



How informed are endocrine surgery patients about the risks of surgery after approving an informed consent?

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ABSTRACT

Objective: The aim is to evaluate if patients reach the level of competence that enables them to make the best decision for themselves with oral and written informed consent process that is legally valid.

Material and Methods: This study included 62 patients who applied to Ege University Hospital Department of General Surgery Endocrine Surgery Clinics and in whom oral and written informed consent was obtained by a surgeon. Patients who were willing to participate in the study were asked to fill in a questionnaire containing questions regarding the concept of consent.

Results: Seventy-one percent of patients were female and 29% were male, with a mean age of 50.4 ± 17.9 years. Six percent of patients were illiterate, 51.6% had primary education and 16.1% were college graduates. One in every two patients stated that they have never heard of informed consent concept before, 16% stated that they signed the consent without reading it. Among these patients, 88% reported that they trusted the physician and did not bother reading because they have already been verbally informed. Verbal briefing by the doctor was detected as 92%. Similarly, 91% of the patients reported that the time allocated to read and fill-in the form was enough.

Conclusion: Informing is not composed simply of conveying information, but also to elevate patients to a proficiency level where they could decide with their best interest. It is thought that the results obtained in this study might guide studies to improve the quality of information in patients undergoing surgery.

Key Words: Informed consent, endocrine surgery patients, operative risks

INTRODUCTION

Lawyer Paul G. Gebhard used the concept of informed consent for the first time in 1957, during a medical malpractice case in the USA. Although this terminology was new, the document called "pro corpora mortuoto", which was obtained by physicians from patients or their relatives in the Middle Ages in Italy, France and the Middle East in order to protect themselves from complications that may occur after treatment, constitutes the primitive form of written documentation of informed consent. However, that document was only issued to protect physicians, and did not have a protective structure for patients (1). Historically, a transition in doctor-patient relationship is observed from the paternalistic approach towards sanctity of the human body and the idea that the patient should take an active role in the treatment. The American Medical Association has published a guide for physicians that outlined the minimum information that should be included in the informed consent (2). These are:

- Patient's diagnosis (if known),
- Natural history and purpose of the suggested treatment,
- The risks and benefits of the suggested treatment procedure,
- Alternative therapies,
- The risks and benefits of alternative treatments,
- The natural course of the disease in the absence of treatment, and risks.

Informed consent is of paramount importance not only in endocrine surgery but all surgeries for both medical and legal aspects. According to the 70th article of the law No. 1219 on 'The Practice of Medicine' that was issued on 14 April 1928 in our country, physicians are required to obtain consent (written-oral) from the patients themselves or their representatives. Lately, physicians are careful on this issue due to medico-legal problems. It is expected that patients also show the same diligence in terms of their own health status.

This study aimed to evaluate whether patients who applied to an academic hospital and had an indication for surgery reached the level of competence that enabled them to make the best decision for themselves with oral and written informed consent process.

MATERIAL AND METHODS

Sixty two patients who were admitted to Ege University Medical Faculty Hospital, Department of General Surgery, Endocrine Surgery Department and an oral and written informed consent was obtained

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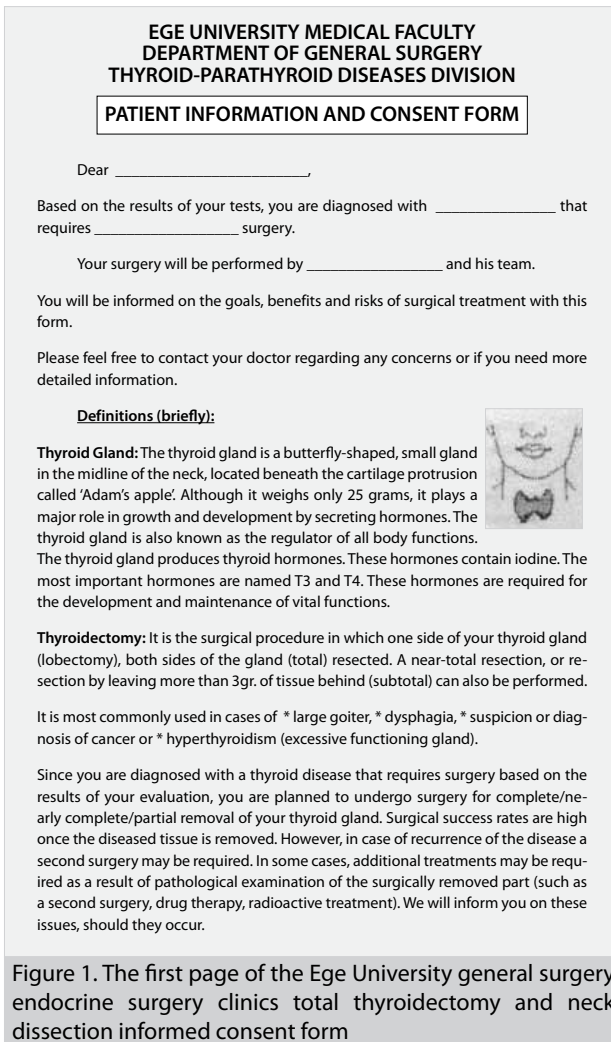


Figure 1. The first page of the Ege University general surgery endocrine surgery clinics total thyroidectomy and neck dissection informed consent form

by a single surgeon (ÖM) were included in the study. In routine practice, patients with a surgical indication were given a previously prepared information and consent form (Figure 1) after being briefed by the surgeon who will perform the operation. It was expected that the patients will read, mark the required components and sign the document by the time of surgery. Patients were reminded that they were free to contact the surgery outpatient clinics during the preoperative period should they have any questions about their disease and/or surgery. Patients who voluntarily participated in the study were asked to respond a questionnaire regarding the concept of informed consent, type and process of disclosure, the content and clarity of written consent, and the extent of information they learned on the risks and benefits of surgery and alternative treatment methods. The survey was composed of 16 questions containing 3 options (Likert scale) and multiple choice questions.

Statistical Analysis

Statistical Package for the Social Sciences (SPSS, Chicago, IL, USA) version 16.0 statistical program was used for evaluation. Descriptive statistics were stated as number and percentage.

RESULTS

The demographic data are shown in Table 1. Seventy-one percent of the patients were female and 29% were male, with a

Table 1. Demographic data of the study group

Age	50.4 (±17.9)
Gender M/F	29/71
Education level	6.5% Illiterate 51.6% Primary school 25.8% High school 16.1% College

mean age of 50.4±17.9 years. Six percent of patients were illiterate, 51.6% were primary school graduates and 16.1% were college graduates. One of every two patients stated that they have never heard of the informed consent concept previously, and 16% stated that they signed the consent form without reading it. Among these patients, 88% reported that they trusted the physician and did not bother reading because they have already been verbally informed. Verbal briefing by the doctor was detected as 92%, but 35% of patients reported that some parts of the form were difficult to understand and complex. Seventy two percent stated that they asked help from a doctor for these sections. It was observed that 94% of patients gained knowledge about possible complications and 3/4 of them were informed about alternative methods of treatment after reading the forms. Eighty eight percent of patients indicated that they knew the purpose the consent form, however 1 out of every 3 patients stated that they considered the form to be insufficient in general. Eighty one percent of patients considered that the consent procedure was a waste of time. Nine out of every 10 patients thought the allotted time to complete the form was adequate, 3 of every 4 patients stated that they read the form 1-2 days prior to surgery, while the remaining patients reported that they read and signed the form immediately before surgery.

DISCUSSION

Informed consent is of the same importance in internal medical sciences as it is in surgical branches. Cassileth et al. (3) has shown an example of this in their study of informed consent from 200 cancer patients receiving chemotherapy. In this study, patients were grouped in terms of their medical condition and level of education. It was determined that only 40% of the patients have read the form carefully, but 60% were informed about the treatment procedure and its nature, and only about 55% were notified about the complications. In our study, 86% of patients have read the form, 94% were informed about the complications after reading the form and 75% were informed about alternative treatment methods. Another striking result of the study by Cassileth et al. (3) was that a large part of patients believed that the purpose of the informed consent form was to protect physicians.

Dawes et al. (4) investigated what patients wanted to know most in informed consents and what was most upsetting for them, with 50 patients who were planned for surgery at an ear, nose and throat surgery clinic. Interestingly, 38% of patients preferred to be informed on all possible complications, whereas 32% stated that they only wanted to know the important ones. They argued that these results showed that all of the complications should not necessarily be dis-

closed within informed consents. However, as noted in the new Turkish Penal Code the patient should be informed on the possible risks of the planned operation, and this issue was considered during preparation of a consent form in endocrine surgery division. Anderson et al. (5) focused on the components of informed consent in their article on 'the practice of informed consent in elective surgery' that was published in 2007. Anderson et al. (5) particularly emphasized recommendations to improve the validity and adequacy of consent forms; the medical idioms should be avoided, the patient should be given sufficient time to read and sign informed consent and the consent should be obtained prior to surgery, an informed consent form should be prepared for every surgical procedure. It is underlined that the procedure itself, its benefits and risks, alternative treatment methods and the risks and benefits if the procedure is not applied must be included as part of the consent form. It is especially stated that an informed consent should be a guide for treatment for many patients rather than a 'permission' form.

Sufficient time should be allocated for both patient information and obtaining written consent, and the form should be understandable. The validity of a consent that is obtained immediately before the procedure and prepared in a different and complex language beyond comprehension of people is controversial. Tümer stated in their article entitled "Informed Consent and Related Issues and Proposed Solutions" that was published in the National Surgical Journal that the informed consent should be obtained by the physician who will perform the procedure, that all the information should be explained clearly and understandably at least 24 hours prior to the surgical procedure, except for emergency surgery, in order to ensure the patient's making a reasonable and appropriate assessment (6). In our study, 9 of 10 patients stated the time given to fill the consent forms was enough, 75% read the form 1-2 days prior to surgery and the remaining patients read and signed the form just before surgery. In addition to this, 35% of patients found the form obscure and complex in general, and asked for help from physicians and health personnel on this issue. Anderson et al. (5) emphasized that a separate consent form is required for each operation. Similarly, in our clinic, separate consent forms are available for total thyroidectomy, total thyroidectomy and neck dissection, completion thyroidectomy, parathyroidectomy, and adrenalectomy.

Tumer also mentioned that the patient's concerns about the process and stress should be eliminated by dialogue with the patient, while obtaining informed consent. This in turn will strengthen the physician-patient relationship, as well as a facilitative effect in solving undesirable situations that may arise later (6). The outpatient physician informed each patient who has applied to the Endocrine Surgery outpatient clinic and had an indication for surgery orally, and then informed consent and disclosure forms were handed out to the patient. The patients were asked to read these forms, contact the clinic if they have any questions and to bring the signed form on the day of surgery. However, 16% of patients stated that they have not read the consent form, 88% of those said

they trusted the doctors and since they were informed orally they did not feel the need to read the information sheet. Although 88% of the patients said they were confident with the doctors and they did not feel the need to read the information sheet, another study conducted in our clinic in 2006 and entitled 'can first year residents obtain informed consent?' found that only 24% of first year residents had sufficient information on the risks and benefits of surgical procedures and alternative treatment methods (7). This observation emphasized the importance of obtaining informed consent by the physician who will perform the procedure, as in Tumer's study.

CONCLUSION

As a result, the purpose of obtaining informed consent should not only be to inform patients about the surgery and to get permission from the patient, but also to provide the patient with high level information so that they can decide about surgery themselves. Therefore, in order to improve the quality of health care and to reduce medico-legal problems to minimum, common consent forms should be created by associations from different surgical branches, their use should be disseminated and if necessary, the use of these consent forms should be mandatory.

The findings obtained in this study enabled the evaluation of awareness of endocrine surgery patients on informed consent and sufficiency information given preoperatively. It has been concluded that these results may guide future studies to improve the quality of information of patients undergoing surgery.

Ethics Committee Approval: The study was consulted with local ethical committee to get ethical committee approval and after assessment it has been concluded that ethical approval has not been warranted.

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