血管形成術時のルーチン血栓除去術には有益性は認められない (Abstract 410-08)

TOTAL：血管形成術時のルーチン血栓除去術に臨床的な有益性は認められず脳卒中リスクを上昇させる可能性がある

TOTAL: Routine thrombectomy during angioplasty associated with no clinical benefit and may increase risk of stroke

血管形成術を施行される患者におけるルーチン血栓除去術は、意図した有益性は得られず脳卒中リスクが上昇する可能性があるとのスタディ結果が第64回American College of Cardiology年次集会で発表され、同時に*New England Journal of Medicine*オンライン版に掲載された。重症心筋梗塞（MI）に対し血管形成術を施行された患者10,000人超を対象としたTOTALトライアルは、半数の患者を血管形成術単独群、残りの半数を血管形成術と手動による血栓除去術の両者施行群にランダムに割り付けた。6か月間の追跡期間後に、血管形成術単独群または血管形成術と血栓除去術の両者施行群では、一次エンドポイント（心血管死、MI再発、心原性ショックおよび最も重度の心不全の複合発現率）に関して差は認められなかった。また解析の結果、スタディの二次エンドポイント（一次エンドポイントとステント血栓症）においても有意差はなかった。しかし、血栓除去術施行群において脳卒中が統計学的有意に増加した。スタディにおいて施行された血栓除去術の全てがシリンジを用いて血栓を吸引する手動での血栓除去術であった。機械的血栓除去術は試されなかった。

Full Text

A technique used to clear blood clots from arteries to the heart in about 20 percent of patients undergoing angioplasty appears to increase the risk of stroke without providing the intended benefit, according to a study presented at the American College of Cardiology's 64th Annual Scientific Session and simultaneously published online in the *New England Journal of Medicine*.

The TOTAL trial, which included more than 10,000 patients undergoing angioplasty in response to a severe myocardial infarction (MI), randomly assigned half of the patients to receive angioplasty alone and half to receive angioplasty with manual thrombectomy, in which the surgeon uses a syringe to create suction to remove clots. Mechanical thrombectomy, an approach that uses machinery to create the suction, was not tested.

After six months of follow-up, researchers found no differences between patients who received angioplasty alone versus those who also received manual thrombectomy in terms of the study's primary endpoint, a composite of the rates of cardiovascular death, subsequent heart attack, cardiogenic shock and the most severe category of heart failure.

"The message from this study is that thrombectomy should not be used as a routine strategy," said Sanjit Jolly, M.D., associate professor and interventional cardiologist at McMaster University, Hamilton, Ontario, Canada, and the study's lead author. "Given the downsides we observed, the findings suggest thrombectomy should be reserved as a bailout therapy to be used only when an initial angioplasty attempt fails to open up the artery."

In the study, bailout thrombectomy was performed in 7 percent of the patients assigned to receive angioplasty alone.

Thrombectomy is an additional technique that can be combined with angioplasty in which the cardiologist creates suction to remove blood clots from the artery. It has been thought that removing clots in this way could reduce the likelihood of subsequent heart attacks or other problems. Current guidelines leave it to physicians to decide whether to routinely perform thrombectomy during angioplasty or use it only as a backup strategy in cases where the angioplasty fails to open the blockage.

The rate of cardiovascular death, subsequent MI, cardiogenic shock and the most severe category of heart failure was 6.9 percent in the group receiving thrombectomy and 7 percent in the control group, a difference that was not statistically significant. In addition to revealing no differences in the composite primary endpoint or the individual components of this endpoint, the analysis also showed no significant differences in the study's secondary endpoint, which included the primary endpoints plus stent thrombosis, an often-fatal condition in which a clot develops in an artery that has been propped open with a stent, or the need for revascularization, a second surgery to clear or bypass the coronary artery.

The study showed a statistically significant increase in stroke in the thrombectomy group. It is possible that removing a blood clot from the heart could increase the risk that the clot will be lost during the removal process and eventually travel to the brain, causing a stroke, but this explanation would likely apply only to strokes that occur soon after the procedure, Jolly said. The relatively small number of strokes observed in the study within 30 days – 33 patients, or 0.7 percent, in the thrombectomy group and 16 patients, or 0.3 percent, in the control group – leaves open the possibility that the finding was due to chance alone.

The researchers saw no difference in outcomes based on the size of the blood clots, despite previous speculation that the procedure might be particularly beneficial in patients with larger clots.

"There are still open questions that aren't resolved by our study, and this procedure could still be beneficial for a small subset of patients," Jolly said. "Clearly, for patients who fail an initial angioplasty attempt, thrombectomy may be very important and is really the only way to open up the artery. We did not design the trial to test the effectiveness of selective or bailout thrombectomy."

Previous smaller studies have suggested benefits of routine thrombectomy or showed mixed results, but these studies involved fewer patients and some were limited to a single hospital. This study included patients from 87 hospitals and 20 countries.

"Our findings illustrate the importance of doing large trials," Jolly said. "There are many things in clinical practice that we believe are beneficial but need to be tested in large randomized trials. Only by doing this can we be certain of what helps patients and move the field forward."

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