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

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.

Am J Cardiol 2002 Nov 15;90(10):1074-8

Effectiveness of adjunctive stent implantation following directional coronary atherectomy for treatment of left anterior descending ostial stenosis.

Bramucci E, Repetto A, Ferrario M, Canosi U, Boschetti E, Brambilla N, Gnecchi M, Merlini PA, Ardissino D, Angoli L, Tavazzi L.

The aim of this study was to evaluate the acute and long-term angiographic and clinical results of optimal plaque debulking by means of directional coronary atherectomy (DCA) followed by stent implantation for treatment of left anterior descending (LAD) ostial stenosis. Eighty consecutive patients (66 men; aged 57 10 years) with angina pectoris, documented anterior myocardial ischemia, and de novo LAD ostial stenosis prospectively underwent DCA and stent deployment. They were evaluated angiographically after 6 months and clinically for up to 30 29 months. The primary success rate was 98%. The in-hospital complications were 1 death due to in-stent subacute thrombosis 7 days after the procedure, 1 non-Q-wave myocardial infarction, and 1 retrograde left main artery dissection. The angiographic binary restenosis rate was 14.5%, and the loss index was 0.38 0.35. The target lesion revascularization (TLR) rates at 6, 12, and 24 months were 6.0%, 14.5%, and 16.3%, respectively, and the combined event rates (death, nonfatal myocardial infarction, TLR) at the same times were 8.7%, 17.5%, and 21.2%, respectively. These results indicate that the combined approach of DCA and stent implantation is feasible and safe in patients with LAD ostial lesions, has a high success rate, a low incidence of restenosis, and a good long-term outcome.

Am J Cardiol 2002 Sep 15;90(6):573-8

Debulking and stenting versus debulking only of coronary artery disease in patients treated with cilostazol (final results of ESPRIT).

Tsuchikane E, Kobayashi T, Kobayashi T, Takeda Y, Otsuji S, Sakurai M, Awata N.

Stenting inhibits vascular constrictive remodeling after directional coronary atherectomy (DCA). Cilostazol has been reported to control neointimal proliferation after stenting. This study's aim was to examine the effect of debulking and stenting with antirestenotic medication on restenosis. After optimal DCA, 117 lesions were randomly assigned to either the DCA with stent (DCA-stent) (58 lesions) group or the DCA only (59 lesions) group. Multilink stents were implanted in the DCA-stent group. Cilostazol (200 mg/day) without aspirin was administered to both groups for 6 months. Ticlopidine (200 mg/day) was given to the DCA-stent group for 1 month. Serial quantitative angiography and intravascular ultrasound (IVUS) were performed at the time of the procedure and at 6-month follow-up. The primary end point was 6-month angiographic restenosis. Clinical event rates at 1 year were also assessed. Baseline characteristics were similar. All procedures were successful. No adverse effects to cilostazol were observed. Postprocedural lumen diameter was significantly larger (3.27 vs 2.92 mm; $p < 0.0001$) in the DCA-stent group. However, the follow-up lumen diameter was not significantly different (2.53 vs 2.41 mm, DCA-stent vs DCA). IVUS revealed that intimal proliferation was significantly larger in the DCA-stent group (4.2 vs 1.5 mm(2); $p < 0.0001$), which accounted for the similar follow-up lumen area (6.5 vs 7.1 mm(2)). The restenosis rate was low in both groups (5.4% vs 8.9%), and the difference was not significant. Clinical event rates at 1 year were also not significantly different. These results suggest that optimal lesion debulking by DCA does not always need adjunctive stenting if cilostazol is administered.

Catheter Cardiovasc Interv 2002 Jun;56(2):222-6

Directional atherectomy of a calcified lesion using a new atherectomy device.

Reimers B, Stankovic G, Prati F, Sommariva L, Karvouni E, Takagi T, Albiero R, Angelini A, Di Mario C, Thiene G, Colombo A.

We report on a case of directional atherectomy performed on a calcified coronary lesion using a novel device with a hardened titanium cutter. The successful removal of calcified plaque was documented by intravascular ultrasound assessment and confirmed by histopathological analysis of the obtained plaque specimen.

Am J Cardiol 2002 Jun 15;89(12):1354-9

Relation of matrix-metalloproteinase 3 found in coronary lesion samples retrieved by directional coronary atherectomy to intravascular ultrasound observations on coronary remodeling.

Schoenhagen P, Vince DG, Ziada KM, Kapadia SR, Lauer MA, Crowe TD, Nissen SE, Tuzcu EM.

We investigated the relation between the presence of matrix-metalloproteinases (MMPs) and direction of remodeling in the coronary lesions of 35 patients. Positive arterial remodeling describes a compensatory expansion of the external elastic membrane (EEM) area of atherosclerotic lesions. An association between positive remodeling and unstable clinical presentation has been previously described. However, the pathophysiology of the remodeling process is not completely understood. Preinterventional intravascular ultrasound images and directional atherectomy (DCA) samples were analyzed. The remodeling ratio was calculated as the EEM area at the lesion site divided by the EEM area at the proximal reference. Positive, intermediate, and negative remodeling were defined as ratios of >1.05, 0.95 to 1.05, and <0.95, respectively. The histologic samples were immunostained for MMP-1, -2, -3, and -9. Positive, intermediate, and negative remodeling was present in 15, 7, and 13 lesions, respectively. Mild and intense cell-associated staining for MMP-1 was found in 21 (68%) and 10 (32%) patients, respectively. Staining for MMP-3 was mild in 20 patients (67%) and intense in 10 patients (33%). Immunostaining for MMP-2 and -9 was mild in all samples. Intense staining for MMP-3 was significantly more common in lesions with positive than negative and/or intermediate remodeling (58% vs 17%; $p = 0.04$; $p = 0.053$ after adjustment for gender). Thus, in this in vivo intravascular ultrasound and histologic study, increased cell-associated MMP-3 staining was associated with positive arterial remodeling.

J Invasive Cardiol 2002 Jun;14(6):315-20

Comparison of dilatation mechanism and long-term vessel remodeling between directional coronary atherectomy and balloon angioplasty assessed by volumetric intravascular ultrasound.

Suzumura H, Hosokawa H, Suzuki T, Fukutomi T, Ito S, Itoh M.

Although acute and late outcomes of coronary interventions have been determined by coronary angiography, this method cannot determine changes in vessel and plaque volume. Volumetric intravascular analysis has the potential to evaluate the morphology and redistribution of plaque after coronary intervention as well as longitudinal vessel remodeling. We used 3-dimensional intravascular ultrasound (3-D IVUS) to delineate the mechanism of coronary dilatation and long-term (> 1 year) remodeling in 25 patients. Ten patients underwent directional coronary atherectomy (DCA), and 15 underwent balloon angioplasty (POBA). No patients exhibited restenosis at 6-month angiographic follow-up. Validated Netra 3-D IVUS was performed pre- and post-intervention, at 6-months and at > 1-year. There were some differences in mechanism of dilatation and time course of change in vessel size between DCA and POBA patients. The principal mechanism was vessel stretching and longitudinal plaque redistribution in the POBA group and plaque debulking in the DCA group. In the POBA group, vessel volume increased just after the procedure; this increase was maintained at 6 months and at > 1-year. However, in the DCA group, vessel volume increased initially 6 months after the procedure. 3-D IVUS revealed a difference in mechanism of dilatation between POBA and DCA; this difference might affect late-term vessel remodeling even in patients without restenosis.

Circ J 2002 Apr;66(4):362-6

Role of plaque proliferation in late lumen loss after directional coronary atherectomy.

Sumitsuji S, Katoh O, Tsuchikane E, Otsuji S, Tateyama H, Awata N, Kobayashi T.

Previous reports suggest that vessel remodeling is the most important factor in late lumen loss in non-stented lesions, but because results of directional coronary atherectomy (DCA) show that increased plaque area (PA) is also important, the aim of this study was to redefine the mechanism of late lumen loss after DCA. One hundred and twenty lesions that underwent DCA with intravascular ultrasound (IVUS) guidance and serial IVUS analysis were studied, and vessel area (VA), lumen area (LA), PA (VA-LA) and corrected values (each value divided by the value of VA pre procedure to correct the vessel size) were analyzed. During follow-up, corrected VA (cVA) decreased by 0.058 0.191, whereas corrected PA (cPA) increased by 0.087 0.159. Though the %PA (PA/VA) after the procedure showed significant negative correlation with the subsequent change in cPA, it did not correlate with the subsequent change in cVA. In conclusions, the mechanism of late lumen loss after DCA consists of both arterial remodeling and plaque proliferation, and the residual %PA after the procedure determines the subsequent lumen loss. With a lower %PA, a change in the PA contributes more to late lumen loss than do changes in VA. With a high %PA, a change in the VA contributes more to late lumen loss.

Am J Cardiol 2002 Mar 1;89(5):505-10

Mechanisms of acute gain and late lumen loss after atherectomy in different preintervention arterial remodeling patterns.

Oikawa Y, Kirigaya H, Aizawa T, Nagashima K, Yajima J, Ishimura K, Hara H, Sahara M, Iinuma H, Fu LT.

The main mechanism of restenosis after directional coronary atherectomy (DCA) remains obscure. We investigated mechanisms of restenosis after DCA in different coronary artery remodeling patterns. DCA was performed in 51 de novo lesions. The lesions were evaluated by intravascular ultrasound (IVUS) before, immediately after, and 6 months after the procedure. According to the IVUS findings before DCA, we classified the lesions into the following 3 groups: (1) positive (n = 10), (2) intermediate (n = 25), and (3) negative (n = 16) remodeling. We measured lumen area, vessel area, and plaque area using IVUS before DCA, immediately after DCA, and at follow-up. Lumen area increase after DCA was mainly due to plaque area reduction in the positive and intermediate remodeling groups (90 plus minus 15% and 80 plus minus 25% increase in lumen area, respectively), whereas that in the negative remodeling group was due to both plaque area reduction (57 plus minus 22% increase in lumen area) and vessel area enlargement (43 plus minus 33% increase in lumen area). The plaque area increase correlated strongly with late lumen area loss in the positive and intermediate remodeling groups ($r = 0.884$, $p < 0.001$; $r = 0.626$, $p < 0.001$, respectively), but the decrease in vessel area was not correlated with lumen area loss. In contrast, both an increase in plaque area and a decrease in vessel area were correlated with late lumen area loss ($r = 0.632$, $p = 0.009$; $r = 0.515$, $p = 0.041$) in the negative remodeling group. Coronary artery restenosis after atherectomy was primarily due to an increase in plaque in the positive and/or intermediate remodeling groups. However, in the negative remodeling group, late lumen loss might have been caused by both an increase in plaque and vessel shrinkage.

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

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.

Am J Cardiol 2003 Feb 1;91(3):287-92

Involvement of C-reactive protein obtained by directional coronary atherectomy in plaque instability and developing restenosis in patients with stable or unstable angina pectoris.

Ishikawa T, Hatakeyama K, Imamura T, Date H, Shibata Y, Hikichi Y, Asada Y, Eto T.

We investigated whether positive immunohistochemical staining of C-reactive protein (CRP) in initial culprit lesions is related to coronary plaque instability and whether it could affect the outcome of directional coronary atherectomy (DCA). The plasma level of CRP is a reliable marker of the risk of coronary events and restenosis after percutaneous coronary intervention. However, the influence of tissue CRP in atheromatous plaque on plaque vulnerability and restenosis remains unknown. Samples of DCA obtained from 12 patients with stable angina pectoris and 15 patients with unstable angina pectoris were immunohistochemically stained with a monoclonal antibody against CRP. We performed follow-up coronary angiography on 22 of 27 patients to evaluate the presence of restenosis after DCA. Immunoreactivity to CRP was localized to macrophages, smooth muscle cells, and necrotic areas. The ratio of CRP positive cells to total cells was significantly higher in DCA samples from patients with unstable (17.9 +/- 2.0%) than with stable angina (11.0 +/- 2.5%) ($p < 0.05$). Follow-up coronary angiography showed that 12 of 22 patients developed restenosis after DCA. The ratio was also significantly higher in DCA specimens from patients with restenosis (19.3 +/- 2.8%) compared with those without restenosis (11.0 +/- 2.0%) ($p < 0.05$). In addition, the ratio significantly correlated with late luminal loss ($r = 0.428$, $p < 0.05$) and loss index ($r = 0.636$, $p = 0.0011$) after DCA. Immunoreactivity to CRP in coronary atheromatous plaque increases in culprit lesions of unstable angina, and it affects restenosis after DCA. These findings suggest that CRP in atheromatous plaque plays an important role in the pathogenesis of unstable angina and restenosis after coronary intervention.

Arterioscler Thromb Vasc Biol 2002 Nov 1;22(11):1838-44

Superoxide generation in directional coronary atherectomy specimens of patients with angina pectoris: important role of NAD(P)H oxidase.

Azumi H, Inoue N, Ohashi Y, Terashima M, Mori T, Fujita H, Awano K, Kobayashi K, Maeda K, Hata K, Shinke T, Kobayashi S, Hirata K, Kawashima S, Itabe H, Hayashi Y, Imajoh-Ohmi S, Itoh H, Yokoyama M.

OBJECTIVE: NADH/NADPH oxidase is an important source of reactive oxygen species (ROS) in the vasculature. Recently, we demonstrated that p22(phox), an essential component of this oxidase, was expressed in human coronary arteries and that its expression was enhanced with the progression of atherosclerosis. The present study was undertaken to investigate its functional importance in the pathogenesis of coronary artery disease. For this aim, the expression of p22(phox), the distribution of oxidized low density lipoprotein (LDL), and the generation of ROS in directional coronary atherectomy (DCA) specimens were examined. METHODS AND RESULTS: DCA specimens were obtained from patients with stable or unstable angina pectoris. The distribution of p22(phox) and of oxidized LDL was examined by immunohistochemistry. The generation of superoxide in DCA specimens was assessed by the dihydroethidium method and lucigenin-enhanced chemiluminescence. ROS were closely associated with the distribution of p22(phox) and oxidized LDL. Not only inflammatory cells but also smooth muscle cells and fibroblasts generated ROS. There was a correlation between ROS and the expression of p22(phox) or oxidized LDL. The generation of ROS was significantly higher in unstable angina pectoris compared with stable angina pectoris. CONCLUSIONS: ROS generated by p22(phox)-based NADH/NADPH oxidase likely mediate the oxidative modification of LDL and might play a major role in pathogenesis of atherosclerotic coronary artery disease.

Am J Cardiol 2002 Nov 15;90(10):1074-8

Effectiveness of adjunctive stent implantation following directional coronary atherectomy for treatment of left anterior descending ostial stenosis.

Bramucci E, Repetto A, Ferrario M, Canosi U, Boschetti E, Brambilla N, Gnecchi M, Merlini PA, Ardissino D, Angoli L, Tavazzi L.

The aim of this study was to evaluate the acute and long-term angiographic and clinical results of optimal plaque debulking by means of directional coronary atherectomy (DCA) followed by stent implantation for treatment of left anterior descending (LAD) ostial stenosis. Eighty consecutive patients (66 men; aged 57 +/- 10 years) with angina pectoris, documented anterior myocardial ischemia, and de novo LAD ostial stenosis prospectively underwent DCA and stent deployment. They were evaluated angiographically after 6 months and clinically for up to 30 +/- 29 months. The primary success rate was 98%. The in-hospital complications were 1 death due to in-stent subacute thrombosis 7 days after the procedure, 1 non-Q-wave myocardial infarction, and 1 retrograde left main artery dissection. The angiographic binary restenosis rate was 14.5%, and the loss index was 0.38 +/- 0.35. The target lesion revascularization (TLR) rates at 6, 12, and 24 months were 6.0%, 14.5%, and 16.3%, respectively, and the combined event rates (death, nonfatal myocardial infarction, TLR) at the same times were 8.7%, 17.5%, and 21.2%, respectively. These results indicate that the combined approach of DCA and stent implantation is feasible and safe in patients with LAD ostial lesions, has a high success rate, a low incidence of restenosis, and a good long-term outcome.

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Debulking and stenting versus debulking only of coronary artery disease in patients treated with cilostazol (final results of ESPRIT).

Tsuchikane E, Kobayashi T, Kobayashi T, Takeda Y, Otsuji S, Sakurai M, Awata N.

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Catheter Cardiovasc Interv 2002 Aug;56(4):452-9

Effective plaque removal with a new 8 French-compatible atherectomy catheter.

Takagi T, Di Mario C, Stankovic G, Reimers B, Alberti A, Liistro F, Kovalenko O, Sgura F, Albiero R, Ribichini F, Pugno A, Colombo A.

The purpose of this study was to evaluate the safety and efficacy of the new 8 Fr guide catheter-compatible Flexicut directional atherectomy device and to compare it with the conventional Atherocath GTO catheter. The 6 Fr Flexicut catheter has a larger cutting window and a titanium nitride-coated cutter to effect more tissue removal as well as treat mildly calcified lesions. A group of 143 lesions in 117 consecutive patients treated with the Flexicut catheter in four centers were compared with a control group of 277 lesions in 212 consecutive patients treated with the GTO device. Postatherectomy luminal diameters were larger (2.92 +/- 0.79 vs. 2.52 +/- 0.64 mm; P < 0.0001), with more luminal gain (relative gain: 0.58 +/- 0.24 vs. 0.48 +/- 0.25; P = 0.0007) using fewer directional coronary atherectomy (DCA) cuts (12 +/- 7 vs. 16 +/- 9; P = 0.0001) in the Flexicut group. A residual diameter stenosis < 20% immediately after DCA was obtained in 77% of the lesions in the Flexicut group vs. 45% in the GTO group (P < 0.0001). Histology in the former group revealed large calcium speckles in the retrieved specimens. In the Flexicut group, there was a lower incidence of access site complications and damage to the coronary ostium (2.5% vs. 7.5%; P = 0.08). The new Flexicut catheter is more effective than the conventional GTO catheter with a trend for reduced guiding catheter-related complications.

Catheter Cardiovasc Interv 2002 Jun;56(2):222-6

Directional atherectomy of a calcified lesion using a new atherectomy device.

Reimers B, Stankovic G, Prati F, Sommariva L, Karvouni E, Takagi T, Albiero R, Angelini A, Di Mario C, Thiene G, Colombo A.

We report on a case of directional atherectomy performed on a calcified coronary lesion using a novel device with a hardened titanium cutter. The successful removal of calcified plaque was documented by intravascular ultrasound assessment and confirmed by histopathological analysis of the obtained plaque specimen.

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Relation of matrix-metalloproteinase 3 found in coronary lesion samples retrieved by directional coronary atherectomy to intravascular ultrasound observations on coronary remodeling.

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J Invasive Cardiol 2002 Jun;14(6):315-20

Comparison of dilatation mechanism and long-term vessel remodeling between directional coronary atherectomy and balloon angioplasty assessed by volumetric intravascular ultrasound.

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Circ J 2002 Apr;66(4):362-6

Role of plaque proliferation in late lumen loss after directional coronary atherectomy.

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Directional Atherectomy

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Am J Cardiol 2002 Nov 15;90(10):1074-8

J Am Coll Cardiol 2001 Apr;37(5):1271-6

Recurrent unstable angina after directional coronary atherectomy is related to the extent of initial coronary plaque inflammation.

Meuwissen M, Piek JJ, van der Wal AC, Chamuleau SA, Koch KT, Teeling P, van der Loos CM, Tijssen JG, Becker AE.

OBJECTIVES: This study was performed to evaluate the relationship between plaque inflammation of the initial culprit lesion and the incidence of recurrent angina for one year after directional coronary atherectomy (DCA). BACKGROUND: A positive correlation between coronary plaque inflammation and angiographic restenosis has been reported. METHODS: A total of 110 patients underwent DCA. Cryostat sections were immunohistochemically stained with monoclonal antibodies CD68 (macrophages), CD-3 (T lymphocytes) and alpha-actin (smooth muscle cells [SMCs]). The SMC and macrophage contents were planimetrically quantified as a percentage of the total tissue area. T lymphocytes were counted as the number of cells/mm2. The patients were followed for one year to document recurrent unstable angina pectoris (UAP) or stable angina pectoris (SAP). RESULTS: Recurrent UAP developed in 16 patients, whereas recurrent SAP developed in 17 patients. The percent macrophage areas were larger in patients with recurrent UAP (27 +/- 12%) than in patients with recurrent SAP (8 +/- 4%; p = 0.0001) and those without recurrent angina (18 +/- 14%; p = 0.03). The number of T lymphocytes was also greater in patients with recurrent UAP (25 +/- 14 cells/mm2) than in patients with recurrent SAP (14 +/- 8 cells/mm2; p = 0.02) and those without recurrent angina (14 +/- 12 cells/mm2; p = 0.002). Multiple stepwise logistic regression analysis identified macrophage areas and T lymphocytes as independent

predictors for recurrent UAP. CONCLUSIONS: There is a positive association between the extent of initial coronary plaque inflammation and the recurrence of unstable angina during long-term follow-up after DCA. These results underline the role of ongoing smoldering plaque inflammation in the recurrence of unstable angina after coronary interventions.

Am J Cardiol 2001 Apr 1;87(7):838-43

Initial and long-term results of directional coronary atherectomy in unprotected left main coronary artery.

Kosuga K, Tamai H, Ueda K, Kyo E, Tanaka S, Hata T, Okada M, Nakamura T, Komori H, Tsuji T, Takeda S, Motohara S, Uehata H.

Angioplasty in the unprotected left main coronary artery (LMCA) has been controversial. Recently, several studies have suggested that new procedures and devices such as directional coronary atherectomy (DCA) and stents may change this situation. Although there are many reports of unprotected LMCA stenting, there are few reports of DCA of this lesion. Therefore, initial and long-term results were evaluated in 101 patients who underwent DCA for unprotected LMCA in our hospital. Emergency procedures were performed in 15 patients and electively in 86 patients. Scheduled angiographic follow-up was routinely performed, and all patients were clinically followed for >4 months after DCA. Technical success was achieved in 99%, and in-hospital outcomes were cardiac death (2%), noncardiac death (4%), Q-wave myocardial infarction (1%), non-Q-wave myocardial infarction (8.9%), coronary artery bypass grafting (0%), and repeat angioplasty (4%). In-hospital results varied considerably, depending on presentation. In-hospital mortality was significantly higher in the emergency, left ventricular ejection fraction < or =35%, and high-risk surgical subgroups. The angiographic restenosis rate was 20.4% at follow-up, and its predictor was postminimal lumen diameter by multivariate analysis. Mean clinical follow-up was 2.8 years; estimated 1- and 3-year survival rates were 87% and 80.7%, respectively. The cardiac survival rate of the low-risk surgical subgroup was significantly higher than that of the high-risk surgical subgroup ($p < 0.05$). Thus, our data show that DCA can be performed safely and effectively in unprotected LMCA with an acceptable low restenosis rate and high survival rate.

J Am Coll Cardiol 1995;25:318-24

Multivariate Predictors of Intravascular Ultrasound End Points After Directional Coronary Atherectomy

Fadi AM, Gary SM, Ellen P, Saturnino PJ, Jeffrey JP, Kenneth MK, Lowell FS, Augusto DP, Martin BL

Objectives. This study attempted to identify the clinical, angiographic, procedural and intravascular ultrasound predictors of directional atherectomy results assessed by intravascular ultrasound.

Background. Several angiographic and intravascular ultrasound variables have been associated with the outcome of directional coronary atherectomy. No study has incorporated both modalities into a predictive model.

Methods. One hundred seventy patients were analyzed using preintervention intravascular ultrasound and quantitative angiography. Clinical and procedural variables were collected by independent chart review. Quantitative and qualitative angiographic analysis was performed using a transducer-tipped catheter, rotating within a stationary imaging sheath, and withdrawn automatically at 0.5 mm/s. Clinical, procedural, angiographic and ultrasound variables were tested in a multivariate linear regression model. Dependent ultrasound variables included postatherectomy lumen cross-sectional area and percent cross-sectional elastic narrowing (plaque plus media/external elastic membrane cross-sectional area) and, in a subgroup of 47 patients studied using volumetric analysis, percent plaque volume removal.

Results. By multivariate stepwise linear regression analysis, predictors of residual lumen area) included arc of calcium and preatherectomy plaque plus media cross-sectional are; predictors of residual cross-sectional narrowing were arc of calcium, preatherectomy plaque plus cross-sectional area and lesion length; and predictors of percent plaque volume removal were arc of calcium and atherectomy device size.

Conclusions. The Preintervention lesion arc of calcium measured by intravascular ultrasound is the most consistent predictor of the effectiveness and results of directional coronary atherectomy.

Summary

1. Predictors of residual lumen area: included arc of calcium, preatherectomy plaque plus media CSA
2. Predictors of residual cross-sectional narrowing: arc of calcium, preatherectomy plaque plus cross-sectional area, lesion length
3. Predictors of percent plaque volume removal: arc of calcium, atherectomy device size.

Circulation 1997;96: 475-483

Remodeling of Human Coronary Arteries Undergoing Coronary Angioplasty or Atherectomy

Takeshi Kimura, Satoshi Kaburagi, Takashi Tamura, Hiroyoshi Yokoi, Yoshihisa Nakagawa, Hiroatsu Yokoi, Naoya Hamasaki, Hideyuki Nosaka, Masakiyo Nobuyoshi, Gary S. Mintz, Jeffery J. Popma, and Martin B. Leon

Background. Recently, long-term constriction of the vessel has been suggested as an alternative mechanism of restenosis after coronary angioplasty.

Methods and Results. To understand remodeling of human coronary arteries undergoing coronary angioplasty or atherectomy, serial intravascular ultrasonographic examinations were performed at preintervention and postintervention examinations and at 24 hours, 1 month, and 6 months. Complete serial data were obtained in 61 lesions (balloon angioplasty, 35 lesions; directional atherectomy, 26 lesions). Lumen area improved from 6.81 ±2.24 mm2 after intervention to 8.22±2.79 mm2 at 1 month (P=.0001) and decreased to 4.88±2.86 mm2at 6 months (P=.0001). Vessel area enlarged from 17.32±5.35 mm2 after intervention to 19.39±5.33 mm2 at 1 month (P=.0001) and decreased to 16.33±5.54 mm2 at 6 months (P=.0001). Plaque+media area increased significantly from postintervention examination to 24 hours (10.51±4.38 versus 10.96±4.49 mm2, P=.0008) and from 24 hours to 6 months (10.96±4.49 versus 11.45±4.45 mm2, P=.03). Changes in lumen area in each study interval correlated more closely with changes in vessel area than with changes in plaque+media area. Restenotic lesions compared with nonrestenotic lesions had a greater decrease in the vessel area between 1 month and 6 months (-4.33±2.73 versus -2.49±2.15 mm2, P=.006) and greater increase in the plaque+media area both within 24 hours (0.84±1.22 versus 0.27±0.38 mm2, P=.04) and between 24 hours and 6 months (1.19±2.19 versus 0.18±1.46 mm2, P=.04).

Conclusions. Remodeling after coronary angioplasty or atherectomy was characterized by early adaptive enlargement and late constriction of the vessel.

Circulation. 1998;97:322-331

Clinical Investigation and Reports

Final Results of the Balloon vs Optimal Atherectomy Trial (BOAT)

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Investigators

Background-Previous directional coronary atherectomy (DCA) trials have shown no significant reduction in angiographic restenosis, more in-hospital complications, and higher 1-year mortality than conventional balloon angioplasty (percutaneous transluminal coronary angioplasty [PTCA]). DCA, however, has subsequently evolved toward a more "optimal" technique (larger devices, more extensive tissue removal, and routine postdilation to obtain diameter stenosis <20%).

Methods and Results-The Balloon vs Optimal Atherectomy Trial (BOAT) was conducted to evaluate whether optimal DCA provides short- and long-term benefits compared with balloon angioplasty. One thousand patients with single de novo, native vessel lesions were randomized to either DCA or PTCA at 37 participating centers. Lesion success was obtained in 99% versus 97% (P=.02) of patients to a final residual diameter stenosis of 15% versus 28% (P<.0001) for DCA and PTCA, respectively, the latter including stents in 9.3% of the patients. There was no increase in major complications (death, Q-wave myocardial infarction, or emergent coronary artery bypass graft surgery [2.8% versus 3.3%]), although creatine kinase-MB >3x normal was more common with DCA (16% versus 6%; P<.0001). Angiographic restudy (in 79.6% of eligible patients at 7.2±2.6 [median, 6.9] months) showed a significant reduction in the prespecified primary end point of angiographic restenosis by DCA (31.4% versus 39.8%; P=.016). Clinical follow-up to 1 year showed nonsignificant 13% to 17% reductions in the DCA arm of the study for mortality rate (0.6% versus 1.6%; P=.14), target-vessel revascularization (17.1% versus 19.7%; P=.33), target-site revascularization (15.3% versus 18.3%; P=.23), and target-vessel failure (death, Q-wave myocardial infarction, or target-vessel revascularization, 21.1% versus 24.8%; P=.17).

Conclusions-Optimal DCA provides significantly higher short-term success, lower residual stenosis, and lower angiographic restenosis than conventional PTCA, despite failing to reach statistical significance for reducing late clinical events compared with PTCA with stent backup.

Summary

Circulation 1998;98: 1604-1609

Stenting After Optimal Lesion Debulking (SOLD) Registry : Angiographic and Clinical Outcome

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Albiero, Massimo Ferraro, and Antonio Colombo

Background-Coronary stenting has reduced restenosis in focal de novo lesions, but its impact has been less pronounced in complex lesion subsets. Preliminary data suggest a role for plaque burden in promoting intimal hyperplasia after stent implantation. The aim of this study was to test the hypothesis that plaque removal with directional atherectomy before stent implantation may lower the intensity of late neointimal hyperplasia, reducing the incidence of in-stent restenosis.

Methods and Results-Seventy-one patients with 90 lesions underwent directional atherectomy before coronary stenting. Intravascular ultrasound-guided stenting was performed in 73 lesions (81%). Clinical success was achieved in 96% of patients. Procedural complications were as follows: emergency bypass surgery in 1 patient (1.4%), who died 2 weeks later; Q-wave myocardial infarction in 2 patients (2.8%); and non-Q-wave myocardial infarction in 8 patients (11.3%). None of the patients had stent thrombosis at follow-up. Angiographic follow-up was performed in 89% of eligible patients at 5.7±1.7 months. Loss index was 0.33 (95% CI, 0.26 to 0.40), and angiographic restenosis was 11% (95% CI, 5% to 20%). Clinical follow-up was performed in all patients at 18±3 months. Target lesion revascularization was 7% (95% CI, 3% to 14%).

Conclusions-Directional atherectomy followed by coronary stenting could be performed with good clinical success rate. Also, these data point to a possible reduction in angiographic restenosis and a significant reduction in the need for repeated coronary interventions. Therefore, a randomized clinical trial seems appropriate to test the validity of this approach.

Journal of the American College of Cardiology, 32:2:329-337

Remodeling after directional coronary atherectomy (with and without adjunct percutaneous transluminal coronary angioplasty): a serial angiographic and intravascular ultrasound analysis from the optimal atherectomy restenosis study

Alexandra J. Lansky, Gary S. Mintz, Jeffrey J. Popma, Augusto D. Pichard, Kenneth M. Kent, Lowell F. Satler, Donald S. Baim, Richard E. Kuntz, Charles Simonton, Robert M. Bersin, Tomaki Hinohara, Peter J. Fitzgerald, Martin B. Leon

Objectives. The intravascular ultrasound (IVUS) substudy of OARS (Optimal Atherectomy Restenosis Study) was designed to assess the mechanisms of restenosis after directional coronary atherectomy (DCA).
Background. Recent serial IVUS studies have indicated that late lumen loss after interventional procedures was determined primarily by the direction and magnitude of arterial remodeling, not by cellular proliferation.
Methods. Complete quantitative coronary angiography (QCA) and IVUS were obtained in 104 patients before and after intervention and during follow-up. All studies were performed after administration of 200 g of intracoronary nitroglycerin. Angiographic measurements included minimum lumen diameter (MLD), interpolated reference diameter and diameter stenosis (DS). Intravascular ultrasound measurements included lesion and reference external elastic membrane (EEM), lumen and plaque+media cross-sectional area (CSA). The axial location of the lesion site was at the smallest follow-up lumen CSA; the reference segment was the most normal-looking cross section within 10 mm proximal to the lesion but distal to any major side branch. Results are reported as mean ± one standard deviation.
Results. The QCA reference decreased from 3.51 ± 0.46 mm to 3.22 ± 0.44 mm; the MLD decreased from 3.22 ± 0.47 mm to 2.03 ± 0.72 mm; and the DS increased from 8 ± 10% to 38 ± 20%. On IVUS, the decrease in lumen CSA (from 8.8 ± 2.5 mm2 to 5.5 ± 4.0 mm2) was associated with a significant decrease in EEM (from 19.7 ± 5.6 mm2 to 16.9 ± 6.2 mm2); there was no significant increase in P+M (from 10.9 ± 4.2 mm2 to 11.3 ± 3.9 mm2). A change in lumen correlated with a change in EEM ($r = 0.790$, $p < 0.0001$), not with a change in P+M ($r = 0.133$, $p = 0.2258$). A decrease in reference EEM (from 19.1 ± 7.7 mm2 to 17.6 ± 8.0 mm2) also correlated with a decrease in lesion EEM ($r = 0.665$, $p < 0.0001$). Results in restenotic lesions were similar.
Conclusion. Restenosis after optimal DCA is caused primarily by a decrease in EEM CSA that extends into contiguous reference segments.

The American Journal of Cardiology, 81:5:552-557

Comparative Early and Nine-Month Results of Rotational Atherectomy, Stents, and the Combination of Both for Calcified Lesions in Large Coronary Arteries

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The aim of this study was to determine the preferred treatment modality for calcified lesions in large (≥3 mm)

coronary arteries, resulting in the largest lumen dimensions and the most favorable late clinical responses. Three hundred six lesions in 306 patients (223 men, mean age 66 ± 11 years) were treated with either rotational atherectomy plus adjunct balloon angioplasty (n = 147), Palmaz-Schatz stents (n = 103), or a combination of rotational atherectomy plus adjunct Palmaz-Schatz stents (n = 56). The procedural success rate was 98.0% to 98.6% for each treatment modality. Minimal lumen diameter (MLD) before therapy was similar for all therapies. Final MLD after combination of rotational atherectomy plus Palmaz-Schatz stents was larger than after stent therapy or rotational atherectomy plus balloon angioplasty (3.21 ± 0.49 mm, 2.88 ± 0.51 mm, and 2.29 ± 0.55 mm, respectively, p <0.0001). Correspondingly, final percent diameter stenosis was lowest after the combination of rotational atherectomy plus stent therapy, and significantly higher for stents or rotational atherectomy plus balloon angioplasty (4.2 ± 15.3%, 14.1 ± 13.3%, and 26.7% ± 16.9%, respectively, p <0.0001). Event-free survival at 9 months was higher for patients treated with the combination of rotational atherectomy plus stents than either stent therapy or rotational atherectomy alone (85%, 77%, and 67%, respectively, log-rank p = 0.0633). The only significant independent predictor of an event during the 9-month follow-up period was the MLD after intervention (odds ratio 0.495, 95% confidence interval 0.308 to 0.796, p = 0.0037). We conclude that preatheroablation using rotational atherectomy, followed by adjunct stent placement for calcified lesions in large arteries, is associated with infrequent complications, the largest acute angiographic results, and the most favorable late clinical event rates.

Circulation 1998 ;97: 332-339.

?ptimal?Directional Coronary Atherectomy : Final Results of the Optimal Atherectomy Restenosis Study (OARS)

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Background-Previous clinical trials of directional coronary atherectomy (DCA) have failed to show significant improvement in early or late outcomes compared with balloon angioplasty (PTCA). The present study tested the hypothesis that more aggressive “optimal” atherectomy could be performed safely to produce larger initial lumen diameters and a lower late restenosis rate.

Methods and Results-The present study was a prospective multicenter registry of consecutive patients undergoing optimal DCA of de novo or restenotic lesions in 3.0- to 4.5-mm native coronary arteries. Optimal DCA was defined as using a 7F atherectomy device and adjunctive PTCA if necessary to achieve a <15% residual stenosis. Six-month angiographic and 1-year clinical follow-up was planned in all patients. A total of

199 patients with 213 lesions met eligibility criteria for enrollment. Short-term procedural success was achieved in 97.5%, with a major complication rate (death, emergency bypass surgery, or Q-wave myocardial infarction [MI]) of 2.5%. There were no early deaths. Non-Q-wave MI (CK-MB >3 times normal) occurred in 14% of patients. Mean reference vessel diameter was 3.28 mm. Mean diameter stenosis was reduced from 63.5% to a final stenosis of 7%. Late 1-year clinical follow-up revealed one cardiac death and a target lesion revascularization rate of 17.8%. The angiographic restenosis rate at 6 months was 28.9%, with the major predictor of restenosis being a smaller postprocedure lumen diameter.
Conclusions-Optimal DCA produced a low residual percent diameter stenosis and a lower restenosis rate than seen in previous trials without an increase in early or late major adverse events.

Journal of the American College of Cardiology, 1998;32:1855-1860

Adjunctive stent implantation following directional coronary atherectomy in patients with coronary artery disease

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Objectives.
This prospective case-control study evaluated the acute and long-term results of stent implantation preceded by debulking of the plaque by means of directional coronary atherectomy.
Background. In comparison with balloon angioplasty, intracoronary stenting produces a larger luminal diameter, maintains artery patency and reduces the incidence of restenosis. Optimal stent deployment is a pivotal factor for achieving the best results, but the bulk of the atherosclerotic plaque opposes stent expansion and may limit the success of the procedure. Debulking of the plaque may provide a better milieu for optimal stent deployment.
Methods.
Directional coronary atherectomy followed by a single Palmaz-Schatz stent implantation was attempted in 100 patients. The successes, complications and angiographic results of the combined procedure were evaluated both acutely and during follow-up. Matched patients undergoing successful Palmaz-Schatz stent implantation alone during the same period served as controls.
Results. Atherectomy followed by stent implantation was performed in 94 patients with 98 lesions;

periprocedural complications were observed in four cases. The stenosis diameter decreased from 76 ± 9% at baseline to 30 ± 13% after atherectomy ($p < 0.0001$), and 5 ± 9% after stent implantation ($p < 0.0001$); it increased to 27 ± 15% at 6-month angiography ($p < 0.0001$). During the 14 ± 10 months of follow-up, none of the patients died or experienced myocardial infarction, but three patients underwent target lesion revascularization. The patients undergoing stent implantation alone achieved smaller acute gains, tended to have a higher late lumen loss, had a higher restenosis rate (30.5% vs. 6.8%, $p < 0.0001$) and showed a greater incidence of clinical events during follow-up ($p < 0.0001$).

Conclusions.

Debulking atherosclerotic lesions by means of directional coronary atherectomy before stent implantation is a safe procedure with a high success rate and a low incidence of restenosis at follow-up.

The American Journal of Cardiology, 1998;82:11:1345-1351

Directional coronary atherectomy for the treatment of Palmaz-Schatz in-stent restenosis

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Management of in-stent restenosis has become a significant challenge in interventional cardiology. The results of balloon angioplasty have been disappointing due to the high recurrence of restenosis at follow-up. Debulking of the restenotic tissue within the stents using directional coronary atherectomy (DCA) may offer a therapeutic advantage. We report the immediate clinical and angiographic outcomes and long-term clinical follow-up results of 45 patients (46 lesions), mean age 63 ± 12 years, 73% men, with a mean reference diameter of 2.9 ± 0.6 mm, treated with DCA for symptomatic Palmaz-Schatz in-stent restenosis. DCA was performed successfully in all 46 lesions and resulted in a postprocedural minimal luminal diameter of 2.7 ± 0.7 mm and a residual diameter stenosis of 17 ± 10%. There were no in-hospital deaths, Q-wave myocardial infarctions, or emergency coronary artery bypass surgeries. Four patients (9%) suffered a non-Q-wave myocardial infarction. Target lesion revascularization was 28.3% at a mean follow-up of 10 ± 4.6 months. Kaplan-Meier event-free survival (freedom from death, myocardial infarction, and repeat target lesion revascularization) was 71.2% and 64.7% at 6 and 12 months after DCA, respectively. Thus, DCA is safe and efficacious for the treatment of Palmaz-Schatz in-stent restenosis. It results in a large postprocedural minimal luminal diameter and a low rate of both target lesion revascularization and combined major clinical events at

follow-up.

J Am Coll Cardiol 1999 Oct;34(4):1050-7

Final results of the STent versus directional coronary Atherectomy Randomized Trial.

Tsuchikane E, Sumitsuji S, Awata N, Nakamura T, Kobayashi T, Izumi M, Otsuji S, Tateyama H, Sakurai M, Kobayashi T

OBJECTIVES: This study was designed to compare primary stenting with optimal directional coronary atherectomy (DCA). BACKGROUND: No previous prospective randomized trial comparing stenting and DCA has been performed. METHODS: One hundred and twenty-two lesions suitable for both Palmaz-Schatz stenting and DCA were randomly assigned to stent (62 lesions) or DCA (60 lesions) arm. Single or multiple stents were implanted with high-pressure dilation in the stent arm. Aggressive debulking using intravascular ultrasound (IVUS) was performed in the DCA arm. Serial quantitative angiography and IVUS were performed preprocedure, postprocedure and at six months. The primary end point was restenosis, defined as > or =50% diameter stenosis at six months. Clinical event rates at one year were also assessed. RESULTS: Baseline characteristics were similar. Procedural success was achieved in all lesions. Although the postprocedural lumen diameter was similar (2.79 vs. 2.90 mm, stent vs. DCA), the follow-up lumen diameter was significantly smaller (1.89 vs. 2.18 mm; p = 0.023) in the stent arm. The IVUS revealed that intimal proliferation was significantly larger in the stent arm than in the DCA arm (3.1 vs. 1.1 mm ; p < 0.0001), which accounted for the significantly smaller follow-up lumen area of the stent arm (5.3 vs. 7.0 mm2; p = 0.030). Restenosis was significantly lower (32.8% vs. 15.8%; p = 0.032), and target vessel failure at one year tended to be lower in the DCA arm (33.9% vs. 18.3%; p = 0.056). CONCLUSIONS: These results suggest that aggressive DCA may provide superior angiographic and clinical outcomes to primary stenting.

Summary

J Am Coll Cardiol 1999 Oct;34(4):1028-35

Effects of adjunctive balloon angioplasty after intravascular ultrasound-guided optimal directional coronary atherectomy: the result of Adjunctive Balloon Angioplasty After Coronary Atherectomy Study (ABACAS).

Suzuki T, Hosokawa H, Katoh O, Fujita T, Ueno K, Takase S, Fujii K, Tamai H, Aizawa T, Yamaguchi T, Kurogane H, Kijima M, Oda H, Tsuchikane E, Hinohara T, Fitzgerald PJ

OBJECTIVES: This study was conducted to evaluate: 1) the effect of adjunctive percutaneous transluminal coronary angioplasty (PTCA) after directional coronary atherectomy (DCA) compared with stand-alone DCA, and 2) the outcome of intravascular ultrasound (IVUS)-guided aggressive DCA. BACKGROUND: It has been shown that optimal angiographic results after coronary interventions are associated with a lower incidence ofrestenosis. Adjunctive PTCA after DCA improves the acute angiographic outcome; however, long-term benefits of adjunctive PTCA have not been established. METHODS: Out of 225 patients who underwent IVUS-guided DCA, angiographically optimal debulking was achieved in 214 patients, then theywere randomized to either no further treatment or to added PTCA. RESULTS: Postprocedural quantitative angiographic analysis demonstrated an improved minimum luminal diameter (2.88 +/- 0.48 vs. 2.6 +/- 0.51 mm; p = 0.006) and a less residual stenosis (10.8% vs.15%; p = 0.009) in the adjunctive PTCA group. Quantitative ultrasound analysis showed a larger minimum luminal diameter (3.26 +/- 0.48 vs. 3.04 +/- 0.5 mm; p < 0.001) and lower residual plaque mass in the adjunctive PTCA group (42.6% vs. 45.6%; p < 0.001). Despite the improved acute findings in the adjunctive PTCA group, six-month angiographic and clinical results were not different. The restenosis rate (adjunctive PTCA 23.6%, DCA alone 19.6%; p = ns) and target lesion revascularization rate (20.6% vs. 15.2%; p = ns) did not differ between the groups. CONCLUSIONS: With IVUS guidance, aggressive DCA can safely achieve optimal angiographic results with low residual plaque mass, and this was associated with a low restenosis rate. Although adjunctive PTCA after optimal DCA improved the acute quantitative coronary angiography and quantitative coronary ultrasonography outcomes, its benefit was not maintained at six months.

Am J Cardiol 1999 Jul 15;84(2):141-6

Coronary artery restenosis after atherectomy is primarily due to negative remodeling.

Meine TJ, Bauman RP, Yock PG, Rembert JC, Greenfield JC Jr

The primary cause of restenosis following directional coronary atherectomy (DCA) remains obscure. “Negative remodeling,” a decrease in vessel area, is believed to be more causative than is increase in plaque area. The DCA technique used in these patients, designed to facilitate the removal of plaque, should allow a more precise evaluation of the relative roles of these two mechanisms. Twenty-five patients underwent DCA. In 17, complete angiographic and intravascular ultrasound (IVUS) images were obtained before and after DCA and at follow-up (6 to 9 months). Internal elastic lamina (IEL), lumen, and plaque areas were calculated at preatherectomy, postatherectomy, and follow-up. Postatherectomy, the mean IEL area increased by 32% and the mean plaque area decreased by 51%, resulting in a significant mean increase in lumen area, 500%. At follow-up when compared to postatherectomy, the change in IEL area was variable; however, the mean did not change significantly ($p = 0.58$). Plaque area change, when standardized for initial vessel size, was small (mean increase 2.8 +/- 3.5%). The mean lumen area did not decrease significantly at follow-up ($p = 0.43$). A highly significant correlation ($r = 0.96$) was noted between IEL area change and lumen area at follow-up. In contrast, the correlation between plaque area change and lumen area change over the same period was much less significant ($r = 0.64$). These data indicate that decrease in IEL area primarily is responsible for restenosis.

*Statistical significance from preatherectomy values

+Statistical significance from postatherectomy

Summary

Am J Cardiol 1999 ;83:1611-6

Comparative analysis of early and late angiographic outcomes using two quantitative algorithms in the Balloon versus Optimal Atherectomy Trial (BOAT).

Lansky AJ, Popma JJ, Cutlip D, Ho KK, Abizaid AS, Saucedo J, Zhang Y, Senerchia C, Kuntz RE, Leon MB, Baim DS

Although substantial intersystem variability has been shown among several commercially available quantitative angiographic (QA) analysis algorithms, no previous study has compared the angiographic

findings using 2 different QA systems performed at the same central angiographic laboratory. The purpose of this study was to compare the early and late QA results obtained with the CMS (MEDIS) and ARTREK (ImageComm) QA systems in the Balloon versus Optimal Atherectomy Trial. Directional atherectomy (n = 496) or balloon angioplasty (n = 490) was performed in 986 patients; late QA follow-up was available in 767 patients (77.7%). QA analysis was performed by 2 independent observers using the CMS and ARTREK systems. Correlation between the 2 QA systems for baseline measurements was good (Pearson's R = 0.78), although the CMS system resulted in larger baseline reference diameter (RD) (3.22 +/- 0.45 vs 3.07 +/- 0.40 mm; p <0.0001) and baseline minimal lumen diameters (MLD) (1.05 +/- 0.35 vs 0.92 +/- 0.32; mm p <0.0001) than the ARTREK system. The final and follow-up RD (+0.17 and +0.11 mm, respectively) were also larger using the CMS system. In contrast, the final and follow-up measurements of MLD and percent diameter stenosis were not significantly different using the 2 QA systems. The QA system did not affect the ability to detect a difference in restenosis rates (>50% follow-up diameter stenosis) between the 2 treatment groups (CMS, directional atherectomy [31.8%]; balloon angioplasty [40.5%]; p = 0.013 and ARTREK, directional atherectomy [33.9%], balloon angioplasty [41.3%]; p = 0.036). Only lesion irregularity contributed to the difference in baseline measurements of MLD and percent diameter stenosis. We conclude that important differences in measurements of RD, baseline MLD, and percent diameter stenosis were noted using the CMS and ARTREK systems. Both systems, however, were able to detect a treatment benefit associated with directional atherectomy in BOAT. The comparability of other angiographic systems will require similar evaluation in other studies.

Summary

1. Correlation between the 2 QA systems for baseline measurements was good (Pearson's R = 0.78).
2. The CMS system resulted in larger baseline reference diameter (RD) (3.22 +/- 0.45 vs 3.07 +/- 0.40 mm; p <0.0001) and baseline minimal lumen diameters (MLD) (1.05 +/- 0.35 vs 0.92 +/- 0.32; mm p <0.0001) than the ARTREK system.
3. The final and follow-up measurements of MLD and percent diameter stenosis were not significantly different using the 2 QA systems.
4. The QA system did not affect the ability to detect a difference in restenosis rates. Only lesion irregularity contributed to the difference in baseline measurements of MLD and percent diameter stenosis.

Am J Cardiol 1999 ;83(11):1518-23

Intravascular ultrasound assessment of the relation between early and late changes in arterial area and neointimal hyperplasia after percutaneous transluminal coronary angioplasty and directional coronary atherectomy.

Mintz GS, Kimura T, Nobuyoshi M, Leon MB

Previous serial intravascular ultrasound (IVUS) analysis after percutaneous transluminal coronary angioplasty or directional coronary atherectomy showed (1) early (within 1 month) increase in arterial area, (2) late (1- to 6-month) decrease in arterial area, and (3) an increase in plaque area from immediately to 6 months after intervention. To further understand these findings, we used serial IVUS to study the relations between changes in arterial and plaque area during the follow-up period after coronary intervention. Serial IVUS was performed before intervention and immediately, 24 hours, 1 month, and 6 months after percutaneous transluminal coronary angioplasty (n = 35) or directional coronary atherectomy (n = 26) in 57 patients. Arterial, lumen, and plaque areas were measured at the lesion site with the smallest preintervention and follow-up lumen areas at all time points. The increase in plaque area in the first month after intervention was accompanied by an equal or greater increase in arterial area ($r = 0.670$, $p < 0.0001$). There was a decrease in arterial area from 1 to 6 months after intervention, which correlated inversely with both the increase in plaque area ($r = 0.434$, $p < 0.0001$) or arterial area ($r = 0.515$, $p < 0.0001$) during the first month after intervention and directly with the 1- to 6-month increase in plaque area ($r = 0.460$, $p < 0.0001$). Comparison of the late (1 to 6 months) and early (within 1 month) delta arterial versus delta plaque area regression lines suggested that the late decrease in arterial area was superimposed on the relation between delta arterial area and delta plaque area. These relations were especially strong in restenotic (vs nonrestenotic) lesions. The early increase and late decrease in stenosis arterial area and neointimal hyperplasia appear to be interrelated, especially in restenotic stenoses.

Summary

Circulation 2000 ;101: 1512-1518.

Carvedilol for Prevention of Restenosis After Directional Coronary Atherectomy : Final Results of the European Carvedilol Atherectomy Restenosis (EUROCARE) Trial

Patrick W. Serruys, David P. Foley, Berthold Hofling, Jacques Puel, Helmut D. Glogar, Ricardo Seabra-Gomes, Javier Goicolea, Pierre Coste, Wolfgang Rutsch, Hugo Katus, Hans Bonnier, William Wijns, Amadeo Betriu, Ulrike Hauf-Zachariou, Eline Montauban van Swijndregt, Rein Melkert, and Rudiger Simon

Background-In addition to its known properties as a competitive, nonselective ß and α-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±2 weeks after the procedure. Of 406 randomized patients, 377 underwent attempted atherectomy, and in 324 (88.9%), a ≤50% diameter stenosis was achieved without the use of a stent. Evaluable follow-up angiography was available in 292 eligible patients (90%). No differences in minimal luminal diameter (1.99±0.73 mm versus 2.00±0.74 mm), angiographic restenosis rate (23.4% versus 23.9%), target lesion revascularization (16.2 versus 14.5), or event-free survival (79.2% versus 79.7%) between the placebo and carvedilol groups were observed at 7 months.

Conclusions-The maximum recommended daily dose of the antioxidant and ß-blocker carvedilol failed to reduce restenosis after successful atherectomy. These findings are in contrast to those of the Multivitamins and Probucol 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.

JACC 2000;36:1853-9

A synergistic approach to optimal stenting : Directional coronary atherectomy prior to coronary artery stent implantation-the AtheroLink registry

Hans-Wilhelm Hopp, Frank Michael Baer, Cem Ozbek, Karl Heinz Kuck and Bruno Scheller for the AtheroLink Study Group

OBJECTIVES

The AtheroLink registry sought to observe the effect of plaque burden reduction by directional coronary atherectomy (DCA) prior to stenting on acute lesion minus rate, on the clinical success rate and on the

incidence of in-stent restenosis six months after intervention.

BACKGROUND

Although coronary stenting has reduced restenosis, its effect has been less favorable in complex lesions with a high plaque burden that results from suboptimal stent expansion. Therefore, plaque removal by DCA may improve the results of coronary stenting.

METHODS

A total of 167 patients with >60% stenosis in a native coronary artery of 2.8 to 4.0 mm in diameter were enrolled in 10 study centers on an intention-to-treat basis. All patients underwent DCA aimed at an optimal result (residual diameter stenosis <20%) followed by stenting. Angiographic follow-up was performed in 120 (71.8%) patients at 5.3 ± 2.8 months.

RESULTS

Lesion success was achieved in 164/167 (98.2%) patients, and the clinical success rate was 95.2% (159/167 patients). The overall restenosis rate in the 120 patients with angiographic follow-up was 10.8% (13/120). Incidence of restenosis was lower (8.4%) in patients with optimal stent deployment following DCA compared to patients with a persisting caliber reduction >15% (restenosis rate 15.3.%) and restenosis occurred with a significantly higher frequency ($p < 0.04$) in distal lesions (37.5%) compared to proximal stenoses (9.0%).

CONCLUSIONS

This observational multicenter registry points to a potential reduction in restenosis by a synergistic approach of DCA and stenting performed under routinely accessible angiographic guidance. Therefore, multicenter-based randomized clinical trials are clearly warranted to finally clarify the validity of this complex approach versus conventional angioplasty plus stenting.

The American Journal of Cardiology, 2000;85:5:563-567

Effectiveness of rotational atherectomy of right coronary artery ostial stenosis

Motwani, Joseph G. MD; Raymond, Russell E. DO; Franco, Irving MD; Ellis, Stephen G. MD; Whitlow, Patrick L. MD

Balloon angioplasty and stenting of right coronary ostial stenosis may frequently be impeded by lesion calcification, whereas rotational atherectomy, which ablates calcified plaque, should treat these lesions effectively. Accordingly, we evaluated procedural success and long-term clinical outcome of rotational

atherectomy of right coronary ostial stenosis. Procedural data were obtained from a comprehensive interventional registry and follow-up information was obtained by chart review and patient enquiry. All patients who developed recurrent angina underwent angiographic restudy. During a 5-year interval, 119 patients underwent rotational atherectomy of right coronary ostial stenosis. Multilesion interventions were performed in 55% of patients. Ostial lesions were 3.73 ± 3.69 mm in length (mean ± SD), and 57.1% were significantly calcified. Reference vessel diameter was 3.42 ± 0.56 mm. Maximum burr:artery ratio was 0.64 ± 0.1 with adjunct balloon angioplasty in 89.1% and adjunct stenting in 9.2%. Procedural success (<50% residual stenosis without major complication) was 97.5%, with 1.7% uncomplicated failure and 0.8% Q-wave infarction. Maximum residual stenosis was 15 ± 17%. During 6-month follow-up, available in 94% of patients, 82.7% remained angina-free, 10.9% developed recurrent angina due to right coronary ostial restenosis, and 6.4% developed recurrent angina due to another lesion. Two years after intervention, target lesion revascularization rate was 16%. Predictors of symptomatic angiographic restenosis were dissection > 10 mm, final minimal luminal diameter <2.5 mm, lesion length > 10 mm, restenotic lesion, and diabetes. We conclude that rotational atherectomy of right coronary ostial stenosis results in excellent acute procedural success and in low incidence of clinical recurrence, with a high proportion of patients remaining angina-free 2 years after intervention.

Summary

FIGURE 3. Long-term freedom from target lesion revascularization

TABLE III Determinants of Symptomatic Angiographic Restenosis of Right Coronary Ostial Lesions Following Rotational Atherectomy

The American Journal of Cardiology, 2000;86:1:88-91

Effectiveness of rotational atherectomy in aortocoronary saphenous vein grafts

William J. Thomas , Michael J. Cowley , George W. Vetrovec , Walter Malloy and Evelyne Goudreau

Management of myocardial ischemia in patients with prior coronary artery bypass graft surgery currently remains a challenging issue. Saphenous vein graft (SVG) disease can be present in 30% to 45% of patients 5 years after surgery, and in patients with recurrent symptoms at 10 years, >80% have developed obstructive disease in the grafts or ungrafted native vessels. Reoperation is associated with an increased (two- to fourfold) risk of periprocedural death and myocardial infarction. Percutaneous revascularization in patients after bypass

surgery continues to be a difficult problem. Contributing factors to reduced success include a marked size transition at the distal graft anastomosis, especially in native vessels <3 mm, making appropriate device sizing difficult. In addition, excessive recoil at ostial and distal anastomotic sites as well as small, calcified, diffuse native vessel disease beyond the graft may also limit the effectiveness of balloon angioplasty. Rotational atherectomy offers potential advantages in these settings. However, the safety and efficacy of rotational atherectomy in or through SVGs is not known. The present study reports our experience with this technique involving SVG anastomotic lesions and distal native disease beyond SVGs.

Rotational atherectomy in this experience was used primarily to treat anastomotic sites (aorto-ostial and distal), and restenotic or fibrotic undilatable lesions, situations for which rotablation and debulking may be particularly useful. Rotational atherectomy may be particularly attractive for smaller vessels with those morphologic features.

The American Journal of Cardiology, 2000;86:1:86-88

Effectiveness of rotational atherectomy in narrowed left internal mammary artery grafts to the left anterior descending coronary artery

William J. Thomas, Michael J. Cowley, George W. Vetrovec, Walter Malloy and Evelyne Goudreau

Over the last 20 years, internal mammary artery (IMA) grafts have been increasingly used as an alternative to saphenous vein grafts for surgical treatment of coronary artery disease. Long-term studies have shown high patency rates associated with improved patient survival. However, recurrence of ischemia after coronary artery bypass surgery has been associated with development of IMA graft stenosis as well as progression of coronary disease of the native vessels beyond the graft insertion. Serial studies have documented the feasibility of percutaneous interventions of these lesions with a high success rate and low restenosis rate. Unsatisfactory results are occasionally obtained secondary to unfavorable lesion characteristics, such as rigid, fibrotic lesions of the graft anastomotic site or of the native distal vessels. Rotational atherectomy offers potential advantages in this setting. The present study addresses the safety and effectiveness of rotational atherectomy for treatment of lesions involving the IMA. In conclusion, rotational atherectomy is feasible and appears to be an effective treatment in selected patients who have IMA insertion lesions or disease beyond the graft insertion.

The American Journal of Cardiology, 2000;86:9:923-926

Assessing a strategy of initial stand-alone extractional atherectomy followed by staged stent placement in degenerated saphenous vein graft lesions

Javed M. Ahmed, Mun K. Hong , Roxana Mehran , Augusto D. Pichard, Lowell F. Satler, Kenneth M. Kent , Gary S. Mintz , Hongsheng Wu and Martin B. Leon

To assess whether a staged strategy (initial stand alone transluminal extraction atherectomy and coumadin therapy followed by stenting six weeks later) could reduce ischemic complications in degenerated saphenous vein graft (SVG) interventions, we studied 72 patients undergoing percutaneous interventions of degenerated SVG. Patients were divided into two groups; 28 were treated with a staged strategy (group I) and 44 with similar lesion characteristics were treated with a definitive initial procedure with transluminal extraction atherectomy ± adjunctive balloon angioplasty and stenting (group II). Procedural success, major in-hospital complications (death, Q-wave myocardial infarction, and emergent coronary bypass surgery), and incidence of distal embolization were compared between the 2 groups. Procedural success was lower (92% vs 100%, P = 0.14) and major in-hospital complications were higher (0% vs 11%, P = 0.14) in group II. Distal embolization occurred in 11% of the patients in group I compared with 23% of the patients in group II (p = 0.19). At 6 week follow-up (group I), 9 patients (33%) had negative symptoms, 11 (41%) underwent stent implantation, 3 (11%) did not require any further therapy (without significant stenosis), and 4 (14%) had total occlusions. We therefore conclude that this staged strategy in degenerated SVG appears to reduce distal embolization but most importantly avoids major in-hospital complications, including any deaths either at the time of initial procedure or during the 6-week follow-up period.

Summary

TABLE 3 Procedural Complications and In-Hospital Outcome

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±10% versus 76±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=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.

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17. Carvedilol for Prevention of Restenosis After Directional Coronary Atherectomy : Final Results of the European Carvedilol Atherectomy Restenosis (EUROCARE) Trial

Patrick W. Serruys, David P. Foley, Berthold Hofling, Jacques Puel, Helmut D. Glogar, Ricardo Seabra-Gomes, Javier Goicolea, Pierre Coste, Wolfgang Rutsch, Hugo Katus, Hans Bonnier, William Wijns, Amadeo Betriu, Ulrike Hauf-Zachariou, Eline Montauban van Swijndregt, Rein

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Circulation 2000 101: 1512-1518.

18. A synergistic approach to optimal stenting : Directional coronary atherectomy prior to coronary artery stent implantation-the AtheroLink registry

Hans-Wilhelm Hopp, Frank Michael Baer, Cem Ozbek, Karl Heinz Kuck and Bruno Scheller for the AtheroLink Study Group

JACC 2000;36:1853-9

19. Effectiveness of rotational atherectomy of right coronary artery ostial stenosis

Motwani, Joseph G. MD; Raymond, Russell E. DO; Franco, Irving MD; Ellis, Stephen G. MD; Whitlow, Patrick L. MD

The American Journal of Cardiology, 2000;85:5:563-567

20. Effectiveness of rotational atherectomy in aortocoronary saphenous vein grafts

William J. Thomas a, Michael J. Cowley a, George W. Vetrovec a, Walter Malloy a and Evelyne Goudreau aA

The American Journal of Cardiology, 2000;86:1:88-91

21. Effectiveness of rotational atherectomy in narrowed left internal mammary artery grafts to the left anterior descending coronary artery

William J. Thomas a, Michael J. Cowley a, George W. Vetrovec a, Walter Malloy a and Evelyne Goudreau aA

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The American Journal of Cardiology, 2000;86:1:86-88

22. The American Journal of Cardiology, 2000;86:9:923-926

Assessing a strategy of initial stand-alone extractional atherectomy followed by staged stent placement in degenerated saphenous vein graft lesions

Javed M. Ahmed a, Mun K. Hong bA, Roxana Mehran c, Augusto D. Pichard a, Lowell F. Satler a, Kenneth M. Kent a, Gary S. Mintz a, Hongsheng Wu a and Martin B. Leon c

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23. 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

Circulation 2000 101: 2484 - 2489