遅れて施行した経皮的冠動脈インターベンションの価値（OAT）

OATサブスタディの結果、心筋梗塞後遅れて経皮的冠動脈インターベンションを施行することによる長期ベネフィットは少ないことが示唆された

OAT substudy suggests that delayed percutaneous coronary intervention after myocardial infarction is associated with little long-term benefit

遅れて施行した経皮的冠動脈インターベンション（心筋梗塞から3～28日後）による長期ベネフィットは小さく、少なからぬ経費がかかる、とAmerican Heart AssociationのLate-Breaking Clinical Trialセッションで発表された。OATスタディの対象は主要な冠動脈が完全閉塞し症状発現から12時間以内に有効な治療を受けなかった患者である。インターベンションと最大限の薬物治療の費用対効果の解析において研究者らは、OATの対象患者951人の組み入れ時および組み入れから4ヵ月後、1年後、および2年後のQOLのデータを得た。インターベンションにより4ヵ月後の身体機能においては臨床的に有意な有益性が得られたが、その有益性は1年後には消失した。精神衛生上はインターベンションによる有意な有益性は認められなかった。二次的なQOLにおいては、インターベンションにより4ヵ月後および1年後の狭心症状がやや軽減したが、その効果は時間とともに減少した。

Full Text

Delayed percutaneous coronary intervention after myocardial infarction is associated with little long-term benefit and considerable financial cost, according to a late-breaking clinical trial presentation at the annual meeting of the American Heart Association.

The substudy results were announced one year after the major clinical study findings were presented last year.

The Occluded Artery Trial (OAT) was an NHLBI-funded prospective, randomized, multicenter trial comparing late intervention (at 3 to 28 days) with medical therapy alone in 2,166 patients with a totally blocked major heart artery who survived acute myocardial infarction. Patients were eligible for OAT if they had not received effective therapy (early intervention or thrombolysis) within the first 12 hours after symptom onset.

"The overall goal of this study was to compare cost and quality of life outcomes in patients randomized to the two arms of OAT," said Daniel Mark, MD, substudy lead author and professor of medicine and director of outcomes research at Duke Clinical Research Institute in Durham, N.C. Patients received either state-of-the art medical therapy alone (which included daily aspirin, beta-blockers, angiotensin-converting enzyme inhibitors and cholesterol-lowering drugs) or medical therapy plus intervention with stenting. Patients' median age was 59 years, 83 percent were Caucasian, and 78 percent were male. All patients were considered high-risk but stable and without evidence of severe ischemia.

Researchers obtained quality of life data from 951 OAT patients at the start of the study, then again during follow-up interviews at four months, one year and two years after enrollment. They also collected medical resource-use data (all OAT patients) and detailed healthcare costs data (U.S. patients only) out to two years. All comparisons were done according to the principal of intention-to-treat., so patients assigned to medical treatment were analyzed as belonging to that group, even if they later crossed over and had a procedure.

Two principal quality of life outcomes were compared: percutaneous coronary intervention was associated with a clinically significant benefit in physical function at four months, but this benefit was not sustained at one year or beyond. There were no significant effects on psychological well being. Of the secondary quality of life outcomes, intervention was associated with a modestly lower level of angina at four months and one year, but these benefits also diminished over time.

In the 469 U.S. OAT patients, 30-day costs (hospital + physician) were about $10,000 higher in the intervention arm than the medical arm. At the end of two years, the cost difference had narrowed somewhat to $7,000. In cost effectiveness analysis, intervention had higher costs and worse health outcomes than medicine.

"This analysis showed that in OAT eligible patients, a strategy of routine late (3-28 day) percutaneous coronary intervention was substantially more expensive than optimal medical therapy alone when the results were examined over a two year period and the small symptom benefits provided were insufficient to make PCI an economically attractive strategy," Mark said.