

## PCIとCABGには10年後の死亡率に差はない

SYNTAX試験: バイパス手術と冠動脈ステント留置術とでは10年後の予後は同等である

SYNTAX: Bypass surgery and coronary stenting yield comparable 10-year survival

新規発症3枝病変および左冠動脈主幹部病変を有する患者において、冠動脈バイパス術(CABG)と薬剤溶出性ステント留置術とでは10年生存率は同等である、とのSYNTAX Extended Survival 試験の結果がESC Congress 2019 で発表され、*Lancet*に掲載された。10年間の追跡調査の結果、患者群全体における生存率は薬剤溶出性ステントを用いたPCIとCABGとで差がなかった( $p=0.092$ )。事前に規定されたサブグループについてさらに解析した結果、3枝病変および進行した複雑な冠動脈病変を有する患者において、CABGは10年生存率において改善を認めた。糖尿病の有無で10年生存率に差はなかった。

### Full Text

Ten-year survival rates are similar for bypass surgery and coronary stenting with drug-eluting stents in randomized patients with de novo three-vessel and left main coronary artery disease, according to late breaking results from the SYNTAX Extended Survival study presented in a Hot Line Session at ESC Congress 2019 together with the World Congress of Cardiology and published in *The Lancet*.

Prespecified subgroup analyses showed that surgery provided a survival benefit in patients with three-vessel disease and more complex coronary artery disease, while no treatment differences were found in patients with left main disease.

Ischemic heart disease is the top cause of death globally. Percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG) are options for patients requiring revascularization. European guidelines advise discussing these patients in a multidisciplinary Heart Team.

Individual randomized trials comparing PCI with drug-eluting stents and CABG have not shown a survival benefit for either therapy at mid-term follow-up (e.g. up to five years). The SYNTAX trial was the first large-scale multicenter, randomized study in patients with de novo three-vessel and left main coronary artery disease that underwent PCI with drug-eluting stents or CABG. When clinical equipoise between PCI and CABG was presumed by the Heart Team, 1,800 patients were randomly assigned to PCI with paclitaxel-eluting stents ( $n=903$ ) or CABG ( $n=897$ ). Survival curves started to diverge after one-year follow-up and continued to diverge up to five years, but without reaching statistical significance.

The SYNTAX Extended Survival (SYNTAXES) study examined 10-year all-cause death rates in patients with de novo three-vessel and left main coronary artery disease randomized to PCI with drug-eluting stents or CABG in the SYNTAX trial. All 85 SYNTAX sites from 18 North American and European countries were contacted to provide survival data, which was obtained from healthcare records and national death registries. Completeness of follow-up was achieved in 94% of patients and was well-balanced between the CABG and PCI arms.

At 10-year follow-up, there was no survival difference between PCI with drug-eluting stents and CABG in the overall cohort of patients. There were 244 deaths after PCI and 211 after CABG (hazard ratio [HR] 1.17; 95% confidence interval [CI] 0.97–1.41;  $p=0.092$ ).

When analyses were conducted according to prespecified subgroups, CABG provided a 10-year survival benefit over PCI in patients with three-vessel disease (151 deaths after PCI versus 113 after CABG; HR 1.41; 95% CI 1.10–1.80;  $p=0.006$ ). CABG also provided a survival benefit in patients with increasingly complex coronary artery disease (defined by higher SYNTAX scores) – this was observed in the overall cohort and in those with three-vessel disease. In the subgroup of patients with left main coronary artery disease, no survival differences existed between PCI and CABG (93 patients died after PCI versus 98 after CABG; HR 0.90; 95% CI 0.68–1.20;  $p=0.47$ ). This resulted in a treatment-by-subgroup interaction according to the presence or absence of left main coronary artery disease ( $p$  for interaction=0.019). Furthermore, CABG and PCI resulted in comparable 10-year survival in patients with and without diabetes.

First author Dr. Daniel Thuijs of the Erasmus University Medical Center, Rotterdam, the Netherlands said: "The SYNTAX Extended Survival study presents robust, clinically relevant, and complete 10-year randomized survival data and can aid a multidisciplinary Heart Team discussion in the process of deciding on the optimal treatment strategy for a patient with coronary artery disease requiring revascularization."

The SYNTAXES study was supported by the German Foundation of Heart Research. The SYNTAX trial (0-5 year follow-up) was supported by Boston Scientific Corporation.

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