

Comparison of Stenting and Surgical Revascularization Strategy in Non-ST Elevation Acute Coronary Syndromes and Complex Coronary Artery Disease (from the Milestone Registry)



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The optimal revascularization strategy in patients with complex coronary artery disease and non-ST-segment elevation acute coronary syndromes is undetermined. In this multicenter, prospective registry, 4,566 patients with non-ST-segment elevation myocardial infarctions, unstable angina, and multivessel coronary disease, including left main disease, were enrolled. After angiography, 3,033 patients were selected for stenting (10.3% received drug-eluting stents) and 1,533 for coronary artery bypass grafting. Propensity scores were used for baseline characteristic matching and result adjustment. Patients selected for percutaneous coronary intervention (PCI) were younger (mean age 64.4 ± 10 vs 65.2 ± 9 years, $p = 0.03$) and more frequently presented with non-ST-segment elevation myocardial infarctions (32.0% vs 14.5%, $p = 0.01$), cardiogenic shock (1.5% vs 0.7%, $p < 0.01$), and history of PCI (13.1% vs 5.5%, $p < 0.01$) or coronary artery bypass grafting (10.6% vs 4.6%, $p < 0.01$). European System for Cardiac Operative Risk Evaluation scores were higher in PCI patients (5.4 ± 2 vs 5.2 ± 2 , $p < 0.01$). Patients referred for coronary artery bypass grafting more often presented with triple-vessel disease and left main disease (82.2% vs 33.8% and 13.7% vs 2.4%, respectively, $p < 0.01$). After adjustment, 929 well-matched pairs were chosen. Early mortality was lower after PCI before matching (2.1% vs 3.1%, $p < 0.01$), whereas after balancing, there was no difference (2.5% vs 2.8%, $p = 0.62$). Three-year survival was in favor of PCI compared with surgery before (87.5% vs 82.8%, hazard ratio 1.44, 95% confidence interval 1.2 to 1.7, $p < 0.01$) and after (86.4% vs 82.3%, hazard ratio 1.33, 95% confidence interval 1.05 to 1.7, $p = 0.01$). Stenting was associated with improved outcomes in the following subgroups: patients aged >65 years, women, patients with unstable angina, those with European System for Cardiac Operative Risk Evaluation scores >5 , those with Thrombolysis In Myocardial Infarction (TIMI) risk scores >4 , those receiving drug-eluting stents, and those with 2-vessel disease. In conclusion, in patients presenting with non-ST-segment elevation acute coronary syndromes and complex coronary artery disease, immediate stenting was associated with lower mortality risk in the long term compared with surgical revascularization, especially in subgroups at high clinical risk. © 2014 Elsevier Inc. All rights reserved. (Am J Cardiol 2014;114:979–987)

Within the past decade, aging of the population and the coexistence of multiple co-morbidities have increased the risk of patients presenting with acute coronary syndromes

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(ACS).^{1,2} Furthermore, a steady decrease in the incidence of ST-segment elevation ACS and an increase in that of non-ST-segment elevation ACS (NSTEMI-ACS) have been observed,^{1,3,4} the latter of which has been shown to be associated with a poorer long-term prognosis.^{5,6} This is related to the complexity of coronary artery disease in patients with NSTEMI-ACS, with nearly half of patients presenting with multivessel coronary artery disease (MVD).⁶ The optimal revascularization strategy in this group of patients is undetermined. Because of clinical presentation, in most patients, an early or a delayed invasive strategy is preferred in American and European guidelines,^{7,8} but the method of revascularization is not specified. Because of high surgical risk, immediate stenting of the culprit lesion and delayed complete percutaneous revascularization are becoming common practice. In contrast, on the basis of anatomic criteria, coronary artery bypass grafting (CABG) should be the standard of care.⁹ Very few studies have addressed thus far the problem of the optimal

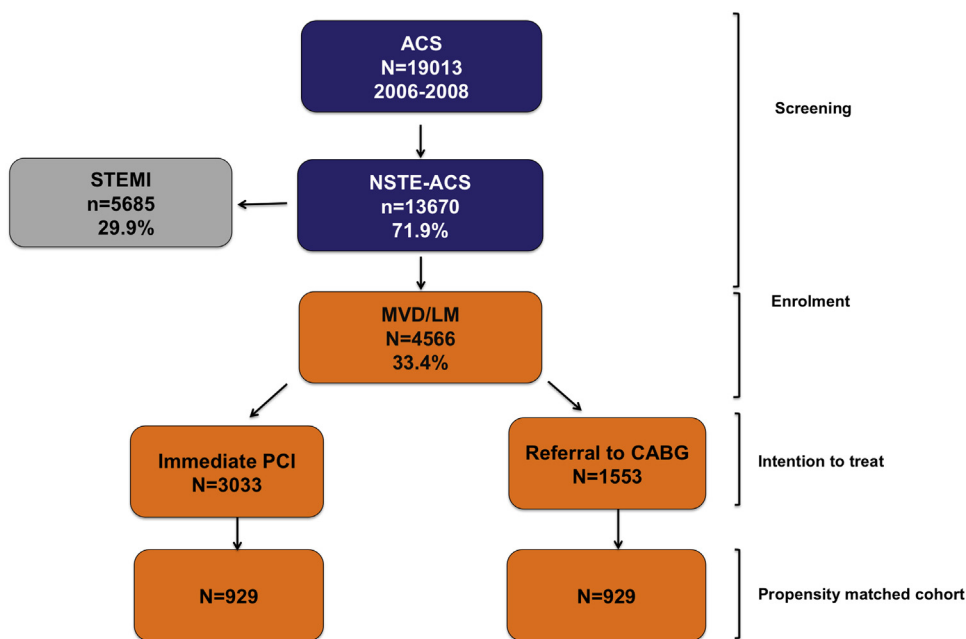


Figure 1. Study flowchart. LM = left main coronary artery disease.

revascularization strategy in patients presenting with MVD and NSTE-ACS. A hypothesis of a positive outcome can be derived from some previous studies comparing bare-metal stenting and CABG, in which most patients presented with NSTE-ACS.¹⁰ Therefore, we aimed to compare early and long-term outcomes after immediate stenting versus referral for surgical revascularization after urgent coronary angiography in this challenging cohort of patients.

Methods

In this multicenter, prospective registry, 4,566 consecutive patients hospitalized with NSTE-ACS and MVD were enrolled from 2006 to 2009. All patients underwent urgent cardiac catheterization in 6 interventional cardiology departments of American Heart of Poland, without cardiac surgery on site. Surgical revascularizations were carried out at 3 cardiac surgery reference centers (the Silesian Center for Heart Diseases in Zabrze, Voivodship Hospital in Opole, and the Upper Silesian Heart Center of the Medical University of Silesia in Katowice).

Adult patients (>21 years of age) with the whole risk spectrum of NSTE-ACS, defined as unstable angina and non-ST-segment elevation myocardial infarction (NSTEMI), were included. Furthermore, the following angiographic criteria had to be met: ≥ 2 lesions with >70% diameter stenosis confirmed by on-line quantitative coronary angiography in native coronary arteries with the involvement of both the right and left coronary arteries (left anterior descending or circumflex). Patients with coexistence of both protected and unprotected left main disease (>50% diameter stenosis) were also enrolled. We excluded patients with ST-segment elevation myocardial infarction and stable angina on admission, the presence of only single-vessel disease, coexistence of significant valvular disease, designation for hybrid revascularization

(percutaneous coronary intervention [PCI] plus CABG) or plain balloon angioplasty.

After immediate coronary angiography (<48 hours after symptom onset), the decision as to whether the patient should undergo bypass surgery or multistage stenting was based on anatomic suitability for PCI, estimation of surgical and clinical risk, or patient preference. All decisions regarding referral for CABG were based on consensus between the surgeon and interventionalist on the basis of teleconferencing and on-line Digital Imaging and Communications in Medicine data transmission using TeleDICOM software (Distributed Systems Research Group, Kraków, Poland). Interventional centers did not have on-site surgical backup at that time, but they were located within ≤ 1 -hour emergency transportation to a reference cardiac surgery department. Group assignment and analysis were based on intention to treat.

In the percutaneous arm, multistage revascularization was the preferred strategy. Initial stenting of the culprit lesion was performed in all patients except those in cardiogenic shock. Second-stage and, if necessary, third-stage procedures on the remaining lesions were planned within 3 to 4 weeks, with the intention of attaining complete revascularization. In patients with high-risk NSTE-ACS stenting was performed ad hoc, otherwise the coronary angiography procedure was delayed (up to 24 hours). In patients selected for stenting, a clopidogrel loading dose (600 mg) was administered during or immediately after the intervention. During the procedure, patients received unfractionated heparin 100 IU/kg intravenously, which was corrected to maintain an activated clotting time >300 seconds. Use of glycoprotein IIb/IIIa receptor inhibitors was at the operator's discretion. All patients were advised to continue taking aspirin indefinitely and clopidogrel for ≥ 1 year after the procedure. Direct stenting was the preferred technique, except for critical and calcified lesions, which were predilated with a small balloon (2.0 to 2.5 mm). Provisional

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