

PCIとCABGの相対的なメリットは未だに 解決されていない

SYNTAXトライアル：最も困難な病変の患者に対する薬剤溶出ステントとバイパス手術を比較したトライアルの結果、安全性は同等であったがPCIの有効性に関しては複雑な結果が得られた

SYNTAX: Trial comparing PCI with drug-eluting stent and bypass surgery in the most complex patients reports comparable safety outcomes but mixed efficacy for PCI group

最も困難な病変の患者に対するバクリタキセル溶出ステントを用いた経皮的冠動脈形成術(PCI)と冠動脈バイパス術(CABG)を比較したSYNTAX(TAXusを用いた経皮的冠動脈形成術とバイパス手術の相乗作用)トライアルの1年間のデータから複雑なメッセージが得られた：安全性は同等であり、PCIに割り付けられた患者の方が脳卒中の合併症発現率が低いが再血行再建術施行率はこれらの患者において高かった。PCIとCABGの直接比較において研究者らは、死亡(4.3%対3.5%、 $p=0.37$)または心筋梗塞(4.8%対3.2%、 $p=0.11$)のリスクに統計学的な有意差がないことを明らかにした。脳卒中のリスクはバイパス手術群で有意に高かった(4.8%対3.2%、 $p=0.11$)。総合すると、これら3つ(死亡、心筋梗塞、脳卒中)のデータポイントから、左主幹動脈病変および多枝病変を有する患者に対するPCIとバイパス手術の安全性は同等であることが示された。この結果はミュンヘンで開催された2008年European Society of Cardiology学会のHot Lineセッションで発表され、Lancetオンライン版に掲載された。

Full Text

One-year data from the SYNTAX trial comparing percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG) in the most complex patients has produced mixed messages: higher rates of revascularization for patients randomized to PCI, but lower rates of stroke. There were no statistically significant differences in rates of death or myocardial infarction between PCI and CABG.

The results of SYNTAX have been eagerly anticipated because the study is the first randomized comparison of PCI with drug-eluting stents vs. bypass surgery in patients with the most complex coronary artery disease -- left main stenosis and three-vessel disease. One-year data from the SYNTAX randomized trial were presented by Patrick Serruys and Friedrich Mohr in a Hot Line session at the European Society of Cardiology Congress 2008 in Munich and published online in The Lancet. They revealed findings for the primary endpoint, focusing on the safety and effectiveness of the two therapies and whether either group experienced more heart attack, stroke, or death, or was more likely to require repeat revascularization procedures (either a second PCI or bypass surgery) by the end of the first year.

All patients in the trial were assessed by a multidisciplinary team that included an interventional cardiologist and cardiac surgeon. If both felt they could offer equivalent revascularization, patients were randomized in a 1:1 fashion to PCI (which used a paclitaxel-eluting coronary stent) or CABG.

The trial enrolled 1800 patients in its randomized arm from 62 EU sites and 23 US sites.

In its head-to-head comparison of PCI vs. bypass surgery, SYNTAX found no statistically significant difference in risk of death (4.3% vs. 3.5%, respectively; $p=0.37$) or heart attack (4.8% vs. 3.2%, respectively, $p=0.11$). The risk of stroke was significantly greater for bypass surgery (0.6% for PCI vs. 2.2% for bypass; $p=0.003$). Taken together as a composite, these three data points (death, heart attack, and stroke) show that PCI and bypass surgery are equally safe options for patients with left main and multi-vessel coronary artery disease.

Other findings from the 12-month data showed that the rate of symptomatic graft occlusion was 3.4% in the CABG group, and the rate of stent thrombosis in the PCI group 3.3% ($P=0.89$).

"The study failed to meet its primary endpoint for non-inferiority," conceded investigator Patrick Serruys of Rotterdam, Netherlands, adding that the outcome was nevertheless "hypothesis generating". He said: "The results for the first time open the way for drug-eluting stents in patients with more complex anatomy and advanced disease who have traditionally been treated with CABG."

"The good news is that both PCI and CABG have improved," said discussant Christian Hamm from Bad Nauheim, Germany.

The "all comes" design of SYNTAX meant that patients who were not considered "eligible" for the randomized trial were enrolled into two registries, 192 to a PCI registry and 644 to a CABG registry.

Results from the registry analysis were also presented yesterday and showed that the total MACCE rate in the PCI registry was 20.4% at 12 months, and in the CABG 8.8%.

"The registry shows that, for patients not considered eligible for CABG, PCI is a viable option," said principal investigator Friedrich Mohr of Leipzig, Germany. "The surgical results are excellent for patients who are not candidates for PCI."

Conference

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