Coronary Stenting After Rotational Atherectomy in Calcified and Complex Lesions

Angiographic and Clinical Follow-Up Results

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Abstract

Background Treatment of calcified (in contrast to simple) lesions with PTCA has been associated with a lower success rate and more procedural complications. Rotablation can improve acute results, but the high restenosis rate remains a problem. The purpose of this study was to evaluate the clinical and angiographic outcome of patients with complex and calcified lesions treated with a combination of rotablation and stenting.

Methods and Results Seventy-five consecutive patients with 106 lesions had rotablation prior to coronary stenting. Intravascular ultrasound–guided stenting was used without subsequent anticoagulation in 93% of patients. Procedural success was achieved in 93.4% of lesions. Acute stent thrombosis occurred in two lesions (1.9%), and subacute stent thrombosis in one lesion (0.9%). Angiographic follow-up was performed in 82.5% of lesions at 4.6±1.9 months with an angiographic restenosis rate of 22.5%. Clinical follow-up was performed in all patients at 6.4±3 months; target lesion revascularization was needed in 18% of lesions, Q-wave myocardial infarction occurred in 1.3%, coronary bypass surgery in 4.0%, and death in 1.3%.

Conclusions Optimal coronary stenting after rotablation in calcified and complex lesions can be performed with a high success rate, an acceptable rate of procedural complications, and a low rate of stent thrombosis. This approach was associated with a low incidence of angiographic restenosis compared with results usually obtained with other interventional strategies in calcified and complex lesion subsets.

Key Words:
stents
balloon
calcium

coronary stenting reduces the morbidity of acute closure and decreases angiographic restenosis when used in discrete lesions. However, treatment of complex lesions, such as fibrocalcific lesions, with PTCA has had lower success rates and higher rates of acute complications and clinical and angiographic restenosis compared with PTCA treatment of simple lesions. In vivo IVUS data have demonstrated that coronary calcium is an important determinant of decreased wall compliance, thus leading to high incidence of dissections when these types of lesions are treated with PTCA. In addition, if coronary stenting is used in this setting, an incomplete and asymmetrical stent expansion occurs in up to 50% of cases. Achieving optimal stent expansion is a crucial factor to decrease the incidence of subacute stent thrombosis and to eliminate the need for postprocedural anticoagulation. In addition, postprocedural residual stenosis is a major determinant of the probability of restenosis, ie, "the bigger the better" hypothesis. The rotablator (Rotablator, Boston Scientific, Inc) pulverizes plaque in a selective manner. Although IVUS have shown favorable acute results with the use of this device, no reduction in restenosis has been reported. The purpose of this retrospective report was to test the clinical relevance of the hypothesis stating that rotablation prior to stenting alters vessel wall compliance, thus allowing optimal stent deployment to be performed and improving immediate and long-term outcome.

Methods

Patient Population

From March 30, 1993, until June 30, 1995, 988 consecutive patients with 1307 lesions underwent intracoronary stenting at Centro Cuore Columbus in Milan, Italy. All patients gave informed consent. Seventy-five consecutive patients (7.6%) with 106 lesions (8.1%) had rotablation prior to stenting.

Rotational Atherectomy

Rotablation was performed by using two general approaches: "facilitated expansion," which uses a single burr with a small burr-to-artery ratio with the intention of altering the plaque structure to allow better balloon expansion, and "debulking," which uses progressively larger burrs to decrease plaque mass. The decision concerning which strategy to employ was made by the operator at the time of the intervention. Rotablation was almost always started with a 1.5- or 1.75-mm burr. Care was taken to avoid long passes. Verapamil, nitroglycerin, and pauses of rotablation runs were used.
to control any slow flow occurring during or after rotablation.

Stent Implantation Procedure

Intracoronary stenting was performed in 82 lesions by using the Palmaz-Schatz stent (Johnson & Johnson Interventional Systems). Other stents included the Gianturco-Roubin stent (Cook Inc; 5 lesions), the Wiktor stent (Medtronic Interventional Vascular; 2 lesions), the AVE stent (Applied Vascular Engineering Inc; 2 lesions), the Wallstent (Schneider; 9 lesions), and a combination of the Palmaz-Schatz stent and other stents (6 lesions). After stent implantation, angiographic optimization was performed to achieve an acceptable angiographic result with <20% residual stenosis by visual estimate. During the period of this study, optimal stent deployment by IVUS was defined by (1) complete apposition of the stent to the vessel wall, (2) symmetrical expansion as defined by an SI >0.7, and (3) minimum intrastent CSA >90% of the distal reference lumen CSA.

Angiographic Analysis

Coronary angiography was done in a routine manner. Angiographic measurements were performed by an experienced angiographer blinded to the IVUS measurements who used digital electronic calipers (Brown and Sharp) and an optically magnified image in the view that showed the most severe narrowing. Digital calipers correlate closely with computer-assisted methods. Several angiographic indexes were derived: acute gain (postprocedure MLD minus preprocedure MLD), late loss (postprocedure MLD minus MLD at follow-up), and loss index (late loss divided by acute gain). Lesions were classified according to the modified American College of Cardiology-American Heart Association classification. Long lesions were defined as a single continuous narrowing >15 mm in length.

IVUS Equipment and Measurements

From March 1993 until November 1993 a 3.9F monorail system with a 25-MHz transducer-tipped catheter (Interpilot Catheter, InterTherapy/CVIS) was used. A cardiovascular imaging system with a 2.9F catheter was used after November 1993. Validation of quantitative measurements and pathological correlation has been reported. Online quantitative measurements were performed during the procedure. The cross section with the smallest lumen area inside the stent was selected for measurements for each pass of the IVUS catheter. The minimum and maximum lumen diameters were recorded, and an SI was derived (SI=MLD divided by maximal lumen diameter). SIs <1 indicate a progressive increase in lumen asymmetry. Measurements in the reference segment were obtained proximal and distal to the stented segment in the closest most normal-appearing segments. The average reference vessel and lumen CSAs were calculated as the average of the proximal and distal reference vessel and lumen CSAs, respectively. No vessel size measurements were performed at the site of narrowing (except for lumen dimensions) because the shadowing induced by calcifications and stent struts limit the ability to define the vessel. Interobserver and intraobserver reproducibility of MLD and lumen CSA measurements have been documented.

Prerotablation IVUS was performed in 36 lesions (34%). The general approach was not to perform preintervention IVUS when calcifications were seen on fluoroscopy at or near the lesion where the operator had already planned to perform rotablation. IVUS was performed in 21 lesions after balloon predilatation because of suboptimal balloon expansion and in 15 lesions because calcification was strongly suspected. Calcified lesions that underwent rotablation were identified as subintimal (superficial) echo-dense structures producing external shadowing and with an arc ≥180°.

Procedural Success and Clinical Events

Angiographic success was defined as a final angiographic residual diameter stenosis of <20% Clinical events were defined as follows: death, any death irrespective of cause; Q-wave MI, by the presence of new Q waves (>0.4 s) on an ECG in conjunction with elevation in creatine kinase to greater than twice normal; non–Q-wave MI, by an elevation of cardiac enzymes to greater than twice normal without new pathological Q waves. Emergency CBS involved transfer of the patient from the catheterization laboratory to the operating room immediately or within 24 hours of the procedure. Elective CBS was defined as bypass surgery performed >24 hours after a stent procedure for procedural failure in the absence of ischemia. Acute thrombosis was defined as angiographically documented occlusion at the stent site occurring within 24 hours of the stent procedure. Subacute thrombosis events were angiographically documented occlusions at the stent site occurring beyond 24 hours of the stent procedure. Repeat angioplasty was defined as angioplasty performed for restenosis.

Follow-Up

Short term follow-up was performed by a telephone conversation with the patient at 2 months. Late follow-up was planned at 6 months unless patients had recurrent symptoms or an event requiring earlier angiographic follow-up.

Statistics

Statistical analysis was performed by using the SPSS statistical package. Continuous normally distributed data are expressed as mean±SD. Comparison of continuous variables between groups was performed by using an unpaired student’s t test. Subgroup comparison of categorical variables was performed by using \( \chi^2 \) analysis. Differences were considered significant at \( P<0.05 \). Logistic regression analysis was used to study predictors of angiographic restenosis and target lesion revascularization. All relevant procedural, angiographic, and IVUS variables were entered into the analysis. A forward conditional stepwise selection model was used. Removal testing was based on the probability of the likelihood-ratio statistic based on conditional parameter estimates.

Results

Patient and Lesion Characteristics

Patients’ clinical data and baseline angiographic characteristics are shown in Tables 1 and 2, respectively.
Indications for Rotablation and Stenting and Procedural Characteristics

Indications for rotablation were calcified (70%) and long (10%) lesions. Other indications (20%) for rotablation included suboptimal balloon expansion and inability to pass an IVUS catheter or a balloon across the lesion. Indications for stenting were elective (69%), suboptimal result after rotablation (12%), restenotic lesions (9%), threatened closure (7%), and chronic total occlusions (3%). Rotablation was performed in the majority of lesions as the initial procedure prior to dilatation (80%). A single burr was used in 64 lesions (60%), two burrs in 35 lesions (33%), and three burrs in 7 lesions (7%). The final burr size was 1.85±0.27 mm, with a burr-to-vessel ratio of 0.61±0.12. An average of 1.7±1 (range, 0.5 to 5) stents per lesion were implanted. The final balloon-to-vessel ratio was 1.17±0.19, with a maximal balloon inflation pressure of 16±3 atm.

Angiographic and IVUS Analysis

Of the total patient cohort, 5 patients (6.7%) had unsuccessful stent implantation; they were excluded from this analysis. Baseline and postprocedural angiographic measurements are shown in Table 3. IVUS following successful stent implantation was performed in 63 of the remaining 70 patients (90%) with 88 lesions (89%). It was not attempted in 4 patients (6%), and it was unsuccessful in 3 patients (4%). A suboptimal final IVUS result was left in 1 patient (2%) with 2 lesions. A final optimal ultrasound was achieved in 62 patients with 86 lesions (87% of lesions with successful angiographic stent implantation).

Postprocedural intrastent minimum lumen CSA was 7.15±2.15 mm², which is similar to the average reference lumen CSA of 7.03±2.20 mm² (P= .38) and larger than the distal reference lumen CSA of 6.32±2.54 mm² (P=.002). Postprocedural intrastent MLD was 2.74±0.51 mm, mean SI achieved was 0.87±0.11, and 91% of lesions had anSI >0.7.

Procedural Success, Complications, and Short-Term Outcome

Initial stent implantation was angiographically successful in 70 patients (93.3%) with 99 lesions (93.4%). The stent implantation procedure was unsuccessful in 5 patients (6.6%), all of whom had procedural complications (Table 4). One patient had a guiding catheter-induced left main dissection that led to the patient’s death; a second had acute stent thrombosis and had to undergo emergency bypass surgery; a third had coronary vessel rupture during stent optimization; the last 2 patients had false lumen stenting of a chronic total occlusion with subsequent no flow. These two patients underwent emergency bypass surgery.

In-hospital events occurred in 3 patients (4%; Table 4). One patient had acute stent thrombosis 12 hours after the procedure and underwent emergency PTCA successfully. A second patient, who had slow flow postprocedure, had elective CBS in 2 days. A third patient had subacute stent thrombosis 4 days postprocedure and underwent emergency PTCA and further stenting successfully without further events.

Short-term follow-up was available in all patients at 2 months (Table 4). One sudden death occurred 7 days after a second stent procedure performed without prior rotablation at the ostium of the left circumflex artery. Stent thrombosis seems the most likely cause of death in this patient. However, it is unclear whether this event occurred in the lesion treated with rotablation prior to stenting or in the lesion treated only with stenting.

Late Events

Long-term follow-up was obtained in all patients at a mean of 6.4±3 months (Table 4). Late events occurred in 18 patients (24%). The majority of these events were due to repeat angioplasty for restenosis, which was performed in 13 patients (17%) on 19 lesions (18%). Three patients (4.0%) underwent elective CBS, 2 for target lesion recanalization and 1 for left main dissection during a follow-up angiogram at another hospital. There was one sudden death (1.3%) 5.5 months after the procedure and 1 month after a follow-up angiogram that showed no restenosis. One patient (1.3%) had a non-Q-wave MI after a repeat angioplasty for restenosis.

Antiplatelet and Anticoagulation Therapy

Sixty-five of the 70 patients (93%) were treated with antiplatelet medications: ticlopidine and aspirin in 62 patients (89%) and aspirin alone in 3 (4%); none of these patients received additional anticoagulation. A total of 5 patients (7%) were treated with a standard anticoagulation regimen of heparin, warfarin for 2 months, and aspirin indefinitely. This group included 2 patients with optimal IVUS criteria: 1 had severe slow flow after the procedure,
and the second underwent stenting of the ostial left anterior descending artery and the ostium of the circumflex artery (left main equivalent). A third patient had suboptimal final IVUS, a fourth had an unsuccessful IVUS examination, and in the fifth patient IVUS was not attempted.

Incidence and Predictors of Restenosis and Target Lesion Revascularization

Fifty-four of 68 eligible patients (79.4%) with 80 lesions (82.5%) had angiographic follow-up at 4.6±1.9 (range, 2.1 to 13.3) months. The overall incidence of restenosis was 22.5% on a per-lesion basis. Factors associated with restenosis are listed in Table 5. All these factors were entered into a stepwise logistic regression analysis model to study their predictive value for angiographic restenosis and target lesion revascularization; results are shown in Table 6.

### Table 5.
Subgroup Comparison: Restenosis vs No Restenosis

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<td>lesion length (mm)</td>
<td>10.37±7.44</td>
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A Subgroup Analysis of Elective Palmaz-Schatz Stenting After Rotablation

This subgroup included 53 patients (age, 61±11 years) with 71 lesions. Type B2 and C lesions were present in 77% of cases. Angiographic proximal reference diameter was 3.24±0.51 mm; lesion length was 10.37±7.44 mm. The presence of moderate to severe calcifications was the indication for rotablation in 75% of cases. A single burr was used in 41 lesions (58%), two burrs in 25 lesions (35%), and three burrs in 5 lesions (7%); the largest burr-to-vessel ratio was 0.6±0.1. Stenting was elective in all lesions (including 8 restenotic lesions and 2 chronic total occlusions), with 1.9±1.1 stents per lesion, a balloon-to-vessel ratio of 1.15±0.18, and maximal inflation pressure of 16±3 atm. Procedural success was achieved in 97% of cases; postprocedural MLD was 3.25±0.55 mm (−3±13% residual diameter stenosis). Acute stent thrombosis occurred in 1 lesion (1.4%) and subacute stent thrombosis in 1 lesion (1.4%). Angiographic follow-up was performed in 57 lesions (85% of eligible lesions) at 5.0±2.0 months. Angiographic restenosis occurred in 13 lesions (23%). Clinical follow-up was performed in all patients at 6.5±2.5 months; 12 lesions (17%) needed repeat angioplasty. Multivariate predictors of angiographic restenosis and target lesion revascularization in this subgroup are shown in Table 6.

Discussion

Rationale

Treatment of calcified and complex lesions with PTCA has been disappointing because of a low success rate, increased frequency of acute complications, and a high restenosis rate. Rotablation emerged as a promising technique for treatment of this subset of lesions. The Rotational Atherectomy Multicenter Registry reports procedural success in 94.7% of cases, but with an angiographic restenosis rate of 37.7%. Similarly, many other studies show favorable acute results but high restenosis rates. Therefore, the need for an alternative strategy to approach this subset of complex lesions is evident.

It is generally accepted that appropriate stent expansion is a crucial factor in preventing stent thrombosis and possibly decreasing the incidence of restenosis. Published data on coronary stenting alone in calcified and complex lesions are limited. Our own experience in this regard is only anecdotal and not based on a randomized protocol. Table 7 compares elective Palmaz-Schatz stenting for calcified lesions with and without rotablation over the same time period. Stenting alone was used for shorter lesions, which require fewer stents, in larger vessels. Stents were expanded by using a high balloon-inflation pressure with a similar balloon-to-vessel ratio. After adjusting for vessel size, the rotablation-stent group had a lower residual angiographic percent diameter stenosis and a higher ratio of minimal stent CSA-to-vessel CSA and a higher SI. In addition, 3 of 41 patients (7%) in the stent-alone group required emergency bypass surgery because of occlusive dissections after stenting. These data are consistent with prior observations suggesting that even balloon pressures >20 atm may be insufficient to overcome the limitations imposed by a severely calcified plaque, and attempts to obtain full expansion of a stent may cause vessel rupture instead of further enlarging the stent. Fig 1 shows images obtained with a 0.018-inch imaging guide wire (CVIS, Boston Scientific, Inc) positioned inside a balloon inflated at 24 atm at the site of an incomplete stent expansion in a calcified lesion not treated with rotablation. It is clear from these images that high-pressure inflation in resistant lesions may be insufficient to achieve nominal balloon size, despite the apparent angiographic complete balloon expansion. Others have shown that the use of an oversized balloon to overcome this problem is associated with significant vessel complications such as vessel rupture. For these reasons we feel that the best approach to facilitate stent expansion in a calcified lesion is to modify vessel wall compliance by partial removal of the plaque using rotablation, as shown in Fig 2.

### Table 7.
Comparison Between Elective Palmaz-Schatz Stenting Alone vs Elective Palmaz-Schatz Stenting After Rotablation for Calcified Lesions

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Figure 1.

A, Angiogram showing left anterior descending artery with a midcalcified lesion (arrow). B, Fluoroscopic image of a 3.5-mm Titan balloon inflated at 24 atm at the lesion site. Note the apparent complete balloon expansion. C, IVUS image obtained with a 0.018-inch imaging guide wire.
guide wire positioned inside this balloon (nominal unconstrained CSA=9.6 mm$^2$). Note that lumen CSA inside the balloon is 5.3 mm$^2$. D, Angiogram showing left anterior descending artery after placing one Palmaz-Schatz stent in midlesion. Note haziness (arrows). E1, Proximal reference (CSA=9.1 mm$^2$); E2, final IVUS image at lesion site (note asymmetrical stent expansion [CSA=3.4 mm$^2$]); E3, distal reference (CSA=8.6 mm$^2$).

**Figure 2.**
A1, Baseline coronary angiogram showing right coronary artery with midcalcified lesion (arrow); A2, IVUS cross section through the culprit lesion; note 360° calcifications (small white arrows). B1, Coronary angiogram showing right coronary artery and culprit lesion (arrow) after rotablation and PTCA; B2, IVUS cross section through culprit lesion after rotablation and PTCA. C1, Coronary angiogram showing culprit lesion poststenting (arrow); C2, IVUS cross section through culprit lesion; note symmetrical and complete expansion of the stent.

### Procedural Success and Complications

Successful outcome of a catheter-based coronary intervention depends on several factors, including operator experience, patient's age, ventricular function, vessel size, and lesion characteristics, especially calcifications and lesion length. The current study describes a success rate of 93.4% using an angiographically defined success of <20% residual stenosis. In this study, IVUS examination poststenting demonstrated that the combined approach clearly accomplished optimal stent deployment by eliminating the problem of asymmetrical and incomplete stent expansion (Fig 3). It is important to consider that 36% of vessels were <3.0 mm in size, 71% of lesions were calcified, 16% of lesions were longer than 15 mm, and lesion types B2 or C were present in 71% of cases. Procedural complications occurred in 6.6% of patients: death in 1.3%, emergency CBS in 4%, Q-wave MI in 1.3% and non-Q-wave MI in 6.7%. Mintz et al. have reported a series of 88 patients with large vessels (>3.0 mm) and calcified lesions who underwent stenting postrotablation without procedural and in-hospital complications; 6-month angiographic and clinical follow-up results were not available. In studies using rotablation and PTCA, Warth et al. report a success rate of 95% with major procedural complications in 3% (1.9% to 4.5%); Ellis et al. report a success rate of 93.5% and major procedural complications in 3.4% and Henson et al. report procedural success in 94% (age >70 years) and 88% (age >80 years). In all these studies procedural success was defined as a final angiographic residual stenosis of <50% of the reference diameter. In addition, lesion complexity, especially calcifications, ranged from 32% to 58%, and the presence of type B2 or C lesions ranged from 36% to 60%. In light of this heterogeneity in vessel size and prevalence of complex lesions and in the definition of success used in other studies, it is difficult to make a direct matched comparison. However, it becomes clear that the procedural success and complication rate reported in this study remain acceptable.

### Slow-Flow Phenomenon and Stent Thrombosis

It has been speculated that coronary stenting postrotablation might increase the risk of stent thrombosis secondary to the slow-flow phenomenon. In the present study refractory slow flow (without optimal response to intracoronary nitroglycerin and verapamil) occurred in 1 lesion (0.9%), and thrombus formation postrotablation occurred in 1 lesion (0.9%). This is comparable with other studies. Warth et al. report slow flow in 1.2% (0.5% to 2.3%) of patients and thrombus formation in 1.6% (0.8% to 2.8%), Ellis et al. report slow flow in 5.1% of cases, and Piana et al. report a 2% incidence of no-reflow.

When a stent was deployed after refractory slow flow, compromised flow persisted, and the patient had to undergo elective bypass surgery within 2 days. The second case of acute stent thrombosis occurred in a patient with acute ischemic syndrome, where a thrombus may have played a role. This brings the incidence of acute stent thrombosis to 1.9%. Subacute stent thrombosis occurred in 1 lesion (0.9%), an incidence that is identical to our
earlier experience with stenting without anticoagulation and without adjunct rotablation. In addition, this rate of stent thrombosis compares favorably with that reported by other investigators with coronary stenting alone. Barragan et al and Morice et al report stent thrombosis in 4.2% and 1.6% of patients, respectively.

The unique and new aspect in the present study is the rather high incidence of acute stent thrombosis. A preliminary conclusion concerning the issue of stent thrombosis and rotablation can be drawn: the incidence of stent thrombosis after rotablation remains low provided attention is paid to the slow-flow phenomenon by following a careful technique and by avoiding stenting in the event that slow flow persists. In addition, the examination of postprocedural stent MLD and CSA suggests a positive role for rotablation through facilitating stent expansion and optimal deployment.

Incidence and Predictors of Restenosis

Restenosis after PTCA is related to clinical and angiographic factors such as vessel size, lesion length, lesion calcifications, and postprocedural residual stenosis. Restenosis rates after rotablation range from 37% to 51%. In this study the restenosis rate was 22.5% with angiographic follow-up accomplished in 82.5% of lesions. At present, there is no published data on angiographic restenosis with coronary stenting in a similar patient population, and our results compare favorably with restenosis rates of coronary stenting in simple lesions. This may suggest that the combined approach of stenting postrotablation in calcified and complex lesions transforms lesions with a high preintervention probability of restenosis to a lower risk category. This concept is further supported by the fact that the loss index in this population was 0.53±0.48, which is similar to that reported poststenting alone of noncalcified lesions. This suggests that rotablation prior to stenting does not increase late loss compared with stenting alone.

Stent type and indication did not differ between the restenosis and no-restenosis groups. However, the number of stent types other than the Palmaz-Schatz and the number of lesions undergoing bailout stenting were too small to draw firm conclusions in regard to their contribution to the restenotic process. Logistic regression analysis showed that the only predictors of restenosis in the total cohort and in the subgroup with elective Palmaz-Schatz stenting were small postprocedural MLD by IVUS (which also predicted the need for repeat angioplasty) and lesion length. These findings are consistent with prior studies. It is of interest to note that the MLD by IVUS was a stronger predictor of restenosis than angiographic measurements, which might stem from the fact that IVUS better defines true lumen dimensions than does angiography.

Study Limitations

Limitations include the fact that this study was a retrospective analysis; no routine preintervention IVUSs were performed to predefine inclusion parameters; and several stent types were used for different indications, which prohibits drawing conclusions in regard to the effect of specific stent type on outcome. Despite these shortcomings, the uniqueness of this population defines a subgroup in which previous interventions have been highly unsuccessful or associated with a very high restenosis rate.

Conclusions

On the basis of our observations, we conclude that rotablation in selected calcified and complex lesions allows optimal coronary stenting to be performed safely without anticoagulation. This approach may also reduce angiographic restenosis and target lesion revascularization compared with the results typically obtained by other catheter-based coronary interventions in similar types of lesions.

Selected Abbreviations and Acronyms

CBS = coronary bypass surgery
CSA = cross-sectional area
IVUS = intravascular ultrasound
MI = myocardial infarction
MLD = minimum lumen diameter
SI = symmetry index

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