

3-Dimensional Bifurcation Angle Analysis in Patients With Left Main Disease

A Substudy of the SYNTAX Trial (SYnergy Between Percutaneous Coronary Intervention With TAXus and Cardiac Surgery)

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Objectives We explore the bifurcation angle (BA) parameters of the left main coronary artery (LM), the effect of percutaneous coronary intervention (PCI) on this angulation, and the impact of BA on clinical outcome.

Background The BA is emerging as a predictor of outcome after PCI of bifurcation lesions. Three-dimensional (3D) quantitative coronary angiography (QCA) overcomes the shortcomings of 2-dimensional analysis and provides reliable data.

Methods This is a substudy of the SYNTAX (SYnergy Between Percutaneous Coronary Intervention With TAXus and Cardiac Surgery) trial. The cineangiograms of the 354 patients who underwent PCI of their LM stem were analyzed with 3D QCA software (CardiOp-B, Paieon Medical, Ltd., Rosh Ha'ayin, Israel). The proximal BA (between LM and left circumflex [LCX]) and the distal BA (between left anterior descending and LCX) were computed in end-diastole and end-systole, both before and after PCI. The cumulative major adverse cardiac and cardiovascular event (MACCE) rates throughout the 12-month period after randomization were stratified across pre-PCI distal BA values and compared accordingly.

Results Complete analysis was feasible in 266 (75.1%) patients. Proximal and distal BA had mean pre-PCI end-diastolic values of $105.9 \pm 21.7^\circ$ and $95.6 \pm 23.6^\circ$, respectively, and were inversely correlated ($r = -0.75$, $p < 0.001$). During systolic motion of the heart there was an enlargement of the proximal angle and a reduction of the distal angle (Δ BA -8.2° and 8.5° , respectively, $p < 0.001$ for both). The PCI resulted in a mean decrease in the distal BA (Δ BA 4.5° , $p < 0.001$). The MACCE rates did not differ across distal BA values; freedom from MACCE at 12 months was 82.8%, 85.4%, and 81.1% ($p = 0.74$) for diastolic values (first through third tertile).

Conclusions Left main BA analysis with 3D QCA is feasible. Both proximal and distal angles are affected by cardiac motion; PCI modifies the distal angle. There is no clear difference in event rates across pre-PCI distal BA values. (J Am Coll Cardiol Intv 2010;3:41–8) © 2010 by the American College of Cardiology Foundation

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The optimal treatment of left main coronary artery (LM) disease remains contentious (1,2), with much of the debate focused on the treatment of its distal part (3,4). Despite increasing data on LM interventions (5–8), the importance of anatomical parameters such as the bifurcation angle (BA) has not been fully appreciated (9).

A number of clinical (10–13) and bench (14,15) studies identify the significance of this angle in predicting the immediate procedural success or the long-term outcome. Limitations to previous studies include ambiguity in the definition of the BA and the specific stenting techniques. The most prominent limitation is that almost all relevant clinical studies rely on 2-dimensional (2D) analysis. The LM bifurcation is particularly difficult to image, because of foreshortening and vessel overlap (16); 3-dimensional (3D) quantitative coronary angiography (QCA) overcomes these shortcomings of 2D analysis and might be beneficial in this setting (16–18).

Abbreviations and Acronyms

BA = bifurcation angle

LAD = left anterior descending coronary artery

LCX = left circumflex coronary artery

LM = left main coronary artery

MACCE = major adverse cardiac and cardiovascular events

PCI = percutaneous coronary intervention

QCA = quantitative coronary angiography

SB = side branch

TLR = target lesion revascularization

3D = 3-dimensional

The purpose of this study was to test the feasibility of assessment of the LM BA with a 3D QCA algorithm, describe the angulation parameters before and after PCI and evaluate their impact on the clinical outcome of the patients.

Methods

Study population. This is a sub-study of the SYNTAX (SYnergy Between Percutaneous Coronary Intervention With TAXus and Cardiac Surgery) trial (19), which was a prospective, randomized, all-comers clinical trial with the overall goal of assessing the op-

timum revascularization treatment for patients with *de novo* 3-vessel disease or LM disease (either isolated or in combination with 1-, 2-, or 3-vessel disease). Patients (n = 1,800) suitable for either treatment option were randomized to PCI with polymer-based, paclitaxel-eluting TAXUS Express (Boston Scientific Corp., Natick, Massachusetts) stents or coronary artery bypass graft surgery; they were also stratified according to the presence or absence of LM disease. For the purpose of this study, we reviewed the cineangiograms of the 354 patients who underwent PCI of the LM stem. Patients with both bifurcation and nonbifurcation LM lesions were included in the study population.

This study was performed in Cardialysis BV (Rotterdam, the Netherlands) as an exploratory analysis and was not subsidized by the official sponsor of the trial, Boston

Scientific Corporation. Prior permission was sought and granted by the Steering Committee to access and analyze this dataset.

Analysis method. Three-dimensional reconstruction was performed offline by 2 experienced operators (C.G. and Y.O.), blinded to individual patient data and clinical outcome, with a validated (20) program for 3D QCA (CardiOp-B system version 2.1.0.151, Paieon Medical, Ltd., Rosh Ha'ayin, Israel); the sequence of a single 3D reconstruction has already been amply described elsewhere (21–23). The software algorithm rendered an image as well as quantitative information including BA values; these were derived from images without any guidewires in place, which could modify the angle.

Two angles are presented in accordance with the European Bifurcation Club consensus document (9). Proximal Angle A is defined as the angle between the proximal main vessel and the side branch (SB), whereas distal Angle B is delineated between the distal main vessel and the SB (Fig. 1). By convention the left anterior descending coronary artery (LAD) was designated as the distal main vessel, and the left circumflex (LCX) as the SB. The LM bifurcation was designated as Y-shaped for distal BA values <70°.

Study design. Three-dimensional reconstructions were performed before and after PCI. To assess the effect of the systolic-diastolic motion on the LM bifurcation angulation, separate 3D images were reconstructed for the end-diastolic and -systolic frames, both before and after the procedure. Systolic-diastolic variation of BA equals the difference of the respective end-diastolic and -systolic values.

Analysis was deemed complete, only if all 4 of the 3D images that were required were successfully reconstructed; outcome of each individual case study was categorized as partially analyzable or nonanalyzable, in cases where <4 or no images at all, respectively, were obtained.

The primary clinical end point of the trial was a composite of major adverse cardiac and cardiovascular events (MACCE) (death from any cause, stroke, myocardial infarction, or repeat revascularization) throughout the 12-month period after randomization.

Statistical analysis. Statistical analysis was performed with SPSS version 16.0 for Windows (SPSS, Inc., Chicago, Illinois) and SAS version 9.2 (SAS Institute, Inc., Cary, North Carolina). Continuous variables are expressed as mean \pm 1 SD and compared between groups by unpaired Student *t* test; paired *t* test was employed for within-group comparisons. Categorical variables are expressed as counts and/or percentages. Correlations between continuous variables were performed with the Pearson coefficient. Cumulative survival free of adverse events was calculated according to the Kaplan-Meier method and compared across the median and the tertile values of pre-PCI distal BA with the log-rank test. All statistical tests were 2-sided, and a p value <0.05 was considered statistically significant.

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