for the abnormal septal motion often noted in conditions of right ventricular volume overload. We felt that our case 4 represented a variant of right ventricular volume overload, as the cavity of the right ventricle was grossly distended by the large tumor. The septum at postmortem examination was noted to be not only infiltrated with tumor, but also displaced into the left ventricle; this convexity was probably further augmented by diastolic filling. With such an abnormal position of the septum at end diastole, its systolic motion would be anterior and, hence, "paradoxical." Echocardiographic views of the apex in our case also demonstrate abnormal septal motion.

We feel that paradoxical septal motion is not an important feature in the diagnosis of right ventricular tumors and would instead re-emphasize the importance of proper echocardiographic technique in examining the right ventricle.

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References


The Ethics of Testing during AMI

To the Editor:

The recent article by Oliva and Breckinridge (Circulation 56: 366, 1977) concerning coronary artery spasm as a feature of acute myocardial infarction with apparent arteriographic documentation, was of considerable interest. Admittedly, the question of coronary artery spasm as an epiphenomenon associated with acute myocardial infarction and subsequent coronary artery thrombosis is an important, if not controversial one which requires further understanding. One cannot read this study, however, without being disturbed by some major ethical considerations which I do not feel the authors addressed themselves to.

Specifically, one has to wonder what sort of justification the authors have to offer in undertaking invasive studies such as these in critically ill patients. Although the studies which Oliva and Breckinridge report attest to their arteriographic skill and may, in the long run, provide some insights into the genesis of acute myocardial infarction, they do not appear to have had any therapeutic benefit for the patients involved.

Certainly in the best and most experienced cardiac catheterization laboratories, coronary arteriography is not a procedure which is free of morbidity and, rarely, mortality. Major complications are most apt to be seen in just those patients who were reported in this study. Common sense would dictate that a patient who is in the process of sustaining an acute myocardial infarction would be placed in serious jeopardy were he to develop a significant arrhythmia or hypotensive episode, which are not infrequent complications following injections of arteriographic contrast media into coronary arteries.

Although the authors report no adverse cardiovascular effects of their studies, they do spend a considerable portion of their discussion marshalling arguments in support of their contention that the arteriographic examinations did not result in further myocardial necrosis. Obviously there was some concern about this potential complication and this being the case, one could reasonably question the justification for doing this type of study in the first place.

Under "Complications" the authors state that two of a total of seventeen patients studied developed femoral artery occlusions as a result of their arteriographic studies. No mention is made as to whether or not operative intervention was required to manage this complication nor whether there was any long-term disability as a result. One also wonders whether or not the possibility of this and other potential complications were discussed with patients beforehand. We are only told that the patients were "requested to voluntarily enter the study." How one obtains truly "informed consent" in an agitated patient with severe chest pain is not at all clear to me. Indeed it is of interest to note that eleven of seventeen patients studied were given morphine sulfate prior to angiography. Was consent obtained in these patients before they were given analgesic relief or was it obtained after the administration of an opiate, when the patients were sedated?

The points may appear trivial to some; however, I believe they raise important ethical, if not medicolegal, issues which should be resolved before further studies of this nature are done and published in reputable journals such as Circulation.

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The authors reply:

To the Editor:

Dr. Galst's concerns about the ethics of the study are exceeded only by our concerns. In order to ensure that informed consent was obtained, the following measures were taken: (1) The purpose and risks of the study were explained to the patient in the presence of a close family member (or, if no family members were available, a close friend) and a patient advocate. The patient advocate was an intern or resident who had no interest in the investigation. The function of the patient advocate was to ensure that the investigator explaining the study to the patient and family (or friend) did so in a clear fashion and did not misrepresent any medical information in order to obtain consent. (2) No patient was included in the study who in the opinion of the investigators, patient, family, or patient advocate was unable to understand the purpose and risks of the study. Any patient whose judgment seemed impaired by pain, alcohol, drugs or psychiatric illness was excluded. (3) The purpose of the study was explicit — to perform coronary arteriography in order to expand our knowledge about the pathophysiology of acute myocardial infarction. No mention or promise of any therapeutic benefit to the patient was made. If the patient asked (as often occurred) if any therapeutic benefit might be expected, we specifically denied this. The large number of patients who refused the study is an indication of our candor. The small number who accepted seemed to be motivated by a desire to contribute to medical knowledge and by altruism.

This project was thoroughly reviewed by the Human Research Committee at our institution and was unanimously approved. In addition, we reviewed the proposed study with prominent local academic cardiologists and obtained their imprimatur.

Dr. Galst's comment that because of "potential complications . . . one could reasonably question the justification for doing this type of study" is specious reasoning. Whenever any investigator does a study involving the performance of a procedure or the administration of a drug, the risk is weighed against the benefit. Knowledge is a form of benefit. The existence of a small risk does not make the study unjustifiable. When Lown et al.1 gave acetyl strophanthidin to patients with an acute myocardial infarction to assess the tolerance for digitalis during acute myocardial infarction, the risk of toxicity was recognized but did not preclude the study. Similarly, when Church et al.2 deliberately induced digitalis intoxication to compare the toxic properties of three different digitalis preparations the potential risk did not prevent the study.

We believe that clinical investigations pertaining to the pathophysiology of disease processes, without immediate benefit to the
The ethics of testing during AMI.
G Galst

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