ステント留置を遅らせても臨床的有益性は示さなかった (LBCT 405-08)

DANAMI-3-DEFER：ステント留置の遅延または延期に関する最大規模のトライアルは有望な予備試験の結果を否定する

DANAMI-3-DEFER: Largest trial of delayed or deferred stent implantations contradicts findings of promising preliminary studies

ST上昇型心筋梗塞（STEMI）を来した患者に対するステント留置の遅延または延期は臨床的な有益性を示さなかった、とのDANAMI-3-DEFERトライアルの研究結果が第65回American College of Cardiology年次集会で発表され、*Lancet*に掲載された。平均追跡期間43か月後に、DEFER群のうち105人（17%）および標準治療群のうち109人（18%）が主要評価項目（総死亡、心不全による入院、2回目のMI、および予定外の再血行再建術の複合評価項目）に合致し、有意差はなかった。これらの結果は、ステント留置の延期は臨床的に有益であるとの予備試験の結果に反論するものである。

Full Text

Delayed or deferred stent implantation in patients experiencing the deadliest form of heart attack—ST-segment elevation myocardial infarction (STEMI)—failed to reduce death from any cause, hospitalization for heart failure, subsequent heart attacks or the need for a repeat revascularization, researchers reported at the American College of Cardiology's 65th Annual Scientific Session.

"The take-home message from this study is that deferred stent implantation cannot be recommended as a routine procedure for STEMI patients treated with primary percutaneous coronary intervention," said Henning Kelbaek, M.D., of Roskilde Hospital, University of Copenhagen, Denmark, and lead author of the study. "Our results completely rebut the promising findings of preliminary studies that suggested deferred stenting should translate to clinical benefit."

After the blocked artery is opened, the blockage site often contains residual blood clots that may, when the stent is implanted, be displaced downstream into the small branches of the artery. If this happens, it can damage heart muscle and block small blood vessels. Previous small studies suggested that delaying stent implantation for a period of time ranging from several hours to several days after reopening the artery might reduce the risk of blood-flow disturbance. The thinking was that medication given during the delay might allow the residual blood clots to diminish, reducing the risk of a displaced clot damaging the small branches of the artery. The DANAMI-3-DEFER trial was the largest trial yet conducted to evaluate whether delaying stent implantation would improve patients' survival and reduce their risk of heart failure or another heart attack.

In the trial, which took place in Denmark, 1,234 patients (average age 61; 75 percent male) with acute STEMI symptoms of less than 12 hours' duration were randomly assigned to receive standard angioplasty with immediate stent implantation or angioplasty followed by stent implantation after a re-examination 24 to 48 hours later. After an average follow-up time of 43 months, 105 patients or 17 percent in the DEFER group and 109 or 18 percent in the standard treatment group met the primary endpoint, a composite of death from any cause, hospitalization for heart failure, a second heart attack, and unplanned repeat angioplasty, a nonsignificant difference.

Although the trial was the largest so far to address the issue of delayed stent implantation, it may not have been large enough to detect a difference between the two treatment groups, Kelbaek said. Another limitation is that the trial did not select patients who were at the highest risk for developing another arterial blockage, such as those over age 65, those who have had more than one heart attack or those known to have a large number of blood clots.

"We cannot rule out that a fraction of our patients who met these criteria might have benefitted from delayed stent placement, especially because we found a small improvement in heart-muscle function 18 months after treatment among patients who underwent deferred stenting," Kelbaek said.

The study was not powered to detect this improvement, but Kelbaek said he and his team would now look carefully for possible "hypothesis-generating" findings in subsets of patients—both those who might have benefitted from the deferred-treatment strategy and, equally important, those in whom this strategy might have worsened their condition.

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