Catheterization and Cardiovascular Interventions 65:247–253 (2005)

Two-Year Follow-Up Intravascular Ultrasound Analysis After Bare Metal Stent Implantation in 120 Lesions

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The objective of this study was to examine long-term changes after bare metal stent implantation in a relatively large number of patients. There are few reports of intravascular ultrasound (IVUS) studies performed on stented and nonstented (reference) segments beyond 6 months after bare metal stenting. Using IVUS, we evaluated serial changes in stented and reference segments between 6 and 24 months after stent implantation in 110 patients with 120 lesions. Serial IVUS images were acquired at five equidistant intrastent sites and at two different reference segment sites. Measurements were made of the external elastic membrane (EEM), stent, lumen, and intimal hyperplasia (IH = stent − lumen) area. For the whole patient group, between 6 and 24 months, the mean IH area in stented segments decreased from 2.6 ± 1.0 to 2.3 ± 0.9 mm^2 ($P < 0.001$), and the mean lumen area increased from 6.2 ± 2.0 to 6.5 ± 1.9 mm^2 ($P < 0.001$). The mean IH area decreased in 91 lesions (76%) and increased in 29 lesions (24%) between 6 and 24 months. There were no significant changes in EEM or lumen area in the reference segments. Late angiographic restenosis (diameter stenosis $\geq$ 50%) occurred in three lesions between 6 and 24 months. A late target lesion revascularization was performed for one lesion. In the period of time between 6 and 24 months after stenting, IH regression occurred in most (76%) stent lesions, resulting in late lumen increase. However, IH progression was observed in 24% of in-stent lesions. No significant changes of EEM or lumen area occurred in the reference segments.

Key words: stent; ultrasonics; coronary disease

INTRODUCTION

Serial (postintervention and 6-month follow-up) intravascular ultrasound (IVUS) studies have demonstrated that the main mechanism of in-stent restenosis is intimal hyperplasia (IH) within the stent [1,2]. Previous serial angiographic studies after bare metal stenting have shown a biphasic pattern involving lumen loss within 6 months and then lumen enlargement between 6 months and 3 years [3–5]. However, there is a paucity of long-term IVUS data beyond 6 months after stenting to evaluate serial long-term IH changes. One report involving 22 patients treated with bare metal stents showed IH regression from 6 to 12 months after stenting [6]. The purpose of the current study was to evaluate serial changes in stented segments and nonstented (reference) segments between 6 and 24 months after bare metal stent implantation in a relatively large number of patients.

MATERIALS AND METHODS

Study Population

One hundred and thirty-eight patients with 150 lesions were enrolled in this prospective serial (postintervention,

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Grant sponsor: the Cardiovascular Research Foundation, Seoul, Korea; the Korean Society of Circulation.

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Received 17 August 2004; Revision accepted 19 January 2005

DOI 10.1002/ccd.20358
Published online 27 April 2005 in Wiley InterScience (www.interscience.wiley.com).

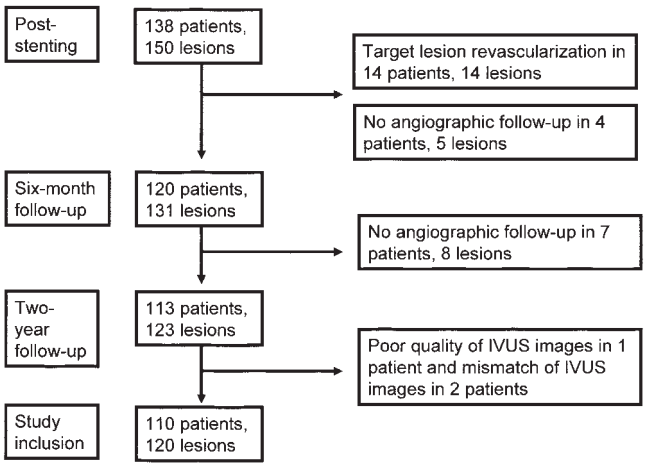

Fig. 1. Flow diagram of the 2-year follow-up IVUS study.

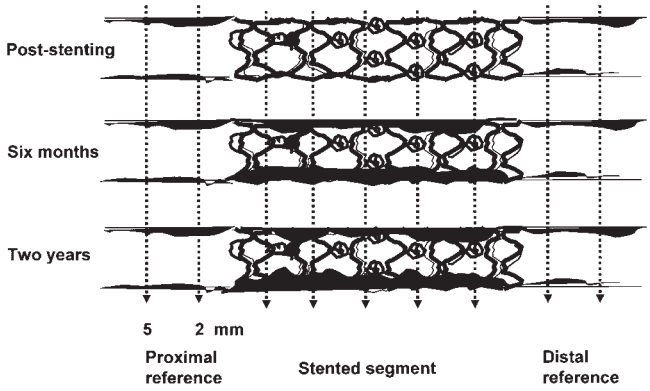

Fig. 2. Matching IVUS image slices (postintervention and 6- and 24-month follow-up) were acquired for two different reference segments (2 and 5 mm from the stent margin) and at five equidistant sites within the stented segment.

6-month, and 2-year) IVUS follow-up study. The inclusion criteria were objective evidence of myocardial ischemia, a native coronary lesion stenosis of $\geq$ 50% angiographic diameter by visual estimate, a reference vessel diameter $\geq$ 3.0 mm, and single bare metal stent implantation (stent length $\leq$ 24 mm). The exclusion criteria were left main coronary artery disease, in-stent restenosis lesion, lower left ventricular ejection fraction $<$ 30%, and contraindication to antiplatelet therapy. Target lesion revascularization (TLR) was performed in 14 patients (14 lesions; 9.3%) before or after the 6-month follow-up angiogram. Follow-up angiogram data at 6 and 24 months were not obtained in four patients (five lesions) and seven patients (eight lesions), respectively, because of refusal to undergo follow-up angiogram (six patients) and loss of clinical follow-up (five patients). The remaining 113 patients with 123 lesions received both 6- and 24-month follow-up angiograms and IVUS examination. Of these 123 lesions, 3 were excluded from final analysis due to poor-quality IVUS images at 6-month follow-up (1 lesion) and mismatch between 6- and 24-month follow-up IVUS images (2 lesions). Therefore, 110 patients with 120 lesions were included in the final analysis (Fig. 1).

IVUS Imaging Protocol

Postintervention and 6- and 24-month follow-up IVUS studies were performed in identical fashion. Intracoronary 0.2 mg nitroglycerin was administered. The ultrasound catheter was advanced approximately 10 mm beyond the lesion site, and an imaging run was performed from beyond the lesion site to the aorto-ostial junction. The studies were performed using a commercially available system (Boston Scientific/Cardiovascular Imaging System, San Jose, CA); this system used a 30 MHz single-element beveled transducer mounted on the end of a flexible shaft and rotated at 1,800 rpm within a 3.2 Fr short-monorail imaging sheath. With this system, the transducer was withdrawn automatically at 0.5 mm/sec to perform the imaging sequence [1,2]. Ultrasound studies were recorded on a 0.5″ high-resolution s-VHS tape for offline analysis. The postintervention IVUS imaging run was the final step in the intervention procedure. At 6- and 24-month follow-up, IVUS imaging was performed before any subsequent intervention.

Quantitative Coronary Angiographic (QCA) Analysis

Coronary angiography was performed after administration of 0.2 mg intracoronary nitroglycerin. Using the guiding catheter for magnification calibration and an online QCA system (ANCOR V2.0; Siemens, Germany), the minimal luminal diameter (MLD) was measured. QCA measurements of the MLD were performed after intervention and at 6- and 24-month follow-up from diastolic frames in a single matched view showing the smallest luminal diameter. Reference diameters were selected from user-defined segments proximal and distal to the lesion.

Quantitative IVUS Measurements

Measurements were performed according to the American College of Cardiology clinical expert consensus document on standards for acquisition, measurement, and reporting of IVUS studies [7]. Measurements were taken of the external elastic membrane (EEM), stent, lumen, plaque and media (P&M = EEM − lumen), and IH (stent − lumen) cross-sectional areas (CSA) with a commercially available program for computerized planimetry (TapeMeasure, Indec System).

On playback of the postintervention and 6- and 24-month follow-up IVUS studies, matching image

TABLE I. Baseline Clinical Characteristics

	Decrease in mean IH CSA	Increase in mean IH CSA	*P*
Number of patients	84	26	
Age (years)	56 ± 10	55 ± 9	0.4
Men	74 (88%)	23 (89%)	0.6
Systemic hypertension	27 (32%)	12 (46%)	0.3
Diabetes mellitus	8 (10%)	2 (8%)	0.6
Hypercholesterolemia (≥ 240 mg/dl)	15 (18%)	3 (12%)	0.3
Cigarette smoking	39 (45%)	8 (31%)	0.24
Clinical presentation			0.4
Stable angina	22 (26%)	5 (19%)	
Unstable angina	38 (45%)	16 (62%)	
Acute myocardial infarction	24 (29%)	5 (19%)	
Number of narrowed coronary arteries			0.7
1	61 (73%)	19 (73%)	
2	16 (19%)	6 (23%)	
3	7 (8%)	1 (4%)	

TABLE II. QCA Measurements

	Decrease in mean IH CSA	Increase in mean IH CSA	*P*
Number of lesion	91	29	
Postintervention			
Proximal reference diameter	3.2 ± 0.6	3.3 ± 0.6	0.3
Distal reference diameter	2.8 ± 0.6	2.9 ± 0.4	0.3
MLD	3.1 ± 0.6	3.2 ± 0.6	0.5
6-month follow-up			
Proximal reference diameter	3.0 ± 0.5	3.1 ± 0.5	0.3
Distal reference diameter	2.7 ± 0.5	2.8 ± 0.5	0.23
MLD	2.1 ± 0.5	2.3 ± 0.5	0.061
2-year follow-up			
Proximal reference diameter	3.0 ± 0.5	3.1 ± 0.5	0.3
Distal reference diameter	2.7 ± 0.5	2.8 ± 0.5	0.5
MLD	2.3 ± 0.5	2.3 ± 0.6	0.6

slices were acquired at two different sites in the reference segment at 2 and 5 mm from the stent margin and at five equidistant sites within the stented segment (Fig. 2) [8]. Mean proximal reference, intrastent, and distal reference values are reported. In practice, the 6-month follow-up target slices were analyzed first, then the distance from each target slice to the closest identifiable axial landmark (i.e., stent edge) was measured using seconds or frames of videotape. Finally, this distance was used to identify the corresponding slices on the postintervention and 24-month IVUS studies. Vascular and perivascular markings were also used to confirm image slice identification. When it was necessary to ensure that matching image slices were measured, the analysis was done side by side and the imaging runs were studied frame by frame. The minimum lumen CSA at 6-month follow-up was also determined.

Statistical Analysis

Categorical data are presented as frequencies. Continuous data are presented as mean ± SD. Comparisons were performed using chi-square or Fisher's exact tests, nonpaired or paired student's *t*-test, and ANOVA with repeated measures using the Bonferroni correction for posthoc analyses. P values < 0.05 were considered to indicate a statistically significant difference.

RESULTS

Initial and long-term angiographic follow-ups were performed at a mean of 6.1 ± 1.2 and 24.0 ± 2.8 months after bare metal stenting, respectively. Late angiographic restenosis (diameter stenosis ≥ 50%) occurring between 6 and 24 months was observed for three lesions. Late TLR was performed for one lesion at the 24-month follow-up. Nontarget vessel revascularization was performed for four lesions. Other than the one late TLR and the four nontarget vessel revascularization, there were no clinical events including death or myocardial infarction during the 24-month follow-up.

Baseline clinical characteristics and QCA measurements are shown in Tables I and II, respectively. QCA MLD showed biphasic changes from 3.2 ± 0.6 mm at postintervention to 2.2 ± 0.5 mm at 6-month follow-up and to 2.3 ± 0.5 mm at 2-year follow-up

TABLE III. Serial IVUS Data

	Postintervention	6-month follow-up	2-year follow-up	*P* (ANOVA)
Distal reference segment				
Mean EEM CSA (mm^2)	13.0 ± 4.0	12.8 ± 4.0[a]	12.7 ± 4.0	< 0.001
Mean lumen CSA (mm^2)	7.6 ± 2.6	7.2 ± 2.6[a]	7.2 ± 2.6	< 0.001
Mean P&M CSA (mm^2)	5.4 ± 2.0	5.6 ± 2.1[a]	5.5 ± 2.1	< 0.001
Stented segment				
Mean stent CSA (mm^2)	8.8 ± 2.3	8.8 ± 2.3	8.8 ± 2.3	0.8
Mean lumen CSA (mm^2)	8.8 ± 2.3	6.2 ± 2.0[a]	6.5 ± 1.9[b]	< 0.001
Mean IH CSA (mm^2)		2.6 ± 1.0	2.3 ± 0.9	< 0.001
Minimum stent CSA (mm^2)	8.4 ± 2.2	8.4 ± 2.2	8.4 ± 2.2	0.7
Minimum lumen CSA (mm^2)	8.4 ± 2.2	4.9 ± 1.9[a]	5.6 ± 1.8[b]	< 0.001
Minimum IH CSA (mm^2)		3.6 ± 1.7	2.9 ± 1.3	< 0.001
Proximal reference segment				
Mean EEM CSA (mm^2)	16.9 ± 4.0	16.7 ± 4.1[a]	16.7 ± 4.1	< 0.001
Mean lumen CSA (mm^2)	9.5 ± 3.1	9.2 ± 3.1[a]	9.2 ± 3.1	< 0.001
Mean P&M CSA (mm^2)	7.4 ± 2.3	7.5 ± 2.3[a]	7.5 ± 2.3	< 0.001

[a]$P < 0.001$ vs. post-intervention.
[b]$P < 0.001$ vs. 6-month follow-up.

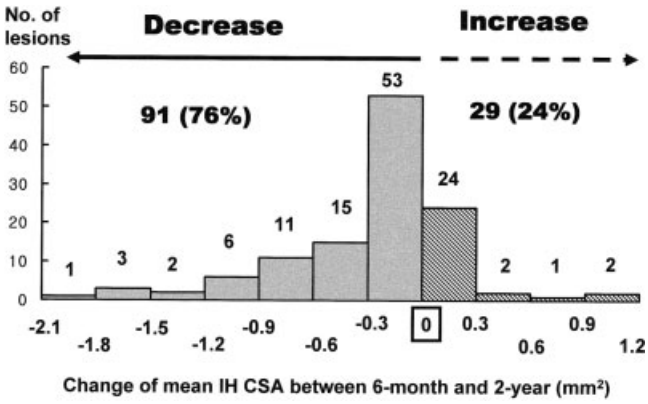

Fig. 3. Frequency of lesions distributed according to changes in mean IH CSA between 6 and 24 months.

(ANOVA, $P < 0.001$); the MLD at 2 years was significantly larger than that at 6 months ($P = 0.004$).

IVUS Results

Serial IVUS findings are presented in Table III. In the stented segment, there was no change in stent CSA between 6 and 24 months. There was a significant decrease in mean IH CSA at 24 months ($P < 0.001$ vs. 6-month follow-up), resulting in a significant increase in lumen CSA at 24 months ($P < 0.001$ vs. 6-month follow-up). Regarding the mean IH CSA, there was a decrease in 84 patients (76%), 91 lesions (76%), and an increase in 26 patients (24%), 29 lesions (24%), between 6 and 24 months (Fig. 3); typical examples of both groups are shown in Figure 4.

In both proximal and distal nonstented reference segments, there was a significant decrease in EEM and lumen CSA and a significant increase in P&M CSA at 6 months ($P < 0.001$ vs. postintervention). There were no significant changes in EEM, lumen, or P&M CSA between 6 and 24 months in either reference segment.

A comparison of IVUS findings between lesions showing decreases and increases in mean IH CSA at 2 years is shown in Table IV. Multivariate regression analysis was performed to identify independent predictors of mean IH CSA increase at 24 months. Variables entered into the model with *P* values less than 0.2 on univariate analysis included QCA MLD and IVUS variables (mean lumen CSA of proximal reference segments at postintervention and 6-month follow-up, and mean and minimum lumen and IH CSA of stented segments at 6-month follow-up). This analysis did not identify any independent predictors of mean IH CSA increase at 24 months.

DISCUSSION

In the present study, in-stent IH regression occurred in most (76%), but not all, lesions between 6 and 24 months after stenting. In some lesions (24%), in-stent IH progression that might be associated with late angiographic restenosis and late TLR in a small number of lesions was also observed. There were no significant changes in EEM and lumen CSA in the reference segments between 6 and 24 months after stenting.

Several studies have reported favorable long-term clinical outcomes of stenting for up to 10 years post-procedure [9–11]. In those studies, the late TLR rate in stented segments was < 10%, and late revascularization procedures in those patients may have been predominantly associated with progressive disease in nonstented segments [9–11].

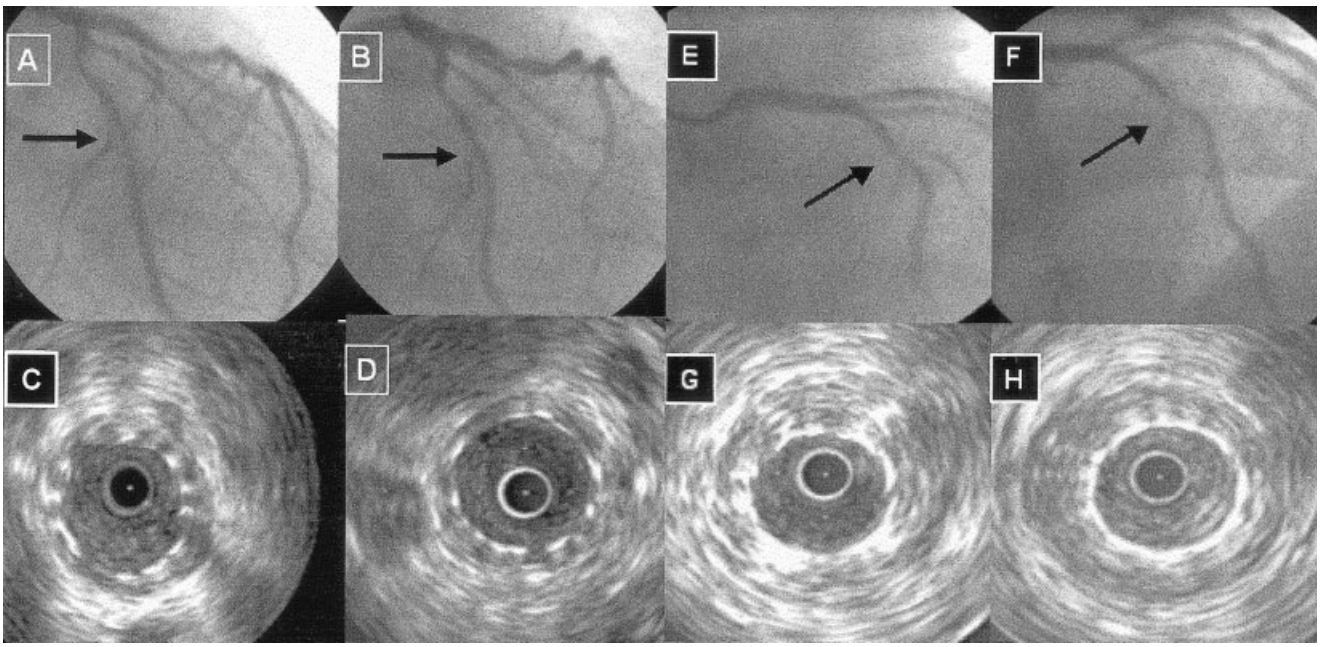

Fig. 4. Typical examples of decreases (A–D) and increases (E–H) in mean IH CSA at 24 months. A and E, and B and F were 6- and 24-month follow-up angiographic findings, respectively. C and G, and D and H were 6- and 24-month follow-up intravascular ultrasound findings, respectively. Minimal lumen CSAs were 2.2 mm^2 in C (at 6 months) and 4.2 mm^2 in D (at 2 years) in lesions showing decreased mean IH CSA, and 4.2 mm^2 in G (at 6 months) and 1.9 mm^2 in H (at 2 years) in lesions showing increased mean IH CSA.

In angiographic studies, restenosis or renarrowing of MLD usually occurred within 6 months after stenting. Several angiographic studies demonstrated clear evidence of improvement in lumen dimensions over the period between 6 months and 2–3 years poststenting [3–5]. One angioscopic study in 12 patients reported in-stent neointimal remodeling based on in-stent neointima that changed from a thick and nontransparent form at 6 months to a thin and transparent form by 3 years [12]. However, IVUS studies evaluating serial long-term changes in IH beyond 6 months after stenting are rare. One such study in 22 patients who received stenting in 25 lesions showed in-stent IH regression between 6 and 12 months after stenting [6]. Animal study has demonstrated that in-stent IH regression involves a reduction in proteoglycan content, changes in collagen subtype, and no changes in smooth muscle cell density [13].

Previous angiographic, angioscopic, and IVUS studies [3–6,12] proposed that, due to the likelihood of IH regression after 6 months, continuous medical therapy was preferred over revascularization procedures in stable patients with mild to moderate myocardial ischemia due to moderate in-stent restenosis narrowing observed at 6-month follow-up [6].

The current IVUS study evaluated serial IH changes between 6 and 24 months after stenting in a relatively large number of patients (110 patients with 120 lesions). The data in this study were consistent with those of a previous IVUS study showing in-stent IH regression beyond 6 months postprocedure [6]. However, our study contrasts with the previous IVUS study [6] because in-stent IH regression occurred in only 76% of lesions rather than all lesions. Furthermore, we observed in-stent IH progression in the other lesions (24%), which may have been associated with the late angiographic restenosis in three patients and the late TLR in one patient. The clinical implications of the current study are that continuous medical therapy might be a preferred therapeutic option in most, but not all, stable patients showing moderate in-stent restenosis narrowing at 6-month angiographic follow-up. In addition, more careful and regular follow-up may be required for the other lesions, and revascularization procedure may be recommended for a small number of lesions due to the possibility of late IH progression or late lumen renarrowing.

Compared to bare metal stents, recent studies using sirolimus- or paclitaxel-eluting stents have reported a dramatic reduction in first-time in-stent restenosis rate [14,15]. A recent long-term IVUS follow-up study showed persistent inhibition of in-stent IH for up to 2 years after sirolimus-eluting stent implantation [16]. If the results of the current study are applied to drug-eluting stents for expecting the long-term efficacy and progression of IH in drug-eluting stents, the period of

TABLE IV. IVUS Findings for Lesions Showing Changes in Mean IH CSA

	Decrease in mean IH CSA	Increase in mean IH CSA	*P*
Postintervention			
Distal reference segment			
Mean EEM CSA (mm^2)	12.9 ± 4.0	12.9 ± 3.0	1.0
Mean lumen CSA (mm^2)	7.5 ± 2.6	7.8 ± 2.3	0.5
Mean P&M CSA (mm^2)	5.4 ± 2.0	5.0 ± 1.5	0.3
Stented segment			
Mean stent CSA (mm^2)	8.8 ± 2.3	8.9 ± 2.3	0.8
Minimum stent CSA (mm^2)	8.5 ± 2.3	8.3 ± 2.1	0.7
Proximal reference segment			
Mean EEM CSA (mm^2)	16.5 ± 4.0	17.1 ± 4.0	0.6
Mean lumen CSA (mm^2)	9.1 ± 3.0	10.3 ± 3.3	0.16
Mean P&M CSA (mm^2)	7.4 ± 2.3	6.8 ± 1.9	0.3
6-month follow-up			
Distal reference segment			
Mean EEM CSA (mm^2)	12.6 ± 4.0	12.7 ± 2.9	0.3
Mean lumen CSA (mm^2)	7.0 ± 2.6	7.5 ± 2.2	0.3
Mean P&M CSA (mm^2)	5.6 ± 2.1	5.2 ± 1.6	0.3
Stented segment			
Mean stent CSA (mm^2)	8.8 ± 2.3	8.9 ± 2.3	0.8
Mean lumen CSA (mm^2)	6.0 ± 1.9	6.8 ± 2.0	0.087
Mean IH CSA (mm^2)	2.8 ± 1.0	2.2 ± 0.8	0.006
Minimum stent CSA (mm^2)	8.5 ± 2.3	8.3 ± 2.1	0.7
Minimum lumen CSA (mm^2)	4.7 ± 2.0	5.3 ± 1.8	0.14
Minimum IH CSA (mm^2)	3.8 ± 1.7	3.0 ± 1.5	0.028
Proximal reference segment			
Mean EEM CSA (mm^2)	16.4 ± 4.1	16.9 ± 4.0	0.6
Mean lumen CSA (mm^2)	8.8 ± 3.0	10.1 ± 3.4	0.14
Mean P&M CSA (mm^2)	7.5 ± 2.3	6.8 ± 1.9	0.23
24-month follow-up			
Distal reference segment			
Mean EEM CSA (mm^2)	12.6 ± 4.0	12.5 ± 2.9	0.9
Mean lumen CSA (mm^2)	7.1 ± 2.6	7.2 ± 2.3	0.8
Mean P&M CSA (mm^2)	5.5 ± 2.1	5.3 ± 1.7	0.5
Stented segment			
Mean stent CSA (mm^2)	8.8 ± 2.3	8.9 ± 2.3	0.8
Mean lumen CSA (mm^2)	6.4 ± 1.9	6.6 ± 2.0	0.7
Mean IH CSA (mm^2)	2.3 ± 0.9	2.3 ± 1.0	1.0
Minimum stent CSA (mm^2)	8.5 ± 2.3	8.3 ± 2.1	0.7
Minimum lumen CSA (mm^2)	5.7 ± 1.8	5.2 ± 1.8	0.3
Minimum IH CSA (mm^2)	2.9 ± 1.2	3.1 ± 1.6	0.4
Proximal reference segment			
Mean EEM CSA (mm^2)	16.4 ± 4.1	16.8 ± 4.0	0.7
Mean lumen CSA (mm^2)	8.9 ± 3.0	10.0 ± 3.4	0.19
Mean P&M CSA (mm^2)	7.5 ± 2.3	6.9 ± 1.9	0.3

time, between 6 and 24 months in bare metal stents, may be further delayed in drug-eluting stents. However, long-term IVUS follow-up beyond 2 years after drug-eluting stent implantation will be needed to evaluate whether the findings of in-stent IH inhibition in drug-eluting stents will appear persistent or delayed phenomenon beyond 2-year follow-up.

A recent long-term follow-up angiographic study by Kimura et al. [9] reported that late luminal renarrowing beyond 4 years was common, demonstrating the need for long-term follow-up. Pathological analysis of stented human coronary arteries demonstrated heavy infiltration of lipid-laden macrophages around the strut beyond 5 years poststenting, and this inflammatory reaction induced late atherosclerotic progression in the stented segment [17]. Therefore, IVUS analysis beyond 2 years poststenting may be needed for a full understanding of serial changes in atheromatous progression in stented segments.

Study Limitations

This study has two limitations. First, the number of patients was not large enough to identify independent predictors of mean IH CSA increase at 24 months. Second, volumetric IVUS analysis was not performed.

In conclusion, in-stent IH regression occurred between 6 and 24 months after stenting in most lesions, resulting in late lumen increase. However, in-stent IH progression was observed in 24% of lesions. The data suggest that continuous medical therapy is the preferred therapeutic option in most, but not all, stable patients showing moderate in-stent restenosis narrowing at 6-month angiographic follow-up. IH progression was observed in a significant portion of patient, indicating careful and long follow-up is required in stent patients.

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