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Informed Consent and Perceptions in Surgical Patients: A Hospital Based Survey

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ABSTRACT

Patient autonomy, known as the right to make healthcare decisions without pressure and informed consent, a comprehensive process of providing information, are vital in the doctor-patient relationship. However, there is a lack of research on informed consent in India. Therefore, this study aimed to assess patients' awareness and understanding of informed consent and analyze their perspectives in a tertiary care hospital in Central India. A cross-sectional survey was conducted at a tertiary care teaching hospital in Central India. The survey targeted patients who had undergone elective or emergency surgery in various surgical departments. Approximately 380 post-operative patients were randomly selected for interviews, utilizing a pre-structured questionnaire. Prior approval was obtained from the Institutional Ethics Committee to conduct the survey. About 62% of patients personally provided their responses. A significant proportion of patients had limited awareness regarding their proposed procedure, with only 69.81% being informed about it. Furthermore, a relatively smaller percentage (33.80%) of patients were acquainted with alternative treatment options. Regarding anesthesia, approximately half of the patients (45.71%) were informed about the type used, while a mere 13.57% received information about the associated complications. Notably, in 5% of cases, patients believed that informed consent was not obtained, despite the existence of documented records suggesting otherwise. In clinical practice, informed consent holds a crucial role in protecting the rights of patients and reducing the potential for legal action against healthcare providers in case of complications arising from treatment. It is essential to raise awareness among doctors and healthcare providers about the significance of obtaining informed consent.

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Key Words
Obesity, body mass index, diabetes mellitus, waist circumference, hypertension

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INTRODUCTION

The right of a patient to make independent decisions about their treatment, free from coercion by healthcare providers, is referred to as autonomy. Informed consent goes beyond a mere signature on a document and involves the entire process of providing patients with information about their medical condition, diagnostic choices and details about intervention methods available for their condition. Patients are also informed about the associated risks and any alternative treatment options that may be available[1,2].

Informed consent is not only a patient's right but also a crucial element in establishing trust and maintaining a strong doctor-patient relationship. To ensure effective communication, it is essential that the consent process uses clear and understandable language that is accessible to patients with varying levels of medical knowledge. It is equally important to ensure that patients fully comprehend the information provided and that the entire process is appropriately documented, ensuring transparency and accountability[3,4].

It is crucial to provide patients with a comprehensive understanding of the advantages and disadvantages of a particular medical procedure, enabling them to make voluntary and informed decisions regarding their treatment options[5,6]. The process of obtaining informed consent varies across countries and medical specialties. While performing surgery may be routine for a surgeon, it is not the same for a patient[7]. Surgical procedures entail greater risks, making the decision-making process for patients more stressful and complex[8]. Therefore, it is essential to ensure that patients receive clear and thorough information to navigate this process effectively.

Therefore, it is of utmost importance for both the surgeon and the patient to have interactive and comprehensive discussions during the process of obtaining consent for a surgical procedure. This allows for the thorough understanding and absorption of all the details and risks involved[9,10]. Patients should have the opportunity to have their questions addressed and engage in discussions to ensure clarity. Informed consent should be viewed as an ongoing and continuous process rather than a one-time encounter[11].

In India, there is a limited number of studies conducted on the topic of informed consent. Taking this into consideration, the present study was conducted at a tertiary care hospital located in Central India. The aims and objectives of the study were twofold. Firstly, the study aimed to assess the levels of awareness and understanding among patients regarding the contents of informed consent. This involved evaluating the extent to which patients were knowledgeable about the information provided to them regarding their medical procedures, potential risks and alternative treatment options. Secondly, the study aimed to analyze the perspectives of patients regarding the process of informed consent in a tertiary care hospital setting. This involved exploring the patients' experiences, perceptions and satisfaction with the informed consent process, with the goal of gaining insights into areas of improvement and enhancing patient-centered care.

MATERIALS AND METHODS

To gather data for the study, a cross-sectional survey was conducted among patients who had undergone either elective or emergency surgery in various surgical departments at a tertiary care teaching hospital located in Central India. The surgical departments included general surgery, obstetrics and gynecology, orthopedics, otolaryngology, ophthalmology, urology and plastic surgery. The survey aimed to capture a comprehensive view of patients across different surgical specialties, allowing for a broader understanding of the informed consent process and its implications in the context of diverse surgical procedures and patient populations.Prior approval was obtained from the Institutional Ethics Committee to conduct the survey and study was conducted according to standard ethical guidelines[12,13].

A total of approximately 380 patients who had undergone surgery were selected randomly for this study. Prior approval was obtained from the Institutional Ethics Committee to conduct the research. Trained data collectors conducted interviews with the patients, using a pre-structured questionnaire, in the local language. The purpose and nature of the study were explained to the patients and those who voluntarily agreed to participate were included in the study. In cases involving minors, information was obtained from either the patient or their attendant, after obtaining their consent. The questionnaire encompassed various aspects related to the awareness and understanding of the consent form and its contents. The collected data were entered into Microsoft Excel and subsequent analysis was performed using Epi Info software.

Patients who declined to participate in the study were excluded from the research sample. Additionally, patients who were experiencing discomfort or were unwell due to factors such as pain, nasogastric tube placement, or any other immediate post-operative complications were not interviewed as part of the study. This ensured that only patients who were in a suitable condition and willing to provide accurate responses were included in the data collection process.

RESULTS

A total of 380 postoperative patients were included in the study, with 62% of them providing their own responses. The majority of informed consents (70.64%) were obtained by postgraduate students, followed by junior residents (15.79%) and a smaller proportion (11.63%) were taken by the surgeon/consultant themselves. Consents were not taken in 19 cases, representing an 5% non-compliance rate. For more detailed information, please refer to Tables 1-5.

DISCUSSIONS

The participants in our study encompassed a wide age range, with both sexes almost equally represented. However, it is important to note that approximately 39% of the participants were classified as illiterate. In a study conducted by Ochieng *et al*.[8], the enrolled patients ranged in age from 18-80 years, with an equal male-female ratio but a higher literacy rate of 94%[8]. Similarly, Falagas *et al*.[3] reported that their study participants fell within the age range of 18-55 years[3], with 56% in that range and 43% being older. In a study by Bullappa *et al*.[14], 45.5% of the patients belonged to the age range of 20-40 years, which closely aligns with the 50% proportion observed in our study within the same age group[14]. Physicians have a legal and ethical obligation to obtain informed consent from their patients prior to initiating any treatment, including surgical procedures. In our study, approximately 62% of patients provided consent for surgery on their own, while around 40% had consent given by their relatives. A study by Ochieng *et al*.[8] reported a higher percentage of patients (81%) giving consent themselves. In contrast, our study found that 5% of patients perceived not having given consent, while a study conducted by Bhugri et al. reported a higher proportion of 20% in the same context[1]. Almost all of the patients in our study were informed about their existing surgical condition. However, a slightly lower percentage, 94.46%, of patients were informed about the specific indication for the surgery. In comparison, Ochieng *et al*.[8] reported a higher percentage of 80% of patients being explained about the indication of surgery in their study. In our study, a total of 252 patients (69.81%) were aware of the proposed surgical procedure, while 122 patients (33.80%) were informed about alternative treatment options. It is worth noting that a majority of patients were provided information about the alternate treatment options. In a study conducted by Ochieng *et al*.[8], a proportion of 17% of patients did not give consent for surgery and a similar proportion was unaware of the type of surgery they had undergone[8]. In cases where patients perceived

Table 1: Socio-demographic profile of the study participants

	No.	Percentage
Age (years)		
<20	39	10.26
21-40	195	51.32
41-60	86	22.63
>60	60	15.79
Gender		
Male	189	49.74
Female	191	50.26
Education		
Illiterate	148	38.95
Primary school	80	21.05
Middle school	55	14.47
Matriculation	69	18.16
Diploma	9	2.37
Graduate	14	3.68
Postgraduate	5	1.32
Occupation		
Unskilled	105	27.63
Semiskilled	26	6.84
Skilled	29	7.63
Clerical job/shop keeping	26	6.84
Farming	14	3.68
Housewife	125	32.89
Student (study)	19	5.00
Professional	6	1.58
Unemployed	30	7.89
Family income (per month)		
<Rs. 1600	54	14.21
Rs. 1601-4809	169	44.47
Rs. 4810-8009	98	25.79
Rs. 8010-12,019	33	8.68
Rs. 12,020-16,019	15	3.95
Rs. 16,020-32,049	6	1.58
>Rs. 32,050	5	1.32

Table 2: Mode of admission and type of surgery

	No.	Percentage
Mode of admission		
Emergency	170	44.74
As outpatient	210	55.26
Type of surgery		
General surgery	78	20.53
Orthopedics	116	30.53
Obstetrics/gynecology	94	24.74
Ophthalmology	23	6.05
Otolaryngology	40	10.53
Urology	19	5.00
Plastic surgery	10	2.63
Nature of surgery		
Elective/planned	332	87.37
Emergency	48	12.63

Table 3: Awareness regarding informed consent among patients

	No.	Percentage
Was informed consent taken?		
Yes	359	94.47
No	21	5.53
Form of informed consent		
Verbal	11	3.05
Written	350	96.95
Informed consent was given by		
Patient	121	33.52
Spouse	130	36.01
Sibling	74	20.50
Friends	5	1.39
Parents	31	8.59
Was consent given voluntarily?		
Yes	352	97.51
No	9	2.49
Information about consent was given by		
Junior resident	57	15.79
Paramedical staff	2	0.55
Postgraduate student	255	70.64
Intern	0	0.00
Nurse	5	1.39
Surgeon	42	11.63

Table 4: Awareness regarding informed consent among patients

	Yes		No	
	No.	Percentage	No.	Percentage
Informed consent was explained in local language	349	96.68	12	3.32
Patient understood of information	301	83.38	60	16.62
Patient had information about surgical condition	355	98.34	6	1.66
Patient had information about indication of surgery	341	94.46	20	5.54
Patient had information about proposed surgical procedure	252	69.81	109	30.19
Patient had information about alternative options	122	33.80	239	66.20
Patient was explanation about alternative treatments	107	91.45	10	8.55
Patient was informed about benefits and outcome of surgery	292	80.89	69	19.11
Patient was informed about the possible complications of surgery	198	54.85	163	45.15
Patient was informed about type of anesthesia	165	45.71	196	54.29
Patient was informed about possible anesthetic complications	49	13.57	312	86.43
Patient was informed about possible drug allergy	120	33.24	241	66.76
Patient was informed about probable duration of hospital stay	232	64.27	129	35.73
Patient was satisfied with the information provided	320	88.64	41	11.36

Table 5: Perceptions regarding Informed consent among patients

	Yes		No	
	No.	Percentage	No.	Percentage
Informed consent was explained in local language	351	97.23	10	2.77
Patient understood of information	299	82.83	62	17.17
Patient had information about proposed surgical procedure	251	69.53	110	30.47
Patient had information about alternative options	120	33.24	241	66.76

that no informed consent was taken, it was found that the medical files actually had a record of consent, indicating that patients might have given consent but either did not recall or it did not register with them during our study. Furthermore, approximately half of the patients received information about the type of anesthesia, while only 49 patients (13.57%) were informed about the potential complications associated with it. Contrary to the findings of Ochieng *et al*.[8], where 98% of patients felt that all aspects of treatment should have been explained to them before surgery, a significant proportion of patients (46%) in our study reported that no issues were discussed with them regarding their situation[8]. The majority of patients in our study expressed satisfaction with the process of informed consent, which is consistent with the findings of Ochieng *et al*.[8] (80%) and a study conducted in Greece by Falagas et al. These studies also reported a high degree of satisfaction with the process of informed consent[8,4]. In our study, the levels of awareness among patients were found to be satisfactory regarding their existing surgical condition, the indication for the surgery, the proposed surgical procedure and its associated benefits. However, it is noteworthy that despite giving their consent, some patients remained unaware of these important factors. This finding aligns with the study conducted by Purcaru *et al*.[11], which reported that a significant proportion of participants (35.3%) do not ask questions and patients from lower socioeconomic backgrounds often provide consent without seeking further details[11]. The overall findings of the study indicate a concerning lack of explanation and understanding regarding alternate treatment options, details of the proposed surgical procedure and the potential complications associated with it. Additionally, patients or the individuals giving consent are not adequately informed about the type of anesthesia being used, its potential complications and the possibility of unpredictable drug allergies. These gaps in the informed consent process highlight the need for improved communication and comprehensive information sharing between healthcare providers and patients or their representatives. The present study has several limitations that should be taken into consideration when interpreting the findings. Firstly, the study was conducted in a single tertiary care hospital, which may limit the generalizability of the results to other healthcare settings, particularly those with limited resources and different workforce capabilities. The findings may not be representative of hospitals with different patient populations and varying levels of infrastructure and staffing. Furthermore, the study relied on self-reported data from patients, which may be subject to recall bias or social desirability bias. The sample size of the study was also relatively small, which may limit the statistical power and precision of the results. Despite these limitations, the study provides valuable insights into the informed consent process in the specific hospital setting and underscores the importance of further research in diverse healthcare contexts. Based on the findings of this study, several recommendations can be made to improve the informed consent process and ensure the protection of patients' rights. Firstly, healthcare providers should make a concerted effort to inform patients about the type of anesthesia being used, its potential complications and any unpredictable drug allergies that may arise. This information is crucial for patients to make informed decisions and actively

participate in their own healthcare. Additionally, healthcare providers should discuss available alternate treatment options with patients, providing them with a comprehensive understanding of the various approaches to managing their condition. It is also worth considering the use of video recordings during the informed consent process, as this can serve as a valuable documentation tool and potentially reduce the likelihood of legal disputes arising from complications. By implementing these recommendations, healthcare providers can enhance the quality and transparency of the informed consent process, promoting patient autonomy and trust in the healthcare system.

CONCLUSION

The concept of informed consent holds a crucial role in clinical practice as it serves as a protective measure for patients' rights and reduces the likelihood of legal repercussions for healthcare providers in the event of therapy-related complications. However, the current study reveals that the quality of the existing informed consent process is suboptimal, highlighting the need for improvements. It is imperative to enhance the understanding and knowledge of both patients and physicians regarding the significance and implementation of informed consent. This necessitates educational initiatives aimed at alerting and sensitizing healthcare providers about the importance of conducting thorough and comprehensive informed consent discussions. By addressing these concerns and raising awareness, the overall quality of the informed consent process can be strengthened, fostering a better patient-provider relationship and upholding patients' rights in clinical settings.

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