Abstract

Background: Gastroenterologists are required to obtain 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 Iran.

Methods: A structured questionnaire about patient's informed consent before endoscopy was used. In the 3rd Iranian international congress of gastroenterology and hepatology, 100 endoscopists (gastroenterologist or internist) participated in this study regarding the quality of informed consent.

Results: 90% of these physicians were male and 57% of them worked in Tehran (capital of Iran). The distribution of positive answers were as follow:

- Detailed information regarding the nature of the endoscopic procedure provided to the patient, 91%;
- The sufficient time to ask questions about the nature of the procedure, 82%;
- Alternative diagnostic tests or treatment explained to the patient, 73%;
- Patient informed about the possible complications of the proposed procedure, 32%;
- The patient informed about the mortality rate of the proposed endoscopic procedure, 15%.

Conclusion: Although information about the procedure is given to the patients in 91% of the procedure, endoscopic practice must respect the ethical aspects of medicine and more attention need to be paid to informed consent and patient's information, especially about potential procedure-related complications and mortality.

Keywords: Ethics, endoscopy, gastroenterology.

Background

In most people's mind the term "ethics" is associated with morality, however, a more extended investigation would provide a wider meaning with considerable significance [1]. Ethical consideration are playing an increasing role in the every day work of the gastroenterologist. Nowhere it is more apparent than in the field of endoscopy, and the most common gastrointestinal intervention considered to be the greatest potential for causing harm in patients. Ethical principles are now dictated that patients should be provided with the informed consent before being exposed to endoscopy. This should include the discussion of the benefits and disadvantage of the procedure, the consideration of alternative management protocols and a description of the potential complications that may arise and their associated treatment [2].

The relationship between physicians and pa-
patients is based on the concept of partnership. Ideally decisions about medical treatment are made through discussion in which the physician's expertise and the patient's needs and preferences are shared. Patients should remain responsible for themselves and the clinicians must respect their concern and self determination [3,4]. Informed consent is a cornerstone of good medical practice that also acts as a shield for the physicians against patient's complication and malpractice claims [5-6]. Gastroenterologists face the question of informed consent particularly in relation to the performance of endoscopic procedures [7]. So this study was performed to determine the quality of information given to patients before conducting the endoscopic procedures in health care centers of Iran.

**Methods**

In a cross sectional study, 100 endoscopists (gastroenterologist or internist) participated, and they had at least 1 year of working experience at endoscopy units. In the 3rd Iranian international congress of gastroenterology and hepatology, a structured questionnaire about patient's informed consent before endoscopy was used. Questions were, as follow:

1. Is detailed information regarding the nature of the endoscopic procedure provided to the patient?
2. Is he/she allowed sufficient time to ask questions about the nature of the procedure?
3. Are alternative diagnostic tests or treatment explained to the patient?
4. Is the patient informed about the possible complications of the proposed procedure?
5. Is the patient informed about the mortality rate of the proposed endoscopic procedure?

<table>
<thead>
<tr>
<th>Questions</th>
<th>Group 1 (28)</th>
<th>Group 2 (31)</th>
<th>Group 3 (41)</th>
<th>Total positive responses (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1  Is detailed information regarding the nature of the endoscopic procedure provided to the patient?</td>
<td>27 Yes</td>
<td>29 Yes</td>
<td>35 Yes</td>
<td>91</td>
</tr>
<tr>
<td>2  Is he/she allowed sufficient time to ask questions about the nature of the procedure?</td>
<td>26 Yes</td>
<td>25 Yes</td>
<td>31 Yes</td>
<td>82</td>
</tr>
<tr>
<td>3  Are alternative diagnostic tests or treatment explained to the patient?</td>
<td>23 Yes</td>
<td>24 Yes</td>
<td>26 Yes</td>
<td>73</td>
</tr>
<tr>
<td>4  Is the patient informed about the possible complications of the proposed procedure?</td>
<td>18 Yes</td>
<td>7 Yes</td>
<td>7 Yes</td>
<td>32</td>
</tr>
<tr>
<td>5  Is the patient informed about the mortality rate of the proposed endoscopic procedure?</td>
<td>7 Yes</td>
<td>6 Yes</td>
<td>2 Yes</td>
<td>15</td>
</tr>
</tbody>
</table>

Table 1. Grouping of participants on the basis of years of experience.

Table 2. Responses of participants to various questions.
questions about the nature of the procedure?
3- Is alternative diagnostic tests or treatment explained to the patient?
4- Is the patient informed about the possible complications of the proposed procedure?
5- Is the patient informed about the mortality rate of the proposed endoscopic procedure?
6- Detailed information regarding the nature of the endoscopic procedure provided to the patient?
7- Is he/she allowed sufficient time to ask questions about the nature of the procedure?
8- Is alternative diagnostic tests or treatment explained to the patient?
9- Is the patient informed about the possible complications of the proposed procedure?
10- Is the patient informed about the mortality rate of the proposed endoscopic procedure?

The questioner also included some basic information such as age, sex, average years of experience as an endoscopist, place of work (training hospital or private hospitals) and whether they are working in Tehran (Capital of Iran) or outside Tehran.

All answers were stored in a database and then analyzed.

Results

Participants were classified according to the years of experience as an endoscopist. The average work experience of the participants was 2.8 years, and average age of the participants was 44 years. Basic information of the participants is shown in Table 1.

Ninety percent (90 participants) of these physicians were male and 10% female. Fifty seven percent of them worked in Tehran.

Responses to various questions are shown in Table 2.

Discussion

Patient satisfaction is an important issue in achieving excellence in health care system. Yacavone et al. [8] from the Mayo Clinic in Rochester suggested seven possible domains of satisfaction with endoscopy: (i) the technical quality of care, including the skills of the endoscopist; (ii) the comfort and tolerability of the procedure; (iii) the "art" of care (the personal manner of the endoscopy staff); (iv) the provision of an adequate explanation of the procedure; (v) communication with the physicians before and after the procedure; (vi) the endoscopy suite environment; and (vii) waiting time or delays. One of the important factors that help in patient satisfaction and also influences patient's tolerance of endoscopy is the information provided to the patient prior to the procedure. To achieve these goals, doctors must give full and unbiased information to patients, provide adequate time for discussion, and encourage them to participate in the process of decision making. Gastroenterologists are expected to provide complete information for consent more often than physicians and obtaining written informed consent is not that simple because endoscopies are invasive procedures. At the same time, it is equally important to know the amount of information that the endoscopist should provide the patient, though this may vary with the case, however, some basic questions need to be answered. These include: (1) the reason that gastroscopy is indicated; (2) the nature (description) of gastroscopy, i.e., what will happen before, during and after the procedure; (3) diagnostic benefits, including therapeutic options; (4) possible risks, complications and mortality rates; (5) alternative diagnostic tests and their advantages and disadvantages, as compared to gastroscopy, and (6) a clear explanation that the patient may withdraw consent at any time prior to endoscopy [9].

Our survey shows that majority of gastroenterologists informed the patients in detail about the endoscopic procedure, allowed the patient enough time to ask questions about the procedure and explain to the patient about alternative diagnostic tests. These findings were similar to Triantafyllou and et al [10] findings in EU and
non EU countries. But only few endoscopists in our study group explained complications and mortality rate of proposed endoscopic procedure to the patients. In EU and non EU countries, majority of gastroenterologists informed patients about possible complications; and similar to our country, they often did not explain mortality rate of proposed endoscopic procedure. A debatable issue is the amount of information that the endoscopist should provide the patient about the complication and mortality rates of diagnostic gastroscopy. A published survey concluded that most patients wish to be informed of a risk greater than 1: 1,000 [11]. On the contrary, another survey showed that 19% of gastroscopy patients wanted to know all possible complications [12], and a third survey reported that 16% of clinical negligence specialists suggested that patients should be told of risks of 1: 1,000,000 [13].

Our study showed that as years of experience and expertise in endoscopy increases, less emphasis was given on the provision of information prior and after the procedure. Does the experience of the endoscopist weigh heavier on the complete informed consent so far as tolerance of the procedure is concerned, remains to be a debatable issue. In Second European Symposium on Ethics in Gastroenterology and Digestive Endoscopy, a consensus was reached on procedure-related factors and emphasized that the endoscopist's technical skill and the endoscopist's personal manner were among high rated factors so far as patient satisfaction concerned. At the same time less experienced endoscopists emphasized more on the informed consent and other issues which were not technique related. How far the informed consent help in the patients to tolerate the procedure done by a less experienced endoscopist is not known. However, if informed consent is used in a proper manner and not merely for the legal propose it can be of particular significance in tolerance of the procedure, especially if procedure is done by an experienced endoscopist.

References