Surgery is Better: I Like NOBLE

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The present ACC/AHA and ESC Guidelines, which are based on the SYNTAX, LE MANS, and PRECOMBAT trials, state that CABG is a COR/LOE I/B recommendation and PCI is either a I/B, IIa/B, or III/B recommendation for left main revascularization based on Syntax score tertile. Because these guidelines indicated that the outcomes of PCI were acceptable only in the patients with coronary artery disease of low or intermediate anatomical complexity, two large randomized trials of PCI with second generation drug-eluting stents versus CABG, the EXCEL l and NOBLE trials, were initiated under the assumption that contemporary metallic drug-eluting stents have a better safety and efficacy profile than do the first-generation stents used in earlier trials.

The NOBLE trial enrolled 1,201 patients in 36 centers, randomly assigned to either PCI primarily with the Biolimus‑eluting stent or CABG. The primary endpoint was MACCE including all-cause mortality, myocardial infarction, stroke, and repeat revascularization at a median follow-up of 3 years. The trial was designed as a non-inferiority trial with a confidence interval of 1.35. The 5-year Kaplan-Meier estimates for MACCE were 29% for PCI and 19% for CABG (HR 1.48 [95% CI 1.11‑1.96]), exceeding the limit for non-inferiority, and CABG was significantly better than PCI (p = 0.0066).

There are several noteworthy findings of the NOBLE trial. First, the 5-year Kaplan-Meier estimates for MACCE of CABG over PCI were significantly lower even in low SYNTAX score tertile. Second, a significantly better 5-year Kaplan-Meier estimates for MACCE was achieved after CABG although optimal CABG procedures were not done; only 16% of patients received the off-pump technique, only 17% of patients received the dual antiplatelet treatment for the postoperative 12 months, only 93% of patients received a left internal mammary artery graft, and 86% of patients received at least one saphenous vein graft. Third, the stroke rate gradually increased over time to an estimated 4.9% at 5 years with PCI, which was a higher incidence than in the CABG group. Fourth, the primary endpoint assessment was changed from the original design of a median 5-year follow-up to median 3 years because it was forecasted that the events to demonstrate the non-inferiority of PCI to

CABG would not be reached within full 5 years of follow-up.

The NOBLE trial state that the incidence of clinically apparent myocardial infarction, need for repeat revascularization and recurrence of angina is higher with PCI although survival is the same. However, patient results might not be applicable in the acute setting because the patients in the NOBLE trial were elective or stabilized. In conclusion, CABG should remain the mainstay of treatment of LMD if a patient is a good surgical candidate.