

COMMENTED SUMMARIES FROM CURRENT MEDICAL LITERATURE

Summary: Gastroenterologists are required to obtain informed consent before undertaking any endoscopic examination. Published data indicate that in practice there are many deficiencies in this process. The aim of this survey was to determine the quality of information given to patients before the endoscopic procedures in countries that are members of the European Society of Gastrointestinal Endoscopy (ESGE). Methods: A structured questionnaire was sent to representatives of endoscopic societies that are members of ESGE regarding the quality of informed consent. Results: The response rate was 59% (26/44). The endoscopist is responsible for giving required information prior to written consent in only 23.1% (6/26) of the countries. Although information about the procedure is given to the patients in 96% of the responding countries, in only 77% is there sufficient time for the patients to ask questions about the nature of the procedure. In 15% (4/26) of the countries neither the diagnostic or therapeutic alternatives to endoscopy are discussed nor the potential complication rates. Finally, the procedure-related mortality is provided in only 23% (6/26) of countries. Conclusion: The procedure of obtaining informed consent for endoscopy varies considerably and may need reevaluation.

Comment: Ethical considerations are playing an increasing role in the everyday work of the gastroenterologist. Endoscopy carries the greatest potential for causing harm among the common gastrointestinal interventions. Ethical principles now dictate that patients should provide their informed consent before being submitted to endoscopy.¹ Patient autonomy is a strongly accepted and protected principle of medical ethics. This principle was stressed in the drafting of the Nuremberg Code in 1947, which sought to protect patients from unwanted medical procedures. According to the principle of autonomy, patients have the right to decide their medical treatment and medical treatments may not be imposed. To protect patient autonomy, informed consent must be obtained prior to performing an invasive procedure. Informed consent insures that the patient understands the risks, benefits and alternatives of a procedure in advance.²

The rapid expansion of medical knowledge and technology has also introduced a range of expensive, complex, and often aggressive diagnostic and therapeutic procedures. Like other specialists, gastroenterologists must often apply general medical ethics principles to specific areas of their activities. One such area is diagnostic and therapeutic endoscopy. Ethical issues peculiar to gastrointestinal endoscopy are often not obvious.³ Interactive videodisc programs to establish informed consent use both graphic and live action sequences to describe in detail the diagnostic procedures of upper alimentary tract endoscopy, colonoscopy and polypectomy. Both benefits and possible risks are listed and described. After each sequence, the patient is asked whether the explanation is understood and/or whether the patient would like to discuss the procedure in more detail with a physician. The programs were designed for use with marginally literate patients and require no reading ability. The programs are also ideal for general patient education.⁴ Nowadays, the health authorities and/or the payers (private or public insurance system) require quality control in the endoscopy unit. This applies to the performance of the procedure and the appropriateness of the indications. Performance is assessed with the following parameters: success in completing the procedure; safety and rate of complications; standard of disinfection of the material; informed consent; and questionnaire on the satisfaction of the patient.⁵ Screening programs are only ethically justifiable if the condition is common and if early detection is capable of preventing disease, thus reducing mortality, morbidity and costs. Besides these beneficial effects in health mortality and morbidity, screening programs must be easily accessible and acceptable to the public.⁶

Neither any fully empowered organizations exist in Iran to supervise the process of obtaining consent from subjects who are candidate for endoscopy, nor is there an authorized body at a high level of government to check the content of the consent forms. The figures presented in the above abstract simply mirror how getting informed consent before performing endoscopy is considered by the members of ESGE and show us that the world is far from the ideal standard of patient care in this realm of science and practice. Unfortunately, neither medical ethics committees nor gastroenterologists in Iran pay attention to this

Commented Summaries

extremely crucial issue; i.e. the patient's informed consent, based on a full understanding of risks and benefits, must be obtained prior to the procedure and sedation.

Information that should be given to the patient prior to endoscopy

The doctor has to first confirm that the patient needs endoscopy (diagnostic/therapeutic). Then, a brief explanation must be given to the patient about the instrument itself, i.e. how it works and what are its diverse, beneficial and well-established applications. Special care must be taken in patients with significant cardiac or pulmonary disease; blood-clotting parameters are checked in those with a history of excessive bleeding. Patients with prosthetic heart valves and those with a history of bacterial endocarditis or a significant right-to-left shunt receive antibiotic prophylaxis. The patient has the right to be informed about the preference of the physician regarding pre-endoscopy sedation, as most endoscopists prefer to administer conscious sedation (after insertion of an intravenous catheter), using diazepam or midazolam for example, for endoscopic procedures. Because of the risk of infection transmission, every endoscope undergoes meticulous cleansing and high-level disinfection, and contaminated surfaces and tubing are replaced after each procedure. The complication rates and mortality of different endoscopic procedures vary widely and the patient should be informed about that fact. Note that the several large surveys suggest a risk of serious complications during diagnostic endoscopy of approximately 1 in 500 and a risk of death of approximately 1 in 10,000. The risks are higher in emergency procedures and in the elderly or seriously ill.

If any relevant information is available during endoscopy that can modify the patient's therapy/diagnosis, the physician will inform him/her. The patient also has the right of being informed that all information collected from him/her during endoscopy will be kept confidential. Make note to the patient that s/he is not obliged to have an endoscopy performed. If the patient has any further questions, s/he can contact a member of the clinic staff and the endoscopist should give the staff's telephone number to the patient.

Sample consent form for endoscopy

I have read the information (according to the above considerations the endoscopist can prepare an information sheet) or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I know that I can refuse to undergo endoscopy without losing any benefits or services to which I am entitled.

I freely agree to undergo endoscopy. After signing below, I will receive a copy of this consent form.

Name of the patient..... Date and Signature.../.... /....

Age.....

Sex.....

Job.....

Name of the witness..... Date and Signature.../.... /....

Name of the physician..... Date and Signature.../.... /....

Elnaz Jafarimehr, Saeed Shahraz MD. Research Center for Gastroenterology and Liver Disease, Tehran, Iran.

Source: Triantafyllou K, Stanciu C, Kruse A, et al. Informed consent for gastrointestinal endoscopy: a 2002 ESGE survey. *Dig Dis*. 2002; **20**: 280 – 3.

References:

1. Axon A. Ethical considerations in gastroenterology and endoscopy. *Dig Dis*. 2002; **20**: 220 – 5.
2. Milkes DE. Tube feeding—right or wrong. The medical, legal and ethical issues. Available at: http://www.thedoctorwillseeyounow.com/articles/senior_living/peg_14/; 2002.
3. Sidorov JJ. Gastroenterology and medical ethics. Available at: http://www.gastroresource.com/GI_Textbook/en/chapter3/3-1-pr.htm.
4. Pernotto DA, Bairnsfather L, Sodeman W. "Informed consent" interactive videodisc for patients having a colonoscopy, a polypectomy, and an endoscopy. *Medinfo*. 1995; **8**: 1699.
5. Lambert R, Rey FJ. Appropriateness of diagnostic digestive endoscopy. *Dig Dis*. 2002; **20**: 236 – 41.
Keighley M, Arnold R. Is colonoscopic screening of a low-risk (normal) population ethically justifiable? *Dig Dis*. 2002; **20**: 246 – 52.