Creative use of endovascular devices in cerebral aneurysm treatment

To The Editor: The “balloon bounce” technique by Wolfe et al. (Wolfe SQ, Farhat H, Moftakhar R, et al: Intraaneurysmal balloon assistance for navigation across a wide-necked aneurysm. Technical note. J Neurosurg 112:1222–1226, June 2010) is a creative solution to the problem of how to navigate a device across the neck of a wide-necked cerebral aneurysm when tortuosity of the afferent artery or a sharp angle of the efferent artery becomes a challenge to all available guidewires and microcatheters. The authors inflated a HyperForm balloon (ev3) within the aneurysm sac to provide a contact surface to “bounce” another remodeling balloon across the aneurysm neck to a stable position. The HyperForm balloon was then deflated and removed, and a microcatheter was placed in the aneurysm for embolization. Three patients had aneurysms successfully occluded using embolization with Onyx 500 (ev3), but endosaccular coiling could surely have been done instead, and the same technique could have been used as a tool for “bouncing” a stent catheter as well. Some years ago I described one technical variant of intraaneurysmal balloon assistance for endovascular coiling of a wide-necked, unruptured aneurysm of the middle cerebral artery. In that case, after exhausting all available technical possibilities of navigating a remodeling balloon across the aneurysm neck, I placed a HyperForm balloon into the aneurysm neck and a microcatheter into the aneurysm fundus distally for coiling. The aneurysm was occluded using platinum coils, with the balloon inflated as the coils were deployed and some length of the balloon system’s guidewire. This inconvenience can be avoided by using a rounded, guidewire-free, flow-directed balloon for intraaneurysmal assistance. Second, Wolfe et al., in which a balloon catheter is navigated over a guidewire into the aneurysm until it makes a complete loop along the dome wall and exits into the afferent artery. Another is the “waffle cone technique” in which one deploys a stent into the aneurysm sac and afferent artery. These techniques have in common the fact that devices designed to bridge the aneurysm neck were instead used inside the aneurysm sac, and the procedures were successful and uncomplicated. It is important that such unconventional, “creative” techniques are subjected to peer review and description in the literature. It is also important to point out that the decision to use such a technique for the first time should be based on the operator’s skills, experience in treating the actual pathology, and extensive experience with the devices involved.

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The effect of carotid endarterectomy

To the Editor: I read with interest the article by Nagaki et al.1 (Nagaki T, Sato K, Yoshida T, et al: Benefit of carotid endarterectomy for symptomatic and asymptomatic severe carotid artery stenosis: a Markov model based on data from randomized controlled trials. Clinical article. J Neurosurg 111:970–977, November 2009). The purpose of this letter was to determine whether the effect of endarterectomy can be assessed only observationally or only experimentally.

For patients with both symptomatic and asymptomatic carotid artery stenosis, several major randomized controlled trials of carotid endarterectomy (CEA) have previously tackled the remaining effects of CEA on the risk of stroke. Nevertheless, because the risk of stroke among patients with asymptomatic carotid artery stenosis is quite low, whether to treat their stenosis with CEA continues to be an important public health concern.

The authors established a Markov model in order to assess the efficacy of CEA. There were 4 different health states modeled. The authors did consider the probability of transition from one health state to another state and calculated such a probability approximately by using data from major randomized controlled trials.

With regard to their baseline analyses, they adopted 3 comorbidity index values. They stated outcomes via the use of the anticipated number of quality-adjusted life years (QALYs) for a theoretical cohort treated with CEA and another without CEA.

In fact, CEA for asymptomatic stenosis had little benefit (0.07 QALY) for normal-risk CEA candidates who were older than 70 years of age, not to mention those who were even much older, according to the authors’ baseline analysis.

It is understood that some ethical and practical issues may hinder randomized trials in medicine and surgery.2 Therefore, despite the fact that the authors established a Markov model in order to assess the efficacy of CEA, of importance in this context is the other fact that in order to determine whether a study is truly experimental, it will be necessary to ascertain at least some comparisons between two groups that differ on the basis of an intervention of interest. Endarterectomy, for instance, is the intervention in the context of current discussion.

In fact, if the endarterectomy treatment is not properly (i.e., with randomized controls) compared to a conservative treatment or condition, the effect of endarterectomy can then be interpreted only as observational, not experimental at all.

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Response: We appreciate the author’s interest in our study. Carotid endarterectomy for asymptomatic carotid artery stenosis has been the focus of many reports and trials during the past decade. Although large randomized control trials have demonstrated a net benefit of CEA beyond that of the best medical treatment,1,4 the initial increase in events associated with perioperative mortality and morbidity required a few years for a benefit in event-free ratio to emerge. Therefore, long-term survival after CEA for asymptomatic stenosis is an important consideration when deciding whether to perform this prophylactic procedure. However, several natural history studies of patients with carotid artery stenosis have demonstrated decreased survival rates compared with the general population.2,3 These findings caused some concern about the long-term overall benefit from CEA.

Moreover, the clinical situation is more complicated than for simple stroke-risk versus treatment-risk analysis. It is undoubtedly important that CEA would be properly compared with a conservative treatment. We used a Markov model to address this problem. Although in order to construct the mathematical model, several simplifications are inevitable, Markov modeling permits an increase in complexity of the model, such as incorporating stroke rate in patients with or without CEA, surgical risk, or the long-term survival rate of “CEA candidates.”

In our baseline analysis for symptomatic stenosis, surgery produced a relatively large QALY gain. Sensitivity analysis regarding symptomatic carotid artery stenosis showed a net benefit of CEA, and the results were robust for parameter variation within clinically plausible ranges. Irrespective of comorbidities limiting life expectancy, as well as advanced age, symptomatic patients were deemed to be operative candidates for CEA. Even if increased perioperative risk was observed in patients with symptomatic stenosis, CEA nonetheless might be beneficial in the long term. On the contrary, in our baseline analysis, treatment for asymptomatic carotid stenosis yielded very little QALY gain, and surgery is not likely to have a large impact upon the burden of stroke. The benefit of CEA for such patients is only marginal and is rapidly lost to be negative because of the increased rate of surgical complications, advanced age, and comorbidities. Our results suggest that only carefully selected conditions, such as very low treatment risks in relatively young patients without comorbidities, could justify CEA for asymptomatic stenosis.

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