

## INTERVENTIONAL ISSUES

# Clinical Trials Versus Clinical Practice



## When Evidence and Practice Diverge— Should Nondiabetic Patients With 3-Vessel Disease and Stable Ischemic Heart Disease Be Preferentially Treated With CABG?

Three sections with opinions separately and independently expressed by:

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The planning of revascularization strategy for multivessel coronary artery disease (CAD) in nondiabetic patients is optimally made through considering the goals of improving survival and/or relieving symptoms. Existing clinical practice guidelines and appropriate use criteria (1-3) state that in nondiabetic patients with multivessel CAD and stable ischemic heart disease (SIHD), either coronary artery bypass grafting (CABG) or percutaneous coronary intervention (PCI) with drug-eluting stents may be used for those with low SYNTAX (Synergy Between PCI With Taxus and Cardiac Surgery) scores, but CABG is preferred for those with intermediate or high SYNTAX scores. In the overall SYNTAX population (4-6), the rates of death and stroke were similar, but the risk of myocardial infarction (MI) and repeat revascularization were higher in PCI-treated patients. At 5-year follow-up, the rates of death/stroke/MI are 8.0% lower, and the rate of repeat revascularization is 12.8% lower in CABG-treated patients. In the low SYNTAX score tertile, these trends are not significantly different, but they are in the intermediate and high SYNTAX score subsets. When considering only survival in the 3 tertiles, there was a 0.9%, 6.7%, and 9.0% difference over 5 years, an average of 0.2% to 1.8% per year. Yet, PCI is more often

performed in multivessel CAD patients, despite the guidelines and clinical evidence. Can this apparent divergence from the evidence base be supported? Drs. Weintraub and Tcheng and colleagues were asked to defend or critique the current guidelines.

### GUIDELINE PROPONENTS

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**EVIDENCE FROM THE SYNTAX TRIAL.** The SYNTAX trial provides the only multicenter, randomized comparison between CABG and drug-eluting stents among nondiabetic patients with left main artery (LM) and/or 3-vessel CAD (3VD) (4). The trial randomized 1,800 patients with 3VD or LM disease to undergo either PCI (n = 903) or CABG (n = 897), with a mean age of 65 years in both groups. Approximately 75% of patients did not have diabetes. The rate of patients at high surgical risk (EuroSCORE [European System for Cardiac Operative Risk Evaluation]  $\geq 6$ ) was ~20% in both groups. Almost 60% of the patients had 3VD (n = 1,095), and 39% of the patients in both groups had LM disease in addition to other vessel involvement. The primary endpoint of major adverse cardiac or cerebrovascular events (MACCE) (composite of death

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## ABBREVIATIONS AND ACRONYMS

**ASCERT** = American College of Cardiology Foundation and the Society of Thoracic Surgeons Collaboration on the Comparative Effectiveness of Revascularization Strategies

**CABG** = coronary artery bypass grafting

**CAD** = coronary artery disease

**CEA** = cost-effectiveness analysis

**CI** = confidence interval

**EES** = everolimus-eluting stent(s)

**HR** = hazard ratio

**ICER** = incremental cost-effectiveness ratio

**LM** = left main artery

**MACCE** = major adverse cardiac or cerebrovascular event(s)

**MI** = myocardial infarction

**PCI** = percutaneous coronary intervention

**QALY** = quality-adjusted life year

**RCT** = randomized, controlled trial

**RR** = risk ratio

**SIHD** = stable ischemic heart disease

**SoS** = The Stent or Surgery Trial

**SYNTAX** = Synergy Between PCI With Taxus and Cardiac Surgery

**3VD** = 3-vessel coronary artery disease

from any cause, MI, stroke, or repeat revascularization) and its components was compared with that in the CABG and PCI groups at 1-, 3-, and 5-year follow-up periods. Both groups were also compared according to low (score  $\leq 22$ ), intermediate (scores of 23 to 32), and high (scores  $\geq 33$ ) SYNTAX scores. The average SYNTAX score was 29.1 in the CABG group and 28.4 in the PCI group ( $p = 0.19$ ) (3). The detailed comparison of clinical endpoints for the CABG group versus the PCI group for SIHD patients with LM or 3VD disease at 1-, 3-, and 5-year follow-up periods (Table 1).

**Clinical outcomes at 1-year.** At 1-year, the CABG group had fewer MACCE compared with the PCI group (4). This was largely driven by a decreased rate of repeat revascularization in the CABG group. Death and MI were comparable in the 2 groups. The SYNTAX score had significant interaction with the treatment groups (Table 1). MACCE were not significantly different between the CABG and PCI groups for low and intermediate SYNTAX scores. However, MACCE were lower in patients undergoing CABG with a high SYNTAX score (Table 1), but the stroke rate was higher in the CABG cohort.

**Clinical outcomes at 3 years.** The 3-year follow-up again demonstrated fewer MACCE in the CABG group compared with the PCI group, driven by a decreased rate of repeat revascularizations and fewer MIs in the CABG group compared with the PCI group (5). In contrast to 1-year follow-up, there was no longer a significant difference in the incidence of stroke between the CABG and PCI groups at 3 years (Table 1). MACCE were

comparable between the CABG and PCI groups for low SYNTAX score (Table 1) (6). In LM/3VD patients with intermediate SYNTAX scores, the CABG group had fewer MACCE, fewer MIs, and a lower rate of repeat revascularization. In LM/3VD patients with a high SYNTAX score, the CABG group had fewer MACCE compared with the PCI group (Table 1).

**Clinical outcomes at 5 years.** Consistent with 1- and 3-year results, CABG remained favorable compared with PCI for LM/3VD with fewer MACCE and a lower rate of repeat revascularization (6). Death of any cause and stroke were not significantly different between the 2 groups (7). MACCE were comparable between the CABG and PCI groups for low SYNTAX score and were significantly lower in the CABG group for intermediate and high SYNTAX scores

compared with the PCI group (Table 1) (7). In a subgroup analysis of patients with 3VD, MACCE were significantly lower in the CABG group compared with the PCI group (24.2% vs. 37.5%,  $p < 0.0001$ ) (7). The 3VD subgroup with a low SYNTAX score had comparable MACCE between the CABG and PCI groups (26.8% vs. 33.3%,  $p = 0.21$ ). However, the 3VD subgroup with intermediate and high SYNTAX scores had lower MACCE with CABG compared with PCI (intermediate SYNTAX score: 25.8% vs. 36.0%,  $p = 0.008$ ; high SYNTAX score: 26.8% vs. 44.0%,  $p < 0.0001$ ) (7).

**Cost-effectiveness analysis of the SYNTAX trial.** A cost-effectiveness analysis (CEA) of the SYNTAX trial was performed for 1- and 5-year outcomes. Although 1-year survival was comparable between the CABG and PCI groups, quality-adjusted life years (QALYs) were lower in the CABG group compared with the PCI group (0.80 vs. 0.82,  $p = 0.003$ ) (7). PCI remained an economically dominant strategy with respect to QALYs gained at 1-year due to the lower cost and higher quality-adjusted survival. Due to the increased rate of repeat revascularization with PCI, CABG remained the approach to use to avoid repeat revascularization. Although the CEA will be limited at 1 year, there was an interaction between the SYNTAX score and the incremental cost-effectiveness ratio (ICER) measured in cost per QALY gained. PCI was found to be a dominant strategy in 3VD patients with low and intermediate SYNTAX scores. However, the ICER for 3VD with high SYNTAX scores was favorable for CABG even at 1 year (Table 1). The cost-effectiveness of CABG compared with PCI at 5-year follow-up demonstrated that the in-trial cost remained \$5,619 higher in the CABG group at 5 years with 0.1 QALY gained compared with PCI (8). Lifetime estimates suggested 0.412 QALY gained for CABG, making CABG an economically attractive strategy with an ICER of \$16,537/QALY gained for LM/3VD patients and \$4,905/QALY gained for 3VD patients. The cost-effectiveness of CABG versus PCI based on SYNTAX score showed CABG as a favorable strategy for those with high SYNTAX scores (ICER for CABG: \$8,219/QALY gained) and intermediate SYNTAX scores (ICER for CABG: \$36,790/QALY). For low SYNTAX scores, PCI remained a dominant strategy (8).

In summary, the clinical and economic outcomes at 5 years in the SYNTAX trial demonstrated CABG to be superior compared with PCI in nondiabetic patients with 3VD and SIHD by reducing MACCE, MI, and repeat revascularization with an attractive ICER of \$12,329/QALY gained. For patients with a high SYNTAX score ( $\geq 33$ ), CABG lowered all-cause mortality at 5 years and still remained highly cost-effective with an ICER of \$8,219/QALY gained compared with PCI.

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