bolytics is premature, as the first tenet of patient care must always be to do no harm.

In our paper we discussed the limitations of ECASS and indicated that the intention-to-treat analysis was closer to what might be expected in routine practice. Our point was to emphasize that ECASS is essentially a negative, not positive, study, as has been suggested. Furthermore, the ECASS results might have been due to the higher dose of rt-PA given or the longer time to treatment. In addition, we did not imply that the casual administration of a thrombolytic was safe and effective. The "specified fashion" represents the only conditions under which the drug may be administered, given the current state of knowledge. Outside the inclusion and exclusion criteria of the NINDS study, at a minimum, there is no evidence of its safety. Individual institutions must develop protocols that ensure these criteria are met. Is even this enough, however?

Two recent studies have underscored the difficulty in using rt-PA safely in actual practice.[1,2] Conducted in 1995, before recent campaigns to increase public awareness of signs of a stroke, a population-based study reported that only 57 percent of respondents were able to name correctly one of the five established warning signs. Among persons older than 75 years, only 47 percent could correctly name one. If patients cannot recognize warning signs, they will not seek care within the requisite 3 hours. More importantly, can the physicians who would most likely make the decision to use rt-PA recognize an intracerebral hemorrhage on a CT scan with 100 percent sensitivity? In a recent study, only 17 percent of emergency physicians, 40 percent of neurologists, and 52 percent of general radiologists achieved this level of discrimination.

The NINDS trial reported a significant positive change in functional outcome at 3 months in those patients who received rt-PA for acute ischemic stroke. A recent analysis of the NINDS data, using a Markov model, estimated an increase in hospital costs of $1.7 million for every 1000 patients treated, with a decrease in rehabilitation costs of $1.3 million and a decrease in nursing home costs of $4.8 million. Also, more patients who received rt-PA were discharged to home than to an inpatient rehabilitation facility or a nursing home (48 versus 36 percent, $P = 0.02$).[3]

Although we believe that we did not simply echo national guidelines and that we appropriately stressed the need for caution in the use of thrombolytics throughout the article, clearly this is the overriding concern for everyone and, in reality, cannot be overemphasized. The bottom line remains: if conditions of NINDS at a minimum cannot be assured, thrombolytic agents should not be administered.

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Benefits of Lipid-Lowering Therapy

To the Editor: In a letter to the editor in the May-June 1998 issue of JABFP, Froom et al stated that we "imply that there are primary prevention trials other than the ones we reviewed; there are none. They imply that there are primary prevention trials in women and the elderly; there are none."[1]

At the time of our editorial, the results of the Air Force/Texas Coronary Atherosclerosis Prevention Study (AFCAPS/TexCAPS) had been presented at an international scientific meeting but were not yet published.[2] These data have since been published and corroborate our assertion that lipid-lowering therapy for primary prevention of acute coronary events is beneficial in populations other than middle-aged men.[3]

In this study, 6605 persons (including 997 women) with low-density lipoprotein cholesterol levels greater than 130 mg/dL were randomized to receive either lovastatin or placebo therapy and were followed for an average of 5.2 years. Patients were as old as 78 years when the study was completed. There was a 40 percent reduction in fatal and nonfatal coronary events, and there was a 25 percent reduction in myocardial infarctions and cardiac deaths. Women and older patients benefited from lipid-lowering therapy as much as men and younger patients. Only 63 patients needed treatment to prevent one heart attack or fatal cardiac event. This finding is what would be expected, because the population was at slightly lower risk than were the patients in the West of Scotland Coronary Prevention Study.[4]

Coincidentally, the exact same number of men older than 50 years needed to be treated with aspirin to prevent one heart attack in the Physician's Health Study.[5] This number is much lower than the number needed to treat to prevent one stroke in patients with mild hypertension.

We were unable to present these data when we wrote the editorial because they had not been published. The AFCAPS/TexCAPS study adds to the overwhelmingly consistent and positive clinical trial data concerning the benefits of lipid-lowering therapy in both sexes and across the age spectrum. We only wish other generally accepted aspects of medical care were so carefully studied and validated.

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