

Rotational atherectomy for the treatment of in-stent restenosis.

Radke PW, Blindt R, Haager PK, Vom Dahl J.

Restenosis after coronary stent implantation remains the major limitation of this treatment modality. At present, re-dilatation is considered the therapeutic option of choice for focal lesions, however, long restenotic lesions (>10 mm) do not respond favourably. Despite the emerging concept of intracoronary radiation, encouraging acute procedural results are also reported for different debulking techniques (Excimer laser angioplasty, directional coronary atherectomy, and rotational atherectomy, or rotablation). Rotablation has been studied most extensively with acute and long-term results published in a total of more than 850 patients. Experimental and first clinical data indicate favourable results for the rotablator as compared to balloon angioplasty alone for the treatment of in-stent restenosis. Data from the first 2 randomized clinical trials (ROSTER-, and ARTIST-trial) have now been published with conflicting results: The european multicenter ARTIST-trial including 300 patients could not prove a benefit for the rotablator as compared to re-dilatation in patients with diffuse stent restenosis. On the contrary, the monocenter ROSTER-trial, which has been presented as an abstract until today, suggests a clinical benefit of patients treated by the rotablator if they were studied with intracoronary ultrasound prior to randomization. Currently, rotablation for the treatment of restenosis cannot be considered as the first line treatment modality in patients with in-stent restenosis. As a result of unsatisfying angiographic and clinical long-term results by the use of a variety of treatment modalities in diffuse stent restenosis, prevention of this iatrogenic entity has become mandatory.

Mechanisms of myocardial hypoperfusion during rotational atherectomy of de novo coronary artery lesions and stenosed coronary stents: insights from serial myocardial scintigraphy.

Koch KC, Radke PW, Kleinhans E, Ninnemann S, Janssens U, Klues HG, Buell U, Hanrath P, vom Dahl J.

BACKGROUND: Rotational atherectomy (rotablation) frequently results in transient myocardial hypoperfusion due to peripheral vessel obstruction. This study compares the incidence, extent, and severity of perfusion defects induced by rotablation of de novo coronary lesions with rotablation of in-stent restenosis. **METHODS AND RESULTS:** Twenty-five patients undergoing rotablation for restenosed stents (group A) were studied by technetium 99m sestamibi single photon emission computed scintigraphy at rest before rotablation, during rotablation, and 2 days after the procedure. For semiquantitative analysis, perfusion in 24 left ventricular regions was expressed as percentage of maximal sestamibi uptake. The results were compared with those of 25 patients treated for de novo coronary lesions (group B). Transient perfusion defects were observed in 22 (88%) of 25 patients in group A and, similarly, in 23 (92%) of 25 in group B. Perfusion was significantly reduced during rotablation in 3.1 ± 2.6 (mean ± SD) regions in group A and in 3.3 ± 2.5 regions in group B. Perfusion in the region with maximal reduction during rotablation in groups A and B was 77% ± 13% and 76% ± 15% at baseline. Technetium uptake decreased to 59% ± 19% and 54% ± 14% during rotablation ($P < .001$ vs baseline, $P =$ not significant for A vs B) and returned to 76% ± 16% and 76% ± 15% after rotablation. Intravascular ultrasonography indicated no correlation between the volume of ablated plaque and the extent and severity of perfusion defects in in-stent restenosis. **CONCLUSIONS:** Incidence, extent, and severity of rotablation-related transient hypoperfusion are influenced by neither the type nor the quantity of ablated plaque material. Thus embolization of ablated plaque may be less important compared with other factors such as microcavitation or platelet aggregation.

Rotational atherectomy does not reduce recurrent in-stent restenosis: results of the angioplasty versus rotational atherectomy for treatment of diffuse in-stent restenosis trial (ARTIST).

vom Dahl J, Dietz U, Haager PK, Silber S, Niccoli L, Buettner HJ, Schiele F, Thomas M, Commeau P, Ramsdale DR, Garcia E, Hamm CW, Hoffmann R, Reineke T, Klues HG.

BACKGROUND: Aim of this trial was to compare rotational atherectomy followed by balloon angioplasty (rotablation [ROTA] group) with balloon angioplasty (percutaneous transluminal coronary angioplasty [PTCA] group) alone in patients with diffuse in-stent restenosis. METHODS AND RESULTS: The ARTIST study is a multicenter, randomized, prospective European trial with 298 patients with in-stent restenosis >70% (mean lesion length, 14 ± 8 mm) in stents, implanted in coronary arteries for ≥ 3 months. In the PTCA group, angioplasty was performed at the discretion of the local investigator, and rotablation was performed by using a stepped-burr approach followed by adjunctive PTCA with low (<= 6 atm) inflation pressure. Intravascular ultrasound during the intervention and at follow-up was used in a substudy in 86 patients (45 PTCA, 41 ROTA). Angiography demonstrated no difference regarding the short-term outcome, with equivalent procedural success rates defined as remaining stenosis <30% (89% PTCA, 88% ROTA). However, the results showed that, in the long term, PTCA was a significantly better strategy than ROTA. Mean net gain in minimal lumen diameter was 0.67 mm and 0.45 mm for PTCA and ROTA, respectively (P=0.0019). Mean gain in diameter stenosis was 25% and 17% (P=0.002), resulting in restenosis (≥ 50%) rates of 51% (PTCA) and 65% (ROTA) (P=0.039). By intravascular ultrasound, the major difference was the missing stent over-expansion during PTCA after ROTA. Six-month event-free survival was significantly higher after PTCA (91.3%) compared with ROTA (79.6%, P=0.0052). CONCLUSIONS: In terms of the primary objective of the study, PTCA produced a significantly better long-term outcome than ROTA followed by adjunctive low-pressure PTCA.

Effect of intracoronary nicorandil administration on preventing no-reflow/slow flow phenomenon during rotational atherectomy.

Tsubokawa A, Ueda K, Sakamoto H, Iwase T, Tamaki S.

A major limitation of the rotational atherectomy (RA) procedure is the occurrence of the no-reflow/slow flow phenomenon and the optimal strategy is still evolving. Recent clinical studies have demonstrated the beneficial effects of nicorandil, an adenosine triphosphate (ATP)-sensitive potassium channel opener, on no-reflow in patients with acute myocardial infarction. The purpose of this study was to evaluate the effect of nicorandil on no-reflow/slow flow phenomenon during RA procedures. Sixty-one patients who underwent RA of complex coronary lesions were randomly divided into 2 groups: (i) nicorandil cocktail (n=24 patients, 37 lesions) and (ii) verapamil cocktail (n=37 patients, 63 lesions). In each group, the drug cocktail mixed with pressurized saline was infused through the 4Fr Teflon sheath of the rotablator system during the RA procedure. In the nicorandil group, the drug cocktail consisted of 24 mg of nicorandil, 5 mg of nitroglycerin, and 10,000 U of heparin. In the verapamil group, the drug cocktail consisted of 10 mg of verapamil, 5 mg of nitroglycerin, and 10,000 U of heparin. Baseline and procedure characteristics did not differ between the 2 groups. RA was performed successfully, and death, Q-wave myocardial infarction, or emergency coronary artery bypass surgery did not occur in any patients. The no-reflow/slow flow phenomenon was observed in 11/63 (17.4%) lesions of the verapamil group, but in only 1/37 (2.7%) lesions of the nicorandil group ($p=0.03$). No untoward complications were observed during nicorandil infusion. These data indicate that the intracoronary continuous infusion of nicorandil during RA procedures is easy and safe, and prevents no-reflow/slow flow phenomenon more effectively than infusion of verapamil.

Rotablator versus cutting balloon for the treatment of long in-stent restenoses.

Braun P, Stroh E, Heinrich KW.

Conventional balloon angioplasty of in-stent-restenoses (ISR) will result in 50-70% re-restenoses. In addition to intracoronary brachytherapy, several ablative and non-ablative interventional technologies have been proposed to manage diffuse ISR. This study was designed to retrospectively assess rotational coronary atherectomy (Rotablator, or RA) and the Cutting Balloon (CB) with respect to the rate of restenoses after 6 months, the need for any additional revascularization at the target lesion (TLR), and the frequency of major cardiac events. **METHODS:** To compare both techniques, we used the RA to treat 51 consecutive patients with long (> 10 mm) ISR. Subsequently, 76 patients with identical indications were treated with the CB. Both groups were comparable with respect to their coronary morphologies, demographic and clinical data. **RESULTS:** Re-angiography was performed in 86% of patients in the RA group and in 72% of patients in the CB group. On quantitative coronary angiography (QCA), the rate of restenoses was 63.9% in the RA and 27.3% in the CB group; the difference was statistically significant ($p < 0.01$). The rate of re-TLR was also significantly lower (18.7%) in the CB than in the RA group (43.2%). The rate of major cardiac events (not requiring TLR) was not different between both groups (CD = 7.3%; RA = 9.1%). **CONCLUSION:** Even when the methodological constraints of retrospective studies are taken into account, the study data indicate that treating diffuse ISR with the CB results in an acceptable long-term outcome and a low complication rate, results which make this method appear superior to RA.

Directional coronary atherectomy vs. rotational atherectomy for the treatment of in-stent restenosis of native coronary arteries.

Sanchez PL, Rodriguez-Alemparte M, Colon-Hernandez PJ, Pomerantsev E, Inglessis I, Mahdi NA, Leinbach RC, Palacios IF.

Management of in-stent restenosis has become a significant challenge in interventional cardiology. Since the mechanism of in-stent restenosis is predominantly intimal hyperplasia, debulking techniques have been used to treat this condition. This study is a nonrandomized comparison of the immediate and long-term results of directional coronary atherectomy (DCA; n = 58) vs. high-speed rotational atherectomy (ROTA; n = 61) for the treatment of in-stent restenosis of native coronary arteries. There were no in-hospital deaths, Q-wave myocardial infarctions, or emergency coronary artery bypass surgery in either group. DCA resulted in a larger postprocedural minimal luminal diameter of (2.57 ± 0.51 vs. 2.14 ± 0.37 mm; P < 0.0001) and a larger acute gain (1.83 ± 0.52 vs. 1.42 ± 0.48 mm; P < 0.0001). Furthermore, 12-month clinically indicated target lesion revascularization (39% vs. 21%; P = 0.02) and long-term follow-up MACE (44% vs. 28%; P = 0.03) was greater in the ROTA group. The present study suggests that DCA appears to be superior to ROTA for the treatment of in-stent restenosis of native coronary arteries. Compared to ROTA, the debulking effect of DCA leads to a larger postprocedure minimal luminal diameter, and a lower incidence of subsequent target lesion revascularization and MACE.

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Successful rotational atherectomy and stenting in a situs inversus patient.

Kay J, Kwok OH, Chow WH.

We describe a case of successful high-speed rotational atherectomy and stenting of a long calcified lesion in a patient with dextrocardia and situs inversus.

Angiographic analysis of the angioplasty versus rotational atherectomy for the treatment of diffuse in-stent restenosis trial (ARTIST).

Dietz U, Rupprecht HJ, de Belder MA, Wijns W, Quarles van Ufford MA, Klues HG, vom Dahl J.

Patients with diffuse in-stent restenoses (ISRs) are at high risk for recurrent restenosis after percutaneous transluminal balloon angioplasty (PTCA). Percutaneous transluminal rotational ablation (PTR) has proved effective in removing neointimal burden in ISRs. This study compares the acute and long-term results of PTCA and PTR for the treatment of diffuse ISR in a randomized, multicenter investigation. The primary end point was the comparison of the minimum luminal diameter (MLD) between both groups at 6-month follow-up. Patients with symptomatic, diffuse, or high-grade ISRs were included; 146 patients were randomized to PTCA and 152 patients to PTR. Diameter stenosis was reduced from 80 ± 12% to 29 ± 10% and from 80 ± 11% to 28 ± 12%, respectively, and MLD increased from 0.55 ± 0.3 to 1.9 ± 0.3 mm in the PTCA group and from 0.54 ± 0.3 mm to 1.9 ± 0.4 mm in the PTR group. Spasm in the treated vessel and an intermittent slow flow phenomenon occurred more often after rotational ablation (17.7% vs 8.6%, $p = 0.001$; 5.3% vs 0%, $p = 0.007$). Minimum stenosis diameter at 6-month follow-up was smaller in the PTR group than in the PTCA group (1.0 ± 0.6 vs 1.2 ± 0.6 mm, $p = 0.008$) and the restenosis rate was higher (64.9% vs 51.2%, $p = 0.027$). Procedural factors did not influence long-term outcome. In the PTR group, the restenosis rate increased with decreasing vessel size, whereas this was not seen in the PTCA group. The lesion length and the baseline diameter stenosis were found to be predictive of restenosis with both treatment strategies; however, a residual diameter stenosis of <30% predicted absence of a restenosis only in the PTR group. Thus, PTCA and PTR of diffuse ISRs yield comparable acute angiographic results. The recurrence of a restenosis is higher after PTR than after PTCA.

Coronary in-stent restenosis: current status and future strategies.

Lowe HC, Oesterle SN, Khachigian LM.

In-stent restenosis (ISR) is a novel pathobiologic process, histologically distinct from restenosis after balloon angioplasty and comprised largely of neointima formation. As percutaneous coronary intervention increasingly involves the use of stents, ISR is also becoming correspondingly more frequent. In this review, we examine the available studies of the histology and pathogenesis of ISR, with particular reference to porcine and other animal models. An overview of mechanical treatments is then provided, which includes PTCA, directional coronary atherectomy and high speed rotational atherectomy. Radiation-based therapies are discussed, including a summary of current problems associated with this modality of treatment. Finally, novel strategies for the prevention of ISR are addressed, including novel developments in stents and stent coatings, conventional drugs, nucleic acid-based drugs and gene transfer. Until recently, limited pharmacologic and mechanical treatment options have been available for both treatment and prevention of ISR. However, recent advances in gene modification and gene transfer therapies and, more particularly, in local stent-based drug delivery systems make it conceivable that the incidence of ISR will now be seriously challenged.

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Dietz U, Rupprecht HJ, de Belder MA, Wijns W, Quarles van Ufford MA, Klues HG, vom Dahl J.

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ROTABLATION

1. Rotational atherectomy for the treatment of in-stent restenosis.

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Minerva Cardioangiol 2002 Oct;50(5):555-63

2. Mechanisms of myocardial hypoperfusion during rotational atherectomy of de novo coronary artery lesions and stenosed coronary stents: insights from serial myocardial scintigraphy.

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J Nucl Cardiol 2002 May-Jun;9(3):304-11

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Circulation 2002 Feb 5;105(5):583-8

4. Effect of intracoronary nicorandil administration on preventing no-reflow/slow flow phenomenon during rotational atherectomy.

Tsubokawa A, Ueda K, Sakamoto H, Iwase T, Tamaki S.

Circ J 2002 Dec;66(12):1119-23

5. Rotablator versus cutting balloon for the treatment of long in-stent restenoses.

Braun P, Stroh E, Heinrich KW.

J Invasive Cardiol 2002 Jun;14(6):291-6

6. Directional coronary atherectomy vs. rotational atherectomy for the treatment of in-stent restenosis of native coronary arteries.

Sanchez PL, Rodriguez-Alemparte M, Colon-Hernandez PJ, Pomerantsev E, Inglessis I, Mahdi NA, Leinbach RC, Palacios IF.

Catheter Cardiovasc Interv 2003 Feb;58(2):155-61

7. Successful rotational atherectomy and stenting in a situs inversus patient.

Kay J, Kwok OH, Chow WH.

J Invasive Cardiol 2002 Nov;14(11):682-5

8. Angiographic analysis of the angioplasty versus rotational atherectomy for the treatment of diffuse in-stent restenosis trial (ARTIST).

Dietz U, Rupprecht HJ, de Belder MA, Wijns W, Quarles van Ufford MA, Klues HG, vom Dahl J.

Am J Cardiol 2002 Oct 15;90(8):843-7

9. Coronary in-stent restenosis: current status and future strategies.

Lowe HC, Oesterle SN, Khachigian LM.

J Am Coll Cardiol 2002 Jan 16;39(2):183-93

10. Angiographic analysis of the angioplasty versus rotational atherectomy for the treatment of diffuse in-stent restenosis trial (ARTIST).

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Am J Cardiol 2002 Oct 15;90(8):843-7

Catheter Cardiovasc Interv 2001;52:435-42

Long-term outcome of patients with proximal left anterior descending coronary artery in-stent restenosis treated with rotational atherectomy.

Moreno R, Garcia E, Soriano J, Acosta J, Abeytua M.

Once a first interventional procedure has failed, patients with proximal left anterior descending in-stent restenosis are frequently sent for surgical revascularization. Data on long-term outcome in selected patients with proximal left anterior descending in-stent restenosis treated with RA are lacking. The study's objective was to evaluate the long-term outcome of patients with proximal left anterior descending artery in-stent restenosis treated with rotational atherectomy. The study population is constituted by 42 patients with proximal left anterior descending in-stent restenosis treated with rotational atherectomy. Patients were followed up for 2.1 +/- 0.9 years (range, 6?4). Restenosis length was 16.5 +/- 9.2 mm, and restenosis was diffuse (> 10 mm in length) in 30 (71.4%). The rotational atherectomy procedure was guided by intravascular ultrasound in 18 patients (42.9%). Maximum burr/artery ratio was > 0.7 in 24 (57.1%) patients. One patient suffered a periprocedural non-Q-wave infarction, but no deaths, Q-wave infarction, or new target vessel revascularization occurred during hospitalization. There were no deaths or myocardial infarctions after discharge. Sixteen patients (38.1%) needed a new revascularization, but only five (11.9%) underwent coronary bypass grafting at the end of the follow-up (2.1 +/- 0.9 years). The rate of surgical revascularization at 6 months, 1 year, and 3 years was 4.8%, 7.4%, and 18.4%, respectively. The rate of new target vessel revascularization at 6 months, 1 year, and 3 years was 16.7%, 36.5%, and 40.5%, respectively. Patients with < or = 5 months since stent implantation had a significantly higher rate of new target vessel revascularization. Patients with proximal left anterior descending in-stent restenosis may be safely treated with rotational atherectomy. This strategy is associated with a very good long-term outcome, with few patients undergoing surgical revascularization.

Catheter Cardiovasc Interv 2001 Jul;53(3):334-40

Three-year follow-up after rotational atherectomy for the treatment of diffuse in-stent restenosis: predictors of major adverse cardiac events.

Radke PW, vom Dahl J, Hoffmann R, Klues HG, Hosseini M, Janssens U, Hanrath P.

Restenosis remains the major limitation of coronary stent implantation, especially in diffuse forms of in-stent restenosis. In this study, rotablation (RA) with adjunct angioplasty of in-stent restenosis was performed in 84 patients. Clinical follow-up and control angiography were obtained 6-month postprocedure. The rate of recurrent restenosis after rotablation for in-stent restenosis at 6-month angiographic follow-up was 45%, resulting in a rate of major adverse cardiac events of 35%. At 3-year follow-up, the cumulative event-free survival rate was 57% for the entire population. The only predictor of MACE at 3-year clinical follow-up by multivariate logistic regression analysis was in-stent lesion length. RA for the treatment of diffuse in-stent restenosis is thereby characterized by high procedural success rates and recurrent angiographic restenosis in 45% of patients with diffuse lesions. Major adverse cardiac events occur most likely within the first 6 months postprocedure. Three years after rotablation of in-stent restenosis, 43% of patients had experienced at least one major adverse cardiac event. *Cathet Cardiovasc Intervent* 2001;53:334-340. Copyright 2001 Wiley-Liss, Inc.

Catheter Cardiovasc Interv 2001;53:213-20

Coronary angioplasty and Rotablator atherectomy trial (CARAT): immediate and late results of a prospective multicenter randomized trial.

Safian RD, Feldman T, Muller DW, Mason D, Schreiber T, Haik B, Mooney M, O'eill WW.

Division of Cardiology, William Beaumont Hospital, Royal Oak, Michigan, rsafian@beaumont.edu Mechanical rotational atherectomy with the Rotablator is widely used for percutaneous coronary revascularization, but the ideal debulking strategy remains unknown. The purpose of this study was to compare the immediate and late

results after Rotablator using two treatment strategies: Large burrs (burr/artery ratio of >0.7) to achieve maximal debulking (lesion debulking strategy) or small burrs (burr/artery ratio ≤ 0.7) to modify lesion compliance (lesion modification strategy). Two hundred twenty-two patients at six centers were prospectively enrolled in this study and randomly assigned to large ($n = 104$ patients with 118 lesions) or small ($n = 118$ patients with 136 lesions) burrs. The primary endpoint was final diameter stenosis at the end of the procedure, and secondary endpoints included inhospital angiographic and clinical complications, and target lesion revascularization at 6 months. Baseline demographic and angiographic characteristics were similar. There were no differences in procedural success, the extent of immediate lumen enlargement, inhospital ischemic complications, or late target vessel revascularization. However, compared with small burrs, patients randomized to large burrs were more likely to experience serious angiographic complications (5.1% vs. 12.7%, $P < 0.05$) immediately after atherectomy. This study suggests that a routine lesion modification strategy employing small burrs (burr/artery ratio ≤ 0.7) achieves similar immediate lumen enlargement and late target vessel revascularization compared with a more aggressive debulking strategy (burr/artery ratio >0.7), but with fewer angiographic complications.

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Rotational atherectomy does not reduce recurrent in-stent restenosis: results of the angioplasty versus rotational atherectomy for treatment of diffuse in-stent restenosis trial (ARTIST).

vom Dahl J, Dietz U, Haager PK, Silber S, Niccoli L, Buettner HJ, Schiele F, Thomas M, Commeau P, Ramsdale DR, Garcia E, Hamm CW, Hoffmann R, Reineke T, Klues HG.

BACKGROUND: Aim of this trial was to compare rotational atherectomy followed by balloon angioplasty (rotablation [ROTA] group) with balloon angioplasty (percutaneous transluminal coronary angioplasty [PTCA] group) alone in patients with diffuse in-stent restenosis. **METHODS AND RESULTS:** The ARTIST study is a multicenter, randomized, prospective European trial with 298 patients with in-stent restenosis $>70\%$ (mean lesion length, 14 ± 8 mm) in stents, implanted in coronary arteries for ≥ 3 months. In the PTCA group, angioplasty was performed at the discretion of the local investigator, and rotablation was performed by using a stepped-burr approach followed by adjunctive PTCA with low (≤ 6 atm) inflation pressure. Intravascular ultrasound during the intervention and at follow-up was used in a substudy in 86 patients (45 PTCA, 41 ROTA). Angiography demonstrated no difference regarding the short-term outcome, with equivalent procedural

success rates defined as remaining stenosis <30% (89% PTCA, 88% ROTA). However, the results showed that, in the long term, PTCA was a significantly better strategy than ROTA. Mean net gain in minimal lumen diameter was 0.67 mm and 0.45 mm for PTCA and ROTA, respectively (P=0.0019). Mean gain in diameter stenosis was 25% and 17% (P=0.002), resulting in restenosis ($\geq 50\%$) rates of 51% (PTCA) and 65% (ROTA) (P=0.039). By intravascular ultrasound, the major difference was the missing stent over-expansion during PTCA after ROTA. Six-month event-free survival was significantly higher after PTCA (91.3%) compared with ROTA (79.6%, P=0.0052). CONCLUSIONS: In terms of the primary objective of the study, PTCA produced a significantly better long-term outcome than ROTA followed by adjunctive low-pressure PTCA.



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Relation of clinical presentation, stenosis morphology, and operator technique to the procedural results of rotational atherectomy and rotational atherectomy-facilitated angioplasty

SG Ellis, JJ Popma, M Buchbinder, I Franco, MB Leon, KM Kent, AD Pichard, LF Satler, EJ Topol and PL Whitlow

BACKGROUND: Rotational atherectomy using the Rotablator has recently become available to treat coronary stenoses. This study was performed to determine the relation of patient characteristics, stenosis morphology, and operator technique to procedural outcome to gain insight into which patients might be best treated with this device. **METHODS AND RESULTS:** Four hundred stenoses from 316 patients randomly selected from the

initial Rotablator experience at three major referral institutions were analyzed. Angiographic data were assessed at a central angiographic laboratory using standardized morphological criteria and caliper measurement. Patients were somewhat more elderly than most percutaneous transluminal coronary angioplasty (PTCA)-treated groups (mean age, 64 +/- 11 years), 74% were men, and the lesions treated were often complex (modified American College of Cardiology/American Heart Association lesion type A, 24%; B1, 40%; B2, 30%; and C, 6%). Elective adjunctive PTCA was used for 82% of stenoses treated. Procedural success was achieved in 89.8% of stenoses (93.5% if results with creatine kinase two to three times normal are not counted as failures), and major ischemic complications (death, 0.3%; non-Q-wave myocardial infarction, 5.7%; Q-wave myocardial infarction, 2.2%; or emergency bypass surgery, 0.9%) occurred in 8.9% of patients. Complications were due to epicardial coronary obstruction in 3.8% of patients and to delayed coronary runoff ("slow reflow") in 5.1% of patients. Procedural failure was correlated independently with outflow obstruction (success rate, 64%; odds ratio for failure, 5.4; multivariate P = .002), lesion irregularity (76%; odds ratio, 3.3; P = .003), stenosis bend > or = 60 degrees (73%; odds ratio, 3.7; P = .03), and female sex (84%; odds ratio, 2.4; P = .03). Ischemic complications were correlated independently with lesion length (> or = 50% narrowing) > or = 4 mm (complication rate, 12%; odds ratio, 3.6; multivariate P = .005), right coronary artery stenosis (13%; odds ratio, 2.4; P = .02), stenosis bend > or = 60 degrees (27%; odds ratio, 6.1; P = .03), and female sex (13%; odds ratio, 3.0; P = .04). Slow reflow was correlated with total burring duration (odds ratio, 1.005/s; multivariate P = .001), right coronary artery stenosis (incidence, 17%; odds ratio, 4.5; P = .009), and to a lesser extent with recent myocardial infarction in the treated territory (44%; odds ratio, 4.3; P = .08). CONCLUSIONS: The procedural outcome of rotational atherectomy is highly correlated with stenosis morphology and location and sex of the patient. After stratification for these parameters, overall outcome with the Rotablator appears to be similar to that with balloon angioplasty and other competing techniques. Short-term outcome with specific subsets of patients may be superior with the Rotablator (calcified stenoses), but this technique might best be avoided in some patients (those with irregular or possibly thrombus-containing stenoses, highly angulated stenoses, and possible right coronary artery stenoses or those associated with impaired distal runoff caused by a recent myocardial infarction or manifest by a fixed thallium defect).

Summary

1. Procedural success: 89.8% of stenoses
2. Major ischemic complications: 8.9%(death, 0.3%; non-Q-wave myocardial infarction, 5.7%; Q-wave myocardial infarction, 2.2%; or emergency bypass surgery, 0.9%)
3. Predictors of procedural failure: outflow obstruction (success rate, 64%; odds ratio for failure, 5.4; multivariate P = .002), lesion irregularity (76%; odds ratio, 3.3; P = .003), stenosis bend > or = 60 degrees (73%; odds ratio, 3.7; P = .03), and female sex (84%; odds ratio, 2.4; P = .03).
4. Predictors of ischemic complications: lesion length (> or = 50% narrowing) > or = 4 mm (complication rate, 12%; odds ratio, 3.6; multivariate P = .005), right coronary artery stenosis (13%; odds ratio, 2.4; P = .02), stenosis

bend \geq 60 degrees (27%; odds ratio, 6.1; $P = .03$), and female sex (13%; odds ratio, 3.0; $P = .04$).

Circulation 1997;96: 128-136.

Coronary Stenting After Rotational Atherectomy in Calcified and Complex Lesions : Angiographic and Clinical Follow-Up Results

Issam Moussa, Carlo Di Mario, Jeffrey Moses, Bernhard Reimers, Lucia Di Francesco, Giovanni Martini, Jonathan Tobis, and Antonio Colombo

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.

Journal of the American College of Cardiology, 1997;30:4:888-893

Angioscopic Evaluation of Rotational Atherectomy Followed by Additional Balloon Angioplasty Versus Balloon Angioplasty Alone in Coronary Artery Disease: A Prospective, Randomized Study

Helene Eltchaninoff, MD, Alain Cribier, MD, FACC, Rene Koning, MD, Charles Chan, MD, Valerie Sicard, MD, Arthur Tan, MD, FACC, Brice Letac, MD, FACC

Objectives. This study sought to compare, by angioscopy, the morphologic changes induced by rotational atherectomy, followed by additional angioplasty, with those observed after balloon angioplasty alone.

Background. Rotational atherectomy and balloon angioplasty act by different mechanisms, which could explain the difference in morphologic changes induced by these two techniques.

Methods. The study group included 50 patients with 50 lesions who were randomly assigned to undergo rotational atherectomy (n = 24) or balloon angioplasty (n = 26). Rotational atherectomy with a single burr (70% of coronary diameter) was systematically followed by additional balloon angioplasty. Angioscopy was performed immediately after the procedure. Abnormal angioscopic findings were 1) flaps, graded from 1 to 3 (1 = intimal flap; 2 = flap protruding into <50% of the lumen; 3 = flap protruding into 50% of the lumen); 2) thrombi, graded from 1 to 3 (1 = flat deposits; 2 = protruding but nonocclusive thrombus; 3 = occlusive thrombus); 3) subintimal hemorrhage; 4) longitudinal dissection. The two groups were comparable for clinical and angiographic baseline data.

Results. On angioscopy, flaps were observed less frequently after rotational atherectomy followed by additional balloon angioplasty (8 [33%] of 24 lesions) than after balloon angioplasty alone (14 [54%] of 26 lesions, p = 0.08) and were also less severe (grade 1 in 6 lesions, grade 2 in 2 and grade 3 in none vs. grade 1 in 4 lesions, grade 2 in 5 and grade 3 in 5). Longitudinal dissections were also significantly less frequent: one versus six (p = 0.05). There was no difference in the incidence of angioscopic thrombi (p = 0.16) or subintimal hemorrhage (p = 0.15), but the power to detect a significant difference was low for these variables (37% and 26%, respectively).

Conclusions. Rotational atherectomy followed by additional balloon angioplasty leads to fewer angioscopic dissections and a trend toward fewer intimal flaps than balloon angioplasty alone. However, our angioscopic differences did not lead to an outcome difference between the two groups.

Circulation, 1998;98:742-748

Activation of Platelets in Platelet-Rich Plasma by Rotablation Is Speed-Dependent and Can Be Inhibited by Abciximab (c7E3 Fab; ReoPro)

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Sharma, MD; ; Jonathan D. Marmur, MD

Background

Rotational atherectomy with the Rotablator catheter has improved percutaneous treatment of certain coronary atherosclerotic lesions, but the “no-reflow” phenomenon remains a serious complication. Because platelet activation by rotablation may contribute to the no-reflow phenomenon, we developed an in vitro system to test the effect of rotablation on platelets in the absence or presence of platelet GP IIb/IIIa receptor blockade with abciximab.

Methods and Results

Platelet-rich plasma (PRP) was prepared from 28 healthy human volunteers. PRP was divided into 4 samples: (1) no treatment, (2) 6D1 (anti-GP Ib), (3) c7E3 Fab (anti-GP IIb/IIIa+ $\nu\beta$ 3), and (4) c7E3 Fab+6D1. Samples were pumped through a flow chamber containing a 2.5-mm burr rotating at various speeds and then placed in an aggregometer. PRP samples tested in the absence of antibody underwent more rapid and extensive aggregation when rotablated at 150 000 and 180 000 rpm compared with 0 rpm ($P<0.001$ at both speeds). Preincubation of platelets with c7E3 Fab decreased the slope of aggregation at each rotablation speed, with 98%, 79%, and 71% reductions at 70 000, 150 000, and 180 000 rpm, respectively ($P=0.09$ for 70 000 and $P<0.001$ for both 150 000 and 180 000 rpm). Preincubation of platelets with 6D1 did not decrease the slope of aggregation at any rotablation speed ($P>0.5$, $P=0.99$, and $P=0.091$ for 70 000, 150 000, and 180 000 rpm). Platelet ATP release, a marker of granule release and cell damage, was markedly increased at 180 000 rpm ($P=0.002$ compared with 0 rpm in the control group). Electron microscopy revealed extensive rotablation-induced platelet damage at 150 000 and 180 000 rpm, and leakage of LDH confirmed platelet lysis at these speeds ($P=0.002$ and $P<0.001$ compared with 0 rpm).

Conclusions

High-speed rotablation induces platelet activation of PRP, leading to aggregation; pretreating PRP with abciximab decreases the aggregation. These data suggest that pretreatment of patients with abciximab may decrease rotablation-induced platelet aggregation during rotational atherectomy.

Journal of the American College of Cardiology, 32:5:1358-1365

Rotational atherectomy for in-stent restenosis: acute and long-term results of the first 100 cases

Samin K. Sharma, Srinivas Duvvuri, George Dangas, Annapoorna Kini, Raghuraman Vidhun, Kakarala Venu,

John A. Ambrose, Jonathan D. Marmur

Objectives. This study evaluated the clinical safety and long-term results of rotational atherectomy (RA) followed by low-pressure balloon dilatation (percutaneous transluminal coronary angioplasty [PTCA]) for the treatment of in-stent restenosis (ISR).

Background. In-stent restenosis is associated with a high incidence of recurrence after interventional treatment. Because ISR is due to neointimal hyperplasia, rotational ablation may be a more effective treatment than PTCA.

Methods. Between November 1995 and November 1996, 100 consecutive patients with first-time ISR were treated by RA. Quantitative coronary angiography and intravascular ultrasound (IVUS) were used to analyze the acute procedural results. The incidence of repeat in-stent restenosis and target vessel revascularization (TVR) at follow-up was determined.

Results. Procedural success without any major in-hospital complications was achieved in 100% of cases. Slow flow was observed in 3% and creatine kinase-MB enzyme elevation $>3\times$ normal occurred in 2%. The mean burr-to-artery ratio was 0.68 ± 0.18 and adjunct balloon dilatation was performed at 4.2 ± 2.1 atm. Minimum luminal diameter increased from 0.86 ± 0.28 mm to 1.89 ± 0.21 mm after RA and to 2.56 ± 0.29 mm after adjunct PTCA. Quantitative IVUS analysis showed that 77% of the luminal gain occurred due to rotational ablation of the restenotic tissue and only 23% occurred after adjunct balloon dilation, and further stent expansion did not contribute to the luminal enlargement. At a mean follow-up of 13 ± 5 months, repeat in-stent restenosis occurred in 28% of patients with TVR of 26%. Univariate predictors of repeat restenosis were burr-to-artery ratio <0.6 , ISR in <90 days of stenting, ostial lesion, stent for a restenotic lesion and diffuse type ISR.

Conclusions. Rotational atherectomy is a safe and feasible technique for treatment of ISR and is associated with a relatively low recurrent restenosis in comparison to historical controls of balloon angioplasty.

Cathet. Cardiovasc. Diagn.44:77-82,1998

Treatment of In-Stent Restenosis With High Speed Rotational Atherectomy and IVUS Guidance in Small < 3.0 mm Vessels

Francois S, Nicolas M, Alain V, Sanjiv G, and Jean-Pierre B,

The management of in-stent restenosis remains a subject for debate because no one revascularization option is

considered the most appropriate. Since a high restenosis rate still occurs after repeat balloon angioplasty, new techniques are atherectomy (HSRA) and adjunctive balloon angioplasty is likely to achieve good results. In small (>3.0 mm diameter) vessels, the risk of interaction between the burr and the stent increases. We thus used intravascular ultrasound (IVUS) guidance in the treatment of in-stent restenosis with HSRA in small >3.0 mm small diameter vessels. Nine patients with in-stent restenosis in small vessels were referred for repeat angioplasty. Initial IVUS examination was used to assess the minimal stent struts diameter and to guide the burr size selection. A combination of HSRA and additional balloon angioplasty was performed under IVUS and angiographic guidance. Mean angiographic reference diameter was 2.25 ± 0.35 mm and mean stent struts diameter was 2.38 ± 0.20 mm. Burr size was selected ~ 0.5 mm smaller than stent struts diameter and ranged from 1.75 to 2.5 mm, with a 0.88 ± 0.12 mean burr/artery ratio (range 0.71, 1.08). In two patients, a second larger burr was used. In 4/9 patients, the burr size chosen under IVUS guidance was close to angiographic MLD at stent implantation and thus larger than what would be used without IVUS guidance. Additional balloon angioplasty was decided in all cases, using a 1.1 ± 0.15 balloon/artery ratio. No complication occurred. Mean relative gain in minimal lumen diameter (MLD) was $94 \pm 90\%$ after HSRA and $54 \pm 34\%$ after balloon angioplasty (total relative gain $180 \pm 100\%$). IVUS guidance allowed safe management of in-stent restenosis in small vessels using combination of HSRA and balloon angioplasty. Long-term follow-up and comparison with other techniques are necessary to assess whether this technique should be used routinely.

Summary

1. Procedural success: 100%, no complication
2. Mean relative gain in minimal lumen diameter (MLD) - $94 \pm 90\%$ after HSRA, $54 \pm 34\%$ after balloon angioplasty (total relative gain $180 \pm 100\%$).

Journal of the American College of Cardiology, 34:1:33-39

Mechanisms of acute lumen gain and recurrent restenosis after rotational atherectomy of diffuse in-stent restenosis : A quantitative angiographic and intravascular ultrasound study

Peter W. Radke, Heinrich G. Klues, Philipp K. Haager, Rainer Hoffmann, Frank Kastrau, Thorsten Reffelmann, Uwe Janssens, Juergen vom Dahl, Peter Hanrath

OBJECTIVES This quantitative angiographic and intravascular ultrasound study determined the mechanisms of acute lumen enlargement and recurrent restenosis after rotational atherectomy (RA) with adjunct percutaneous transluminal coronary angioplasty in the treatment of diffuse in-stent restenosis (ISR).

BACKGROUND In-stent restenosis remains a significant clinical problem for which optimal treatment is under debate. Rotational atherectomy has become an alternative therapeutic approach for the treatment of diffuse ISR based on the concept of "issue-debulking."**METHODS** Rotational atherectomy with adjunct angioplasty of ISR was used in 45 patients with diffuse lesions. Quantitative coronary angiographic (QCA) analysis and sequential intravascular ultrasound (IVUS) measurements were performed in all patients. Forty patients (89%) underwent angiographic six-month follow-up.

RESULTS Rotational atherectomy lead to a decrease in maximal area of stenosis from $80 \pm 32\%$ before intervention to $54 \pm 21\%$ after RA ($p < 0.0001$) as a result of a significant decrease in intimal hyperplasia cross-sectional area (CSA). The minimal lumen diameter after RA remained $15 \pm 4\%$ smaller than the burr diameter used, indicating acute neointimal recoil. Additional angioplasty led to a further decrease in area of stenosis to $38 \pm 12\%$ due to a significant increase in stent CSA. At six-month angiographic follow-up, recurrent restenosis rate was 45%. Lesion and stent length, preinterventional diameter stenosis and amount of acute neointimal recoil were associated with a higher rate of recurrent restenosis.

CONCLUSIONS Rotational atherectomy of ISR leads to acute lumen gain by effective plaque removal. Adjunct angioplasty results in additional lumen gain by further stent expansion and tissue extrusion. Stent and lesion length, severity of ISR and acute neointimal recoil are predictors of recurrent restenosis.

Cathet. Cardiovasc. Intervent. 48:48-53, 1999.

Novel approach to rotational atherectomy results in low restenosis rates in long, calcified lesions: Long-term results of the San Antonio rotablator study (SARS)

R. Stefan Kiesz, M. Marius Rozek, Douglas G. Ebersole, David M. Mego, Christine W. Chang, Robert L. Chilton

Ablation technique and adjunctive strategy may affect restenosis after rotational atherectomy. To minimize trauma to the vascular wall, we changed the technique of rotablation as follows: the RPM range was decreased to 140,000-160,000 RPM, the ablation was performed using a repetitive pecking motion, avoiding a decrease in the rotational speed of the burr greater than 3,000 RPM, long lesions were divided into segments and each segment was separately ablated, and the burr-to-artery ratio was intended to be approximately 0.75. To prevent

coronary spasm, before and after each pass, 100-200 g nitroglycerin and 100-200 g verapamil i.c. boluses were administered. Adjunctive PTCA was performed using a closely sized 1.1:1 balloon-to-artery ratio with a noncompliant balloon at low pressures for 120 sec. The study incorporated 111 patients with a combined total of 146 calcified lesions.

Results. A total of 31.5% of patients underwent a multivessel procedure. No deaths occurred. Q-wave MI and/or creatine kinase elevation greater than three times baseline levels occurred in 4.5% of patients. By quantitative coronary angiography (QCA), the reference vessel diameter was 3.13 ± 0.59 mm, mean lesion length was 33.41 ± 18.58 mm. Percent stenosis and mean luminal diameter were as follows: at baseline $75.7\% \pm 10.8\%$, or 0.76 ± 0.41 mm, Post-rotational atherectomy $41.5\% \pm 3.6\%$, or 1.83 ± 0.43 mm, Post-PTCA $18.2\% \pm 11.9\%$, or 2.56 ± 0.50 mm. Six-month angiographic follow-up was available in 64 (57.7%) pts. Net luminal gain was 1.15 ± 0.76 mm, with a late luminal loss of 0.65 ± 0.84 mm. The mean diameter stenosis at follow-up was $37.6\% \pm 28.5\%$, with MLD 1.91 ± 1.21 mm. The binary restenosis rate was 28.1%. Therefore, modification of rotational atherectomy technique with adjunctive PTCA resulted in a favorable restenosis rate in long, calcified lesions.

Am J Cardiol 1999 Mar 15;83(6):862-7

Clinical and angiographic predictors of recurrent restenosis after percutaneous transluminal rotational atherectomy for treatment of diffuse in-stent restenosis.

vom Dahl J, Radke PW, Haager PK, Koch KC, Kastrau F, Reffelmann T, Janssens U, Hanrath P, Klues HG

Due to the widespread use of stents in complex coronary lesions, stent restenosis represents an increasing problem, for which optimal treatment is under debate. "Debulking" of in-stent neointimal tissue using percutaneous transluminal rotational atherectomy (PTRA) offers an alternative approach to tissue compression and extrusion achieved by balloon angioplasty. One hundred patients (70 men, aged 58 ± 11 years) with a first in-stent restenosis underwent PTRA using an incremental burr size approach followed by adjunctive angioplasty. The average lesion length by quantitative angiography was 21 ± 8 mm (range 5 to 68) including 22 patients with a length ≥ 40 mm. Twenty-nine patients had complete stent occlusions with a lesion length of 44 ± 23 mm. Baseline diameter stenosis measured $78 \pm 17\%$, was reduced to $32 \pm 9\%$ after PTRA, and further reduced to $21 \pm 10\%$ after adjunctive angioplasty. Primary PTRA was successful in 97 of 100 patients. Clinical success was 97%, whereas 2 patients developed non-Q-wave infarctions without clinical sequelae. Clinical follow-up was available for all patients at 5 ± 4 months without any cardiac event. Angiography in 72

patients revealed restenosis in 49%, with necessary target lesion reintervention in 35%. The incidence of re-restenosis correlated with the length of the primarily stented segment and the length of a first in-stent restenosis. Thus, PTRA offers an alternative approach to treat diffuse in-stent restenosis. Neointimal debulking of stenosed stents can be achieved effectively and safely. PTRA resulted in an acceptable recurrent restenosis rate in short and modestly diffuse lesion, whereas the restenosis rate in very long lesions remains high despite debulking.

Summary

1. Clinical success rate: 97% (2 patients: non-Q MI)
2. No clinical event during follow-up
3. Restenosis rate: 49%, TLR: 35%
4. The incidence of re-restenosis correlated with the length of the primarily stented segment and the length of a first in-stent restenosis.

J Am Coll Cardiol 1999;33(4):998-1004

Influence of a platelet GPIIb/IIIa receptor antagonist on myocardial hypoperfusion during rotational atherectomy as assessed by myocardial Tc-99m sestamibi scintigraphy.

Koch KC, vom Dahl J, Kleinhans E, Klues HG, Radke PW, Ninnemann S, Schulz G, Buell U, Hanrath P

OBJECTIVES: This study evaluated the effect of the glycoprotein IIb/IIIa (GPIIb/IIIa) antagonist abciximab on myocardial hypoperfusion during percutaneous transluminal rotational atherectomy (PTRA). **BACKGROUND:** PTRA may cause transient ischemia and periprocedural myocardial injury. A platelet-dependent risk of non-Q-wave infarctions after directional atherectomy has been described. The role of platelets for the incidence and severity of myocardial hypoperfusion during PTRA is unknown. **METHODS:** Seventy-five consecutive patients with complex lesions were studied using resting Tc-99m sestamibi single-photon emission computed tomography prior to PTRA, during, and 2 days after the procedure. The last 30 patients received periprocedural abciximab (group A) and their results were compared to the remaining 45 patients (group B). For semiquantitative analysis, myocardial perfusion in 24 left ventricular regions was expressed as percentage of maximal sestamibi uptake. **RESULTS:** Baseline characteristics did not differ between the groups. Transient perfusion defects were observed in 39/45 (87%) patients of group B, but only in 10/30 (33%) patients of group A

($p < 0.001$). Perfusion was significantly reduced during PTRAs in 3.3 ± 2.5 regions in group B compared to 1.4 ± 2.5 regions in group A ($p < 0.01$). Perfusion in the region with maximal reduction during PTRAs in groups B and A was $76 \pm 15\%$ and $76 \pm 15\%$ at baseline, decreased to $56 \pm 16\%$ ($p < 0.001$) and $67 \pm 14\%$, respectively, during PTRAs ($p < 0.01$ A vs. B), and returned to $76 \pm 15\%$ and $80 \pm 13\%$, respectively, after PTRAs. Nine patients in group B (20%) and two patients in group A (7%) had mild creatine kinase and/or troponin T elevations ($p = 0.18$). Patients with elevated enzymes had larger perfusion defects than did patients without myocardial injury (4.2 ± 2.7 vs. 2.3 ± 2.5 regions, $p < 0.05$). CONCLUSIONS: These data indicate that GPIIb/IIIa blockade reduces incidence, extent and severity of transient hypoperfusion during PTRAs. Thus, platelet aggregation may play an important role for PTRAs-induced hypoperfusion.

Summary

Am Heart J 1999 ;137(1):93-9

Impact of target lesion calcification on coronary stent expansion after rotational atherectomy.

Henneke KH, Regar E, Konig A, Werner F, Klauss V, Metz J, Theisen K, Mudra H

BACKGROUND: Calcified lesions carry the risk of suboptimal stent expansion. The purpose of this study was to investigate the impact of target lesion calcification on intracoronary ultrasound (ICUS) guided stent expansion after rotational atherectomy. **METHODS:** Stent expansion was assessed by ICUS in 39 patients with the aid of the proximal stent/proximal reference lumen, the minimal stent/mean reference lumen, and the minimal stent/minor reference lumen ratios as well as the symmetry index. Thirty-nine stent implantations in uncalcified lesions served for comparison. **RESULTS:** Relative stent expansion ranged between $76.3\% \pm 6.7\%$ and $98.4\% \pm 16.4\%$. Categorization according to an ICUS-derived arc of superficial lesion calcium of <180 degrees (average 102 ± 74 degrees) or >180 degrees (average 248 ± 71 degrees) revealed decreased stent symmetry in calcified lesions >180 degrees compared with the control group ($P < .05$). Despite a trend toward less expansion with increasing calcium load, no significant differences of the lumen area ratios between the study groups was present. **CONCLUSION:** Rotational atherectomy before ICUS-guided stent implantation enables adequate stent expansion even in significant superficial target lesion calcification.

Summary

Figure. Comparison of relative stent expansion in rotastent group specified according to circumferential target lesion calcium of <180 degrees and >180 degrees with the control group (no target lesion calcium).

Circulation 2000 ;101: 2484-2489.

Treatment of In-Stent Restenosis With Excimer Laser Coronary Angioplasty Versus Rotational Atherectomy : Comparative Mechanisms and Results

Roxana Mehran, George Dangas, Gary S. Mintz, Ron Waksman, Alexandre Abizaid, Lowell F. Satler, Augusto D. Pichard, Kenneth M. Kent, Alexandra J. Lansky, Gregg W. Stone, and Martin B. Leon

Background-Atheroablation yields improved clinical results for balloon angioplasty (percutaneous transluminal coronary angioplasty, PTCA) in the treatment of diffuse in-stent restenosis (ISR).

Methods and Results-We compared the mechanisms and clinical results of excimer laser coronary angioplasty (ELCA) versus rotational atherectomy (RA), both followed by adjunct PTCA; 119 patients (158 ISR lesions) were treated with ELCA+PTCA and 130 patients (161 ISR lesions) were treated with RA+PTCA. Quantitative coronary angiographic and planar intravascular ultrasound (IVUS) measurements were performed routinely. In addition, volumetric IVUS analysis to compare the mechanisms of lumen enlargement was performed in 28 patients with 30 lesions (16 ELCA+PTCA, 14 RA+PTCA). There were no significant between-group differences in preintervention or final postintervention quantitative coronary angiographic or planar IVUS measurements of luminal dimensions. Angiographic success and major in-hospital complications with the 2 techniques were also similar. Volumetric IVUS analysis showed significantly greater reduction in intimal hyperplasia volume after RA than after ELCA (43 ± 14 versus 19 ± 10 mm³, $P < 0.001$) because of a significantly higher ablation efficiency ($90 \pm 10\%$ versus $76 \pm 12\%$, $P = 0.004$). However, both interventional strategies had similar long-term clinical outcome; 1-year target lesion revascularization rate was 26% with ELCA+PTCA versus 28% with RA+PTCA ($P = \text{NS}$).

Conclusions-Despite certain differences in the mechanisms of lumen enlargement, both ELCA+PTCA and RA+PTCA can be used to treat diffuse ISR with similar clinical results.

Eur Heart J. 2000 ;21(21):1759-66.

A randomized comparison of balloon angioplasty versus rotational atherectomy in complex coronary lesions (COBRA study)

Dill T.; Dietz U.; Hamm C.W.; Kuchler R.; Rupprecht H.-J.; Haude M.; Cyran J.; Ozbek C.; Kuck K.-H.; Berger J.; Erbel R.

Aims: Rotablation is a widely used technique for the treatment of complex coronary artery lesions but is so far only poorly supported by controlled studies. The Comparison of Balloon-Angioplasty versus Rotational Atherectomy study (COBRA) is a multicentre, prospective, randomized trial to compare short- and long-term effects of percutaneous transluminal coronary angioplasty (PTCA) and rotablation in patients with angiographically pre-defined complex coronary artery lesions. **Methods and Results:** At seven clinical sites 502 patients with pre-defined complex coronary artery lesions were assigned to either PTCA (n=250) or rotablation (n=252). Primary end-points were procedural success, 6-month restenosis rates in the treated segments, and major cardiac events during follow-up. Procedural success was achieved in 78% (PTCA), and 85% (rotablation) (P=0.038) of cases. Crossover from PTCA to rotablation was 4% and 10% vice versa (P=0.019). There was no difference between PTCA and rotablation with respect to procedure-related complications such as Q wave infarctions (2.4% each), emergency bypass surgery (1.2% versus 2.4%), and death (1.6% versus 0.4%). However, more stents were required after PTCA (14.9% versus 6.4%, P<0.002), predominantly for bailout or unsatisfactory results. Including bail out stents as an end-point, the procedural success rates were 73% for angioplasty and 84% for rotablation (P=0.006). At 6 months, symptomatic outcome, target vessel reinterventions and restenosis rates (PTCA 51% versus rotablation 49%, P=0.33) were not different. **Conclusion:** Complex coronary artery lesions can be treated with a high level of success and low complication rates either by PTCA with adjunctive stenting or rotablation. The long-term clinical and angiographic outcome is comparable. (C) 2000 The European Society of Cardiology.

South Med J, 93(4):415-23,2000

Left main coronary artery rotational atherectomy and stenting.

Nayak AK ; Davis R ; Reddy HK ; Krishnan MS ; Voelker DJ ; Aggarwal K

BACKGROUND: Coronary artery bypass surgery is a difficult option in patients who are not candidates for bypass surgery and high-risk patients with critical left main coronary artery (LMCA) disease. We report outcomes and short-term follow-up of patients who had LMCA rotational atherectomy and/or stenting, assess the role of these interventions in protected and unprotected significant LMCA stenosis, and review the literature. **METHODS:** We reviewed the cases of seven men with critical LMCA stenosis for whom coronary artery bypass surgery was considered a high risk. Five patients had rotational atherectomy, one had coronary artery stenting, and one had both. **RESULTS:** In all cases, angiographic success was achieved, and symptoms were relieved. Six patients were discharged from the hospital in 3 to 6 days. One patient who had cardiogenic shock, respiratory failure, and acute renal failure before the procedure died of arrhythmia 4 days afterward. Another patient had elective coronary artery bypass graft surgery 3 weeks later for recurrent angina. Cardiac catheterization was repeated in 1 month for chest pain in three patients at 4 to 7 months follow-up, and none had progression of residual stenosis in the LMCA. **CONCLUSIONS:** Our study suggests that LMCA rotational atherectomy and stenting are safe and effective revascularization procedures in high-risk patients and patients who are not candidates for bypass surgery.

Catheter Cardiovasc Interv, 48(3):275-8, 1999

Intracoronary adenosine administered during rotational atherectomy of complex lesions in native coronary arteries reduces the incidence of no-reflow phenomenon.

Hanna GP ; Yhip P ; Fujise K ; Schroth GW ; Rosales OR ; Anderson HV ; Smalling RW

Rotational atherectomy (RA) of complex, calcified lesions has been associated with a high incidence of no reflow ranging from 6%-15% and concomitant myocardial necrosis with adverse prognostic implications. There are no uniform strategies for preventing this complication. The role of intracoronary adenosine for the prevention of this phenomenon during RA has not been fully evaluated. We studied the procedural outcome of 122 patients who underwent RA of complex native coronary artery lesions. Fifty-two patients received no adenosine but a variety of other agents. Seventy patients received intracoronary adenosine boluses (24 to 48 microgram prior to and after each RA run). There was no difference in the type of lesion studied, run time, or Burr to artery ratio (0.6-0.7) between the two groups. Six patients without adenosine experienced no reflow

(11.6%), with resultant infarction in the target artery territory, while only 1 of 70 patients (1.4%, $P = 0.023$) in the adenosine group experienced no reflow. No untoward complications were observed during adenosine infusion. Intracoronary adenosine bolus administered during rotational atherectomy is easy, safe, and may significantly reduce the incidence of no reflow, which may improve the 30-day outcome of this procedure.

Circulation, 101(21):2484-9 2000

Treatment of in-stent restenosis with excimer laser coronary angioplasty versus rotational atherectomy: comparative mechanisms and results.

Mehran R ; Dangas G ; Mintz GS ; Waksman R ; Abizaid A ; Satler LF ; Pichard AD ; Kent KM ; Lansky AJ ; Stone GW ; Leon MB

BACKGROUND: Atheroablation yields improved clinical results for balloon angioplasty (percutaneous transluminal coronary angioplasty, PTCA) in the treatment of diffuse in-stent restenosis (ISR). **METHODS AND RESULTS:** We compared the mechanisms and clinical results of excimer laser coronary angioplasty (ELCA) versus rotational atherectomy (RA), both followed by adjunct PTCA; 119 patients (158 ISR lesions) were treated with ELCA+PTCA and 130 patients (161 ISR lesions) were treated with RA+PTCA. Quantitative coronary angiographic and planar intravascular ultrasound (IVUS) measurements were performed routinely. In addition, volumetric IVUS analysis to compare the mechanisms of lumen enlargement was performed in 28 patients with 30 lesions (16 ELCA+PTCA, 14 RA+PTCA). There were no significant between-group differences in preintervention or final postintervention quantitative coronary angiographic or planar IVUS measurements of luminal dimensions. Angiographic success and major in-hospital complications with the 2 techniques were also similar. Volumetric IVUS analysis showed significantly greater reduction in intimal hyperplasia volume after RA than after ELCA (43 ± 14 versus 19 ± 10 mm³, $P < 0.001$) because of a significantly higher ablation efficiency ($90 \pm 10\%$ versus $76 \pm 12\%$, $P = 0.004$). However, both interventional strategies had similar long-term clinical outcome; 1-year target lesion revascularization rate was 26% with ELCA+PTCA versus 28% with RA+PTCA ($P = \text{NS}$). **CONCLUSIONS:** Despite certain differences in the mechanisms of lumen enlargement, both ELCA+PTCA and RA+PTCA can be used to treat diffuse ISR with similar clinical results.

Summary

Circulation, 101(13):1512-8 2000

Carvedilol for prevention of restenosis after directional coronary atherectomy : final results of the European carvedilol atherectomy restenosis (EUROCARE) trial.

Serruys PW ; Foley DP ; Hfling B ; Puel J ; Glogar HD ; Seabra-Gomes R ; Goicolea J ; Coste P ; Rutsch W ; Katus H ; Bonnier H ; Wijns W ; Betriu A ; Hauf-Zachariou U ; van Swijndregt EM ; Melkert R ; Simon R

BACKGROUND: In addition to its known properties as a competitive, nonselective beta and alpha-1 receptor blocker, carvedilol directly inhibits vascular myocyte migration and proliferation and exerts antioxidant effects that are considerably greater than those of vitamin E or probucol. This provides the basis for an evaluation of carvedilol for the prevention of coronary restenosis. **METHODS AND RESULTS:** In a prospective, double-blind, randomized, placebo-controlled trial, 25 mg of carvedilol was given twice daily, starting 24 hours before scheduled directional coronary atherectomy and continuing for 5 months after a successful procedure. The primary end point was the minimal luminal diameter as determined during follow-up angiography 26 \pm 2 weeks after the procedure. Of 406 randomized patients, 377 underwent attempted atherectomy, and in 324 (88.9%), a atherectomy. These findings are in contrast to those of the Multivitamins and Probuco Trial, which raises doubts regarding the validity of the interpretation that restenosis reduction by probucol was via antioxidant effects. The relationship between antioxidant agents and restenosis remains to be elucidated.

Summary

J Am Coll Cardiol, 35(3):619-23 2000

Application of a continuous regression model of restenosis to saphenous vein grafts after successful percutaneous transluminal coronary angioplasty or directional coronary atherectomy.

Bruce CJ ; Kuntz RE ; Popma JJ ; Pieper KS ; Topol EJ ; Holmes DR Jr

OBJECTIVES: To evaluate a quantitative model of restenosis in patients with vein graft disease undergoing percutaneous transluminal coronary angioplasty (PTCA) or directional coronary atherectomy (DCA). **BACKGROUND:** A quantitative relationship between acute gain and late loss has been developed to describe the late changes in lumen dimension after native vessel coronary intervention. This same relationship may also be seen after treatment of saphenous vein graft disease. **METHODS:** Patients with native coronary artery stenoses (CAVEAT-I) or saphenous vein graft lesions (CAVEAT-II) were randomized to either DCA or PTCA, and data from these trials were analyzed retrospectively. Angiographic results of the target lesions were reviewed, and each lesion was assessed for vessel caliber and reference diameter, absolute minimal lumen diameter, percent diameter stenosis, percent stenosis of the cross-sectional area, acute gain and late loss. Linear regression models were used to determine late loss and to detect differences in angiographic outcomes. **RESULTS:** Vein grafts had significantly larger reference vessel diameters than native coronary arteries; they also had significantly more acute gain and more late loss. Directional coronary atherectomy was associated with a larger acute gain in both studies. Patients undergoing DCA also experienced greater late loss although the effect was statistically significant only in the CAVEAT-I study. After adjusting for the acute gain, the treatment effect on late loss became nonsignificant in both studies. **CONCLUSIONS:** In patients undergoing DCA or PTCA of saphenous vein graft narrowings, the relationship between late loss and acute gain is also demonstrated, similar to the device-independent relationships seen in native coronary lesions. In CAVEAT-II, larger degrees of acute gain were also associated with higher degrees of late lumen loss.

Summary

Table 3. Differences Between Native Coronary Arteries and Saphenous Vein Grafts.

EEL = external elastic lamina; IEL = internal elastic lamina.

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Directional coronary atherectomy in intermediate sized vessels: final results of the intermediate vessel atherectomy trial (IVAT).

Cannon L ; Senior D ; Feit F ; Attubato MJ ; Rosenberg J ; O'Donnell MJ ; Hirst J ; Gibson M

Revascularization options for intermediate sized vessels (2.5-2.9 mm) have historically been limited. IVAT is a pilot study to assess the efficacy and safety of debulking intermediate sized vessels using directional coronary atherectomy (DCA). Between March 1996 and June 1997, 50 patients were enrolled at seven hospitals in the United States. Of those patients, 70% presented with unstable angina and 52% had single vessel disease. Of the lesions treated, 96% were de novo. Adjunctive PTCA after DCA was performed in 90% of cases at the discretion of the investigator to maximize luminal diameter. The GTO DCA device was used in 90% of cases. Procedural success (residual stenosis <50% without major complications) was 94%. Stents were placed in 12% of patients. The only complications were three non-Q wave MIs. Mean reference vessel diameter increased from 2.49 mm pre-procedure to 2.57 mm after DCA and 2.61 post-procedure; mean MLD increased from 0.76 mm to 2.03 mm to 2.31 mm; and mean stenosis decreased from 70% to 21% post DCA and to 11% post procedure. At six months follow-up, 18.0% of target lesions required revascularization. Total revascularization, including non-target vessels, was 32%. These results suggest that DCA has a high procedural success rate and a low target lesion revascularization rate in intermediate sized vessels.

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Impact of intravascular ultrasound guidance on directional coronary atherectomy.

Koschyk DH ; Nienaber CA ; Schaps KP ; Twisselmann T ; Hofmann T ; Lund GK ; Langes K ; Meinertz T

In contrast to the luminogram of coronary angiography, intravascular ultrasound (IVUS) has proven to accurately assess both coronary lumen and vessel morphology due to its 360 degrees imaging capacity. Directional coronary atherectomy (DCA) improves the coronary lumen by removing plaque mass rather than stretching the vessel and compressing the plaque as with conventional percutaneous transluminal coronary angioplasty. In an attempt to optimize the procedural result of DCA we prospectively investigated the impact of IVUS guidance in a head to head comparison to on-line quantitative coronary angiography (QCA) on the result of DCA. In 16 consecutive patients IVUS demonstrated significant residual plaque mass after DCA irrespective of a satisfactory angiographic result. After a mean of 9 +/- 2 cuts luminal improvement was obtained with an area stenosis by angiography of 39 +/- 17% and by IVUS of 50 +/- 10% ($p < 0.05$), a diameter stenosis by angiography of 23 +/- 10% and IVUS of 35 +/- 14% ($p < 0.05$) and finally a minimal lumen diameter (MLD) by angiography of 2.9 +/- 0.5 mm and by IVUS of 2.3 +/- 0.5 mm ($p < 0.005$). After both on-line QCA and

IVUS measurements a second series of 7 +/- 2 cuts were initiated to debulk more atheroma and improve stenosis dimensions. After additional cuts IVUS revealed further luminal improvement with an area stenosis by angiography of 25 +/- 16% and IVUS of 21 +/- 18% (n.s.), a diameter stenosis by angiography of 16 +/- 11% and by IVUS of 13 +/- 19% (n.s.) and finally a MLD by angiography of 3.1 +/- 0.5 mm and by IVUS of 2.8 +/- 0.3 mm ($p < 0.05$). Intraprocedural use of IVUS is superior to on-line QCA to assess the immediate result of DCA. IVUS-guided DCA results in more effective atheroma debulking than luminographic evaluation. Results of larger follow-up studies are needed to substantiate the intraprocedural advantage of IVUS with DCA.

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Effect of plaque debulking and stenting on short- and long-term outcomes after revascularization of chronic total occlusions.

Gruberg L, Mehran R, Dangas G, Hong MK, Mintz GS, Kornowski R, Lansky AJ, Kent KM, Pichard AD, Satler LF, Stone GW, Leon MB

OBJECTIVES: We evaluated the effect of plaque burden modification (debulking) on the short- and long-term clinical outcomes of patients with a totally occluded native coronary artery undergoing successful stent deployment. **BACKGROUND:** Although the primary success rate of crossing a chronic totally occluded coronary artery has improved with the development of new interventional devices and guidewires, the rate of acute reocclusion and restenosis remains high. **METHODS:** The in-hospital and late clinical outcomes of 150 patients who had undergone successful stenting of 176 chronic total occlusions were analyzed. After successful crossing of the lesion, 44 patients with 50 lesions underwent debulking by laser angioplasty, rotational or directional atherectomy followed by stenting, whereas 106 patients with 126 lesions underwent stent implantation without prior debulking. **RESULTS:** Baseline clinical and angiographic characteristics were similar for the two groups, except for a higher incidence of left anterior descending coronary artery location and longer lesions in the group of patients who underwent debulking prior to stenting. In-hospital mortality, myocardial infarction and repeat angioplasty rates were similar for the two groups. At a mean 14 +/- 8 months follow-up time, there were no deaths in either group, and target lesion revascularization rates were the same (16.3% in the debulking plus stent group vs. 14.4% in the stent alone group, $p = NS$). **CONCLUSIONS:** Treatment of chronic total native coronary artery occlusions with stent deployment with and without lesion modification (debulking) results in a favorable in-hospital outcome, with relatively low long-term target lesion

revascularization rates.

Summary

Rotablation

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