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Routine angiographic follow-up versus clinical follow-up in patients with diabetes following percutaneous coronary intervention with drug-eluting stents in Korean population

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ABSTRACT

Aims: The usefulness of routine angiographic follow-up (RAF) and clinical follow-up (CF) after percutaneous coronary intervention (PCI) in patients with diabetes is not well understood. We compare 3-year clinical outcomes of RAF and CF in diabetic patients underwent PCI with drug-eluting stents (DES).

Methods: A total of 843 patients with diabetes who underwent PCI with DES were enrolled. RAF was performed at 6–9 months after PCI (n = 426). Rest of patients were medically managed and clinically followed (n = 417); symptom-driven events were captured. After propensity score matched analysis, 2 propensity-matched groups (262 pairs, n = 524, C-statistic = 0.750) were generated. The primary endpoint was major adverse cardiac events (MACE), the composite of total death, non-fatal myocardial infarction (MI), target lesion revascularization (TLR), target vessel revascularization (TVR), non-target vessel revascularization (Non-TVR).

Results: During the 3-year follow-up period, the cumulative incidence of target lesion revascularization [TLR: hazard ratio (HR), 4.07; 95% confidence interval (CI), 1.18–9.34; p = 0.001], target vessel revascularization (TVR: HR, 4.02; 95% CI, 1.93–8.40; p < 0.001), non-TVR (HR, 4.92; 95% CI, 1.68–14.4; p = 0.004) and major adverse cardiac events (MACE: HR,

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2.53; 95% CI, 1.60–4.01, p < 0.001) were significantly higher in the RAF group. However, the incidence of total death, non-fatal MI were similar between the two groups.
Conclusions: RAF following index PCI with DES in patients with diabetes was associated with increased incidence of revascularization and MACE without changes of death or re-infarction rates and increased TLR and TVR rates in both first- and second-generation DES.

1. Introduction

The usefulness of follow-up coronary angiography (CAG) after percutaneous coronary intervention (PCI) is still debatable. In 2014, the European guideline [1] classified routine angiographic follow-up (RAF) after high-risk PCI as Class IIb (Level of Evidence: C). Recently in prospective multicenter, randomized clinical trial, Shiomi et al. [2] reported RAF after PCI showed no clinical benefit and cannot be recommended as a clinical strategy. Diabetes is present in up to 25–30% of all patients undergoing PCI [3]. In general, the patients with diabetes more frequently require re-intervention procedure than the patients without diabetes and the pattern of coronary artery disease in patients with diabetes is often complex, with multiple lesions and diffuse disease [4,5]. Despite of the advances in revascularization devices and antiplatelet agents, many studies demonstrated that the patients with diabetes showed much more unfavorable clinical outcomes compared with the patients without diabetes [6–9]. Kawano reported that there were up to 19% of the patients with silent myocardial ischemia among the asymptomatic patients with type 2 diabetes mellitus (T2DM) without a history of cardiovascular disease (CVD) [10]. In Korea, the number of the patients with diabetes and absolute burden of cardiovascular disease are still rising [11]. However, there is limited data whether there are benefit in RAF strategy regardless of patient's symptoms after a successful PCI with drug-eluting stents (DES) in overall patients with diabetes as compared with clinical follow-up (CF) strategy, particularly in a series of Korean population. We aimed to compare 3-year clinical outcomes between two different strategies, RAF and CF in the patients with diabetes who underwent PCI with DES.

2. Material and methods

This study is a single-center, prospective, all-comer registry designed to reflect the "real world" practice since 2004. Data were collected by a trained study-coordinator with a standardized case report form. This study has been examined and approved by the local ethics committee that the subjects gave informed written consent. This study has been performed in accordance with the ethical standards laid down in the 1964 declaration of Helsinki.

2.1. Study population

From January 2004 to May 2011, a total of 843 patients with diabetes at Cardiovascular Center, Korea University Guro Hospital, Seoul, South Korea were enrolled. If they suffered from cardiovascular events such as death, any recurrent myocardial infarction (MI), unplanned revascularization, or unplanned CAG due to typical or atypical chest pain before CF, especially during 1-year after index PCI were excluded (Fig. 1). In general, most of the procedure related complications are occurred within 1-year after index PCI. Because we want to know the real beneficial effects on MACE between RAF and CF during the follow-up period these patients were excluded. During 1-year after index PCI, our study strictly defined patients who were underwent CAG solely as scheduled (6–9 months after index PCI) without having above procedure related conditions as considered RAF group. We classified them into either RAF group (n = 426) or CF group (n = 417) according to the two different follow-up strategies (Fig. 2). The choice of follow-up modality after index PCI was decided by physician's preference. A total 8 interventional cardiologists of our single center were participated in our registry. By accident, among them 4 physicians insisted RAF and the other 4 physicians insisted CF. And each physician did not change his policy until the end of study so the enrolled patients were not crossed-over. Although this manner has some limitation we feel this manner has great advantages in that it reflects real and routine hospital clinical practice and naturally semi-randomized.

2.2. Percutaneous coronary intervention procedure and medical treatment

A diagnostic CAG and PCI were done through either the femoral or radial artery after an administration of unfractionated heparin (70–100 IU/kg). Patient's activated clotting time (ACT) was maintained above 250 s during the procedure. Revascularization was considered clinically indicated when the patient had typical angina and/or signs of ischemia and ≥50% diameter restenosis or ≥70% diameter restenosis in a coronary artery by visual estimation even in the absence of signs and symptoms. The use of cilostazol (Pletaal™; Otsuka Pharmaceutical Co., Tokyo, Japan) or platelet glycoprotein IIb/IIIa receptor blockers was left to the discretion of the individual operators. A successful PCI was defined as the achievement of an angiographic residual stenosis was less than 30% and final thrombolysis in myocardial infarction (TIMI) blood flow grade was 3. During hospitalization, enrolled patients had taken cardiovascular beneficial medications, including beta-blockers (BB), angiotensin converting enzyme inhibitors (ACEI), angiotensin receptor blockers (ARB), calcium channel blockers (CCB), and lipid lowering agents. After discharge, the patients were encouraged to stay on the same medications they received during hospitalization. Especially dual