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Original Research Article

Patient Perspectives on Informed Consent for Medical and Surgical Procedures: A Cross-Sectional Study from an Indian Tertiary Care Hospital

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Abstract:

Background and Objectives: In the realm of medical practice, informed consent goes beyond a mere signature on a document; it encapsulates the comprehensive process wherein patients are equipped with knowledge pertaining to their illness, diagnostic alternatives, and specifics regarding intervention strategies for their particular condition. In the Indian context, there is a scarcity of studies delving into the landscape of informed consent. Against this backdrop, the present study was done to assess the levels of awareness and comprehension regarding the contents of informed consent and to scrutinize the patient's viewpoint concerning the informed consent process within the setting of an Indian tertiary care hospital.

Methodology: Employing a cross-sectional survey design, the study targeted patients who had undergone medical or surgical procedures. The patients were randomly selected for participation. Utilizing a pre-structured questionnaire, interviews were conducted with the patients, with 60.5% responding personally.

Results: Among the 345 patients surveyed, 69.29% were acquainted with the proposed procedure, while only 33.15% received information about alternative treatments. Approximately 46.19% were informed about the procedure or type of anesthesia, and merely 13.48% were apprised of its potential complications. Intriguingly, in 8% of cases, patients perceived a lack of informed consent despite documentary evidence suggesting otherwise.

Conclusion: In clinical practice, informed consent assumes an indisputable role as a protector of patient rights and serves to mitigate the likelihood of legal repercussions for treating physicians in case of complications arising from the prescribed therapy. This study underscores the critical necessity to sensitize healthcare practitioners about the nuances of informed consent.

Keywords: Informed Consent, Medical Procedures, Medical Ethics, Patients perception.

Introduction

A patient's autonomy, defined as the right to make treatment decisions free from external pressures, is a crucial aspect of medical ethics. In the context of healthcare, informed consent goes beyond a mere signature on paper; it encapsulates a comprehensive process wherein the patient is provided with knowledge pertaining to their illness, diagnostic alternatives, and details concerning intervention approaches for their condition. This includes an explicit disclosure of associated risks and exploration of alternative treatment options [1,2].

Given that informed consent is fundamental to the trust and rapport between a doctor and a patient, it is essential for the consent process to be articulated in clear, layman's terms and fully comprehended by the patient, with appropriate documentation. The communication of details such as the advantages and disadvantages of a specific medical procedure should enable patients to make voluntary decisions [3-6].

The execution of informed consent varies across countries and medical specialties. While a medical or surgical procedure may be routine for a doctor, it holds a different significance for the patient. Consequently, in cases involving procedure or surgery, where the associated risks elevate the stress and complexity of the decision-making

process for patients, obtaining consent becomes a critical interaction between the surgeon and the patient [7,8]. It is imperative that both parties engage in comprehensive discussions, ensuring that the patient fully understands all pertinent details and associated risks. Rather than a one-time event, informed consent for procedures should be viewed as an ongoing process, allowing patients to have their questions addressed and engage in meaningful discussions [9-11].

In the Indian context, there is a scarcity of studies focusing on informed consent. Against this backdrop, the present study was conducted to assess the levels of awareness and comprehension regarding the contents of informed consent and to scrutinize the patient's viewpoint concerning the informed consent process within the setting of an Indian tertiary care hospital. [12,13].

Material and Methods

A cross-sectional survey was conducted among individuals who had undergone medical or emergency surgical procedures in various departments at a tertiary care teaching hospital in India. Approximately 345 randomly selected post-operative and post-procedural patients were interviewed using a pre-structured questionnaire.

Patients were provided with a clear explanation of the study's purpose and nature, and only those who willingly agreed participated. In the case of minors, information was obtained from the patient or the consenting attendant. The questionnaire focused on aspects related to awareness and comprehension of the consent form and its contents. Collected data were entered into MS Excel 2007, and analysis was performed using Epi Info 6.

Individuals declining to participate or those who were unwell or uncomfortable due to factors such as pain, nasogastric tube, or immediate post-operative complications were excluded from the study.

Results

For this investigation, 345 individuals who had undergone postoperative or post-procedural interventions were chosen through a random selection process. The gender distribution among these participants adhered to a ratio of 0.99 males to every female. The patients themselves actively participated in majority of the instances by providing their responses. Notably, a majority of consents were obtained by postgraduate students, followed by junior residents, and least frequently by the surgeon or consultant personally. It is noteworthy that in 8.12% of cases, consent was not obtained, as indicated in [Tables 1-4 and Figure 1].

Table 1: Socio-demographic Characteristics of Study Participants

Variable	n	%
Age group		
<20 years	37	10.72
21–40 years	173	50.14
41–60 years	78	22.61
>60 years	57	16.52
Gender	0	0.00
Males	172	49.86
Females	173	50.14
Education		
Illiterate	130	37.68
Primary school	71	20.58
Secondary school	49	14.20
Matriculation	66	19.13
Diploma	9	2.61
Graduate	14	4.06
Professional degree	6	1.74
Occupation		
Not employed	29	8.41
Unskilled labourer	94	27.25
Semiskilled worker	24	6.96
Skilled worker	26	7.54
Clerical work/shop work	24	6.96
Agriculture	13	3.77
Domestic/Housewife	109	31.59
Student/Study	18	5.22
Professional	8	2.32

Family Income per month		
<1600 rupees	49	14.20
1601–4809 rupees	149	43.19
4810–8009 rupees	89	25.80
8010–12,019 rupees	28	8.12
12,020–16,019 rupees	16	4.64
16,020–32,049 rupees	8	2.32
>32,050 rupees	6	1.74

Table 2: Awareness regarding Informed consent procedure

Parameters	**n**	**%**
Was informed consent taken		
Yes	317	91.88
No	28	8.12
Was consent given voluntarily?		
Yes	325	94.20
No	20	5.80
Type of consent		
Verbal	21	6.09
Written	324	93.91
Consent was given by		
Patient	113	32.75
Spouse	121	35.07
Sibling	68	19.71
Friends	9	2.61
Parents	34	9.86
Information about consent was given by		
Postgraduate student	232	67.25
Junior Resident	53	15.36
Senior Resident	8	2.32
Intern	5	1.45
Paramedical staff	7	2.03
Physcisan/Surgeon	40	11.59

Table 3: Elements of informed consent procedure

Parameter	**Yes**		**No**	
	n	**%**	**n**	**%**
Explanation given in native language for informed consent	332	96.23	13	3.77
Comprehension of details	289	83.77	56	16.23
Details regarding the medical/surgical condition	337	97.68	8	2.32
Details about the indication for procedure/surgery	325	94.20	20	5.80
Details about the proposed medical/surgical procedure	239	69.28	106	30.72
Information regarding alternative choices	114	33.04	231	66.96
Clarification of alternative treatment	308	89.28	37	10.72
Awareness of the advantages and outcomes of the procedure/surgery	278	80.58	67	19.42
Awareness of potential procedure/surgery complications	189	54.78	156	45.22
Knowledge of the type of anesthesia	159	46.09	186	53.91
Awareness of potential anesthesia complications	48	13.91	297	86.09
Information about any potential drug allergies	115	33.33	230	66.67
Details about the expected duration of hospital stay	218	63.19	127	36.81
Satisfaction with information provided by the medical staff	303	87.83	42	12.17

Table 4: Patients' perception on the process of informed consent

Parameter	Yes		No		p value
	n	%	n	%	
Explanation given in native language for informed consent	332	96.23	13	3.77	0.022
Comprehension of details	289	83.77	56	16.23	0.035
Details about the proposed medical/surgical procedure	239	69.28	106	30.72	0.042
Information regarding alternative choices	114	33.04	231	66.96	0.041
Awareness of the advantages and outcomes of the procedure/surgery	278	80.58	67	19.42	0.045

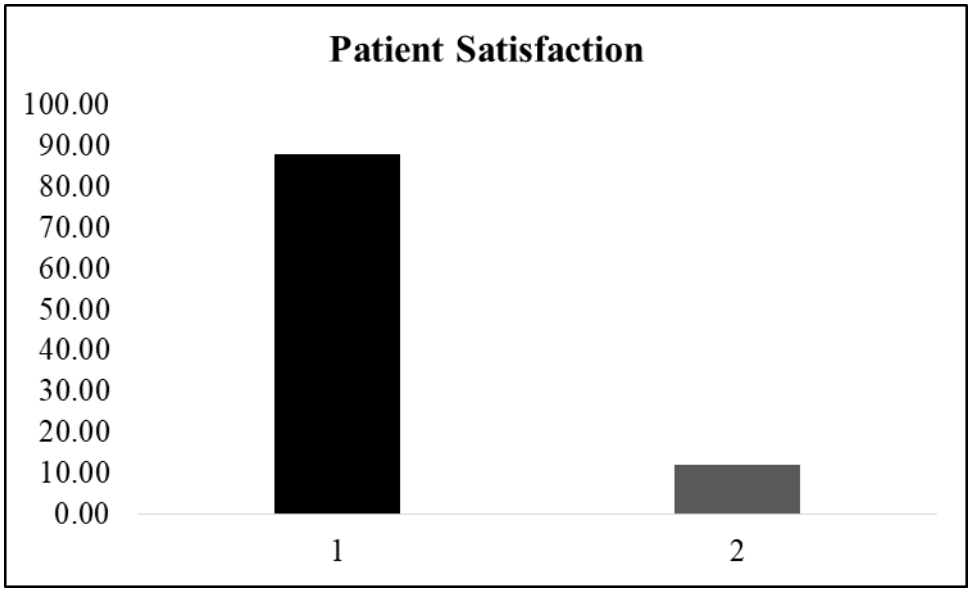

Figure 1: Proportion of patients satisfied with the information provided on informed consent before the procedure/surgery (1=Satisfied, 2=No)

Discussion

In the current investigation, the study cohort exhibited a diverse age distribution, with near-balanced representation from both genders, although approximately 38% of the participants were characterized as illiterate. In a study by Ochieng et al., participants ranged in age from 18 to 80 years, with an equal male-female ratio but a notably higher literacy rate at 94% [7]. Contrarily, Falagas et al. reported patients falling within the age range of 18–55 years (56%), with 43% surpassing this age bracket [4]. Simha et al. observed that 45.5% of their participants were aged between 20 and 40 years, a trend mirrored by our study with a comparable proportion of 50% in that age group [13].

The legal and ethical obligations placed on physicians necessitate obtaining informed consent from patients before commencing any treatment or surgical intervention. In our study, 60% of patients independently provided consent for surgery, while approximately 40% had consent facilitated by their relatives. This differs from Ochieng et al., where 81% of patients autonomously gave consent [7]. Notably, Bhurgri et al. reported a stark contrast with only 8% obtaining self-consent in our study and 20% in their study [1].

In our investigation, 97.68% of patients were informed about their prevailing surgical condition, while 94.20% were apprised of the surgery's indication; a rate comparable to 80% reported by Ochieng et al. [7]. However, only 69.28% were aware of the proposed procedure, and 33.04% were informed about alternative treatments. Ochieng et al. found that 98% of their patients were explained all aspects of treatment, but paradoxically, 46% reported the absence of discussions about their situation [7].

Notably, 46.09% of patients in our study received information about the type of anesthesia, and merely 13.91% were informed about its complications. This contrasts with Ochieng et al., where 98% of patients believed all treatment aspects should be explained, yet 46% reported the absence of discussions about their situation [7].

Satisfaction with the informed consent process was high in our study (87.83%), akin to Ochieng et al. (80%) and a study in Greece by Falagas et al. [7,4]. However, despite satisfactory consent processes, a

considerable portion of participants demonstrated a lack of awareness regarding existing surgical conditions, indications, proposed procedures, and benefits. Purcaru et al. noted that 35.3% of participants did not pose questions, especially those from economically disadvantaged backgrounds who often consented without seeking detailed information [12]. Overall, the findings reveal shortcomings in explaining alternate treatment options, procedural details, potential complications, and details of anesthesia, signaling the need for improved communication in the informed consent process.

Conclusion

In clinical practice, the significance of informed consent is unequivocal, serving as a paramount protector of patients' rights. Additionally, it serves to mitigate the potential legal repercussions faced by the treating physician in the event of complications arising from the proposed therapeutic intervention. However, an evaluation of the current study reveals suboptimal standards in the existing informed consent process, highlighting the imperative to enhance it. This improvement necessitates comprehensive education for both patients and physicians. It is imperative to underscore the urgency of alerting healthcare providers and physicians to address this deficiency.

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