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Research

Informed consent in surgical practice with patients' experiences: A cross-sectional study

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Abstract

This study aims to evaluate patients' experiences and perspectives regarding informed consent in surgical practice. Data for this cross-sectional study were collected from 276 patients using a questionnaire developed by Falagas et al. Descriptive statistics were employed for all questions. Statistical tests such as the Mann-Whitney U test, Kruskal-Wallis test, and Spearman's rank correlation analysis were performed, and Cohen's effect sizes were reported. IBM SPSS 23.0 was used for all analyses, and $p<0.05$ was considered statistically significant. A high score on both The Delivered Information Index and The Patient-Physician Index represents a positive informed consent process. Among the participants, 65.2% indicated that they understood all parts of the consent form. Of all patients, 92.8% reported that information about the specific surgical procedure was provided by physicians. However, 47.5% of the patients reported that they did not feel comfortable with their surgeons. The mean score of the Delivered Information Index was 5.63 (2.38). The mean patient-physician relationship score was 14.38 (3.31). There was a moderate positive correlation between the delivered information index and the patient-physician relationship ($r=0.50$; $p<0.001$). In addition, there was a moderate positive correlation between the delivered information index and the time spent on the informed consent process, as well as between the patient-physician relationship and the time spent on the informed consent process ($r=0.52$; $r=0.40$, respectively). The study emphasized the lack of communication between patients and physicians, the limitation of information on treatment risks, adverse effects, and alternative treatment options.

Keywords

Informed consent, patient rights, comprehension, patient experience

Introduction

Informed Consent (IC) is an essential element of comprehensive medical care,[1] in which patients are provided with information regarding the purpose, benefits, and potential risks associated with medical or surgical interventions.[2] IC is more than a mere form that patients are required to read and sign.[3] It entails the provision of both written and verbal information tailored to the patient's culture,[4] the level of comprehension, and decision-making abilities.[5]

IC involves the dissemination of an adequate amount of information to the consenting individuals, addressing their concerns, fears, and questions, and engaging in discussions on potential positive or negative outcomes.[6] Consequently, IC helps establish a stronger physician-patient relationship, while empowering patients to make informed decisions regarding their treatment and disease.[3] Studies assessing IC from the patient's perspective report that patients are generally insufficiently informed.[4] García-Álvarez et al. (2023) found that the informed consent forms employed in surgical care lacked adequate quality and compliance.[7] Gong (2018) emphasized that physicians often fail to effectively communicate medical information in a manner that patients can comprehend, leading to inadequate patient-physician communication. As a result, patients often struggle to understand medical information, cannot have a say in clinical decisions, and simply sign informed consent forms.[8] The literature explains that patients' poor knowledge about surgery leads to poor participation in informed decision-making and loss of patient autonomy.[9] To facilitate patient-centered care and promote active patient involvement in clinical decisions, it is essential to examine the informed consent process from the patient's perspective and address the existing deficiencies in the patient-physician relationship.[6,10] However, studies on informed consent in Türkiye are limited to this particular perspective. In this regard, this study aims to address this gap by exploring the comprehensibility of information provided during the informed consent process, patients' communication with healthcare professionals, the adequacy of time allocated for the informed consent process, and the appropriateness of informed consent procedures. The detailed information obtained from this study is expected to contribute to patients' participation in clinical decisions, and valuable insights for physicians and healthcare managers regarding deficiencies in the informed consent process. The research specifically focuses on evaluating patients' experiences and perspectives on informed consent within three surgical departments of a training research hospital in Türkiye.

Materials and Methods

The cross-sectional study was conducted in the neurosurgery, general surgery, and ophthalmology departments of a training research hospital in Türkiye between February 2019 and January 2020. Purposive sampling was employed as the sampling method. The sample size was determined based on a study by Falagas et al.[11] Within the study hospital, there are approximately 9,000 operations performed annually. For the study, the sample size was set to 306, with a 0.05 margin of error and a 0.95 confidence interval level. Initially, 300 patients were identified to participate in the study; however, 24 patients (8.0%) failed to fill out all the survey items. The missing values were excluded from the study. Ultimately, a sample size of 276 patients was considered eligible for inclusion in the study. Post hoc power analysis indicated that the study had over 95% power.

The Questionnaire

The questionnaire developed by Falagas et al. (2009) was employed after receiving permission from the original researchers. Two linguists translated the questionnaire from English to Turkish. Then, it was backtranslated into English by two different experts. Subsequently, another linguist reviewed the translated questionnaire, and six academicians examined both the Turkish and original English versions of the items to obtain the most appropriate questionnaire. The questionnaire was administered in a face-to-face manner before surgery by one of the researchers at the study hospital.

The questionnaire comprised four sections, encompassing the descriptive characteristics of patients, the Delivered Information Index (DII), the Patient-Physician Index (PPI), and items relating to attitudes and awareness of the informed consent (IC) process and its proper implementation. The DII section included items about patients' awareness of the IC process, while the PPI section contained items on the patient-physician relationship. The DII scores ranged from 0 to 10, while the PPI scores ranged from 0 to 20. In reporting the results for DII and PPI, the groupings proposed by Falagas et al. (2009) were utilized: the DII scores were divided into three groups, namely 0-5, 6-8, and 9-10 points. In addition, individuals who scored 13 or less on the PPI were classified as having a "low" patient-physician relationship, while those scoring higher were deemed to have a "high" patient-physician relationship. A high DII score indicates a good level of patient awareness regarding the IC process, while a high PPI score indicates a positive patient-physician relationship.[11]

Statistical Analysis

Descriptive statistics were employed to analyze all the items in the study. The assumption of normality was assessed using graphical methods, as well as the Shapiro-Wilk and Kolmogorov-Smirnov tests. However, it was determined that not all variables met the assumption of normality. As a result, non-parametric tests, namely the Mann Whitney-U (Test statistics value is z) and Kruskal Wallis tests (Test Statistics value is Chi-Square) were used. Results of statistical comparisons were reported with median and interquartile range (IQR) due to using nonparametric analysis. Test statistics and Cohen's effect sizes (d) were also reported for the statistical tests. Effect sizes as small ($d=0.2$), medium ($d=0.5$), and large ($d\geq 0.8$). Spearman's rank correlation analysis (r) was used to assess correlations. All statistical analyses were performed using IBM SPSS 23.0, and $p<0.05$ was considered to indicate statistical significance.

Ethical Considerations

The study was approved by the Non-Interventional Clinical Studies Ethics Committee of İstanbul Medipol University (Approval No: 2019/35, date: 06.03.2019).

Results

The participants were mostly male, in old age, married, and secondary school graduates. The DII median score was 5 (3). Most respondents were aware of their treatment (DII items 1-2), and the benefits of the surgery were adequately explained to them, and it was sufficient for them.

The median value of the PPI was 15.0 (5.0). The results of the Patient-Physician Index (PPI) are presented in Table 2. The majority of patients reported always or often trusting and respecting their surgeon. However, nearly half of the patients indicated that they always or often feel uncomfortable with their surgeon.

The statistical difference between the indicators was reported in Table 3. There was a medium difference between the DII scores of those who understand CI and those who do not ($d=0.57$), those who understand CI have a higher DII score. Likewise, a medium difference was found between the PPI scores of those who understand CI and those who do not ($d=0.43$). The difference between participants who perceived IC as necessary, both DII and PPI scores, respectively, was small ($d=0.19$ and $d= 0.10$,

Table 1: Responses to Items in the Delivered Information Index (DII)

Items	Responses	
	Yes (%)	**No (%)**
Are you aware of your problem and diagnosis?	241 (87.32)	35 (12.68)
Are you aware of why you are having this operation?	220 (79.71)	56 (20.29)
Were you informed about the duration of your hospital stay?	118 (42.75)	158 (57.25)
Did you feel that the inconveniences and potential risks of the operation were explained?	164 (59.42)	112 (40.58)
Were the risks explained in case you decided against the operation?	160 (57.97)	116 (42.03)
Were the potential benefits of the operation explained?	205 (74.28)	71 (25.72)
Were postoperative issues (such as complications) discussed?	114 (41.30)	162 (58.70)
Were you informed about the duration of your treatment?	112 (40.58)	164 (59.42)
Did you receive too much information?	49 (17.75)	227 (82.25)
Were you satisfied with the amount of the information you received?	171 (61.96)	105 (38.04)
The delivered information index	Median (IQR) 5.00(3.00)	

respectively). The difference between receiving information about other possible therapeutic options and DII and PPI, respectively, were medium (d= 0.43) and small (d=0.20) (Table 3).

There was a moderate positive correlation between the DII and the PPI (r=0.50; p<0.001). Additionally, moderate positive relationships were found between DII and the time spent on the IC process, as well as between PPI and the time spent on the IC process (r=0.52; r=0.40, respectively).

Participants were asked about their opinions regarding the implementation and understanding of the IC. Of the participants, 56.2% stated that they understood their rights concerning IC, while 31.2% were uncertain about their understanding. The percentage of participants who reported being informed about other possible treatment options was 55.8%. Of them, 19.6% expressed uncertainty regarding their knowledge about this matter, and 17.8% stated that they were not informed. In terms of the time allocated to the consent process, 51.4% of the patients stated that it was less than 5 minutes, while 30.8% indicated that the process took 5-10 minutes. Participants were also asked to provide their understanding of the IC in their own words. A total of 72 participants responded to this question. Of these responses, 46.5% mentioned the risks and disadvantages associated with the treatment. Additionally, 7 participants (4.5%) described the IC form as a means for the patient to take responsibility. One of these participants addressed shared responsibility between the patient and the physician, while another expressed it as an assurance for physicians themselves. Approximately 29.0% of the participants referred to the IC as an information process, information letter, or form. One participant stated that it allowed them to make a more informed decision about the surgery, while another regarded it as a beneficial practice in terms of being well-informed. Another participant stated, "It provides information, but I do not understand the medical terminology." Of the respondents, 22 (14.2%) patients defined the IC as a consent form or signature paper, using phrases such as "need to sign," "signature paper," and "accept the surgery." Most of the participants consider IC

Table 2: Responses to Items on the Patient-Physician Index (PPI)

Items	Never (%)	Seldom (%)	Sometimes (%)	Often (%)	Always (%)
Do you trust your surgeon?	0 (0.00)	4 (1.45)	27 (9.78)	119 (43.12)	126 (45.65)
Do you feel uncomfortable with your surgeon?	48 (17.39)	40 (14.49)	57 (20.65)	72 (26.09)	59 (21.38)
Do you respect your surgeon's opinion?	0 (0.00)	4 (1.45)	30 (10.87)	121 (43.84)	121 (43.84)
Did you express your concerns about the operation to the surgeon?	8 (2.90)	40 (14.49)	83 (30.07)	64 (23.19)	81 (29.35)
Did you feel that the surgeon heard and understood your opinions and concerns?	8 (2.90)	11 (3.99)	63 (22.83)	101 (36.59)	93 (33.70)
The Patient-Physician Index	Median (IQR) 15.00 (5.00)				

Table 3: Comparison of the Delivered Information Index and Patient-Physician Index Scores Between Subgroups

		Delivered Information Index					Patient-Physician Relationship				
	Measure/ Count	Median	IQR	Test Statistics	p	Effect Size	Median	IQR	Test Statistics	p	Effect Size
Gender	Male	6.00	3.00	0.55	0.58	0.03	14.00	5.00	0.20	0.84	0.01
	Female	5.00	4.00				15.00	5.00			
Age	<25	6.00	5.00	7.23	0.20	0.18	15.00	4.25	10.25	0.07	0.28
	26-35	5.50	4.00				15.00	4.00			
	36-45	5.00	5.50				15.00	5.30			
	46-55	6.00	3.00				14.00	5.00			
	56-65	6.00	3.00				14.00	5.00			
	>65	5.00	3.25				13.00	5.00			
Education Level	elementary school and lower education	5.00	3.00	-0.68	0.50	-0.04	15.00	5.00	-1.63	0.10	-0.10
	high school and higher education	6.00	3.00				14.00	4.00			
Comparison of the right to informed consent	Yes	7.00	4.00	-9.53	p<0.001	-0.57	16.00	4.00	7.12	p<0.001	0.43
	No	4.00	3.00				12.00	4.00			
Other Therapeutic options	Yes	6.00	4.00	-7.06	p<0.001	-0.43	15.00	5.25	3.36	p<0.001	0.20
	No	4.49	2.02				14.00	5.00			
Perception of informed consent	Important	6.00	3.00	-3.09	0.002	-0.19	15.00	5.00	1.73	0.09	0.10
	Not Important	3.00	4.25				12.00	7.00			
Clinic	Neuro-surgery	6.00	5.00	7.00	0.03	0.27	15.00	5.00	7.71	0.02	0.29
	General Surgery	5.00	3.00				14.00	5.00			
	Ophthalmology	5.00	3.00				14.00	6.00			

as a document that explains the risks of treatments, which must be signed, and which leads the patients to take responsibility. It is noteworthy that the rate of those who think that patient consent forms provide information to patients is less.

Among the participants, 65.2% indicated that they understood all parts of the consent form. Out of the remaining 96 participants (34.8%) who reported not understanding all parts of the consent form, 35 stated that they did not read the form at all. Additionally, 11 participants stated unfamiliarity with the terminology used in the IC, 10 participants mentioned lack of time as the reason for not reading it, and 5 participants stated that a family member had read the form on their behalf. Of the participants, 50% stated that they thought they could change their minds after accepting the surgery. Among the participants, 229 individuals raised questions about the surgery, while 47 participants did not ask any questions. As for the reasons provided by those who did not ask questions, 23 individuals (49%) stated a lack of time, 15 individuals (32%) stated that the consent document was open, 1 individual (%0.2) felt a pressure of the healthcare staff, and 8 individuals (%17) stated other reasons.

A majority of the participants (55.7%, 162 patients) expressed that the IC process is 'important' or 'very important'. Out of these, 127 participants stated that the IC process is important because it assists in decision-making, while 47 participants stated that it is important because it provides legal protection to physicians and ensures the legality of the process. On the other hand, 55 participants who did not consider the IC process important expressed that they would follow the surgeon's instructions regardless of the IC, and 26 participants stated that they had already decided to undergo the operation, thus considering the IC process ineffective.

Discussion

The study, aimed to evaluate the patient's patient experiences and perspectives about IC, showed that although patients place trust in their physicians, there is a notable lack of communication between patients and physicians.

The results of the study revealed that patients received substantial information about their health condition, diagnosis, and treatment before undergoing surgical procedures. However, the study concluded that there were limitations in providing information regarding the duration of hospital treatment, potential risks, disadvantages, and complications. Patients expressed their trust and respect for surgeons as the key decision-makers in the treatment process. However, 47.5% of the patients reported that they did not feel comfortable with their surgeons. This is an important limitation in patient-physician communication. Nearly 35% of the patients stated that they did not fully understand the informed consent, primarily due to not reading the consent form. This raises concerns regarding the readability of the consent form. Around 56% of patients considered IC important, while 46% believed it to be effective in clinical decision-making. Notably, a considerable portion of the participants expressed doubts about the necessity and effectiveness of IC.

The DII and PPI scores obtained in the present study were lower than those reported by Falagas et al. (2009).[11] The present study found that almost half of the participants perceived the information they received as insufficient, in contrast to the study conducted by Falagas et al. (2009), where over 80% of participants deemed the information sufficient. Consistent with previous research[5,11,13] the study indicated a better level of information provided regarding the benefits of treatments rather than expressing disadvantages. Overall, there are still notable gaps in adequately informing patients during the IC process.

The findings of the study indicated that participants who reported understanding their rights regarding IC and receiving information about alternative treatment methods had significantly higher scores on the DII and PPI compared to others. Likewise, in the study by Falagas et al. (2009), these two groups also exhibited significantly higher DII values than the remaining group consistent with the results of Falagas et al. (2009), a statistically significant positive correlation between DII and PPI was observed.[11] Another significant finding was that both DII and PPI scores increased with the duration of time allocated to the IC process. In the study by Falagas et al. (2009), a positive relationship was found only between the time allocated for IC and PPI.[11] Hence, the results suggest a mutually supportive relationship between the patient-physician relationship and the IC process.

Studies on IC raise questions about the individuals involved in the process, yielding different outcomes. For instance, in a study conducted in Ethiopia (2022), 87.8% of the participants stated that they were unaware of who provided counseling.[5] In a Turkish study,[12] physicians informed 55.7% of the patients. In this study, 92.8% of the participants reported being informed by their physicians. Thus, it was concluded that physicians played an active role in the IC process in the hospital where this study took place.

Pitt et al. (2016) reported that discussions related to the disease, surgical procedure, and potential complications were more common; however, patients' overall understanding of informed consent (IC) was not thoroughly assessed.[10] On the other hand, Convie et al. (2020) argued that IC studies should focus on evaluating the patients' comprehension rather than solely examining the amount of information provided to them.[15] In this study, 35% of the patients indicated that they were unable to understand all aspects of the IC. The primary reasons for this lack of understanding, as reported by 96 participants, included not reading the consent form, facing unfamiliar terminology, and time constraints. Numerous studies[3,6,14-16] have emphasized that patients often do not read the informed consent form. When considering the collective findings of these studies, it becomes evident that difficulties in reading the IC form contribute to the challenges associated with understanding the consent process.

We also asked the patients to explain their understanding of IC, and nearly half of the participants described IC in terms of the risks and disadvantages associated with treatment. The research results indicated that other common responses included perceiving IC as an information form (29.0%) or a document requiring signature/approval (14.2%). In recent years, studies on IC have increasingly focused on assessing patients' comprehension of the consent process. However, when examining the outcomes of various studies, different percentages of participants who demonstrate an understanding of IC are reported, ranging from 67.7% (6) to 30.0%.[16] Thus, rather than solely inquiring about patients' understanding of informed consent, it is crucial to evaluate not only whether patients comprehend the information but also what aspects they understood and to what extent.

There were some limitations in the study. Firstly, the reversed questionnaire was not tested on the same characteristics of the sample group before applying the sample group. The study was also limited to patients who were operated in a tertiary care hospital and patients agreed to participate.

Of note, this study revealed a lower percentage of patients spending more than 10 minutes on the IC process, while a higher percentage reported spending less than 5 minutes. Patients mentioned insufficient time as one of the reasons for not asking questions about the surgery. This finding should be considered together with the observation that patients do not feel comfortable with their surgeons, emphasizing the importance of addressing communication barriers.

Conclusion

In Türkiye, there is a need for improvements in the informed consent process. First of all, it was concluded that physicians play an active role in the IC process. Although patients trust their physicians, there are challenges in communication, indicating that a paternalistic physician style is still predominant over a participatory treatment approach. Clinicians should establish a patient-physician relationship that encourages patients to ask questions and make comfortable communication. Some patients perceive IC as a mere formality or as an exchange of risks, underscoring the importance of clarifying the significance of the informed consent process for patient participation in clinical decisions. The study emphasized the need for expanding the provision of information on treatment risks and adverse effects. Time constraints appear to be significantly effective in informing patients. Clinicians should allocate more time for information-sharing and communication with patients or assign other healthcare professionals in the IC process. Patient education has a crucial role in enabling patients to perceive informed consent as a means of active participation in the treatment process.

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