EDITORIALS

ON THE ADVERSE REACTIONS TO CONTRAST MEDIA, AND THEIR INCIDENCE

PROGRESS in radiology has, in a large measure, paralleled the evolution and development of contrast media. Our daily studies investigating the gastrointestinal, urinary, and biliary tracts, and the more intricate procedures involved in vascular and neuroradiologic examinations bespeak the advances that have been made, and attest to the ever broadening horizon of clinical and scientific investigation at our command. The benefits that have accrued therefrom are immeasurable.

The requirements for high technical standards, clear cut sharply defined radiographic images, are exceeded only by the demands for increased patient safety—undisturbed anatomy and physiology of the tissues and organs involved, absence of toxicity and morbidity—following the administration of contrast media.

The progress that has been made in the development of contrast media, especially in the last decade, is most heartening, yet the specter of adverse reactions, morbidity and death following their use still haunts us. This becomes all the more significant with the rapid increase if not explosive rise in the number of vascular procedures performed.

The mechanism of adverse reactions remains obscure and the cause unknown. Occurrence is unpredictable and unwelcome. Although some statistical studies may reveal a relatively low incidence of morbidity and death, the fact remains that for the patient who succumbs to a fatal reaction the incidence is 100 per cent. This is neither the time nor the place to debate the theories attempting to explain the causes of adverse reactions, but to take cognizance of such occurrence, and of the potential hazard to the patient, the anguish to the radiologist, the distress and grief to the family.

The results of several surveys on adverse reactions have appeared in the literature. The large series reporting on fatal reactions are those of Jungmichel (1940), Pendergrass *et al.* (1942, 1958), DeBacker (1950), Coliez *et al.* (1955), Frommhold and Braband (1960), Wolfromm *et al.* (1965), and Toniolo and Buia (1966). These include over 25,000,000 intravenous urographies with a total of 258 deaths and about 7 million intravenous cholangiographies with a total of 48 deaths. The number of unreported deaths remains unknown. Other much smaller series indicated adverse reactions and death following cardiac and vascular studies.

It is thus obvious that while we have at our disposal contrast media of greater safety than in the past, both fatal and nonfatal reactions still occur. Their incidence is higher in some types of investigation than in others.

However, the true incidence of these reactions is not known. Routine reporting of adverse reactions or death is uncommon, and there is no machinery set up for such reporting. At present, reporting of adverse reactions is on isolated cases, on a voluntary basis, to the A.M.A. Registry on Adverse Reactions, to The Food and Drug Administration, or to the manufacturer. Such reporting does not reflect total activity or number of patients examined, and therefore is of no statistical significance. The need for a more effective and complete system of reporting is quite obvious. Only

then can the number of adverse reactions be related to the total examinations performed and a true incidence determined.

The gap in our knowledge in this area was recognized at the last International Congress of Radiology. As a result a group of Radiologists joined together to form the Committee on Safety of Contrast Media.

This Committee consists of: Dr. James Ryan, Australia; Dr. George Ansell, England; Dr. Robert Coliez, France; Prof. Walter Frommhold, Germany; Prof. G. Toniolo, Italy; Prof. George F. Saltzman, Sweden; Dr. William H. Shehadi, U.S.A., *Chairman.*

The purpose of this Committee is to encourage adequate and complete reporting by interested radiologists. This calls for a central pool for the collection of data. The free exchange of information so gained can do much to prevent avoidable complications and at the same time provide material for research, which may bring us closer to an understanding of the nature of adverse reactions and a discovery of their cause. A program for a broad prospective survey with accurate, well controlled continuous reporting should thus be established. This will require the full cooperation of interested radiologists and other physicians, working in different centers, coordinating their efforts, pooling their information with continuous reporting of all examinations.

Keen interest in the incidence and grave concern over the problem of adverse reactions was in strong evidence at a recent meeting in Berlin with representatives of the major companies which manufacture contrast media throughout the world. A great deal of work is being done on the pharmacology and physiology of contrast media. It is the intention of this Committee to help coordinate this work and bring about free exchange of information and valuable data.

In conducting such a survey an acceptable and comprehensive form will be provided to the participating physicians. This form can be readily attached to the request for radiologic contrast studies to be completed at the end of the examination. Filling out such a form should be quite simple and not time consuming, since the greater number of patients will not manifest any reactions. The minor reactions should be easy to record, and only the rare major reactions will call for detailed reporting. Such a survey will not only bring out the type and nature of the reactions to contrast media but also the effect or role, if any, of other concurrently administered drugs or medications.

To some such work may seem tedious and laborious. In the long run this will prove to be a most rewarding and valuable contribution. All information and data will be shared by interested radiologists, investigators and institutions on a national and international level. The cooperation of all concerned will serve Radiology and will enhance patient safety.

The search for newer and safer contrast media continues.

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