

Acute and Follow-up Results of Laser Angioplasty : Single Center Experience

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Abstract

Excimer laser angioplasty was used to treat total occluded coronary arteries and instent restenosis lesions with high success rate. To assess immediate and long-term results of patients treated with excimer laser, we analyzed demographic information and the immediate results of 44 patients who underwent ELCA. The patients were followed up and assessed for clinical restenosis. The initial success rate of ELCA was 86.4 per cent which is comparable to plain balloon angioplasty performed during the same period. Clinical restenosis was 29 per cent. In conclusion, ELCA for patients with coronary artery disease can be performed with initial high success rate and reasonable long-term restenosis.

Key word : Laser Angioplasty, Excimer Laser, Instent Restenosis, Total Occlusion

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Excimer laser angioplasty facilitates revascularization through the mechanism of ablation of atheromatous tissue and avoiding problems with embolization, thus allowing more complete dilatation to be achieved with adjunctive balloon angioplasty^(1,2). Excimer Laser Coronary Angioplasty (ELCA) has been shown to have acceptable acute success rates in large registry reports⁽¹⁻³⁾. These registry reports including a total of almost 4000 patients treated with excimer laser coronary angioplasty, relative risk analysis and comparison with historical control suggested that patients with total occlusions, aorto-ostial stenoses, long lesions, saphenous vein graft lesions, and balloon dilatation failure are the most likely to benefit from treatment with excimer laser angioplasty. Recently in-stent restenotic lesions have been reported to be successfully treated with excimer laser^(4,5).

The purpose of this study was to describe the acute outcome and intermediate term follow-up of excimer laser coronary angioplasty in lesions known not to be ideal for balloon angioplasty because of their morphology, or location and in-stent restenotic lesions.

PATIENTS AND METHOD

Patients' Entry: Between November 1997 and December 1998, 44 patients were treated with excimer laser at Her Majesty Cardiac Centre. Patients were considered for the procedure only if they had symptomatic coronary artery disease and/or objective evidence of myocardial ischemia sufficient to warrant either balloon angioplasty or coronary artery bypass graft surgery (CABG). The selection to use excimer laser or plain balloon angioplasty was by the preference of each operator. However, the majority of lesions were considered to be non-ideal for plain balloon angioplasty. Patients undergoing an evolving myocardial infarction were not considered for excimer laser angioplasty. Exclusion criteria included patients with contra-indication for CABG, acetyl salicylic acid, and heparin or lesion within an acute angle of $>60^\circ$ and vessels <2.5 mm in diameter.

Excimer Laser Source: We used the CVX 300™ System (Spectranetic Corporation, Colorado Spring, Colorado) which is an XeCl excimer laser system operating at 308 NM, with a fluence range of 30 to 60 mJ/mm². The average pulse duration was 135 ns, and laser pulses were delivered at a rate of 25 Hz. The laser catheters were multifiber

monorail catheters with diameters of 1.4, 1.7, or 2.0 mm that contained at least 200 individual of 50 -100 mm optical fibers. A warm saline flush technique was used and followed by appropriately-sized balloon dilatation in every case. The details of the laser technique used were previously described⁽³⁾. Intracoronary stent was used as per the operator's preference. A 0.018 inch diameter laser guide wire could be used in totally occluded lesions only after at least 15 minutes of unsuccessful attempts with a conventional guide wire.

Definitions: Clinical success was defined as <50 per cent residual stenosis after laser with or without adjunctive balloon angioplasty, and the absence of a major complication (death, Q wave or non Q wave myocardial infarction, abrupt vessel closure or need for coronary artery bypass surgery) at anytime during hospitalization. Angiographic restenosis was indicated by the presence of 50 per cent stenosis at the treated site or by the need for revascularization (coronary artery bypass surgery or repeat angioplasty) of the target vessel at anytime during follow-up. Clinical restenosis was defined by the presence of angiographic restenosis or recurrence of angina, positive exercise treadmill test with ECG change in the same lead to tests done prior to the procedure or development of myocardial infarction in an area of the left ventricle that receives blood supply from the treated vessel. The overall restenosis rate was calculated by combining the angiographic and clinical restenosis rate in patients who did not undergo follow-up angiography. Abrupt vessel closure was defined by total or subtotal occlusion of the vessel after attempted angioplasty with corresponding Thrombolysis In Myocardial Infarction (TIMI) grade 0-1 flow, with or without associated symptoms or signs of ischemia. Coronary artery dissection was defined as either a radiolucent area, often linear, within the coronary lumen during contrast injection, parallel tracts or double lumen separated by a radiolucent area, contrast outside the coronary lumen but within the wall of the vessel, or spiral luminal filling defect^(6,7). Lesion types A, B₁, B₂ and C were defined as previously described⁽⁶⁾. Coronary artery perforation was defined by a persistent extravascular collection of medium contrast beyond the vessel wall with a well-defined exit port. Myocardial infarction was defined by prolonged angina (>30 minutes), total creatinine kinase or creatinine kinase iso-enzyme increase to greater than the upper limit

of normal, with electrocardiographic evidence of myocardial infarction (which was defined as either ST-segment elevation, primary ST-segment depression, or new significant Q wave 2 continuous leads).

Statistical Analysis: Data were described as mean \pm SD or percentage as appropriate. Categorical variables were compared by using the Chi-square test. Student's t-test was used to determine the quantitative difference between ELCA and balloon angioplasty. P-value equal to or less than 0.05 is considered as significant difference.

RESULTS

There were 44 patients (35 males, 9 females) who underwent excimer laser angioplasty for 44 lesions during 13 month period. The average age was 63 ± 9.5 years old (range 39-82). The main indication for ELCA was stable angina pectoris (Fig. 1). During the same period, 330 simple plain balloon angioplasties were performed (Table 1). There was no difference of demographic findings between the two groups except a higher average lesion treated per patient in plain balloon PTCA group. Most patients had more than one conven-

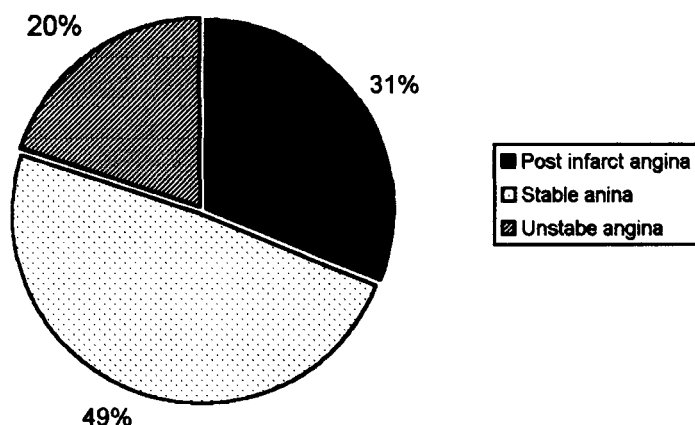


Fig. 1. Clinical status of patients at the times of ELCA.

Table 1. Characteristics of patients who underwent ELCA and balloon PTCA.

	ELCA		Balloon PTCA		p-value
		%		%	
Total number	44		330		
Number of lesion	44		457		
Lesion/procedure	1.0		1.4		
Total Occlusion	1	25	98	21.4	
M : F	35 : 9		246 : 84		ns
Age (years)	63 \pm 9.5		62.3 \pm 11.0		ns
Indication					
Stable AP	21	49	147	45	
ACS	9	20	148	45	
Post MI AP	14	31	27	8	
Other	-		8	2	

M = male, F = female, AP -angina-pectoris, MI = myocardial infarction, ACS = Acute coronary syndrome (unstable angina and acute MI)

tional risk factor of coronary artery disease (Table 2) similar to patients who underwent plain balloon PTCA.

Of the 44 lesions treated, in 33 lesions only laser catheters were used for ablation, in 9 lesions only laser wires were used and in 2 lesions both the laser wires and catheters were used. More than half of the lesions were located proximally in each vessel with the majority in the left anterior descending artery (Table 3) which were similar to location of lesions treated by plain balloon PTCA except there were very few lesions treated by ELCA located in the distal coronary arteries. (There were 3 distal lesions treated by ELCA and 85 lesions treated by balloon located distally, $p=0.05$). However, there was a lower percentage of the lesion in the circumflex artery treated by ELCA compared to plain balloon angioplasty. Of the lesions treated by

ELCA, 13 lesions were instant restenosis, 19 lesions were type B₂, and 12 lesions were type C. Of these lesions, 25 lesions procedural results were totally occluded which more common than in the balloon PTCA group.

Procedural Results (Table 4): From the 44 patients who underwent ELCA, complete procedural success was obtained in 38 patients (86.4%) with 22 patients achieving complete revascularization. In the remaining 6 patients, the procedures were unsuccessful because of failure to pass the laser guide wire (after failed attempt of conventional guide wire) in chronic total occlusion. The success rate of a laser guide wire in this type of lesion ($n=11$) was 45.5 per cent. Of the 6 patients with failed procedure, 3 had coronary artery perforation without any major complications or contrast leakage at the end of the procedure. One patient had

Table 2. Risk factors of patients who underwent ELCA and balloon PTCA.

	ELCA		Balloon PTCA		p-value
		%		%	
Diabetes mellitus	22	50	120	36.4	ns
Hypertension	26	59.1	182	55.2	ns
Hypercholesteral	31	70.5	184	55.8	ns
Smoking	9	20.5	-		
Family history	3		-		

Table 3. Location of lesions treated.

	ELCA (n=44)	Plain PTCA (n=457)	p-value
LAD	25 (57%)	206 (45%)	ns
proximal	17	115	
mid	8	79	
dist	-	12	
LCx	4 (9%)	104 (23%)	0.04
proximal	2	41	
mid	2	40	
distal	0	23	
RCA	15 (34%)	142 (31%)	ns
proximal	7	51	
mid	5	46	
distal	3	45	
LM	0	3 (0.6%)	-
LIMA	0	2 (0.4%)	-

CAD - left anterior descending coronary artery

LCx - left circumflex artery, RCA - right coronary artery

LMT - left main coronary artery,

LIMA - left internal mammary arterial graft

Table 4. Procedural complications and results.

	ELCA		Plain PTCA		p-value
		%		%	
Lesion attempt	44		457		
Success	38	86.4	141	90.6	ns
Coronary perforation	4	9.1	4	0.9	<0.05
Vessel dissection	5	11.4	63	13.8	ns
Side branch occlusion	0	0	4	0.9	-
Number of patients	44		330		
AMI	0	0	1	0.3	-
Emergency surgery	0	0	2	0.6	n
CVA	0	0	1	0.3	n
Dead	1	2.3	1	0.3	ns

AMI - acute myocardial infarction, CVA - cerebrovascular accident

Table 5. Timing of recurrent symptoms and revascularization.

Event	No. of patients	Timing after procedure/months
Repeat PTCA	4	2, 3, 9, 11
CABG	4	1, 3, 8, 9
Recurrent angina	2	10, 11
Fatal MI	1	14

CABG - coronary artery bypass graft surgery

MI - myocardial infarction

laser angioplasty 48 hours after cardiogenic shock and died 3 days after a failed attempt to open an occluded proximal left anterior descending artery.

The procedure successful rate of totally occluded lesions of laser catheters after being crossed by a guide wire (n=19) was 100 per cent. Overall success rate for the total occlusion (n=25) was 76 per cent with 6 lesions being uncrossable with laser guide wire. One hundred per cent success rate was obtained from 13 lesions of in-stent restenosis.

Of the 38 patients who had successful procedures, one had perforation which was subsequently sealed off following balloon angioplasty, 5 had non-occlusive dissection and one had acute vessel closure during the procedure. There were 20 stents used in 20 patients for 20 lesions. The rest of the lesions required only one low pressure (3 ATM) balloon inflation. There was no patient who developed acute myocardial infarction or needed emergency bypass surgery. Except the one who died,

all patients were discharged within 2 days. The success and complication rates of patients who had ELCA were not different from those who underwent only plain balloon angioplasty during the same period.

Follow-up Results: There was complete follow-up of the 38 subjects who had successful laser angioplasty at the average follow-up time of 20.3 ± 5.5 month. Eleven patients had recurrent ischemia at different times (Table 5). Ten patients had angiographic restenosis at the treated site and underwent repeated plain balloon PTCA and stent implantation. One patient who had recurrent angina and subsequent fatal MI.

The other 27 patients, all of whom had positive treadmill exercise stress test prior to the ELCA, repeated the exercise stress test during follow-up and showed no evidence of ischemia. Nineteen patients were in the New York Heart Association functional class I and 8 patients were in functional class II. The overall restenosis rate was 29 per cent.

DISCUSSION

In this series we described acute and intermediate outcomes of excimer laser angioplasty from a single center experience. Our acute clinical success rate was 86 per cent and overall restenosis rate was 29 per cent. The acute success rate was slightly lower than other single center in experience⁽⁸⁻¹¹⁾, but similar to a multicenter registry⁽¹²⁾. The lower restenosis rate compared to other reports^(11,12) may be due to a higher rate of stent usage in our report.

This study is not a randomized investigation but was designed to describe the effect of a new technology of coronary angioplasty on new lesions' indication and clinical outcomes. The results of these new indications are comparable to simple lesions which had plain balloon angioplasty in our laboratory. The lesions being treated with excimer laser in our report are mainly total occlusion and instant restenosis. There are not many other equipment option of percutaneous revascularization to treat these types of lesions. Other complex lesions which were reported to have benefit if treated by excimer laser such as aorto-ostial, and saphenous vein graft lesions^(1-5,12,13) were not present in our series. Except the patient with cardiogenic shock who died following the failed procedure, our complication rates are comparable to previous report⁽¹²⁾.

Excimer laser coronary angioplasty was first investigated as a method of reducing stenosis, but it was lately found that it cannot overcome this problem. The overall re-stenosis rate of only 29 per cent in our report may reflect the bias inherent in the low rate of angiographic follow-up and widely available stent usage during the time of the study. Using the model of Califf *et al*⁽¹⁴⁾ an estimate res-

tenosis rate of 18 per cent in asymptomatic patient who did not have angiography, we would expect an angiographic restenosis rate of 48 per cent which is comparable to multicenter registry report⁽¹²⁾.

Limitation of the Study

The major limitation of this study is its lack of randomization of the laser and conventional technique. However, few patients in this report had lesions which were favorable with plain balloon angioplasty. Because this was our initial experience with the technique, patients selected to undergo this procedure were those in whom the operator thought had a reasonable chance of success based on previous experience with balloon angioplasty. As a result, there was selection bias in the study. Another limitation is the angiographic follow-up which is incomplete. Greater accuracy in identifying restenosis rates would have been obtained with complete angiographic follow-up.

SUMMARY

The authors' initial experience with excimer laser angioplasty suggests that it can be used as an adjunct to balloon angioplasty. It may be particularly well suited to totally occluded and instant restenotic lesions. Restenosis rate following the procedure was not reduced compared to historical control plain balloon angioplasty.

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ผลการขยายหลอดเลือดหัวใจด้วยแสงเลเซอร์

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การใช้แสงเลเซอร์ขยายหลอดเลือดหัวใจที่มีการอุดตันอย่างถาวร หรือในกรณีที่มีการตีบซึ่งของหลอดเลือดหัวใจในบริเวณขดลวด สามารถทำได้อย่างปลอดภัย การศึกษานี้ได้รวบรวมผลการรักษาด้วยวิธีดังกล่าวและติดตามดูผลในผู้ป่วย 44 ราย พบว่าความสำเร็จของการใช้แสงเลเซอร์เท่ากับร้อยละ 84.6 และเมื่อติดตามผู้ป่วยเป็นระยะเวลา 20.3 ± 5.5 เดือน พบว่ามีการตีบตันขึ้นอีกร้อยละ 29

คำสำคัญ : หลอดเลือดหัวใจตีบ, เลเซอร์, ขดลวด, การขยายหลอดเลือด

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