

# Drug-Eluting Stents Compared With Bilateral Internal Thoracic Artery Grafts for Diabetic Patients

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**Background.** Diabetic patients with multivessel coronary artery disease who undergo coronary artery bypass grafting (CABG) or percutaneous coronary interventions (PCI) are at greater risk of late morbidity and mortality than nondiabetic patients. We questioned earlier comparisons of these two approaches that showed no differences in survival rates. This study compares drug-eluting stents (DES) and bilateral internal thoracic artery (BITA) grafting in diabetic patients with multivessel coronary artery disease.

**Methods.** All diabetic patients who underwent left-sided arterial revascularization with BITA grafting between January 2002 and May 2006 were evaluated. Their outcomes were compared with those of diabetic patients who underwent PCI with DES (Cypher). The Cox proportional hazards model defined predictors of outcome events after forcing propensity score with patients' characteristics into the model.

**Results.** The outcomes of 226 BITA patients were compared with those of 271 DES patients (mean fol-

low-up 62 months). The 5-year reintervention-free survival (Kaplan-Meier 86% versus 65%, log rank  $p = 0.000$ ) and major adverse cardiovascular events-free survival (81% versus 54%,  $p = 0.001$ ) were significantly better in the BITA group. Assignment to the PCI group was associated with decreased adjusted survival (hazard ratio 3.01, 95% confidence interval: 1.59 to 5.73,  $p = 0.000$ ) and increased risk of target vessel reinterventions (hazard ratio 7.00, 95% confidence interval: 3.1 to 15.70). The adjusted risk of major adverse cardiovascular events increased with the number of DES-treated vessels.

**Conclusions.** This is the first demonstration of significantly better long-term adjusted survival and outcomes of diabetic patients who underwent CABG with BITA grafting compared with diabetic patients who underwent PCI with DES.

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Coronary artery bypass grafting (CABG) of the left anterior descending (LAD) with the internal thoracic artery (ITA) in patients with multivessel coronary artery disease (CAD) is still the only proven method of improving their survival [1]. In the Bypass Angioplasty Revascularization Investigation (BARI) study and Arterial Revascularization Therapy Study (ARTS) trial, CABG incorporating ITA to LAD was associated with significantly better survival and reintervention-free survival in diabetic patients, when compared with percutaneous interventions (PCI) [2, 3].

Considerable reduction of restenosis and reintervention rates was reported in diabetic patients treated with drug-eluting stents (DES) [4]. A recent meta-analysis of data from 10 randomized trials confirmed a distinct survival advantage for CABG over PCI in diabetic patients. Five-year mortality for diabetic patients was 20% with PCI, compared with 12.3% with CABG (hazard ratio

[HR] 0.70, 95% confidence interval [CI]: 0.56 to 0.87) [5]. In the Synergy Between PCI With Taxus and Cardiac Surgery (SYNTAX) trial [6], the major adverse cardiovascular and cerebrovascular events rate at 1 year for the diabetic patients was twice as high with PCI using paclitaxel-eluting stents compared with CABG.

Bilateral internal thoracic artery (BITA) grafting is associated with improved survival and reduced occurrence of reintervention compared with single ITA and saphenous vein grafting [7]. Similar findings were recently observed by Lev Ran and colleagues [8] among diabetic patients. Those investigators reported that the 7-year survival and freedom from cardiac mortality and cardiac events were better in the BITA group, whereas occurrence of sternal infection was similar for the BITA and single ITA groups [8]. Skeletonized BITA grafting is our preferred method of myocardial revascularization for diabetic patients with multivessel CAD [8]. The purpose of this report is to compare long-term outcomes of BITA grafting with those of PCI incorporating DES in diabetic patients with multivessel CAD.

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**Abbreviations and Acronyms**

BITA	= bilateral internal thoracic artery
CABG	= coronary artery bypass graft surgery
CAD	= coronary artery disease
CI	= confidence interval
DES	= drug-eluting stent
HR	= hazard ratio
ITA	= internal thoracic artery
LAD	= left anterior descending artery
MACE	= major adverse cardiac events
MI	= myocardial infarction
PCI	= percutaneous coronary intervention
TVR	= target vessel revascularization

**Patients and Methods**

This retrospective review of the medical records and the use of a telephone questionnaire for obtaining follow-up information were approved by the Institutional Review Board of Tel Aviv Medical Center (informed consent was waived). Between January 2002 and April 2006, 542 consecutive diabetic patients with multivessel CAD underwent either left-sided (LAD and circumflex coronary systems) BITA grafting or PCI with Cypher stents (Cordis, Hialeah, FL). Twelve patients who lived abroad were not available for follow-up. Thirty-three additional patients could not be reached by telephone, but they were alive at the close of this study according to the National Registry database. Long-term follow-up data were available for the remaining 497 patients (226 CABG and 271 PCI), and they form the cohort for this report.

During the study period, selection criteria for CABG versus PCI were mainly technical and according to cardiologist and patient preferences. In principle, there was a preference to refer patients for surgery in cases of complex type C lesions (calcified coronary arteries, lesion length over 20 mm, twisted arteries, suspicion of a thrombus in an artery), bifurcation lesions involving a major diagonal or marginal branch, and chronic total occlusions that mandated revascularization.

Stent implantation in the PCI group was performed after balloon angioplasty dilation. All patients received aspirin (325 mg daily) before and after the procedure, as well as a loading dose of 300 mg to 600 mg clopidogrel (Plavix; Sanofi-Aventis US, Bridgewater, NJ) 1 day before the procedure and 75 mg daily after the procedure. The recommendation for the PCI patients was to continue clopidogrel treatment (75 mg daily) for 6 months after stent implantation. They all received intravenous heparin during the procedure. Intravenous platelet glycoprotein IIb/IIIa inhibitors (eptifibatide [Integrilin; Schering-Plough, Brussels, Belgium] or tirofiban [Aggrastat; Merck, Sharp and Dohme, Haarlam, Holland]) were used in only 6 PCI patients. All LAD lesions in the PCI group were treated with DES: one DES (Cypher) was used for the target vessel in 160 of them, and 111 patients received two or more Cyphers when necessary (ie, long lesion, coronary dissection, bifurcation lesion). Drug-eluting

stents, bare-metal stents, or plain balloon angioplasty were used for non-LAD lesions. One hundred and one patients were treated with two or more Cyphers. Bare-metal stents were used in 132 patients. Nine patients whose vessel diameter was less than 2.25 mm or had focal in-stent restenosis underwent balloon angioplasty.

Ninety-nine (43.8%) of the 226 surgically treated patients were operated on without extracorporeal circulation. All ITAs were harvested as skeletonized vessels and used preferentially for left-sided (LAD plus circumflex) revascularization. We used the right ITA either as an in-situ graft or as a free graft attached end-to-side to the left ITA (composite T-graft) [8].

Revascularization of the right coronary system (posterior descending artery or posterolateral branch of the right coronary artery) was performed with saphenous vein grafts in 97 patients (43%), with radial artery in 15 (6.6%), with the right ITA in 7 (the distal free end of a composite T-graft), and with the right gastroepiploic artery in 6.

We treated all CABG patients with a high-dose intravenous infusion of isosorbide dinitrate (Isoket; Schwarz Pharma AG, Monheim, Germany) 4 to 20 mg/h during the first postoperative 24 to 48 hours. From the second postoperative day, radial artery and right gastroepiploic artery patients were treated with oral calcium channel blockers (diltiazem), 90 mg to 180 mg. All CABG and PCI patients were treated permanently with aspirin, 100 mg daily, as well as with statins.

**Definitions and Data Collection**

Patients' data were analyzed according to American College of Cardiology/American Heart Association clinical data standards [9]. Diabetic patients included patients treated with insulin or oral hypoglycemic agents. A periprocedural myocardial infarction (MI) was defined as the postprocedure appearance of new Q waves or ST-segment elevation of more than 2 mm on an electrocardiograph accompanied by creatine phosphokinase-myocardial band greater than 50 mU/mL with or without a regional wall motion abnormality. Major adverse cardiac events (MACE) were defined as the occurrence of cardiac-related mortality, nonfatal MI, or the need for repeat intervention. Target vessel revascularization (TVR) was defined as repeat revascularization of a vessel previously treated either with a Cypher or a bypass graft. Complete revascularization was defined as revascularization of all coronary systems with vessel stenosis greater than 70%.

**Statistical Analysis**

Data are expressed as mean  $\pm$  SD or proportions, as appropriate. Continuous variables were compared using *t* tests, and categorical variables were compared by using  $\chi^2$  or Fisher exact tests, as appropriate. Kaplan-Meier curves were used to show freedom from time-related events, and a multivariable Cox proportional hazards model was used to identify predictors of time-related events. The time-related events studied were survival, reintervention, and MACE. To account

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