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What do patients recall from informed consent given before orthopedic surgery?

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Objectives: We aimed to evaluate the effectiveness of the consent process and the retention of relevant information in patients with orthopedic trauma and those undergoing elective surgery.

Methods: The study enrolled 142 consecutive patients (79 women, 63 men; mean age 52.02±20.05 years) undergoing either elective or trauma-related surgery. The patients were introduced to the consent process, which involves a verbal and written explanation of the orthopedic condition, surgical procedure, and intraoperative and postoperative risks. At postoperative 1-3 days, patients were asked to recall the orthopedic condition, procedure they underwent, and risks of the surgery.

Results: The rate of recall by patients was 131/142 patients (92.3%) for diagnosis, 86/142 patients (60.6%) for surgical procedure, and 32/142 patients (22.5%) for potential complications. Fifty-nine patients (41.5%) could not recall any potential complications. Gender did not influence the ability to describe the operation or potential complications ($p>0.05$). Advanced age negatively affected recall of information about the surgery and complications ($p<0.01$), and educational level was correlated with the recall rate ($p<0.05$). Forty-two patients (29.6%) claimed to have read the consent form before signing it. A greater percentage of patients undergoing elective surgery had read the consent form ($p<0.05$). Rate of not recalling any potential complications was higher in the trauma group compared with the elective surgery group ($p<0.01$).

Conclusion: Patients had poor retention of information presented during the consent procedure. Further attention should be focused on enhancing patients' understanding of several components of the informed consent process for surgery.

Key words: Informed consent; orthopedics; surgery.

The medical procedures and treatments applied to patients by doctors are performed only after a series of decisions. For diagnosis, the doctor makes the majority of decisions, such as which physical examination techniques and tests to apply, which laboratory tests and imaging techniques will be performed, and which consultations will be required. Although the physician has the authority to make the decision, in the choice of some invasive procedures and treatment, currently, a compromise is reached between patient and doctor.[1-3] This compromise has a professional application as "informed consent" and is a basic element of the doctor-patient relationship.[4]

Informed consent supports the principle of respect for autonomy, which is one of the fundamental principles of medical ethics,[5] and in many countries, including Turkey, it is compulsory to apply this as a legal requirement before medical procedures.[6,7] One of the

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most important reasons for legal cases brought against doctors is the lack of or insufficient informed consent. Another reason is complications of surgery.[8,9]

Informed consent is based on the subjective assumption that the patient will understand and remember information provided preoperatively; however, the level of understanding and recall of information derived from the procedure of informed consent may be different for patients being treated for trauma. Such persons are not prepared and have not previously made a decision regarding the operation when it is performed under emergency conditions or within a few days of the event. In contrast, patients undergoing elective orthopedic surgery have participated in a preoperative decision-making process. The process of informed consent has a considerable effect on the decision-making of the patient regarding the operation. When the patient has insufficient recall postoperatively, legal complications may arise, especially in cases in which there is a question of malpractice.

This study aimed to examine the level of recall of information given in informed consent to patients undergoing major orthopedics surgery, and whether the level of recall was the same for patients with orthopedic trauma as for patients undergoing elective orthopedic surgery. In addition, this study seeks to formulate recommendations in the light of this information.

Patients and methods

This prospective study comprised a total of 142 consecutive patients (79 women, 63 men; mean age 52.02±20.05 years, range 18-92 years) who underwent surgery on medium and large joints and bones at the Orthopedics and Traumatology Clinic between September and December 2009. Verbal and written information was given to the patient and a companion or relative while the patient was hospitalized prior to surgery. One of the authors (A.Ö.) gave verbal information regarding the diagnosis, recommended treatment, other treatment choices, and potential complications specific to the surgery. An explanation was provided, adhering to a specific written form. Simple Turkish terminology was used to enable the patients to understand the explanations. The patients' questions were answered.

Later, patients were given the detailed written consent form, which contained the same information under the same headings, and were asked to read and sign it with a witness. Considering our country's cultural characteristics, it was assumed that patients would want to consult their relatives regarding the decision to undergo surgery, so having obtained the patient's permission, information was given to the patient and relative together. While explaining the potential complications, issues that could affect the patient's decision were listed under seven or eight headings of equal importance. The orthopedic conditions and risks pertaining to surgery were explained to the patient and the relative. Potential complications for trauma patients were delayed or nonunion of a fracture, malunion, infection, failure of implant, nerve or vascular damage, deep vein thrombosis, and wound healing problems. Potential complications of elective orthopedic surgery were infection, deep vein thrombosis, implant wear, wound healing problems, non-recovery from the condition (or recurrence), lack of relief from pain (or increased pain), and loss of movement and function.

All patients included in the study were over 18 years of age, hospitalized for surgery, and accepted surgical treatment. Patients excluded from the study were those who were having revision surgery for same problem, those who could not give consent due to trauma or confusion, and those who were suffering from dementia. There were no health professionals among the patients. No patient refused to join the study at the stage of evaluating the information.

At 1-3 days postoperatively, the other author (N.Ş.) interviewed the patients. To measure what the patients had understood from the informed consent, a questionnaire was prepared in parallel to the consent form, and was completed by the author in a postoperative interview with the patient, which lasted approximately 10 min. The form included open-ended questions to ascertain the patient's knowledge regarding the diagnosis, surgery being performed, and complications specific to the disease.

In each area, the patient's knowledge was sorted into three levels: no knowledge, insufficient knowledge, and full knowledge. When patients were stating the diagnosis, describing the surgery, and listing potential complications, Turkish definitions were accepted as correct answers. For example, a patient stating "broken hip" for femoral head fracture,

"plate put in" for osteosynthesis, or "implant put in" for hemiarthroplasty was accepted as having full knowledge. At the author's discretion, those who could not state the diagnosis completely and describe the surgery adequately were evaluated as having insufficient knowledge, and those who could not state the diagnosis or describe the surgery minimally were assumed to have no knowledge.

When evaluating specific complications, to be able to standardize the level of recall, if a patient could cite three or more major complications, knowledge was evaluated as "full", one or two complications "insufficient", and no recall of complications, "no knowledge". Demographic and clinical data of the patients recorded were age, gender, educational level, literacy, and type of surgery. The patients were questioned as to whether they had read the form, and if so, whether they had understood it.

A statistical comparison was made between elective orthopedic surgery patients and trauma patients with regard to the rates of recall of the information given to patients in informed consent, and the effect of educational level, age, and gender on recall of that information. This study was approved by the Local Ethics Committee. Statistical analysis was performed using the SPSS 13.0 statistics program. The relationship between variables was examined with Spearman correlation coefficients. Data were examined categorically using Pearson chi-square test and Fisher's exact test. Significance level was defined as $p<0.05$.

Results

Of the 150 patients evaluated, 142 were included in the study. Six cases of revision surgery and two patients with dementia were excluded. The trauma group comprised 72 patients (50.7%), and the elective orthopedic surgery group 70 patients (49.3%) (Table 1). Educational levels of patients were as follows: 30 patients (21.1%) were illiterate, 83 patients (58.5%) were primary school educated, 21 patients (14.8%) were high-school educated, and eight patients (5.6%) were university graduates.

Evaluation of all patients revealed that 131 patients (92.3%) had full knowledge of the diagnosis, nine (6.3%) had insufficient knowledge, and two patients (1.4%) had no knowledge. With regard to the surgery, 86 patients (60.6%) had full knowledge, 44 patients (31.0%) had insufficient knowledge, and 12 patients (8.5%) had no knowledge. In terms of potential complications, 32 patients (22.5%) had full knowledge, 51 patients (35.9%) had insufficient knowledge, and 59 patients (41.5%) had no knowledge (Table 2). While 42 patients (29.6%) stated that

Table 1
Number of patients undergoing several types of surgery

Elective orthopedic surgery	
Arthroplasty	28
Arthroscopy, ACL	32
Other (HTO, hallux valgus, benign bone tumour)	10
Total	70
Orthopedic trauma	
Femoral head fracture	32
Large bone diaphysial fracture	20
Multiple fractures	7
Other (foot-ankle, forearm, lower humeral fracture)	13
Total	72

ACL: Anterior cruciate ligament, HTO: High tibial osteotomy.

Table 2
Recall of diagnosis, operation, and complications by study patients [n (%)]

	Diagnosis	Operation	Complications
Full knowledge	131 (92.3%)	86 (60.6%)	32 (22.5%)
Insufficient knowledge	9 (6.3%)	44 (31.0%)	51 (35.9%)
No knowledge	2 (1.4%)	12 (8.5%)	59 (41.5%)
Total	142 (100%)	142 (100%)	142 (100%)

they had read the consent form, 100 patients (70.4%) stated that they had not. The form had been read by 17 patients (23.6%) with orthopedic trauma, and 25 patients (35.7%) having elective orthopedic surgery ($p<0.05$). The form has been understood by 40 (95.2%) of the 42 patients who had read it.

While gender appeared to have no effect on recall of diagnosis, surgery, or complications ($p>0.05$), age was negatively correlated with the awareness of surgery and complications ($p<0.01$). When educational level was evaluated, the high school and university graduates were more knowledgeable about the complications than were the illiterate and those educated to the primary school level ($p<0.05$).

In a comparison between patients with orthopedic trauma and those who underwent elective surgery, no difference was found between the two groups in terms of age, gender, or educational level ($p>0.05$). More patients in the elective surgery group had read the consent form ($p<0.05$). No significant difference was determined between the two groups in rates of awareness of diagnosis, surgery, and complications ($p>0.05$). Compared with the patients who underwent elective surgery, there were more patients in the trauma group who had no recollection of potential complications ($p<0.01$) (Table 3).

Discussion

After the appearance of some legal cases in the USA in the eighteenth and nineteenth centuries, the following decision given by Justice Cardoza in a 1914 case became an important turning point for informed consent, by emphasizing the right of a patient to make a personal decision regarding health care: *"Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault."*[4] From the second half of the twentieth century the concept of "informed consent" began to enter codes of law, and in our country, first appeared in the 1998 Patients Rights Regulations.[1,4,6] The reason for a significant number of legal cases brought against doctors is the lack of consent, inadequacy of informed consent, or complications arising from surgery.[8,9]

An American study examining 30,504 legal cases between 1984 and 2004 showed that 1,810 cases (5.9%) had involved orthopedic surgery. Inadequate informed consent was the reason for 28 of those cases being brought.[7] As malpractice legal action creates a serious threat to physicians continuing their profession, it seemed to be vital to acquire sufficient knowledge and experience for the legal dimension of the medical profession. Today, it has become compulsory to obtain patient consent explicitly and officially. For a rational patient of sound mind to be able to make a decision, the surgeon must explain to the patient the disease, treatment choices, why surgery is necessary, potential results of surgical treatment, and risks of surgery.[7] This information must be comprehensible, comprehensive, and scientifically true.[10]

However, giving informed consent should not be a mini medical education for the patient.[11] It is crucial that the patient understand the operation, the benefits, risks, and other treatment choices. It has been reported that when patients are evaluating the infor-

Table 3

Recall of diagnosis, operation, and complications by patients with respect to type of surgery [n (%)]

	Orthopedic trauma			Elective orthopedic surgery		
	Diagnosis	Operation	Complications	Diagnosis	Operation	Complications
Full knowledge	69 (95.8%)	38 (52.8%)	17 (23.6%)	62 (88.6%)	48 (68.6%)	15 (21.4%)
Insufficient knowledge	1 (1.4%)	25 (34.7%)	14 (19.4%)	8 (11.4%)	19 (27.1%)	37 (52.9%)
No knowledge	2 (2.8%)	9 (6.3%)	41 (56.9%)	0 (0%)	3 (4.3%)	18 (25.7%)
Total	72 (100%)	72 (100%)	72 (100%)	70 (100%)	70 (100%)	70 (100%)

mation related to the anticipated operation, in consideration of anxiety, too much detail offers no advantage over simple explanations.[12,13] With informed consent, a signed consent form is the basis of documentary evidence of communication with the patient. When the informed consent process is carried out by the surgeon, better communication is established, and there is a lower risk of legal problems. A signed consent form is in itself of little value as evidence, however, the surgeon's own documentation of the consent procedure has greater legal value.[7]

Patients who had completed informed consent were all immediately pleased with the process, but postoperatively, the same groups of patients remembered less than 50% of the risks related to the operation.[14-21] In our study, when questioned during the informed consent process, all the patients stated that they had understood the information they had received from their physicians about their state of health, and were satisfied with the process. Nonetheless, the informed consent given by patients about to undergo surgery in this study did not always meet this objective. In the interviews conducted in the early postoperative period, all of the patients immediately and correctly stated the diagnosis and described operation; however only 32 patients (22.5%) could recall three or more major risks associated with the operation, and 59 patients (41.5%) could not recall any complications. Even though the patients' rate of recall of complications was low, the consent procedure contributed to the patients' decision-making, and the rapport created by communication with the surgeon increased patient satisfaction.

Recall of information conveyed during the informed consent procedure was lower after emergency surgery than after non-emergency operations.[14,18,19] It has been reported that the rate of recall of surgical risk is lower in patients who have sustained orthopedic trauma than in patients who have undergone non-emergency elective orthopedic surgery.[14] Bhangu et al.[14] conducted a study of 81 patients, comparing the level of recall of informed consent in patients with orthopedic trauma and those undergoing elective orthopedic surgery. In that study, 100% of the elective surgery patients and 90% of the trauma patients were able to describe the operation. The rates of recall of the complications related to the operation were found to be 22% of the trauma group and 62% of the elective orthopedic patients. In our study, the level of awareness of the diagnosis and operation showed no difference between the trauma patients and elective orthopedic patients. Forty-one patients (56.9%) in the trauma group and 18 patients (25.7%) in the elective group did not recall any potential surgical complications ($p<0.01$). This difference can be explained by the fact that the time to operation was shorter for the trauma group than for the elective orthopedic surgery group, who might have had the opportunity to research the orthopedic condition and the proposed procedure, and to speak with doctors on several occasions.

It has been stated that advanced age and low educational level decrease the rate of recall of the potential risks of an operation, and younger, better educated patients have a better recall of complications.[17,18] Gender does not appear to have any effect on recall.[17] In a study by Pette et al.[22] on Turkish and German patients, 69% of the patients were able to state their diagnosis correctly, and 76% were able to describe their treatment. In the same study it was noted that the Turkish patients had a lower rate of recall of diagnosis and treatment than did their German counterparts, this relationship reflecting their demographic differences. In our study, demographic information was obtained, and a comparison was made between the two groups. While advanced age and low educational level were not seen to affect the rate of patient awareness of the diagnosis and operation being performed, a negative correlation was seen with the recall of risks related to the operation.

Giving written explanations in addition to the verbal information generally has a positive effect on the level of recall for the patient.[16,18,23] In a study by Langdon et al.[16] involving 126 patients undergoing primary or revision arthroplasty, it was shown that patients who had received additional written information remembered postoperative complications better than did those who had received only verbal information. Mauffrey et al.[24] reported that the addition of written information to the oral discussion made a significant contribution to the recall of surgical risks in elective lumbar vertebrae surgery; however, Shurnas et al.[15] showed written information to have no influ-

ence. Another point is that, for various reasons, the informed consent form given to the patients is not always read. A study by Lavelle-Jones et al.[18] reported that the form was not read by 69% of the patients. In our study, each patient was given a written consent form and was asked to read it in addition to the verbal information; however, 30 patients (21.1%) were illiterate. Of the 42 patients (29.6%) who read the informed consent form, 40 patients (95.2%) stated that they had understood the form. One of the reasons for the low rate of reading the form is that many of our patients were illiterate or had only primary education. The low rate of reading the written consent form had a negative effect on the rate of recall of the information given to the patients in the informed consent process. Similarly, the rate of recall of information was found to be higher in patients undergoing elective orthopedic surgery; a greater percentage of these patients had read the form.

Previous studies have stated that the information given in the form is forgotten over time. Best recalled just after signing the form, information is recalled at the lowest level 6 months later.[18,25] In those studies, various questionnaires and forms with multiple-choice questions were used. In our study, to prevent patients guessing or giving the correct answer by chance, they were questioned directly by one of the authors who then recorded their answers. The patients were questioned in the early postoperative period, when there is a high rate of recall. In order to be able to standardize the scoring, the patients were not expected to have complete recall; however, specific statements regarding the diagnosis and operation, and listing a certain number of complications were accepted as full knowledge.

Although the patients stated that they had understood the information given in the informed consent process, it is not clear whether the inadequate rate of recall of the given information, particularly of potential complications, is attributable to lack of understanding or to forgetting. This distinction was not clarified in our study. Even though there was inadequate recall of the information after consent, during the process of obtaining consent, good communication was achieved between the surgeon and patient, which satisfied the patients. Unfortunately, it is not clear to what extent the surgical risks should be explained or written. There may be differences according to the laws of a country. The American Academy of Orthopedic Surgeons recommends that orthopedic surgeons additionally explain and document at least one major complication such as death or amputation.[26]

One of the limitations of this study is that the patients undergoing major orthopedic and trauma surgery were admitted to the study while anticipating different surgical procedures, and having different potential complications explained to them. The potential complications that were described were organized in a numbered list in an attempt to overcome this problem. On the other hand, even if every patient has a standard form, and if the same information is given using plain Turkish terminology, specific answers to the patient's questions would necessarily focus on different information, which could affect the standardization of the information given. Also, the illiterate patients and those who did not read the form disturbed the uniformity of the information. Although every patient could not be informed in the same way, the study attempted to compensate for these differences.

In conclusion, for orthopedics and traumatology specialists to be able to overcome legal problems that may arise in the future, it is necessary to spend sufficient time on the process of informed consent and to establish good communication with the patient. Considering that some of the information given to the patient will be forgotten after a time, informed consent process should include signed documentation. Also, we believe that because the influence of informed consent and extent of recall are lower for patients who have sustained orthopedic trauma in emergency situations, the process of informed consent must be applied with greater care to these patients.

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