

Informed consent for digestive endoscopy

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Abstract

Informed consent is necessary in good clinical practice. It is based on the patient's ability to understand the information about the proposed procedure, the potential consequences and complications, and alternative options. The information is written in understandable language and is fortified by verbal discussion between physician and patient. The aim is to explain the problem, answer all questions and to ensure that the patient understands the problems and is able to make a decision. The theory is clear but what happens in daily practice?

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INTRODUCTION

There is a general consensus that every patient coming for digestive endoscopy has the right and should be informed in an adequate, appropriate and understandable way about the procedure. This information should be given in a timely fashion before the endoscopy and should provide a description of the test comprehensibly, explain the reason for investigation, the alternatives, possible risks and benefits, and main implications. It is mandatory to have time and the opportunity to ask additional questions. The decision to undergo endoscopy should not be made under duress and confirmed by the patient's signature on a written form of informed consent. Thus, everything is clear. However, daily routine practice is a little bit more complicated.

PATIENTS AND METHODS

According to a survey of the European Society of Gastrointestinal Endoscopy (ESGE) in 2002^[1], the procedure for obtaining informed consent for digestive endoscopy varies considerably. A structured questionnaire regarding the quality of informed consent was sent to particular endoscopic societies that are members of the ESGE. The response rate was 59% (26/44). The required information is given prior to written consent in only 23% (6/26) of the countries. Information about the procedure is given to the patients in 96% of the responding countries and in only 77% is there sufficient time for patients to ask questions about the nature of the test. In 15% (4/26) of the countries, neither diagnostic nor therapeutic alternatives to endoscopy or the potential complication rate are discussed^[1]. Other published data available is rather controversial. Several studies had different experiences. For instance, in one survey, 92% of patients were properly informed^[2], while according to others, 51% felt dissatisfied because they would have

wanted more information (before diagnostic endoscopy) and 25% to 76% had not been adequately informed about the potential risks (of diagnostic endoscopy or endoscopic retrograde cholangiopancreatography) and alternative methods (to percutaneous endoscopic gastrostomy)^[3-5]. In a Veterans Administration study^[6], all patients signed the consent form before sigmoidoscopy but only 14% of patients actually read all of it (most thought that they had enough information to proceed with the endoscopy). Most patients (93%) were given the opportunity to ask questions but only 22% actually did so^[6]. Some gastroenterologists are afraid that patients undergoing open access endoscopy are less likely to be properly informed about their endoscopic procedure than the group of patients referred from specialized clinics^[7]. Others propose to send information booklets or leaflets on endoscopy procedures in advance by post^[8] or provide patients with information by means of computer-based visualization^[9]. Despite all non-homogenous data, it is quite clear that informed consent is only one of the items of information needed by patients before digestive endoscopy.

However, some demands are difficult to meet. Mayberry^[10] studied levels of information required by patients (516 persons contacted) and solicitors specializing in clinical negligence (79 subjects addressed) before gastroscopy and flexible sigmoidoscopy. Of the solicitors, 86% felt that patients needed to be informed about the procedure on at least two occasions and favored booklets and videos. Both 75% of solicitors and 44% of patients thought that informed consent for endoscopy should be obtained 2 wk before the test. Forty-eight percent of solicitors and 38% of patients felt that patients should be told of very uncommon risks (16% of solicitors even expected information about risks of 1 in 1 000 000)^[10]. According to the British Society of Gastroenterology Guidelines for Informed Consent^[3], the patient should be fully informed by the endoscopist ideally at least 24 h before the procedure; however, for busy units these are impossible standards^[3].

A significant number of patients (41%) signing informed consent were worried by the explanation of the risks (before laparoscopy)^[11].

Another study was carried out at the Inverclyde Royal Hospital, Greenock, Scotland. Demosthenous *et al.*^[12] used validated tests of memory on 59 patients undergoing lower limb arthroplasty to assess how well they learned and recalled information about their planned procedure. Neuropsychological tests were administered to measure the patient's ability to receive, store and recall information delivered verbally. All patients showed an ability to learn new material; however, younger age and higher educational achievement correlated with better performance (patients were excluded if they had any condition impairing memory or communication: dementia, cerebrovascular disease, epilepsy, head injury, dysphasia or aphasia). These results have serious implications for orthopedic surgeons discussing planned procedures. They identified groups of patients who may require en-

hanced methods of communicating the objectives, risks and alternatives to surgery.

One third of patients were distressed or surprised to be given oral or written information in a French study, obtaining informed consent for digestive endoscopy was distressing for 20% of those subjects^[13]. In another French study^[14], 10% of patients considered that the written consent for gastrointestinal endoscopy altered their trust in their endoscopist. Discussions of risk must especially be made in a friendly manner^[15] and should not frighten the patient or even discourage him/her from undergoing the endoscopy.

Informed consent has been set within the framework of medical ethics. Whenever possible, patients should remain responsible for themselves. Where a choice of investigation/treatment might be reasonably offered, the physician may always advise the patient of his/her recommendation (together with reasons for such a suggestion). Clinicians must respect the need to maintain the autonomy and self-determination of patients^[16]. Nevertheless, the question of protecting physicians from malpractice claims is a major aspect of the guidelines for informed consent of the British Society of Gastroenterology^[16] and the American Society for Gastrointestinal Endoscopy^[17].

It is questionable whether all endoscopy units working within particular societies of gastrointestinal endoscopy should use identical protocols of informed consent. For instance, the British Society of Gastroenterology^[16] recommends that each unit should develop its own code of practice suitable to its mode of operation. However, some elements are universal and should always be included. The clinician proposing an endoscopic procedure should explain the reasons for the test and describe its essential elements^[16,18]. Prior to the endoscopy, patients should be provided with written information in a timely fashion and in a form understandable to the patient^[12,15].

The written information describes the principles of investigation and the reasons it is performed. It must list diagnostic/therapeutic alternatives to the test and explain possible major complications (in terms that the patient will understand). It is important to mention in writing that findings within endoscopy and/or possible complications may extend the investigation and/or change the treatment. It is mandatory to inform the patient about who has overall responsibility for the procedure and reassure him/her that the endoscopist and all the staff will do their best for the patient's benefit. A special part of informed consent should provide information about conscious sedation and its consequences (the patient will not be able to drive a vehicle, operate apparatus requiring full vigilance and must refrain from alcohol consumption for 24 h after the test). The patient must have an opportunity to ask additional questions. He/she must be also advised whom to contact in case of any complaint or complication after his/her discharge from the unit (including telephone number for consultation). A psychological approach to the patient is essential, in-

cluding further clarification, reassurance and calming of any possible fears. Naturally, the form (appended with date, time and place) identifies not only the patient but also the unit and the responsible physician. After a full explanation and comprehension, the informed consent is signed by the patient and responsible physician. The form for informed consent should be prepared in duplicate, one for patient and one for medical records.

There are some special situations that should also be mentioned. The first one is “uninformed consent”. Some patients agree with endoscopy but state that they do not wish to receive any information about the procedure and this should be respected. Ethically, information cannot be forced on them but their uninformed consent would still be valid if they are offered detailed information and if they understand that such information is available for them^[18]. Parents (or guardians) will give (and sign) informed consent on behalf of their children and guardians (or first-degree relatives) on behalf of mentally disabled patients^[18]. Special endoscopic procedures (insertion of esophageal or biliary stents and percutaneous endoscopic gastrostomy placement) should also be discussed in detail, including matters of long-term management and potential problems. Some of these patients are in a serious condition and their capacity to give consent may vary due to cerebral dysfunction. Consent may be possible orally or by gesture alone but since gastrostomy placement is an invasive procedure, a reasonable degree of certainty that the patient has consented plus discussion with relatives is needed in every case^[16]. Since informed consent is a process and not a single event, post procedural follow-up of patients is obligatory^[18]. In cases of an emergency (when the situation is life threatening or it is necessary to relieve severe pain and suffering), no consent is necessary, the endoscopist takes full responsibility and acts in the patient’s best interest^[16,18]. The understanding of the risks of endoscopy is insufficient, especially in the cases of older, poorly educated patients and outpatients^[19]. It is also very important to respect a language barrier^[20].

Technological progress has recently brought a lot of new endoscopic methods and devices. The 21st century especially has enriched gastroenterology with new great possibilities: balloon or deep enteroscopy, capsule enteroscopy, confocal laser endomicroscopy, biodegradable stents *etc.* Some of new endoscopic methods are still under evaluation and their yield and safety aspects must be further determined. These facts must be taken into account in the informed consent.

Lastly but not least, it is necessary to emphasize that the patient has a right to withdraw his/her previous consent at any time before or during the endoscopy. If the patient is under conscious sedation when requesting to end the procedure, the physician should make a judgement based on the best interests of the patient^[18]. The Latin saying “salus aegroti suprema lex” (the patient’s benefit is the highest law) must not be forgotten at any time.

CONCLUSION

Informed consent is only one of the items of information needed by patients before digestive endoscopy. It is mandatory to give the patient time and the opportunity to ask additional questions. The clinician proposing an endoscopic procedure should explain the reasons for the test and describe its essential elements. Prior to the endoscopy, patients should be provided with written information in a timely fashion and in a form understandable to the patient. It is necessary to emphasize that the patient has a right to withdraw his/her previous consent at any time before or during the endoscopy.

Movement away from “informed consent” towards an “informed decision” would be the target we should reach in the near future.

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