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Meta-analysis of randomized trials of percutaneous transluminal coronary angioplasty versus atherectomy, cutting balloon atherotomy, or laser angioplasty
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OBJECTIVES: We conducted a systematic overview (meta-analysis) of randomized trials of balloon angioplasty versus coronary atherectomy, laser angioplasty, or cutting balloon atherotomy to evaluate the effects of plaque modification during percutaneous coronary intervention. BACKGROUND: Several mechanical approaches have been developed that ablate or section atheromatous plaque during percutaneous coronary interventions to optimize acute results, minimize intimal injury, and reduce complications and restenosis. METHODS: Sixteen trials (9,222 patients) constitute the randomized controlled experience with atherectomy, laser, or atherotomy versus balloon angioplasty with or without coronary stenting. Each trial tested the hypothesis that ablative therapy would result in better clinical or angiographic results than balloon dilation alone. RESULTS: Short-term death rates (<31 days) were not improved by the use of ablative procedures (0.3% vs. 0.4%, odds ratio [OR] 0.94 [95% confidence interval 0.46 to 1.92]), but periprocedural myocardial infarctions (4.4% vs. 2.5%, OR 1.83 [95% CI 1.43 to 2.34]) and major adverse cardiac events (5.1% vs. 3.3%, OR 1.54 [95% CI 1.25 to 1.89]) were increased. Angiographic restenosis rates (6,958 patients) were not improved with the ablative devices (38.9% vs. 37.4%, OR 1.06 [95% CI 0.97 to 1.17]). No reduction in revascularization rates (25.2% vs. 24.5%, OR 1.04 [95% CI 0.94 to 1.14]) or cumulative adverse cardiac events rates up to one year after treatment were seen with ablative devices (27.8% vs. 26.1%, OR 1.09 [95% CI 0.99 to 1.20]). CONCLUSIONS: The combined experience from randomized trials suggests that ablative devices failed to achieve predefined clinical and angiographic outcomes. This meta-analysis does not support the hypothesis that routine ablation or sectioning of atheromatous tissue is beneficial during percutaneous coronary interventions.
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Catheter Cardiovasc Interv (2005);64:45-52
Directional coronary atherectomy plus stent implantation vs. left internal mammary artery bypass grafting for isolated proximal stenosis of the left anterior descending coronary artery
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The aim of this study was to compare the short- (< 30 days) and long-term (>/= 30 days) clinical outcomes of left internal mammary artery bypass grafting (LIMA-LAD) and directional coronary atherectomy plus stent implantation (DCA + stent) in the treatment of isolated proximal left anterior descending coronary (LAD) lesions. One hundred and twenty-six patients underwent LIMA-LAD and 132 consecutive patients underwent DCA + stenting. The primary endpoint was the incidence of short- and long-term major adverse cardiac events (MACE); the secondary endpoints included any periprocedural events and long-term target vessel revascularization (TVR). We found no significant between-treatment difference in the occurrence of short-term MACE, and the long-term

MACE rate per 100 person-years was 3.0 in the LIMA-LAD group and 4.6 in the DCA + stent group. After 5-year follow-up, 79% of the patients in the DCA + stent group and 89% of those in the LIMA-LAD group were still MACE-free. The risk of any periprocedural events was six times lower in the DCA + stent group, and the risk of TVR was six times higher. We conclude that both procedures lead to good short- and long-term follow-up results in isolated proximal LAD disease. As fewer periprocedural events and more TVRs occur after DCA + stenting than after LIMA-LAD, they can be considered valuable alternatives to each other. Catheter Cardiovasc Interv 2005;64:45-52. (c) 2004 Wiley-Liss, Inc.
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Catheter Cardiovasc Interv (2004);62:308-17
Initial experience with the novel 6 Fr-compatible system for debulking de novo coronary arterial lesions
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The purpose of this study was to determine the efficacy of a novel system for debulking of de novo native coronary arterial lesions. The Helixciser De Novo system is a novel 6 Fr-compatible catheter with a cutter encased in a slotted-orifice housing to excise atheromatous plaque. The cutter rotates at 15,000 rpm, debulking the plaque as it tracks through the lesion over a straight wire or a self-expanding nitinol helical-shaped wire. The tissue is aspirated via an Archimedes screw pump to vacuum collection chamber. The device was evaluated in a porcine toxic coronary stent model of chronic occlusion and in five patients with focal de novo native coronary arterial lesions. Procedural variables along with outcomes were reviewed. Quantitative angiography (QCA) and volumetric intravascular ultrasound (IVUS) analysis were performed. In a porcine model of chronic occlusion, QCA demonstrated pretreatment minimal lumen diameter (MLD) increased from 0.77 +/- 0.59 to 1.88 +/- 0.25 mm postdebulking. IVUS analysis demonstrated pretreatment lumen volume (LV) increased from 15.8 +/- 22.2 to 46.4 +/- 28.9 mm(3) postdebulking. In human clinical feasibility cases, QCA demonstrated pretreatment MLD increased from 0.96 +/- 0.40 to 2.04 +/- 0.19 mm postdebulking. IVUS analysis demonstrated pretreatment LV increased from 38.40 +/- 12.78 to 52.05 +/- 15.68 mm(3) postdebulking. Preliminary results document the feasibility of Helixcision De Novo for treatment of focal de novo native coronary arterial lesions. Quantitative angiographic and IVUS analysis indicate that this system can effectively debulk plaque from selected noncalcified atherosclerotic lesions and thus may represent an alternative treatment strategy for coronary artery disease.
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Catheter Cardiovasc Interv (2004);61:35-43
Early experience with a novel plaque excision system for the treatment of complex coronary lesions
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The use of directional coronary atherectomy (DCA) in current practice has been limited. The SilverHawk System is a newly developed plaque excision device that aims to overcome the drawbacks of prior DCA platforms. The device was evaluated in a porcine coronary model and in a series of patients. Procedural variables along with outcomes were reviewed. Quantitative angiography (QCA) was performed and excised tissue fragments were weighed and examined histologically. In porcine cases, pretreatment MLD increased from 0.51 +/- 0.26 to 2.36 +/- 0.59 mm postdebulking and 19.9 +/- 7.6 mg of tissue was retrieved. In human cases, pretreatment MLD increased from 0.8 +/- 0.4 to 2.2 +/- 0.5 mm postdebulking and 15.2 +/- 7.8 mg of tissue was retrieved without complications. These data show that the SilverHawk System may offer significant utility in treating a wide variety of complex coronary lesions.
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Quantitative angiographic and intravascular ultrasound study >5 years after directional coronary atherectomy
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Aggressive and optimal directional coronary atherectomy (DCA) using intravascular ultrasound (IVUS) guidance provides favorable outcomes within 1 year. However, no previous data are available on the changes that occur in target lesions for the long term after stand-alone DCA. This study's aim evaluates, using quantitative angiography and intravascular ultrasonography, the natural history of changes that occur in target lesions between short- (about 6 months) and long-term (>5 years) follow-up angiography after stand-alone DCA. Of 186 patients (221 lesions) with successful stand-alone DCA, 48 patients (53 lesions) underwent revascularization within 6 months, and 14 patients subsequently died, leaving a study population of 124 patients (154 lesions). Complete quantitative coronary angiography (QCA) was obtained in 91 patients (101 lesions) and complete serial IVUS assessment was obtained for 38 lesions before and after intervention and during follow-up. From short- to long-term follow-up angiography, the minimal luminal diameter significantly increased (from 2.12 to 2.56 mm; p <0.0001); lesion subgroups with >30% diameter stenosis at short-term follow-up angiography showed significant late regression as asse

lesions
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Angiographic thrombus is associated with poorer procedural and clinical outcomes. We report our experience with the X-Sizer thrombectomy device (EndiCOR Medical) from March 2001 to December 2002. Indications for use in 44 patients (33 male; mean age, 60) included myocardial infarction (27), unstable angina (6), periprocedural thrombosis (2), acute (< 24 hr) stent thrombosis (1), and subacute (> 24 hr) stent thrombosis (8). Three cases involved vein grafts. Deployment was successful in 42/44. Difficulty traversing the stent occurred in 5/9 cases of in-stent thrombosis. Median TIMI flow increased from 1 to 2 (P = 0.01) postthrombectomy. Median final TIMI flow was 3. Complications included dissection (1), perforation, device jam on stent (1), disruption of a covered stent (1), distal macro-embolization (4), and transient no-reflow (5). The X-Sizer thrombectomy device improves TIMI flow but does not always prevent distal embolization. Care is needed when treating in-stent thrombosis.
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