7-1-2021

Excimer laser coronary angioplasty in coronary lesions: Use and safety from the NCDR/CATH PCI Registry

Marc Sintek
Washington University School of Medicine in St. Louis

Edward Coverstone
Mercy Hospital South

Richard Bach
Washington University School of Medicine in St. Louis

Alan Zajarias
Washington University School of Medicine in St. Louis

John Lasala
Washington University School of Medicine in St. Louis

See next page for additional authors

Authors

Marc Sintek, Edward Coverstone, Richard Bach, Alan Zajarias, John Lasala, Howard Kurz, Kevin Kennedy, and Jasvindar Singh

Circulation: Cardiovascular Interventions

ORIGINAL ARTICLE

Excimer Laser Coronary Angioplasty in Coronary Lesions

Use and Safety From the NCDR/CATH PCI Registry

Marc Sintek, MD; Edward Coverstone, MD; Richard Bach, MD; Alan Zajarias, MD; John Lasala, MD; Howard Kurz, MD; Kevin Kennedy, MS; Jasvindar Singh, MD

BACKGROUND: Excimer laser coronary angioplasty (ELCA) uses an ultraviolet laser catheter for the treatment of coronary artery disease. ELCA has been used for various coronary lesions, but current safety and frequency of use are unknown.

METHODS: We performed a retrospective, registry-based study of ELCA use during coronary interventions reported to the National Cardiovascular Data Registry/CATH percutaneous coronary intervention registry from 2009 to 2018 (n=6 043 596 total interventions evaluated). The primary safety end point was the combination of any perforation, dissection, tamponade, or death. ELCA use per 10 000 interventions was evaluated for the study duration. Subgroups of interest were identified including in-stent restenosis lesions, saphenous vein graft lesions, chronic total occlusions, and thrombotic lesions.

RESULTS: A total of 19 688 lesions were identified with ELCA use (0.3% of all lesions). The rate of ELCA use increased across the study period from 14 ELCAs performed per 10 000 interventions in 2009 to 70 ELCAs performed per 10 000 interventions in 2018. The primary safety end point occurred in 4.2% of lesions and was higher than in cases where no ELCA was used (3.0% $P<0.001$). After adjusting for baseline differences among the subgroups who received ELCA, the in-stent restenosis group had the lowest rate of complications (odds ratio, 0.51 [95% CI, 0.42–0.63]), followed by the saphenous vein graft group (odds ratio, 0.72 [95% CI, 0.5–1]). The chronic total occlusion group had a higher risk for complications (odds ratio, 2.01 [95% CI, 1.61–2.40]).

CONCLUSIONS: The use of ELCA has remained low but has increased in recent years. Complications are significantly higher when ELCA is used, but this effect is variable with respect to lesion subtype. ELCA is frequently used to treat in-stent restenosis with a low risk of complication. ELCA use during chronic total occlusion interventions is associated with a 2-fold increased risk of complications. Together these findings provide guidance for lesion selection to optimize safety with ELCA use.

GRAPHIC ABSTRACT: A graphic abstract is available for this article.

Key Words: coronary artery disease ■ death ■ dissection ■ lasers ■ percutaneous coronary intervention

Interventional cardiologists often face complex coronary lesions, including restenosis from prior stenting, calcified lesions, bypass graft stenoses, chronic total occlusions (CTO), and thrombotic lesions in the setting of myocardial infarction. Excimer laser coronary angioplasty (ELCA) has been available for >25 years for the percutaneous treatment of coronary artery stenoses, and there has been renewed interest in its use for various complex lesion subsets. ELCA uses a pulse waved, ultraviolet laser catheter that was first reported to vaporize cadaveric atherosclerotic tissue with minimal thermal damage in 1985.[1] Thereafter, the first reports of clinical

Correspondence to: Marc Sintek, MD, Washington University, 660 S Euclid, Campus Box 8086, St Louis, MO 63110. Email msintek@wustl.edu

The Data Supplement is available at https://www.ahajournals.org/doi/suppl/10.1161/CIRCINTERVENTIONS.120.010061.

For Sources of Funding and Disclosures, see page 707.

Circulation: Cardiovascular Interventions is available at www.ahajournals.org/journal/circinterventions

WHAT IS KNOWN

- Excimer laser coronary angioplasty (ELCA) is used for treatment of complex lesions, including in-stent restenosis, saphenous vein graft lesions, chronic total occlusions, and thrombotic lesions, but has been associated with coronary perforations and dissections.

WHAT THE STUDY ADDS

- ELCA use has increased substantially over the study time period and is associated with increased complications.
- ELCA use for treatment of in-stent restenosis is associated with less complications.
- ELCA use for the chronic total occlusion subset is associated with a 2-fold increased risk of complications.
- This study helps to identify lesions where ELCA use is safer.

Nonstandard Abbreviations and Acronyms

CTO	chronic total occlusion
ELCA	excimer laser coronary angioplasty
ISR	in-stent restenosis
NCDR/CATH PCI registry	National Cardiovascular Data Registry/ CATH Percutaneous Coronary Intervention registry
SVG	saphenous vein graft

use in coronary stenoses showed significant luminal gain with low complication rates.[2,3] ELCA was shown to be effective in coronary lesions found to be poorly treated with balloon angioplasty alone, including aorto-ostial lesions, long calcified lesions, and saphenous vein graft (SVG) lesions.[4,5] Enthusiasm for ELCA was tempered by elevated complication rates compared with percutaneous transluminal coronary angioplasty alone,[6] further reports suggesting a marginal benefit of luminal gain with ELCA pretreatment[7] and the refinement of coronary stents and other atherectomy devices, such as rotational atherectomy.[8] More recently, ELCA has seen a resurgence for use in complex coronary disease in some centers[9] and has shown effectiveness in the treatment of in-stent restenosis (ISR),[10] debulking of SVG lesions,[11] facilitating CTO interventions,[12] and treatment of thrombotic lesions.[13] A recent large registry study from the UK confirmed an increased use of ELCA with an additional increased risk of dissection, perforation, and slow flow compared with non-ELCA interventions.[14]

Although evidence suggests an increase in the use of ELCA, the magnitude of this increase is unknown in current US practice. In addition, current safety and complications related to ELCA use and ELCA use in complex lesion subsets is unknown. The National Cardiovascular Data Registry/CATH percutaneous coronary intervention (NCDR/CATH PCI) registry provides a robust registry with over 2400 participating hospitals and over 6 million interventions performed since 2009.[15] This study sought to investigate overall ELCA use and rates of complications in the NCDR/CATH PCI registry, and the safety of ELCA use in lesion subsets of interest, including ISR lesions, SVG lesions, CTO, and thrombotic lesions.

METHODS

Because of the nature of the data collected for this study, requests to access the data set from qualified researchers trained in human subject confidentiality protocols may be sent to NCDR/CATH PCI registry. We performed a retrospective, registry-based study of ELCA use during coronary interventions using version 4.4 of the NCDR/CATH PCI registry. Approval for the project was obtained through the NCDR/CATH PCI registry Research and Projects committee and review committee, including research oversight on human subjects with deidentified data. Approximately 6 million coronary interventions from 2009 until 2018 were queried for use of ELCA during the intervention using prespecified data fields for ELCA use (field 7225 with the following: Device 275 ELCA Coronary Laser Catheter Rx or Device 276 ELCA Coronary Laser Catheter over the wire). A priori cohorts were then identified for complex lesion subsets as follows: thrombotic lesions (field 7195=yes and field 7175=not in graft and field in-stent thrombosis 7165=no), CTOs (field 7120=yes), ISR (field 7160=yes), and SVG lesions (field 7175=vein). The registry was also queried and the primary end point analyzed for any PCI, any CTO PCI, and any ISR PCI for comparison with ELCA use in these groups.

Study End Points

The primary end point for the study was the combined complication end point of any perforation, dissection, tamponade, or death before discharge from the index procedure. A secondary combined end point of any perforation, dissection, or tamponade was also evaluated. Absolute ELCA use per 10 000 interventions was evaluated for each quarter available in the registry.

Statistical Analysis

Data are shown as mean±SD for continuous and n (%) for categorical variables, and compared using the Student *t* test or χ^2 testing where appropriate. A multivariable regression model was created using significant and clinically important covariates using a hierarchical logistic regression model with a random intercept for site. The primary exposure variable for this model was specific lesion characteristics (thrombotic, SVG, ISR, CTO, multiple, and none), and we adjusted for the following variables: presentation (ST-segment–elevation myocardial infarction, non–ST-segment–elevation myocardial infarction, and nonmyocardial infarction), age, diabetes, prior shock, prior arrest, prior pad, and dialysis. The complication rate over time was compared using the Cochran-Armitage test.

RESULTS

Using the most current NCDR/CATH PCI registry, 19688 lesions were identified where ECLA was performed (0.3% of total lesions available). The overall rate of ELCA use during the study was 33 lasers performed per 10000 interventions, with a significant increase in ELCA use observed starting around 2014 (Figure 1). ELCA was used in 14 cases per 10000 interventions in 2009 and increased 5-fold to 70 cases per 10000 interventions in 2018. The overall complication rate for the combination of death, cardiac tamponade, any dissection, or any perforation was 4.2% and was higher than in cases where no ELCA was used (3.0% P<0.001). The overall complication rate for the combination of cardiac tamponade, any dissection, or any perforation was 2.7% and was also higher than in cases where no ELCA was used (1.4% P≤0.001). There was no increased risk of in-hospital death in cases where ELCA was used compared with cases where no ELCA was used (1.7% versus 1.7%; P=0.53). Compared with interventions where no ELCA was used, the interventions where ELCA was used were more likely to be in patients with prior coronary artery bypass grafting (33.9% versus 17.6%, P<0.001), diabetes(49.8% versus 38.3%, P<0.001), peripheral vascular disease (21% versus 12.3%, P<0.001), end-stage renal disease (4.8% versus 2.7%, P<0.001), and left ventricular systolic dysfunction (16.6% versus 11.8%, P<0.001), and they required significantly longer fluoroscopy time to complete the procedure (26.6±20 versus 15.2±12 minutes, P<0.001; Table I in the Data Supplement). Radial access was higher in the group with ELCA use (25% versus 23%; P<0.001). ELCA use significantly increased over the study period but the complication rate remained similar (P=0.169 for primary combined end point and P=0.385 for combined secondary end point; Figure 1). There was high variability in rates of complications per quarter, likely influenced by small sample sizes in which ELCA was used, until ELCA use increased significantly towards the end of 2015. There were significant differences in complications among the various lesions subsets treated (Table 1). There were 7469 lesions that did not meet a lesion subset definition. There were 6249 ISR only lesions, 1196 SVG only lesions, 1685 CTO only lesions, and 936 thrombus only lesions (Figure 2A). There were 2153 lesions that met multiple lesion definitions (Figure 2A). The use of ELCA in all lesion subsets increased over the study but use in the ISR group was the most pronounced (Figure 2B). The rate of the combination of death, cardiac tamponade, any dissection, or any perforation associated with ELCA use was highest in the group of patients with thrombotic lesions (8.0% versus all other ELCA lesions 3.9%, P<0.001). This was driven by a higher incidence of death (5.1% versus all other lesions 1.5%, P<0.001) that may have been related to a

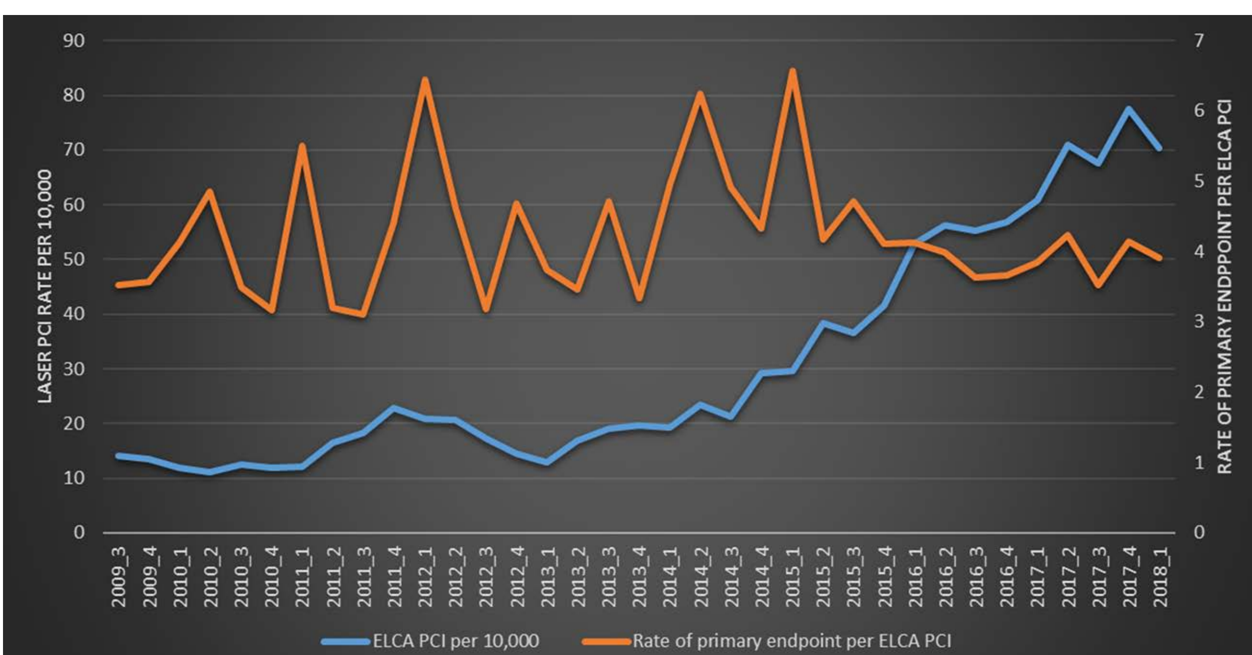

Figure 1. Excimer laser coronary angioplasty (ELCA) use and complication rate in the National Cardiovascular Data Registry/CATH percutaneous coronary intervention (NCDR/CATH PCI) registry version 4.4.

ELCA use is reported per 10000 interventions for each year_quarter available. The rate of the combined primary end point of any perforation, dissection, tamponade, or death before discharge from the index procedure is plotted for each quarter and is not significantly different over time (P=0.169).

Table 1. Baseline Characteristics and Complication Frequency in All Patients Treated With Laser Atherectomy and in Patients Treated With Laser Atherectomy in Prespecified Subgroups

Variable	Overall, N=19 688	ISR, N=8128	SVG, N=2130	Thrombotic, N=1298	CTO, N=2849
Baseline characteristics					
Age, y	68±11	66.5±10.9	70.8±10.0	64.3±12.8	65.5±11
Male	13 956 (70.9%)	5672 (69.8%)	1638 (76.9%)	934 (72%)	2145 (75.3%)
Hypertension	17 913 (91%)	7650 (94.1%)	2003 (94.1%)	1022 (78.7%)	2589 (90.9%)
Hyperlipidemia	17 585 (89%)	7674 (94.5%)	2006 (94.2%)	974 (75.1%)	2630 (92.3%)
Diabetes	9806 (49.8%)	4390 (54%)	1136 (53.4%)	498 (38.4%)	1423 (50%)
Prior MI	9366 (47.6%)	4757 (58.5%)	1229 (57.7%)	434 (33.4%)	1489 (52.3%)
Peripheral arterial disease	4135 (21%)	1926 (23.7%)	653 (30.7%)	182 (14%)	599 (21%)
Any LV dysfunction	3269 (16.6%)	1394 (17.2%)	436 (20.5%)	170 (13.1%)	591 (20.7%)
STEMI/NSTEMI at presentation	4110 (20.9%)	1448 (17.8%)	597 (28%)	756 (58.2%)	303 (10.6%)
Cardiogenic shock	300 (1.5%)	80 (1.0%)	31 (1.5%)	81 (6.2%)	31 (1.1%)
Complications					
Any tamponade	75 (0.4%)	17 (0.2%)	5 (0.2%)	8 (0.6%)	18 (0.6%)
Significant dissection	271 (1.4%)	65 (0.8%)	14 (0.7%)	26 (2.0%)	71 (2.5%)
Any perforation	275 (1.4%)	68 (0.8%)	19 (0.9%)	19 (1.5%)	101 (3.5%)
Acute kidney injury	1645 (10.2%)	618 (9.5%)	215 (11.7%)	140 (12.3%)	188 (8.3%)
Emergency CABG	157 (0.8%)	40 (0.5%)	7 (0.3%)	14 (1.1%)	15 (0.5%)
Death before discharge	344 (1.7%)	90 (1.1%)	43 (2.0%)	66 (5.1%)	43 (1.5%)

A total of 7469 lesions were not associated with any lesion subset, 1196 were SVG only, 6249 were ISR only, 1685 were CTO only, and 936 were thrombus only. A total of 2153 lesions contained multiple subsets, the most common being 850 CTO+ISR lesions. CABG indicates coronary artery bypass grafting; CTO, chronic total occlusion; ISR, in-stent restenosis; LV, left ventricle; MI, myocardial infarction; PCI, percutaneous coronary intervention; STEMI/NSTEMI, ST-segment–elevation/non–ST-segment–elevation myocardial infarction; and SVG, saphenous vein graft.

higher incidence of cardiogenic shock (4.4% versus all other lesions 1.1%; *P*<0.001), and ST-segment–elevation myocardial infarction (30.5% versus all other lesions 2.6%, *P*<0.001). The rate of the combination of death, cardiac tamponade, any dissection, or any perforation associated with ELCA use was also higher in patients with CTO lesions (6.7% versus all other ELCA lesions 3.7%, *P*<0.001) and was lowest in the patients with ISR (2.5% versus all other ELCA lesions 5.3%, *P*<0.001) and patients with SVG lesion (3.3% versus all other ELCA lesions 4.3%; *P*=0.04). Excluding death, the rate of the combination of cardiac tamponade, any dissection, or any perforation was highest in the CTO group (5.8% versus all other ELCA lesions 2.2%, *P*<0.001), followed by the thrombotic lesion group (3.7% versus all other ELCA lesions 2.6%, *P*=0.02), and was lowest in the ISR lesion group (1.6% versus all other ELCA lesions 3.5%, *P*<0.001) and SVG lesion group (1.4% versus all other ELCA lesions 2.8%, *P*<0.001). After adjusting for baseline differences between lesion subsets, there remained a significant association between CTO interventions and complications with ELCA use, whereas the ISR and SVG had the lowest complication rates (Table 2). After adjusting for baseline differences between lesion subsets, use of ELCA in the thrombotic lesion group was not associated with increased complications (Table 2). Applying this same model to ELCA versus non-ELCA lesions in these subgroups; ELCA was significantly associated with an increased rate of complications (Table II in the Data Supplement). Other significant predictors of the rate of complication were increasing age, acute myocardial infarction, and cardiogenic shock (Table 2). There were a significant number of lesions that were not included in a prespecified subgroup. These lesions had similar complication rates as those lesions placed into a subgroup of interest (Table III in the Data Supplement).

In 16 812 CTO procedures in the NCDR/CATH PCI registry where ELCA was not used, the combined end point of death, cardiac tamponade, any dissection, or any perforation was 3.7% compared with 6.7% in patients where ELCA was used (*P*<0.001). For the secondary end point of cardiac tamponade, any dissection, or any perforation, the rate was still significantly higher among CTO procedures when ELCA was used than CTO procedures where ELCA was not used (5.8% versus 2.2%, *P*<0.001). Dissection (2.5% versus 1.2%, *P*<0.001), perforation (3.5% versus 1.0%, *P*<0.001), and tamponade (0.6% versus 0.3%, *P*=0.02) were all significantly higher in the CTO group where ELCA was used compared with the CTO group where ELCA was not used. In contrast, among 622 658 procedures performed for ISR without ELCA use in the NCDR/CATH PCI registry, the combined end point of death, cardiac tamponade, any dissection, or any perforation was 2.2% compared with 2.5% in patients where ELCA was used (*P*<0.021). For the combined end point of cardiac tamponade, any

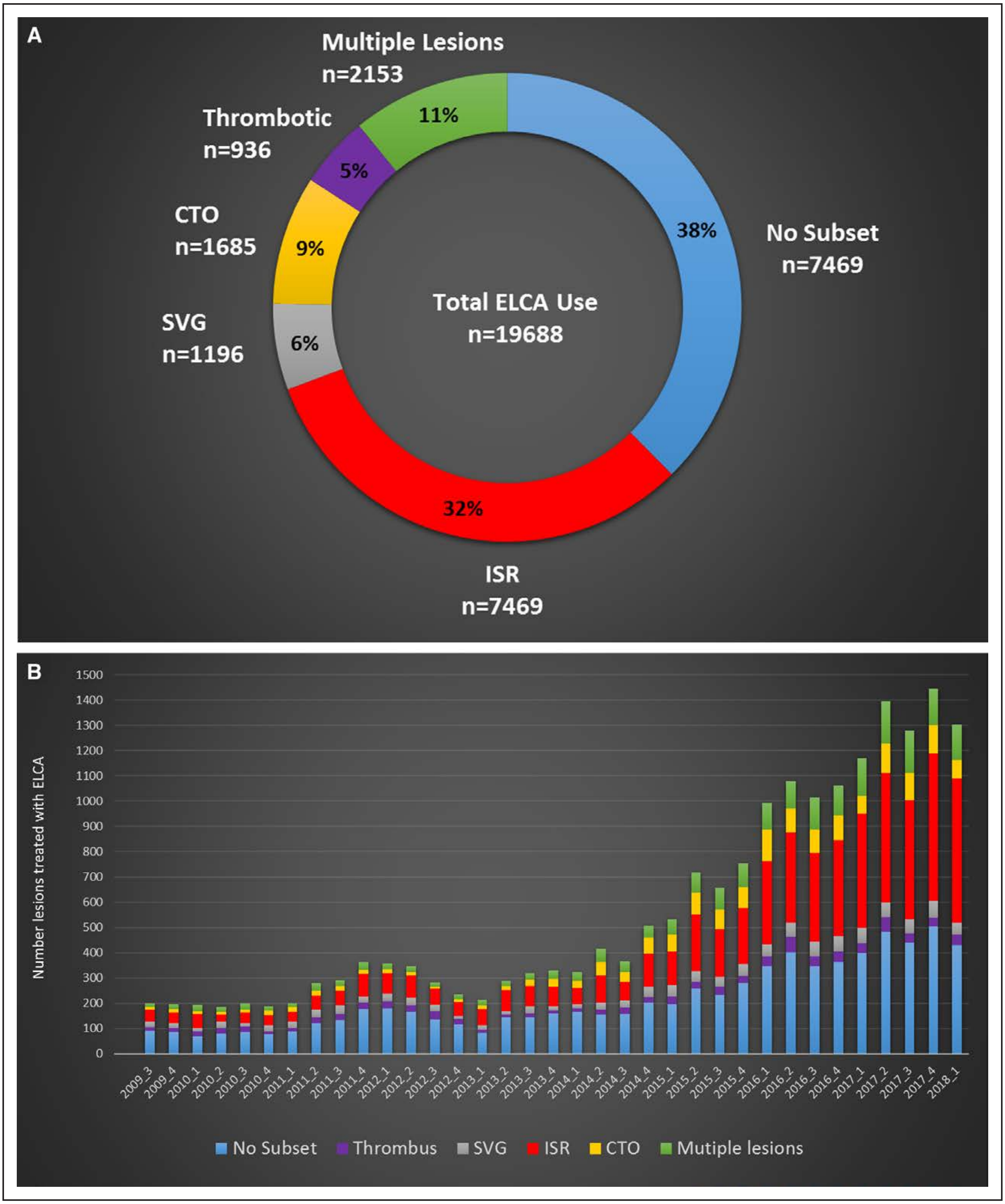

Figure 2. Excimer laser coronary angioplasty (ELCA) lesion subset analysis.

A, Total number of ELCA cases analyzed and frequency of subgroups treatments over the study duration. **B**, Quarterly trend in absolute number of lesion subsets treated with ELCA over the study period. CTO indicates chronic total occlusion; ISR, in-stent restenosis; and SVG, saphenous vein graft.

dissection, or any perforation, ELCA use during ISR procedures resulted in complications in 1.6% versus 1.1% (P<0.001) in procedures where ELCA was not used. The rate of perforation was less in the group where ELCA was used (0.8% versus 1.8%, P<0.001).

DISCUSSION

ELCA has long been available for use in the percutaneous treatment of coronary artery disease, and herein, we report the largest study to date examining safety and

Table 2. Multivariable Model Comparing the Combined End Point of Death, Perforation, Dissection, or Cardiac Tamponade (End Point 1) or the Combined End Point of Perforation, Dissection, or Cardiac Tamponade (End Point 2) in Important Subgroups Where ELCA Was Used

Variable	Combined end point 1		Combined end point 2	
	Odds ratio (95% CI)	*P* value	Odds ratio (95% CI)	*P* value
Thrombus only	1.18 (0.87–1.61)	0.29	1.15 (0.75–1.78)	0.51
SVG only	0.72 (0.52–1)	0.05	0.49 (0.31–0.79)	0.004
ISR only	0.51 (0.42–0.63)	<0.0001	0.45 (0.35–0.58)	<0.0001
CTO only	2.01 (1.61–2.49)	<0.0001	2.31 (1.82–2.92)	<0.0001
Multiple subsets	0.93 (0.72–1.18)	0.53	0.95 (0.71–1.27)	0.75
STEMI	1.76 (1.3–2.39)	0.0003	0.55 (0.31–0.98)	0.04
NSTEMI	1.36 (1.15–1.32)	0.001	1.07 (0.84–1.36)	0.60
Age (+10 y)	1.23 (1.15–1.32)	<0.0001	1.1 (1.01–1.19)	0.02
Diabetes	1.1 (0.95–1.27)	0.22	0.9 (0.75–1.07)	0.22
PAD	1.33 (1.12–1.57)	0.001	1.24 (1–1.52)	0.045
Current dialysis	1.43 (1.07–1.91)	0.015	0.7 (0.43–1.15)	0.16
Cardiogenic shock	9.74 (7.29–13.02)	<0.0001	0.89 (0.4–2)	0.78
Cardiac arrest	1.72 (1.07–2.77)	0.025	1.28 (0.44–3.72)	0.65

A total of 7469 lesions were not associated with any lesion subset, 1196 were SVG only, 6249 were ISR only, 1685 were CTO only, and 936 were thrombus only. A total of 2153 lesions contained multiple subsets. CTO indicates chronic total occlusion; ELCA, excimer laser coronary angioplasty; ISR, in-stent restenosis; PAD, peripheral arterial disease; STEMI/NSTEMI, ST-segment–elevation/non–ST-segment–elevation myocardial infarction; and SVG, saphenous vein graft.

complication rates associated with its use. Despite a significant increase in use of ELCA over the past 4 to 5 years, the overall use of ELCA still remains low. Complications with ECLA use are significantly greater than interventions without ELCA use, but this effect varies among types of lesions treated. Our data suggest that ELCA use during CTO procedures is associated with a 2-fold increased risk of complications, while ELCA use during treatment of ISR and SVG lesions is associated with a lower risk of complications. Together these findings provide guidance for lesion selection to optimize safety with ECLA use.

Litvack et al[16] published the largest ELCA experience to date analyzing complications and effectiveness in nearly 3000 patients treated with ELCA.[16] ELCA success was high and improved with operator experience. In-hospital death occurred in 0.5% of patients, perforation occurred in 1% of patients, and coronary dissection occurred in 13%. Perforation occurred in upwards of 2% of ELCA cases in a large case series reported by Ellis et al.[6] Thereafter, complications related to ELCA were shown to be mitigated by continuous saline administration.[17] In addition, the current laser catheter has also undergone modifications, making it smaller and potentially providing a safer device. The most recent data from 119 patients treated with current ELCA catheters and techniques showed a dissection rate of 3%, a perforation rate of 1.7% and no procedure-related deaths. Complications were more common among lesions classified as CTOs.[18] Protty et al[14] published a large, retrospective evaluation of ELCA use in the United Kingdom. In 1471 ELCA cases, there was an increased risk of perforation (1.7% versus 0.3%; $P<0.01$), dissection (4.1% versus 1.7%, $P<0.01$), and in-hospital unadjusted death (2.2% versus 1.4%; $P=0.01$). Our current study draws upon a much larger, real-world evaluation of ELCA use and safety but has very similar findings as the recently published UK ELCA experience. Among nearly 20 000 procedures with documented ELCA usage, the complication rate for the combination of death, cardiac tamponade, any dissection, or any perforation was low at 4.2%. The rate of dissection and perforation was 1.4% and 1.4%, respectively, in procedures where ELCA was used. These complications are higher than in lesions where no ELCA was used; for example, perforation was nearly 3-fold higher in the ELCA group (1.4% versus 0.4%, $P<0.001$). However, ECLA was used in patients with greater comorbid illnesses and longer procedure times, suggesting higher baseline risk for adverse outcomes. We speculate that operators are choosing ELCA for lesion and patient characteristics that are associated with a greater risk of complications compared with routine PCI, and this will bias observed complication rates. ELCA complication rates reported herein also compare favorably with other atherectomy devices, such as rotational atherectomy.[19] Importantly, the observed complication rate has not significantly changed despite a nearly 5-fold increase in the use of ELCA. We also identified characteristics, such as acute myocardial infarction and cardiogenic shock, where complications may be high. Avoidance of ELCA use in these scenarios could lower the rate of complications further.

This study further supports the ideal of careful case selection in choosing an atherectomy device. There were important differences in complications with respect to the types of lesions being treated with ELCA. ELCA has shown effectiveness in the treatment of restenosis within both bare metal and drug-eluting stents especially with stent underexpansion.[10,20–23] ELCA treatment of restenotic lesions compared with cutting balloon angioplasty showed less vessel damage by optical coherence tomography, improved 6-month lumen late loss, and a strong trend towards lower target lesion revascularization.[24] ISR was the most frequently represented lesion subset in our study with nearly 40% of lesions treated with ELCA in this registry involving restenosis. Importantly, this subset also had a low rate of complications and was comparable to PCI in lesions where laser was not used; the complication rate for the combination of cardiac tamponade, any dissection, or any perforation was 1.6% with ELCA compared with 1.1% without ELCA ($P \leq 0.001$), with a notable lower incidence of perforation. Possible mechanistic explanations of this include a reduction in need for aggressive predilatation and possible coronary trauma from balloon rupture or over distension. ISR appeared to be protective against complications from ELCA compared with other ELCA lesion subgroups with an adjusted HR of 0.51 (95% CI, 0.42–0.63) for the combination of cardiac tamponade, any dissection, any perforation, or death. Although there is limited, large-scale efficacy data for ELCA use in ISR treatment, this safety data suggests the risk associated with ELCA is lower when treating ISR.

The same cannot be said for ELCA use in lesions identified as a CTO. ELCA has found important roles for the treatment of CTO including modification of the proximal lesion cap to facilitate wire entry.[12] Clearly, CTO interventions are more complex and as such associated with higher risks of perforation and dissection. In most cases, dissection and luminal reentry has been adopted as the route for successful CTO intervention. However, the complication rate for the combination of cardiac tamponade, any dissection, or any perforation was significantly elevated in the CTO procedures where ELCA was used compared with CTO procedures where ELCA was not used in the NCDR registry (5.8% versus 3.2%, $P<0.001$). Even after adjusting for confounders between ELCA lesion subgroups, there was a nearly 2-fold increased rate of serious complications related to ELCA use during CTO interventions. This study is unable to suggest a mechanism for this increased risk. Although we might speculate that the increased risk may be related to use of larger laser catheters, high energy levels, or differing amounts of flush, it may ultimately be related to a confounder such as the difficulty of the CTO intervention that cannot be measured. Importantly, off-label techniques such as proximal cap modification without a guidewire could not identified in this registry. This study does highlight the need for caution with ELCA use in CTO interventions, with 23% (n=192 out of a total of 810 total complications) of the entire cohort complications arising from the CTO group, highlighting a need to understand how to make ELCA use safer in this lesion subset.

Limitations

This study is subject to the quality and accuracy of a large, national, self-reported registry. Although generally regarded as accurate, ELCA use, lesion characteristics, outcomes, and complications were self-reported. In addition, associations observed between ELCA use and end points cannot determine causality. Additionally, the technique used, including saline contrast flush or use of contrast, cannot be accounted for nor can the complexity of cases in which ELCA was used. There is clear selection bias for ELCA use which cannot be accounted for. Finally and most importantly, there is no longitudinal data regarding efficacy of ELCA.

Conclusions

The use of ELCA in PCIs has seen an increase, although overall use remains low. ELCA is associated with a higher risk of complications compared with non-ELCA PCI, but there is important differences in complications with respect to various lesion types. In the NCDR registry, ELCA is frequently used to treat ISR and has a lower risk of serious complication in this lesion type. ELCA use during CTO interventions is associated with a 2-fold increased risk of complications. Further research is needed with regards to efficacy of ELCA in these lesions subtypes, but this study highlights lesion selection for ELCA use where there is a strong safety profile.

ARTICLE INFORMATION

Received August 31, 2020; accepted April 26, 2021.

Affiliations

Mercy Hospital South, St Louis, MO (E.C.). Washington University, St Louis, MO (M.S., R.B., A.Z., J.L., H.K., J.S.). Mid American Heart Institute, St Luke's Health System, Kansas City, MO (K.K.).

Sources of Funding

The funding for this study was provided by an investigator-initiated grant from Phillips Volcano Corporation.

Disclosures

Dr Sintek reports funding for this project was provided by an investigator-initiated grant from Phillips/Volcano Corporation. The other authors report no conflicts.

Supplemental Materials

Online Tables I–III

REFERENCES

1. Grundfest WS, Litvack F, Forrester JS, Goldenberg T, Swan HJ, Morgenstern L, Fishbein M, McDermid IS, Rider DM, Pacala TJ. Laser ablation of human atherosclerotic plaque without adjacent tissue injury. *J Am Coll Cardiol*. 1985;5:929–933. doi: 10.1016/s0735-1097(85)80435-6
2. Litvack F, Eigler NL, Margolis JR, Grundfest WS, Rothbaum D, Linnemeier T, Hestrin LB, Tsoi D, Cook SL, Krauthamer D. Percutaneous excimer laser coronary angioplasty. *Am J Cardiol*. 1990;66:1027–1032. doi: 10.1016/0002-9149(90)90499-q
3. Safian RD, Freed M, Lichtenberg A, May MA, Juran N, Grines CL, O'Neill WW. Are residual stenoses after excimer laser angioplasty and coronary atherectomy due to inefficient or small devices? Comparison

with balloon angioplasty. *J Am Coll Cardiol*. 1993;22:1628–1634. doi: 10.1016/0735-1097(93)90587-q
4. Reifart N, Vandormael M, Krajcar M, Göhring S, Preusler W, Schwarz F, Störger H, Hofmann M, Klöpper J, Müller S, et al. Randomized comparison of angioplasty of complex coronary lesions at a single center. Excimer Laser, Rotational Atherectomy, and Balloon Angioplasty Comparison (ERBAC) Study. *Circulation*. 1997;96:91–98. doi: 10.1161/01.cir.96.1.91
5. Appelman YE, Piek JJ, Strikwerda S, Tijssen JG, de Feyter PJ, David GK, Serruys PW, Margolis JR, Koelemay MJ, Montauban van Swijndregt EW, et al. Randomised trial of excimer laser angioplasty versus balloon angioplasty for treatment of obstructive coronary artery disease. *Lancet*. 1996;347:79–84. doi: 10.1016/s0140-6736(96)90209-3
6. Ellis SG, Ajluni S, Arnold AZ, Popma JJ, Bittl JA, Eigler NL, Cowley MJ, Raymond RE, Safian RD, Whitlow PL. Increased coronary perforation in the new device era. Incidence, classification, management, and outcome. *Circulation*. 1994;90:2725–2730. doi: 10.1161/01.cir.90.6.2725
7. Safian RD, Freed M, Reddy V, Kuntz RE, Baim DS, Grines CL, O'Neill WW. Do excimer laser angioplasty and rotational atherectomy facilitate balloon angioplasty? Implications for lesion-specific coronary intervention. *J Am Coll Cardiol*. 1996;27:552–559. doi: 10.1016/0735-1097(95)00495-5
8. Mehran R, Dangas G, Mintz GS, Waksman R, Abizaid A, Satler LF, Pichard AD, Kent KM, Lansky AJ, Stone GW, et al. Treatment of in-stent restenosis with excimer laser coronary angioplasty versus rotational atherectomy: comparative mechanisms and results. *Circulation*. 2000;101:2484–2489. doi: 10.1161/01.cir.101.21.2484
9. Niccoli G, Giubilato S, Conte M, Belloni F, Cosentino N, Marino M, Mongiardo R, Crea F. Laser for complex coronary lesions: impact of excimer lasers and technical advancements. *Int J Cardiol*. 2011;146:296–299. doi: 10.1016/j.ijcard.2010.10.092
10. Pal N, Din J, O'Kane P. Contemporary management of stent failure: part one. *Interv Cardiol*. 2019;14:10–16. doi: 10.15420/icr.2018.39.1
11. Niccoli G, Belloni F, Cosentino N, Fracassi F, Falcioni E, Roberto M, Panico RA, Mongiardo R, Porto I, Leone AM, et al. Case-control registry of excimer laser coronary angioplasty versus distal protection devices in patients with acute coronary syndromes due to saphenous vein graft disease. *Am J Cardiol*. 2013;112:1586–1591. doi: 10.1016/j.amjcard.2013.07.015
12. Rinfret S. *Percutaneous Intervention for Coronary Chronic Total Occlusion the Hybrid Approach*. Springer; 2016.
13. Topaz O, Minisi AJ, Bernardo NL, McPherson RA, Martin E, Carr SL, Carr ME, Jr. Alterations of platelet aggregation kinetics with ultraviolet laser emission: the "stunned platelet" phenomenon. *Thromb Haemost*. 2001;86:1087–1093.
14. Protty MB, Hussain HI, Gallagher S, Al-Raisi S, Aldalati O, Farooq V, Sharp ASP, Egred M, O'Kane P, Ludman P, et al. Excimer laser coronary atherectomy during complex PCI: an analysis of 1,471 laser cases from the British Cardiovascular Intervention Society database. *Catheter Cardiovasc Interv*. 2020;97:E911–E918. doi: 10.1002/ccd.29377
15. Dehmer GJ, Weaver D, Roe MT, Milford-Beland S, Fitzgerald S, Hermann A, Messenger J, Moussa I, Garratt K, Rumsfeld J, et al. A contemporary view of diagnostic cardiac catheterization and percutaneous coronary intervention in the United States: a report from the CathPCI Registry of the National Cardiovascular Data Registry, 2010 through June 2011. *J Am Coll Cardiol*. 2012;60:2017–2031. doi: 10.1016/j.jacc.2012.08.966
16. Litvack F, Eigler N, Margolis J, Rothbaum D, Bresnahan JF, Holmes D, Untereker W, Leon M, Kent K, Pichard A. Percutaneous excimer laser coronary angioplasty: results in the first consecutive 3,000 patients. The ELCA Investigators. *J Am Coll Cardiol*. 1994;23:323–329. doi: 10.1016/0735-1097(94)90414-6
17. Deckelbaum LI, Natarajan MK, Bittl JA, Rohlfs K, Scott J, Chisholm R, Bowman KA, Strauss BH. Effect of intracoronary saline infusion on dissection during excimer laser coronary angioplasty: a randomized trial. The Percutaneous Excimer Laser Coronary Angioplasty (PELCA) Investigators. *J Am Coll Cardiol*. 1995;26:1264–1269. doi: 10.1016/0735-1097(95)00330-4
18. Badr S, Ben-Dor I, Dvir D, Barbash IM, Kitabata H, Minha S, Pendyala LK, Loh JP, Torguson R, Pichard AD, et al. The state of the excimer laser for coronary intervention in the drug-eluting stent era. *Cardiovasc Revasc Med*. 2013;14:93–98. doi: 10.1016/j.carrev.2012.12.008
19. Sakakura K, Inohara T, Kohsaka S, Amano T, Uemura S, Ishii H, Kadota K, Nakamura M, Funayama H, Fujita H, et al. Incidence and determinants of complications in rotational atherectomy: insights from the national clinical data (J-PCI registry). *Circ Cardiovasc Interv*. 2016;9:e004278. doi: 10.1161/CIRCINTERVENTIONS.116.004278
20. Mehran R, Mintz GS, Satler LF, Pichard AD, Kent KM, Bucher TA, Popma JJ, Leon MB. Treatment of in-stent restenosis with excimer laser coronary angioplasty: mechanisms and results compared with PTCA alone. *Circulation*. 1997;96:2183–2189. doi: 10.1161/01.cir.96.7.2183
21. Hirose S, Ashikaga T, Hatano Y, Yoshikawa S, Sasaoka T, Maejima Y, Isobe M. Treatment of in-stent restenosis with excimer laser coronary angioplasty: benefits over scoring balloon angioplasty alone. *Lasers Med Sci*. 2016;31:1691–1696. doi: 10.1007/s10103-016-2039-z
22. Dahm JB, Kuon E. High-energy eccentric excimer laser angioplasty for debulking diffuse iIn-stent restenosis leads to better acute- and 6-month follow-up results. *J Invasive Cardiol*. 2000;12:335–342.
23. Hamburger JN, Foley DP, de Feyter PJ, Wardeh AJ, Serruys PW. Six-month outcome after excimer laser coronary angioplasty for diffuse in-stent restenosis in native coronary arteries. *Am J Cardiol*. 2000;86:390–394. doi: 10.1016/s0002-9149(00)00952-8
24. Nishino M, Lee Y, Nakamura D, Yoshimura T, Taniike M, Makino N, Kato H, Egami Y, Shutta R, Tanouchi J, et al. Differences in optical coherence tomographic findings and clinical outcomes between excimer laser and cutting balloon angioplasty for focal in-stent restenosis lesions. *J Invasive Cardiol*. 2012;24:478–483.