Emotional Responses to Detailed Risk Disclosure for Anesthesia, a Prospective, Randomized Study

JAMES W. LANKTON, M.D.,* BARRON M. BATCHelder, M.D.,* ALAN J. OMINSKY, M.D.†

With arguments based on the theory that a man should have control over his own body, several court decisions indicate that the risks and possible complications of a medical procedure must be disclosed before truly informed consent can be given. As the standard for disclosure, recent decisions have cited risks that a prudent person would consider significant. For this purpose, significant risks have been defined as those whose disclosure might cause a patient to reject a particular form of medical therapy.

Concern that excessively detailed risk disclosure might frighten patients, and perhaps even itself add to risk because of increased apprehension, was first expressed in an early discussion of consent for treatment. As a consequence, the courts recognize that the physician has a "carefully circumscribed" privilege to withhold information which "would present a threat to the patient's well-being." However, a priori presumption of adverse patient reaction to detailed risk information may be unwarranted, as suggested by the overall favorable patient response to knowledge of possible complications of angiography.

From the point of view of the anesthesiologist, there are two major questions. First, which risks should be disclosed? Suggestions have ranged from none, aside from the surgical risk of "death or serious harm," to those specifically defined as significant. Second, what effect will risk disclosure have on most patients? Legal decisions will continue to deal with the first question. To help answer the second, we carried out a prospective study of patient responses to detailed discussion of risks of anesthesia.

METHODS

Twenty-eight healthy (physical status 1 and 2) gynecologic patients were prospectively and randomly divided into two groups. The control group (12 patients) received a conventional preoperative visit the night before operation. During the visit, the anesthesiologist discussed the planned procedure (anesthetic and surgical) but avoided mention of specific complications. The experimental group (16 patients) received a similar visit, along with a discussion of the following possible complications:

1) Phlebitis associated with intravenous infusion
2) Drug-induced reactions, including hepatic failure
3) Injury to lips and teeth
4) Prolonged sore throat and hoarseness
5) Aspiration pneumonitis
6) Hypotension causing cardiac or central nervous system damage
7) Peripheral nerve injury from pressure or stretch
8) Pharmacogenetic problems, e.g., malignant hyperthermia

Patients receiving the "detailed risk discussion" were told that the overall incidence of anesthetic deaths was approximately 1:10,000.

All preoperative interviews were done by the same physician (JWL), who emphasized the unlikelihood of the serious complications. Both groups received the same preoperative medication: secobarbital, 2.2 mg/kg, im, given one hour preoperatively.

We obtained the following data:

1) An assessment of patient apprehension before anesthetic induction. Two anesthesiologists, both unaware of the type of preoperative visit, independently interviewed each patient, just before the patient was taken into the operating room. They recorded their estimates of the patient's apprehension by marking a measured 13-cm line at an appropriate point between ends marked "very calm" and "very apprehensive." The distance (in centimeters) from the end of the line marked "very calm" was later measured, and provided the observer score for patient apprehension.

2) A numerical estimate by the patient of her own apprehension, obtained just before anesthetic induction. This estimate was obtained and recorded by one of the observer anesthesiologists after that observer had recorded his own impression.

3) A systematic interview with the patient postoperatively concerning
CLINICAL REPORTS

TABLE 1. Assessment of Apprehension*

<table>
<thead>
<tr>
<th>Group</th>
<th>Observer 1</th>
<th>Observer 2</th>
<th>Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>6.74 ± 1.15</td>
<td>7.21 ± 0.87</td>
<td>6.02 ± 1.37</td>
</tr>
<tr>
<td>B</td>
<td>5.36 ± 0.54</td>
<td>5.37 ± 0.47</td>
<td>5.31 ± 0.87</td>
</tr>
</tbody>
</table>

*Apprehension assessments made by observers 1 and 2 and the patients themselves. Scores given as means ± SE. The values ranged from 0.5 to 12.4, out of a possible 0 to 15, with 0 as very calm and 15 indicating extreme apprehension.

RESULTS

The two patient groups proved similar with regard to most surgical and sociologic considerations, including seriousness of illness (benign, questionable, or malignant); planned surgical procedure; length of time between premedication and evaluation for apprehension. Despite randomization, the patient groups differed significantly with respect to age, with the control group (45.6 ± 2.8 years, mean ± SE) older than the experimental group (34 ± 2.7 years).

The apprehension scores given by the independent physician observers and by patients themselves are listed in table 1. There was no statistically significant difference between either the observers or the two groups. To assess the possible contribution of patient age to response to informed consent, we compared the apprehension scores of patients younger than 40 years old with those of patients more than 40 years old, and found no significant difference.

Postoperative Interview Results

All of the patients remembered the occurrence of their preoperative visits; for the informed-consent group, the numbers of previously discussed complications actually recalled ranged from 0 to 5. In response to the question, "Would you like complete disclosure of the risks of anesthesia if you were to have surgery again?" 7/12 controls and 7/16 in the informed-consent group said they would not. In response to the question, "Did the detailed discussion of possible complications frighten you?" four of the 16 patients in the detailed-disclosure group responded that they had indeed been frightened by the discussion.

Miscellaneous Observations

At their preoperative interviews, three of the patients in the detailed-disclosure group requested that the list of complications be stopped before all risks could be discussed, while none of the patients in the control group asked whether there were complications of anesthesia.

Comments made at the postoperative interviews included statements of two patients that the risk discussion had been very interesting, and that they had enjoyed learning about anesthesia. One patient who developed sore throat and hoarseness postoperatively said that learning preoperatively about the possibility of these complications had made them less frightening when they actually occurred. Negative comments included one patient's statement that the detailed risk discussion had made her very angry, since she "saw no point to it," and felt she had "no choice" about the anesthesia. As an explanation for the fact that she could remember only one of the complications discussed, one patient volunteered that she had probably "blocked out the other complications" in an effort not to be bothered by them.

DISCUSSION

In our sample, no patient refused anesthesia. We could not demonstrate a statistically significant difference in preoperative apprehension between the patient groups. Possible explanations include: 1) no such difference existed; 2) any difference was obscured by other patient variables, such as age; 3) premedication, the doctor-patient relationship, and/or patient denial had already blunted apprehension, and our method was inadequate to detect remaining subtle differences.

The assessment of apprehension is notoriously difficult, particularly in a clinical setting. Although such autonomic reflections of subjective feelings as galvanic skin response and forearm blood flow have been measured and may reflect patient apprehension, the application of these methods and their validation are difficult. We believe that the most useful method for assessing apprehension utilizes a combination of an observer's judgment and the patient's subjective assessment, recorded in as quantitative and reproducible a way as possible.

Individual responses to detailed risk disclosure ranged from gratitude, on one hand, to anxiety severe enough to make a patient request that no further complication be mentioned, on the other. It is clear that some patients definitely do want
detailed discussion of risks before anesthesia, but it is equally clear that some do not. At least for some patients, discussion of risks and the increased physician dialog that goes with it may be beneficial. However, our data are also compatible with the hypothesis that certain patients are unable or unwilling to tolerate a detailed discussion of possible anesthetic risks, and that such a discussion may not be in their best interest. At the present time, we feel the most reasonable approach is to tell all patients that there are serious, although remote, risks of anesthesia, but to allow the individual patient to decide how much additional information he or she wishes to obtain about these risks.

Anesthesiology
46:296–297, 1977

Anesthesia, Sleep Paralysis, and Physostigmine

MICHAEL SPECTOR, M.D.,* AND DENIS L. BOURKE, M.D.,†

Sleep paralysis, a relatively unknown and uncommon disease, is characterized by an inability to execute any voluntary activity while fully awake. During such an episode, loss of muscle tone, decreased blood pressure, and hypoventilation, often with irregular respiration, are observed. Episodes usually occur upon awakening (hypnagogic or posthypnoidal) or, more rarely, on falling asleep (hypnagogic or predorminal). Sleep paralysis may occur as a single entity, but commonly is found together with the narcolepsy syndrome.

REPORT OF A CASE

A 33-year-old white woman was admitted to the hospital with pain in the right lower quadrant of the abdomen of several weeks’ duration, initially slight but recently increasing in intensity. In the past the patient had received general anesthesia at least five times with no untoward sequel. Past medical history was remarkable only in that the patient had had recurrent episodes of sleep paralysis, for which she had received unsuccessful treatment. The patient had no allergy, took no drug, did not smoke, had minimal alcohol intake, had no other diseases, and had no history of psychiatric illness.

* Resident in Anesthesiology, New England Medical Center Hospital.
† Assistant Anesthetist, New England Medical Center Hospital; Assistant Professor in Anesthesiology, Tufts University School of Medicine.

Received from the Department of Anesthesiology, Tufts-New England Medical Center Hospital, 171 Harrison Avenue, Boston, Massachusetts 02111. Accepted for publication November 12, 1976.

Address reprint requests to Dr. Spector.

Physical examination was non-contributory with the exception of tenderness in the right lower quadrant and slight rebound tenderness. Results of laboratory examinations, including chest x-ray, ECG, and IVP, were within normal limits. The patient was scheduled for exploratory laparotomy the next day.

During the preanesthetic interview, the patient expressed considerable anxiety over the possibility that one of her episodes of sleep paralysis might be misinterpreted as a cardiac arrest and unnecessary cardiopulmonary resuscitation begun, as had occurred during a previous hospital stay. This had not occurred in the peri-anesthetic period, but the patient was determined to alert everyone to the possibility.

On the morning of operation, the patient was premedicated with morphine, 10 mg; diazepam, 10 mg, and atropine, 0.4 mg, iv. She arrived in the anesthesia area sedated and in good spirits. She was prepared for anesthesia, taken to the operating room, and anesthetized. The surgical procedures consisted of abdominal exploration and left ovarian cystectomy. Anesthesia was maintained with nitrous oxide, oxygen, fentanyl, 0.1 mg, and pancuronium, 4 mg. Following the operation the residual action of pancuronium was reversed with neostigmine, 3.0 mg, and atropine, 1.0 mg, iv. Response to electrical nerve stimulation indicated minimal paralysis, and the patient was able to generate inspiratory force to 50 torr. The trachea was extubated and the patient was taken to the recovery room. In the recovery room she manifested an unusual glassy-eyed stare, and was unresponsive to either verbal command or noxious stimuli. Respirations were very irregular, with alternating periods of apnea, sighs, and tachypnea without evidence of airway obstruction. The patient’s husband, a physician, said she appeared as though she were having an episode of