

The informed consent status for surgery patients in eastern Turkey: a cross-sectional study

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Abstract

This study assesses the quality of the informed consent process and satisfaction with the informed consent process, for surgery patients in Turkey. Four hundred and eighty three patients were interviewed after their surgeries. More than half of the patients were satisfied with the information on eight issues that pertained to the informed consent process. A majority of patients (91 per cent) were satisfied with the information regarding why an operation necessary. However, only 205 of 483 patients (42 per cent) indicated that they had received sufficient information on the potential side effects and complications of surgery. Patients' educational level and the type of surgery - urgent or elective - were associated with the satisfaction status.

Introduction

In the past decade, interest in the field of medical ethics has expanded significantly. The traditional paternalistic way of treating patients has increasingly been replaced by a model of mutual participation, in which patient education, patient involvement and shared decision-making are the conventions, and patient autonomy the new ethos (1, 2). These changes have come about partly because of rapid developments in healthcare, increased patient knowledge generated by the mass media and better education, and growing individualism (3). As a result, patients' rights play a more prominent role than they ever have before in developed countries.

In Turkey the legal doctrine of informed consent is enshrined in the Medical Ethics Rules in Turkey, passed by the Turkish Medical Association in 1998 (4). The patient has the right to information about treatment and its consequences. However, there is uncertainty regarding patients' satisfaction with this practice. The goal of this study was to assess perceptions of, and satisfaction with, the informed consent process in patients undergoing surgical procedures in Turkey.

Material and methods

Participants were selected from patients over the age of 18 years who had undergone elective or urgent (emergency) surgery in three university teaching hospital clinics in eastern Turkey between May and November 2003. Permission was obtained from these hospital directorates to interview patients

admitted under their care. Patients were selected from the intra-thoracic, intra-peritoneal, retroperitoneal and orthopaedic surgical wards; the emergency department, operation theatres, intensive care units and coronary care units were excluded from the study. Patients were not interviewed if they were unwell or uncomfortable because of pain or the presence of a nasogastric tube, or if they demonstrated intellectual deficiencies such as dementia or behavioural abnormalities that would hamper successful communication.

Patients were informed verbally of the study's purpose and then asked for their verbal consent to be interviewed. Interviews were conducted between one and six days post-operatively, whenever the patients accepted to be interviewed. The interviews were of approximately 10 minutes' duration.

The first section of the questionnaire consisted of demographic data. The second section consisted of nine questions designed to obtain information regarding the respondent's experience of and satisfaction with the informed consent process before surgery. The nine questions were based partly on the Turkish Medical Ethics Rules (4). They were answered on a five-point Likert scale ranging from 1 ("fully satisfied") to 5 ("fully dissatisfied"). When analysing the data, the responses "fully satisfied" and "satisfied" were merged.

The patients interviewed consisted of 383 patients who had undergone elective surgery and 99 patients who had undergone emergency surgery. Details of the patients are seen in Table 1. The groups were not age, sex and educational level matched, but none of the differences between groups were significant.

Analysis

Categorical variables related to patients in the elective and urgent surgery groups were analysed by the Chi-square test; when necessary Fischer's exact test was employed. Numerical continuous variables (age) were compared by independent t-test. Statistical significance was set at the 0.05 level and p-values were two-tailed. Data analysis was performed using the SPSS(r) statistical software package (SPSS Inc., Chicago, USA).

Results

There was no statistically significant difference between

elective and urgent surgery patient groups in terms of sex, age [40.2±12.1 and 39±11.4 respectively] and education status [18 per cent vs 16.2 per cent respectively with more than 11 years of education; $p=0.674$]. Of the total sample 17.6 per cent had a graduate degree as the highest education level (more than 11 years of education), and 82.4 per cent did not have a graduate degree (1-11 years of education).

Patient ratings of satisfaction with the informed consent process before the operation are shown in Table 2. Urgent surgery patients (USP) group had lower ratings of satisfaction than elective surgery patients (ESP) group. The ESP group was significantly ($p<0.05$) more satisfied than the USP group regarding the information provided on subjects such as the need for surgery, the type of operation, benefits of having the operation, alternative therapies to surgery, consequences of not having the operation, and the surgeon who would perform the operation. However, there was no obvious difference between

years of education as compared to those with one to 11 years of education.

Discussion

The study investigated informed consent in patients undergoing surgery using questionnaire-based interviews carried out in the post-operative period. This was thought to best represent the perceptions and satisfaction the patients would take with them from the inpatient episode.

As seen in Table 2, regarding eight issues pertaining to the informed consent process, more than half of the patients were satisfied regarding seven of these issues. Further, 91 per cent were satisfied with the information regarding why an operation was necessary. However, only 42 per cent of patients undergoing surgery received sufficient information on the potential side effects and complications of the surgery. The results also show that surgery type - urgent or elective - as well

Questions asked of surgery patients to assess their satisfaction status

1. Are you satisfied with the information given to you prior to surgery about why you needed a surgical operation? (There are many reasons to have surgery. Some operations can relieve or prevent pain. Others can reduce a symptom of a problem or improve a body function. Some surgeries are performed to diagnose a problem. Surgery can also save your life.)
2. Are you satisfied with the information given to you prior to surgery about the type of operation you needed? (Your surgeon should explain what will happen during the operation, and inform you where the cuts will be and how big they will be.)
3. Are you satisfied with the information given to you prior to surgery about the kind of anaesthesia you needed and what the risks were? (Anaesthesia is used so that surgery can be performed without unnecessary pain. Your anaesthetist should tell you whether you will need local or general anaesthesia. Although anaesthesia is safe for most patients, possible side effects and risks should be explained.)
4. Are you satisfied with the information given to you prior to surgery about what the risks of this operation were and what the risks were for you? (Complications such as infection, too much bleeding, reaction to anaesthesia and accidental injury can happen at the time of the operation, or there may be side effects after the operation. Some people have an increased risk of complications because of other medical conditions. Your surgeon must inform you about your risk probability.)
5. Are you satisfied with the information given to you prior to surgery about the benefits of having the operation? (The surgeon should you inform about what you will gain by having the operation and how long the benefits will last. For some operations the benefits only last a short time. You might need a second operation later. For other operations the benefits may last a lifetime.)
6. Are you satisfied with the information given to you prior to surgery about alternative therapies to surgery? (Sometimes surgery is not the only answer to a health problem. Medicines or other non-surgical treatments might help you just as much or more. Your surgeon should talk about alternative treatments are suitable or not for you.)
7. Are you satisfied with the information given to you prior to surgery about what if you didn't have this operation? (Your surgeon should tell you what will you gain - or lose - by not having the operation.)
8. Are you satisfied with the information given to you prior to surgery about who would do the operation and what their skills were? (The surgeon should declare who will be doing the operation and the success rate at the hospital you are going to.)
9. Are you satisfied with the information given to you prior to surgery about how long it would take you to recover? (Your surgeon should say how you might feel and what you will be able to do in the first few days, weeks or months after the operation.)

the ESP and USP group in the information given on the kind of anaesthesia and its risks, the risk of the operation, and the time to recover. Overall, the ESP group had higher ratings than the USP group.

In relation to the patient's education, all ratings of patient satisfaction were significantly higher for those with over 11

as education levels of patients were related to the satisfaction status.

There are certain limitations to this study. Information given before the surgery may have been forgotten by the patient in the post-operative period; previous studies have reported that the elderly and individuals with lower levels of education

are more likely to forget information necessary for informed consent (5, 6, 7). Second, patients interviewed in the post-operative period may also have impaired recall of pre-operative pain and the effects of pre-operative analgesia this is not measured in the study (8). Furthermore, it is possible that some patients' poor recall contributed to their perception that insufficient information was given at the time of consent. A number of studies indicate that retention of information about

legal requirement.

Many strategies have been reported to improve patient recall and understanding. These include adequate time for discussion with the patient prior to informed consent, and consent forms with larger print size for older or visually-impaired patients. A combination of verbal and written information can be used to improve recall of operation details (12, 13). Appropriate measures must be taken to ensure that patients are truly informed of the treatment procedure.

Table 1. Details of patients interviewed

Group	Elective	Urgent
No. of patients	383	99
Male (%)	44.5	48.7
Mean age in years ± (SD)	40.2 ± 12.1	39 ± 11.4
1-11 years of education	82.0%	83.8%
>12 years of education	18.0%	16.2%
Median delay from operation to interview in days	2(1-8)	2(1-11)
* Range given in brackets		

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Table 2. Patient ratings of satisfaction with the informed consent process

Were you satisfied with the information given to you prior to surgery about the following	Elective surgery patients N=383	Urgent surgery patients n=99	1-11 years of education n=397	>11 years of education n=85	Overall n=482
Why you need a surgical operation	Satisfied n(%) 355(92.7)*	Satisfied n(%) 85(84.8)	Satisfied n(%) 357(89.7)	Satisfied n(%) 83(97.6)*#	Satisfied n(%) 440(91.1)
What type of operation you need	213(55.5)*	41(41.4)	196(49.2)	58(68.2)*#	254(52.8)
What kind of anaesthesia you need and what the risks are	212(55.2)	51(51.5)	199(50.0)	64(75.3)*#	263(54.5)
What the risks of this operation are and what the risks are for you	166(43.2)	39(39.4)	149(37.4)	56(65.9)*#	205(42.4)
What the benefits are of having the operation	244(63.0)*	51(51.5)	225(56.5)	70(82.4)*#	295(61.1)
What the alternative therapies to surgery are	242(63.0)*	48(48.5)	218(54.8)	72(84.7)*#	290(60.0)
What if you don't have this operation	268(69.8)*	54(54.5)	251(63.1)	71(83.5)*#	322(66.7)
Who will do the operation and what their skills are	257(66.9)*	50(50.5)	241(60.6)	66(77.6)*#	307(63.6)
How long it will take you to recover	199(51.8)	44(44.4)	184(46.2)	59(69.4)*#	243(50.3)

p<0.05, between elective and urgent surgery groups. *# p<0.05, between 1-11 and >11 years of education groups.

the purpose of treatment, benefits, consequences and potential risks is often minimal (9, 10, 11). Nevertheless, the lack of certain information provided by the surgeon during the consent process is of concern.

Conclusion

The process of informed consent in surgical practice remains undeveloped in Turkey. Failure to obtain informed consent may be a reflection of poor communication. Strategies for improving the informed consent process may be implemented at a number of levels including individual practice, hospital policies and procedures, as well as in the pre- and postgraduate medical education system. Obtaining informed consent should be seen as central to good practice rather than an administrative or

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