Section: Community Medicine

Original Research Article

KNOWLEDGE, AWARENESS AND PERCEPTION OF THE PRE-OPERATIVE INFORMED CONSENT PROCESS AMONG SURGICAL PATIENTS IN A TERTIARY CARE TEACHING HOSPITAL: A CROSS-SECTIONAL STUDY

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Received *: 12/01/2026*
Received in revised form *: 22/02/2026*
Accepted *: 10/03/2026*

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DOI: 10.70034/ijmedph.2026.1.594

Source of Support: Nil,
Conflict of Interest: None declared

Int J Med Pub Health
2026; 16 (1); 3470-3475

ABSTRACT

Background: Patients often have limited understanding of the informed consent process and the information provided before surgery. The present study aimed to assess the knowledge, awareness and perception of pre-operative informed consent process among surgical patients and study association between socio-demographic characteristics and their level of knowledge and awareness in a tertiary-care hospital.

Materials and Methods: This cross-sectional study was conducted among 100 adult surgical patients admitted to a tertiary-care teaching hospital in Indore, over six months. Data was collected using a pre-validated semi-structured questionnaire A composite scoring system was used to categorize participants into adequate and inadequate knowledge/awareness groups. Descriptive statistics were used to summarize the data, and the association between socio-demographic variables and knowledge/awareness was analysed using the Chi-square test.

Results: Mean age of participants was 41.6±3.8 years, and 65% were male. Overall, 64% of patients demonstrated adequate knowledge/awareness of informed consent process. Most patients reported receiving information regarding their medical condition (79%), details of surgery (67%), and surgical complications (69%). Only 58% were informed about anaesthesia and 35% about anaesthesia-related complications. 74% patients reported that information provided was useful and 72% expressed satisfaction with the consent process. Educational status was significantly associated with knowledge/awareness (p=0.003).

Conclusion: Although most surgical patients received basic information regarding their procedure, gaps remain in awareness of the informed consent process, particularly regarding anaesthesia-related risks and understanding of the consent form. Strengthening patient-centred communication strategies and improving health literacy may enhance effectiveness of the informed consent process.

Keywords: Informed consent, surgical patients, knowledge, health literacy, awareness

INTRODUCTION

Informed consent is a crucial ethical and legal prerequisite for any surgical intervention, to protect patient autonomy and safety.[1] It refers to a patient's voluntary agreement to a proposed treatment or procedure after adequate explanation by the healthcare provider.[1] Valid consent must be free from coercion, fraud, misrepresentation, or undue influence and must be based on an informed and rational understanding of the procedure.[2,3] It is not merely a signed document but a communication process in which clinicians explain the diagnosis, nature of the procedure, expected benefits, potential risks or complications, and available alternatives in a manner understandable to the patient.[1,4,5] Patients should also be informed of their right to refuse or withdraw consent, and the process must be properly documented to meet medicolegal requirements.[1] National and international guidelines reinforce these standards, and regulatory bodies in India emphasize patients' rights to full information and informed consent in clinical care.[6,7]

Studies have shown that patients often fail to fully understand the information conveyed during the pre-operative consent process, resulting in patients agreeing to procedures with limited comprehension.[8–10] Surgeons may also underestimate patients' desire for detailed information regarding surgical risks, complications, and long-term outcomes.[11,12] This is evident in developing country healthcare systems, where patient awareness of medical rights is often limited and health literacy levels may be low.[7] Cultural norms, language barriers, and traditionally paternalistic doctor–patient relationships may further limit patient engagement in decision-making.[8] Research from Indian medical institutions similarly indicates that many surgical patients have limited understanding of consent information and are often unaware of their rights, including the ability to reconsider their decision after signing the consent form.[7,13] Additionally, important aspects of surgical care, such as anaesthesia-related risks, are not always adequately communicated during consent discussions.[1] As a result, patients may provide consent without a complete understanding of the procedures they are undergoing.[1]

Inadequate informed consent may result in unrealistic patient expectations, reduced satisfaction with care, and diminished trust in the healthcare system, and may also lead to ethical concerns and medicolegal disputes if risks or alternatives are not adequately explained.[1] Recognizing these issues, healthcare authorities, including the World Health Organization, emphasize verification of informed consent as an essential component of surgical safety.[7] Experts also recommend patient-centred strategies such as simplified communication, translated consent forms, and audiovisual aids to improve patient understanding and participation in decision-making.[8] However, current consent practices are often considered insufficient to support informed decision-making.[13] Therefore, the present study was undertaken to assess the knowledge, awareness, and perception of the pre-operative informed consent process among surgical patients and to examine the association between socio-demographic characteristics and patients' level of knowledge and awareness in a tertiary care teaching hospital.

MATERIALS AND METHODS

This hospital-based cross-sectional study was conducted at a tertiary care teaching hospital in Indore, Madhya Pradesh, over a period of six months after approval from the Institutional Ethics Committee. The study population comprised 100 adult patients admitted to surgical wards who had undergone surgical procedures requiring pre-operative informed consent. Patients aged ≥18 years who were clinically stable and able to communicate were included, while critically ill patients, individuals with cognitive impairment or psychiatric illness affecting decision-making capacity, and those unwilling to participate were excluded.

Data was collected using a pre-designed semi-structured questionnaire developed after reviewing relevant literature. The instrument consisted of two sections: socio-demographic characteristics and items assessing knowledge, awareness, and perception regarding the informed consent process. The questionnaire was validated for content and clarity by three subject experts from Community Medicine and Surgery, and necessary modifications were made. It was pilot tested among ten surgical patients not included in the final analysis to ensure comprehensibility. Internal consistency of the questionnaire was assessed using Cronbach's alpha. For objective assessment, a composite scoring system was used in which correct or affirmative responses to key domains of informed consent were assigned one point each, generating a maximum score of eight; participants scoring ≥50% were categorized as having adequate knowledge/awareness, while those scoring <50% were categorized as having inadequate knowledge/awareness. Operationally, knowledge referred to understanding of the purpose and components of informed consent, awareness indicated familiarity with the existence and requirement of consent prior to surgery, and perception reflected patients' views regarding adequacy and usefulness of information provided during the consent process.

Eligible participants were approached during their hospital stay, and after explaining the purpose of the study, written informed consent was obtained prior to data collection. Interviews were conducted face-to-face by trained investigators in Hindi to ensure accurate comprehension and completeness of

responses. Data was entered into Microsoft Excel and analysed using SPSS v.20 (trial). Descriptive statistics were used to summarize variables, with categorical variables expressed as frequencies and percentages and continuous variables as mean and standard deviation. Associations between socio-demographic variables and knowledge and awareness of informed consent were examined using the Chi-square test. p-value <0.05 considered statistically significant.

RESULTS

A total of 100 surgical patients were included in the study. The mean age of participants was 41.6± 3.8 years, with the largest proportion belonging to the 40–49 years age group (26%). The study population consisted predominantly of males (65%). Most participants had at least secondary level education, with 32% having completed secondary education and 38% being graduates or postgraduates. 23% were unemployed, 17% unskilled workers, and 42% belonging to skilled or professional occupations. 75% were admitted under General Surgery, followed by Orthopaedics (25%) [Table 1]. 64% of participants demonstrated adequate knowledge and awareness regarding the informed consent process. 42% were aware of the existence of a consent form prior to signing and 54% reported reading the consent form before signing it. A majority of participants stated that they were informed about their medical condition (79%), details of surgery (67%), and surgical complications (69%). However, information related to anaesthesia and anaesthesia-related complications was reported less frequently. 75% of patients reported being informed about alternative treatment options, and 68% stated that they were given an opportunity to ask questions during the consent process [Table 2]. The consent form was most commonly explained by a consultant surgeon or duty doctor (36% each), while 28% of patients reported that the explanation was provided by paramedical staff. In 58% of cases, the consent form was signed by the patient, whereas in 42% it was signed by a relative. Consent was most frequently obtained one day prior to surgery (40%). 51% participants reported spending 15–30 minutes reading the consent form [Table 3]. With respect to patient perception, a majority of participants reported positive experiences with the consent process. 74% stated that the information provided was useful, and 72% expressed overall satisfaction with the consent process. Importantly, 90% of patients reported that they were not pressured to sign the consent form [Table 4]. Analysis of the association showed that education was significantly associated with knowledge/awareness of the informed consent process (p=0.003). Participants with graduate or postgraduate education demonstrated substantially higher levels of adequate knowledge (94.7%) compared to those with illiterate or primary education (26.7%). In contrast, no statistically significant association was observed between knowledge/awareness and gender (p=0.42) or occupation (p=0.08) [Table 5].

Table 1: Socio-demographic characteristics of study participants (n=100)

Variable	Frequency (n)	Percentage (%)
Age group (years)		
18–29	18	18
30–39	22	22
40–49	26	26
50–59	20	20
≥60	14	14
Gender		
Male	65	65
Female	35	35
Education		
Illiterate	14	14
Primary	16	16
Secondary	32	32
Graduate	24	24
Postgraduate	14	14
Occupation		
Unemployed	23	23
Unskilled worker	17	17
Semi-skilled	18	18
Skilled	20	20
Professional	22	22
Department of surgery		
General Surgery	75	75
Orthopaedics	25	25

Table 2: Awareness of the pre-operative informed consent process (n=100)

Variable	Yes n (%)	No n (%)
Awareness of existence of consent form	42 (42%)	58 (58%)
Read the consent form before signing	54 (54%)	46 (46%)
Informed about medical condition	79 (79%)	21 (21%)
Informed about details of surgery	67 (67%)	33 (33%)
Informed about surgical complications	69 (69%)	31 (31%)
Informed about anaesthesia	58 (58%)	42 (42%)
Informed about anaesthesia complications	35 (35%)	65 (65%)
Informed about alternative treatment options	75 (75%)	25 (25%)
Opportunity given to ask questions	68 (68%)	32 (32%)

Table 3: Characteristics of the informed consent process (n=100)

Variable	Frequency (n)	Percentage (%)
Person who explained the consent form		
Consultant surgeon	36	36
Duty doctor	36	36
Paramedical staff	28	28
Person who signed the consent		
Patient	58	58
Relative	42	42
Timing of consent		
At admission	27	27
Day before surgery	40	40
Morning of surgery	29	29
Inside operation theatre	4	4
Time taken to read consent form		
5–15 minutes	28	28
15–30 minutes	51	51
>30 minutes	21	21

Table 4: Patient perception regarding the informed consent process (n=100)

Variable	Yes n (%)	No n (%)
Information provided was useful	74 (74%)	26 (26%)
Satisfied with consent process	72 (72%)	28 (28%)
Felt pressured to sign consent	10 (10%)	90 (90%)

Table 5: Association between socio-demographic factors and knowledge/awareness of informed consent (n=100)

Variable	Adequate Knowledge n (%)	Inadequate Knowledge n (%)	p-value
Gender			
Male	44 (67.7%)	21 (32.3%)	0.42
Female	20 (57.1%)	15 (42.9%)	
Education			
Illiterate / Primary	8 (26.7%)	22 (73.3%)	0.003
Secondary	20 (62.5%)	12 (37.5%)	
Graduate / Postgraduate	36 (94.7%)	2 (5.3%)	
Occupation			
Unemployed / Unskilled	16 (40%)	24 (60%)	0.08
Skilled / Professional	48 (80%)	12 (20%)	

DISCUSSION

Informed consent is a continuous process of communication between the clinician and the patient, and it extends beyond simply obtaining a signature on a consent form. It is based on key ethical principles such as patient autonomy, shared decision-making, and the transparent disclosure of potential risks and benefits.[1–5,7–10,14]

The demographic profile of our participants, with a mean age of 41.6±3.8 years, aligns closely with Hassan IN et al,[15] who reported a nearly identical mean age of 42.0±14.3 years, while Patil A et al,[9] observed a mean age of 41.72 years. These findings indicate that most elective surgical patients belong to the active middle-aged population. Our study population was predominantly male (65%), which contrasts with the findings of Saha P et al,[14] and Patil A et al,[9] where females comprised the majority (60.5% and 60.6%, respectively). Such variations may be due to local patient intake patterns and the specific surgical specialties evaluated.

Regarding overall awareness, 64% of our participants demonstrated adequate knowledge of the informed consent process. Hassan IN et al,[15] noted that while 91.5% of their patients recognized the importance of informed consent, only 33.6% understood its medico-legal significance. Bullappa D et al,[2] reported a higher awareness, with 88.8% of participants knowing about the consent form, likely due to the urban setting of their study.

The association between educational status and informed consent knowledge was highly significant in our study (p=0.003), with graduates and postgraduates exhibiting 94.7% adequate knowledge

compared to only 26.7% among those with illiterate or primary education. This strong correlation is mirrored by Arshad MA et al,[4] who identified educational status as a significant barrier to the self-signing of consent forms (p=0.002). El-Wakeel et al,[11] also observed significant differences between educational groups regarding the understanding of alternative options (p=0.023) and the consequences of not undergoing a procedure (p=0.026). These findings underscore that health literacy remains the single most influential factor in achieving truly informed consent.

In our study, 79% of patients were informed about their medical condition, while 67% received details regarding their surgery. These findings are consistent with previous studies that have reported high rates of disclosure of patients' medical conditions, including Singh AD et al,[13] (97.83%) and Patel VC et al,[5] (97.68%). However, the proportion of patients informed about surgical complications in our study (69%) was higher than that reported by Patel VC et al,[5] where only 13.48% of patients were informed about potential complications, and by Patil A et al.,[9] who reported a rate of 41.2%. In contrast, our findings are more comparable to those reported by Tripathy S et al,[16] who observed that 94.62% of patients undergoing caesarean sections were informed about surgical risks.

Communication regarding anaesthesia and its complications was 58% and 35%, respectively in our study, However, Tripathy S et al,[16] reported that 98.92% of patients were unaware of the type of anaesthesia, while Singh AD et al,[13] found that only 13.85% were informed about anaesthetic complications. This suggests that clinicians emphasize surgical details while giving less attention to anaesthesia-related risks, a trend also noted by Naidu and Gopalan,[17] and Saha P et al.[14]

The process of obtaining consent in our study was done by consultant surgeons (36%) and duty doctors (36%). Saha P et al,[14] reported that 91.5% consents were obtained by consultants, leading to higher patient satisfaction. Conversely, Hassan IN et al,[15] and Patel VC et al,[5] found that junior staff (residents and postgraduate students) obtained consent in 62.1% and 67.25% of cases, respectively. This raises concerns, as junior doctors may lack the confidence and training to obtain valid surgical consent.[15]

In our study, 58% patients signed their own consent form, while 42% were signed by relatives. This was higher than the study by Hassan IN et al,[15] (17.1%) and Arshad MA et al,[4] (14.8%) but lower than the 81% reported by Ochieng et al. in a low-resource setting.[18]

Our study had a satisfaction rate of 72% and a strong perception that the information provided was useful (74%). This level of satisfaction aligns with Singh AD et al,[13] (87.77%) and Patel VC et al,[5] (87.83%), though it is lower than that reported by Saha P et al,[14] (94%). However, Hassan IN et al,[15] discussed that high satisfaction does not necessarily correlate with comprehension, as patients often report satisfaction based on trust in the provider rather than a full understanding of the procedure.

The study highlights a gap between the information provided during the informed consent process and patients' actual understanding, influenced by factors such as limited health literacy and frequent proxy signing.

CONCLUSION

A majority of surgical patients received information regarding their medical condition and procedure, however, significant gaps remain regarding awareness of the informed consent process, particularly anaesthesia-related risks and understanding of the consent form. Educational status was strongly associated with patients' knowledge and awareness of informed consent. These findings highlight the need for improved patient-centred communication strategies and structured consent processes to ensure better patient understanding and participation in surgical decision-making.

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