Assessment of the quality and psychological impact of information delivered using official consent forms in digestive endoscopy

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SUMMARY

Aim — To test the impact of information brochures and informed consent forms in patients undergoing digestive endoscopy procedures.

Method — All patients undergoing digestive endoscopy procedures during a two-month period were given information about the procedure to be performed by delivery of an information form produced by the French Endoscopy and Gastroenterology Societies. The patients were then asked to sign an informed consent form. A questionnaire about the informed consent form and the consent experience was given to all patients after the endoscopic procedure.

Results — The questionnaire was completed by 108 consecutive patients. The informed consent form was completely read by 96.3% and understood by 95%. Sixteen percent asked for complementary information, all about complications. Twenty percent were distressed by the explanations. Receiving written information was surprising for 22.2% of the patients, and distressing for 18.5% mainly when endoscopy was planned without general anesthesia (P = 0.01 versus general anesthesia). Obtaining informed consent was qualified as a normal procedure for 47.2%, but distressing for 19.4%. It was considered by 41.1% as a way for doctors to be discharged from their obligations.

Conclusion — The informed consent forms written by scientific societies are easy to understand. One third of the patients were distressed or surprised to be given oral or written information. To sign a written consent form before an endoscopy procedure is considered by 41.1% as a way for doctors to be discharged from their responsibilities.

RÉSUMÉ

Evaluation de la qualité et de l’impact de l’information transmise par les fiches d’endoscopie digestive élaborées par les sociétés savantes

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Objectifs — Évaluer la valeur informative et l’impact psychologique de la fiche officielle d’information ainsi que le vécu de la signature d’un consentement éclairé avant une gastroscopie ou une coloscopie.

Méthodes — Sur une période de deux mois, avant toute endoscopie haute et basse, 108 malades consécutifs ont reçu, après une information orale, la fiche d’information élaborée conjointement par les Sociétés Savantes (SFED, SNPOE, SNFCP) concernant la réalisation et les risques de cet acte, avant de signer un document stipulant la remise de cette fiche et leur accord pour la réalisation de l’endoscopie. Un auto-questionnaire sur le contenu de l’information, l’impact psychologique de cette fiche et celui de la signature d’un document était remis aux malades après l’endoscopie.

Résultats — La fiche d’information a été lue complètement par 96,3 % des malades et comprise par 95 %. Seize pour cent des malades ont souhaité des informations supplémentaires. Celles-ci concernaient exclusivement les complications des actes. Vingt pour cent ont été angoissés par les explications fournies oralement. La remise d’un document écrit est apparue étonnante à 22,2 % des malades et angoissante pour 18,5 %, surtout si l’examen se déroulait sans anesthésie générale (P = 0,01 vs anesthésie générale). L’obtention d’un consentement a été jugée normale pour 47,2 % des malades, angoissante pour 19,4 % et considérée pour 41,1 % des malades comme une décharge du médecin de ses responsabilités. L’impact du consentement demandé avant de réaliser l’endoscopie n’était pas significativement différent entre les malades ayant déjà ou non signé un consentement.

Conclusion — Les fiches d’information officielles sont explicites. Un tiers des malades ont trouvé cette procédure angoissante ou étonnante. La signature d’un consentement est ressentie par plus d’un malade sur trois comme une décharge des responsabilités du médecin.

Patient information is at the heart of the patient-physician relationship.

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Article 35 of the French Code of Deontology states that « when a physician examines, provides care, or gives advice to a person, he/she must give that person loyal, clear, and appropriate information concerning his/her status and the proposed investigations or care ». Several scientific societies have developed information documents concerning endoscopy procedures to assist gastroenterologists in providing their patients with appropriate information [1]. These societies include the French Society of Digestive Endoscopy (SFED), the French Society of Gastroen...
terology (SNFGE), and the French Society of Coloproctology (SNFCP) and more recently the French Association for Liver Study (AFEP). These information brochures were designed to provide the patient with complementary information in addition to the oral information provided by the physician. These brochures generally have two parts, the first part describing the procedure and the second part the risks involved. Patient understanding of these information brochures and the way they are used has not been sufficiently evaluated [2, 3].

Certain court decisions awarding indemnities to medical accident victims have been based on the argument that patients were given defective information. Furthermore, in its decision on the Hédéreul case (February 25, 1997) the French High Court of Appeals ruled that it is the physician who must prove delivery of information. In order to meet this legal obligation, the physician may, after delivering an information brochure, ask the patient to sign a receipt proving delivery of information. Moreover, the physician may request the patient who has read the information brochure to sign a consent form for the endoscopy procedure. This approach, which is widely used in North America, is currently the subject of much debate in France and little work has been done to assess the impact of this type of medical attitude. Demonstration of a negative psychological impact of such an approach could be an argument against soliciting the patient’s signature in all situations.

The aims of this work were to evaluate, in patients undergoing digestive endoscopy procedures: i) their understanding of official information brochures concerning gastroscopy and colonoscopy, ii) the impact of delivering these information brochures and of the information they contain, and iii) the impact of signing an informed consent form.

Patients and methods

This study was conducted during a two-month period, under routine conditions of practice, among all patients attending the digestive endoscopy unit of the Rouen University Hospital for gastroscopy or colonoscopy, excluding patients with dementia or characteristic psychiatric disorders and non-French speaking patients. All patients were given two types of information concerning the endoscopy procedure. They were first informed orally in a non-standardized manner about the purpose of the examination, its usefulness, and expected benefit. The procedure itself, the way it is conducted, and the risks involved were also described. This oral information was delivered by the prescribing physician during a consultation a few days before the procedure and/or by the endoscopist (either during the consultation or a few minutes before the endoscopy). Complementary information was also given to the patients in the form of an information brochure elaborated conjointly by three French gastroenterology societies (SFED, SNFGE, SNFCP). These brochures were delivered either by the prescribing physician or by the nurse in the consultation room. Certain patients (referred by other hospital units for endoscopy or more exceptionally outpatients referred by a general practitioner) received the information brochure by mail with their appointment card. In exceptional situations, the brochure was delivered in the waiting room a few minutes before the endoscopy procedure.

A specific information brochure was used for each type of endoscopy (gastroscopy or colonoscopy). Each brochure detailed the reasons for choosing this examination, the type of preparation required, the procedure itself, and possible complications (early or late complications such as perforation, bleeding, cardiovascular or cardiorespiratory disorders, infection). When the procedure was to be conducted under general anesthesia the brochure describing the endoscopic procedure was never delivered at the same time as the brochure detailing the anesthesia.

During the study period, all patients were asked, after reading the information brochure, to sign a document stipulating i) that they had received the brochure explaining the examination and had understood the information it contained, and ii) that they accept the endoscopic procedure, which was generally programmed five days later (mean). Hereafter, this second document shall be called the « informed consent form ».

The impact of these different interventions was assessed using a self-administered questionnaire given to each patient shortly after the procedure when the procedure was performed without general anesthesia. The patients who had general anesthesia completed the questionnaire two or three hours later. The self-administered questionnaire included items concerning reading the information brochure (all or part, understanding its purpose, and desire for further information). The patients were also asked to state how they perceived the information in the brochure and how they felt about giving their consent for the endoscopic procedure.

Results

None of the patients declined reading the information brochure or acknowledging writing reception of the brochure.

The exact number of patients who declined the endoscopic procedure after receiving oral information or the information brochure could not be determined precisely. Nevertheless, less than 10 patients declined the proposed endoscopic procedure, including two patients who declined the procedure despite minor digestive bleeding.

One hundred eight consecutive patients (55 men and 53 women), mean age 52.4 years (range : 20 – 86) completed the self-administered questionnaire. Most of these patients had attended consultations in the gastroenterology unit prior to endoscopy. Forty-five colonoscopies and 63 gastroscopies were performed 9 gastroscopies and 33 colonoscopies under general anesthesia.

Oral information was delivered by a physician to 84 patients (77.8%) and by a nurse to 24 patients (22.3%). The information brochure was generally delivered by someone other than a physician : by a consultation nurse for 50 patients (46.3%) and by mail delivery with the appointment card for 23 patients (21.3%).

Nearly all patients stated they had read the entire brochure (104/108, 96.3%) and found it easy to understand with no difficult words (103/108, 95%).

Ninety patients (83.3%) asked questions to obtain further information. Forty (44.4%) asked questions during the consultation when the decision to perform an endoscopy was taken. Fifty patients (55.5%) asked questions after reading the information brochure. These questions were addressed to the physician who was to perform the procedure (n = 23) and to medical assistants in the endoscopy room just before the procedure (n = 27). None of the questions concerned wording in the brochure poorly understood by the patient, nor how the procedure was to be done. All of the questions concerned a request for further information about complications. Eighteen patient (16.7%) stated they would have liked the brochure to include further information on the frequency of complications and their management. None of the patients stated they would have changed the part of the brochure describing the procedure itself.

Among the 66 patients who did not have general anesthesia, 97% considered that the description of the procedure was exact and 89% felt the information on the procedure itself was complete. Fifty-eight of these 66 patients (87.8%) felt the information brochure prepared them well for the endoscopy.

Three-quarters of the patients undergoing endoscopy under general anesthesia felt that receiving oral and written information

ABBREVIATIONS :

AFEF : Association Française pour l’Étude du Foie
SFED : Société Française d’Endoscopie Digestive
SNFCP : Société Nationale Française de Colo-proctologie
SNFGE : Société Nationale Française de Gastroentérologie
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Table I. – Experience of oral information (endoscopy with general anesthesia or not)

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Number of patients (%)</th>
<th>With general anesthesia (n = 42)</th>
<th>Without general anesthesia (n = 66)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>59 (54.6)</td>
<td>30</td>
<td>29</td>
</tr>
<tr>
<td>Surprising</td>
<td>12 (11.1)</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>Distressing</td>
<td>22 (20.3)</td>
<td>5</td>
<td>17</td>
</tr>
<tr>
<td>Instructive</td>
<td>27 (25)</td>
<td>11</td>
<td>16</td>
</tr>
<tr>
<td>Other</td>
<td>0 (0)</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

As some patients used more than one qualification the number of responses is greater than 108. Differences were not significant.

Table II. – Experience of written informed consent (endoscopy with general anesthesia or not)

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Number of patients (%)</th>
<th>With general anesthesia (n = 42)</th>
<th>Without general anesthesia (n = 66)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>64 (59.2)</td>
<td>32</td>
<td>32</td>
</tr>
<tr>
<td>Surprising</td>
<td>24 (22.2)</td>
<td>6</td>
<td>18</td>
</tr>
<tr>
<td>Distressing</td>
<td>20 (18.5)</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>Other</td>
<td>0 (0)</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

* P = 0.01.

Table III. – Experience of written information according to the person explaining the endoscopic procedure and experience of the written information consent form according to the patient’s perception.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Surprised</th>
<th>Distressed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>yes a</td>
<td>no a</td>
</tr>
<tr>
<td>Oral information</td>
<td>11</td>
<td>73</td>
</tr>
<tr>
<td>Physician (n = 84)</td>
<td>11</td>
<td>73</td>
</tr>
<tr>
<td>Nurse (n = 24)</td>
<td>1</td>
<td>23</td>
</tr>
<tr>
<td>Written information</td>
<td>10</td>
<td>25</td>
</tr>
<tr>
<td>Physician (n = 35)</td>
<td>10</td>
<td>25</td>
</tr>
<tr>
<td>Nurse (n = 50)</td>
<td>11</td>
<td>39</td>
</tr>
<tr>
<td>Mail delivery (n = 23)</td>
<td>3</td>
<td>20</td>
</tr>
</tbody>
</table>

* a: not significant b: not significant.

The informed consent form was signed by all 108 patients undergoing endoscopy. For 82 patients (76%), this was the first informed consent form they had signed before a medical procedure. The other 26 patients had previously signed a consent form. For 52 patients (47.2%) obtaining prior consent before the procedure was normal. It was surprising for 30 (27.7%), distressing for 21 (19.4%), and even shocking for 6 (5.5%). The negative (surprising, distressing, shocking) impact of signing an informed consent form was the same regardless of the format in which the form was delivered (table IV). There was no significant difference in the impact between patients who had previously signed a form and those who had not (table V).

Only 85 of the 108 patients (78.7%) answered the question about the requirement to give informed consent before the procedure. Thirty-five of these 85 patients (41.1%) considered that providing written consent was a way of discharging the physician from his responsibility for prescribing the examination. Inversely 30 (35.3%) felt signing the consent form was a positive element proving the patient’s agreement. The other 20 patients considered that written consent had no consequence on the physician’s or their own implication in the decision making process.

**Discussion**

The self-administered questionnaire used in this study had a limited number of items in order to facilitate its implementation. We attempted to achieve a nearly 100% response rate concerning the quality of the information brochure and the signed consent process. The questionnaire was completed after the procedure so the patients could give their assessment of both the quality of the information brochure and the signed consent process. Similarly, to improve feasibility, a psychological evaluation test which would have been useful to interpret the impact of the information as a function of the patient’s psychological status, but which would have require another 20 minutes to complete, was not added on to the self-administered questionnaire.

The data presented here were obtained from 108 patients who answered the questionnaire after their endoscopy procedure. The number of patients who had received oral and written information but finally did not undergo endoscopy could not be determined. There is the possibility that some of the patients did not attend their endoscopy session because of the information in the brochure. Likewise, no data was available concerning the influence of the delivery mode (direct or mail) on endoscopy attendance.

Table IV. – Experience of the written informed consent process according to the way the document was delivered to the patient.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Surprised</th>
<th>Distressed</th>
<th>Shocked</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>yes a</td>
<td>no a</td>
<td>yes b</td>
</tr>
<tr>
<td>Physician (n = 35)</td>
<td>9</td>
<td>26</td>
<td>7</td>
</tr>
<tr>
<td>Nurse (n = 50)</td>
<td>11</td>
<td>39</td>
<td>9</td>
</tr>
<tr>
<td>Mail delivery (n = 23)</td>
<td>10</td>
<td>13</td>
<td>5</td>
</tr>
</tbody>
</table>

* a: NS b: NS c: NS
The principal aim of this work was to ascertain the patients’ opinion on the information brochures elaborated by the three medical societies (SPED, SNFGE, SNFPC). Quality information requires a hierarchic presentation, valid underlying data, and presentation of expected benefits before announcing drawbacks and potential risks [4]. In addition, instructions must be comprehensive, clear, and understandable to as many patients as possible [2, 3]. These prerequisites were met by the information brochures written by the French Endoscopy and Gastroenterology Societies used in this study because they were read entirely by nearly all the patients (96.3%), well understood by an equally large majority (95%), and did not contain incomprehensible wording for the patients. This successful result cannot be considered as an obvious consequence of this type of survey because information brochures are not necessarily easy to understand. Recent work by the endoscopy unit of the Colmar hospital pointed out that 20% of the patients poorly understood the endoscopic procedure presented in the brochure [5]. In addition, information in the brochure well adapted to patients because information brochures are not necessarily easy to understand. Recent work by the endoscopy unit of the Colmar hospital pointed out that 20% of the patients poorly understood the information sheet developed in that unit [5]. The description of the endoscopic procedure presented in the first part (front side of the document) of the brochure used in the present study appears to be satisfactory since 87.8% of the patients considered they were well prepared for the procedure. The information given on the back side of the brochure, which presents complications, may however be insufficient. Eight out of ten patients had further questions about complications and their management after reading the brochure and 16.7% stated they would have liked to have read the answers on the information document. It would be important to make these changes if these brochures are to be designed as official legal documents to be used in court for determining the appropriateness of the information delivered by the physician to the patient [6].

Information given to patients concerning their health status, possible diagnostic and therapeutic procedures, and their expected advantages and potential risks is an essential element in the patient-physician relationship [7]. How patients perceive this information is still poorly understood in France. About one-third of patients are surprised or distressed by this information. Until recently, this information was given orally [8, 9]. Compared with an information brochure, oral information is more personal. Our work demonstrates that it is not always easy to transmit information orally and that it can, for some patients, have a stressful effect (11% of our patients were surprised and 20% were distressed by the information received). We found that the patients perceived oral and written information in a similar way whether it was delivered by a physician or a nurse. There was nevertheless a tendency for more stressful perception of information delivered by a physician compared with information delivered by a nurse (p = 0.09). We were unable to determine whether this was due to a difference between the act of deciding to perform endoscopy and the act of delivering the brochure or the fact that a physician delivers more disquieting information than a nurse, information sometimes involving both the consequences of the procedure and the diagnosis. The frequency of anxiety was not different after delivery of written or oral information. It is noteworthy however that the brochure, which by definition is a standardized document not necessarily perfectly adapted to each individual patient, triggered a stressful feeling in certain patients who had not been distressed by the oral information. Brochure-related anxiety may have been underestimated since the patients who declined the proposed endoscopy did so after reading the brochure. One might expect impersonal mail delivery to be more stressful, but the impact of information contained in the brochure was not different for the different modes of delivery (direct delivery by physician or nurse, mail delivery). This might be related to the clear presentation of the information in the brochure well adapted to patients’ needs. Nevertheless, here again the results do not take into account patients who did not attend the endoscopy session.

Our final objective was to analyze the impact of signing a document acknowledging receipt of the information brochure and serving as an informed consent form. When this study was initiated, signature of this type of document was recommended by the Court of Appeals judge M. Sargos [10, 11], the other options that could be used to validate the reality of delivery of information on endoscopy (presence of a third person when the information is delivered and questions are asked) appearing to be rather impractical. Signed acknowledgment appears to be the most effective means of proving that a patient has been informed of the risks. Oral information is often retained for a short period of time. Stock et al. [12] reported that 6 to 24 hours after colonoscopy, 30% of the patient had forgotten information delivered before the procedure. Our work shows that signing a consent form raises different problems. More than half of the patients felt that signing the form was a negative experience, qualified as surprising by 27.7%, distressing by 19.4% and shocking by 5.5%. These results are similar to those reported by Denis et al from Colmar hospital who found that among 100 patients who signed a consent form, 28 were upset, 30 were shocked, and 40 were less confident because of this attitude. These French data are very different from those reported in studies conducted in North America where the patient-physician relationship is different and patients consider it normal to sign a consent form. The fact that signing a consent form alters the patient-physician relationship is demonstrated by the fact that 41% of our patients and 52% of the patients in the Colmar study considered that signing the consent form discharged the physician from his/her responsibilities. Although the French Association for Liver Study (AFEF) proposes adding an informed consent form to is new liver biopsy information brochure, our findings would favor abandoning the principle of patient signature. This position is also advocated by the official drug agency (ANAES) [1].

The official information brochures for endoscopic procedures, which must be used as a complement to oral information, meet the prerequisites of proper delivery of information. Delivering the brochures and their content are stressful for 20% of the patients. Signing an informed consent form is perceived negatively by a majority of the patients as a means of obtaining proof for the physician. It is thus essential that patients learn that this way of delivering information is normal medical practice and not a means of producing arguments against the patient in case of disagreement and court action initiated by a patient claiming he/she was poorly informed.

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