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Five year Clinical Outcomes of Drug Eluting Stents According to the On label and Off label Usage

Background and Objectives : The purpose of this study was to evaluate clinical outcomes of drug-eluting stent (DES) according to on versus off-label indication for 5 years.Materials and Methods : A total of 929 consecutive patients who performed percutaneous coronary intervention (PCI) with DES from April 2005 to December 2007 were enrolled. Those patients were divided into two groups according to on(n=449) versus off-label(n=480) indication. Off label usage of DES was indicated in patients with long lesion(>30mm), total occlusion, bifurcation, ostial lesion, left main disease, multivessel diasease, saphenous vein graft and thrombus. Clinical outcomes of major adverse cardiac event(MACE) including death, target vessel revascularization(TVR), target lesion revascularization(TLR), myocardial infarction(MI) and stent thrombosis(ST) were compared between two groups for 5 years.Results : There were no difference between two groups in baseline characteristics, except diabetes(24.9% [Group1] vs. 35.4%[Group2], p=0.002). At one year, group2 was associated of higher incidence of MACE(1.9% vs. 7.5%, p=0.000), because of TLR(1.4% vs. 3.4%, p=0.047) and stent thrombosis(0.2% vs. 1.5%, p=0.042). From 1 year until 5 year clinical follow up, group2 also had a higher incidence of MACE(6.4% vs. 11.3%, p=0.014) because of TLR(3.7% vs. 7.1%, p=0.029). The rate of total MACE were higher in off-label usage than those of on-label (9.1% vs. 20.0%, p=0.000). Multivessel disease[HR 2.0, p=0.004] and diabetes[HR 1.7 p=0.017] were independent risk factors for MACE in multivariate analysis.Conclusions : Patients with On-label indication of DES had better long-term clinical outcomes than those with off-label. Further large clinical trials will be warranted.