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AJNR Am J Neuroradiol 1998, 19 (8) 1387

<http://www.ajnr.org/content/19/8/1387.citation>

This information is current as
of June 22, 2025.

can be contemplated, but when disease has weakened the blood-brain barrier, high-dose administration of gadolinium compounds should not be approached with impunity until more experimental work has demonstrated the safety and efficacy of this procedure. The article by Ray et al gives us the appropriate

model and a baseline of information from which to proceed.

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Intracranial Angioplasty: A Little Science Enters into the Mix

Since the publication in 1980 of the first report of successful balloon angioplasty for symptomatic basilar artery atherosclerotic stenotic disease in two patients (1), several articles have appeared in the literature providing additional reports of the successes, limitations, and pitfalls of this evolving technique. All of the articles have had severe limitations in their study design, including small numbers of patients, loosely defined inclusion and exclusion criteria, lack of randomization, and retrospective analysis. The most encouraging results of any of the studies published to date suggest that balloon angioplasty for symptomatic intracranial atherosclerotic disease is probably the highest risk procedure with the least certain long-term clinical benefits in the therapeutic armamentarium of the interventional neuroradiologist. Despite this fact, the busy practicing interventional neuroradiologist is frequently referred for consideration for balloon angioplasty the desperate patient with symptomatic intracranial atherosclerotic disease, who has not responded to "maximal medical therapy," and is not considered a viable candidate for extracranial-intracranial bypass surgery. With everybody's personal experience with the procedure being relatively small, and the existing literature being confusing and somewhat conflicting, it is difficult for the interventional neuroradiologist to provide wise counsel to the patient and referring clinician.

In this issue of the *American Journal of Neuroradiology* (page 1525), Mori et al provide the readership useful information regarding angiographic characterization of intracranial atherosclerotic stenotic lesions. Using angiographic lesion characteristics described in the coronary artery angioplasty literature, the authors retrospectively sorted treated intracranial lesions into three categories and found significant differences in clinical success rates and the primary end points of death, ipsilateral stroke, or ipsilateral bypass surgery among the three categories. Forty-two patients were examined retrospectively, making this the largest published intracranial balloon angioplasty series. The authors are to be commended for providing the readership with guidelines regarding which lesions may be amenable, with acceptable risk, to balloon angioplasty.

Mori et al are careful to point out the many limitations of their study design. One addition potential

source of confusion deserves further comment. One of the inclusion criteria for balloon angioplasty was for the patients to be "unresponsive to maximal medical therapy." Unfortunately, what constituted maximal medical therapy was not defined. Were patients unresponsive to aspirin or warfarin anticoagulation or a combination of both? If patients were on warfarin anticoagulation, were they at therapeutic levels of anticoagulation at the time of failure? This is theoretically important, given the data we have from the warfarin-aspirin symptomatic intracranial disease study (2), another retrospective study that demonstrated a significantly lower percentage of major vascular events in patients treated with warfarin compared with patients treated with aspirin. In this study, of 88 patients treated with warfarin for a median duration of 14.7 months, six patients (7%) had an ischemic stroke (five nonfatal, one fatal).

Mori et al conclude their discussion by calling for a randomized trial comparing balloon angioplasty with medical therapy for the treatment of type A intracranial atherosclerotic lesions. This is certainly laudable, but in reality has little chance of being accomplished in the foreseeable future. The relative rarity of the proposed disease to be studied with nearly equivalent event rate of stroke expected between the two study groups will make it difficult to enroll enough patients to test the primary study hypothesis with sufficient power. Continuing advancements in catheter technology and the eventual introduction of stents capable of being deployed intracranially will make it increasingly tempting to treat patients with intracranial atherosclerotic disease endovascularly. We must remain cognizant, however, that warfarin anticoagulation at therapeutic levels remains an effective form of therapy for the majority of patients with this disease.

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