Early experience with low speed rotational angioplasty

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Abstract

Objective—Preliminary assessment of the efficacy and safety of the low speed rotational angioplasty catheter system (ROTACS).

Design—Open prospective trial.

Setting—Department of cardiology in a teaching hospital.

Patients—Eleven patients (10 with chronic stable angina and one with acute coronary occlusion after conventional angioplasty) in whom a coronary angiogram showed occlusion or critical stenosis of the coronary artery (right in seven patients, circumflex in two, and left anterior descending in two). The nature or severity of the lesion ruled out conventional coronary angioplasty.

Interventions—An attempt was made to cross the lesion with a rotating guide wire with a blunt swelling at its tip. Where necessary progress was assessed by simultaneous injection of contrast into both main coronary arteries.

Main outcome measures—Progress of the ROTACS through the lesion that allowed a guide wire to pass into the distal vessel was regarded as a device specific success. When a guide wire crossed the lesion aided only by the support of the ROTACS without the use of rotation this was counted as a success that was not device specific. Failure to cross the lesion and any associated complications were noted.

Results—The ROTACS crossed only two of the 10 chronic lesions (20% device specific success rate); however, the support it provided enabled a guide wire to cross a further two lesions and allowed subsequent successful angioplasty in four of the 10 patients. One of these four patients presented after five months with recurrent angina requiring bypass grafting. The other three were symptom free at follow up seven months after the procedure. In the one patient with acute coronary occlusion the ROTACS was advanced over the guide wire to allow passage of an angioplasty balloon where this had previously proved impossible. An excellent final result was obtained and this patient remains symptom free. Three of the six patients in whom the ROTACS was unsuccessful had coronary artery dissection without sequelae.

Three patients required subsequent elective coronary bypass grafting for control of symptoms while the other three remain well on medical treatment.

Conclusions—The ROTACS may extend the range of patients with coronary artery occlusion or critical stenosis who can be treated non-surgically. The low device specific success rate (20%) achieved in this study indicates that it should be compared with other simpler mechanical devices that may be just as effective.

Coronary angioplasty has revolutionised the treatment of coronary artery stenoses but, because of its low success rate when used to attempt vessel recanalisation, it has had relatively little impact on the treatment of chronic coronary artery occlusion. Various devices have been developed in an effort to improve the results of transcoronary attempts at recanalisation. In this study we describe our initial experience with the low speed rotational angioplasty system (ROTACS).

Patients and methods

We studied 11 patients (one woman and 10 men, aged 49–72 (mean 57.4)). Ten had a history of chronic stable angina. These 10 patients were referred for coronary arteriography, which showed complete occlusion or a critical coronary stenosis of a single coronary artery with or without important disease in the other coronary arteries (table). The severity of the coronary lesion was such that we would not have attempted conventional angioplasty. All patients had exercise tests showing ischaemic changes (≥1.5 mm ST segment depression) in leads consistent with the site of critical stenosis or occlusion. The duration of occlusion or critical stenosis, estimated from sudden appearance of angina or occurrence of a myocardial infarction, ranged from four to 31 months (mean 13 months). Informed consent was obtained from all patients.

EQUIPMENT

The device evaluated in this study was the rotational transluminal angioplasty catheter system (ROTACS) manufactured by Dr Ing
Data on patients treated with the ROTACS

<table>
<thead>
<tr>
<th>No</th>
<th>Age</th>
<th>Vessel attempted</th>
<th>Age of lesion</th>
<th>Length of lesion (cm)</th>
<th>TIMI grade</th>
<th>1, 2, or 3 vessel disease</th>
<th>NYHA grade</th>
<th>anginal SOB</th>
<th>ROTACS size (mm)</th>
<th>Outcome</th>
<th>Complications</th>
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<tr>
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<td>3/1</td>
<td>1/2</td>
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<td>—</td>
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<td>3-8</td>
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<td>False lumen + limited</td>
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<td>—</td>
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<td>2/1</td>
<td>1/2</td>
<td>Failure</td>
<td>Extensive dissection</td>
<td>—</td>
<td>—</td>
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<tr>
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<td>54</td>
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<td>—</td>
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<td>2/1</td>
<td>1-4</td>
<td>Success</td>
<td>—</td>
<td>—</td>
<td>Symptom free</td>
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TIMI grading system: grade 0, no antegrade flow beyond point of occlusion; grade 1, contrast passes beyond obstruction but "hangs up" and falls to opacify the entire distal coronary bed; grade 2, contrast passes beyond obstruction opacifying the distal coronary bed and rate of entry or clearance of contrast is retarded; CABG, coronary artery bypass grafting; Ca, circumflex coronary artery; LAD, left anterior descending coronary artery; PTCA, percutaneous transluminal coronary angioplasty; RCA, right coronary artery; SOB, shortness of breath.

P Ospyka GmbH (distributed in the UK by S-PACE). It consists of a flexible drive shaft with an olive shaped swelling (1-2, 1-4, or 1-6 mm diameter) at its tip (fig 1). The drive shaft is hollow and can take an 0-014 inch guide wire. The drive shaft is contained in a flexible sheath which provides support. This whole assembly is inserted through an 8 or 9 French gauge angioplasty guiding system. The proximal end of the drive shaft exits though a haemostatic valve and connects to a sterilisable battery powered variable speed motor unit (fig 1) that can drive the shaft at up to 200 rpm under load conditions.

PROCEDURE

Patients underwent routine preparation for coronary angioplasty and surgical cover was available for all procedures. The first two procedures were performed via the brachial route but the production of a longer ROTACS catheter enabled subsequent procedures to be performed from the femoral artery. A check angiogram was performed to assess the length of the occlusion or stenosis. Where there was no antegrade filling of the distal segment the other main coronary artery was catheterised simultaneously from the left femoral artery. This enabled visualisation of both left and right coronary systems with the collateral supply opacifying the distal segment (fig 2). The table shows the TIMI perfusion score of the vessels attempted.

After 10 000 IU of heparin had been given the guiding system was introduced into the culprit vessel. We attempted to cross the occlusion/stenosis with a guide wire (0-014 inch high torque intermediate or standard) alone but this was invariably unsuccessful (cost considerations precluded the use of an angioplasty balloon to support the guide wire). The ROTACS was then passed via the guiding system into the coronary artery. The olive shaped head was rotated as it was moved slowly forward out of the supporting catheter and into the lesion (fig 3). Its progress was assessed periodically by contrast injection.

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Figure 1 The ROTACS (A). A battery powered motor drive unit drives a flexible stainless steel drive shaft that emerges from its supporting catheter to terminate in (B) an olive-shaped tip.

Figure 2 Angiogram of right coronary artery showing opacification of occluded distal segment by collateral flow from a second catheter in the left coronary artery.
through the guiding system and, if necessary, retrograde opacification from the other coronary artery. When successful an 0.014 inch high torque floppy exchange wire was advanced out of the central lumen of the drive shaft and left in position across the lesion while the ROTACS was exchanged for a conventional balloon angioplasty catheter. The small size of the lumen created by the device meant that further angioplasty was invariably required. After angioplasty all patients were routinely treated with a calcium antagonist and aspirin.

Results
The table summarises the individual results. On only two occasions did the ROTACS drill successfully through a chronic coronary lesion (fig 4). On two other occasions it provided additional support for the guide wire and enabled it to cross the lesion; however, it is possible that these lesions could have been crossed by a conventional guide wire supported by an angioplasty balloon. In one patient who had had acute coronary occlusion during angioplasty the device was successfully used over a guide wire to create a passage for an angioplasty balloon. Previous attempts to pass an angioplasty balloon over the wire and through the occlusion had failed.

In the remaining six patients we were not able to cross the lesion with the ROTACS. In three of these patients the drill seemed to make good progress through the lesion but subsequent contrast injection showed that the device had failed to enter the distal lumen and dissection proximal and distal to the lesion (fig 5). No sequelae followed these dissections which all occurred in the right coronary artery and in lesions on a curve. In two other patients instability of the guiding system prevented any progress being made with the ROTACS, and in the final patient, who had a lesion in a tortuous circumflex vessel, no progress was made. Thus in only 20% of the patients with chronic coronary lesions was the rotary action of the ROTACS device of importance in crossing the lesion.

Follow up
The patients in whom the procedure was successful have now been followed for seven months. Four (80%) remain symptom free and two returned to work within two weeks of the
rotational angioplasty. The fifth patient was symptom free for five months and then presented with unstable angina caused by restenosis at the site of the original dilatation. She is now well after single vessel coronary artery bypass grafting.

Three (30%) of the patients in whom the procedure failed required non-emergency coronary artery bypass grafting for persistent symptoms. The other three remain well controlled on medical treatment alone.

**Discussion**

Conventional balloon angioplasty is an effective treatment for non-occlusive coronary disease and for acute coronary occlusions. The efficacy of angioplasty falls steadily as the age of occlusion increases. Many other non-surgical approaches to reopening coronary occlusions are being assessed including the use of hollow guide wires, the Magewire (a 0.021 inch wire with an olive shaped swelling on its tip), ultrasound, and laser and thermal energy. Varying success rates have been reported for these treatments, though no formal comparison has been made of their relative efficacy. The ROTACS represents a development of the simple mechanical approach offered by the stiff guide wire but without the technical complexity and costs associated with laser and ultrasound. It uses a smooth, olive shaped swelling at the tip of a flexible drive shaft to displace the substance of the atheromatous plaque and enables passage of a guide wire and subsequent conventional angioplasty.

Kaltenbach and Vallbracht at the University of Frankfurt have the biggest current series of patients treated with the device. So far they have reported the use of the device in 60 patients selected because their coronary lesion could not be crossed by a guide wire. Of these, 46 had right coronary artery occlusions, eight left anterior coronary artery occlusions, four circumflex artery occlusions, and two aorto-coronary bypass grafts with a mean duration of occlusion of 8.2 months. The success rate in the first 10 patients was 30% and this improved to 60% in the second 10 and subsequently remained at this level. They reported coronary artery dissection in three of their first 20 patients and in one subsequent patient who required emergency coronary artery bypass grafting. They did not report any patients in whom a guide wire was able to cross the coronary lesion without the aid of the support provided by the ROTACS catheter. We report a lower device specific success rate (20%) and a higher incidence of complications, though fortunately none was serious. We also had problems with binding of the drive shaft on the internal guide wire, though this can be avoided by complete removal of the guide wire before rotation of the device.

The high incidence of arterial dissection noted in our patients is worrying. We found that in some patients the ROTACS successfully crossed an occlusion but then caused a dissection instead of entering the distal lumen. This was presumably because the ROTACS passed behind the intima and stripped it from the media. Once this occurs the device can travel in this plane of low resistance without re-entering the vessel lumen. In all our patients the lesion was probed with a guide wire before the ROTACS was used. Recently the manufacturer has advised against performing rotational angioplasty within one month of probing the lesion with a guide wire. This suggests that such probing may be a potential cause for the dissections noted.

Kaltenbach and Vallbracht reported follow up angiograms four months after angioplasty with a ROTACS in 17 patients. Three (18%) showed a good result, eight (47%) had significant restenosis and had a successful repeat angioplasty, and six (35%) had re-occluded. We have not formally assessed restenosis with angiography but three of four patients remain symptom free while one required coronary artery bypass grafting for restenosis at the site of the device.

From our small series of patients it is hard to draw conclusions about which features of the lesion can affect the success rate and incidence of subsequent restenosis. The effect of patient age, sex, duration of the occlusion, and the appearance of the occlusion and its position within the coronary tree remain unknown. From our experience the stiffness of the device and the need for torque transmission preclude its use in tortuous vessels. The use of the ROTACS for lesions on a curve may increase the incidence of vessel dissection.

We assessed the use of the ROTACS in patients with critical coronary stenoses and complete occlusions. The primary success rate was low and use of the device was associated with frequent vessel dissection. There was a high incidence of restenosis and re-occlusion. The efficacy and cost effectiveness of this device need to be compared with simpler mechanical devices such as the Magnum wire before its widespread use can be recommended.
