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Percutaneous Coronary Intervention for Small Caliber Proximal Coronary Artery Vessels：To Stent or Not to Stent?

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Abstract：Background：The optimum interventional strategy for treating small proximal coronary arteries remains unclear. To determine whether or not stenting is beneficial in patients with small proximal coronary artery lesions, we compared the clinical outcomes of 1504 patients who either underwent stenting or received no stenting of the small proximal coronary arteries.

Methods：We identified 1504 consecutive patients with percutaneous coronary interventions for the 1722 lesions in the small proximal coronary arteries from the database of the Cardiovascular Research Foundation, and then compared in-hospital and 1-year clinical outcomes in patients with stenting to those without stenting. Any cases demonstrating acute myocardial infarction, saphenous vein graft lesions and ostial lesions were excluded.

Results：Diabetes was present in 33% of the population. In addition, no differences other than the left ventricular ejection fraction in the baseline patient characteristics were observed between the groups. The reference vessels were larger for the stent group. The success of this procedure was higher (99.3% vs. 95.7% , $p<0.0001$) and the number of in-hospital major complications was less frequent in the stent group than in the non-stent group (1.3% vs. 2.9%, $p=0.034$). At one-year, however, there was a significantly higher incidence of target lesion revascularization (TLR) (28.7% vs. 22.3% , $p=0.007$) and there also tended to be a higher incidence of major adverse cardiac events (30.4% vs. 25.7%, $p=0.055$) in the patients undergoing stenting than in the non-stent intervention cases.

Conclusion：In comparison to the patients with non-stent intervention, the stenting of a small *proximal* coronary lesions was associated with a higher TLR rate despite a higher procedural success and lower rates of major in-hospital cardiac events. As a result, the stenting of small proximal coronary arteries may be best indicated for cases showing suboptimal results for non-stent treatment.

Key words：**Percutaneous coronary intervention (PCI), Small proximal coronary artery, Stent, Target lesion revascularization (TLR), Major adverse cardiac events (MACE)**

Introduction

Although percutaneous coronary intervention (PCI) is a well-established treatment for coronary artery disease, the high incidence of restenosis after PCI has limited the beneficial effects of this technique.[1)2)] The efficacy of coronary stenting in preventing restenosis after PCI has been proven in patients with a vessel size of >3.0 mm,[3)4)] however, the benefit of small coronary artery stenting still remains controversial.

Angiographically small coronary arteries are heterogeneous；some are anatomically small, while others have a larger caliber with a high plaque burden. Generally, small proximal coronary ar-

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teries (by coronary angiography) are of larger caliber with a greater plaque burden (by intracoronary ultrasonography) than small distal coronary arteries. This may influence the restenosis rate of small proximal arteries where the optimal interventional strategy remains poorly defined.

This study was performed to evaluate the beneficial effects of stenting on reducing restenosis after PCI in patients with small proximal coronary lesions.

Subjects and Methods

Study Design：From the database of the Cardiovascular Research Foundation, we identified 1504 consecutive patients who underwent PCI of the proximal right coronary artery, left anterior descending artery, left circumflex, first diagonal and ramus intermedius at the Washington Hospital Center from February 1990 through October 1999 and who also had a 1-year clinical follow-up. A small coronary artery was defined as a reference vessel diameter <3 mm. Any patients with an age of >70, acute myocardial infarction (MI) within 72 hours and ostial lesions were excluded.

We then compared the success of the procedures, in-hospital complications (death, Q-wave MI, coronary bypass surgery (CABG), repeat PCI, abrupt closure at target site, renal failure, cerebrovascular accident and major in-hospital complications) and 1-year clinical events (death, MI, CABG, repeat PCI, target lesion revascularization(TLR) and major adverse cardiac events (MACE)) of both the stented patients and the non-stented patients. A successful procedure was defined as a reduction of stenosis of $<50\%$ in all lesions without any complications, major in-hospital complications was defined as in-hospital death, Q-wave MI or CABG, TLR was defined as CABG or repeat PCI caused by restenosis of the target lesion of the first PCI, MACE was defined as combined events of all-cause death, Q－wave MI and TLR.

Angiographic analysis：A qualitative and quantitative angiographic analysis was performed using the CMS-GFT algorithm (MEDIS, Leiden, The Netherlands) before and after PCI. The percent diameter stenosis (%DS) was calculated as ((1－minimum lumen diameter/reference vessel diameter) $\times 100$).

Statistical methods：A statistical analysis was performed using the SAS software package (SAS Institute, Cary, NC). Categorical variables were expressed as percentages and compared using either the Chi-square test or Fisher's exact test. Continuous variables were expressed as the mean$\pm$SD and compared using Student's t-test. $P<0.05$ was considered to indicate significant.

Results

The patient characteristics of the 621 stented patients and 883 non-stented patients are presented in Table 1. There was no significant difference in the baseline patient characteristics between the two groups except for a younger patient age and higher left ventriclular ejection fraction (LVEF) in the stent group. The prevalence of diabetic patients was similar between the stent and non-stent groups (31.8% vs. 33.7%, $p=0.45$) The baseline lesion length was similar in both groups, while the

Table 1. Baseline Patient Characteristics

	Stent (N＝621)	Non-stent (N＝883)	P value
Age	57.3±8.7	58.8±8.6	0.001
Male (%)	68.5	72.7	NS
Current smoker(%)	59	55.7	NS
BSA (m^2)	1.95±0.22	1.96±0.22	NS
Diabetes (%)	31.8	33.7	NS
Hypertension (%)	58.7	62.1	NS
Prior MI (%)	49.6	50.9	NS
Prior CABG (%)	31.2	35	NS
LVEF (%)	48±13	45±13	0.011

BSA＝Body Surface Area, MI＝Myocardial Infarction,
CABG＝Coronary Artery Bypass Grafting, LVEF＝Left Ventricular Ejection Fraction

reference vessel diameter was significantly larger in the stent group than in the non-stent group (Table 2).

The post-procedure %DS was significantly smaller (3±11, 15±18 mm, p<0.0001) and the successful procedure rate was significantly higher in the stent group than in the non-stent group (99.3, 95.7%, p<0.0001).

In-hospital complications: In-hospital events are presented in Table 3. There was no statistically significant difference in all-cause deaths, Q-wave MI, CABG, or repeat PCI between the stent and non-stent groups. However, the frequency of major in-hospital complications was significantly lower in the stent group than in the non-stent group (1.3 vs. 2.9%, p=0.034) (Figure 1).

Clinical outcomes at 1-year: The incidence of clinical events at 1-year is shown in Table 4. There were no significant differences in all-cause deaths or Q-wave MI at 1-year in the stented versus the non-stented patients. However, there was a significantly higher incidence of TLR-PCI (21.0 vs. 15.5%, p=0.0098) in the stent group than in the non-stent group. Although there was no significant difference in the incidence of TLR-CABG, PCI was more common for TLR than CABG. As a result, there was a significantly higher incidence of entire TLR (28.7 vs. 22.3%, p=0.007) (Figure 2) and there tended to be a higher MACE (30.4 vs. 25.7%, p=0.055) in the stent group than in the non-stent group.

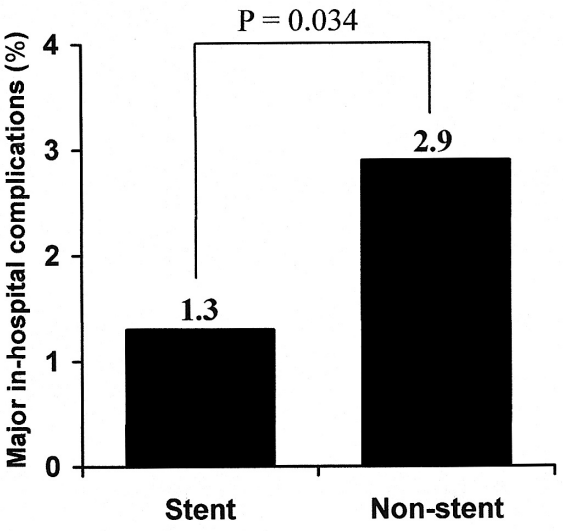

Figure 1. Major in-hospital complications

Table 2. Baseline lesion characteristics

	Stent (N=670)	Non-stent (N=1052)	P Value
Lesion length (mm)	11.30±8.23	10.88±11.44	NS
Reference (mm)	2.57±0.47	2.25±0.54	<0.001
Restenotic (%)	17.0	14.9	NS
LAD (%)	42.5	44.8	NS
Pre %DS (%)	86±10	87±9	NS
Final %DS (%)	3±11	15±18	<0.0001
Procedure success (%)	99.3	95.7	<0.0001

LAD=Left Anterior Descending Coronary Artery, %DS=Percent Diameter Stenosis

Table 3. In-Hospital Complications

	Stent (N=621)	Non-stent (N=883)	P Value
Death (%)	0.5	0.5	NS
Q-wave MI (%)	0.0	0.5	NS
Re-PCI (%)	1.1	2.3	NS
CABG (%)	1.0	2.2	NS
CVA (%)	0.0	0.1	NS
Abrupt closure (%)	0.5	0.3	NS
Renal Failure (%)	2.3	3.1	NS

MI=Myocardial Infarction, PCI=Percutaneous Coronary Intervention,
CABG=Coronary Artery Bypass Grafting, CVA=Cerebrovascular Accident

Discussion

In the current study, we presented 1-year clinical outcomes of 1504 patients with lesions in small proximal coronary arteries who underwent PCI either with stenting or without stenting. Stents were initially used to manage or prevent acute vessel closure after balloon angioplasty. In our study, the incidence of major in-hospital complications was significantly lower in the stent group than the non-stent group. Despite a better initial gain in luminal diameter and better in-hospital clinical outcomes, the TLR rate was higher in the stent group. There tended to be a higher MACE in the stent group than in the non-stent group at 1-year follow-up.

The vessel size was observed to be inversely correlated with the risk of restenosis and an adverse outcome after PCI.[5] Although the efficacy of coronary stents in preventing restenosis after PCI has been proven by randomized trials in large vessels,[1)3)] both stenting and non-stent PCI have been associated with equally favorable results in small vessels.[6)-8)]

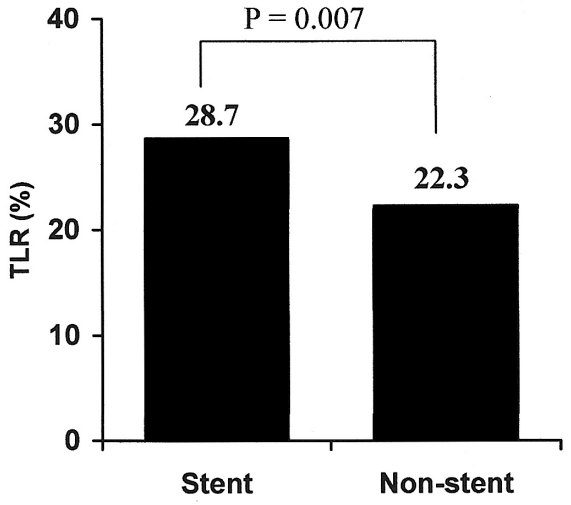

Figure 2. Target lesion revascularization (TLR) at 1-year

The vessel diameter in proximal coronary arteries are generally larger than that in distal coronary arteries. Consequently, small proximal coronary arteries have a higher plaque burden than small distal coronary arteries. Prati et al.[9)] demonstrated that late in-stent neointimal proliferation has a direct correlation with the amount of a residual plaque burden after coronary stent implantation.[10)] In our study, the TLR rate in the stent group was significantly higher than that in the non-stent group. The large plaque burden in the proximal coronary artery lesions may have influenced the higher restenosis rate in the stent group in this study.

As a result, the short term benefits of stenting in small proximal coronary arteries is offset by a higher need for long-term revascularization and therefore such treatment may best be reserved for patients with suboptimal non-stent intervention results.

Recently, the use of drug-eluting stents (DES) has resulted in a drastic reduction in restenosis after PCI. Moses et al.[11)] demonstrated that a sirolimus-eluting stent significantly reduced the restenosis rate when compared with a bare metal stent and this efficacy was consistent in small coronary arteries. Although DES will not be on the market in Japan for several months, DES may change the treatment strategy for small proximal coronary lesions.

The major limitation of this study is the non-randomized assignment of the stent and non-stent groups. Since patients in this study were accumulated from a single center, there was a potential

Table 4. Clinical Follow-up at 1-year

	Stent (N=621)	Non-stent (N=883)	P value
Death (%)	3.5	4.5	NS
Q-wave MI (%)	0.9	1.2	NS
TLR-PCI (%)	21.0	15.5	0.0098
TLR-CABG (%)	9.4	7.8	NS
MACE (%)	30.4	25.7	0.055

MI=Myocardial Infarction, TLR-PCI=Target Lesion Revascularization by Percutaneous Coronary Intervention, TLR-CABG=Target Lesion Revascularization by Coronary Artery Bypass Grafting, MACE=Major Adverse Cardiac Events

for selection bias between the stented and non-stented patients. Although the baseline patient and lesion characteristics were closely matched, the patient age and LVEF are known to be important predictors of cardiac death, and the reference vessel diameter is a known predictor of restenosis. However, all of these parameters were favorable for the stent group. Therefore, these differences may not negatively influence our conclusions.

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