Percutaneous Transluminal Coronary Rotary Ablation with Rotablator (European Experience)

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This study reports the results from 3 European centers using rotary ablation with Rotablator™, a device that is inserted into the coronary artery and removes atheroma by grinding it into millions of tiny fragments. Rotary ablation was performed in 129 patients. Primary success (reduction in percent luminal narrowing >20%, residual stenosis <50%, without complications) was achieved by rotary angioplasty alone in 73 patients (57%). An additional 38 patients (29%) had successful adjunctive balloon angioplasty. Thus primary success was achieved in 111 patients (86%) at the end of the procedure. Acute occlusion occurred in 10 patients (7.7%). Recanalization was achieved by balloon angioplasty in 7: urgent bypass grafting was undertaken in 2. Q-wave and non-Q-wave myocardial infarction occurred in 3 and 7 patients, respectively. No deaths occurred. Follow-up angiography was performed in 74 patients (60%). Restenosis, defined as the recurrence of significant luminal narrowing (>50%) occurred in 17 of 37 patients (46%) who underwent rotary ablation alone, and 11 of 37 patients (30%) who had adjunctive balloon angioplasty. The overall angiographic restenosis rate was 37.8%. In conclusion, rotary ablation is technically feasible, and relatively safe in the coronary circulation. The low primary success rate reflects the limited size of the device, which can be introduced through available guiding catheters, and limits the use of rotary ablation as a stand-alone procedure to lesions in small arteries or in distal locations. No reduction in restenosis was seen, but the role of this device combined with balloon angioplasty in larger arteries needs to be further defined.

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The original description of percutaneous transluminal coronary angioplasty has led to major changes in the clinical practice of cardiology, and has stimulated innovative expression in research. In the last 5 years, significant improvements have been made in the initial balloon catheter system described by Gruentzig et al.[1] However, the major problem of restenosis, which occurs in up to 40% of cases after an initially successful procedure,[2] and continuing technical difficulties in dealing with certain types of lesion (particularly those that are calcified or in distal locations) have stimulated research into alternative methods of dealing with atheromatous coronary obstructions. One such technique, coronary atherectomy, has been developed to produce an improvement in lumen diameter by direct mechanical removal of atherosclerotic material from the vessel wall in situ. Several techniques for this purpose have been described including directional (or excisional) atherectomy, transluminal extraction atherectomy, and high speed rotary ablation. In this study, we present the results obtained in 3 European centers using high-speed rotary ablation with Rotablator™.

METHODS

The Rotablator (Heart Technology, Inc., Bellvue, Washington) consists of an abrasive tip (Figure 1) welded to a long flexible drive shaft tracking along a central flexible guidewire. The abrasive tip is an elliptically shaped burr, manufactured in various sizes (from 1.0 mm to 2.75 mm in diameter), whose distal portion is coated with diamond chips 30 to 50 μ in diameter. Rotational energy is transmitted by a disposable compressed air motor that drives the flexible helical shaft at very high speeds (up to 190,000 rpm). The number of revolutions per minute is measured by a fiberoptic light probe and displayed on a control panel. The speed of rotation is controlled by the air pressure, which is itself controlled by the operator using a foot pedal. During rotation, a small volume of sterile saline solution irrigates the catheter sheath to lubricate and cool the rotating parts. The burr and the drive shaft move freely over a central coaxial guide wire (0.009 inch in diameter), with a flexible radioopaque platinum distal part (20 mm long), which does not rotate with the burr during abrasion. This central guidewire can be controlled and moved with a pin vise. The wire and the abrasive tip can be advanced independently, which allows the wire to be placed in a safe distal location before the burr is advanced into the diseased artery.

Protocol: All patients received nifedipine (60 mg orally in 3 divided doses) and aspirin (500 mg orally) the day before the procedure. Chlorodiazepate (50 mg intravenously) was given on the day of the procedure as premedication. A sheath (9Fr) was inserted into the femoral artery under local anesthesia and a standard 9Fr guiding catheter was advanced to the ostium of the coronary artery. After intracoronary injection of isosorbide dinitrate (2 mg), a baseline angiogram was recorded in 3 projections, and heparin (10,000 IU) was given intravenously.

Rotary ablation began with the placement of the small guidewire across the lesion to a safe distal vessel location, sometimes guided by a 3Fr infusion catheter which was positioned first. The burr and the drive shaft were then manually advanced over the guidewire to the site of the lesion, and rotation was begun. When an adequate speed of rotation (>150,000 rpm) had been achieved, the abrasive tip was advanced gently over the guidewire. If resistance was encountered the tip was successively pulled back and advanced to maintain a high speed of rotation. Several slow passes were usually required to achieve maximal plaque removal. Typical results of the procedure are shown in Figures 2 and 3. The angiographic results of the patients studied in Lille and Rotterdam were assessed by computerized quantitative coronary angiography (as described later). When the residual stenosis after atherectomy remained significant (>50%), an additional percutaneous balloon angioplasty was performed. Patients were discharged with nifedipine (60 mg/day) and aspirin (100 to 500 mg/day) and underwent repeat coronary angiography 3 to 6 months after the procedure. The study protocol was approved by the local Research Ethics Committee, and written informed consent was obtained from all patients.

Primary success of rotary ablation was defined as a significant reduction (>20%) of stenosis with residual stenosis <50% without complications during hospitalization. Restenosis was defined as the recurrence of a significant narrowing (reduction of luminal diameter >50%).

Study population: One hundred twenty-nine patients (107 men and 22 women, mean age 57 ± 8 years, range 33 to 68) underwent rotary ablation. Sixty-five patients were treated in Lille, France, 54 in Mainz, Germany, and 10 in Rotterdam, the Netherlands.

Clinical characteristics: Most of the patients (n = 68 or 53%) had severe (Canadian Cardiovascular Grade 3) stable effort angina, 13 or 10% had angina on effort and at rest, 15 (11.5%) had unstable angina, 15 complained of angina at rest, and only 6 (5%) had atypical chest pain; finally, 12 patients had no chest pain.

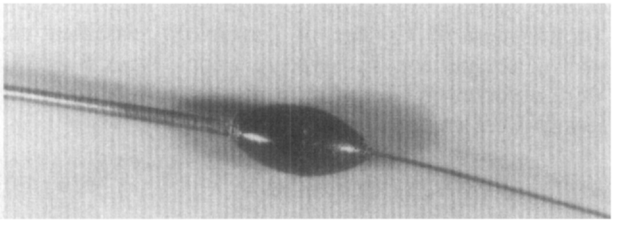

FIGURE 1. Distal part of the Rotablator with the burr.

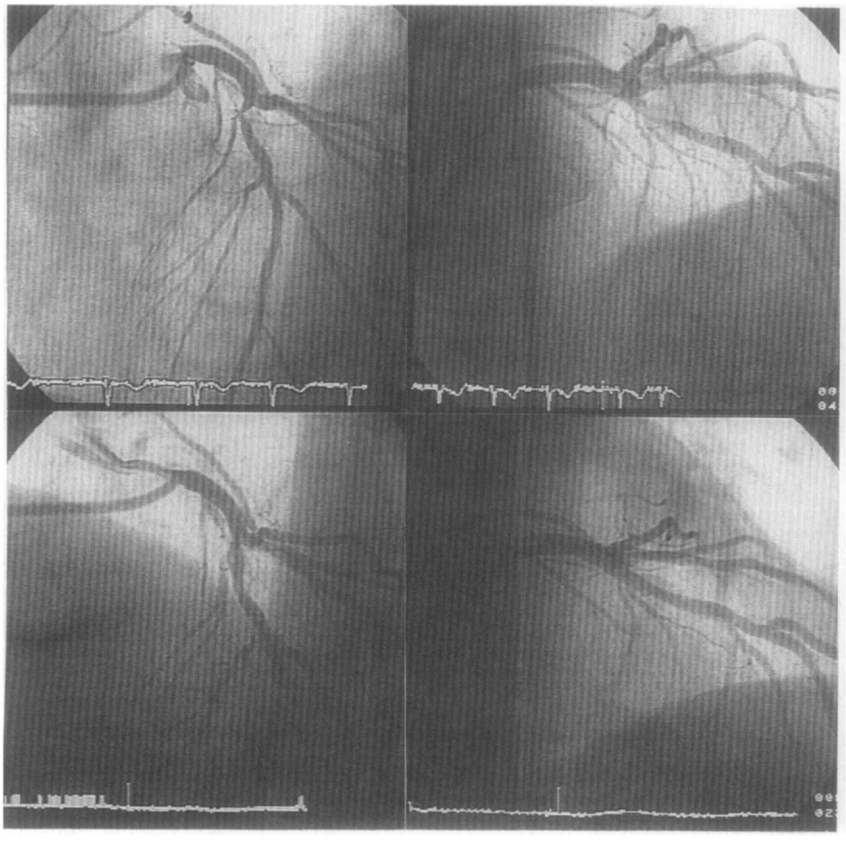

FIGURE 2. Rotablator as a stand-alone procedure for a lesion of the proximal left anterior descending coronary artery. *Upper panels*, before Rotablator; *lower panels*, after Rotablator.

TABLE I Quantitative Coronary Analysis After Rotary Ablation

Ablation	Rotary Ablation		After Rotary + Balloon
	Before	After	
Rotary ablation (mm)	0.72 ± 0.30	1.46 ± 0.43	—
Stand alone procedure (%)	73 ± 12	42 ± 13*	—
Rotary ablation + balloon angioplasty			
mm	0.49 ± 0.37	1.14 ± 0.36*	2.2 ± 0.46*
%	80 ± 12	61 ± 13	31 ± 9*

*p <0.01.

Angiographic data: Coronary angiograms showed 1-, 2- and 3-vessel disease in 68, 25 and 7%, respectively. In all patients only 1 coronary segment was treated by rotary ablation. The procedure was performed on the left anterior descending artery in 63 patients, the right coronary artery in 47 patients and the circumflex artery in the remaining 19 patients. Most of the stenoses were routine lesions: According to American Heart Association/American College of Cardiology classification, 48% of the patients had type A lesions; types B and C were observed in 36 and 16% respectively. Twenty-six lesions were calcified.

Quantitative coronary angiography: Coronary arteriograms were analyzed with use of a computerized automatic-analysis system (Computerized Assisted Evaluation of Stenosis and Restenosis). The cine film was projected with a Tagarno projector and the end-diastolic frame selected for analysis was scanned with a CCD JVC video camera. The signal produced by the video camera was digitized and processed with a software system on a 386 computer provided with an automatic edge-detection algorithm. The diameter of the coronary catheter was used to convert the imaging data from pixels to millimeters. The frames for analysis were chosen by a cardiologist who was not involved in the study protocol. The dilated vessel segment was defined by measuring the distance from a side branch of the dilated vessel to the narrowest point of the stenosis on the angiogram immediately before ablation. All measurements were performed on angiograms recorded after the intracoronary injection of 2 mg of isosorbide dinitrate.

Statistical analysis: All data are expressed as mean ± SD. Comparisons between vessel diameters (or percentage reduction in luminal diameter) before rotary ablation, immediately after rotary ablation and at follow-up were performed with use of paired Student's *t* tests. A p value <0.05 was considered statistically significant.

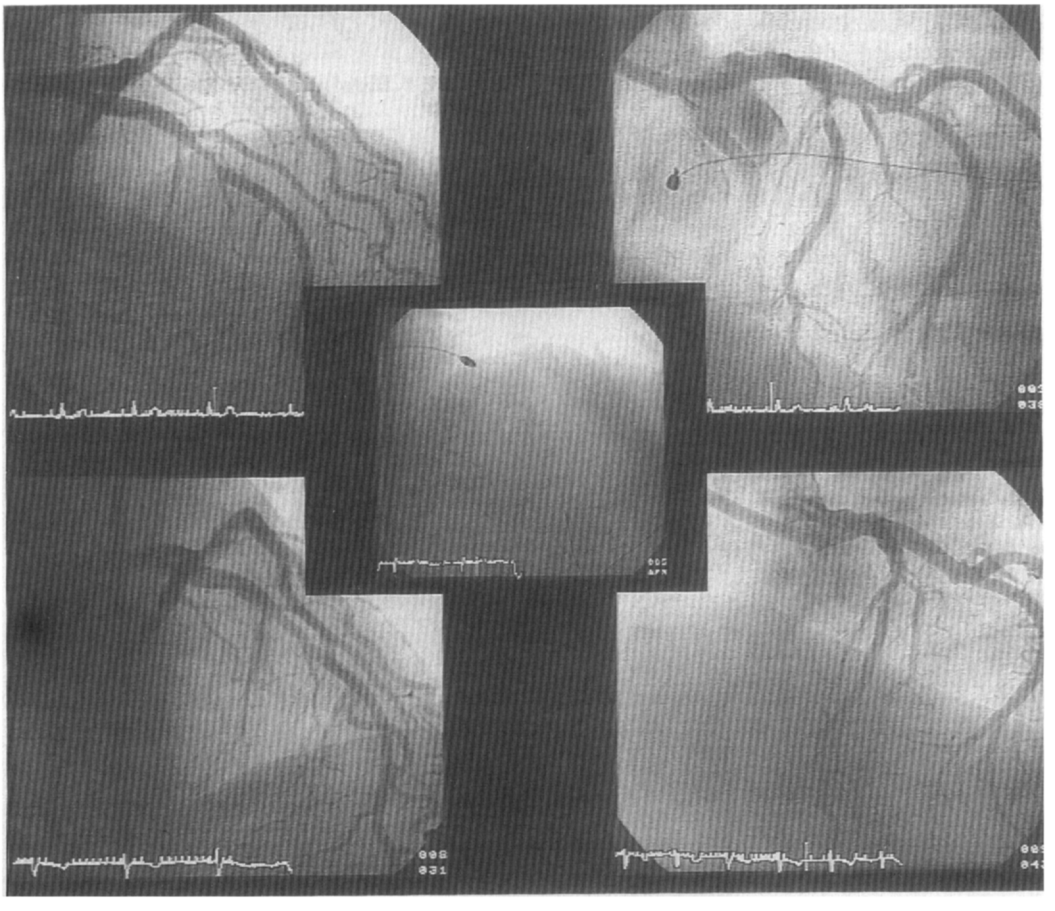

FIGURE 3. Rotary ablation with a 2.5 mm burr of a mid–left anterior descending lesion. *Upper panels*, before Rotablator; *lower panels*, after Rotablator.

RESULTS

Rotary ablation was performed in 128 patients; in 1 patient the guidewire could not be passed across a very tight and tortuous stenosis. Rotary ablation as a stand-alone procedure was achieved in 88 patients; in 40 patients, rotary ablation was completed by adjunctive balloon angioplasty because of abrupt closure in 10 and insufficient results in 30 who still had significant stenosis after the procedure. Thus, primary success was achieved by rotary ablation alone in 73 patients (57%). This relatively low success rate was mainly the result of the small size of the channel created by rotary ablation. This was due to the limited size of the burr acceptable for guiding catheters available at the beginning. With the help of additional successful balloon angioplasty in 40 patients the overall success rate of 86% (111 of 129 patients) was at the end of the procedure.

Complications: A transient (few seconds) bradycardia was observed early in our experience in 6 patients. In 3 patients this occurred during a procedure on the right coronary artery and may have been related to microembolization of the atrioventricular nodal artery. In all subsequent treatment of the right coronary artery a pacing catheter was placed in the right ventricle before the procedure. Immediately after the procedure 8 patients developed a long diffuse coronary spasm distal to the treated site, which was promptly relieved by the intracoronary injection of isosorbide dinitrate. Abrupt closure occurred during the procedure in 10 patients (7.8%): In 7, the lesion was easily recrossed with a balloon, 2 required rapid bypass surgery without further complications or infarction, and in 1 recanalization of the abrupt closure was not attempted because the area supplied by the vessel was relatively small (no increase in cardiac enzymes and no subsequent complications occurred in this particular patient). Three patients developed late occlusion (at 6 hours, 24 hours and 6 days after the procedure). Myocardial infarction (Q wave in 3, non-Q-wave in 7) developed in 10 patients (7.8%). Except for these 10 patients, serial creatine kinase measurements never exceeded the upper normal limit. There were no deaths related to the procedure.

Quantitative angiographic measurements: Before and immediately after rotary ablation, quantitative angiographic measurements (as previously outlined) were performed in the patients studied in Lille and Rotterdam (n = 69). The results of rotary ablation as a stand-alone procedure are outlined in Table I. The mean minimal lumen diameter increased from 0.72 ± 0.30 mm before to 1.46 ± 0.43 mm immediately after the procedure ($p < 0.001$). The ratio minimal luminal diameter/burr size was 0.7 ± 0.25. The mean percent reduction in internal luminal diameter decreased from 73 ± 12 to 42 ± 13%. Where the procedure was completed by adjunctive balloon angioplasty the mean residual minimal diameter was 2.2 ± 0.46 mm, and the mean residual percent stenosis was 31 ± 9%.

Angiographic follow-up: Seventy-four patients underwent repeat coronary angiography at a mean of 4.6 months (range 3 to 6) after the procedure. The angiographic results at follow-up were analyzed in 2 groups of patients: group A (n = 37) underwent rotary ablation as a stand-alone procedure and group B (n = 37) underwent rotary ablation with adjunctive balloon angioplasty. Seventeen patients (46%) in group A had typical restenosis. In group B, restenosis was observed in 29.7% of patients. For the whole group the restenosis rate was 37.8%.

DISCUSSION

The main mechanism of action of Rotablator is an abrasion of the occlusive material allowing restoration of lumen patency. The diamond chips on the burr remove material in millions of tiny particles. Previous experimental studies in animals, and observations made on segments of human iliac arteries treated with rotary angioplasty showed that the resulting arterial lumen was smooth and polished.

Two major concerns have been expressed regarding the use of rotary ablation in the coronary circulation; one relates to its potential to damage adjacent nonatheromatous tissue, the other to the size of the particles generated by the procedure. Studies in animals and in human peripheral arteries[3-7] have shown that rotary ablation selectively removes firmer noncompliant material, while the normal elastic tissue is deflected away from the probe. This potential for selective removal of diseased tissue, with particular affinity for harder material such as calcium, is obviously of great clinical relevance. The removal of the endothelium may contribute to the occurrence of vasospasm which we observed in some patients. However, in our patients vasospasm was usually seen 2 or 3 cm beyond the site of ablation and may have been related to vibrations transmitted to the guidewire during rotation of the burr. A similar phenomenon has been reported by Hansen[5] after rotational atherectomy in a rabbit model of atheroma.

No-flow phenomenon, transient bradycardia and atrioventricular blocks may be related to production of microcavitations. As a result of high velocity at the burr, surface cavitations are produced according the Bernoulli equation, and this was previously documented in experimental studies.[8]

The second concern relates to the size of particles created by rotary ablation. This concern has been investigated in several animal models[6] and in human peripheral arteries. These observations suggest that the debris generated by rotary ablation is usually small enough to pass safely through the capillary bed. Moreover, in 32 cases we assessed left ventricular motion before and after rotary ablation and we did not observe wall motion abnormality after rotary ablation.

The size of the burr used in the coronary artery is a limitation of the Rotablator. The device must be inserted in the coronary artery through a guiding catheter. However, even with the largest available guiding catheters, the inside luminal diameter does not exceed 2.5 mm. Thus, although burrs are available in sizes up to 4.5 mm, only those <2.5 mm in diameter can be used in the coronary circulation. Moreover, the ratio residual

minimal lumen diameter/burr diameter is only 0.7: this suggests that the "effective abrasive diameter" is inferior to the maximal diameter of the burr. It is very likely that at the end of abrasion, the elastic arterial wall deflects away, allowing the passage of the device through the lesion. From these experimental observations and our early clinical experience 2 different strategies may be adopted. One approach would be to start with an intentionally undersized burr, with stepwise increments in size until an optimal result is obtained. The other would involve the use of a small burr to "debulk" the vessel, leaving a smooth residual surface, and to complete the procedure with conventional balloon angioplasty but using a very low inflation pressure. The results in our patients would support this second approach. Until further information from comparative studies and longer follow up data are available, the role of rotary ablation in the treatment of coronary disease remains to be defined. The available evidence suggests that high-speed rotary ablation appears to be most useful for (1) lesions in vessels of 2.2 to 2.8 mm in diameter, (2) lesions in distal locations, (3) calcified or nondistensible lesions, and (4) eccentric lesions. However, its use should be avoided in patients with (1) lesions in large coronary vessels (>3.7 mm), (2) lesions in vessels with angiographically apparent thrombus, and (3) lesions in degenerated saphenous vein grafts where the atherosclerotic material is likely to be friable.

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