LETTERS TO THE EDITOR

Unethical Placebo Assignment in Clinical Trials of Thrombolysis

Marcia Angell, Executive Editor of the *New England Journal of Medicine*, recently argued that "the most frequent types of unethical research occurring today involve obtaining informed consent as a legalism, without truly informing the subjects, and inappropriately using a placebo group in a clinical trial." (1)

From Figure 1, showing the chronologic relation of the main placebo-controlled trials (2-16) of intravenous thrombolysis in acute myocardial infarction, one can readily realize that the research recently reported in the Journal by Munkvad and colleagues (10) is of this type.

Between 1986 and 1987, after publication of the results of some large studies (2-5) (arrows in Figure 1), it became evident that thrombolysis is a life-saving treatment for patients with acute myocardial infarction. For this reason, some investigators ended their placebo-controlled trials sooner than planned (6,8), or at least modified the study design (10).

Unfortunately, this sensitive behavior has not been shared by all, including the Esbjerg investigators (16), who began to randomize patients to placebo versus recombinant tissue-type plasminogen activator (rt-PA) on October 1, 1987, which is exceedingly late, and continued the trial to the planned end on June 1, 1988.

A short time ago, I noted (17) that the investigators of the Thrombolysis Early in Acute Heart Attack Trial (TEAHAT) study (15), completed in April 1988, were the very last to have deliberately deprived patients with acute myocardial infarction of a potentially helpful thrombolytic treatment. Now the Esbjerg investigators hold this unpleasant record. I hope that it will not be exceeded once more, or at least that scientific journals will no more reward such unethical research through publication.

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References


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