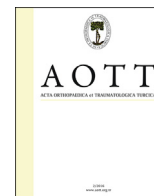


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Evaluation of the informed consent procedure for total knee arthroplasty patients in Turkey



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ABSTRACT

Objective: The purpose of this research is to evaluate the ethical aspects of informed consent process of total knee arthroplasty (TKA) patients in Turkey.

Methods: The study included 50 patients undergoing TKA in Gazi Mustafa Kemal State Hospital Orthopedics Clinic. A face to face survey was conducted to determine the ethical appropriateness of the main components of informed consent process such as; disclosure of material information about the disease and alternative treatment options, understanding the disclosed information, comprehending the written consent form and voluntariness in deciding.

Results: The survey revealed that all TKA patients signed informed consent form, 80% of the participants received material information about their disease, 62% were disclosed information about TKA operation, 56% read (in personal or with the assistance of a relative) the written informed consent form, 28% received information regarding possible complications of TKA and 85% were not given any information about the alternative treatments.

Conclusions: Informed consent process in TKA patients have flourished compared to previous years, but still there are some aspects in need of improvement. Using short and understandable language, developing multi-media sources and involving patients to informed consent form development process would contribute to the process.

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Introduction

The word *autonomy*, derived from the Greek *authos* ('self') and *nomos* ('rule,' 'governance'), referred to self-governance of city-states in ancient times. The definition of the term has since been expanded to include concepts such as individual choice, freedom of will, and right to liberty. In the context of medical ethics, autonomy is defined as the patient's right and ability to decide on the medical intervention for him- or herself, free from both controlling interference by others and limitations such as inadequate understanding and paternalistic approach of the physician that prevent making an informed rational choice.¹ Respect for the autonomy of the

patient is considered as one of the main principles of medical ethics. Informed consent is the practical implementation of respect for the principle of autonomy and is defined as the autonomous authorization of a medical intervention or participation in research.

Informed consent should be regarded with particular interest for total knee arthroplasty (TKA) patients. One reason for this is that patients undergoing TKA tend to be seniors, and old age may augment pre- and postoperative risks and diminish the competency of patients required for autonomous consent.² Another important aspect of informed consent in TKA patients is the possibility of increased exposure to lawsuits in the absence of proper written informed consent.³ The legal immunity acquired by the orthopedist through proper written informed consent is crucial, as the average settlement against orthopedic surgeons is higher than that of other surgical specialties. In a study by the American Knee and Hip Surgeons Association, it was determined that 78% of orthopedic surgeons face at least one malpractice lawsuit in their careers.⁴ Studies in the literature propose that enhancing the

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orthopedic surgeon's knowledge and setting the standards for obtaining informed consent from patients may help to diminish the legal problems that may arise as a result of surgical procedures.⁵ Despite this understanding, very little research has been conducted regarding the legal and ethical appropriateness of the informed consent procedure in TKA patients in Turkey. The purpose of this survey was to evaluate the informed consent procedure for TKA patients in Gazi Mustafa Kemal State Hospital from an ethical perspective. This evaluation serves to identify the ethical problems in the procedure and discuss possible interventions to overcome them.

Patients and methods

The informed consent procedures of 50 patients, selected by simple randomization method among competent patients undergoing TKA, were evaluated between February and April 2015. Five orthopedic surgeons participated and obtained the informed consent forms from the study group.

The survey began by collecting demographic data regarding age, sex, and diagnosis of the patients. This section was followed by questions on the information given to patients through the informed consent procedure about their diagnosis, the surgical treatment, alternative treatments other than TKA, and most probable complications they may face. Participants were asked if they had read and understood the written informed consent form, as well as about their perception about the clarity of the form. Patients who did not read the written informed consent form were asked further about the reason of their avoidance.

Informed consent of each patient was obtained prior to their participation. This study was approved by the local ethical committee.

Forty-three female and 7 male patients participated in the study. The average ages of female and male participants were 66.1 years and 81.8 years, respectively. Twenty-seven patients (54%) had right knee gonarthrosis, 16 (32%) left knee gonarthrosis, and 7 (14%) bilateral gonarthrosis. Twenty-nine patients (58%) had undergone prior surgery, and 21 revealed that they were not presented with an informed consent form (Table 1).

Written and signed informed consent was taken from all patients. Forty patients (80%) stated that they had received sufficient information about their disease, while 10 (20%) were not satisfied with the amount of information given. The dissatisfied patients explained that they would like to learn more about the etiology, course, and severity of the disease, as well as the duration of treatment. Thirty-one participants (62%) revealed that they were given sufficient information about the TKA procedure, while 19 (38%) said the information was insufficient or deficient, or that they received no information. The dissatisfied group was asked about the information they would like to have. Feedback from the group

indicated that duration of hospitalization and time until return to routine activities of daily living were of primary concern (Table 2).

Most participants were not satisfied with the disclosed information about possible complications of TKA. Only 14 participants (28%) said they received enough information about complications, and 36 (72%) said they wished to have obtained more comprehensive information. The questions on information disclosure on alternative treatment options—an essential component of informed consent, with the utmost importance—were answered positively by 15 participants (30%), who stated the information they were given on this issue was sufficient. Furthermore, 2 of these 15 participants revealed that they had tried alternative medical and physical treatments but did not benefit from them, leading them to elect TKA after consultation with their physicians. Thirty-one participants (62%) were not content with the information they were given regarding alternative treatment options, and 4 (8%) said they were completely ignorant of the possibility of treatment options besides TKA (Graph 1).

Participants were asked if they read the informed consent form; 15 participants (30%) said that they had read the informed consent form. Twelve participants (24%) said their relatives read the form to them, the reasons for this mainly being because these patients were illiterate or possessed inadequate reading skills to independently comprehend the form. Twenty-three participants (43%) did not read the form or did not have it read to them. The reasons for not reading the form were as follows:

- There were too many foreign words which they did not understand.
- The font of the letters was too small to see and read.
- They were already told by their physicians what was written in the form.
- They believed they would not comprehend the form even if they read it.

This data is presented in Graph 2 and Table 3.

Twenty-two participants who read the informed consent form or had a relative read the form to them said that they understood the content. Five participants revealed that they did not understand what they read. The reasons for not being able to understand were as follows:

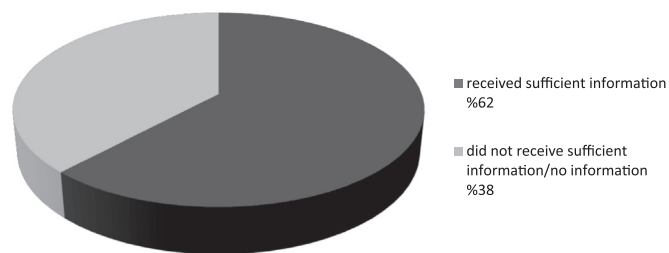
Table 2
Case distribution.

Right knee gonarthrosis	27 (54%)
Left knee gonarthrosis	16 (32%)
Bilateral gonarthrosis	7 (14%)

Table 1
Demographic data of participants.

Age (years)	N	%
51–60	8	16
61–70	26	52
71–80	15	30
81–90	1	2
Gender	N	%
Female	43	86
Male	7	14
Education	N	%
Illiterate	13	26
Literate (without graduation from primary school)	14	28
Primary school	21	42
Secondary school	2	4

Receiving sufficient information about TKA procedure



Graph 1. Satisfaction by the disclosed information.

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