短期抗血小板薬2剤併用療法はMIリスクを上昇させる (Abstract 18-LB-18938-ACC)

SMART-DATE：6か月間の抗血小板薬2剤併用療法により心筋梗塞が増加する

SMART-DATE: Myocardial infarction increases with six-month dual antiplatelet therapy

薬剤溶出性ステント植え込み後、6か月または最低12か月の抗血小板薬2剤併用療法（DAPT）にランダムに割り付けされた急性冠症候群（ACS）患者において、18か月以内の総死亡、心筋梗塞（MI）または脳卒中の複合発現率には有意差がなかった。しかし、DAPTを6か月しか施行されなかった患者は、12か月以上継続した患者に比べMIリスクが2倍以上高かった、とAmerican College of Cardiology's 67th Annual Scientific Session で発表され、同時に*Lancet* に掲載された。

Full Text

The combined rate of death from any cause, myocardial infarction (MI) or stroke within 18 months was not significantly different in patients with acute coronary syndrome (ACS) who were randomly assigned to receive dual antiplatelet therapy (DAPT) for either six months or at least 12 months after receiving a drug-eluting stent. Patients who were given DAPT for only six months, however, had more than double the risk of an MI compared with those treated for at least 12 months, according to research presented at the American College of Cardiology's 67th Annual Scientific Session and simultaneously published online in the *Lancet*.

"Based on our findings, we can't say that short-term DAPT is safe in patients with ACS who have received drug-eluting stents," said Hyeon Cheol Gwon, MD, a professor in the Division of Cardiology at Sungkyunkwan University, director of the cardiac center at Samsung Medical Center in Seoul, South Korea, and principal investigator of the study. "We conclude that current guidelines that recommend prolonged DAPT in patients with ACS who are not at excessive risk for bleeding should continue to be followed."

Current guidelines published by the American College of Cardiology and the American Heart Association recommend that ACS patients not at excessive risk for bleeding should be treated with DAPT — aspirin plus clopidogrel or a similar drug such as ticagrelor — for at least 12 months after the implantation of a drug-eluting stent. However, there is limited evidence that12 months or more is the optimal duration for DAPT, Gwon said.

Two recently reported studies suggested that six months of DAPT might offer similar benefits in terms of reducing patients' risk for death, myocardial infarction (MI) or stroke, bleeding or other adverse events. These studies, however, had too few participants to provide definitive answers, he said. "This is the largest trial to address the optimal duration of DAPT in patients with ACS," Gwon said.

The SMART-DATE trial enrolled a total of 2,712 Korean patients with ACS who were undergoing angioplasty. Their median age was 63 years, and 75 percent were male. Patients were randomly assigned to receive either DAPT for at least 12 months (DAPT-12) or DAPT for six months followed by aspirin alone for at least another six months (DAPT-6). The primary endpoint was the combined rate of death from any cause, MI or stroke within 18 months after stent insertion.

At 18 months, 63 patients (4.7 percent) in the DAPT-6 group and 56 patients (4.2 percent) in the DAPT-12 group had experienced at least one of the primary endpoint events. Thus, over the entire 18-month follow-up period, DAPT-6 was significantly not worse (or non-inferior) than DAPT-12, Gwon said.

Rates of death from any cause were not significantly different in the two groups (2.6 percent in the DAPT-6 group vs 2.9 percent in the DAPT-12 group). However, the risk of heart attack was 2.4-fold higher in the DAPT-6 group, with MIs occurring in 1.8 percent of DAPT-6 patients vs. 0.8 percent of DAPT-12 patients.

Moreover, during the period between six and 18 months after stent insertion when patients in the DAPT-6 group were being treated with aspirin only, there was a 5.1-foldrisk of having an MI in DAPT-6 patients compared with DAPT-12 patients.

During this period, patients in the DAPT-6 group also had a 69 percent higher risk of dying from any cause or having an MI or stroke.

Limitations of the study, Gwon said, include the absence of blinding — that is, both patients and doctors knew whether a patient was in the DAPT-6 or the DAPT-12 group — and the absence of a group that was randomly assigned to receive a placebo. However, study statisticians and those whose role was to assess outcomes worked independently from those overseeing the trial, he said.

Patients in the trial will be followed for an additional 18 months, for a total of three years of follow-up, Gwon said.

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