

# Randomized comparison of debulking followed by stenting versus stenting alone for ostial left anterior descending artery stenosis: Intravascular ultrasound guidance

Young-Hak Kim, MD,<sup>a</sup> Myeong-Ki Hong, MD, PhD,<sup>a</sup> Seung-Wan Lee, MD,<sup>a</sup> Cheol Whan Lee, MD, PhD,<sup>a</sup> Ki Hoon Han, MD, PhD,<sup>a</sup> Jae-Joong Kim, MD, PhD,<sup>a</sup> Seung-Wook Park, MD, PhD, FACC,<sup>a</sup> Gary S. Mintz, MD, FACC,<sup>b</sup> and Seung-Jung Park, MD, PhD, FACC<sup>a</sup> *Seoul, Korea, and New York, NY*

**Background** Although directional coronary atherectomy (DCA) before stenting has the advantage of combining substantial removal of atheromatous plaque and prevention of elastic recoil, there has been no randomized study to investigate its efficacy in ostial left anterior descending artery (LAD) lesions. This study was aimed to evaluate the effect of DCA followed by stenting on ostial LAD stenosis under the guidance of intravascular ultrasound (IVUS).

**Methods** Eighty-six patients with ostial LAD stenoses were randomly assigned to DCA followed by stenting (group I) or stenting alone (group II). Aggressive DCA or optimal stenting was performed in both groups under the guidance of IVUS. The primary end point was angiographic restenosis at 6 months.

**Results** Baseline clinical and angiographic characteristics were similar between the 2 groups. The postprocedural minimal lumen diameter was larger in group I than group II ( $4.0 \pm 0.4$  mm vs.  $3.5 \pm 0.5$  mm,  $P < .001$ ). However, the angiographic restenosis rates were not significantly different between the 2 groups (9/32 [28.1%] in group I vs. 11/30 [36.7%] in group II,  $P = .472$ ). The postprocedural IVUS stent area was the only independent determinant of restenosis by multivariate analysis (odds ratio .61, 95% CI 0.41–0.92,  $P = .018$ ).

**Conclusions** DCA followed by stenting achieved greater lumen gain than stenting alone for ostial LAD stenosis. However, DCA did not improve angiographic restenosis. (Am Heart J 2004;148:663–9.)

Ostial left anterior descending artery (LAD) lesions pose a special problem for percutaneous coronary intervention since treating ostial LAD lesions can compromise the left circumflex (because of plaque shifting), and suboptimal results are common due to lesion rigidity and elastic recoil.<sup>1,2</sup> Directional coronary atherectomy (DCA) has unique advantages in treating ostial coronary lesions because it removes atheromatous plaque, limiting both elastic recoil and plaque shifting. Previous trials suggested that aggressive

plaque removal by sequential DCA might lead to further reduction of restenosis rate.<sup>3–7</sup> In addition, DCA followed by coronary stenting has been regarded as having a synergistic benefit combining removal of atheromatous plaque and prevention of elastic recoil and remodeling.<sup>8–10</sup> Recently, 1 observational study showed the safety and efficacy of DCA followed by stenting for ostial LAD stenoses.<sup>11</sup> However, there has been no randomized comparison of the effect of debulking and stenting versus stenting alone for ostial LAD stenosis.

Intravascular ultrasound (IVUS) may result in more aggressive and effective debulking because IVUS is the only currently available in vivo method to evaluate plaque distribution and the extent of the disease.<sup>6,7,10</sup> Moreover, coronary imaging by IVUS allows measurement of true vessel size and vascular remodeling and might provide data predicting long-term outcome.<sup>12–20</sup> This prospective randomized study used quantitative coronary angiography (QCA) and IVUS to evaluate the effect of IVUS-guided DCA followed by stenting on ostial LAD stenosis.

---

From the <sup>a</sup>Department of Medicine, Asan Medical Center, University of Ulsan College of Medicine, Seoul, South Korea and the <sup>b</sup>Cardiovascular Research Foundation, New York, NY.

This study was partly supported by Cardiovascular Research Foundation, Seoul, Korea. Submitted October 3, 2003; accepted May 4, 2004.

Reprint requests: Seung-Jung Park, MD, PhD, Department of Medicine, University of Ulsan, College of Medicine, Asan Medical Center, 388-1 Poongnap-dong, Songpa-gu, Seoul 138-736, South Korea.

E-mail: sjpark@amc.seoul.kr

0002-8703/\$ - see front matter

© 2004, Elsevier Inc. All rights reserved.

doi:10.1016/j.ahj.2004.05.011

## Methods

### Study design

This was a randomized study conducted in a single center between March 2000 and March 2003. The population consisted of 86 patients with angina pectoris, objective evidence of anterior myocardial ischemia, and de novo atherosclerotic ostial LAD lesions that were suitable for stenting and DCA. All of the patients with lesions located within 3 mm of the LAD ostium with diameter stenosis  $\geq 75\%$ , length  $\leq 15$  mm, and reference vessel diameter  $> 2.5$  mm were included. Exclusion criteria were contraindication to antiplatelet agents, acute myocardial infarction, stroke within the previous 3 months, peripheral vascular disease precluding use of a 10F femoral sheath, left ventricular dysfunction (ejection fraction  $< 40\%$ ), previous percutaneous or surgical myocardial revascularization procedures, heavily calcified lesions, involvement of the left main coronary artery or the ostium of the left circumflex artery, or chronic total occlusion. After online QCA, patients were randomly assigned either to DCA followed by stenting (group I) or stenting alone (group II). All participants gave informed consent, and the study protocol was approved by the institutional review board.

### DCA or stenting procedures

In group I, DCA was performed using the 7F-compatible Atherocath GTO system (Guidant, Temecula, Calif) in a standard clinical manner. Preprocedural IVUS information was used for window orientation. Multiple cuts were obtained using gradually increasing balloon pressures to achieve optimal DCA. The goal of angiographic optimal DCA was  $\leq 20\%$  angiographic residual stenosis by visual estimation.<sup>3,5,10</sup> After achievement of optimal DCA, IVUS was repeated to evaluate the residual plaque burden. If the residual plaque burden was  $> 50\%$  as assessed by IVUS, DCA was repeated in a more aggressive manner based on IVUS information. When the residual plaque burden reached  $\leq 50\%$  or the operator felt that further debulking could not be done despite significant residual plaque, the DCA procedure was stopped.

After predilation or DCA (determined by randomization), slotted-tube stents were implanted in the standard manner as previously described.<sup>21</sup> Various types of stents were used at the operator's discretion. High-pressure balloon dilatation was routinely used to achieve a residual stenosis  $< 20\%$  by visual estimation. IVUS was also performed after stenting to evaluate the stent optimization in both groups.

During the procedure, patients received a 10,000 U bolus of heparin with a repeat bolus of 5000 U to maintain the activated clotting time  $\geq 250$  seconds. After stenting, patients were treated with aspirin (200

mg once a day, indefinitely) and ticlopidine (250 mg twice a day for 1 month) or clopidogrel (75 mg once a day for 1 month). Abciximab was not routinely used.

### IVUS imaging protocol

A postintervention IVUS study was performed after intracoronary administration of 0.2 mg nitroglycerin. The ultrasound catheter was advanced approximately 10 mm beyond the target lesion, and an imaging run was performed from beyond the target lesion to the aorto-ostial junction. Studies were performed with a commercially available system (Boston Scientific Corporation/Cardiovascular Imaging System Inc, San Jose, Calif) that used a 30-MHz transducer within a 3.2F short monorail imaging sheath with automatic pull-back device (0.5 mm/s). Ultrasound studies were recorded on 1/2-inch high-resolution S-VHS tape for off-line analysis.

### QCA analysis

Coronary angiography was performed after the administration of 0.2 mg intracoronary nitroglycerin. Coronary angiographic results were analyzed by 2 experienced angiographers not involved in the stenting procedure. Using the guiding catheter for magnification calibration and an on-line QCA system (ANCOR V2.0, Siemens, Solna, Sweden), minimal lumen diameter and reference vessel diameter were measured before and after intervention and at follow-up from diastolic frames in single, matched views showing the smallest lumen diameter. Significant stent jail of the left circumflex artery ostium was defined as stent coverage  $> 50\%$ . Angiographic restenosis was defined as a diameter stenosis of  $> 50\%$  at follow-up.

### Quantitative IVUS analysis

Quantitative IVUS analysis was performed in lesions for which adequate serial images were obtained before procedure, after DCA, and after stenting. Validation of cross-sectional area (CSA) measurements of external elastic membrane (EEM), lumen, and plaque and media (P&M) by IVUS have been reported previously.<sup>12,13</sup> The EEM CSA (representing total arterial CSA) and lumen CSA were measured by tracing the leading edge of the adventitia and the intima/plaque, respectively. The P&M CSA was calculated as EEM - lumen CSA. The plaque burden (%) was measured as  $100 \times (\text{P\&M} \div \text{EEM CSA})$ . The target lesion and distal reference segment were assessed quantitatively. The preintervention lesion site was the image slice with the smallest lumen CSA. Among image slices with the same minimum lumen CSA, the one with the largest plaque burden was measured. The distal reference segment was the most normal-looking segment within 5 mm distal to the lesion. The EEM, stent, and lumen CSA were

measured with a commercially available program for computerized planimetry.

### Clinical and angiographic follow-up

All patients were evaluated clinically by office visit or telephone interview at 1, 3, and 6 months and then every 4 months after stenting. Repeat coronary angiography was performed at 6 months after stenting or earlier if clinically indicated. Inhospital events including death, myocardial infarction, and repeat revascularization of the target lesion were evaluated. The primary end point was angiographic evidence of restenosis. Secondary end points were the occurrence of any major cardiac event (death, myocardial infarction, and target lesion revascularization) during the follow-up period.

### Statistical analysis

The study was powered to detect a 25% difference in the angiographic restenosis rate ( $\alpha$  of .05 and  $\beta$  of .80), with a minimum of 86 patients (angiographic follow-up rate 80%). Analysis was made on an intention-to-treat basis. Data are expressed as a mean  $\pm$  SD for continuous variables and as frequencies for categorical variables. Differences between groups were assessed by  $\chi^2$  statistics for categorical variables and Student *t* test for continuous variables. Logistic multivariate regression analysis was performed to identify independent determinants of angiographic restenosis. The multivariate analysis included age, sex, and the variables that had a *P* value  $\leq$  .10 by the univariate analysis. A *P* value  $<$  .05 was considered statistically significant.

## Results

### Baseline patient and lesion characteristics

Baseline patient demographic and clinical data are shown in Table I. No significant differences between the 2 groups with regard to patient characteristics were observed. Lesion length, reference vessel dimension, and preintervention minimal lumen diameter were similar between the 2 groups (Table II).

### Procedural data and inhospital clinical outcomes

There was no significant difference in procedural data between the 2 groups (Table II). Glycoprotein IIb/IIIa inhibitor was not used in any patient. The maximal pressure used in the balloon dilatation of the DCA catheter in group I was  $3.4 \pm 0.7$  atm (range, 2–6). Procedural success rates were 100% in both groups. Postprocedural CK-MB elevation  $\geq 3$  times normal occurred in 3 patients (7.1%) in group I and 2 patients (4.5%) in group II (*P* = .607). Inhospital events including stent thrombosis, Q-wave myocardial infarction, emergency bypass surgery, or death did not occur in any patient.

**Table I.** Baseline clinical characteristics

	Group I (n = 44)	Group II (n = 42)	P value
Age (y)	59 $\pm$ 7	57 $\pm$ 9	.305
Men/women	36/8	33/9	.705
Current smoker	18 (41%)	23 (55%)	.199
Diabetes mellitus	7 (16%)	9 (21%)	.511
Hypercholesterolemia (>200 mg/dL)	12 (27%)	14 (33%)	.541
Systemic hypertension	12 (27%)	15 (36%)	.399
Previous myocardial infarction	2 (5%)	2 (5%)	.962
Left ventricular ejection fraction (%)	65 $\pm$ 8	61 $\pm$ 11	.143
Unstable angina pectoris	33 (75%)	28 (67%)	.395
Multivessel coronary disease ( $\geq 2$ )	5 (11%)	7 (17%)	.478

**Table II.** QCA findings

	Group I (n = 44)	Group II (n = 42)	P value
Lesion length (mm)	11.9 $\pm$ 3.9	12.0 $\pm$ 5.2	.912
Stent length (mm)	15.0 $\pm$ 3.5	15.9 $\pm$ 6.2	.402
Balloon-to-artery ratio	1.1 $\pm$ 0.2	1.1 $\pm$ 0.2	.798
Maximal inflation pressure (atm)	14.8 $\pm$ 2.6	14.5 $\pm$ 2.9	.543
Reference vessel diameter (mm)	3.6 $\pm$ 0.5	3.6 $\pm$ 0.6	.435
Minimal lumen diameter (mm)			
Baseline	1.1 $\pm$ 0.4	1.0 $\pm$ 0.5	.168
Final	4.0 $\pm$ 0.4	3.5 $\pm$ 0.5	<.001
Follow-up	2.3 $\pm$ 0.9	2.0 $\pm$ 0.9	.187
Diameter stenosis (%)			
Baseline	68.6 $\pm$ 10.4	71.9 $\pm$ 14.2	.217
Final	-10.0 $\pm$ 13.4	1.5 $\pm$ 12.2	<.001
Follow-up	37.3 $\pm$ 28.5	44.8 $\pm$ 21.8	.250
Acute gain (mm)	2.8 $\pm$ 0.5	2.5 $\pm$ 0.7	.007
Late loss (mm)	1.7 $\pm$ 0.9	1.5 $\pm$ 0.7	.242
Loss index*	0.63 $\pm$ 0.35	0.69 $\pm$ 0.46	.576
Significant stent-jail of LCX ostium	4 (9.1%)	4 (9.5%)	.945
Restenosis rate	9/32 (28%)	11/30 (37%)	.711

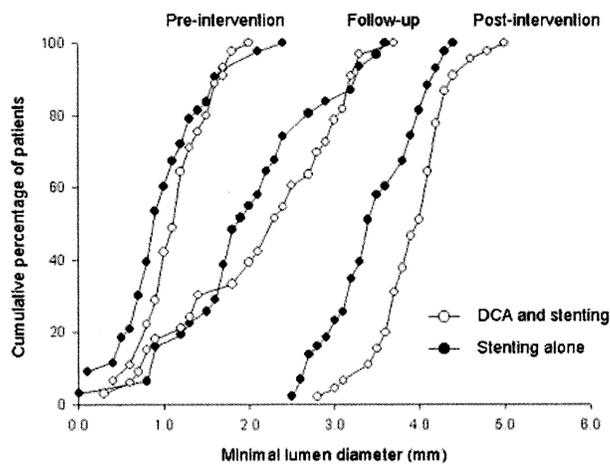
LCX, left circumflex artery.

\*Late loss/acute gain.

### QCA and IVUS data

Quantitative angiographic data are listed in Table II and cumulative frequency distribution curves of the minimal lumen diameter in Figure 1. The postprocedural minimal lumen diameter was larger in group I than group II ( $4.0 \pm 0.4$  mm vs  $3.5 \pm 0.5$  mm, *P*  $<$  .001), and acute lumen gain was also greater in group I than group II ( $2.8 \pm 0.5$  mm vs  $2.5 \pm 0.7$  mm, *P* = .007). Significant stent jail of the left circumflex artery ostium was observed in 8 of 86 lesions (9.1% in group

Figure 1



Comparison of the cumulative distribution of the minimal lumen diameter for group I (DCA and stenting), or group II (stenting alone) before procedure (Pre-intervention), immediately after procedure (Post-intervention), and at follow-up (Follow-up). The acute gain was greater in group I than group II ( $P < .05$ ). However, the minimal lumen diameter at follow-up was not statistically different due to the tendency for greater late loss in group I than group II.

I and 9.5% in group II,  $P = .945$ ). All cases of stent jail were mainly developed by stent protrusion into the circumflex artery by IVUS analysis.

Complete adequate serial IVUS studies (baseline, post-DCA, and post-stenting) were obtained in 67 patients (78%) from a total of 86 patients. Optimal debulking (residual plaque burden  $\leq 50\%$  after DCA) was obtained in 46% of patients. Quantitative IVUS analysis is shown in Table III. Quantitative IVUS characteristics before and after the procedure were not statistically different between group I and group II except residual plaque burden after stenting. Residual plaque burden after stenting was smaller in group I than group II ( $45.2 \pm 5.1\%$  vs  $50.4 \pm 7.0\%$ ,  $P = .004$ ). The lesion lumen CSA after stenting was increased from  $1.9 \pm 0.3 \text{ mm}^2$  to  $10.0 \pm 1.5 \text{ mm}^2$  in group I and from  $1.9 \pm 0.3 \text{ mm}^2$  to  $9.0 \pm 2.4 \text{ mm}^2$  in group II. A stent CSA larger than the distal reference lumen CSA after the procedure was achieved more commonly in group I, with 22 of 37 lesions (68.8%), than in group II, with 10 of 30 lesions (31.3%) ( $P = .033$ ).

#### Angiographic and clinical follow-up

Of a total 86 patients, 9 patients did not reach the eligible period of 6 months, and angiographic follow-up was performed for 62 of the 77 eligible patients (follow-up rate, 81%) including 32 patients in group I and 30 patients in group II. The rate of angio-

Table III. Quantitative IVUS characteristics

	Group I (n = 35)	Group II (n = 32)	P value
Distal reference EEM CSA ( $\text{mm}^2$ )			
Preintervention	$15.0 \pm 3.0$	$14.9 \pm 3.7$	.920
Post-DCA	$15.3 \pm 3.2$		
Postintervention	$15.5 \pm 2.8$	$15.3 \pm 3.6$	.851
Distal reference lumen CSA ( $\text{mm}^2$ )			
Preintervention	$9.5 \pm 2.1$	$9.7 \pm 2.7$	.840
Post-DCA	$10.0 \pm 2.4$		
Postintervention	$10.3 \pm 2.0$	$9.1 \pm 2.4$	.783
Lesion EEM CSA ( $\text{mm}^2$ )			
Preintervention	$14.2 \pm 3.7$	$13.7 \pm 3.9$	.576
Post-DCA	$16.1 \pm 3.9$		
Postintervention	$18.3 \pm 3.2$	$18.2 \pm 3.6$	.897
Lesion lumen CSA ( $\text{mm}^2$ )			
Preintervention	$1.9 \pm 0.3$	$1.9 \pm 0.3$	.952
Post-DCA	$7.8 \pm 1.7$		
Postintervention*	$10.0 \pm 1.5$	$9.0 \pm 2.4$	.075
Plaque burden (%)			
Preintervention	$85.8 \pm 3.4$	$85.3 \pm 3.1$	.632
Post-DCA	$50.7 \pm 9.4$		
Postintervention	$45.1 \pm 5.1$	$50.4 \pm 7.0$	.004

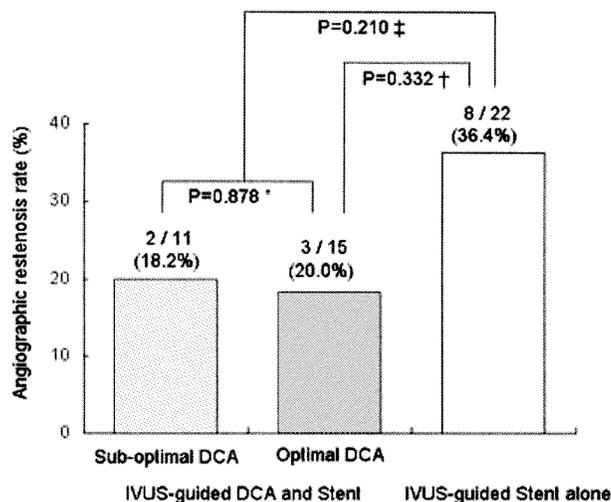
EEM, external elastic membrane; CSA, cross-sectional area; DCA, directional atherectomy.

\*Postinterventional lesion lumen CSA represents stent CSA.

graphic restenosis was not significantly different between the 2 groups (9/32 [28%] in group I vs 11/30 [37%] in group II,  $P = .472$ ). Because of the tendency for a greater late loss in group I than group II ( $1.7 \pm 0.9 \text{ mm}$  vs  $1.5 \pm 0.7 \text{ mm}$ ,  $P = .242$ ), the minimal lumen diameter at follow-up was not significantly different between the 2 groups ( $2.3 \pm 0.9 \text{ mm}$  vs  $2.0 \pm 0.9 \text{ mm}$ ,  $P = .187$ , Table II).

In 67 patients who underwent adequate serial IVUS examinations, angiographic follow-up was performed in 26 patients of group I and in 22 patients of group II. Optimal debulking defined as a residual plaque burden  $\leq 50\%$  was not associated with angiographic restenosis, compared to suboptimal debulking or stenting alone under the guidance of IVUS (Figure 2). On the contrary, postprocedural stent CSA were greater in the group without restenosis than in the group with restenosis ( $9.9 \pm 1.7 \text{ mm}^2$  vs  $8.4 \pm 1.9 \text{ mm}^2$ ,  $P = .011$ ). The multivariate analysis included the following 8 variables: age, sex, 2 preprocedural variables including reference EEM CSA and plaque burden, and 4 postprocedural variables including minimal lumen diameter, reference EEM CSA, reference lumen CSA, and lesion lumen CSA. In the multivariate analysis, the postprocedural IVUS lesion lumen CSA (representing stent CSA) was the only independent IVUS determinant of angiographic restenosis by multivariate analysis (odds ratio 0.61, 95% CI 0.41–0.92,  $P = .018$ ).

**Figure 2**



Comparison of the restenosis rate between the optimal DCA group (residual plaque burden  $\leq 50\%$ ) and the suboptimal DCA group, \* between the optimal DCA group and the stent alone group, † and between the DCA followed by stent group and the stent alone group ‡ under the guidance of IVUS.

Mean duration of clinical follow-up was  $18.6 \pm 8.9$  months (range 0.6 to 34.2). Death or myocardial infarction did not occur during follow-up. Target lesion revascularization was performed in 5 patients (11%) of group I and in 5 patients (12%) of group II ( $P = .94$ ). Event-free survival rate at 18 months was  $89\% \pm 5\%$  in group I and  $89\% \pm 5\%$  in group II ( $P = .98$ ).

## Discussion

This study demonstrated that stenting with or without debulking for ostial LAD stenosis may be performed safely with a high procedural success rate and favorable long-term clinical and angiographic outcomes. Procedural success rate was 100% and the rate of significant stent jail occurrence  $<10\%$  in the 2 groups. Overall angiographic restenosis rate and target lesion revascularization rate were 32% and 12%, respectively. This result is similar to recent studies evaluating the procedural safety and feasibility of stenting with or without debulking for ostial LAD stenosis.<sup>11,21,22</sup> In this study, IVUS guidance was used in both groups to optimize final stent dimensions, which might lead to very good results. It has been shown in previous studies that IVUS-guided stenting leads to improved results compared to stenting with angiographic guidance alone.<sup>16,17</sup> However, the present study did not demonstrate a reduction of restenosis by aggressive debulking before stenting for ostial LAD stenosis.

DCA has unique advantages in treating ostial lesions because it removes atheromatous plaque, limiting both elastic recoil and plaque shifting. However, DCA alone does not eliminate arterial remodeling after intervention and may not reduce late restenosis.<sup>1,6</sup> Coronary stents reduce angiographic restenosis by inhibiting acute recoil and chronic arterial remodeling.<sup>23</sup> Therefore, debulking followed by coronary stenting has been suggested to overcome the limitations of each device.<sup>24</sup> In addition, Prati et al demonstrated with IVUS analysis that late in-stent neointimal proliferation had a direct correlation with the amount of residual plaque burden after coronary stent implantation, suggesting that plaque removal before stent implantation might reduce restenosis.<sup>18</sup> Bramucci E et al recently reported excellent initial and long-term outcomes of angiography-guided DCA with stenting.<sup>11</sup>

This is the first report specifically addressing the use of DCA and stenting, versus stenting alone, for ostial LAD stenosis with IVUS guidance. In the present study, DCA prior to stenting provided greater acute lumen gain and resulted in increased postprocedural minimal lumen diameter. However, the greater lumen gain with DCA was not converted to a reduction of the restenosis rate because of the tendency for greater late loss. This finding was also observed in the Stenting after Optimal Lesion Debulking (SOLD) registry, in which the amount of acute lumen gain obtained after DCA and stenting was associated with a similar proportional late lumen loss.<sup>10</sup> The unpublished data of the AMIGO trial, a large multicenter randomized trial estimating the efficacy of DCA prior to stenting for complex coronary lesions, presented a similar tendency to this study. It showed a similar restenosis rate between the 2 groups (24.1% in DCA and stenting vs 19.6% in stenting alone,  $P = .22$ ) due to larger late loss of DCA and stent in spite of greater acute gain. The mechanism of the greater late loss might be partly explained by the additional stimulus to hyperplasia that DCA may promote. Otherwise, this suggests that the amount of plaque reduction with DCA prior to stenting might be insufficient in this study or that the residual plaque burden might not be associated with angiographic restenosis.<sup>19</sup>

In the group with DCA followed by stenting, the residual plaque burden after DCA was 50.7%, similar to previous studies designed to evaluate the effect of aggressive DCA.<sup>6,7</sup> The residual plaque burden after DCA was 45.6% in the Adjunctive Balloon Angioplasty After Coronary Atherectomy Study (ABACAS) trial<sup>6</sup> and 52.4% in the Stent versus Directional Coronary Atherectomy Randomized Trial (START) trial.<sup>7</sup> Given the fact that ostial lesions impose technical difficulties to optimal plaque reduction with DCA, the results in our study might be the best that can be achieved with conventional DCA devices in the real world. This study

showed that the optimal debulking (residual plaque burden  $\leq 50\%$  after DCA) obtained in 46% of patients did not have a lower restenosis rate than suboptimal DCA or stent alone under the guidance of IVUS. However, a final plaque burden  $\leq 40\%$  after the procedure obtained in 27.0% (10/37) of group I and in 6.7% (2/30) of group II ( $P = .052$ ) was more likely to be associated with a lower restenosis rate than a final plaque burden  $>40\%$  after the procedure (0% vs. 32%,  $P = .081$ ). This might support the postulate that the old version of the DCA device (Atherocath GTO system) might not be optimal for debulking ostial lesions. This suggests further studies using the next generation of atherectomy device, such as the Flexicut atherectomy catheter (Guidant) or the Fox Hollow atherectomy device (Fox Hollow, Calif). Recent published data indicated that optimal debulking was obtained more commonly with Flexicut DCA device than with Atherocath GTO system (77% [n=143] vs 45% [n=277],  $P < .001$ ).<sup>25</sup>

From these data, we conclude that DCA prior to stenting does not improve the angiographic outcome after percutaneous coronary intervention for ostial LAD stenosis because of the tendency for greater late loss. With IVUS analysis, this negative result might be explained in part by the insufficient reduction of atheromatous plaque with conventional DCA devices. Moreover, IVUS analysis of this study suggests that the achievement of a large stent area after stenting with or without DCA might be most important to reduce angiographic restenosis rate.

### Study limitation

Patients with previous percutaneous or surgical revascularization procedures, involvement in the left main coronary artery, or involvement of the ostium of the left circumflex artery were excluded from the study. Thus, our findings cannot be generalized to these patient populations. The most important limitation of our study is the small sample size. This study may not have enough power to clarify the efficacy of debulking prior to stenting for ostial LAD stenosis. Although we showed that DCA prior to stenting did not produce a significant reduction in the angiographic restenosis rate, there was a tendency for a lower restenosis rate and larger minimal lumen diameter at follow-up in the group with DCA and stenting compared to the group with stenting alone. In addition, IVUS was used to optimize the final stent CSA in both groups; there was a trend to a larger final stent CSA only in patients treated with debulking followed by stenting, and the final stent CSA was the only independent determinant of restenosis.

In this study, bare metal stents were used, and our results may not be applicable to patients treated with drug-eluting stents. Further studies may be needed to

clarify the role of debulking strategy in the drug-eluting stent era.

### References

1. Mathias DW, Mooney JF, Lange HW, et al. Frequency of success and complications of coronary angioplasty of a stenosis at the ostium of a branch vessel. *Am J Cardiol* 1991;67:491-5.
2. Sabri MN, Cowley MJ, DiSciascio G, et al. Immediate results of interventional devices for coronary ostial narrowing with angina pectoris. *Am J Cardiol* 1994;73:122-5.
3. Baim DS, Cutlip DE, Sharma SK, et al. Final results of the Balloon vs Optimal Atherectomy Trial (BOAT). *Circulation* 1998;97:322-31.
4. Yock PG, Fitzgerald PJ, Linker DT, et al. Intravascular ultrasound guidance for catheter-based coronary interventions. *J Am Coll Cardiol* 1991;17(Suppl B):39-45.
5. Boehr JD, Ellis SG, Pieper K, et al. Directional atherectomy versus balloon angioplasty for coronary ostial and nonostial left anterior descending coronary artery lesions: results from a randomized multicenter trial. *J Am Coll Cardiol* 1995;25:1380-6.
6. Suzuki T, Hosokawa H, Katoh O, et al. Effects of adjunctive balloon angioplasty after intravascular ultrasound-guided optimal directional coronary atherectomy: the result of the Adjunctive Balloon Angioplasty After Coronary Atherectomy Study (ABACAS). *J Am Coll Cardiol* 1999;34:1028-35.
7. Tsuchikane E, Sumitsuji S, Awata N, et al. Final results of the Stent versus Directional Coronary Atherectomy Randomized Trial (START). *J Am Coll Cardiol* 1999;34:1050-7.
8. Painter JA, Mintz GS, Wong SC, et al. Serial intravascular ultrasound studies fail to show evidence of chronic Palmaz-Schatz stent recoil. *Am J Cardiol* 1995;75:398-400.
9. Kimura T, Kaburagi S, Tamura T, et al. Remodeling of human coronary arteries undergoing coronary angioplasty or atherectomy. *Circulation* 1997;96:475-83.
10. Moussa I, Moses J, Mario CD, et al. Stenting after Optimal Lesion Debulking (SOLD) registry: angiographic and clinical outcome. *Circulation* 1998;98:1604-9.
11. Bramucci E, Repetto A, Ferrario M, et al. Effectiveness of adjunctive stent implantation following directional coronary atherectomy for treatment of left anterior descending ostial stenosis. *Am J Cardiol* 2002;90:1074-8.
12. Nishimura RA, Edwards WD, Warnes CA, et al. Intravascular ultrasound imaging: in vitro validation and pathologic correlation. *J Am Coll Cardiol* 1990;16:145-54.
13. Tobis JM, Mallery J, Mahon D, et al. Intravascular ultrasound imaging of human coronary arteries in vivo: analysis of tissue characteristics with comparison to in vivo histologic specimens. *Circulation* 1991;83:913-26.
14. Hoffmann R, Mintz GS, Mehran R, et al. Intravascular ultrasound predictors of angiographic restenosis in lesions treated with Palmaz-Schatz stents. *J Am Coll Cardiol* 1998;31:43-9.
15. Kasaoka S, Tobis JM, Akiyama T, et al. Angiographic and intravascular ultrasound predictors of in-stent restenosis. *J Am Coll Cardiol* 1998;32:1630-5.
16. Schiele F, Meneveau N, Vuilleminot A, et al. Impact of intravascular guidance in stent deployment on 6-month restenosis rate: a multicenter, randomized study comparing two strategies-with and

- without intravascular ultrasound guidance. *J Am Coll Cardiol* 1998;32:320–8.
17. Fitzgerald PJ, Oshima A, Hayase M, et al. Final results of the can routine ultrasound influence stent expansion (CRUISE) study. *Circulation* 2000;102:523–30.
  18. Prati F, Di Mario C, Moussa I, et al. In-stent neointimal proliferation correlates with the amount of residual plaque burden outside the stent: an intravascular ultrasound study. *Circulation* 1999;99:1011–4.
  19. Hong MK, Park SW, Lee CW, et al. Relation between residual plaque burden after stenting and six-month angiographic restenosis. *Am J Cardiol* 2002;89:368–71.
  20. Hong MK, Lee CW, Kim JH, et al. Impact of various intravascular ultrasound criteria for stent optimization on the six-month angiographic restenosis. *Catheter Cardiovasc Interv* 2002;56:178–83.
  21. Park SJ, Lee CW, Hong MK, et al. Stent placement for ostial left anterior descending coronary artery stenosis: acute and long-term (2-year) results. *Catheter Cardiovasc Intervent* 2000;49:267–71.
  22. Asakaura Y, Takagi S, Ishikawa S, et al. Favorable strategy for the ostial lesion of the left anterior descending coronary artery: influence on narrowing of circumflex coronary artery. *Catheter Cardiovasc Diagn* 1998;43:95–100.
  23. Painter JA, Mintz GS, Wong SC, et al. Serial intravascular ultrasound studies fail to show evidence of chronic Palmaz-Schatz stent recoil. *Am J Cardiol* 1995;75:398–400.
  24. Moussa I, Moses J, Colombo A. Atherectomy plus stenting: what do we gain? *Semin Intervent Cardiol* 2000;5:217–25.
  25. Takagi T, Di Mario C, Stankovic G, et al. Effective plaque removal with a new 8 French-compatible atherectomy catheter. *Catheter Cardiovasc Interv* 2002;56:452–9.