When Recanalization Does Not Improve Clinical Outcomes

Shelagh B. Coutts, MD, FRCPC; Mayank Goyal, MD, FRCPC

See related article, pages 2761–2768.

Treatment of ischemic stroke is intuitively simple with fast recanalization of blood vessels being the goal. However, this is frequently easier in theory than in practice. That is why there is some optimism in the stroke community regarding novel devices (eg, MERCI retriever system, Penumbra catheter, balloon angioplasty, and so on) for revascularizing intracranial vessels. The concept of the penumbra device is straightforward with clot aspiration using a vacuum pump being central to its success. The penumbra investigators describe the results of a study designed to meet regulatory standards assessing the use of this catheter for clot aspiration in acute stroke.

The study was a prospective cohort study that enrolled 125 patients with a comparison to a historical control (the MERCI clot retriever study). Patients were enrolled with moderate to severe ischemic stroke (National Institutes of Health Stroke Scale ≥8) within 8 hours of symptom onset. A total of 81.6% of patients had their target vessel successfully recanalized to Thrombolysis In Myocardial Infarction (TIMI) 2 to 3. However, this did not translate into improved clinical outcomes with only 25% achieving a modified Rankin Scale score of ≤2 at 90 days. This is the major unanswered question from this article: if the vessel was recanalized, why would the patient not do well? Perhaps related to this are a couple of pieces of data missing from the manuscript. First, there is no description of the baseline imaging characteristics. Use of a semiquantitative scale such as the Study Group Alberta Stroke Programme Early CT Score (ASPECTS) may have explained the lack of clinical response in some patients. Second, time to recanalization is not discussed. Our personal experience is that when this device works, it works extremely well, with fast results, but this is not the case in all patients. Recanalization at a late time point with extensive early ischemic changes may in fact be harmful rather than helpful. The patients also appeared to have a mean delay between presentation and groin puncture of 2 hours. We wonder if there was an inverse relationship between time to puncture and likelihood of a good outcome. This is the drawback of any interventional procedure in that there is an inherent delay in getting the angiography suite mobilized. With the penumbra device, there is an opportunity to assess brain circulation and site of occlusion while the device is functioning and suction is on. It would have also been interesting to have seen data on time to clot removal once the system was in place. The authors also do not discuss in how many patients the direct thrombus removal part of the system was used. How frequently or not did investigators use this part of the system?

The bottom line is that the recanalization data are promising with the penumbra catheter; however, it remains to be seen whether this translates into improved patient outcomes. Perhaps better to regard this device as another “arrow in the quiver” rather than as the whole answer. Trials such as the Interventional Management of Stroke III study, which compares the intra-arterial approach with the current standard of care (intravenous tissue plasminogen activator), are really important if we are to progress in our knowledge of this disease. We hope in the near future to see an efficacy study using this device that uses clinical status as the primary outcome. In the absence of such a study, readers should interpret the “high” recanalization rate with caution.

Disclosures

None.

References


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