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Objectifying the level of incomplete revascularization by the residual SYNTAX score and evaluating its impact on the one-year outcome of percutaneous coronary intervention in patients with multi-vessel disease

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ABSTRACT

Background: Previous studies reported conflicting results regarding the impact of incomplete revascularization on the outcome of percutaneous coronary intervention (PCI). We evaluated the association between residual SYNTAX score (RSS) as a quantitative measure of incomplete revascularization and one-year outcome of patients with native multi-vessel disease undergoing PCI.

Methods: A total of 760 patients (mean age = 59.14 ± 10.36 years, 70.4% males) who underwent successful PCI with the incomplete revascularization strategy between September 2008 and March 2010 were included. The RSS was used to quantify the extent and complexity of residual coronary stenosis following PCI. Multivariable analysis was used to evaluate the impact of RSS on one-year major adverse cardiac events (MACE) including death, myocardial infarction, and revascularization.

Results: Overall incidence of one-year MACE was 4.74%. Using ROC curve analysis a cut-off of >5 for baseline RSS had a significant association with occurrence of 12-month MACE (area under the curve = 0.769; P value < 0.001, sensitivity = 75% and specificity = 72%). Unadjusted effect of RSS > 5 on 12 months MACE showed a hazard ratio of 7.34 (p value < 0.001). By multivariable analysis, effect of the RSS > 5 on 12 months MACE was adjusted for potential confounders. After adjustment to clinical SYNTAX score as the sole confounder, RSS > 5 remained a strong associate with 12 months MACE and its effect outweighed that of before adjustment (hazard ratio = 8.03, p value < 0.001).

Conclusions: The RSS is a quantified measure of the complexity of residual coronary stenoses, and RSS > 5 could be able to discriminate patients with an increased risk of one-year MACE.

1. Introduction

The optimal PCI strategy in multi-vessel disease patients continues to be a matter of controversy. Previous studies have reported conflicting results regarding the prognostic impact of incomplete revascularization on the outcome of PCI [1–6]. There are possible reasons for this incongruity. Firstly, it seems to be due to the lack of a universally accepted definition for incomplete revascularization. That is to say, the definitions of incomplete revascularization in previous studies varied according to the stenosis severity, vessel size diameter and nature of residual coronary stenosis after PCI, all of which can influence the outcome [3,4,7,8]. The second reason is that these studies evaluated the impact of incomplete revascularization in different clinical settings such as acute coronary syndrome and unprotected left main coronary artery PCI [9,10]. Such incongruities underscore the need for a systematic characterization and quantification of residual atherosclerosis following PCI to augment the prognostic utility of incomplete revascularization. The residual SYNTAX score (RSS) has been recently introduced for patients with acute coronary syndrome [9]. The RSS could be calculated after PCI to provide an objective and potentially useful quantification of incomplete revascularization.

The aim of the present study was to evaluate the prognostic value and the acceptable cut-off of the RSS as a quantitative measure of

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incomplete revascularization in the prediction of the one-year outcome of patients with native multi-vessel disease undergoing PCI in a real-world practice.

2. Methods

The data were retrospectively extracted from a computerized registry of interventional cardiology. A total of 760 consecutive patients with multi-vessel disease who underwent successful PCI with the incomplete revascularization strategy between September 2008 and March 2010 were included in the current study. Incomplete revascularization was defined as treatment of all coronary artery segments with higher than 50% diameter stenosis. Patients who underwent primary PCI were excluded. Since the SYNTAX score has been validated mainly for patients with native coronary artery disease, patients with a history of coronary artery bypass grafting (CABG) and those in whom the SYNTAX score was unable to be calculated because of technical reasons were also excluded. A policy of maximum feasible revascularization in one procedure was followed. In the case of staged PCI procedures (defined as a second planned PCI procedure 8 weeks after the initial intervention), the final planned procedure was used as the entry point for this study. If there was any event between the procedures we used the first plan. Detailed demographic, clinical and procedural characteristics and clinical outcome were documented in our registry. The follow-up data were obtained through organized clinical visits or telephone contacts by trained research physicians and nurses at hospital discharge and subsequently at one, 6, and 12 months after PCI (mean follow up = 11.56 ± 1.92 months). The study was approved by the institutional review board.

The baseline SYNTAX score and the RSS were calculated by summing up the individual scores for each lesion with a diameter stenosis ≥ 50% in vessels with a diameter ≥ 1.5 mm in the angiography obtained before and after the procedure. The SYNTAX algorithm of scoring is fully described elsewhere [11,12]. All the angiographic variables to calculate baseline and residual SYNTAX score were evaluated by two experienced cardiologists trained to assess the SYNTAX score and blinded to the procedure and the clinical outcome. In case of disagreement, the opinion of a third observer was obtained and the final decision was made by consensus. The modified ACEF score was calculated based on the glomerular filtration rate (GFR) and left ventricular ejection fraction (LVEF) recorded before PCI, using the formula age/LVEF + 1 point for every 10 ml/min/1.73 m^2 reduction of GFR below 60 ml/min/1.73 m^2 (1 point for GFR between 59 and 50, 2 points for GFR between 49 and 40 and 3 points for GFR between 39 and 30 ml/min/1.73 m^2) [13]. The GFR is calculated via the Cockroft–Gault equation using age, gender weight and serum creatinine before PCI [14]. The baseline SYNTAX score was then multiplied by the modified ACEF score to obtain the baseline clinical SYTAX score [13,15].

All the patients received Aspirin (325 mg), Clopidogrel loading dose (300 mg or 600 mg at least two hours before the procedure), and weight-adjusted intravenous unfractionated Heparin (80–100 U/kg) before PCI. The selection of the specific type of revascularization and procedural devices was based on the decision of the interventional cardiologist. All patients with successful procedure were treated with dual antiplatelet therapy according to recommended guidelines. In this regard, patients in the drug-eluting stent (DES) group received Clopidogrel (75 mg/d) plus Aspirin (325 mg/d) for at least 12 months and participants in the bare-metal stent (BMS) or plain old balloon angioplasty (POBA) group were prescribed Clopidogrel (75 mg/d) plus Aspirin (325 mg/d) for at least three months. Aspirin (80 mg/d) was prescribed for an indefinite period after PCI in all the patients. Most of the DES stents were first generation type dominantly Taxus and Cipher. About 25% of the DES stents were second generation one particularly Xience and Promus.

Major adverse cardiac events (MACE) included one-year rates of all-cause death, cardiac death, nonfatal myocardial infarction (MI), and revascularization including target vessel revascularization (TVR), target lesion revascularization (TLR) and CABG. Myocardial injury immediately after PCI was defined as either ECG changes or a higher than threefold increase in the level of serum creatine kinase or troponin and was considered as in-hospital MI. In-hospital MI was not included as MACE. The diagnosis of TVR and TLR was made based on angiographic findings.

2.1. Statistical analysis

Continuous variables were presented as mean with standard deviation (SD) or median with interquartile range (IQR); and were compared between RSS groups using independent samples t or Mann–Whitney test. Categorical variables were expressed through frequency and percentage; and were compared among RSS groups' applying chi-squared or Fisher's exact test. The discrimination power of the RSS on one-year MACE was measured using area under the receiver operating characteristics (ROC) curve and the optimum cut-off value was identified through maximum value of Youden's index. Survival curves were generated using Kaplan–Meier method and groups were compared using log-rank test. Variables which were simultaneously associated with RSS groups and 1-year MACE with p-values less than 0.2 in univariate analyses were detected as potential confounders. A Cox proportional hazards (PH) model was used to evaluate the effect of RSS on 1-year MACE adjusted for detected potential confounders. Effect of RSS on one-year MACE was reported as hazard ratio (HR) with 95% confidence interval (CI). IBM SPSS statistics for Windows, version 20.0 (Armonk, NY: IBM Corp.) was used to conduct the analyses.

3. Results

Demographic and clinical characteristic of study patients are presented in Table 1. Mean age of the patients was 59.14 ± 10.36 years and most of them were male (70.4%). The most frequent risk factor was hyperlipidemia (67.1%). From 760 patients, 53% had a history of myocardial infarction and 11.7% had previously undergone PCI. Baseline clinical SYNTAX score had a median of 15.24 (9.73, 26.09) and median value for RSS was 4.0 (2.0, 6.0). Using ROC curve analysis we found that a cut-off of >5 for baseline RSS had a significant association with

Table 1-
Demographic and clinical characteristics of 760 study patients.

Variable	
Age (years)	59.14 ± 10.36
Male	535 (70.4)
Body mass index (kg/m^2)	24.69 ± 4.22
Positive family history	177(23.3)
Diabetes mellitus	253(323.3)
Hypertension	431(56.7)
Hyperlipidemia	510(67.1)
Current smoking	181(23.8)
Previous Myocardial Infarction	403(53.0)
Any Previous PCI	89(11.7)
Serum Creatinine (mg/dl)	1.10 (0.90, 1.30)
Glomerular filtration rate[a]	71.82 (56.86, 90.0)
Renal dysfunction[b]	220 (28.9)
Left ventricular EF (%)	50.40 ± 10.12
Number of diseased vessels	
Two vessel disease	493 (64.9)
Three vessel disease	267 (35.1)
Baseline Clinical Syntax Score	15.24 (9.73, 26.09)
Clinical Syntax Categories (n, %)	
Low-risk	253 (33.3)
Medium-risk	254 (33.4)
High-risk	253 (33.3)

Values are mean ± SD, n (%) or median (percentile 25–75).
PCI = Percutaneous Coronary Intervention, EF = Ejection Fraction.
[a] Glomerular filtration rate (ml/min/1.73 m^2) is calculated using the Cockroft–Gault equation.
[b] Patients with glomerular filtration rate < 60 ml/min/1.73 m^2 were considered to have renal dysfunction.