短期間の抗血小板薬2剤併用療法は有効である (Abstract 2218)

NIPPON：新たな薬剤溶出性ステント留置後の患者において、短期の抗血小板薬2剤併用療法は長期投与と同等である

NIPPON: Short-term dual antiplatelet therapy equivalent to longer course in patients with a newer drug-eluting stent

ある特定の薬剤溶出性ステント（DES）を留置された患者において、短期抗血小板薬2剤併用療法（DAPT）は、長期投与に比べ非劣性を示した、と2016年ESC Congressで発表された。トライアルの対象となったすべての患者は、生体吸収性ポリマー溶出のNoboriステントを留置され、アスピリン（1日81～162 mg）とクロピドグレル（1日75 mg）またはチクロピジン（1日200 mg）によるDAPTを施行された。今回のNIPPONスタディの結果から、正味の臨床的脳血管有害イベント－主要評価項目－発現率は、6か月および18か月のDAPT期間で同等であり、出血の合併症にも差がないことが示された。

Full Text

A short-term course of dual antiplatelet therapy (DAPT) is non-inferior to a longer course in patients who have undergone placement of a particular kind of drug-eluting stent (DES).

Results of the NIPPON (NoborI dual antiplatelet therapy as aPPrOpriate DuratioN) study, presented at ESC Congress 2016, showed similar rates of "net adverse clinical and cerebrovascular events" (NACCE) – the main outcome – with both 6 and 18-month DAPT durations, and no difference in bleeding complications.

"Based on these findings, a combination of short DAPT and a newer DES with bioabsorbable abluminal coating should be able to minimize the incidence of thrombotic events and bleeding complications simultaneously," concluded investigator Masato Nakamura, MD, PhD, of Toho University Ohashi Medical Center in Tokyo, Japan.

All patients in the trial had received the Nobori bioabsorbable abluminal-coated stent, with DAPT consisting of aspirin (81–162 mg/day) combined with clopidogrel (75 mg/day) or ticlopidine (200 mg/day).

The study enrolled 3,775 patients with coronary artery disease or acute myocardial infarction who had undergone percutaneous coronary intervention and stent placement at 130 Japanese institutions.

It incorporated broad inclusion criteria to reflect the real-world clinical setting.

However, an interim analysis showed slow enrollment and substantially lower events than expected, and the study was terminated early.

Results from only the first 2,772 patients to be followed for at least 18 months showed there was a 0.46% difference in occurrence of the primary endpoint among patients randomized to either short or long-term DAPT (1.92% vs. 1.45% respectively), confirming the non-inferiority of short-term therapy.

The rate of bleeding events was similar (0.73 % of the long-term and 0.96% of the short-term DAPT group), as was the rate of stent thrombosis (0.07% in both).

"The results of the present study should be interpreted with caution before trying to draw firm conclusions," cautioned Professor Nakamura. "The interpretation of the NIPPON trial is complicated by the fact that the event rate was lower than the expected incidence of the primary endpoint in both groups. Therefore, the statistical power may not have been adequate to fully assess the risk of primary endpoint."

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