Percutaneous Coronary Rotational Angioplasty in Humans: Preliminary Report

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Percutaneous coronary rotational angioplasty was attempted in 12 patients. The procedure was performed with a flexible rotating shaft with an abrasive tip, varying in diameter from 1.25 to 3.5 mm, tracking along a central guide wire. Among the 12 patients (mean age 58 years), 4 had a stenosis in the left anterior descending coronary artery and 8 a stenosis in the right coronary artery. After the guide wire crossed the stenosis, the abrasive tip was slowly advanced and several passes across the stenosis were made. The residual stenosis was measured with computerized automatic quantitative coronary angiography. Success was defined as a reduction of percent stenosis by >20%. If residual stenosis remained significant (>50%), the procedure was completed by balloon dilation. The device could not be inserted in 2 of the 12 patients.

Five of the 10 patients underwent rotational angioplasty alone, and 5 had the procedure completed by balloon dilation. The stenosis was significantly enlarged from 0.56 ± 0.31 mm to 1.26 ± 0.28 mm. The outline of the vessel appeared smooth and regular.

There were no complications related to the procedure and all patients were free of symptoms when discharged 2 to 3 days after the procedure. Thus, coronary rotational angioplasty is a simple and safe procedure allowing marked dilation of the narrowed segment. However, long-term follow-up is required for further evaluation.

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Over the last 10 years, it has been clearly demonstrated that percutaneous coronary balloon angioplasty is an efficient method of myocardial revascularization (1,2). However, restenosis, which occurs in 30% to 35% of cases, remains a major limitation to the long-term benefit of this procedure (3). Alternative techniques, most of them still investigational, have, therefore, been proposed. The main goal of these new techniques is to remove totally or partially the atherosclerotic plaque rather than simply to dilate the vessel. In a few cases, vaporization of the plaque by laser energy has been attempted. Mechanical atherectomy, as proposed by Simpson et al. (4), is more attractive and the preliminary results in human beings are very promising.

In this study, we describe a new technique of coronary rotational angioplasty with a device designed to remove atherosclerotic material by the abrasive effect of its high speed rotating tip. The excellent results obtained with this technique in experimental animal models (5–7) and in human peripheral arteries (8,9) led us to treat coronary artery narrowing. In this study, we report our preliminary results in patients with coronary artery disease.

Methods

The coronary rotational device. The device (Rotablator®, Biophysics International) (Fig. 1) consists of a rotating abrasive burr of variable diameter (from 1.25 to 3.5 mm) that can be advanced over a thin (0.23 mm) stainless steel central guide wire. The last 2 cm of the wire is composed of radiopaque platinum spring. The abrasive surface of the tip is composed of 30 to 40 μm diamonds embedded in nickel. The central guide wire and the abrasive tip can be advanced independently. The steerable guide wire allows selection of the vessel and crossing of the stenosis but is fixed during rotation of the burr. The drive mechanism is rotated up to 180,000 rpm by an air turbine. The drive shaft is housed in a 4F Teflon sheath through which small volumes of saline
solution are infused during rotation to lubricate and cool the system, which is disposable.

Procedure. The patients received nifedipine (60 mg) and aspirin (500 mg) the day before the procedure. Sedation was obtained with an intravenous injection of 50 mg of chlorodi-azepate. After administration of local anesthesia, a 9F sheath was inserted into the femoral artery. A standard 9F guiding catheter was placed into the ostium of the coronary artery to perform an initial angiogram made in three different projections after intracoronary injection of 2 mg of isosor-bide dinitrate. Then, 10,000 U of heparin was intravenously injected. The atherectomy device was introduced into the guiding catheter and positioned just before its distal tip. Under fluoroscopy, the steerable guide wire was advanced through the narrowing and directed into the distal part of the vessel. Then, the abrasive tip was advanced along the guide wire, placed in contact with the stenosis and the rotation was started. When an adequate speed of rotation was reached (150,000 to 180,000 rpm) the abrasive tip was advanced gently over the guide wire. If resistance was encountered, the tip was alternately advanced and withdrawn to maintain a high speed rotation. Once the abrasive tip crossed the lesion, it was pulled back and several passages were performed until the impression of mechanical resistance disappeared. On average, the rotation was stopped after six to eight passages, and the abrasive tip was removed into the guiding catheter while the guide wire remained distally. After dye injection verified the results of the procedure, the rotational catheter and its guide wire were completely withdrawn.

The protocol was approved by the Ethical Committee of the University of Lille, the French Ministry of Health and the United States Food and Drug Administration. All patients gave informed consent.

Coronary angiography. The angiographic results were assessed with computerized quantitative coronary angiography. The image of the vessel was digitized and three regions of interest (size 100 × 100 pixels) encompassing three arterial segments were selected. The edges of the arterial segments were automatically detected by the computer on the basis of the weighted sum of first and second derivative functions applied to the digitized brightness information. The results were expressed in absolute values (in millimeters) by using the guiding catheter as a scaling device.

Primary success of rotational angioplasty was defined as a significant reduction (>20%) of percent stenosis without complications. When the residual stenosis after rotational angioplasty remained significant (>50%), balloon angioplasty completed the procedure. Within the first 24 h, several electrocardiograms (ECG) were recorded and serum creatine kinase was measured serially.

Follow-up. The patients were discharged on a regimen of aspirin (500 mg/day) and nifedipine (60 mg/day). They were restudied 3 months later with a treadmill exercise test (Bruce protocol) and underwent repeat coronary angiography.

Study patients. Twelve patients, 10 men and 2 women with an average age of 58 years (range 46 to 69), underwent coronary rotational angioplasty. Six patients had a history of prior myocardial infarction. All complained of severe typical effort angina (mean duration 7 months) and 8 were in New York Heart Association functional class IV. No patient had prior coronary angioplasty or surgical bypass grafting. All patients had lesions suitable for myocardial revascularization. Coronary angiography showed single vessel disease in 10 patients and double vessel disease in 2. The treated segment was located in the right coronary artery in eight patients and in the left anterior descending coronary artery in four.

The mean diameter of the treated coronary stenosis was 0.58 ± 0.35 mm, and one patient had a subtotaly occluded vessel. On average, the degree of luminal diameter reduction of the stenosis was 74 ± 24%. The length of the narrowing averaged 8 ± 3.2 mm. Two stenoses were calcified and three were eccentric. In two cases, the ergonovine test performed during prior coronary angiography induced spasm of the treated segment.

At the beginning of our experience, the patients were selected on the basis of the morphology of the coronary stenosis. Thus, discrete, very tight, focal lesions were selected, and small size burrs were used, taking into account the mismatch between the large burrs (>1.75 mm) and the guiding catheter. Ultimately, the availability of "giant" lumen catheters allowed the use of a large burr and the size of the drill was carefully matched to the diameter of the proximal normal segment of the vessel.

Statistics. All data are presented as mean values ±1 SD. Differences in vessel diameter were analyzed by paired t test. A difference of p < 0.05 was considered statistically significant.
12 patients
ROTATIONAL ANGIOPLASTY

SUCCESS       FAILURES

10 patients    2 patients

Residual stenosis

< 50 %        > 50 %

5 patients    5 patients

Balloon dilation

Resid. sten. < 50% : 5 patients

Figure 2. Immediate results of coronary rotational angioplasty in 12 patients. In the two failures, the stenosis was not crossed by the guide wire. Resid. sten. = residual stenosis.

Results

Immediate results (Fig. 2). In two patients, the steerable guide wire was unable to pass through the narrowed vessel, and therefore, the device could not be inserted. In five patients, we used a small abrasive tip (<1.50 mm). Although marked enlargement of the narrowed channel was obtained (from 0.43 ± 0.38 mm to 1.17 ± 0.20 mm), the degree of residual stenosis (60 ± 13%) required us to complete the procedure with balloon dilation, after which the residual stenosis was nonsignificant. In five patients, rotational angioplasty alone yielded an excellent result with a nonsignificant (<50%) residual narrowing. In this group, the average absolute diameter of the stenosis increased from 0.72 ± 0.05 mm to 1.4 ± 0.3 mm (p < 0.01). The percent of luminal narrowing significantly decreased from 73% to 46% (p < 0.01). A typical example is shown in Figure 3.

Complications. There were no untoward incidents or major complications during the procedure. No patient experienced chest pain or ST segment changes during rotational angioplasty. In three patients with a dominant right coronary artery, transient (few seconds) atrioventricular block occurred. During hospitalization, no patient developed chest pain, ECG changes or serum enzyme rise (mean creatine kinase = 28 ± 14 international units). Nine of the 10 patients were discharged 2 or 3 days later. All nine, especially those with unstable angina, were in markedly improved condition and were free of symptoms at discharge.

Four days after a successful rotational angioplasty of the left anterior descending coronary artery, one patient (a 69 year old woman) developed an acute painful abdominal pain syndrome. She died 1 day later (5 days after the procedure). Autopsy revealed extensive mesenteric infarction without embolization. Careful study of the heart and left anterior descending coronary artery revealed no myocardial damage, a patent vessel and a smooth treated segment; again, there was no distal embolization. On scanning electron microscopy the vessel surface was smooth, with thin furrows related to the drilling, and free of platelet deposition.

Discussion

New devices to remove atherosclerotic plaque. The main goal of the different techniques of myocardial revascularization is to restore adequate coronary flow by enlarging the atherosclerotic arterial lumen. This can be achieved by percutaneous balloon angioplasty, which increases the diameter of the vessel by several mechanisms including compression, redistribution, disruption of the plaque and inelastic
stretching of the arterial wall. New methods that attempt to produce recanalization by removing atherosclerotic material are currently under investigation. These methods include vaporization of the plaque by laser energy; however, perforation and thrombotic vessel occlusion are frequently observed with laser angioplasty. More interesting are atherectomy devices that remove the excised part of the atheroma. The initial results obtained by Simpson et al. (4) with a small and flexible coronary atherectomy catheter are already very promising, although the procedure is somewhat time consuming. Another approach uses vascular drills, and several prototypes of these are being investigated.

These new devices raise a question of semantics: is it right to call these techniques atherectomy? Usually the suffix "ectomy" means removal. The excisional method of Simpson et al. (4) removes the atherosclerotic material from the coronary vessel and deserves the name of atherectomy. Rotational methods remove the plaque that is ground up by the abrasive head of the device. Should we call this method rotational athero-abrassion? In any case, the main purpose is to remove atherosclerotic material that is pulverized in small particles and therefore the word atherectomy rather than angioplasty could be applied.

Previous studies with rotational angioplasty. Several experimental studies, in vitro and in animals, were performed within the last 3 years. In 13 atherosclerotic rabbit iliac arteries, Hansen et al. (5) achieved a significant reduction of stenosis with rotary atherectomy. Only two complications occurred: one perforation related to the guide wire and an acute occlusion due to an oversized olive burr. Ahn et al. (6) demonstrated in human cadavers the capability of the device to transform calcified or fibrous plaques into a colloidal suspension composed of microparticles, generally smaller than 5 μm. They did not find embolic or necrotic sequelae after peripheral injection of ablation particle fragments into dogs. We recently reported (8) the histopathologic analysis of human peripheral arterial segments resected after rotational angioplasty. Scanning electron microscopy showed that the treated surface was smooth and polished with minimal thrombogenicity. In vivo, the first human rotational angioplasty was performed by Zacca et al. (9) in six patients with femoropopliteal stenosis. All the stenotic segments were crossed and treated successfully without complications. In coronary arteries, Hansen et al. (7) showed in 11 normal canine coronary arteries that this high speed rotating abrasive technique could be safely applied and resulted in minimal vessel damage. Finally, our study reports the first preliminary experience in coronary arteries of humans (10).

Problems related to the pulverization of the plaque. The system is designed to remove atherosclerotic stenosis by creating small particles. All the previous studies show that high speed rotation produces small particles. Analysis of particles produced by the abrasive tip in atherosclerotic aortas indicated that 98% of the particles produced were <10 μm diameter (6). In our study (8) performed in peripheral arteries, 75% of particles were <10 μm in diameter. Thus, the debris particles are too small to clog capillaries. In the present study, there was no clinical or angiographic evidence of distal coronary embolization because the patient did not develop ST segment changes or serum enzyme release.

One limitation of this device could be the size of the abrasive tip. Obviously, the device should be introduced through a guiding catheter. Even in a 9F catheter, the inner diameter is only 2 mm and most often is 1.9 mm at the site of the connector. Therefore, the diameter of the new channel is most often limited to 1.75 mm. For a vessel with a diameter of 3 to 3.2 mm, the residual stenosis could be 45% to 50%. This limitation explains why in five cases the procedure was completed by balloon dilation. In the future, a guiding catheter with a larger diameter should allow the introduction of larger burrs able to open the narrowing up to a diameter of 3 mm.

Clinical implications. This preliminary study demonstrates that percutaneous coronary rotational angioplasty with a high speed rotational device is a safe procedure allowing successful angiographic and clinical results. However, some technical improvements (flexibility of the central guide wire, guiding catheters with a larger inner lumen) should provide the interventional cardiologist a very useful
and rapid method for safe removal of atherosclerotic material. However, these encouraging results require further studies especially with regard to long-term follow-up results.

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References


