# PCI前の血栓吸引は生存率を改善しない

TASTEトライアルは心筋梗塞後に血栓を吸引する現在の診療に異議を唱えた

TASTE trial challenges current practice of blood clot aspiration after myocardial infarction

冠動脈再開通前に心筋梗塞を引き起こした血栓をバルーンカテーテルを用いて吸引を行うことは、バルーン拡張およびステント留置のみを施行する場合に比べ生存率を改善しないとの、Thrombus Aspiration in ST- Elevation myocardial infarction in Scandinavia（TASTE）トライアルの結果が2013年European Society of Cardiology学会で発表された。多施設前向き無作為化コントロールオープンラベルのこのトライアルでは、ST上昇心筋梗塞（STEMI）と診断されたスウェーデン、デンマークおよびアイスランドのSTEMI患者7,244人が組み入れられた。患者の半分は経皮的冠動脈インターベンション（PCI）群に、残りの半分はPCI前に血栓を吸引される群に割り付けられた。施術後30日間の死亡率はグループ間で有意差がなかった（それぞれ3.0%対2.8%）。同様に、新たな心臓発作、脳卒中および治療に関連した合併症などの二次エンドポイントに関しても、2群間で差はなかった。喫煙者、糖尿病患者および血栓が大きい患者などのハイリスク患者であっても、いずれの群でも同等の結果であった。TASTEトライアルの結果は血栓吸引をルーチンに付加することに疑問を投げかけており、国際ガイドラインにおけるこれを一般的に使用することに関する勧告はおそらく引き下げるべきであろう、と筆者らは述べている。

## Full Text

Aspiration of the thrombus that causes a myocardial infarction before re-opening a patient's artery with a balloon catheter does not improve survival compared to performing balloon dilation and stenting alone according to the results of the Thrombus Aspiration in ST- Elevation myocardial infarction in Scandinavia (TASTE) trial.

"We believe that TASTE questions the usefulness of thrombus aspiration as a routine adjunct and the recommendation for its general use in international guidelines should probably be down-graded," said lead author Ole Fröbert, M.D., Ph.D., from the Department of Cardiology at Örebro University Hospital, in Örebro, Sweden.

The multicenter, prospective, randomized, controlled open-label trial enrolled 7244 patients with STEMI from Sweden, Denmark and Iceland who had a diagnosis of ST-elevation myocardial infarction (STEMI).

Half of the patients were assigned to balloon treatment only (percutaneous coronary intervention, or PCI) and the other half had their blood clot aspirated before PCI.

The mortality rate at 30 days post-procedure was not statistically different between the groups (3.0% versus 2.8% respectively).

Similarly, there was no difference between the two groups for secondary endpoints including risk of new heart attack, stroke and complications related to the treatment.

Even high risk groups such as smokers, patients with diabetes or patients with large clots had similar results with either approach.

"Our findings do not support a role for this additional procedure as a routine future treatment," said Dr. Fröbert. The study results will likely have an immediate impact on clinical practice, he added.

Current European Society of Cardiology guidelines on treatment of patients with ST-elevation myocardial infarction (STEMI) recommend that thrombus aspiration should be considered and "most opinion leaders advocate its use," said study co-chair Stefan James M.D., Ph.D., from the Department of Cardiology and Uppsala Clinical Research Center at Uppsala University Hospital in Uppsala, Sweden. Since the presentation of the TAPAS trial that suggested a mortality benefit (*N Engl J* Med 2008;358:557-67) thrombus aspiration has "gained an enormous popularity," he explained. "The therapy is so popular among interventional cardiologists because it intuitively feels beneficial to aspirate the clot that closes the artery."

But recent research has suggested that thrombus aspiration also carries risks. In 2012, a meta-analysis associated the procedure with a borderline significantly higher rate of stroke (Int J Cardiol 2012;166:606-12.) and another study showed that systemic embolization can occur as result (*Circ J* 2009;73:1356-8).

The TASTE trial is the first large-scale randomized trial of thrombus aspiration for STEMI to be large enough to reveal meaningful findings on mortality and morbidity.

It enrolled more patients than all previous randomized trials of this procedure combined and included a much broader range of patients in order to make the results relevant to everyday clinical practice.

"An even more far-reaching impact is that our trial is the first trial ever to use the registry based trial concept, which we invented, " added Dr. Fröbert.

The study's unique Registry-Based Randomized Clinical Trial (RRCT) protocol used national registries as on-line platforms for randomization, case record forms and follow-up, making the trial economically and administratively feasible.

"This concept reduces costs to 1% or less of a conventional randomized trial and enables the testing of treatments that have no revenue potential. since commercial interest is often the main incentive behind large-scale randomized clinical trials," he said. "In general fewer of these trials are being performed because of the huge costs involved. This trial concept can help to break the deadlock of clinical trials."

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