Original Article

Efficacy and Safety of Excimer Laser Catheter in Patient with Complex or High Thrombotic Coronary Artery Stenosis

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Background: Indications of excimer laser use in percutaneous coronary intervention (PCI) are uncrossable device after coronary guidewire passing and thrombus modification in Acute Coronary Syndrome lesion (ACS). The excimer laser has been used for more than twenty years. However, there are inconsistent data of the efficacy and safety in an excimer laser use over the drug-eluting stent (DES) era. The authors gathered data of patient that underwent PCI using excimer laser in contemporary PCI strategy. Primary outcome was efficacy of the excimer laser defined as technical success excimer laser.

Materials and Methods: The present study was a single-center retrospective analysis of 115 lesions from 112 patients over eight years with 1.1% of all PCI used excimer laser-assisted catheter. The patient data were extracted from hospital-based inpatient and outpatient medical records. A technical success excimer laser was defined as the laser catheter could cross the entire length of the stenotic lesion determined by angiographic evidence of tip catheter beyond lesion or mention in the procedural record.

Results: The mean patient age was 67.1 years old with 65.2% being male and 45.2% having diabetes. The average left ventricular ejection fraction (LVEF) was 51.9%. Chronic total occlusion was 39.1% followed by 33.9% of thrombotic lesion. Intravascular imaging was used in 64.4%. Overall technical success of excimer laser was 74.8% with significantly higher success rate in thrombotic groups at 94.9 versus 64.5% ($p<0.001$). Overall procedural PCI success was 87.8% and no difference was observed between groups at 94.9% versus 84.2% ($p=0.135$). The slow flow phenomenon was significantly higher in the thrombotic groups at 17.9% versus 2.6% ($p=0.007$), whereas coronary perforation, major dissection, and death were not different. The authors found that older age such as 80 years or older and non-thrombotic lesions were significantly associated with technical failure of excimer laser use.

Conclusion: Excimer laser had a high success rate in the thrombotic lesion and a fair success rate in non-thrombotic lesions. The PCI procedure success was high in both groups

Keywords: Excimer laser; Percutaneous coronary intervention; Uncrossable lesion; Adjunctive lesion modification

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Complex percutaneous coronary intervention (PCI) in a patient with significant coronary artery stenosis has multiple factors that contribute to the peri-procedural success and good outcome. In the past, coronary artery bypass graft (CABG) was the first choice in a patient with complex coronary lesion due to high PCI complication rate and low chance of success. After adjunctive ablative devices were introduced, the success rate of PCI was improved[1]. Excimer laser and rotational atherectomy have been used for more than 20 years and still play an important role in complex cases nowadays[2]. In complex high-risk cases, rotational atherectomy and excimer laser are used in combination. Despite observed higher vascular complications, data showed that Major Adverse Cardiac and Cerebrovascular Events (MACCE) or mortality did not increase[3]. The data showed that routine ablative procedures did not improve long-term outcomes and they were associated with higher periprocedural-related complication[4,5]. Selection of the proper case and devices are a critical issue. Patient with heavy coronary calcification and undilatable lesion still represents a challenge for interventional cardiology. In chronic total occlusion

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lesion, balloon uncrossable lesion after coronary guidewire crossing is as high as 9% and has a high clinical risk and failure rate if performed without special coronary device backup[6]. The excimer laser can modify plaque in chronic total occlusion lesions and facilitate other devices as recommended in the algorithm[7]. Calcified lesion of more than 180 degrees of vessel wall required adequate lesion modification before stent placement with an adjunctive device such as rotational atherectomy, which is the first line for lesion modification in heavily calcified undilatable lesion[8]. Nonetheless, this strategy required passing a dedicated guidewire called Rotawire™ (Boston scientific) beyond the stenotic segment. However, a limitation of this dedicated guidewire is the suboptimal maneuverability and limit torque response compared with regular workhorse coronary guidewire[9]. The orbital atherectomy also required a special dedicated wire called ViperWire™ (St. Paul, Minnesota) 0.014", which has superior maneuverability compared to the Rotawire™. However, the system is still not available in the authors' country[8]. In a situation when the Rotawire™ cannot go through the lesion, the excimer laser can deliver with the standard 0.014" guidewire[10]. Besides, lesions with high thrombus burden in patients presenting with acute coronary syndrome increase risk of slow coronary blood flow, the use of the excimer laser improved maximal gain of thrombus dissolution and account for a lower rate of distal embolization at the end of the procedure[11,12]. This plaque modification concept is also similar to those with saphenous vein graft lesions[13]. One data registry in Japan compared the efficacy of excimer laser-assisted PCI in thrombotic and non-thrombotic lesions and showed a high success rate in both groups but noted higher slow flow complications in the thrombotic arm[14]. However, glycoprotein IIb/IIIa is not available in Japan, which is different from Thailand.

Excimer laser properties with photochemical, photo-thermal, and photomechanical have been utilized for lesion modification and help improve final coronary blood flow and mitigated risk of slow flow after stenting[15]. Moreover, excimer laser also helps plaque modification that microcatheter failed to traverse[16]. In the drug-eluting stent (DES) era, the excimer laser still plays an important role in the treatment of complex coronary lesions[17]. Stent under-expansion, in which coronary balloon failed to achieve optimal result, had benefit from the excimer laser coronary angioplasty assisted PCI[18]. Currently, the better profile of excimer laser catheter helps improve the success rate with less complication[19]. Although higher periprocedural complications in excimer laser-assisted PCI were observed compared with regular PCI cases, excimer laser does not increase in-hospital MACCE[20].

In Thailand, there are only a few high-volume center hospitals that have excimer laser available due to its high cost and maintenance. Nevertheless, the complication rate of these complex procedures is also another important issue, especially, with the risk of perforation and dissection during the procedure. The lack of long-term superior outcome when applying in routine PCI made all the plaque modification devices reserves for, the last resort, very complex case and with anticipation of higher complication rate. The present study center has the highest number of excimer lasers used in Thailand, so, the authors performed retrospectively analysis data of both efficacy and safety issues for excimer laser devices in those with complex coronary lesions and high thrombotic risk and analyze the factors associated with excimer laser failure. Primary outcome was efficacy of the excimer laser defined as technical success excimer laser. Secondary outcomes were success rate of PCI procedure, success rate compared between groups, In-hospital mortality, and safety in term of coronary perforation, coronary slow flow, major dissection. The factors associated with technical failure excimer laser were analyzed.

Materials and Methods

Between January 2013 and December 2020, all patients in Siriraj Hospital, Bangkok, Thailand who had at least one vessel of coronary artery stenosis and that underwent coronary angioplasty with the excimer laser atherectomy were included in the present study. The present trial was approved by Siriraj IRB (COA no. Si 491/2021). All adult patients aged 18 years or older who had complex coronary anatomy and could pass the coronary guidewire beyond the stenotic or occlusion segment and then required a coronary adjunctive device with at least one size catheter of the excimer laser, which the excimer laser had to be able to pass into some part of the coronary vessel, were candidate for enrollment in the present study. The key exclusion criteria were the lesion that could not pass the coronary guidewire beyond the lesion, which was a contraindication for using the excimer laser. The catheter size of the excimer laser and the number of catheters used were selected according to operator consideration. The authors used the Spectranetics CVX-300 (Spectranetics, Colorado

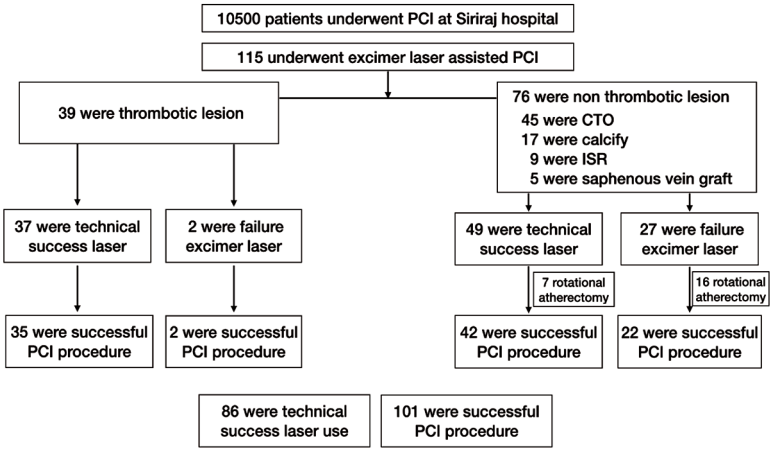

Figure 1. Patient outcome.

Springs, CO) excimer laser coronary atherectomy system with Vitesse or Turbo Elite excimer laser catheter. The fluency or amount of the energy (mJ) at the catheter tip per area unit (mm^2) had a range from 25 to 80 Hz or pulses per second. The catheter was advanced just proximal to the lesion, then the laser was activated and slowly moved forward through the lesion. The excimer laser technical success was defined as the laser catheter crossing the entire length of the stenotic lesion determined by angiographic evidence of the tip catheter beyond the lesion or referenced in the operative record[9]. Successful PCI procedure was defined as a final reduction of lumen diameter stenosis to less than 30% and thrombolysis in the myocardial infarction (TIMI) grade 3 flow. The thrombotic lesion was defined in a patient with acute coronary syndrome lesion (ACS) and angiographic evidence of thrombus or filling defect. Complications were recorded for coronary perforation defined as persistent extravascular contrast media classified per the Ellis classification[21], major dissection defined as type C or worse according to the National Heart, Lung and Blood Institute classification, and slow or no-reflow defined as inadequate myocardial perfusion through a given segment coronary circulation without angiographic evidence of mechanical vessel obstruction[14]. Inpatient adverse events were recorded after the start of the use of the excimer laser until hospital discharge. Data were obtained from the inpatient medical record and outpatient medical record. Coronary angiogram were reviewed from the Philips Xcelera patient data record system.

Statistical analysis

Sample size was calculated based on estimation proportion of one group formula. Categorical data were calculated as percentage frequency and proportion. Continuous data were summarized as mean ± standard deviation or median (interquartile range 25 to 75). Comparison of continuous variables used the Wilcoxon test, and categorical variables were compared using chi-square or Fisher's exact test. A p-value of less than 0.05 was considered to be statistically significant. Factors associated with excimer laser failure were calculated by univariate and multivariate logistic regression analysis.

Results

One hundred fifteen lesions from 112 patients, or 1.1% of all PCI patients, were enrolled in the present study between January 2013 and December 2020 as shown in Figure 1. There were 75 males (65.2%). The mean patient age was 67.1±11.6 years old. Of the 112 patients, 45.2% of the patients were diabetic, 87% had hypertension, 39.1% had chronic kidney disease, 39.1% had a history of previous PCI, and 10.4% were previous CABG. The average left ventricular systolic function (LVEF) was 51.9±15.9%. Most patients presented with chronic coronary syndrome (CCS) in 42.6% followed by non-ST-elevation acute coronary syndrome in 27.8%, and ST-elevation myocardial infarction in 29.6% as shown in Table 1.

Peri-procedural details

Of the total 115 lesions, the two main indications for excimer laser use were chronic total occlusion (CTO) in 39.1% and thrombotic lesion in 33.9% with high thrombus burden[22]. High thrombus burden was defined as thrombolysis in myocardial infarction (TIMI) thrombus grade 4 or 5 and was present in

Table 1. Baseline patient characteristics

	All lesions (n=115)	Technical success laser (n=86)	Technical failure laser (n=29)	p-value
Sex: male; n (%)	75 (65.2)	57 (66.3)	18(62.1)	0.681
Age (year); mean±SD	67.1±11.6	64.5±11.3	74.9±8.7	<0.001
Age ≥80 years; n (%)	14 (12.2)	5 (5.8)	9 (31.0)	0.001
Diabetes; n (%)	52 (45.2)	36 (41.9)	16 (55.2)	0.213
Hypertension; n (%)	100 (87.0)	72(83.7)	28 (96.6)	0.110
Dyslipidemia; n (%)	99 (86.1)	73 (84.9)	26 (89.7)	0.758
Creatinine; mean±SD	1.7±1.9	1.7±2.0	1.7±1.5	0.946
Chronic kidney disease (GFR <60); n (%)	45 (39.1)	29 (33.7)	16 (55.2)	0.041
Cerebrovascular disease; n (%)	6 (5.2)	4 (4.7)	2 (6.9)	0.641
Previous PCI; n (%)	45 (39.1)	27 (31.4)	18 (62.1)	0.003
Previous CABG; n (%)	12 (10.4)	6 (7.0)	6 (20.7)	0.071
Acute coronary syndrome; n (%)	66 (57.4)	55 (64.0)	11 (37.9)	0.014
LVEF; mean±SD	51.9±15.9	52.4±16.1	50.6±15.5	0.630
LVEF <40%; n (%)	25 (21.7)	18 (20.9)	7 (24.1)	0.717
Thrombotic lesion; n (%)	39 (33.9)	37 (43.0)	2 (6.9)	<0.001
Chronic total occlusion; n (%)	45 (39.1)	30 (34.9)	15 (51.7)	0.108

SD=standard deviation; GFR=glomerular filtration rate; PCI=percutaneous coronary intervention; CABG=coronary artery bypass graft; LVEF=left ventricular ejection fraction

Table 2. Peri-procedural detail

	All lesions (n=115); n (%)
Lesion characteristic	
Thrombotic lesion	39 (33.9)
TIMI thrombus grade 1-3	4 (10.3)
TIMI thrombus grade 4	5 (12.8)
TIMI thrombus grade 5	30 (76.9)
Chronic total occlusion	45 (39.1)
Calcified	17 (14.8)
In-stent restenosis	9 (7.8)
Saphenous vein graft	5 (4.3)
Lesion site	
Left main	5 (4.3)
Left anterior descending	30 (26.1)
Left circumflex	13 (11.3)
Right coronary artery	67 (58.3)
Radial access	52 (45.2)
Number of laser catheter	
One catheter	98 (85.2)
Two catheters	16 (13.9)
Three catheters	1 (0.9)
Size of laser catheter	
0.9 mm	91 (79.1)
1.4 mm	30 (26.1)
1.7 mm	11 (9.6)
Balloon predilatation	19 (16.5)
Adjunctive imaging	
IVUS	44/101 (43.6)
OCT	21/101 (20.8)
No imaging use	36/101 (35.6)

TIMI=thrombolysis in myocardial infarction; IVUS=intravascular ultrasound; OCT=optical coherence tomography

89.7% or 35 of 39 patients. One size of excimer laser catheter was used in most patients (85.2%). The default strategy was direct excimer laser catheter used without pre-dilatation. Only 16.5% of patients had upfront pre-dilatation. Half of all patient target lesions were right coronary artery (RCA) in 58.3%. Intravascular imaging was performed around two-third of those successful PCI cases divided into 43.6% of intravascular ultrasound (IVUS) and 20.8% of optical coherence tomography (OCT) use as shown in Table 2.

Procedural variables for PCI patients with thrombotic and non-thrombotic lesions were as presented in Table 3. The numbers of coronary balloon use were higher in the non-thrombotic compare with the thrombotic lesion group with a median of 4 (2 to 5) versus a median of 2 (1 to 2) (p=0.001). Due to contraindication of rotational atherectomy in a thrombotic lesion, subsequent rotational atherectomy was therefore performed only in the non-thrombotic group of 23 patients (30.3%) after the excimer laser. It is noted that 21 out of 23 patients (91.3%) had successful PCI results.

The overall excimer laser technical success was 74.8%. The success rate was significantly higher in the thrombotic lesions compare to the non-thrombotic lesions at 94.9% versus 64.5% (p<0.001). However, the overall PCI procedure success rate is not different between the thrombotic and the non-thrombotic groups at 94.9% versus 84.2% (p=0.135). The adjunctive use of rotational atherectomy in the non-

Table 3. Procedure detail between non thrombotic and thrombotic groups

	All lesions (n=115)	Non-thrombotic (n=76)	Thrombotic (n=39)	p-value
Technical success laser; n (%)	86 (74.8)	49 (64.5)	37 (94.9)	<0.001
Successful PCI procedure; n (%)	101 (87.8)	64 (84.2)	37 (94.9)	0.135
Rotational atherectomy use; n (%)	23 (20.0)	23 (30.3)	0 (0.0)	-
Coronary balloons; median (P25 to P75)	3 (2 to 4)	4 (2 to 5)	2 (1 to 2)	0.001
Coronary stents; median (P25 to P75)	2 (1 to 2)	2 (0 to 3)	1 (1 to 2)	0.066
Length of stay after PCI (days); median (P25 to P75)	1 (1 to 3)	1 (1 to 2)	3 (2 to 6.25)	0.001
IABP use; n (%)	8 (7.0)	3 (3.9)	5 (12.8)	0.118
Fluoroscopic time (minute); mean±SD	41.2±21.8	49.0±21.1	25.9±13.4	<0.001
Radiation dose (Gy); mean±SD	3.95±2.6	4.7±2.6	2.5±1.7	<0.001
Contrast volume (mL); mean±SD	188.7±77.1	205.8±75.9	154.9±68.7	0.001
Procedure time (minute); mean±SD	111.89±48.4	126.9±47.8	83.0±34.6	<0.001

SD=standard deviation; PCI=percutaneous coronary intervention; IABP=intra-aortic balloon pump

Table 4. Complication rate between non thrombotic and thrombotic groups

	All lesions (n=115); n (%)	Non-thrombotic (n=76); n (%)	Thrombotic (n=39); n (%)	p-value
Perforation	9 (7.8)	7 (9.2)	2 (5.1)	0.716
Slow flow	9 (7.8)	2 (2.6)	7 (17.9)	0.007
Major dissection	9 (7.8)	8 (10.5)	1 (2.6)	0.164
Mortality	3 (2.6)	2 (2.6)	1 (2.6)	1.000
Any complication listed above	27 (23.5)	17 (22.4)	10 (25.6)	0.695

thrombotic lesion because of the technical failure laser as either partially cross or failed, was 16 out of 27 patients and success rate of the procedure was very high with 15 out of 16 (93.8%).

Overall procedural success was 87.8%. The complex 2-stent technique was done in 4.3%. Catheter size 0.9, 1.4, and 1.7 mm laser catheter were used in 91 (79.1%), 30 (26.1%), and 11 (9.6%) patients, respectively. Coronary perforation was 7.8%. The coronary slow flow was 7.8%. Major dissection was 7.8%. Neither cardiac tamponade nor pericardiocentesis was found in the present study. In-hospital mortality was 2.6%. No patient died during the procedure. The median time of hospital stay was one day. Within the patients with successful PCI procedures, plain old balloon angioplasty (POBA) only without stenting was done in 16 patients (15.8%).

The complication rate between the thrombotic and non-thrombotic groups is as described in Table 4. The slow flow/no-reflow phenomenon was higher in the thrombotic group at 17.9% versus 2.6% (p=0.007). The coronary perforation and major dissection were not different at 5.1% versus 9.2% (p=0.716) and 2.6% versus 10.5% (p=0.164), respectively. There was no difference in mortality and hospital stays. Fluoroscopic time, radiation dose, contrast volume, and procedure time were all significantly higher in the non-thrombotic group.

Association of technical failure excimer laser was increasing age, chronic kidney disease, previous PCI, previous CABG, ACS presentation, non-thrombotic lesion, and chronic total occlusion lesion (p<0.05 unadjusted). After multivariate analysis adjusted for baseline comorbidities and procedural variables, the factors that remained significantly associated with technical failure of excimer laser use were age of 80 years or older and non-thrombotic lesion (p<0.05) as shown in Table 5.

Discussion

In patients with complex and high-risk lesions who underwent PCI with excimer laser-assisted in the present study, a higher technical failure rate was observed in non-thrombotic lesions, which was different from the other studies in Japan that claimed equal success rate between thrombotic and non-thrombotic groups. This might be due to higher proportion of in-stent restenosis (ISR) patients in that study[14]. The difference of disease nature should also be taken into consideration. A higher proportion of CTO in the present study might be a

Table 5. Factors associated with technical failure excimer laser

Factors	Univariate analysis		Multivariate analysis	
	OR (95% CI)	p-value	OR (95% CI)	p-value
Age ≥80 years	7.29 (2.20 to 24.15)	0.001	6.18 (1.72 to 22.25)	0.005
Hypertension	5.44 (0.68 to 43.37)	0.109		
Chronic kidney disease (GFR<60)	2.42 (1.03 to 5.70)	0.043		
Previous PCI	3.58 (1.49 to 8.60)	0.004		
Previous CABG	3.48 (1.03 to 11.82)	0.046		
Acute coronary syndrome	0.34 (0.14 to 0.82)	0.016		
Nonthrombotic lesion	10.19 (2.28 to 45.6)	0.002	9.13 (1.98 to 42.06)	0.005
Chronic total occlusion	2.00 (0.85 to 4.69)	0.111		

OR=odds ratio; CI=confidence interval; GFR=glomerular filtration rate; PCI=percutaneous coronary intervention; CABG=coronary artery bypass graft

factor influencing the lower technical excimer laser success rate. Definition of technical success laser was another important issue. If partial excimer catheter crossing with plaque modification was judged to be a success excimer laser used as in another study[9], a higher success rate of excimer would be observed. Even when the technical success of excimer laser in CTO lesion is limited, it can facilitate the device crossing. For thrombotic lesions, the present study had a high percentage of technical success excimer lasers consistent with other studies[12]. The overall success of the PCI procedure was high and similar to the studies mentioned before. Almost 90% of thrombotic cases in the present study were high thrombus burden defined as TIMI thrombus grade 4 or 5. This group of patients was forecasted to benefit from excimer laser, the present study had a high success rate of passing excimer laser in these thrombotic cases, which is possibly applicable in the real practice. In the non-thrombotic group, one interesting point was the use of rotational atherectomy combined with an excimer laser. It can increase the rate of successful PCI procedure in a population of technical failure excimer laser, although no head-to-head randomized data were conducted. Incidentally, there was a study that showed a trend toward decreasing combined use, which might be due to the better balloon profile and more popular extension catheter use[3].

For non-thrombotic heavily calcified lesions, the authors still suggest that rotational atherectomy be the first option for lesion modification, however, a major limitation of rotational atherectomy system is failure to pass the 0.009" dedicated coronary guidewire (Rotawire™, Boston scientific) beyond the lesion. Due to its inferior profile compared with 0.014" standard guidewire, this dedicated guidewire is usually inserted over a microcatheter. If the microcatheter could not pass the lesion, excimer laser is an alternative option. Uncrossable lesions are still challenging issue after regular guidewire crossing. Excimer laser work on those 0.014" guidewire and modified lesion that facilitate microcatheter crossing especially for proximal cap and contribute to subsequent rotational atherectomy use in the calcified lesion[9]. Lack of superiority for the long-term result of these adjunctive devices may affect the threshold for use, however, two-third of the patients in the present study underwent coronary imaging-guided PCI for optimization of stenting, which was much higher than a previous trial[4]. However, the benefit still needs further study and a larger population to prove the benefit.

The present study data findings were consistent with the previous evidence that the slow flow or no-reflow phenomenon was higher in thrombotic lesions but still achieved a high technical success rate[14]. The perforation rate in the present study was higher compared to the previous data. This could be related to multiple factors such as lesion tortuosity, the aggressiveness of lesion modification with larger size of the laser catheter, and unexpectedly high perforation rate of saphenous vein graft total occlusion lesion (two perforations out of five patients). However, all patients can be successfully managed with conservative strategy. Neither hemodynamically tamponade physiology nor pericardiocentesis was found. Comparing between thrombotic and non-thrombotic groups, coronary perforation, major dissection, and in-hospital mortality were not different. Factors associated with a predicted technical failure excimer laser after adjusting for variable were patients aged 80 years or older and non-thrombotic lesions. Incidentally, the excimer laser was not routinely used in the present study center but limited for particularly complex case, which were around 1.1% of all PCI case and were highly selected and

remained the last resort for use. This may explain the higher complication rate than the routine simple case. There were limitations to the present study. First, the sample size was relatively small. Second, the study was not a randomized control trial and the spectrum of patients selected for this device was dependent on the operator's decision. Third, there was no long-term outcome after PCI as well as no data of stent patency.

Conclusion

The excimer laser is another option for lesion modification with a high success rate in thrombotic lesions. In non-thrombotic lesions, the excimer laser could be safely used in uncrossable lesions with a fair success rate and facilitating the passing of other devices and yield high procedural PCI success with an acceptable complication rate. Predictors of the technical failure excimer laser were patients 80 years or older and non-thrombotic lesion.

What is already known on this topic?

Excimer laser is one of the adjunctive devices that worked on 0.014" guidewire and is indicated in both non-thrombotic lesion after guidewire passage and thrombus modification in thrombotic lesion. Excimer laser surpassed the limitation of rotational atherectomy in the situation that the dedicated Rotawire™ could not pass the lesion. Data of technical excimer laser success and safety were high but there were variations in the studies.

What this study adds?

This study is the first publication of excimer data in Thailand. The authors demonstrated the overall good excimer laser success rate and showed that thrombotic lesions had significantly higher success rate compared with non-thrombotic lesions within clear definition of technical success. However, overall success PCI procedure were not different. This study revealed that patient 80 years or older and non-thrombotic lesions were associated with failure of excimer laser.

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Conflicts of interest

The authors declare no conflict of interest.

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