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Flow Diversion for Cerebral Aneurysms: A Cautionary Tale

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COMMENTARY

Flow Diversion for Cerebral Aneurysms: A Cautionary Tale

The article by Kulcsár et al[1] in this issue of the *American Journal of Neuroradiology* represents a sobering view of the potential pitfalls of flow-diversion therapy for cerebral aneurysms. Flow-diversion therapy of aneurysms has been available in Europe for some time, with the Silk device (Balt, Montmorency, France) and the Pipeline Embolic Device (ev3, Irvine, California) receiving CE mark in January and June 2008, respectively. Despite relatively widespread use of flow diversion for intracranial aneurysms in perhaps more than 2000 cases treated in Europe, South America, and elsewhere, to my knowledge, relatively few clinical studies have been published to date. In the United States, flow-diversion therapy remains investigational and limited to a few centers, but US Food and Drug Administration approval might happen soon and likely will lead to widespread clinical application of the technology. Physicians in the United States would be wise to carefully peruse the published experience of physicians around the world before adopting flow diversion in their own practice.

Adverse events related to flow-diversion therapy are now receiving much attention. The hemorrhages described are devastating and especially tragic when one considers that they occurred in some patients who had few or no symptoms. On the other hand, the aneurysms described by Kulcsár et al[1] typically have not only a poor natural history but also substantial adverse event rates with current therapies. This multicenter study does not provide us with an overall number of aneurysms treated with flow diversion, so we cannot know the rate of serious hemorrhagic complications. Such hemorrhages have been absent in the few larger case series published to date. Lylyk et al[2] and Szikora et al[3] reported flow-diversion treatment of 63 and 19 aneurysms, respectively, with no hemorrhages. We have treated 18 aneurysms at Mayo Rochester and fortunately have not yet had any serious adverse events (unpublished data, H.J.C.). These single-center experiences suggest that the overall risk of such hemorrhages with flow-diversion treatment of cerebral aneurysms might be less than 5%, but as Kulcsár et al point out, there may be subtypes of aneurysms that have a higher risk of hemorrhagic complication.

Patient selection will be a key issue as flow diversion is more widely introduced in the United States. Physicians should be careful not to be seduced by the new technology, calling in patients who have not needed treatment in the past (eg, asymptomatic or minimally symptomatic cavernous aneurysms) to be treated with flow-diversion therapy. We would recommend against calling in stable patients whom you have been following for years. Because of the risk of thromboemboli and parent artery occlusion,[4] it is important to ensure that patients are going to be compliant with medication. Psychosocial situations that are likely to lead to noncompliance are a contraindication to flow-diversion therapy. As we move forward, we will be able to better recognize those patients who are likely to benefit from flow-diversion therapy, as well as those who are likely to suffer serious complications.

With much attention now placed on the complications of flow-diversion therapy, we may be seeing an exaggerated hype cycle.[5] Perhaps the hopes for flow-diversion therapy were so high that they led to an unusually high peak of inflated expectations, which then set us up for a steeper-than-usual fall into a trough of disillusionment. Another issue may be that the hemorrhagic complications are particularly disturbing because we did not predict them and we still do not fully understand their pathophysiology. The hemorrhages that we are beginning to see with flow-diversion treatment of unruptured aneurysms are not like anything we have seen with conventional endovascular therapy with coils. This contrasts with hemorrhagic complications associated with the development of Onyx (ev3) embolization of arteriovenous malformations, which have been reported to occur at a higher rate than previously described with *n*-butyl cyanoacrylate embolization[6] but seem to have caused less anxiety among neurointerventionalists because they are likely due to familiar pathophysiologic mechanisms.

Flow diversion is undoubtedly a major advance in the treatment of cerebral aneurysms. Numerous impressive outcomes have been demonstrated in high-risk aneurysms for which there was no good treatment before the introduction of flow-diversion therapy. Currently, flow-diversion therapy seems to be best suited for aneurysms that are not amenable to coil therapy or surgical clipping or that are likely to recur following coil therapy. The ruptures of previously unruptured aneurysms and the need for antiplatelet medications suggest that flow diversion will not be widely applicable to ruptured aneurysms in their current form. Perhaps future generations of flow-diversion devices will replace coil therapy for many or most cerebral aneurysms, but this is not going to happen overnight. We have a lot to learn as we move forward with flow-diversion therapy, and the work of Kulcsár et al[1] is an important early contribution to our knowledge of the potential dangers of this emerging technology.

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