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SYNTAX Score and Long-Term Outcomes

The BARI-2D Trial

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ABSTRACT

BACKGROUND The extent of coronary disease affects clinical outcomes and may predict the effectiveness of coronary revascularization with either coronary artery bypass graft (CABG) surgery or percutaneous coronary intervention (PCI). The SYNTAX (Synergy Between Percutaneous Coronary Intervention With Taxus and Cardiac Surgery) score quantifies the extent of coronary disease.

OBJECTIVES This study sought to determine whether SYNTAX scores predicted outcomes and the effectiveness of coronary revascularization compared with medical therapy in the BARI-2D (Bypass Angioplasty Revascularization Investigation 2 Diabetes) trial.

METHODS Baseline SYNTAX scores were retrospectively calculated for BARI-2D patients without prior revascularization ($N = 1,550$) by angiographic laboratory investigators masked to patient characteristics and outcomes. The primary outcome was major cardiovascular events (a composite of death, myocardial infarction, and stroke) over 5 years.

RESULTS A mid/high SYNTAX score (≥23) was associated with a higher risk of major cardiovascular events (hazard ratio: 1.36, confidence interval: 1.07 to 1.75, $p = 0.01$). Patients in the CABG stratum had significantly higher SYNTAX scores: 36% had mid/high SYNTAX scores compared with 13% in the PCI stratum ($p < 0.001$). Among patients with low SYNTAX scores (≤22), major cardiovascular events did not differ significantly between revascularization and medical therapy, either in the CABG stratum (26.1% vs. 29.9%, $p = 0.41$) or in the PCI stratum (17.8% vs. 19.2%, $p = 0.84$). Among patients with mid/high SYNTAX scores, however, major cardiovascular events were lower after revascularization than with medical therapy in the CABG stratum (15.3% vs. 30.3%, $p = 0.02$), but not in the PCI stratum (35.6% vs. 26.5%, $p = 0.12$).

CONCLUSIONS Among patients with diabetes and stable ischemic heart disease, higher SYNTAX scores predict higher rates of major cardiovascular events and were associated with more favorable outcomes of revascularization compared with medical therapy among patients suitable for CABG. (Bypass Angioplasty Revascularization Investigation in Type 2 Diabetes; NCT00006305) (J Am Coll Cardiol 2017;69:395–403) © 2017 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

CABG = coronary artery bypass graft

CI = confidence interval

HR = hazard ratio

MI = myocardial infarction

PCI = percutaneous coronary intervention

SYNTAX = Synergy Between Percutaneous Coronary Intervention With Taxus and Cardiac Surgery

Coronary revascularization improves coronary blood flow, either by placing a conduit to bypass atherosclerotic obstructions in coronary artery bypass graft (CABG) surgery, or by expanding narrowed segments in percutaneous coronary intervention (PCI). Given this treatment mechanism, it seems likely that the clinical effectiveness of coronary revascularization should increase in proportion to the extent of underlying coronary disease, as suggested in early studies (1). The recently developed SYNTAX (Synergy Between PCI With Taxus and Cardiac Surgery) score characterizes the extent of coronary disease in terms of the number of lesions, their functional importance (2), and their complexity (3). Previous studies have categorized the SYNTAX score to identify patients at low (≤22), medium (23 to 32), and high risk (≥33) (4).

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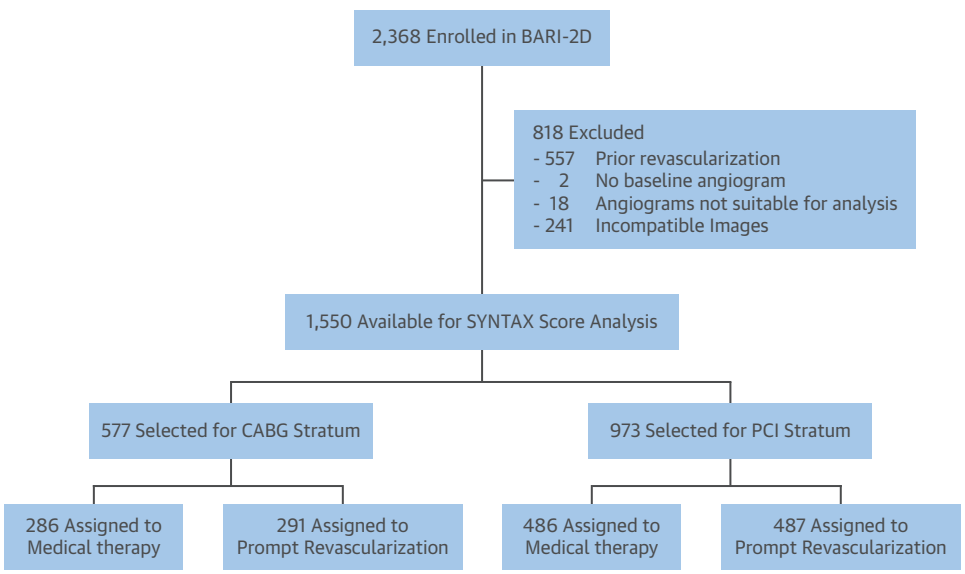
The BARI-2D (Bypass Angioplasty Revascularization Investigation 2 Diabetes) trial compared the strategies of: 1) adding prompt coronary revascularization to intensive medical therapy; and 2) intensive medical therapy alone among patients with type 2 diabetes mellitus and stable coronary disease (5). Randomization was stratified by the intended method of revascularization (PCI or CABG) declared before randomization. BARI-2D reported a significantly lower rate of the composite of all-cause death, myocardial infarction (MI), or stroke between revascularization and the medical strategy in the CABG stratum, but not in the PCI stratum (6). Patients in the CABG stratum had more extensive coronary disease, and it is possible that effect of revascularization is simply more pronounced among patients with the most extensive coronary disease. We sought to determine whether SYNTAX scores measured in BARI-2D patients could predict major cardiovascular events (death, MI, stroke), and hypothesized that revascularization would have greater effectiveness relative to medical therapy among patients with higher SYNTAX scores.

METHODS

STUDY GROUP. The BARI-2D design, protocol, and patient characteristics have been described previously (6,7). Briefly, the BARI-2D trial was an international, multicenter trial comparing 2 major treatment approaches in a 2 × 2 factorial design: prompt coronary revascularization versus intensive medical therapy; and insulin sensitization versus insulin provision strategies. Patients with type 2 diabetes mellitus and evidence of myocardial ischemia were enrolled between January 1, 2001, and March 31, 2005.

FIGURE 1 Flow Diagram



Flowchart for patients included in the BARI-2D SYNTAX score analysis. BARI-2D = Bypass Angioplasty Revascularization Investigation in Type 2 Diabetes; CABG = coronary artery bypass graft; PCI = percutaneous coronary intervention; SYNTAX = Synergy Between PCI With Taxus and Cardiac Surgery.