Quality of information transfer for informed consent:
an experimental study in 21 patients

Difficultés du transfert d'information en vue d'un consentement éclairé.
Étude expérimentale chez 21 patients

M. Ghrea [1], C. Dumontier [1], A. Sautet [1], C. Hervé [1]


RÉSUMÉ

Situé au cœur de l'éthique médicale, le devoir d'information concerne tout particulièrement le chirurgien orthopédiste, appelé, de par sa discipline, à porter atteinte à l'intégrité physique d'autrui pour des raisons purement fonctionnelles. Pour savoir si l'information était correctement transmise au cours d'une consultation, nous avons réalisé une étude prospective sur l'information reçue lors d'une consultation pour des lésions chroniques de la coiffe des rotateurs relevant d'un traitement arthroscopique pendant qu'un observateur assistait à la consultation. Au cours de notre étude, nous avons montré qu'il existait une différence importante entre l'information donnée par le médecin et l'information comprise et retenue par le patient. La concordance entre l'information donnée par le chirurgien et celle retenue par le patient variait de 15 à 50 %. Dès lors, la validité du concept du consentement éclairé est mise en doute si l'information qui doit le précéder n'est pas accessible au patient. La question éthique qui se pose aux chirurgiens est de savoir comment rendre cette information accessible aux patients, non pas pour pouvoir se défendre auprès des tribunaux, mais pour donner aux patients tous les éléments nécessaires à la prise de décision finale.

Mots clés : Éthique médicale, information des patients, chirurgie, complications.

ABSTRACT

Purpose of the study

Delivering information to the patient, an ethical obligation that has been recognized for years, has recently become a legal obligation. Proof of information delivery has become the legal responsibility of the surgeon. We conducted a prospective study to evaluate the quality of information transfer by assessing patient comprehension of information delivered in an orthopedic surgery unit.

Material and methods

All patients attending consultations before undergoing arthroscopic treatment for rotator cuff tendinopathy were enrolled in this study when the consultation was conducted in the presence of an observer. Two questionnaires, one for the patient and one for the surgeon, were used to collect what information was given about the pathological condition, the modalities of treatment, and the expected results of the treatment and its complications.

Results

All 21 patients included in the study considered they had been well informed and that they had understood their pathological condition as well as the complications of the proposed treatment. However, agreement between their stated comprehension and the information delivered was poor, varying from 15% to 50%. Furthermore, 90% of the patients stated they had understood the potential complications of the surgical procedure, even though the consulting surgeons had not (generally) provided information on such complications.

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**Discussion**

There is a gap between what the surgeon says (or thinks he or she says) and what the patient understands. Potential biases in this study (non-unbiased observer) might explain this discrepancy, which was probably related to the unequal relationship between patient and physician in any consultation. Therefore, the basis of informed consent cannot be found in the details concerning complications actually delivered to the patient. Surgeons must become aware that the patients understand very little of their explanations. This does not mean that the information should not be delivered but on the contrary that it must be. The important point is not necessarily the information content but rather the quality of the human relationship enabling information transfer.

**Key words:** Ethics, informed consent, surgery, complications.

**INTRODUCTION**

Although the information given to the patient is part of the physician’s daily practice and has long been in the medical ethics code (http://www.conseil-national.medecin.fr), the quality of this information has become a major preoccupation for physicians for essentially legal reasons. The notion of information is regularly put forward in the different decisions that punctuate the relations between doctors, patients, and the courts. It first appeared in France in the Martin-Birot decisions of the Court of Appeals on May 29, 1951 “it must be proven that the latter has failed by not informing the injured party and not soliciting his consent” However, an important change has taken place over the last few years, profoundly changing the state of this question: a reversal of the weight of proof of information, for the physician in private practice (Hédreul decision, 1st Court of Appeals, February 25, 1997), and the hospital physician (CE January 5, 2000), which has led the profession to redefine what information is and the way it is transmitted and understood. Since the Kouchner law of March 4, 2002, informing the patient has become a legal obligation. To verify in clinical practice that the law is applicable and well adapted, we have sought to evaluated the reality of a transfer of complete, loyal, and intelligible information during an orthopedic hospital consultation.

**METHODOLOGY**

To obtain a homogenous set of information to transmit to patients, we limited the information delivered and received by consultants who were proposing arthroscopic treatment for nonruptured tendinopathy of the rotator cuff of the shoulder.

Two questionnaires (Annexes I and II) were constructed; the first comprised 22 questions (20 multiple choice and 2 open-ended questions) and was designed to be given to patients; the second included 16 questions (14 multiple choice and 2 open-ended questions) for the surgeon who had just determined the indication for surgical treatment and given the information necessary to obtain the patient’s informed consent. These questionnaires covered the chosen pathology, the treatment modalities, the results of this treatment, and its complications (Annexes I and II). The two surgeons who participated in this survey (CD and AS) were senior-level physicians with several years of surgical and arthroscopic experience. We retained patients who were consulting for the first time in the department and who had never undergone surgical treatment for their shoulder problems. Each surgeon carried out the consultation as desired, but knew that a consultation form would have to be filled out at the end of the consultation. Explanations were given orally, with no written document available. In certain cases, the surgeon used a hand-drawn diagram on the patient’s x-ray folder to explain the pathology of the rotator cuff of the shoulder.

With the goal of being able to compare what the surgeons said and what the patients retained, an observer was present at all consultations. The surgeon filled out the questionnaire alone, gave it to the observer, and left the consultation room. The observer (MG), who stayed with the patient, let him fill out the questionnaire and gave no more than technical assistance if the patient had problems filling out the questionnaire. The observer then had to compare the responses given by the patient, taking into account the explanations provided by the physician. We only included in the study those consultations that took place in the presence of an observer.

The multiple choice questionnaires provided formalized criteria for the study of the ratio of patient comprehension and interpretation. Since the criteria retained were comparable between the two questionnaires – physician’s and patient’s – for each criterion, it was possible to study the discrepancy between what the surgeon considered had been said and what the patient had understood. The observer made it possible to validate the authenticity of the responses provided by both parties.

**RESULTS**

We were able to include 21 patients (16 men and five women) over a period of 6 months (January-June 2001). The patients’ mean age was 53.6 years (range, 34-68 years). Eighteen were manual workers, there was one accountant, a former musician, and a housewife. They had all been referred by their family physician or another physician who had initially cared for the patient.

The results were studied question by question. Since the study sample was fewer than 30 patients, no statistical
validation was carried out on the qualitative variables discussed below.

**Patient comprehension of the explanations given on the patient’s disorder (patient question no. 6 and 20, physician question no. 3)**

All patients considered that the explanations given were comprehensible (question no. 6) but only five of them (23.8%) were able to give even the approximative name of the disorder they were consulting for after having listened to the explanations, (question no. 20). The physicians (question no. 3) thought that their explanations were very comprehensible in eight cases (38%), and in 13 cases (62%) reasonably comprehensible.

**Comprehension of the explanations given on the treatment modality (patient questions no. 7-10, physician questions no. 4-7)**

All patients judged the explanations given by the surgeon on the treatment proposed to be comprehensible (question no. 7). The physicians judged that their explanations had been very comprehensible in three cases (14.5%) and reasonably comprehensible in 16 cases (76%). In two cases, there was no explanation on the postoperative period (one of the patients did not wish to consider surgical treatment).

However, the more detailed questions on the length of the hospital stay, the duration of immobilization, and the duration of rehabilitation provided responses that were less homogeneous (Table I).

Responses on the length of the hospital stay (question no. 8) are summarized in Table II. In one case, the question was not brought up. There was agreement on the length of the hospital stay planned by the physician and the duration that was memorized by the patient in only nine cases (43%).

Responses on the duration of immobilization (question no. 9) are summarized in Table III. In two cases, there was no explanation on immobilization. There was agreement in only 14.5% of cases between the physician’s explanation and what the patient had understood, even though the questions were brought up in 19 consultations out of 21. In one of the two cases where there was no explanation, the patient thought there would be no immobilization after surgery.

Responses on the planned length of rehabilitation (question no. 10) are detailed in Table IV. In two cases, there was no explanation on the duration of rehabilitation. There was agreement in only 14.5% of cases between the duration planned by the physician and that memorized by the patient.

**Responses related to the advantages of the surgical treatment proposed (patient questions no. 11-13 and physician questions no. 12-14)**

The explanations related to the advantages of the surgical treatment seemed very clear for 100% of the patients, whereas the physicians had judged their explanations as comprehensible in seven cases (33.4%) and reasonably comprehensible in 14 cases (66.6%).

We attempted to evaluate patient comprehension by asking them questions on the results expected concerning pain and shoulder mobility (Table I).

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<th>Table I. – Concordance observed between patient and surgeon responses.</th>
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<td>Duration of hospital stay</td>
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<td>Postoperative conditions and complications</td>
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<td>Worsening or no improvement of condition</td>
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<th>Table II. – Duration of hospitalization estimated by patients and physicians after consultation.</th>
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<th>Table III. – Duration of immobilization estimated by patients and physicians after consultation.</th>
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Pain (patient question no. 12): 17 patients (81%) thought there would be clear improvement and four (19%) thought the pain would completely disappear, whereas the physicians (physician question no. 13) had predicted a clear improvement in 15 cases (71%) and disappearance of pain in six cases (29%). Between the physician explanations and patient responses, there was agreement only in 52.5% of cases.

Mobility (patient question no. 13): ten patients (47.6%) thought there would be clear improvement, six patients (28.6%) thought there would be complete recovery, three patients (14.4%) expected slight improvement, and two patients (9.5%) thought there would be no improvement. In 11 cases (52.5%), physicians (question no. 14) predicted complete recovery, in three cases (14.4%) clear improvement, and in seven cases (33.3%) slight improvement. Agreement between physician and patient responses occurred in only 24% of cases.

Possible complications of the surgical treatment (patient questions no. 14-17, physician questions no. 8-11)

Nineteen patients (90.5%) found the physicians’ explanations on the possible complications of the surgery (question no. 14) very comprehensible and two patients (9.5%) considered that they did not receive explanations on the possible complications of surgery. For the same question (physician question no. 8), the physician responded that no explanation was given in 17 cases and the explanation was judged reasonably comprehensible in three cases (14.5%). In one case, the question was not brought up because the patient did not wish to have surgical treatment. For the same question (physician question no. 11), in 18 cases (85.7%), physicians considered that there was a minimal risk. The surgeons responded that there was a minimal risk in 11 cases (52.4%) and no risk in eight cases (38.1%). Only three patients were actually informed of the possibility of neurological complications (14.5%).

Is there a risk of worsening or absence of improvement after surgical treatment (question no. 17)? Twelve patients (57%) could not respond, six (28.5%) thought that there was no risk, and three patients (14.5%) thought that there was minimal risk. The physicians explained that there was a possibility that there would be no improvement or a worsened condition during the consultation in 20 out of 21 cases (in one case, the explanation was not given because the patient did not wish to have surgical treatment). For the same question (physician question no. 11), in 18 cases (85.7%), physicians considered that there was a minimal risk of worsening or no improvement and in two cases (9.5%), they considered that this risk was nil. Agreement was 19% between the explanations given by the physician and the response of the patients.

DISCUSSION

This survey confirms the importance of the discrepancy between the information delivered by the practitioner and that heard and understood by the patient. All patients were satisfied with the explanations given, all thought they had received good-quality information, and yet the study shows that the consent obtained was not informed consent in the sense expected by a judge in court. Surgeons believed they had given comprehensible or very comprehensible information; patients found it comprehensible and complete, and yet they actually had perceived only a very limited part of the information delivered!

Other authors have studied the patient’s comprehension of information [Bossi Ferraz et al. [1], Gattellari et al. [2], Lloyd et al. [3], Savornin et al. [4], Smith [5]] or the reality of the information provided by the physician [Alfonsi [6], Edward et al. [7], Sargos [8]]. The originality of our study lies in introducing an observer who could both judge the reality of the information delivered and its immediate comprehension. His role was to verify the reality of the information given by the surgeon and to compare this with what the patients had understood. He was instructed not to intervene except to help patients fill out the questionnaire when they hesitated on the phrasing of certain questions.

Before concluding that patients are not capable of sufficiently retaining the information given during consultation, the many biases possible of a so-called sociological survey must be eliminated.

| TABLE IV. – Duration of planned rehabilitation for patients and physicians after consultation |
|-----------------|----------------|-----------------|-----------------|----------------|----------------|
|                 | < 1 month | 1-3 months | > 3 months | Don’t know | Total |
| Patients        | 2         | 7           | 3           | 9          | 21   |
| Physicians      | 3         | 5           | 11          | 2 explanations not given | 21   |
Was the patient questionnaire comprehensible?

All the questionnaires were corrected by a specialist in methodological problems (Marc-Alain Descamps, Université Paris V). Then the patient questionnaire was validated on the first five patients (not included in the study), which allowed us to modify the phrasing of certain questions to make them more easily understood for those not in the medical professions. Nevertheless, potentially confusing terms remained: for example, the alternation of the terms “physician” and “surgeon” could introduce an identification bias (the patient’s family physician and the surgeon seen in consultation). The term “immobilization” (question no. 9) may be confusing in terms of immobilization of the upper limb and the immobilization of the patient (autonomy, cessation of professional activity, etc.). The neurological complication (question no. 16) in shoulder surgery many not have a particular meaning for a person who is not initiated to technical terms. Despite its ambiguity or possible imprecision, we deemed the questionnaire practical and accessible to a nonmedical population during this study.

Were the explanations given clear and comprehensible?

During the study, the observer judged that the information given by the practitioners was complete and understandable, other than the complications that were not discussed. The consulting surgeons judged the risk minimal in agreement with the medical literature [Boardman et Cofield [9], Boynton et Enders [10], Bruhlart et al. [11], Tillander et Norlin [12]] and did not believe it necessary to bring up the question, despite the presence of an observer during the consultation, who evaluated the relevance of the information given. It is surprising that absent or partial information was perceived as satisfying by 90% of the participating patients. This may be a subjective impression of comprehension or it may be the observer in a white coat present while they filled out their questionnaire that caused the patients to respond in this way. The patients were with a surgeon in a white coat (the observer), and may have believed that this person found that the explanations they – the patients – found difficult were clear. The patients perhaps did not dare say that they had not understood, so as to please the observer or not question the decision of his colleague and therefore the medical institution that the observer clearly represented. This raises the problem of the bias introduced by the presence of the observer.

Was the observer truly neutral?

The influence of the survey and the presence of the observer apparently did not change the surgeons’ attitude, because even knowing that they would be questioned, they did not report potential complications. The importance of the doctor-patient relationship seems to have overridden the survey. Replacing the observer-surgeon with an observer who was not a physician would not have changed much because the observer would have acquired a greater “surgical culture” than the patient after a few consultations. Changing the observer each time would have introduced other biases. The presence of an observer, with the limits cited above, was useful in confirming that the information was delivered, even it was not understood. Several studies, some with video recordings, showed that the information the physician thought he had given was not actually delivered in all cases [Gattellari et al. [2]].

If the information was given, why was it poorly understood?

Is it because the information is delivered in a condensed form that it is difficult for the patient to understand? Is there an emotional factor that makes it difficult to understand and remember? In the context of a hospital consultation, lasting on the average 10-15 min, it seems difficult, if not impossible, to control all the factors involved. The first moment of the doctor-patient meeting is a time to establish contact, and immediately there is an unequal relation set up between the physician who has both knowledge and the power to heal, and the unwell patient who hopes to benefit from this knowledge to relieve his suffering. In the context of a surgical consultation, the patient is first questioned and then examined; after the complementary examinations have been studied, the indication for operation is given, although in the pathology chosen for the present study, patients were sent by another doctor (general practitioner, rheumatologist, etc.). The indication for operation can seem like a punishment (even the medical literature uses the terminology of punishment!). For the surgeon, the intervention is a technical act that is a part of daily practice, but the patient experiences it as an aggression. His physical integrity will be breached, in his best interests of course, but the patient experiences this moment as a sentence. It is at this very moment, when the patient is the most vulnerable, that the practitioner begins to provide the information necessary for understanding the disorder and the therapy to follow. Ideally, the physician begins by describing the characteristics of the organ involved using the most appropriate terms, then he gives explanations on the cause of the disorder, and describes the principle of the surgical treatment and how the different stages will progress. He explains to patients the benefits expected from the treatment proposed and the possible alternatives, and ends by listing and describing the different potential complications reported in the medical literature. The patient may receive an informational brochure that has been evaluated and validated by a learned committee. Then the doctor attempts to evaluate whether the patient has understood the information given by asking questions such as: “Have you understood everything?” “Are there any points you would like more information on?” “Do you have further questions?” All in roughly 15 minutes. Then the patient will be asked to sign an informed consent form if he has accepted the surgical treatment.
During this ideal doctor-patient meeting, the physician is expected to respect all of the recommendations set forth by the Agence Nationale d’Accréditation et d’Évaluation en Santé (ANAES) [13], and to respect the law of March 4, 2002, and respect the ethics code, and protect himself legally by noting the details of the meeting in the medical chart [Sargos et al. [14]]. However, in practice, the patient leaves the doctor’s office having retained only a very small part of this loyal and intelligible information, exactly what our study showed. How can one expect that condensed information given in a short lapse of time in an emotionally charged context to an individual who has come to have his suffering relieved, be considered as loyal and intelligible? Admittedly it is loyal and intelligible to the physician, but it is not and never will be for the patient, whose consent obtained in these conditions cannot be valid.

This difference between the information provided (or that we believe we provide) and what is retained has been found in other studies. Savornin et al. [4] studied the comprehension and memorization of information given before an operation in orthopedics: 53.8% of their patients had retained all the explanations concerning their pathology. For the surgical indication, this figure was 26.9%. A total of 34.6% of the patients had understood the technique of the operation and 43.6% the postoperative care. However, only 6.4% of the patients had assimilated the complications and 16.7% had understood the prognosis. In this investigation, several preoperative consultations had taken place, which explains that certain results were better when compared to our study. What is remarkable is that the memorization rate concerning complications and prognosis was so low, even after several consultations. Did patients truly wish to hear that surgery includes risks? Do they consciously accept this risk? In the study conducted by Savornin et al., 19.2% of the patients included had come for a second operation. They therefore already knew a part of the information and the study shows that these patients retained 67.2% of the overall information. This difficulty in retaining information on the complications was also found in the investigation of Lloyd et al. [3]. One month after having received detailed information from a senior neurosurgeon on the risks of carotid endarterectomy, only one of the 71 patients included in the study remembered the exact numbers of the risk of stroke. More than 10% had multiplied the risk of the operation by 10, some had forgotten that there could be a risk, and 11% did not know! We found the same tendency for medical pathologies. Gattellari et al. [2] showed that in cancer patients, 40% had not understood the goal of the treatments and less than 20% could describe the chances of success. Having the patient sign a document does not improve the quality of the information retained. In a clinical study where the information is legal, mandatory, and under the control of a CCPPRB, a questionnaire was sent to 70 diabetic patients in whom a DNA sample had been taken, after informed consent, in a study on the genetics of diabetes [Hervé et al. [15]]. Of the 51 responses obtained, none of the patients remembered that they had given DNA, none knew whether the DNA analyses had been done, and none remembered having signed the informed consent form! Twenty-nine percent knew that had participated in a medical research protocol and 16% knew the role of DNA in cells [Hervé et al. [15]]. All of these studies show that information, even when it is properly provided or judged as properly provided, is poorly assimilated by the patients. Patients do not want, or cannot, retain all of the information given.

Can the information be made more easily accessible to improve patient memorization?

Orally transmitted information remains at the basis of knowledge transfer. It is vital because it can be adapted to each person. It is part of the relational climate allying listening and consideration of the patient’s expectations. However, it is often incomplete and in any case difficult to retain, whatever effort is made by surgeons. The literature shows that the information is better understood and retained if it is also provided with another source. Those who have been given an informational brochure or a video understand the details better than those who have not received such aids [Galletari et al. [2]]. However, writing this information is difficult. Of 79 informational brochures analyzed, six were of a reading level equivalent to the British Medical Journal! In another study, of 50 brochures, 48 were considered as more difficult to read than an editorial of a weekly news magazine [Arthur [16]]. Software that can be personalized to the patient’s case also seems effective. Patients who have had access to personalized information show more satisfaction than those who read nonpersonalized brochures, reuse the computer one out of three times, are better informed, and in practice it costs only half as much, since the patients can print their information [Jones et al. [17]]. Use of the video or multimedia tools proposed by the ANAES [13] can be a solution in certain centers, but extending this use is nearly impossible. Add to that the language obstacle for foreigners living in France, the socioeconomic barrier of illiterate patients who cannot make use of written materials or patients who believe that the doctor must make the final decision, and the real conditions of a surgical practice come to light.

The March 4, 2002 law requires that physicians provide information to their patients and they must be able to prove that they have indeed informed the patient. For the last 8 years (in practice, since the Hédreul decision of February 25, 1997), we have seen a number of publications demonstrating that all the information provided to a patient is poorly understood and only partially assimilated. Ethically and legally, it is the physician’s responsibility to make the information provided understandable. One must be aware, however, as our study shows, that even with the greatest will, patients retain little, for a variety of reasons. To consent, the
patient must understand. This requires that the information be adapted to the person, and designing brochures validated by professionals for hypothetically typical patients is ethically insufficient, even if they have an undeniable practical use. Only once the information has been provided and understood can one obtain the consent of the patient for treatment. This informed consent is indispensable but it is also the weak link in the chain, exploited by North American lawyers, which explains that between 1989 and 1994 more than 3000 articles on informed consent were published [Dumontier [18]]. The patient’s understanding is one of the least researched criteria in informed consent in the United States. Actually, consent is a legally simple concept, binary, but medically complex and nuanced.

Informing the patient is a social, psychological, and cultural question, and not only arising from medical technique. Analysis of the causes of patient complaints concerning physicians brings out that it is not so much the information that is lacking but rather a certain quality of communication in a context that is not always favorable to the ideal exchange, so decisive are the limitations in these complaints. The way the information is expressed is undoubtedly more important than the quantity of the information provided. Our study showed that patients are satisfied with the information given because they feel that they are well received, listened to, and that the surgeon makes an attempt to explain. Respect of their dignity is a decisive element in the voluntary and active acceptance by the patient of the therapeutic option proposed and not imposed by the surgeon. It is more the quality of the relation than the listing of complications that are incomprehensible to the patient that incites the patient to trust the physician. It is important to provide explanations, not so much to make a surgeon out of the patient, but to show that he is respected. This attitude is necessary to obtain the patient’s active participation in the treatment and to share the responsibility of the final decision [Hervé et Wolf [19]]. A signature at the bottom of an informed consent form extracted from the patient at the end of a consultation cannot have ethical value [Hervé [20]].

Before consenting to a surgical act, the patient should meet with the same surgeon several times, who orally provides total and loyal information at each consultation, if necessary accompanied by a written informational brochure. The surgeon should attempt to evaluate the patient’s comprehension of the information provided at each consultation, in a detailed manner, and leave sufficient time for this information to be assimilated by the patient between each consultation. Only when the patient has understood all the information can informed consent have a true value. However, taking the example of a hospital where each practitioner consults a maximum of twice a week, with 30-40 patients each time, this could take several months. Making a suffering patient wait is probably not a much more ethical practice. Ricoeur [21] has describe ethics as “targeting a good life, with and for others, in fair institutions.” If we hope to continue our profession “with and for others,” we should attempt to find solutions so that our monologue during the consultation can become a dialogue with our patients. For the “institution to remain fair,” it is again incumbent upon us to find ways to make the patient-doctor relationship more equitable, for out patients’ benefit and to prevent this task from becoming the domain of jurists, lawyers, judges, the government, consumer groups and victims’ groups!

CONCLUSION

The concept of informed consent is one of the validation criteria of the healthcare contract and research [Voelker [22], Weisstub [23]]. Yet its validity can be doubted when the information that should come first is not accessible to patients. Does the subject have true autonomy when a decision is made based on information that has not been understood? Our results confirm others and show the limits of informed consent: legally mandatory, but in daily practice unachievable in a way that is fully satisfying for the patient, the surgeon, and the lawyer.

References


