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Original Research Article

A Cross-Sectional Study on Patient's Satisfaction and Related Factors with the Preoperative Informed Consent Protocol

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Abstract

Background: To meet the expectations of patients, informed consent is a time-consuming and labour-intensive process. A variety of clinical practice issues can contribute to patient dissatisfaction with the preoperative informed consent process. This study evaluated patient satisfaction and factors related to the informed consent process for elective surgery subjects.

Methods: A cross-sectional study included 202 postoperative patients who provided informed consent for elective surgery. The study participants were selected using a systematic sampling procedure. The modified Leiden perioperative patient satisfaction tool was used to evaluate patient contentment with the preoperative informed consent approach. Data was analysed by SPSS 20.0. Bivariate and multivariable logistic regression were used to find independent variables linked with patient satisfaction with the preoperative informed consent process. A p-value of less than 0.05 was utilized to determine the statistical importance.

Results: The general rate of patient satisfaction with the preoperative informed consent process was 70.3%. A multivariable logistic regression analysis found that male gender (AOR: 4.75), primary school (AOR: 8.42), secondary school (AOR: 2.17), rural residence (AOR: 1.8), and general anaesthesia (AOR: 2.92) were all considerably associated with client satisfaction with the informed consent process.

Conclusion: In summary, patients were not very satisfied with the preoperative informed consent procedure. Patient satisfaction with the informed consent procedure was substantially correlated with being male, having a low level of education, residing in a rural region, and undergoing general anaesthesia. More has to be done by surgeons and anaesthesiologists to increase patient satisfaction with the preoperative informed consent procedure. Periodically evaluating patient satisfaction and the factors influencing it is demanded of researchers.

Keywords: Informed consent, autonomy, patients will, doctor-patient relationship.

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Introduction

Among the main principles of informed consent is the ability of patients to participate in the decision-making process regarding the treatment they receive [1]. Patients should be given enough information to aid in their decision-making process and be qualified to make the specific choice [2].

Since informed consent is a continuous conversation between patients and their doctors over the course of the patient's treatment, it is best understood as a process rather than an event. Preoperative evaluation is the first step, followed by surgery and after care [3–6]. No patient can be coerced, directly or indirectly, into accepting treatment that they may refuse, even whether it is painless, advantageous, risk-free, or even life-threatening, since the Informed Consent Process is considered a fundamental requirement of a doctor-patient relationship [7]. Informed consent, which empowers honouring patients' autonomy and dignity, is the foundation of medical ethics and surgical practice.

Even when a patient is accused of negligence, improper informed consent may result in legal action against health professional. Therefore, improved comprehension of the informed consent procedure safeguards clinical care practices for both patients and medical personnel [7]. At the moment, the nation is promoting compassionate,

respectful, and caring healthcare practices. It represents upholding the professional oath, helping patients with compassion and understanding, and setting an example for aspiring professionals. Among the key elements of compassionate care is informed consent, which calls for adequate sharing of information along with compassion and understanding in order to reach a mutually agreeable and well-informed treatment plan decision. Research indicates that compassionate care has been linked to better clinical results, higher patient satisfaction, greater treatment adherence, not as many malpractice claims, and lower health care costs [8]. However, very few researches have been done on how the compassionate care program affects patients' satisfaction with the quality of healthcare they receive, especially during surgery and anaesthesia.

Several aspects of clinical practice may influence patient dissatisfaction with the preoperative informed consent procedure [9,10]. The degree of education and health literacy of patients, the knowledge and expertise of medical personnel, and other sociodemographic characteristics may all have an impact on how satisfied patients are with the preoperative informed consent procedure.

There is insufficient data on how satisfied patients are with the preoperative informed consent procedure in the research environment, especially in our region. The purpose of this study was to evaluate surgical inpatients' satisfaction with the preoperative informed consent procedure and related factors.

Methods and Materials

From 1st October 2024 to March 30, 2025, a multi-centre cross-sectional study was carried out in two separate hospitals in National capital region. These hospitals anticipate doing major surgery on 4560 patient year on average. Patients with known mental illnesses and critically ill patients were dropped from the study, but all elective surgical patients between the ages of 18 and 65 were considered.

The study participants were chosen proportionately from the chosen institutions using a systematic sampling procedure based on the regular operating schedule listings. Utilizing an interviewer-administered data collection technique, the designed survey was modified from the Modified Leiden Perioperative Care Patient Satisfaction questionnaire tool and various literatures to the local context in order to evaluate patients' satisfaction and related factors with the preoperative informed consent process.

Epi-data version 4.20 was used to enter the whole set of data, which was then exported to SPSS version 20.0 for analysis. The 95% confidence interval was used to calculate descriptive statistics and the relationship between the components and the outcome variable. The strength of correlation was determined using the Adjusted Odds Ratio (AOR). Statistical significance was declared when the p-value was less than 0.05.

Operational definitions: Fulfilling patient's expectations throughout the preoperative informed consent process is a measure of patient satisfaction. A questionnaire containing ten statements and five-point Likert scale responses—five for entirely satisfied, four for satisfied, three for neutral, two for unhappy, and one for completely dissatisfied—was used to evaluate it. The percentage of patients who were deemed satisfied had a mean score of greater than three on the Likert scale questions [12–14].

Results

Socio-demographic traits: Participants in the current assessment include 202 individuals with a 95.5% response rate. Participants in the study were 40 years old on average, with a standard deviation of 12 years. The majority of patients (71.3%) reside in rural areas, and over half (62.4%) of those involved in the study only completed primary school.

Clinical traits and research participant's satisfaction: In this study, over half (58.4%) of the patients underwent spinal anaesthesia, and the majority (77.2%) had their first operation. Following a caesarean section, orthopaedic surgery was a routine surgical treatment. It was discovered that 70.3% of patients were generally satisfied with the preoperative informed consent procedure (Table 1).

Factors related to patients' overall satisfaction with the informed consent procedure before surgery:

Bivariate analysis revealed a statistically significant relationship between the preoperative informed consent procedure and the patients' the extent of education, if the procedure was performed according to the plan, whether it was their first time, and the type of anaesthesia used. To find independent predictors of patient satisfaction, variables with a p-value < 0.25 were selected for multivariable analysis. Consequently, there was a statistically significant correlation between patients' satisfaction with the informed consent procedure and their gender, level of primary and secondary education, rural domicile, and type of anaesthesia (GA) (Table 2).

Annex

Questionnaire

Objective: To evaluate elective surgical patients' satisfaction and related aspects using the preoperative informed consent process.

General details: I am ……, and I am here on behalf of the Department of ……at …… Hospital. The purpose of this survey is to gauge surgical patients' satisfaction with the preoperative informed consent procedure and related elements in ……. hospital in 2023. Therefore, the purpose of this study is to evaluate, from the viewpoint of the patients, their satisfaction with preoperative informed consent and related aspects during the informed consent procedure.

Therefore, your truthful answers to the following questions will be very helpful in improving the process of gaining preoperative informed consent, which will ultimately increase patient satisfaction with the surgical procedure. Your involvement is voluntary. We will only examine anonymised data, and participant confidentiality will be rigorously maintained. You will not suffer any negative effects or gain any advantages from taking part in this study. The maximum duration for this interview is twenty minutes. We greatly appreciate your genuine answers to the questions.

Are you willing to take part?

1. Proceed to the following page if the participant consents to participate.
2. Move on to the next participant if the first one declines to take part in the study.

Name of the data collector: _____Date: _____ Sig. _____

Name of the supervisor: _____Date: _____ Sig. _____

Questionnaire ID _____

Part I: Sociodemographic Features of Study Volunteers (please enclose the participant's preference).

Ser. No.	Question Categories	Response Categories	Remarks
1.	Gender	Male/Female	
2.	Age	…../…..	
3.	Marital Status	Married/Unmarried/Divorced/Widowed	
4.	Literacy Status	Both read & write/Read only/None	
5.	Formal Education	1º/2º/College level	
6.	Residence	Rural/Urban	
7.	Religion	Hindu/Orthodox/Muslim/Sikh/others	
8.	Occupation	Farmer/Teacher/Self-employed/others	
9.	Are you local resident or visitor?	Local/Visitor	
10.	Diagnosis	…….	
11.	Number of previous Surgeries	1/2/3/>3	
12.	Type of Surgery planned	Abdominal/Caesarean/Gynae. Surgery/Ortho/ENT/Neurosurgery/Others	
13.	Type of Anaesthesia	GA/SA	

Table 1: Socio demographic characteristics of elective surgical patients in the study period, 2021

Variables	Frequency (N=??)	Percent
1. Gender – Male/Female	80/122	39.6/60.4
2. Age (yr.)		
18-29	58	28.7
30-39	62	30.7
40-49	42	20.8
50+	40	19.8
3. Marital Status		
Married	180	89.1
Unmarried	10	5
Divorced	10	5
Widowed	2	1

4. Level of Literacy		
Can read and write	102	50.5
Can read only	12	5.9
Illiterate	88	43.6
5. Level of Education		
Primary School	126	62.4
Secondary School	50	24.8
Diploma	16	7.9
Degree & above	10	5.0
6. Residency		
Rural	144	71.3
Urban	58	28.7
7. **Religion**		
Hindu	174	96
Muslim	6	3
Orthodox	2	1
Sikh	-	
Other	-	
8. Occupation		
Farmer	128	63.4
Merchant	20	9.9
Teacher	10	5
Other	44	21.9
9. Residency		
Local	180	89.1
Visitor	22	10.9

Table 2: Factors associated with Informed Consent prior to Surgery

Variables	p-Value	AOR
1. Male Gender	0.02	4.75
2. Literacy level 1^{o}	0.00	8.42
3. Literacy level 2^{o}	0.00	2.17
4. Diploma level	0.51	0.65
5. Can read only	0.55	1.38
6. Can read and write	0.53	0.79
7. Rural Residence	0.00	1.8
8. Number of Surgery	0.16	1.57
9. Day of Surgery same as discussed	0.77	1.11
10. Risk explained (Y)	0.63	1.2
11. Alternatives explained (Y)	0.91	0.97
12. Age gp. (18-29)	0.05	0.43
13. Age gp. (30-39)	0.07	0.43
14. Age gp. (40-49)	0.03	0.39
15. Type of Anasthesia (GA)	0.00	2.92

Discussion

Depending on clinical circumstances, patients' satisfaction with the informed consent process for surgery and anaesthesia may differ. Since there are numerous variables that could affect patient satisfaction, achieving it may not be simple. While some aspects are organizational (such as the number of beds, staff performance, and the use of electronic medical records), others are patient-related (such as sociodemographic characteristics, health status, and the patient-physician interaction) [11]. Patients' expectations of healthcare services, which vary from culture to society based on social, cultural, economic, political, and religious aspects, may also have an impact on how satisfied patients are with the services they receive [16].

According to the results of the current study, 70.30 percent of patients were happy with the information they received and the choice they made throughout the informed consent process. This result appears to be in line with research from the various other countries at different times, which found that the respective rates were 80.8%, 80%, 62.1%, and 67.4% [8–10,15]. The current study's results, however, were much greater than those of the investigations carried out by F Jahan, Gillies MA and Hallock JL which showed 43%, 48.4%, and 45%, respectively [12,16,17]. This disparity could be explained by variations in the quality of health care services provided, the study population, and the study period.

Multivariable analysis in the present study revealed that patients' overall satisfaction with the informed consent procedure was statistically significantly correlated with male gender, elementary and secondary school education level, living in a rural area, age group (40–49 years), and type of anaesthesia. Kiryowa et al. reported a modest negative correlation between patients' years of education and satisfaction, with higher education levels being linked to lower levels of patient satisfaction [10]. This finding is partially consistent with a study by Ahmad et al. that found age to be a significant factor in determining the level of satisfaction. The reason might be because the medical staff had higher expectations for those patients. According to Rosique I., married patients and patient satisfaction have a high association [18].

Contrary to what we found, research by Goswami et al revealed that patients from urban areas were twice as likely to be happy with the informed consent procedure as those from rural areas [9]. This discrepancy may be caused by variations in the sociodemographic traits of the research participants, which impact the degree of comprehension of the provided data and the duration of the investigation.

Preoperative contentment with a decision to undergo surgery is linked to comprehension following an informed consent discussion, reflecting in general high satisfaction with the decision, according to an observational study conducted at John Hopkins University Medical School. Greater understanding of the intended procedure was substantially correlated with a patient's preoperative contentment with their choice. Age, race, education level, anxiety score, and health literacy did not significantly differ between the groups in this study that were satisfied and those that were not. The research study came to the conclusion that a patient's satisfaction with their choice to have surgery is significantly influenced by their knowledge and comprehension of the procedure. In order to more effectively handle preoperative expectations, boost patient satisfaction, and enhance the informed consent process, doctors may find it useful to gauge patients' comprehension following informed consent conversations [16].

Patients with children were the most satisfied group, according to a different study conducted in Saudi Arabia on patients to evaluate the relationship between satisfaction with treatment and the calibre of the informed consent procedure. With a mean score of 85.07, the age group between 56 and 65 was the most satisfied. According to the Pearson correlation coefficient, the degree of pleasure was strongly positively correlated with the disclosure and understanding score. Of the participants, half (50%) were not aware of alternative treatment choices. 79.6% of people who didn't comprehend the form didn't even read it. The other factors in the patient satisfaction questionnaire score, such as the patient's educational level, did not differ significantly [9].

Conclusion

The preoperative informed consent procedure was rated as satisfactory by almost two-thirds of the participants in this study. Patients' satisfaction with the informed consent procedure was substantially correlated with their gender, level of education, rural residence, and use of general anaesthetic. To uphold the ethical standard of the informed consent process, we advise medical professionals to increase patient safety procedures and apply the standard guidelines governing the informed consent process. Maintaining better patient care and safety would also require regular evaluation of patient satisfaction and related variables.

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