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CLINICAL RESEARCH

2-Year Results of the AUTAX (Austrian Multivessel TAXUS-Stent) Registry

Beyond the SYNTAX (Synergy Between Percutaneous Coronary Intervention With TAXUS and Cardiac Surgery) Study

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Objectives The multicenter AUTAX (Austrian Multivessel TAXUS-Stent) registry investigated the 2-year clinical/angiographic outcomes of patients with multivessel coronary artery disease after implantation of TAXUS Express stents (Boston Scientific, Natick, Massachusetts), in a "real-world" setting.

Background The AUTAX registry included patients with 2- or 3-vessel disease, with/without previous percutaneous coronary intervention (PCI) and concomitant surgery.

Methods Patients (n = 441, 64 ± 12 years, 78% men) (n = 1,080 lesions) with possible complete revascularization by PCI were prospectively included. Median clinical follow-up was 753 (quartiles 728 to 775) days after PCI in 95.7%, with control angiography of 78% at 6 months. The primary end point was the composite of major adverse cardiac (nonfatal acute myocardial infarction [AMI], all-cause mortality, target lesion revascularization [TLR]) and cerebrovascular events (MACCE). Potential risk factor effects on 2-year MACCE were evaluated using Cox regression.

Results Complete revascularization was successful in 90.5%, with left main PCI of 6.8%. Rates of acute, subacute, and late stent thrombosis were 0.7%, 0.5%, and 0.5%. Two-year follow-up identified AMI (1.4%), death (3.6%), stroke (0.2%), and TLR (13.1%), for a composite MACCE of 18.3%. The binary restenosis rate was 10.8%. The median of cumulative SYNTAX score was 23.0 (range 12.0 to 56.5). The SYNTAX score did not predict TLR or MACCE, due to lack of scoring of restenotic or bypass stenoses (29.8%). Age (hazard ratio [HR]: 1.03, p = 0.019) and acute coronary syndrome (HR: 2.1, p = 0.001) were significant predictors of 2-year MACCE. Incomplete revascularization predicted death or AMI (HR: 3.84, p = 0.002).

Conclusions With the aim of complete revascularization, TAXUS stent implantations can be safe for patients with multivessel disease. The AUTAX registry including patients with post-PCI lesions provides additional information to the SYNTAX (Synergy Between Percutaneous Coronary Intervention With TAXUS and Cardiac Surgery) study. (Austrian Multivessel TAXUS-Stent Registry; NCT00738686) (J Am Coll Cardiol Intv 2009;2:718–27) © 2009 by the American College of Cardiology Foundation

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The introduction of drug-eluting stents (DES) in recent years demonstrating superiority over bare-metal stents in reducing the restenosis incidence has narrowed the reintervention gap between coronary artery bypass graft surgery (CABG) and percutaneous coronary intervention (PCI) in multivessel coronary artery disease (CAD) (1–7); multivessel stenting with DES has therefore moved into the foreground again as an alternative option for CABG.

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The high revascularization rate with DES compared with CABG remains a critical end point in multivessel CAD (8,9). However, given the approximate 7% frequency of in-hospital vein graft occlusion (10,11) and the degeneration of vein grafts over time, DES may still be a more durable means than CABG as a revascularization strategy. Interestingly, even if stenting of multiple lesions is classified as an "off-label" indication for DES, approximately 10% of all PCIs in Europe and the U.S. are performed in patients with multivessel CAD.

Although current randomized trials involving the comparison of DES and CABG in multivessel CAD have encouraged inclusion of a wide variety of lesion sets, data suggest a significant variation in anatomical complexity between PCI and CABG patients (12,13). In the study by Hoffman et al. (1), only 2% to 12% of the patients screened could be randomized to either PCI or CABG (1). The goal of the SYNTAX (Synergy Between Percutaneous Coronary Intervention With TAXUS and Cardiac Surgery) trial, with randomized and registry cohorts, was to provide guidance on optimal revascularization strategies for patients with high-risk stenosis (12,14). However, the trial included only patients with de novo lesions, whereas the rapid increase in PCI in the last 10 years has led to turn the anatomy of the coronary lesions to present more complex morphology, involving restenosis, aneurysms, vessel remodeling, and phenotypic modulation of intima post-stenting (15). Accordingly, registries of nonrandomized patients with suboptimal lesions (e.g., restenotic stented lesions; or occluded, calcified, bypass; or small vessels) for either revascularization strategy may provide revascularization outcome data as robust as those from randomized analyses (13).

The aim of the AUTAX (Austrian Multivessel TAXUS-Stent) registry was to conduct a multicenter prospective registry including patients with multivessel CAD with/without previous PCI or concomitant cardiac surgery with possible complete revascularization by PCI, and treated solely with multiple TAXUS Express stent (Boston Scientific, Natick, Massachusetts) implantations in a "real-world" setting, and to report the short (30 days), medium (6 months), and long-term (1 and 2 years) angiographic and clinical outcomes.

Methods

Study design. The prospective academic nonrandomized AUTAX registry included consecutive patients with multivessel CAD at 9 Austrian medium- and high-volume PCI centers.

Study population. Between June 2004 and September 2005, 441 consecutive (all incoming) patients (age 64.4 ± 11.8 years, 78% men) with symptomatic multivessel CAD and possible percutaneous complete anatomical revascularization were prospectively included in the registry. Assignment to multivessel PCI with DES, rather than to CABG, was made on the basis of the individual clinical assessments by cardiologists and cardiac surgeons, involving a spectrum of factors such as extent and anatomy of CAD, the feasibility of achieving complete revascularization, age, prior surgery, current cardiac function, comorbidities, general health, pulmonary function, risk of anticoagulation, likelihood of compliance with continuing clopidogrel therapy, urgency of revascularization, assumption of risk of percutaneous procedure, and the waiting period for CABG in nonurgent cases. The multidisciplinary team, which also included noninvasive cardiologists, ensured that the most balanced and appropriate advice was consistently offered regarding the choice of revascularization strategy.

Abbreviations and Acronyms

AMI = acute myocardial infarction
CABG = coronary artery bypass graft surgery
CAD = coronary artery disease
CI = confidence interval
CK = creatine kinase
DES = drug-eluting stent(s)
HR = hazard ratio
MACCE = major adverse cardiac and cerebrovascular event(s)
MLD = minimal lumen diameter
NSTEMI = non–ST-segment elevation myocardial infarction
PCI = percutaneous coronary intervention
TLR = target lesion revascularization
UA = unstable angina

The study protocol conformed to the Declaration of Helsinki and was approved by the Interventional Working Group of Austrian Society of Cardiology and the institutional review committees of all centers. All patients gave their written informed consent and received optimal medical therapy according to current guidelines.

The inclusion criteria were symptomatic 2- or 3-vessel disease with/without left main disease, age >18 years, stable angina, or acute coronary syndrome (unstable angina and non–ST-segment elevation myocardial infarction [UA/NSTEMI]). Exclusion criteria were ST-segment elevation myocardial infarction within 48 h, cardiogenic shock, noncompliance with the study protocol, expected survival less than 2 years, hemorrhagic diathesis, and/or platelet count $<100{,}000/ml^3$.