16年経過してもPCIは未だ血栓溶解療法に勝る

DANAMI-2試験：冠動脈ステント留置により死亡または再梗塞を1年以上遅らせることができる

DANAMI-2: Death or reinfarction delayed by more than one year with coronary stenting

転院を含むプライマリ経皮的冠動脈インターベンション（PCI）治療により、血栓溶解療法に比べ死亡または再梗塞を1年以上遅らせることができる、との DANAMI-2試験の結果が ESC Congress 2019 の Hot Line Session で発表され、*European Heart Journal* に掲載された。プライマリPCIを施行された患者は、16年間の総死亡または再梗塞からなる複合エンドポイント発現率が持続的かつ有意に低かった。これはコホート全体（PCI 58.7% vs. 血栓溶解療法 62.3%、ハザード比 [HR] 0.87）および紹介病院からPCI可能な高度医療センターに転送された患者（PCI 58.7% vs. 血栓溶解療法 64.1%、HR 0.84）、いずれにおいても明らかであった。

Full Text

Death or reinfarction is delayed by more than one year with a primary percutaneous coronary intervention (PCI) strategy that includes hospital transfer, compared to fibrinolysis, to late breaking results from the DANAMI-2 trial presented in a Hot Line Session at ESC Congress 2019 together with the World Congress of Cardiology and published in *European Heart Journal*.

"In the longest follow-up to date, the analysis confirms that primary PCI should be offered to ST-segment elevation myocardial infarction (STEMI) patients if transfer to a PCI center can be achieved within 120 minutes," said first author Pernille Thrane of Aarhus University, Denmark.

The DANish Acute Myocardial Infarction 2 (DANAMI-2) trial was the first to show that a reperfusion strategy with interhospital transport for primary PCI is superior to fibrinolysis at the local hospital in patients with STEMI at 30 days. Follow-up studies found sustained benefit at three and eight years.

"Very long-term outcomes are important to understand the full clinical impact of primary PCI versus fibrinolysis in STEMI patients," said principal investigator Dr. Michael Maeng of Aarhus University Hospital and Aarhus University. "But high costs and logistical challenges often limit the follow-up period in randomized trials."

This analysis of the trial investigated cardiovascular outcomes and mortality after 16 years of follow-up. A total of 1,572 STEMI patients were enrolled at 24 referral hospitals and five invasive centers in Denmark. Patients were randomly allocated to primary PCI or fibrinolysis. Patients randomized to primary PCI at referral hospitals were immediately transported to the nearest invasive center. For the first three years patients were followed- up with visits at the randomizing hospital. Afterwards, outcome data was obtained from Danish registries. The primary endpoint for this analysis was a composite of all-cause death or reinfarction.

Patients treated with primary PCI had a sustained and significantly lower rate of the composite endpoint of all- cause mortality or reinfarction at 16 years compared to patients treated with fibrinolysis. This was evident in both the entire cohort (PCI 58.7% versus fibrinolysis 62.3%) and in patients transported from a referral hospital to a PCI-capable tertiary hospital (PCI 58.7% versus fibrinolysis 64.1%).

Hazard ratios (HRs) for the benefit of primary PCI over fibrinolysis were 0.87 for the entire cohort and 0.84 for the transferred subgroup. The difference was primarily driven by a consistently reduced rate of reinfarction with primary PCI compared to fibrinolysis (PCI 17.5% versus fibrinolysis 21.8%; HR 0.78).

The average time to the composite endpoint was 10.6 years in the primary PCI group, leading to an average event postponement of 12.3 months compared to fibrinolysis. Furthermore, primary PCI reduced cardiac mortality by an absolute 4.4% (PCI 18.3% versus fibrinolysis 22.7%; HR 0.78), which is the first time that a single study has been able to demonstrate this benefit.

ESC guidelines recommend that STEMI patients are immediately transferred for primary PCI if the time from first medical contact to reperfusion is within 120 minutes. "This timeframe is based on the initial DANAMI-2 results and the long-term benefits are confirmed by this 16-year follow-up," said Ms. Thrane.

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