Informed consent for gastrointestinal endoscopy: a patient-opinion survey

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Résumé

But — La formalisation écrite du consentement éclairé n’est pas recommandée en France sous prétexte qu’elle risque d’altérer la confiance du malade en son médecin. Le but de ce travail était d’élaborer un formulaire de consentement éclairé pour l’endoscopie digestive et d’évaluer l’opinion des malades sur la formalisation écrite du consentement éclairé.

Méthodes — Sept soignants et sept malades ou usagers ont élaboré conjointement un formulaire de consentement éclairé ainsi qu’un questionnaire de 24 questions portant sur le consentement éclairé. Le formulaire de consentement et la fiche d’information sur l’examen endoscopique étaient remis au malade, avant l’examen endoscopique, accompagnés d’explications orales. Pendant une période de 9 jours consécutifs, le questionnaire était remis à tous les malades après l’endoscopie digestive.

Résultats — Cent quarante-trois malades étaient éligibles ; 28 malades ont été incapables de lire le formulaire. Au total, 100 malades ont répondu au questionnaire. Soixante-six % des malades ont apprécié qu’on leur demande de signer un formulaire de consentement éclairé. Seuls 10 % des malades ont estimé que cette procédure de signature d’un formulaire de consentement éclairé détrônerait la confiance en leur médecin. Quatre-vingt-dix-huit % des malades ont été satisfaits par le formulaire de consentement éclairé tel qu’il était rédigé et quatre-vingt-dix-sept % l’ont trouvé clair et compréhensible. Quatre-vingt pour cent des malades l’ont trouvé rassurant.

Conclusion — La formalisation écrite du consentement éclairé n’altère pas la confiance du malade en son médecin. Elle est comprise et acceptée par la majorité des malades. Le formulaire de consentement éclairé que nous avons rédigé satisfait la quasi totalité des malades et pourrait servir à l’élaboration d’un document standardisé.

Résumé

Aim — Written consent is not advised in France because it is thought it may alter the patient’s trust in his/her doctor. Our aim was to elaborate a consent form for gastrointestinal endoscopy and to assess the patient’s opinion concerning the written consent process.

Methods — Seven health professionals and seven patients or users elaborated a consent form and a list of 24 questions about the written consent process. The consent form, accompanied with an information form, was given to the patients before endoscopy. For a period of 9 consecutive days, all patients undergoing gastrointestinal endoscopy were asked to fill out the questionnaire at the end of the procedure.

Results — One hundred and forty-three patients participated in the survey. Twenty-eight were unable to read the form. One hundred patients filled out the form. Sixty-six percent of the patients were satisfied with the written consent process. Only 10 % considered that the written consent process altered their trust in their doctor. Ninety-eight percent of the patients were satisfied with the consent form and 97 % felt it was clear and comprehensible. Eighty percent of the patient felt it was reassuring.

Conclusions — Written consent does not alter the patient’s trust in his/her doctor. The majority of the patients understood the written consent process and agreed with it. Almost all patients were satisfied with the consent form we elaborated, suggesting that its use could be generalized.

Informed consent is a legal concept arising from contractual analysis. Consent is a necessary element of any contract and without it the contract does not exist. For the consent and thus the contract, to be valid, the consenting person must be properly informed. Informed consent is the keystone to the patient-physician relationship and good clinical practice. In gastroenterology, physicians are daily confronted with the question of informed consent from patients undergoing endoscopic procedures. French law is very clear on this point: the patient’s informed consent must be obtained before all investigations or healthcare procedures. The legislation concerning the modalities of informed consent are however much less straightforward. Written consent is not mandatory, except for biomedical research, organ procurement, and medically assisted reproduction. For all other domains of medical activity, informed consent modalities are left open, leading to a wide variety of practices. A
Patient’s consent can be implicit or explicit, in which case it can be oral or written. In routine clinical practice in France, patient consent is generally implicit or oral and formal written consent is rare. Some consider that written consent may alter the patient’s trust in his/her doctor [1-4]. In other countries, particularly the United States [5], written consent is an integral part of everyday practice. The purpose of our work was first to elaborate an informed consent form in collaboration with our patients undergoing gastrointestinal endoscopy, and secondly to collect patient’s opinions concerning the written consent process for gastrointestinal endoscopy.

Patients and methods

A working group was constituted including seven health workers and seven former patients and healthcare users. The health workers were members of the gastroenterology team at the Colmar Civil Hospital, Colmar, France: a physician, a head nurse, two nurses, a psychologist, a secretary, and a hostess. The former patients included four who had been treated in the gastroenterology unit and a member of an association of hepatitis C patients. The consent form is an integral part of everyday consumer protection association and a hospital administration trainee. This working group met four times to elaborate an informed consent form (appendix 1) and a questionnaire to be used for evaluation. The consent form was partially adapted from the informed consent form used in the endoscopy unit of Guy’s Hospital in London [6]. The questionnaire included 24 items: nine questions concerning the principle of a signed written consent, five questions concerning the form compiled by the working group, and ten questions concerning general information. The fourteen questions devoted to informed consent are presented in appendix 2. The initial questionnaire was modified twice after tests conducted in two groups of ten patients.

The survey was conducted during nine consecutive days in September 2000. All patients who were scheduled for gastrointestinal endoscopy in our unit during this period were questioned. Patients requiring emergency endoscopy were excluded. The patients were given a document prepared by the French Society of Gastrointestinal Endoscopy (SFED) and the French National Society of Gastroenterology (SNFGE) which contains medical information concerning the scheduled endoscopy and the informed consent form presented in appendix 1. These two documents were given to the patient by the endoscopy physician at the pre-endoscopy consultation. If this consultation had not been performed by the endoscopist, they were delivered by the physician who prescribed the endoscopy (for hospitalized patients), by a nurse (for hospitalized ambulatory surgery patients), or by a hostess when outpatients arrived at the unit for their scheduled procedure. Oral information was also provided at the time the documents were delivered to the patients. The survey was conducted shortly after the endoscopy procedure (generally a few hours after procedures conducted without general anesthesia) or as soon as the patient was able to answer the questions after procedures conducted under general anesthesia (generally after leaving the recovery room). The inquirers, a secretary and a hostess, wore civil clothes. They read the questionnaire to the patient and recorded their answers.

Results

Two hundred five endoscopy procedures were performed in 170 patients during the 9-day study period. Twenty-seven procedures conducted in an emergency setting were excluded from the analysis. One hundred forty-three patients who underwent 179 procedures were eligible for questioning. Six patients declined participation and 28 were unable to read the questionnaire because of their poor health status (n = 13), inadequate knowledge of French (n = 10), or inability to read (n = 5). The survey was not conducted in nine other patients. In all, 100 patients were able to read the consent forms and completed the questionnaire. These 43 men and 57 women, mean age 56.5 years, had undergone 112 endoscopy procedures: 59 upper gastrointestinal endoscopies, 35 colonoscopies, 13 rectosigmoidoscopies, 4 endoscopic ultrasound explorations, and one endoscopic retrograde cholangiography. General anesthesia was used for 38 patients. This was the first endoscopic procedure for 47 patients. Forty-four percent of the patients were outpatients. The other 56% were either hospitalized in a gastroenterology ward (n = 19), a tradition medical or surgery ward (n = 16), or an ambulatory surgery ward (n = 21). The patients were given the medical information document and the informed consent form several days before their exploration (n = 40), the day before their exploration (n = 14), or the same day of their exploration at hospital admission or upon arrival in the endoscopy unit (n = 46). The results obtained from 100 patients who could read the forms and who filled out the questionnaire are given in appendix 2. Two patients stated they did not understand why they should need to sign an informed consent form. One patient suggested that the phrase “does not discharge the physician or the hospital from their legal responsibilities” should be written in bold type. There was no difference in opinion by gender, age, and first or other than first endoscopic exploration.

Discussion

Two hundred five endoscopy procedures were performed in 170 patients during the 9-day study period. Twenty-seven procedures conducted in an emergency setting were excluded from the analysis. One hundred forty-three patients who underwent 179 procedures were eligible for questioning. Six patients declined participation and 28 were unable to read the questionnaire because of their poor health status (n = 13), inadequate knowledge of French (n = 10), or inability to read (n = 5). The survey was not conducted in nine other patients. In all, 100 patients were able to read the consent forms and completed the questionnaire. These 43 men and 57 women, mean age 56.5 years, had undergone 112 endoscopy procedures: 59 upper gastrointestinal endoscopies, 35 colonoscopies, 13 rectosigmoidoscopies, 4 endoscopic ultrasound explorations, and one endoscopic retrograde cholangiography. General anesthesia was used for 38 patients. This was the first endoscopic procedure for 47 patients. Forty-four percent of the patients were outpatients. The other 56% were either hospitalized in a gastroenterology ward (n = 19), a tradition medical or surgery ward (n = 16), or an ambulatory surgery ward (n = 21). The patients were given the medical information document and the informed consent form several days before their exploration (n = 40), the day before their exploration (n = 14), or the same...
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Appendix 1 - The informed consent form written for the survey.

You are going to undergo a gastrointestinal endoscopy.
— Read carefully the attached information sheet and this informed consent form.
— If the explanations given are not clear for you, or if you desire further information about endoscopy, do not sign this document for the time being. You will have the opportunity to discuss this with the doctor and ask him/her any questions you have before the endoscopy.
— If you have understood all the information given and do not have any questions to ask, please indicate your agreement for the examination by completing the consent form below.
— Bring this form with you to the Endoscopy Unit the day of the examination.
I the undersigned....................................................................................
— have been sufficiently informed concerning the examination and have received answers to my questions.
— know that I can ask the doctor any other question I have,
— know that having signed the consent form, I may still decline the examination.
My refusal will not alter the quality of my relationship with my doctor,
— give my consent to undergo the gastrointestinal endoscopy under the conditions that have been indicated by Doctor(s)....................................

signed at ...................................., date

Signature:

Appendix 2 - The questionnaire used for this survey and results in 100 patients who filled out the questionnaire.

You have received an informed consent form for signature. Here are a few questions concerning the principle of signing an informed consent form

1) Globally, did you appreciate being asked to sign an informed consent form?
   yes: 40% yes, somewhat: 26% not really: 16% no: 18%
2) Do you think it is normal that you participate in the decision to undergo an examination by signing an informed consent form?
   yes: 48% yes, somewhat: 18% not really: 11% no: 22%
3) Do you think an informed consent form preserves your right to accept or decline an examination?
   yes: 65% yes, somewhat: 16% not really: 2% no: 17%
4) Do you think that signing an informed consent form changes your trust in your doctor?
   more trust: 18% no change in trust: 72% less trust: 10%
5) If you decline the examination, do you think your relationship with your doctor will change?
   yes: 21% yes, somewhat: 11% not really: 6% no: 62%
6) Were you shocked to be asked to sign a form?
   yes: 20% yes, somewhat: 10% not really: 4% no: 66%
7) Was it disturbing to be asked to sign a form?
   yes: 16% yes, somewhat: 12% not really: 6% no: 65%
8) Does signing a form make you less trustful?
   yes: 17% yes, somewhat: 23% not really: 3% no: 57%
9) Do you think the doctor has you sign a form to release him/her from his/her legal responsibilities?
   yes: 39% yes, somewhat: 13% not really: 11% no: 37%

The following questions concern the informed consent form you received (show the form)

10) Did you read the form entirely before signing?
   yes all of it: 96% yes, nearly all: 4% only partially: 0% no: 0%
11) As written, are you satisfied with this consent form?
   yes: 86% generally yes: 12% not really: 1% no: 1%
12) As written, do you think this consent form is clear and understandable?
   yes: 93% generally yes: 4% not really: 1% no: 2%
13) As written, do you think this consent form is reassuring:
   reassuring 33% somewhat reassuring: 47% somewhat disquieting: 13% disquieting: 6%
14) Do you have suggestions to make concerning this informed consent form?
REFERENCES