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Adjunctive Coronary Stenting Improves the Six-Month Rate of Stenosis in Patients with Acute Myocardial Infarction vs. Direct Balloon Angioplasty Alone and Adjunctive Directional Coronary Atherectomy

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Abstract: Although direct angioplasty has proved useful in treating patients with acute myocardial infarction, restenosis continues to be a significant problem. Coronary stenting and directional atherectomy (DCA) have been sometimes successful in patients with acute coronary syndrome in whom direct angioplasty resulted in suboptimal results. We investigated whether coronary stenting could reduce the incidence of restenosis in 91 patients with acute myocardial infarction who underwent direct angioplasty alone, adjunctive coronary stenting or adjunctive DCA within 6 hours of the onset of AMI. Successful fine revascularization was defined as a residual stenosis $< 25\,\%$ with a TIMI grade III flow. Direct angioplasty achieved fine revascularization in 46 patients (PTCA group). The remaining 45 patients underwent adjunctive coronary stenting (Stent group, $n = 23$) or adjunctive DCA (DCA group, $n = 22$) because of direct angioplasty failed to achieve fine revascularization due to coronary dissection or recoil in these patients. Successful revascularization was achieved in patients (96 %) in the Stent group and patients (91 %) in the DCA group. Revascularization of target lesions was required before discharge in 8 patients in the PTCA group, and within 6 months in 13 PTCA patients, 2 Stent patients and 7 DCA patients. The minimal luminal diameter at 6 months was significantly greater in the Stent group ($2.79 \pm .62$ mm) than in the DCA group ($1.88 \pm .89$ mm) and the PTCA group ($1.70 \pm .72$ mm) ($p < 0.01$). The % diameter stenosis was significantly smaller in the Stent group ($18.6 \pm 11.4\,\%$) compared with the DCA group ($43.5 \pm 27.6\,\%$) and the PTCA group ($45.2 \pm 24.1\,\%$) ($p < 0.01$). Thus, adjunctive coronary stenting and adjunctive DCA were useful bail-out strategies. Coronary stenting but not DCA, reduced the 6-month rate of restenosis, achieving a large lumen.

Key words: Restenosis, Stenting, Acute myocardial infarction

Direct percutaneous transluminal coronary angioplasty (PTCA) is used to treat patients with acute myocardial infarction (AMI)[1–3], but abrupt closure and threatened coronary arterial occlusion complicate approximately 10 to 25 % of coronary angioplasties[4]. Moreover, coronary restenosis occurs in 45 % of patients who undergo direct PTCA[5]. Both coronary stenting and directional coronary atherectomy (DCA) have proved useful in patients with acute coronary syndrome in whom PTCA resulted in suboptimal results[6–9]. Stenting results in a larger luminal diameter and a lower rate of restenosis than balloon angioplasty in patients with stable angina[10]. In the present study, we evaluated the six-month follow-up results of patients with AMI

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who underwent direct PTCA alone, adjunctive coronary stenting or adjunctive DCA to determine whether coronary stenting reduces coronary restenosis in patients with AMI as well as in patients with stable angina.

Methods

Patient population: Between July 1994 and December 1995, 108 patients with AMI were treated with direct PTCA at Kofu Jounan Hospital. Direct PTCA was performed in patients who showed ST- segments elevation in more than two continuous leads in association with chest pain. Successful fine revascularization in our hospital was defined as a residual stenosis $<$ 25 % with a TIMI grade III flow. We selected 91 patients who underwent direct PTCA alone, adjunctive coronary stenting or adjunctive DCA within 6 hours of the onset of AMI and in whom the infarct-related artery had a diameter of $>$ 2.5 mm. Successful fine revascularization was achieved by direct PTCA alone in 46 patients (PTCA group) (Table 1). Forty five patients could not obtain fine revascularization (so called suboptimal results) because of coronary dissection in 35 patients and recoil in 10 patients. For these patients, coronary stenting was performed when definitive intracoronary thrombus was not observed angiographically, and DCA was performed in 22 patients (DCA group) when definitive intracoronary thrombus was observed (Table 2). The mean age was significantly greater in Stent group, but there were no significant differences in other clinical characteristics among 3 groups.

Direct PTCA: After all patients were classified into Forrester subsets, a bolus dose of 10,000 IU of heparin was administrated intravenously to achieve anticoagulation. Additional heparin was administrated as needed to maintain an active clotting time $>$ 300 seconds. In addition, patients received an intracoronary bolus injection of isosorbide dinitrate (ISDN) 2.5 mg just before direct PTCA. Direct PTCA was performed using the standard technique. The ratio of the dilating balloon to the reference diameter was $\leq$ 1.1 visually. The results of PTCA was confirmed by a single-view angiographic projection of the dilated vessel recorded within the

Table 1. Clinical characteristics of 91 patients

	STENT group (n = 23)	DCA group (n = 22)	PTCA group (n = 46)
Age (y.o)	71 ± 15*	62 ± 13	63 ± 12
Gender male	16	14	35
Coronary Risk Factor (%)			
DM	43 %	41 %	39 %
HT	22 %	27 %	28 %
Obsity	35 %	27 %	30 %
Hyperlipidemia (T.Cho.$>$ 220 mg/dl)	35 %	27 %	30 %
Smoking	70 %	64 %	61 %
Time to reperfusion (hour)	3.8 ± 1.5	3.9 ± 1.3	3.8 ± 1.9
Killip Score $\geq$ III (%)	13 %	9 %	19 %
Forrester subset $\geq$ III (%)	21 %	22 %	19 %
Previously MI (%)	4 %	0 %	4 %

*p $<$ 0.01 for DCA and PTCA group MI = myocardial infarction

Table 2. Characteristics of 91 lesions

	STENT group	DCA group	PTCA group
TIMI grade flow (0-1)%	73 %	68 %	89 %
TIMI grade flow (2-3)%	27 %	32 %	11 %
Rentrop grade (0-1)%	57 %	55 %	63 %
Rentrop grade (2-3)%	43 %	45 %	37 %
Infarct-related artery (No. of vessels)			
LAD	11	12	23
RCA	7	6	21
Lcx	4	4	2
LMT	1	0	0
Reason for Stenting or DCA			
Dissection %	78 %	77 %	
Recoil %	22 %	23 %	

LAD = left descending artery ; RCA = right coronary artery ; Lcx = left circumflex coronary artery ; LMT = left main trunk
Recoil was defined as a $\geq$ 10 increase in post-PTCA residual stenosis occurring 15 to 30 minutes after direct PTCA.

first 5 minutes after the last balloon inflation. When fine revascularization which was defined as a residual stenosis $<$ 25 % with a TIMI grade III flow was not obtained, we performed coronary stenting or DCA. We chose coronary stenting (n = 23) to treat these suboptimal results when definitive intracoronary thrombus was absent angiographically, while we chose DCA (n = 22) when it was present.

Indications for stenting and DCA: Post-PTCA coronary dissection with threatened occlusion was present in 18 and 17 lesions in the Stent and DCA groups respectively, and recoil (defined as a $>$ 10 % increase in the post-PTCA residual stenosis occurring 15 to 30 minutes after successful PTCA) was identified in 5 and 5 lesions, respectively.

Placement of stent: The technique used for intracoronary stenting has been previously described[11]. We used coronary stent slightly larger than the reference diameter of the vessel to be stented (1.1/1 stent / reference diameter ratio). Stenting was performed with Palmaz-Schatz stents in 19 patients and 4 Wiktor stents in 4 patients. The final stent balloon dilatations were performed with compliant short balloons which were oversized according to a visual estimate as judged by angiography, using a maximal inflation pressure $\leq$ 14 atm. Early 3 patients received anticoagulation therapy, consisting of 75 mg of oral dipyridamole 3 times daily, 240 mg of oral aspirin 3 times daily and oral warfarin for 3 months after successful stenting. The rest 19 patients received 200 mg of ticlopidine two times daily. Intravenous heparin was infused continuously for 7 days after the stent placement.

DCA: DCA was performed with 6 or 7F DCA atherocath (SCA-EX, Devices for vascular Intervention) an average of 10 times all round the artery at the site of the target lesion according to a previously described method[8,9]. During DCA, supporting balloons were inflated at low pressures (10 to 30 psi).

Coronary angiography and measurement of coronary stenosis: Similar single-view projections were obtained at each angiographic exam-

ination. Angiographic evidence of restenosis was defined as $>$ 50 % stenosis at the dilated segment of the vessel. We tried to revascularize whenever symptomatic or asymptomatic restenosis of target lesion existed. The % diameter stenosis (% DS), the reference diameter (RD) and the minimal luminal diameter (MLD) were determined after intracoronary administration of 2.5 mg of ISDN, using quantitative coronary angiography (QCA) . The absolute RD and MLD were determined in millimeters using a guiding catheter filled with a contrast medium for calibration. The single view showing the most severe degree of stenosis was used for analysis. Follow-up coronary angiography was performed in 38 PTCA patients, 22 stent patients, and 20 DCA patients at approximately 6 months or earlier if symptoms recurred. In 8 PTCA patients, target lesion revascularization was required before the time of discharge.

In-hospital and follow-up events: We monitored the rates of major in-hospital complications (death, target lesion revascularization, and emergency coronary artery bypass graft surgery), local vascular complications requiring blood transfusion or surgical repair, and the 6-month rates of major ischemic events (death, target lesion revascularization, AMI, and coronary artery bypass graft surgery).

Statistical analysis: Continuous variables are reported as the mean $\pm$ SD and categorical variables as frequencies. Continuous variables were analyzed by the Student's t test. Categorical variables were analyzed by the chi-square method. A value of $p < 0.05$ was considered statistically significant.

Results

Stent group: Stenting achieved successful fine revascularization (residual stenosis $<$ 25 %) in 22 (96 %) of the 23 patients ; in one patient, the balloon mounted stent was unable to pass through the target lesion, despite use of the bare stent technique, because the infarct-related artery was very tortuous.

DCA : DCA achieved successful fine revascularization in 20 (90 %) of 22 patients. The housing of the DCA catheters was unable to pass through the target lesions in 2 patients. Fibrin thrombi were seen in the excised tissue of 20 patients.

In-hospital and follow-up events: There was no deaths or AMIs within the 6-month follow-up in any group and no patient required emergency or elective coronary artery bypass graft surgery. Target lesion revascularization was performed in 8 PTCA patients before discharge due to symptomatic or asymptomatic cardiac ischemia, but none of the Stent or DCA patient required target lesion revascularization before discharge ($p < 0.05$). Target lesion revascularization was required because of symptomatic or asymptomatic restenosis during the 6-month follow-up period in only 2 (9 %) of 22 Stent patients compared with 7 (35 %) of 20 DCA patients and 13 (34 %) of 38 PTCA patients ($p < 0.05$). The two patients of the Stent group had asymptomatic restenosis and one of the two had silent occlusion of the target lesion. Three stenotic lesions of 7 DCA patients with restenosis were in association with aneurysmal change of coronary arteries.

Angiographic parameters: There was no difference in the reference diameter among groups (Table 3). The MLD was significantly greater and the % DS was significantly smaller in the Stent and DCA groups compared with the PTCA group immediately after procedures ($p < 0.01$ vs. PTCA group). The MLD was significantly greater and the % DS was significantly smaller at discharge ($p < 0.05$ vs. DCA group,

Table 3. Angiographical Parameters

	Post-Procedure			Discharge		6 months	
	RD (mm)	MLD (mm)	% DS	MLD (mm)	% DS	MLD (mm)	% DS
STENT group	2.93 ± .23	2.89 ± .37*	7.8 ± 2.8	2.92 ± .14*,**	10.2 ± 5.8*,**	2.79 ± .62#	18.6 ± 11.4#
DCA group	2.88 ± .27	2.80 ± .37*	10.0 ± 7.2	2.65 ± .52$	16.2 ± 12.4$	1.88 ± .89	43.5 ± 27.6
PTCA group	2.95 ± .32	2.56 ± .35	13.2 ± 6.1	2.21 ± .68	23.8 ± 12.2	1.70 ± .72	45.2 ± 24.1

* ; $p < 0.01$ for PTCA group # ; $p < 0.01$ for DCA and PTCA group
$; $p < 0.05$ for PTCA group ** ; $p < 0.05$ for DCA group
RD = reference diameter ; MLD = minimal luminal diameter ; % DS = percent diameter stenosis

$p < 0.01$ vs. PTCA group) and at the 6-month follow-up ($p < 0.01$ vs. PTCA and DCA groups) in the Stent group, compared with the DCA and PTCA groups. There was no significant difference in the MLD or the % DS at the 6-month follow-up between the DCA and PTCA groups.

Discussion

This is the first study to evaluate restenosis following successful coronary stenting compared with direct PTCA alone and adjunctive DCA in patients with AMI. Recent randomized studies have demonstrated that direct PTCA is beneficial in patients with AMI[1–3]. However, abrupt closure threatened vessel occlusion and restenosis continue to be significant problems. Coronary stenting and DCA have been found to prevent acute closure and to improve suboptimal results obtained by PTCA in patients with acute coronary syndrome or stable angina[13–18]. In the present study, coronary stenting and DCA were associated with a high success rate, a low mortality rate and a low incidence of target lesion revascularization in patients with AMI, which is consistent with the results of previous studies[6,7,9].

The incidence of target lesion revascularization required due to symptomatic or asymptomatic restenosis was 46 % (21/46) in the PTCA group during 6 months, which was consistent with the results of previous reports[3,5]. We were unable to reduce the rate of restenosis by PTCA alone although we possibly attempted to achieve fine revascularization (defined as a residual stenosis < 25 %). This result suggests that somewhat adjunctive therapy to PTCA is necessary to reduce the rate of restenosis.

Restenosis occurred in 7 (35 %) of 20 patients in the DCA group, which is consistent with the results of previous studies[8,9,16–18]. Aneurysmal changes in the coronary arteries were observed in 3 of 7 lesions, which may have been responsible for restenosis in DCA group[19,20].

Target lesion revascularization for restenosis was required in 2 patients (9 %) in the Stent group during the 6-month follow-up period, which is consitent with restenosis rates associated with stenting in previous studies in patients with stable angina[3,13]. Acute coronary thrombosis did not occur and target lesion revascularization was not necessary before discharge in any patient in the Stent group. These good results may have been achieved because we tried to obtain as large a lumen as possible using a minimally compliant balloon with a high pressure for post-stenting dilatation. In addition, Wiktor stents were used when a target lesion included a large side branch, which may have precluded side-branch occlusion.

Fine revascularization was defined as a residual stenosis < 25 % based on the theory that

bigger is better for preventing restenosis[16]. The restenosis rate was lowest in the Stent group, in which the largest lumen was obtained.

Study limitation: The same physicians performed direct PTCA, DCA and stenting at the same hospital, which is an advantage. However, the number of patients was small and the duration of follow-up was only 6 months. This study was unable to be randamized because only patients without definitive thrombus underwent coronary stenting to prevent acute coronary thrombosis. Therefore, the present results suggest that coronary stenting is useful in a selected group of patients in whom the results of direct PTCA of the infarct-related artery are suboptimal due to coronary dissection or recoil without definitive thrombus. Further studies are needed to determine whether coronary stenting is useful as a primary strategy to prevent acute closure and restenosis in patients with AMI.

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