Informed consent and special procedures

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The legal doctrine of informed consent is not new; however, it has not been widely applied by physicians. Should it be widely used? The patient today is considerably more curious than his father or grandfather. The mass media have made the average American acutely aware of the possible complications and hazards in various procedures, and have repeatedly focused attention on medical malpractice. Informed consent has become an issue and, for this reason, it seems logical that a study of its application be made. The purpose of this communication is to point out the patient's reaction to informed consent and to help the physician who is contemplating its use to understand his patient and exchange information with him.

Informing a patient of complications which might occur as a result of special procedures is often a thorny problem. The physician has a legal responsibility to obtain an informed consent before undertaking a procedure which carries serious risk. However, many physicians regard the task as disagreeable, time-consuming, and likely to make the patient apprehensive. Questions which arise immediately are: What information should be given the patient? How should it be presented? To what extent should the physician pursue the issue to be certain that his patient is truly giving an informed consent? Will the patient refuse because of the information he has received?

In a preliminary report in May 1971, most patients about to undergo arteriography reacted favorably to knowledge of possible complications associated with the procedure.[1] Specifically, 89% of 232 considered this information useful, and the majority felt that all patients should receive this information. Ninety-eight percent consented to the procedure. This communication presents additional data on 800 patients, 790 of whom underwent arteriography after informed consent was obtained. Experience to date has strengthened our conviction that informed consent benefits both patient and physician.

Methods

All patients undergoing arteriography were given consent forms and appended questionnaires before angiography and before the administration of medication. Consent forms were given to patients the evening before the angiographic procedure when the patients were prescheduled (approximately 70% of cases). When the patient was a minor, the parents or legal guardian were given the consent forms. The next of kin were requested to give consent when the patient was incapable of giving an "informed consent." The following consent form was given to each of 800 patients referred for angiography. The only exceptions were emergencies.

Consent for angiography

Dear Patient,

Your doctor has referred you for an angiogram, which is a study of your blood vessels. This is one of the most accurate studies we can make concerning the condition of your blood vessels. As with all medical procedures, it carries some risks, about which we think you should be informed. Your doctor is aware of these risks and has determined that the benefit in diagnostic information which may be obtained from the arteriogram outweighs the potential risk of the procedure.

In this procedure, a small tube (catheter) is introduced into one or several of your blood vessels. Through this tube, a solution will be injected which will enable us to see your blood vessels on x-ray films. This tube is introduced into a blood vessel, either in your arm or your groin, by means of minor surgery, under local anesthesia.

Patients, understandably, wonder what complications can occur from this procedure. It does involve some minor surgery and it does involve entering the body and the blood stream. The usual complications which we would consider relatively minor, but nevertheless can be distressing to patients, are accumulations of blood in the tissues where the catheter has been introduced (hematoma), or a small outpouching of the artery at the site where it was entered by the catheter. There are less frequent complications we consider more serious, which might lead to serious damage or to loss of an organ. Surgery may be required to correct the complication.

Very rarely, complications from the procedure have resulted in death. This has occurred four times in the 6,500 angiograms we have performed. Our overall serious complications rate is approximately one in 500 angiograms.

It would be impractical, and probably misleading to the average person, to describe here in detail all of the complications which might possibly result from this procedure. If you would like more detailed information, we will be glad to discuss it with you.

Sincerely yours,

I, _____, have read the above and give my consent to have an angiographic procedure performed.

_____
Signature of patient

_____
Date

1. Do you regard the above information as useful? Yes ___ No ___
2. Do you think all patients should receive the above information? Yes ___ No ___
3. Do you desire further information regarding specifics of possible medical complications of this procedure? Yes ___ No ___
4. Has this information caused you to change your mind as to whether to go through with this procedure?
   a. Makes me more comfortable going ahead with it.___
   b. Did not affect me one way or the other.___
   c. Makes me less comfortable going ahead with the procedure. ___
   d. Has caused me to decide not to go ahead with the procedure. ___

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As in the preliminary study, these consent forms were given to patients by members of the nursing or resident staff. No explanation was given to eliminate bias and obtain uniformity. Patients who requested additional information concerning complications were spoken to by members of the professional staff.

Results

Results of the questionnaire presented in *Table* show that 87% of patients considered this information

Table. Informed consent, 800 cases

	Yes	No	Not checked
1. Do you regard the above information as useful?	703	42	6
2. Do you think all patients should receive the above information?	629	106	16
3. Do you desire further information regarding specifics of possible medical complications of this procedure?	126	604	21
4. Has this information caused you to change your mind as to whether to go through with this procedure?			
a. Makes me more comfortable going ahead with it, 254			
b. Did not affect me one way or the other, 286			
c. Makes me less comfortable going ahead with the procedure, 202			
d. Has caused me to decide not to go ahead with the procedure, 10			

9 patients did not check 4a-c
39 patients checked none of the questions but gave consent
790 patients gave consent—10 patients refused

useful, which compares favorably with 89% who gave affirmative answers to the same question in the preliminary study. Despite the disclosure of this information, 98.8% of patients consented to the procedure; 10 patients refused.

Most patients (78%) felt that the information should be provided to all patients. Approximately 15% felt the need for additional information concerning possible complications. Answers to questions 4A through C indicate that 67% of patients (4A plus 4B) were not disturbed by this information or felt reassured by it. The remaining 202 patients (25%) expressed increased apprehension but consented to the procedure.

Discussion

The consent form used in this study is straightforward. A less detailed study of the patient's reaction might have been criticized as not constituting an informed consent. On the other hand, critics of this form have maintained that it did not go far enough, and that all possible complications should be explained.[2] We have taken a middle position on this issue and will maintain it until a court case proves it necessary to do otherwise. The form was designed to eliminate an exhaustive list of extremely rare complications which we believe could only serve to increase apprehension. The author and legal counsel believe that the statements in this form are sufficient to constitute the basis for a truly informed consent.

Statistical results indicate general acceptance of such a form, but significant questions remain. How best can the patient be made aware of complications and yet be spared undue apprehension? (It will be remembered that 25% of patients stated that the information imparted to them caused them to be less comfortable in going ahead with the procedure.)

A verbal, personal communication between patient and physician has several advantages. The physician can establish good rapport and quickly answer the patient's questions. This can generally be accomplished in the presence of another physician or a nurse, and a note to this effect entered in the patient's chart. The absence of a specific form and signature of the patient giving consent may, however, have legal disadvantages. In instances when a patient is unconscious following complications of the procedure, it would be impossible to determine from the patient whether informed consent had actually been obtained.

The written form presented here is impersonal and strongly worded but may have more legal significance. Future revision of this form hopefully will decrease apprehension but not significantly alter the context.[3] Perhaps both verbal or written consents may prove acceptable. It remains to be seen how a detailed informed consent obtained by either method will be judged in a court of law. Many courts have rejected general consent forms for the reason that they lack information concerning specific implications and complications of the proposed procedure. To my knowledge, specific consent forms such as that which appear in this article have not been tested in court.

One published argument opposing the use of this consent form maintains that frequently patients are uninformable, do not understand the language, are uneducated, unintelligent, senile,

or too intelligent to be given the form.[2] In contrast to this position there are other physicians who use similar forms. Acceptance by the patients has been good.

An additional advantage to informed consent is that it may serve to prepare the patient psychologically for complications which may occur. In brief it is suggested that you be honest with your patient. The author has felt much more at ease performing angiography on the informed patient.

References

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2. Demy NJ: Informed opinion on informed consent. JAMA **217:** 696–697, 1971.
3. Meaney TF, Lalli AF, Alfidi RJ: Complications and Legal Implications of Special Procedures. St. Louis, C V Mosby Company, 1973.