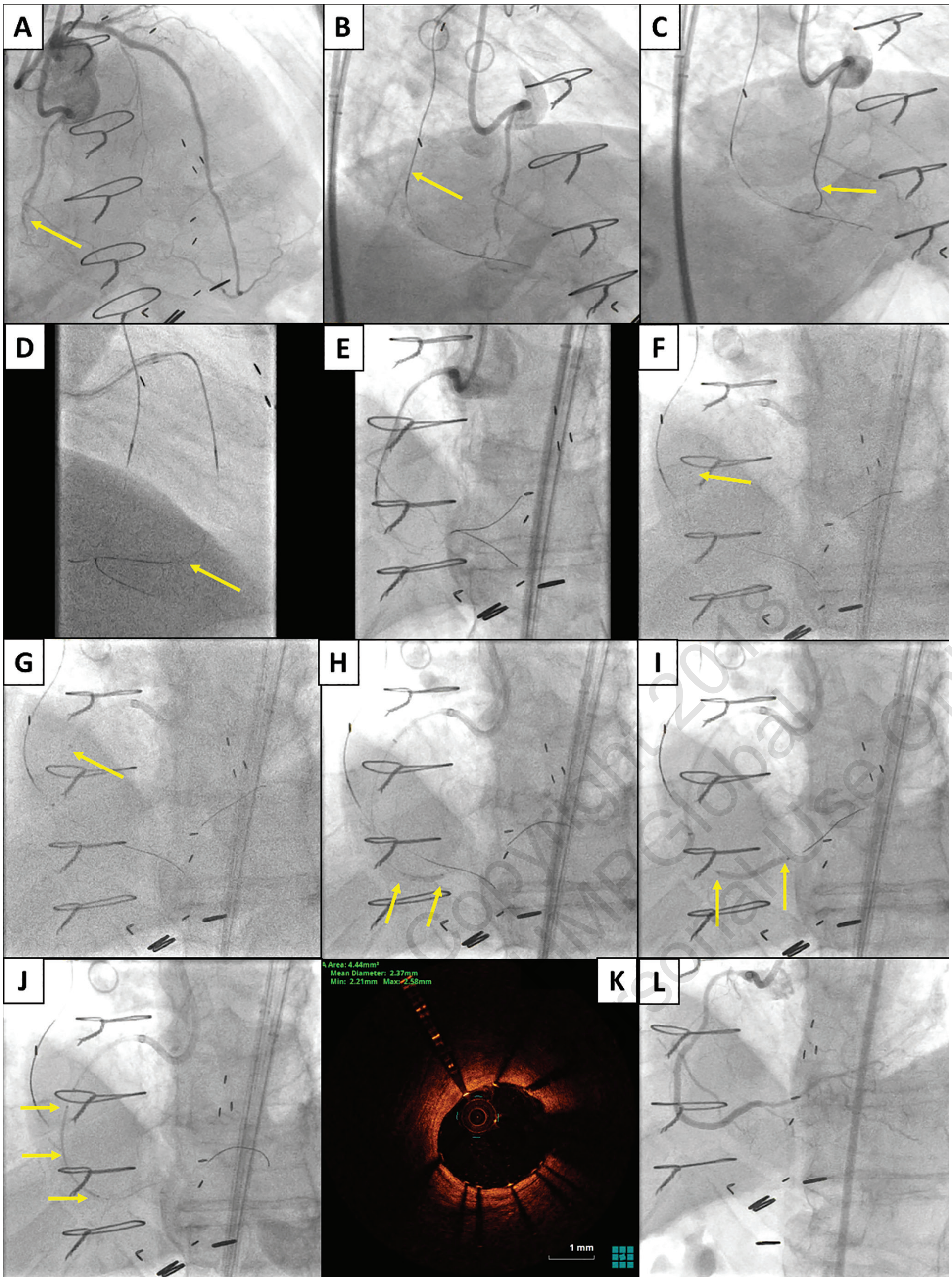

FIGURE 2. Use of laser in a balloon-uncrossable chronic total occlusion. (A) A 66-year-old man with medically refractory angina was referred for percutaneous coronary intervention of a right coronary artery chronic total occlusion. (B) A retrograde crossing attempt via an occluded saphenous vein graft failed; the wire was exchanged later to a Pilot 200 but could not make progress. (C, D, E) Antegrade crossing attempts with a Fielder FC guidewire resulted in successful lesion crossing. (F) The lesion could not be crossed even with small balloons (1.5 x 20 mm). (G) Laser atherectomy was performed with a 0.9 mm laser catheter at 60 mJ/mm^2 fluency and 40 Hz frequency without any complications. (H) The lesion could then be crossed with balloons and predilated. (I, J) A 2.25 x 32 mm drug-eluting stent was deployed distally and a 2.5 x 38 mm drug-eluting stent was deployed in the mid part of the vessel. (K) Optical coherence tomography showed well-apposed stents with no dissection. (L) Final angiography showed well-expanded stents with TIMI 3 antegrade flow and no complications.

published DERIST (combined use of Drug-eluting balloon and Excimer laser for coronary artery Restenosis In-Stent Treatment) study enrolled 80 patients with ISR treated with laser and drug-coated balloons. This study showed clinical and angiographic long-term success in 91% of the patients without any postprocedural complications.[16] While this technique of combining laser atherectomy with contrast injection may be associated with a higher risk of perforation, it is one of the only interventional options to successfully dilate an under-expanded stent.

ISR can be challenging to treat, especially when it is due to stent under-expansion. The safety and efficacy of laser was shown to be equal to balloon angioplasty in 146 patients with ISR, despite higher lesion complexity in the multicenter LARS (Laser Angioplasty for Restenotic Stents) registry.[17]

Thrombus was the indication for ELCA in 12.3% of our study lesions (Figure 3; Supplemental Appendix S1). As expected given the acute presentation, thrombotic lesions were associated with the lowest technical and procedural success rates (81.3% and 87.5%, respectively), and the highest MACE rate (6.25%). Laser atherectomy in acute MI has several advantages, such as rapid removal of the thrombus with vaporization of procoagulant reactants, reduction of the risk of distal embolization, and debulking of underlying plaque.[18] Furthermore, the interaction of laser with platelets can result in "stunned platelets" – ie, decreased platelet aggregation and reduced platelet force development.[19] Only one small, prospective, randomized trial with 27 patients evaluated laser angioplasty compared

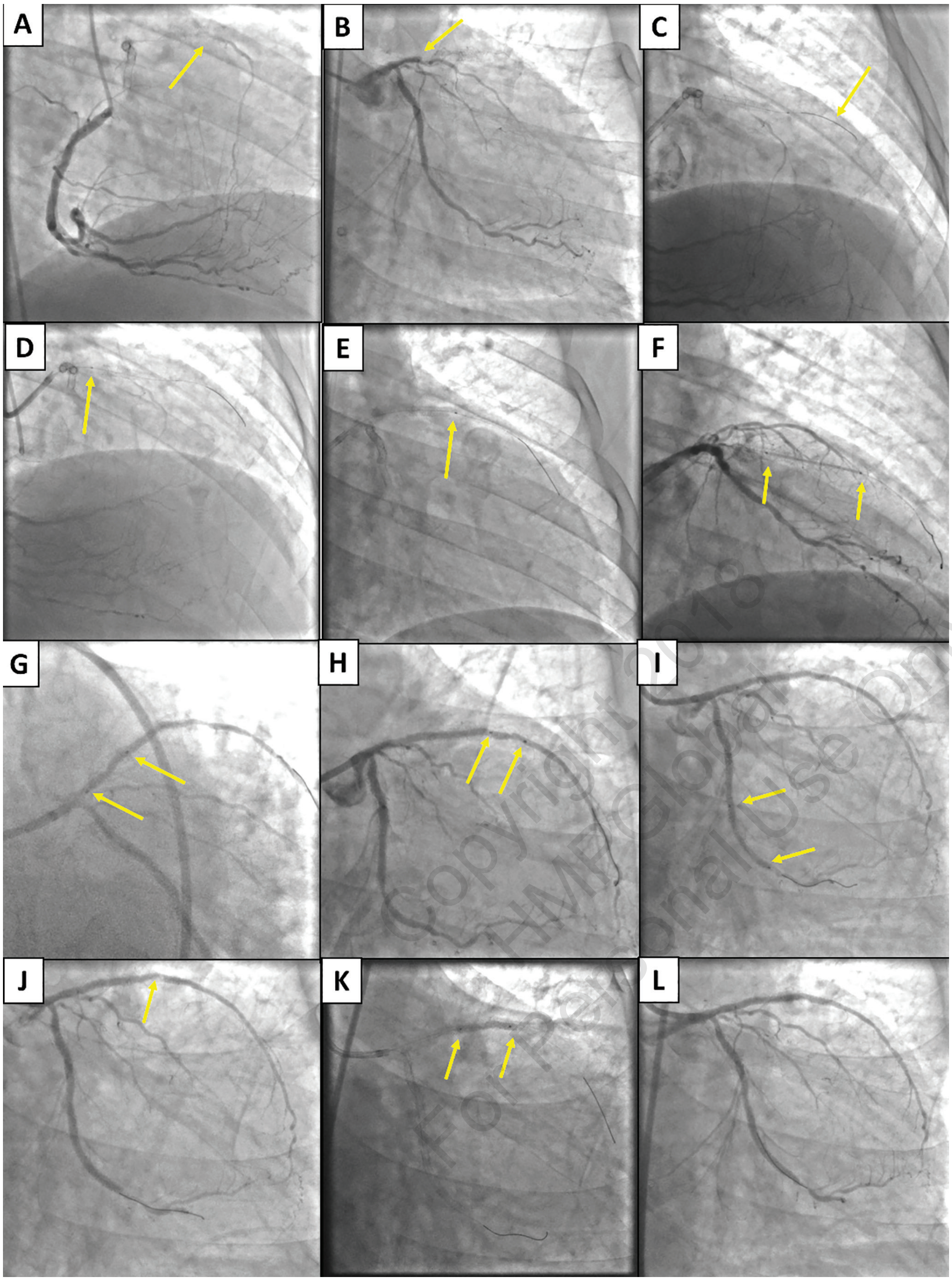

FIGURE 3. Use of laser for treating a thrombotic lesion. (A) A 60-year-old man with multiple prior percutaneous coronary interventions presented with non-ST elevation myocardial infarction. Coronary angiography revealed an occluded left anterior descending coronary artery (LAD). (B) Angiography of the right coronary artery (RCA) revealed filling of the LAD from the RCA through septal collaterals. Bilateral femoral access was obtained. (C) The LAD in-stent restenotic lesion was crossed with a Pilot 200 wire; contralateral injections verified the wire to be in the distal true lumen. (D) Thrombectomy was done with a 7 Fr Export catheter. (E) Laser atherectomy was performed with a 0.9 mm laser catheter at 60 mJ/mm^2 fluency and 40 Hz frequency, restoring antegrade flow. (F, G, H) The lesion was predilated and stented with drug-eluting stents. (I) The in-stent restenosis in the circumflex was then treated with a 2.75 x 28 mm drug-eluting stent. (K) A filling defect was noted in the LAD stents, and was treated with balloon dilation and intravenous tirofiban. (L) Final angiography revealed TIMI 3 flow in both vessels.

with conventional treatment in MI. The Laser-AMI (Laser angioplasty in Acute Myocardial Infarction) study showed no difference in the main procedural outcomes between the groups, although the improvement in corrected TIMI frame count was higher in the laser group.[20] The ULTRAMAN (Utility of Laser for TRanscatheter Atherectomy — Multicenter Analysis around Naniwa) registry evaluated success rate, TIMI flow, blush score, and complications between the rich-thrombus group (acute coronary syndrome and SVG) vs the poor-thrombus group (ISR, CTO, calcification, and long or bifurcation lesions) in 328 patients. Both groups were associated with high technical success rates (94.5% vs 97.3%; P=.28), but the TIMI flow grade and blush score were significantly lower and the complications rate was significantly higher in the rich-thrombus group.[18] The CARMEL (Cohort of Acute Revascularization in Myocardial Infarction with Excimer Laser) registry examined outcomes of 151 acute MI patients (54% Q-wave and 46% non-Q wave), several of whom had high-risk characteristics, such as cardiogenic shock (13%) and SVG as the target lesion (21%). The study reported laser success in 95% and overall procedural success in 91%, with relatively low complication rates (death, 4%; dissection, 5%; perforation, 0.6%; distal vessel occlusion, 0.6%; and distal embolization, 2%). Maximal laser gain was achieved in the lesions with extensive thrombus burden.[21]

Other indications for laser included complications (such as guidewire entrapment) and SVG lesions. SVG lesions can be challenging to treat because of the high rates of distal embolization and ISR.[22] Laser atherectomy can be useful in the treatment of these lesions because its 308 nm wavelength is absorbed by both atherosclerotic plaque and thrombus, potentially reducing the risk for distal embolization and the resultant periprocedural MI.[23] Another potential utilization of ELCA is the treatment of CTOs, which often require managing various challenges such as an "impenetrable proximal cap."[24] In addition to this, ELCA could assist freeing the guidewire in case of entrapment; Kadohira et al reported a case where ELCA was used to free a guidewire that was entrapped between a newly deployed coronary stent and severely calcified vessel wall.[25]

Study limitations. First, LAVA is an observational registry without adjudication of clinical events by an independent events committee. Second, core laboratory analysis was not performed, and therefore, assessment of angiographic characteristics was susceptible to operator-related bias. Third, procedures were performed by operators experienced in ELCA-assisted PCI, limiting extrapolation of the study results to less experienced centers and operators. Fourth, all study sites were VA hospitals, treating a primarily male population with multiple comorbidities.

Conclusion

In a contemporary multicenter United States registry, ELCA was commonly used in highly complex lesions and was associated with high technical and procedural success rates and low incidence of MACE. ELCA is a valuable tool in contemporary complex PCI practice.

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Supplemental Appendix S1. Study details.

A. Participating Centers

Denver VA Medical Center, Denver, Colorado
Southern Arizona VA Health Care System, Tucson, Arizona
VA North Texas Healthcare System, Dallas, Texas

B. Electronic Data Capture Tools

Study data were collected and managed using Research Electronic Data Capture (REDCap) electronic data capture tools managed by Veterans Affairs Information Resource Center (VIReC).[1] REDCap is a secure, web-based application designed to support data capture for research studies, providing (1) an intuitive interface for validated data entry, (2) audit trails for tracking data manipulation and export procedures, (3) automated export procedures for seamless data downloads to common statistical packages, and (4) procedures for importing data from external sources.

C. Definitions

ELCA-assisted PCI was defined as coronary lesions treated with excimer laser atherectomy.
Calcification was assessed by angiography as mild (spots), moderate (involving ≤50% of the reference lesion diameter), and severe (involving >50% of the reference lesion diameter).
Moderate proximal vessel tortuosity was defined as the presence of at least 2 bends >70° or 1 bend >90°, and *severe tortuosity* as 2 bends >90° or 1 bend >120° in the target vessel.
Technical success was defined as successful lesion revascularization with achievement of <30% residual diameter stenosis within the treated segment and restoration of Thrombolysis In Myocardial Infarction (TIMI) grade 3 antegrade flow.
Laser success was defined as technical success achieved by laser atherectomy.
Procedural success was defined as achievement of technical success with no in-hospital major adverse cardiac events (MACE).
In-hospital MACE included any of the following adverse events prior to hospital discharge: death, myocardial infarction, urgent repeat target-vessel revascularization with either PCI or coronary artery bypass graft surgery, tamponade requiring either pericardiocentesis or surgery, and stroke.
Myocardial infarction was defined using the Third Universal Definition of Myocardial Infarction.[2]
The following laser catheters were used at the discretion of the operator: 0.9 mm, 1.4 mm or 1.7 mm rapid-exchange excimer laser catheter or 0.9 mm over-the-wire catheter.

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