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Randomised trial of excimer laser angioplasty versus balloon angioplasty for treatment of obstructive coronary artery disease

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Summary

Background Excimer laser coronary angioplasty is reported to give excellent procedural results for treatment of complex coronary lesions, but this method has not been compared with balloon angioplasty in a randomised trial.

Methods Patients (n=308) with stable angina and coronary lesions longer than 10 mm on visual assessment were included. 151 patients (158 lesions) were assigned randomly to laser angioplasty and 157 (167 lesions) to balloon angioplasty. The primary clinical endpoints were death, myocardial infarction, coronary bypass surgery, or repeat coronary angioplasty of the randomised segment during 6 months of follow-up. The primary angiographic end-point was the minimal lumen diameter at follow-up in relation to the baseline value (net gain), as determined by quantitative coronary angiography.

Findings Laser angioplasty was followed by balloon angioplasty in 98% of procedures. The angiographic success rate was 80% in patients treated with laser angioplasty compared with 79% in patients treated with balloon angioplasty. There were no deaths. Myocardial infarction, coronary bypass surgery, and repeat angioplasty occurred in 4.6%, 10.6%, and 21.2%, respectively, of the patients in the laser angioplasty group compared with 5.7%, 10.8%, and 18.5% of the balloon angioplasty group. Net mean (SD) gain in minimal lumen diameter was 0.40 (0.69) mm in patients treated with laser angioplasty and 0.48 (0.66) mm in those treated with balloon angioplasty (p=0.34). The restenosis rate (>50% diameter stenosis) was 51.6% in the laser angioplasty group versus 41.3% in the balloon angioplasty group (p=0.13).

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Interpretation Excimer laser angioplasty followed by balloon angioplasty provides no benefit additional to balloon angioplasty alone with respect to the initial and long-term clinical and angiographic outcome in the treatment of obstructive coronary artery disease.

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Introduction

Excimer laser coronary angioplasty (ELCA) is one technique used for treatment of obstructive coronary artery disease. The excimer laser system exhibits favourable characteristics for ablation of atherosclerotic tissue compared with other laser devices because of its small penetration depth and the induction of limited damage to the vascular wall.^{1–4} Compared with results after balloon angioplasty,⁵ prospective non-randomised studies of ELCA^{6–8} showed a substantial improvement in primary success rate and procedural complications in patients with complex coronary lesions. These promising results warranted a randomised trial to establish the role of laser angioplasty as an alternative approach in the treatment of obstructive coronary artery disease. Most patients considered suitable for coronary angioplasty have long (>10 mm) coronary lesions. These considerations led us to undertake a randomised trial to evaluate initial and long-term clinical and angiographic outcome of ELCA compared with balloon angioplasty in patients with long coronary lesions.

Methods

Selection of patients

After completion of a pilot phase including 71 patients,⁹ the multicentre Amsterdam-Rotterdam (AMRO) trial was started in September, 1991, and completed in November, 1993. Based upon the results of nonrandomised studies of ELCA, we expected the primary procedural success rate after ELCA to be greater than 85% and less than 70% after balloon angioplasty. Thus, with an alpha-error of 0.05 and a beta error of 0.20, 120 patients with complete follow-up were required in each treatment group. 300 patients were considered necessary for inclusion taking into account that 20% of the patients were not eligible for follow-up angiography. All patients (either with single or multivessel disease) with stable angina pectoris, coronary lesions longer than 10 mm on visual assessment, and total or functional

occlusions (thrombolysis in myocardial infarction [TIMI] flow grade 0 or 1)¹⁰ who were suitable for coronary angioplasty were screened for inclusion in the trial. Clinical exclusion criteria were: unstable angina, myocardial infarction within the previous 2 weeks, a life expectancy of less than 1 year, and factors that made clinical or angiographic follow-up difficult. Angiographic exclusion criteria were: intended angioplasty of a venous bypass graft, unprotected left main disease, extreme tortuosity of the vessel, highly eccentric lesions, vessels with ostial lesions, angulated lesions of more than 45°, bifurcation lesions, aorta-ostial lesions, lesions with angiographic evidence of a thrombus or dissection, and total occlusions with a low likelihood of passage with a guide wire.¹¹ The protocol was approved by the institutional review boards of the participating centres.

Randomisation

Patients were assigned randomly by telephone from a central office to laser angioplasty or balloon angioplasty after eligibility had been established and written informed consent obtained. Lesions suitable for balloon angioplasty only were indicated before the randomisation in patients with multiple lesions. All coronary lesions in a patient who fulfilled the selection criteria were treated according to the same treatment allocation.

Laser angioplasty and balloon angioplasty

Patients' anti-anginal medication was continued until the procedure. A calcium antagonist (nifedipine 20 mg three times a day) was added during in-hospital stay. Acetyl salicylic acid (250–500 mg daily) was given a day before the procedure and continued for 6 months afterwards. The excimer laser systems (wavelength 308 nm) used were: the Dyrmer 200+ (Advanced Interventional Systems Inc, Irvine, CA, USA), with a pulse duration of 210 ns and a repetition rate of 20 Hz, delivered by multifibre over wire laser catheters with a diameter of 1.3, 1.6, or 2.0 mm, at a fluence of 45–65 mJ/mm²; and the CVX-300 system (Spectranetics, Colorado Springs, CO, USA), which emits a pulse duration of 135 ns at a repetition rate of 25 Hz, delivered by 1.4, 1.7 or 2.0 mm laser catheters, with a similar fluence. The 1.3z mm laser catheter was used after its introduction in 1992. The 1.3/1.4 mm laser catheter was used for vessels with diameter of 1.8–2.3 mm, 1.6/1.7 mm laser catheter for vessels with a diameter of 2.3–3.0 mm, and 2.0 mm laser catheter for vessels with a diameter of 3.0 mm or more.

Cardiac catheterisation in all patients was by the percutaneous femoral approach. Heparin was administered intravenously to maintain the activated clotting time at more than 400 s and was continued for at least 12 h after the procedure. After crossing the lesion with the guide wire, the laser catheter was advanced at a speed of about 1 mm/s. A larger laser catheter was used if the angiographic result was unsatisfactory after one passage of the laser catheter. Additional balloon angioplasty was done to optimise the angiographic result. Serum creatine kinase myocardial band concentration was measured routinely within 12 h after the initial procedure.

Quantitative coronary angiography

Quantitative coronary angiography, before and after the procedure and at 6 months' follow-up, was done after administration of 0.1–0.3 mg of nitroglycerin or 1–3 mg of isosorbine dinitrate by the intracoronary route. The angiograms were analysed, in a central laboratory with the computer-assisted cardiovascular angiography analysis system (CAAS) for determination of the interpolated reference diameter, the minimal lumen diameter, and the percentage diameter stenosis.¹² Lesion length was determined by the maximal lesion length between the crossing point of the computerised contour detection line and the interpolated reference diameter line. If a revascularisation procedure involving the treated segment had been done before the angiography at 6 months, the most recent angiogram obtained before this intervention was used as the follow-up angiogram regardless of the timing of the second intervention. If the time from intervention to follow-up

	ELCA	Balloon angioplasty
Number of patients	151	157
Clinical characteristics		
Mean (range) age (yr)	58.1 (32–83)	59.4 (35–79)
Sex (male/female)	115/36	114/43
Smoking status		
Never	41	50
Previous	74	68
Current	33	36
Unknown	3	3
Diabetes mellitus	15	20
Previous conditions		
History of hypertension	57	50
History of hypercholesterolaemia	58	59
History of stroke	4	5
History of peripheral vascular disease	9	14
Myocardial Infarction	70	68
Coronary artery bypass grafting	10	13
Balloon angioplasty	16	25
Exertional angina (CCS class*)		
I	11	8
II	44	49
III	82	86
IV	14	14
Non exertional angina	77	81
Mixed angina	76	80
Medication at screening		
Nitrates	95	108
Ca-antagonists	122	133
Beta-blockers	120	113
Monotherapy	25	20
Double-therapy	57	65
Triple-therapy	66	68
No therapy	3	4
Extent of coronary artery disease		
One-vessel disease	83	79
Two-vessel disease	51	63
Three-vessel disease	17	15
Number of lesions	158	167
Angiographic characteristics		
Location of lesion		
Right coronary artery	56	61
Left anterior descending	61	64
Left circumflex	41	42
Type of lesion†		
A	1	0
B1	0	2
B2	83	71
C	74	94
Ulcerated	53	55
Multiple irregularities	83	97
Calcified	33	39
Eccentric	100	104
Tandem	18	26
Length by visual assessment (mm)		
<10	1	3
10–20	122	109
>20	33	44
Unknown	2	11
Grade of perfusion‡		
0	26	27
I	23	27
II	27	24
III	85	89

*According to classification of Canadian Cardiovascular Society;¹³ †according to modified American College of Cardiology/American Heart Association task force criteria;¹⁴ ‡according to TIMI-study group.¹⁰

Table 1: Base-line clinical and angiographic characteristics of 308 patients included in the intention-to-treat analysis

angiography was less than 3 months and no second intervention was performed, the patient was asked to undergo angiography again after 6 months. In the absence of a second angiogram at 6 months, the angiogram obtained most recently within the previous 3 months was used.

Clinical and angiographic follow-up

Patients were seen after 1 and 6 months for an interview, physical examination, and electrocardiogram. Follow-up coronary angiography was done after 6 months. Repeat intervention was

performed based on recurrent symptoms of angina and/or objective evidence of myocardial ischaemia and a diameter stenosis of more than 50% on visual assessment.

End-points

Primary clinical end-points were the occurrence of any of the following events during a 6 month (± 1 month) follow-up: cardiac death, myocardial infarction (based on the presence of at least two of the following: typical chest pain and/or a serum rise of more than twice the normal upper limit of the creatine kinase myocardial band level and/or new pathological Q-wave formation on the electrocardiogram), coronary bypass surgery, or a second angioplasty because of recurrent symptoms of angina and/or objective evidence of myocardial ischaemia by positive exercise testing related to the randomised segment. Coronary bypass surgery was defined to include emergency (within 12 h after the procedure) or elective bypass surgery. All the clinical events were reviewed by the critical-event committee, which was unaware of the treatment assignment.

Primary angiographic end-point was the minimal lumen diameter at the treated coronary site at 6 months follow-up relative to the baseline value before the procedure (net gain). Secondary end-points were: (1) laser success defined as a more than 20% reduction in diameter stenosis after laser angioplasty only on visual assessment; (2) angiographic success defined as a less than 50% residual stenosis at the end of the procedure on visual assessment; (3) acute gain defined as the minimal lumen diameter at the treated coronary site at the end of the procedure relative to the baseline value; (4) functional class at 6 months according to the classification of the Canadian Cardiovascular Society;¹³ (5) the percent diameter stenosis at the treated coronary site at 6 months' follow-up relative to the baseline value (net gain in percentage diameter stenosis); (6) restenosis rate defined as a more than 50% diameter stenosis at the treated coronary site at 6 months' follow-up angiography as determined by automated contour detection analysis; and (7) late loss defined as the minimal lumen diameter at the treated site at 6 months' follow-up relative to the minimal lumen diameter after the procedure.

Statistical analysis

Continuous variables (age, reference diameter, lesion length, percentage diameter stenosis, and minimal lumen diameter) were expressed as mean (SD) and were compared with the unpaired *t* test. Chi-squared analysis and Fisher's exact test for two by two tables were used to compare dichotomous variables. Clinical events and angiographic complications were compared by relative risk (RR) and 95% confidence interval. A *p* value less than 0.05 was considered statistically significant.

Results

Patient characteristics and randomisation

313 consecutive patients (330 lesions) were randomly assigned to ELCA (155 patients/162 lesions) or balloon angioplasty (158 patients/168 lesions). In five patients (four assigned to laser angioplasty, one to balloon angioplasty) the randomised segment was not treated. Of these five patients, one withdrew his informed consent and received balloon angioplasty. Two patients received no coronary intervention because the randomised segment showed a non-significant stenosis on the pre-procedural angiogram. One patient was randomised twice. The randomised segment was not treated in one patient due to emergency coronary bypass surgery after treatment of a non-randomised segment. These five patients were not included in the final analysis since there was no intention for treatment according to randomisation.

Clinical and angiographic baseline characteristics of the remaining 308 patients were similar and are shown in

table 1. Approximately half of the patients had multivessel disease and 50% had experienced a previous myocardial infarction. One third of the randomised coronary segments were total or functional coronary occlusions (TIMI 0 or 1).

158 lesions (151 patients) were randomly assigned to ELCA. ELCA could not be done during 25 procedures (25 patients) because of inability to cross the coronary lesion with any guide wire (16 lesions), or cross-over to balloon angioplasty (in total nine lesions: five because of inability to pass the guide wire, three due to technical failure of the laser system, and one because of presumed risk of perforation). Of the remaining 133 lesions, 130 were treated with additional balloon angioplasty to obtain an optimal angiographic result. Standalone laser angioplasty was done with three lesions (2%). In 89 of the 133 (67%) treated lesions, a laser catheter not larger than 1.3/1.4 mm was used. In 19 lesions more than one laser catheter was used.

167 lesions (157 patients) were randomly assigned to balloon angioplasty. Balloon angioplasty was not done during 22 procedures because the lesion could not be crossed with a guide wire. In two patients the lesion could not be crossed with the balloon; one of these was successfully treated with laser angioplasty only and one with laser angioplasty followed by balloon angioplasty. The remaining 143 lesions were treated with balloon angioplasty only.

Procedural results

The intention-to-treat analysis yielded a laser success by visual assessment in 68% (107 lesions) of the 158 lesions randomly assigned to ELCA. The angiographic success rate by visual assessment was 80% (126 lesions) in patients treated with ELCA compared with 79% (132 lesions) in patients treated with balloon angioplasty. The angiographic success rate by quantitative coronary angiography yielded similar results (80% in patients assigned to ELCA compared with 78% in patients assigned to balloon angioplasty).

The per protocol analysis yielded a success rate of 81% after ELCA, which increased to 91% after additional balloon angioplasty in patients allocated to ELCA compared with an angiographic success rate of 92% in

	ELCA (n=151)	Balloon angioplasty (n=157)	Relative risk (95% CI)	<i>p</i>
Death	0	0
Myocardial infarction	7 (4.6)	9 (5.7)	0.81 (0.31-2.12)	0.67
Q-wave	4 (2.6)	3 (1.9)	1.39 (0.32-6.10)	0.72
Periprocedural	2 (1.3)	2 (1.3)	1.04 (0.15-7.29)	0.97
Follow-up	2 (1.3)	1 (0.6)	2.08 (0.19-22.70)	0.54
Non-Q-wave	3 (2.0)	6 (3.8)	0.52 (0.13-2.04)	0.50
Periprocedural	3 (2.0)	3 (1.9)	1.04 (0.21-5.07)	0.96
Follow-up	0	3 (1.9)	0.15 (0.01-2.85)	0.09
Coronary artery bypass grafting	16 (10.6)	17 (10.8)	0.98 (0.51-1.87)	0.95
Periprocedural	7 (4.5)	3 (1.9)	2.43 (0.64-9.21)	0.18
Follow-up	9 (6.0)	14 (8.9)	0.67 (0.30-1.50)	0.32
Repeat angioplasty	32 (21.2)	29 (18.5)	1.15 (0.73-1.80)	0.55
Periprocedural	2 (1.3)	3 (1.9)	0.69 (0.12-4.09)	0.68
Follow-up	30 (19.9)	26 (16.6)	1.20 (0.75-1.93)	0.45
Primary clinical endpoint*	50 (33.1)*	47 (29.9)	1.11 (0.80-1.54)	0.55

*Death, myocardial infarction, coronary artery bypass grafting, or repeat angioplasty.

Table 2: Number (%) clinical events during the procedure and 6 months' follow-up

	ELCA	Balloon angioplasty	Difference (95% CI)	p
Number of lesions	124	126
Reference diameter* (mm)	2.51 (0.47)	2.47 (0.59)
Length (mm)	17.69 (5.58)	18.82 (7.15)
Diameter stenosis (%)				
Before angioplasty	68.5 (18.3)	68.9 (18.6)
After angioplasty	37.6 (10.3)	37.9 (8.9)	-0.4 (-2.8 to 2.0)	0.76
At follow-up	56.1 (23.3)	52.6 (23.4)	3.4 (-2.4 to 9.3)	0.25
Restenosis (%)	51.6	41.3	10.3 (-2.0 to 22.6)	0.13
Minimal lumen diameter (mm)				
Before angioplasty	0.77 (0.44)	0.77 (0.47)
After angioplasty	1.69 (0.41)	1.59 (0.34)	0.10 (0.01 to 0.19)	0.05
At follow-up	1.17 (0.71)	1.25 (0.68)	-0.08 (-0.25 to 0.93)	0.34
Net gain† (mm)	0.40 (0.69)	0.48 (0.66)	-0.08 (-0.25 to 0.09)	0.34
Acute gain‡	0.92 (0.53)	0.82 (0.50)	0.10 (-0.03 to 0.23)	0.15
Late loss§ (mm)	0.52 (0.70)	0.34 (0.62)	0.18 (0.15 to 0.35)	0.04

Figures are mean (SD) unless indicated.

*Reference values are interpolated diameters of normal vessels; †minimal lumen diameter (MLD) at follow-up minus MLD before initial procedure; ‡MLD after initial procedure minus MLD before initial procedure; §MLD after initial procedure minus MLD at follow-up.

Table 3: Quantitative analysis

patients allocated to balloon angioplasty (RR 0.99, 95% CI 0.92-1.06; p=0.69).

There were no deaths. The incidence of Q-wave and non-Q-wave myocardial infarctions was similar in both groups (table 2). Most non-Q-wave myocardial infarctions were small in both groups (maximal creatine kinase-myocardial band concentration <20 U/L).

Seven patients (4.5%) randomly assigned to ELCA required emergency coronary bypass surgery for the following reasons: severe dissection of the randomised segment (four patients, two of whom were treated with stenting as a bridge to coronary bypass surgery), perforation of the randomised segment (one patient), extravasation of contrast (one patient), and unstable angina (one patient). Emergency coronary bypass surgery was required in three patients (1.9%) randomly assigned to balloon angioplasty due to the occurrence of a severe dissection.

Intimal dissections after completion of the procedure occurred in 74 lesions (46.8%) in the patients treated with ELCA. Most of these dissections (91%) were minor: type A in 27 lesions, type B in 22 lesions, and type C in 18 lesions.¹⁵ The dissection rate was similar in patients treated with balloon angioplasty (54.5% [91 lesions] of patients) with 90% of dissections being minor: type A in 33 lesions, type B in 37 lesions, and type C in 12 lesions. The procedure was complicated by coronary spasm in seven patients treated with ELCA and in two patients treated with balloon angioplasty (RR 3.70, 95% CI 0.78-17.54; p=0.1). Coronary perforation resulting in haemodynamic deterioration occurred in one patient in the ELCA group. This complication did not occur in the balloon angioplasty group. The incidence of transient occlusions of the randomised segment was significantly higher in patients allocated to ELCA (ten patients) than in those allocated to balloon angioplasty (one patient) (10/57, 1.37-81.62; p=0.005).

Clinical and angiographic outcomes

Clinical follow-up was complete in 98% of patients. A primary clinical end-point was reached in 50 patients (33.1%) treated with ELCA versus 47 patients (29.9%)

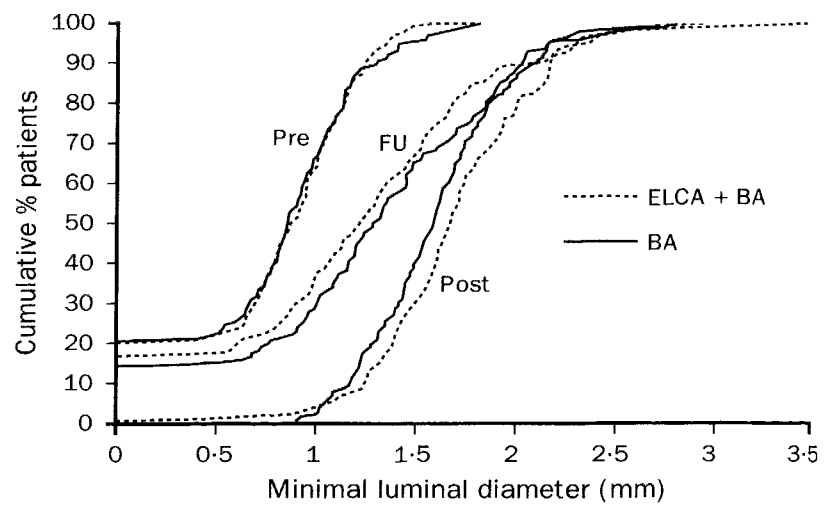


Figure: Cumulative frequency distribution curves

Minimal luminal diameters are shown before the initial intervention (Pre), after the initial intervention (Post), and at follow-up angiography (FU) for 151 patients treated with ELCA followed by additional balloon angioplasty (ELCA+BA) and 157 patients treated with balloon angioplasty (BA).

treated with balloon angioplasty. The incidences of myocardial infarction, coronary bypass surgery, and repeat angioplasty were similar in both groups (table 2).

Of the 151 patients randomly assigned to ELCA, 91 patients had no angina, 17 patients were graded as functional class I, 31 patients as class II, 11 patients as class III, and one patient as class IV according to the Canadian Cardiovascular Society classification criteria¹³ after 6 months' follow-up. Of the 157 patients randomly assigned to balloon angioplasty, 94 patients had no angina, 17 patients were graded as functional class I, 27 patients as class II, 17 patients as class III, and two patients as class IV after 6 months' follow-up.

Follow-up angiography was not requested in 22 of the 151 patients in the ELCA group due to failure of the initial procedure or coronary bypass surgery. Repeat angiography was performed in 120 of the remaining 129 patients (93%). Follow-up angiography in the balloon angioplasty group was requested in 131 of the 157 patients. Repeat angiography was done in 123 of these patients (91%).

The net gain in minimal lumen diameter was similar in both groups (table 3). The net gain in the ELCA group was the result of a small, but non-significant, increase in the acute gain minus a significant greater late loss compared with the balloon angioplasty group. The cumulative distribution of the minimal lumen diameter is shown in the figure. The net mean (SD) gain in diameter stenosis was 12.4 (25.1)% in the ELCA group versus 16.2 (25.9)% in the balloon angioplasty group (difference -3.9%, 95% CI -10.2 to 2.5; p=0.2). The incidence of restenosis was 51.6% in the ELCA group compared with 41.3% in the balloon angioplasty group (p=0.13).

Discussion

The purpose of this randomised study was to compare the clinical and angiographic outcome of ELCA versus balloon angioplasty in the treatment of longer (>10 mm) coronary lesions. The more recent data from ELCA registries indicate an increased use of additional balloon angioplasty, which is consistent with the results of our study.¹⁶⁻¹⁸ ELCA was followed by balloon angioplasty in 98% of procedures and therefore this trial in fact comprises a comparison between combined ELCA and balloon angioplasty versus balloon angioplasty only.

We have shown that ELCA and balloon angioplasty for the treatment of obstructive coronary artery disease yield similar initial and long-term clinical and angiographic outcomes in a selected cohort of patients with stable angina and coronary lesions longer than 10 mm.

Clinical outcome for primary clinical and angiographic end-points were similar in both groups. With respect to the differences observed, there was a significantly higher rate of transient occlusions in the ELCA group compared with the balloon angioplasty group (6.3% *vs* 0.6%). This may be explained by a response of the vascular wall due to the mechanical effects caused by a fast expanding and imploding vapour bubbles generated during ELCA.^{19,20} In general, this complication can be dealt with by administration of intracoronary nitroglycerin and additional balloon angioplasty.

Furthermore, there was a significant greater late loss in minimal lumen diameter in the ELCA group compared with the balloon angioplasty group. This finding may be related to an accelerated degree of neointimal response due to the mechanical effects of rapid vapour bubble formation during laser application or a negative influence on the geometric remodelling process after intracoronary interventions.^{21,22} The greater late loss in minimal lumen diameter resulted in a higher restenosis rate after ELCA—51.6% versus 41.3% in the balloon angioplasty group.

It is difficult to compare the results of the present study with data from non-randomised ELCA registries.^{6-8,16-18} Most of these registries focus attention on the initial results after laser angioplasty and have reported completeness of angiographic follow-up in 73–88% of patients after successful ELCA. In our trial, the clinical follow-up was complete in 98% of patients in both groups, and angiographic follow-up was complete in 93% of patients in the ELCA group and 91% of patients in the balloon angioplasty group. Furthermore, patients included in the registries had a variety of coronary lesions and the reported procedural success rates relate to those procedures in which the coronary lesion was successfully crossed with the guide wire. This explains why success rates in our study based on the intention-to-treat analysis are lower than in the ELCA registries, whereas results of the per protocol analysis are comparable to the registry data. Moreover, quantitative coronary analysis was performed by an independent core laboratory, whereas most angiographic results in the registries were based on visual assessment or semi-quantitative assessment. Finally, our trial, unlike the ELCA registries, included a routinely measured serum creatine kinase band level after each procedure.

A comparison of our balloon angioplasty group with randomised trials of balloon angioplasty shows similar results with respect to the clinical event rate and complication rate.²³⁻²⁶ However, there was a marked difference in our study in the procedural dissection rate observed in both treatment groups. The high incidence of dissections in our study might be related to selection of more complex coronary lesions compared with the other studies.⁵ Although the incidence of dissections was high, the majority of dissections were type A, B, or C, which are benign.

The serum level of the creatine kinase myocardial band was systematically assessed in our trial. In this respect, the periprocedural myocardial infarction rate (3.2%), including Q and non-Q-wave myocardial infarctions, cannot be compared with randomised balloon angioplasty

studies. The incidence of myocardial infarctions is low compared with other studies in which the serum creatine kinase myocardial band level was evaluated after intracoronary interventions. These studies reported substantial increases in enzymes in 10–20% of procedures after balloon angioplasty or after application of other new devices such as directional atherectomy or coronary stenting.^{27,28}

This first randomised clinical trial of ELCA versus balloon angioplasty in obstructive coronary artery disease demonstrated no additional benefit of ELCA. Consequently, is there a role for ELCA in the treatment of coronary lesions? It is important to mention that the additional cost of ELCA favours the use of other treatments. Several modifications of the current laser technique are under investigation to optimise the results of intracoronary laser angioplasty. Adjustments in laser techniques to reduce formation of fast expanding and imploding vapour bubbles include a flushing protocol,²⁹ application of sequential laser fibre activation,³⁰ use of lower energy fluence,³¹ and use of a new laser catheter design in which homogeneous light distribution is provided.

The results of this trial demonstrate no additional benefit of ELCA over balloon angioplasty with the current laser technique.

Institutions participating in the AMRO study (number of patients enrolled): Academic Medical Center, University of Amsterdam, Netherlands (144); Thorax Center, Rotterdam, Netherlands (99); Catharina Hospital, Eindhoven, Netherlands (57); and Miami Heart Institute, Miami, Florida, USA (13).

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