INTERVENTIONAL CARDIOLOGY AND SURGERY

Clinical and angiographic outcome of directional atherectomy followed by stent implantation in de novo lesions located at the ostium of the left anterior descending coronary artery

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Background: Lesions located at the ostium of the left anterior descending coronary artery (LAD) are considered an ideal target for directional atherectomy (DCA), but few data are available about the value of using this strategy before stenting in comparison with stenting alone.
Objectives: To investigate the immediate and mid term clinical and angiographic results of DCA followed by stent implantation for ostial LAD lesions.
Design: Retrospective comparison of the immediate and mid term angiographic and clinical results of a series of 117 consecutive patients with de novo lesions located at the ostium of the LAD. Of these, 46 underwent DCA before stenting and 71 were treated with stenting alone.
Results: Technical success in the two groups was similar at around 98%. DCA plus stenting provided a larger minimum lumen diameter at the end of the procedure than stenting alone (3.57 (0.59) mm *v* 3.33 (0.49) mm, p = 0.022). There were no differences for in-hospital major adverse events (MACE) (7.5% for atherectomy plus stenting, and 5.3% for stenting alone; p = 0.41). All patients had clinical follow up at a mean of 7.9 (2.7) months. Angiographic follow up was done in 89 patients (76%) at a mean of 5.9 (2.2) months. The atherectomy plus stenting group had a larger minimum lumen diameter than the stenting group (2.79 (0.64) mm *v* 2.26 (0.85) mm, p = 0.004) and a lower binary restenosis rate (13.8% *v* 33.3%, p = 0.031). Six month MACE were reduced in the atherectomy plus stenting group (8.7% *v* 23.9%, p = 0.048).
Conclusions: Debulking before stenting in de novo lesions located at the ostium of the LAD is safe and is associated with a high rate of technical success. Follow up data show that DCA plus stenting results in a significantly larger minimum lumen diameter and a lower incidence of restenosis than stenting alone.

The treatment of coronary lesions located at the ostium of the left anterior descending coronary artery (LAD) still represents a challenge for interventional cardiologists. A high rate of restenosis and concern over procedural complications, including plaque shift towards the circumflex artery, are the two main issues. For these reasons, such lesions are often referred for aorto-coronary bypass grafting. Studies looking specifically at the proximal LAD have reported a high risk of restenosis after conventional balloon angioplasty or stent implantation.[1–4] The presence of a large plaque burden at this site, richness in elastic elements, and the fibrous characteristics of these lesions are possible explanations for the high restenosis rate. Moreover, the frequent involvement of the distal left main coronary artery, as demonstrated by intravascular ultrasound studies (IVUS),[5] may contribute to a reduced procedural success and a higher rate of complications, such as compromise of the ostium of the left circumflex coronary artery during balloon dilatation or stent implantation.[6 7] These lesions are located in accessible large vessels with large and often eccentric plaques. They are therefore ideal targets for directional atherectomy.[8–10] The addition of stent implantation to prevent elastic recoil appears to be a reasonable approach.[11–13]

In this study, we investigated the immediate and mid term clinical and angiographic results of directional atherectomy followed by stent implantation for ostial LAD lesions. The results were compared with a series of matched lesions treated with stent implantation alone, without directional atherectomy debulking.

METHODS

Patients

This study reports the results from a series of 46 patients with lesions located at the ostium of the LAD artery that had been treated with directional atherectomy followed by stent implantation between January 1997 and December 2001 (atherectomy plus stenting group). These lesions were matched with a series of 71 ostial lesions located at the ostium of the LAD which underwent stenting without directional atherectomy (stenting group). This control group was selected from 175 lesions treated by elective stent implantation without previous debulking by directional atherectomy. The matching process was based on criteria derived from Umans and colleagues.[14] The database was reviewed sequentially, and for each lesion treated with directional atherectomy plus stenting, a lesion encountered in the stenting group that

Abbreviations: AMIGO, atherectomy and multilink stenting improves gain and outcome; CABG, coronary artery bypass graft; IVUS, intravascular ultrasound; LAD, left anterior descending coronary artery; MACE, major adverse coronary events; PTCA, percutaneous transluminal coronary angioplasty; TIMI, thrombolysis in myocardial infarction satisfied the matching variables was chosen. The matching variables, in order of sequential selection, were:

- diabetes: present or not
- reference diameter ±0.3 mm
- baseline minimum lumen diameter ±0.1 mm
- lesion length ±1 mm.

All the patients examined in the present study complained of angina or had objective evidence of myocardial ischaemia. Those who had had angioplasty after recent myocardial infarction (less than 72 hours from the onset of symptoms) were not included. The angiographic inclusion criterion was the presence of a de novo lesion with a diameter stenosis of more than 50% within 3 mm of the ostium of the LAD. Patients with total occlusions, restenotic lesions, or more than 50% stenosis of the left main coronary artery or at the ostium of the left circumflex artery (or of a large intermediate branch) were excluded. The use of other debulking devices (rotational atherectomy, laser), brachytherapy, or drug eluting stents was also an exclusion criterion.

Patients were followed for at least six months. Repeat angiographic evaluation was done after six months, or earlier if clinically indicated.

Procedural protocol
At the beginning of the procedure, patients received an intravenous bolus of heparin (70–100 U/kg) supplemented according to the activated clotting time value (targeted at 200–250 seconds). All patients received a four week course of oral antiplatelet treatment consisting of aspirin 100 mg and ticlopidine 250 mg twice daily (or clopidogrel 75 mg once daily), starting at least three days before the procedure, or a 300 mg clopidogrel loading dose. All patients received aspirin indefinitely.

In the atherectomy plus stenting group, a 7 French Atherocath GTO system (Guidant Corporation, Santa Clara, California, USA) was used in 35 lesions through a 10 French guiding catheter, and a 6 French atherectomy catheter, the Flexicut (Guidant Corporation, Temecula, California, USA), was employed in 11 lesions through an 8 French guiding catheter. The mean (SD) number of cuts per lesion was 16.3 (8.1) with the 7 French cutter and 13.1 (5.0) with the Flexicut cutter, respectively. In the stenting group, balloon predilatation was undertaken in 64 cases (90.1%), while in the remaining seven cases (8.9%) the stents were deployed with a direct stenting technique. The more commonly used stents, with percentages for the atherectomy plus stenting and stenting groups, respectively, were: ACS Multi-link DUET and Multi-link Tetra (Guidant Corporation), 28% and 26%; BxVelocity (Cordis, Warren, New Jersey, USA), 14% and 10%; the NIR stent (Medinol, Jerusalem, Israel, and Scimed, Boston Scientific, Maple Grove, Minnesota, USA), 23% and 21%; the beStent (Medtronic AVE, Minneapolis, Minnesota, USA), 17% and 15%; other slotted tubular stents, 18% and 30%.

Angiographic analysis
Matched orthogonal views were used for quantitative analysis (quantitative coronary angiography), before and after treatment, using contrast filled catheters for calibration. Angiography was done after an intracoronary infusion of glyceryl trinitrate (100–200 µg) or isosorbide dinitrate (1–3 mg). Angiograms were analysed off-line with a validated automated edge detection system (CMS, version 4.0 Medis, Medical Imaging System, Leiden, Netherlands).

Quantitative coronary angiographic measurements were done at the LAD ostium at baseline, after directional atherectomy, after stent implantation, and at follow up; and at the left circumflex ostium (or intermediate branch if present) at baseline, after stent implantation on the LAD, and at follow up. The angle between the LAD and left circumflex ostia was measured in the 30° caudal, 30° right view, and such angle was considered narrowed if less than 80%.[6]

Table 1 Baseline clinical characteristics

	DCA+S (n=46)	S (n=71)	p Value
Age (years) (mean (SD))	57.2 (10.8)	61.4 (12.7)	0.069
Male/female (n)	41/5	58/15	0.308
Diabetes mellitus	17.1	19.7	0.806
Hypertension	45.0	63.4	0.074
Smoking	52.5	47.9	0.695
Hypercholesterolaemia	63.4	65.0	0.865
Family history of CAD	42.5	39.4	0.841
Stable angina	34.9	32.4	0.882
Unstable angina	57.1	61.8	
Asymptomatic	7.9	5.9	
Previous PTCA	20.0	22.5	0.814
Previous CABG	8.5	5.0	0.709
LVEF (%) (mean (SD))	59.7 (9.2)	57.4 (12.7)	0.304
Mulitvessel coronary disease	50.0	54.3	0.695

Values are per cent unless stated.
CABG, coronary artery bypass grafting; CAD, coronary artery disease; DCA, directional coronary atherectomy; LVEF, left ventricular ejection fraction; PTCA, percutaneous transluminal coronary angioplasty; S, stenting.

Definitions
Optimal atherectomy was defined as achievement of < 20% residual stenosis with angiographic TIMI flow grade 3 and with the absence of dissection of ⩾ type B.

Angiographic success was defined as a final diameter stenosis of < 30% after stent implantation.

Procedural success was defined as angiographic success without death, emergency coronary artery bypass graft (CABG), repeat transvascular resection at the target vessel, or non-Q wave or Q wave myocardial infarction in hospital.

MACE was defined as death, non-Q wave and Q wave myocardial infarction, or the need of target vessel revascularisation (with either percutaneous transvascular coronary angioplasty (PTCA) or coronary artery bypass surgery).

Myocardial infarction was defined as Q wave type if there was a new Q wave with a duration of at least 0.04 s in two or more contiguous ECG leads, with post-procedure creatine kinase concentrations above normal; and as non-Q wave type if, in the absence of new Q waves, the plasma creatine kinase was at least two times the upper limit of normal, accompanied by elevation of MB isoenzymes.

Acute lumen gain was defined as the difference between minimum lumen diameter at the end of the intervention and the baseline minimum diameter, and *relative gain* as the ratio between baseline reference diameter and acute gain.

Late lumen loss was defined as the difference between final minimum lumen diameter and the minimum diameter at follow up.

Loss index was defined as the ratio between late lumen loss and acute lumen gain, and *net gain* as the difference between minimum lumen diameter at follow up and baseline minimum diameter.

Restenosis was defined dichotomously as a diameter stenosis of ⩾ 50% of proximal reference by repeat coronary angiography at follow up.

Statistical analysis
Data are expressed as mean (SD) for continuous variables and as frequencies for categorical variables. Comparisons were done with the Student *t* test for continuous data and Pearson's χ^2 test or Fisher's exact test for discrete data. Significance was accepted for a two sided probability value of $p < 0.05$.

Table 2 Angiographic results on lesion located on the ostium of the left anterior descending coronary artery

	DCA+S	S	p Value
Baseline data (number of lesions)	(46)	(71)	
Vessel reference diameter (mm)	3.45 (0.49)	3.43 (0.37)	0.876
Minimum lumen diameter (mm)	1.17 (0.50)	1.20 (0.61)	0.833
Diameter of the stenosis (%)	65.4 (14.5)	63.5 (17.6)	0.539
Lesion length (mm)	9.0 (5.1)	8.5 (4.8)	0.667
Post-DCA			
Minimum lumen diameter (mm)	2.53 (0.46)	–	
Diameter of the stenosis (%)	28.7 (15.1)	–	
Post-stenting			
Vessel reference diameter (mm)	3.74 (0.54)	3.61 (0.43)	0.135
Minimum lumen diameter (mm)	3.57 (0.59)	3.33 (0.49)	0.022
Diameter of the stenosis (%)	4.2 (9.9)	7.4 (9.9)	0.090
Acute gain (mm)	2.40 (0.78)	2.13 (0.80)	0.078
Relative gain (mm)	0.70 (0.23)	0.61 (0.22)	0.123
Balloon to artery ratio	1.19 (0.13)	1.12 (0.17)	0.530
Six month follow up (number of lesions)	(36)	(57)	
Vessel reference diameter (mm)	3.45 (0.46)	3.31 (0.40)	0.164
Minimum lumen diameter (mm)	2.79 (0.64)	2.26 (0.85)	0.004
Degree of stenosis (%)	19.9 (14.3)	32.2 (22.6)	0.005
Restenosis rate (%)	5 (13.8)	20 (33.3)	0.031
Late loss (mm)	0.80 (0.63)	1.05 (0.84)	0.123
Loss index	0.33 (0.31)	0.59 (0.65)	0.015
Net gain (mm)	1.66 (0.83)	1.03 (1.07)	0.006

Values are mean (SD) or n.
DCA, directional coronary atherectomy; S, stenting.

RESULTS

Baseline data

Patient demographic details and clinical data are reported in table 1. The two groups were well matched for all the variables considered. Table 2 shows the baseline angiographic measurements. No significant differences were found between the atherectomy plus stenting group and the stenting group at baseline. Moderate or heavy calcification, identified by fluoroscopic examination, was present in 13% of lesions in the atherectomy plus stenting group and in 15.5% of lesions in the stenting group (NS), while eccentric lesions were present in 39% and 31% of the lesions, respectively (NS). Narrow angles between LAD and left circumflex ostia were present in 24% of patients in the atherectomy plus stenting group and in 25.3% in the stenting group (NS).

Procedural results and hospital course

Angiographic success was achieved in all cases in the atherectomy plus stenting group and in 95.8% of the stenting group. Procedural success was obtained in 93.5% of the atherectomy plus stenting group and in 91.5% of the stenting group (p = 0.70). In one case (2.1%), coronary artery perforation without tamponade occurred during directional atherectomy and was successfully treated with implantation of a PTFE covered stent. During the hospital stay there were no deaths or urgent repeat PTCA or CABG procedures. Three non-Q wave myocardial infarcts (6.5%) in the atherectomy plus stenting group and three (4.2%) in the stenting group were recorded (p = 0.68).

The use of glycoprotein IIb/IIIa receptor inhibitors, intra-aortic balloon pump support, final balloon pressure, the number of stents implanted in the ostial LAD, and the mean stent length did not differ significantly between the two groups (table 3). IVUS was more commonly used in the atherectomy plus stenting group than in the stenting group, but the difference did not reach significance (45.7% *v* 32.4%; p = 0.174) (table 3).

The angiographic changes in ostial LAD lesions produced by directional atherectomy and by stent implantation are given in table 3. Optimal debulking—defined as residual percentage of stenosis of less than 20%—was achieved in 15 cases (33%). Final minimum lumen diameter and relative lumen gain were greater in the atherectomy plus stenting group (table 2) and there was a trend towards greater acute lumen gain (p = 0.08). No additional stent implantation in the left main coronary artery was required in either of the two groups.

Table 3 Adjunctive procedures and procedural data

	DCA+S (n=46)	S (n=71)	p Value
Glycoprotein IIb/IIIa receptor antagonists	25.0	18.3	0.467
IABP			
Elective	2.1	0	0.393
Emergency	2.1	2.1	1.000
IVUS	45.7	32.4	0.174
Stent length (mm) (mean (SD))	15.2 (5.5)	14.4 (4.0)	0.446
Maximum balloon pressure (atm) (mean (SD))	14.8 (4.2)	15.2 (3.0)	0.581
Post-dilatation	4.3	4.2	0.974

Values are per cent unless stated.
DCA, directional coronary atherectomy; IABP, intra-aortic balloon pump; IVUS, intravascular ultrasound; S, stenting.

Effects on the left circumflex artery

Baseline values and changes in ostial diameter of the left circumflex artery (or of the intermediate branch if present) are reported in table 4. No significant stenosis (> 50%) at the left circumflex ostium was observed in the atherectomy plus stenting group (0%), while in the stenting group there were three cases (4.2%) of > 50% stenosis in the left circumflex artery after stent implantation in the LAD (p = 0.28). In two cases, PTCA with stent implantation in the left circumflex artery, followed by final kissing balloon inflation in the LAD and left circumflex, was done because of compromise of the left circumflex ostium. At follow up, no patient from the atherectomy plus stenting group (0%) and five patients from

Table 4 Angiographic results at the left circumflex coronary artery ostium

	DCA+S	S	p Value
Baseline data (number of lesions)	(46)	(71)	
Vessel reference diameter (mm)	3.14 (0.67)	3.12 (0.76)	0.909
Minimum lumen diameter (mm)	2.95 (0.57)	2.75 (0.67)	0.302
Diameter of the stenosis (%)	5.4 (10.6)	10.6 (12.7)	0.081
Post-stenting on LAD			
Vessel reference diameter (mm)	3.21 (0.61)	3.10 (0.63)	0.553
Minimum lumen diameter (mm)	2.97 (0.62)	2.57 (0.64)*	0.040
Diameter of the stenosis (%)	7.4 (9.4)	16.6 (14.1)*	0.009
>50% stenosis (%)	0	3 (4.2)	0.278
Six month follow up (number of lesions)	(31)	(54)	
Vessel reference diameter (mm)	3.19 (0.73)	2.99 (0.60)	0.365
Minimum lumen diameter (mm)	2.98 (0.69)	2.40 (0.60)*	0.009
Diameter of the stenosis (%)	4.2 (6.2)	16.9 (17.3)*	0.005
>50% stenosis (%)	0	4 (7.4)	0.155

Values are mean (SD) or n.
*p<0.01 *v* baseline value (Student's *t* test for paired data).
DCA, directional coronary atherectomy; LAD, left anterior descending coronary artery; S, stenting.

the stenting group (7.0%) showed > 50% stenosis in the left circumflex ostium (p = 0.16). In three of these five cases, a further PTCA was done on the left circumflex artery for restenosis. In none of the five patients was there a narrow angle between LAD and left circumflex ostia at baseline.

Mid term clinical and angiographic results

Mid term follow up with documentation of MACE and angiography was at a mean of 7.6 (2.3) months. Angiographic evaluation was undertaken in 36 (78.2%) of the atherectomy plus stenting group and in 57 (80.3%) of the stenting group (p = 0.82).

The angiographic measurements are presented in table 2. A greater minimum lumen diameter and a lower percentage diameter stenosis were observed in the patients treated with debulking before stenting than in those treated with stenting alone. Late loss did not differ between the two groups, but the loss index was significantly lower and the net gain significantly higher in the atherectomy plus stenting group than in the stenting group. Binary restenosis occurred in five patients (13.8%) from the atherectomy plus stenting group and in 20 patients (33.3%) in the stenting group (p = 0.03). Among lesions treated with atherectomy plus stenting, no difference was observed between those with optimal debulking (2/12, 16.6%) and the remaining lesions (3/24, 12.5%; NS).

The six month clinical outcome is shown in table 5. Cumulative MACE were significantly lower in the atherectomy plus stenting group than in the stenting group (8.7% *v* 23.9%; p = 0.048). Death, incidence of myocardial infarction, and the need for target vessel revascularisation were also lower in the atherectomy plus stenting, but those differences did not attain significance.

Table 5 Cumulative adverse events at follow up

	DCA+S (n=46)	S (n=71)	p Value
Death (%)	0	4 (5.6)	0.278
MI (%)	3 (6.5)	5 (7.0)	0.675
Need for TVR (%)	4 (8.7)	12 (16.9)	0.275
Need for PTCA on LCx ostium	0	3 (4.2)	0.278
Total MACE (%)	4 (8.7)	17 (23.9)	0.048

Values are n (%).
LCx, left circumflex coronary artery; MACE, major adverse coronary events; MI, myocardial infarction; PTCA, percutaneous transluminal coronary angioplasty; target vessel revascularisation.

DISCUSSION

Previous studies have shown a higher incidence of myocardial infarction following directional atherectomy than after angioplasty.[15] The results from our matched group study indicate that directional atherectomy and stenting of lesions located at the ostium of the LAD artery is associated with a similar rate of acute procedural success to that observed in patients treated with stenting alone. In both groups, the most common complication was non-Q wave myocardial infarction (6.5%). The use of glycoprotein IIb/IIIa receptor antagonists has been advocated to reduce the frequency of myocardial infarction in patients treated with directional atherectomy.[16] These agents were used in only 20% of our cases and—perhaps because of the small number of adverse events—there was no evidence of a lower incidence of myocardial infarction among the patients who received them. There was only one major complication (coronary perforation) during directional atherectomy. Arterial perforation during this procedure is reported in between 1–3% of cases,[17] but the availability of PTFE covered stents means that the perforations can be successfully sealed in more than 90% of cases without the need for emergency surgery.[18]

Effects on mid term outcome

The only available randomised trial comparing the angiographic results of debulking and stenting with stenting alone (atherectomy and multilink stenting improves gain and outcome (AMIGO) trial: ACC 2002, 51st Annual Scientific Meeting, late breaking clinical trials; www.acc.org/2002ann_meeting/home_02.htm) did not show any advantage of adjunctive debulking in comparison with stenting alone in unselected coronary lesions. In the AMIGO trial, no information is given concerning the results on ostial LAD lesions. An important difference between our series and the AMIGO trial is that we found a significantly greater post-procedural minimum lumen diameter in patients treated with directional atherectomy and stenting than in those treated with stenting alone. This may explain the low incidence of restenosis (13.8%) in our series. The results in the matched patients treated with stenting alone from our series compare favourably with historical data from other centres, where reported restenosis rates have varied between 20–40%.[6 7 19] The superiority of directional atherectomy before stenting in comparison with stenting alone has already been reported in a retrospective comparison study from our group in unselected lesions in the LAD (6.3% *v* 23.1% for directional atherectomy plus stenting and stenting alone, respectively, p < 0.05).[20] Aggressive plaque removal, with a mean residual stenosis after directional atherectomy of 28.7 (15.1)%, and the large minimum lumen diameter reached after directional atherectomy and stent implantation (3.57 (0.59) mm) are possible reasons for the low incidence of restenosis in this series of ostial LAD lesions. The more frequent use of IVUS in the atherectomy plus stenting group than in the stenting group in the present study could have facilitated optimal debulking and led to reduced restenosis. However, restenosis rates in lesions where IVUS was used were not different from those without IVUS. We suspect that the reduction in restenosis associated with directional atherectomy before stenting is more likely to reflect the larger lumen size obtained after stent implantation than a lower degree of neointimal proliferation, as late loss was only slightly less after debulking and stenting than after stenting alone.

Effects of LAD ostial stenting on left circumflex ostium

Plaque shift, difficulties in correct placement of the proximal edge of the stent in the LAD, and the presence of a narrow angle between the LAD and the left circumflex artery are the main reasons for impingement of the left circumflex ostium following ostial LAD stenting.[6 7]

Asakaura and colleagues reported a significant reduction in the left circumflex ostial diameter in a series of patients treated with stenting alone of the LAD ostium, while no changes were observed among those treated with directional atherectomy before stent implantation.[6] Such left circumflex ostial impairment was reported to occur immediately after ostial LAD stenting without further worsening at follow up. These results were only partially duplicated by Park and colleagues.[7] Those investigators described a left circumflex ostium diameter reduction but, in their experience, this effect was not influenced by the use of directional atherectomy (undertaken in 30% of the cases). Moreover, they reported a progressive decrease in left circumflex ostial diameter during follow up. We also found a significant reduction in ostial left circumflex diameter following ostial LAD stenting, and a progressive reduction in minimum lumen diameter of the left circumflex ostium was seen during follow up. However, in our experience, such a phenomenon occurred only in patients treated with stenting alone, while directional atherectomy before stent expansion was effective in avoiding a significant lumen reduction in the left circumflex artery, and the consequent need for adjunctive revascularisation procedures on this vessel. The importance of the angle between the LAD ostium and the left circumflex ostium has not been confirmed by our findings, as many other factors such as plaque distribution, mode of debulking, and stent placement may play an important role in inducing plaque shift towards the left circumflex ostium.

Study limitations

The main limitation of this study is the non-randomised design. Selection bias for the different treatments cannot be excluded. However, operator choice would probably have led to the use of directional atherectomy for more complicated and higher risk lesions. The matching process was used to equalise the selection bias, but this was done only for certain variables. This technique is still limited by the nature of retrospective evaluations. Moreover, the number of lesions is limited and the experience is derived from a single clinical centre. IVUS examination was not done in all cases and thus its role in this setting is not clearly defined; neither it is possible to establish if directional atherectomy before stenting may have been associated with more precise stent positioning.

Conclusions

Stenting following directional atherectomy appears to be advantageous in ostial LAD lesions in comparison with stenting alone. Similar success rates but lower restenosis rates, a lower incidence of MACE, and no need for adjunctive interventions on the left circumflex ostium are potential benefits provided by the more complex and costly procedure. Even in the forthcoming era of drug eluting stents—which may reduce the incidence of restenosis[21]—directional atherectomy in ostial LAD lesions may still play a role by reducing the risk of left circumflex ostial impingement and by avoiding the need for further complex angioplasties on the left circumflex ostium.

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