# Patient Knowledge, Attitudes and Practices Regarding Informed Consent before Surgery: A Cross-Sectional Study from a Tertiary Care Centre in Kerala, India

**Anu V. Babu; Shraddha Murali; Devi V. S; Thushara K. Thampy**
Department of Surgery, Sree Gokulam Medical College & Research Foundation,
Venjaramoodu, Thiruvananthapuram, Kerala, India

Corresponding Author: **Dr. Devi V. S**

## Abstract

**Background:** Written informed consent is a fundamental ethical and legal requirement in surgical practice, intended to safeguard patient autonomy and promote shared decision-making. Despite its universal implementation, concerns remain regarding patients' understanding of the consent process and the adequacy of information disclosed. **Objective:** This study aimed to assess patients' knowledge, attitudes, and practices related to the informed consent process before elective surgical procedures. **Materials and Methods:** A cross-sectional, questionnaire-based study was conducted in March 2024 among adult inpatients who underwent elective surgery at Sree Gokulam Medical College and Research Foundation, Kerala, India. A total of 150 patients were selected using simple random sampling and interviewed on the second postoperative day. A validated structured questionnaire was used to evaluate patient awareness of essential components of informed consent, including diagnosis, nature of surgery, risks, benefits, alternative treatment options, and the right to refuse treatment. The quality and completeness of written consent forms were assessed using a standardised observation checklist. Data were analysed using SPSS version 29 and expressed as frequencies and percentages. **Results:** All participants (100%) reported having signed a written informed consent form. While all patients were informed about their diagnosis and the nature of the surgical procedure, only 84.6% were aware of the expected benefits, and 76.7% understood the consequences of declining surgery. Information regarding surgical risks was provided to 92% of patients; however, 75% desired further clarification. Only 61.4% reported being informed about alternative treatment options. Although 92% felt they had adequate time to understand the consent form, 7.3% perceived the explanation as unclear. Evaluation of consent documents revealed omissions, particularly the absence of explicit statements regarding alternative treatments and patients' rights to refuse or withdraw consent. **Conclusion:** Although the existing informed consent process satisfies ethical and legal requirements for most patients, important gaps persist, especially in communicating alternative treatment options and patient rights. Enhancing the clarity, completeness, and patient-centred nature of the informed consent dialogue is essential to ensure genuine patient autonomy and informed decision-making in surgical care.

**Keywords:** Informed consent, surgical patients, patient autonomy, consent form quality, preoperative education

## Introduction

Informed consent is a cornerstone of ethical and legal medical practice, forming the foundation of patient-centred care and shared decision-making. It ensures that patients are empowered to make autonomous decisions regarding their health after receiving adequate, comprehensible information about their diagnosis, proposed interventions, available alternatives, and potential outcomes. The ethical principle of autonomy, central to modern bioethics, affirms an individual's right to self-determination and freedom from coercion or undue influence in matters concerning their own body and medical care [1,2].

The concept of informed consent has evolved over centuries. Historical evidence suggests that as early as the seventeenth century, medical practices in the Eastern Mediterranean recognised the importance of documenting voluntary treatment decisions, reflecting early respect for patient choice [2]. In contemporary medicine, however, informed consent has developed into a structured, regulated, and legally enforceable process. Modern ethical and legal standards require more than the mere provision of information; clinicians are obligated to ensure that patients meaningfully understand the nature of the proposed procedure, its risks and benefits, reasonable alternatives, and the consequences of declining treatment [3,4].

Current ethical frameworks define informed consent as comprising four essential components: adequate disclosure of information, patient comprehension, decision-making competence, and voluntariness [5]. These principles translate into five core patient-facing elements: understanding of the diagnosis, details of the proposed treatment, potential risks and expected benefits, awareness of alternative treatment options where applicable, and knowledge of the consequences of refusing the recommended intervention [5,6]. The absence of any of these elements undermines the validity of consent and compromises patient autonomy.

Despite its central role in ethical medical practice, evidence suggests a persistent gap between the theoretical requirements of informed consent and its real-world implementation. Studies from diverse healthcare settings have demonstrated deficiencies in both communication and documentation. For instance, research conducted in Addis Ababa reported that only a small proportion of patients received all components of valid informed consent [6]. Similarly, an audit of informed consent documents from hospitals in the United States revealed that fewer than one-third contained all the essential elements required for legally and ethically sound consent [7]. These findings raise concerns regarding the adequacy of consent practices even in well-resourced healthcare systems.

Against this backdrop, the present study was conceptualised to evaluate the informed consent process from the patient's perspective in a tertiary care hospital in Kerala, India—a state known for its high literacy rates and comparatively strong health indicators. The objectives of this study were to assess patients' knowledge and understanding of the informed consent process, evaluate whether all five core components of informed consent were adequately addressed, explore patient-perceived clarity, satisfaction, and practical challenges associated with the consent process, and examine the content and completeness of the written informed consent documents used by the institution.

## Materials and Methods

### Study Design and Setting

This was a hospital-based, cross-sectional observational study conducted over one month from 1 March to 31 March 2024 in the Department of General Surgery, Sree Gokulam Medical College and Research Foundation (SGMCRF), a tertiary care teaching hospital in Kerala, India.

### Study Population and Eligibility Criteria

### Inclusion Criteria

Patients were eligible for inclusion if they met all of the following criteria:

- Aged 18 years or older
- Underwent major or minor elective surgical procedures
- Admitted as inpatients and available for interview on the second postoperative day
- Conscious, oriented, and able to communicate in Malayalam or English

### Exclusion Criteria

Patients were excluded if they:

- Were pediatric patients
- Underwent emergency surgical procedures (excluded to maintain homogeneity of elective surgical care)
- Had a documented mental illness or cognitive impairment that could affect comprehension or recall
- Underwent repeat surgical procedures during the same hospital admission

### Sample Size Estimation and Sampling Technique

The minimum required sample size was calculated as **150 patients** using the formula for a **single population proportion**. The following assumptions were applied:

- **Confidence level (Z):** 1.96 (95% confidence interval)
- **Margin of error (d):** 5%
- **Estimated prevalence (p):** 26.5%, based on previous studies assessing awareness of informed consent [6]

Eligible patients were selected using simple random sampling from the daily elective surgery admission list until the desired sample size was achieved. Both verbal and written informed consent were obtained from all participants before enrolment in the study.

### Data Collection Tools and Procedure

Data were collected through face-to-face interviews conducted on the second postoperative day, using a structured and validated questionnaire. The questionnaire comprised three sections:

- Sociodemographic characteristics
- Basic service-related characteristics
- Patient awareness and understanding of key components of informed consent

In addition, an observation checklist was employed to evaluate the content and completeness of the institution's standard written informed consent form, with specific attention to the inclusion of core ethical elements.

### Statistical Analysis

Collected data were coded, entered, and analysed using Statistical Package for the Social Sciences (SPSS) version 29.0. Descriptive statistics were used to summarise study variables, and results were presented as frequencies and percentages.

### Results

A total of **150 patients** admitted for elective surgical procedures were enrolled in the study. All participants provided valid responses and consented to the survey. The findings are presented in terms of sociodemographic profiles, basic service characteristics, informed consent components, evaluation of the informed consent form, patient satisfaction, and perceived clarity.

### 1. Sociodemographic Characteristics of Participants

**Table 1. Sociodemographic characteristics of patients undergoing elective surgery (N = 150)**

| Variable | Category | Frequency (n) | Percentage (%) |
|---|---|---|---|
| **Age Group (years)** | 18–25 | 37 | 24.7 |
| | 26–40 | 57 | 38.0 |
| | 41–60 | 45 | 30.0 |
| | >60 | 11 | 7.3 |

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|---|---|---|---|
| **Sex** | Male | 50 | 33.3 |
| | Female | 100 | 66.7 |
| **Education Status** | Cannot read or write | 5 | 3.3 |
| | Primary education | 9 | 6.0 |
| | Secondary education | 95 | 63.7 |
| | College or higher | 41 | 27.0 |
| **Marital Status** | Single | 12 | 8.0 |
| | Married | 138 | 92.0 |
| **Occupation** | Homemaker | 63 | 42.0 |
| | Unemployed | 26 | 17.3 |
| | Private sector | 25 | 16.7 |
| | Farmer | 12 | 8.0 |
| | Daily wage worker | 12 | 8.0 |
| | Government employee | 12 | 8.0 |

### 2. Basic Service Characteristics

All respondents underwent elective surgeries, as emergency cases during the study period were exclusively pediatric and hence excluded.

- In 84.6% (n = 127) of cases, a doctor explained the consent process to the patient.
- In 15.4% (n = 23) cases, a nurse explained.
- One hundred per cent (n = 150) of the patients received and signed the consent form on the day before surgery. No cases of consent being taken on the day of surgery or in the operating room were reported, indicating compliance with preoperative timing protocols.

### 3. Information Received Before Surgery

Patients were assessed for their knowledge and recall of key elements of informed consent. The major findings are summarised below:

- Diagnosis and Procedure: All patients (100%) were informed about their diagnosis, the nature of surgery, and the type of anaesthesia to be used.
- Surgeon Identity: 84.6% (n = 127) of patients were aware of who would perform the surgery.

- Estimated Duration: Only 66.7% (n = 100) had been told about the expected duration of the procedure.

**Benefits and Risks:**

- 84.6% (n = 127) understood the benefits of surgery.
- 92% (n = 138) were informed of the associated risks, though 16.7% (n = 25) desired further explanation or reassurance.

- Consequences of Refusal: 76.7% (n = 115) were aware of the potential consequences of not undergoing the procedure, while 15.3% (n = 23) were not, and 8% (n = 12) could not recall.
- Alternative Treatment Options: Only 61.4% (n = 92) were informed about alternative treatments, whereas 30.6% (n = 46) were not, and 8% (n = 12) were unsure.
- Follow-up T
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- reatment: 92% (n = 138) were informed about the need for postoperative care or follow-up interventions.

**Time for Decision-making:**

- 92% (n = 138) believed they were given adequate time to read and understand the consent.
- 84.6% (n = 127) felt they had enough opportunity to ask questions.

These findings suggest a generally robust process, with some noticeable deficiencies in the discussion of alternatives, procedure duration, and patient choice.

### 4. Completeness of Informed Consent Components

Based on the five fundamental components of informed consent (diagnosis, procedure, risks/benefits, consequences of refusal, and alternatives), it was found that:

- 76.9% (n = 115) received at least four out of five components.
- 23.1% (n = 35) received only three or fewer components.
- The most commonly missing element was information on alternative treatment options, absent in 38.6% of cases.

This highlights a gap in holistic disclosure, which could compromise the true autonomy of patient decision-making.

### 5. Patient Satisfaction and Clarity

Most patients reported clear explanations of the informed consent process, with 92% perceiving the information as clear and only 8% reporting partial clarity. Overall satisfaction was high, with 76.9% of patients being highly satisfied and the remaining 23.1% satisfied, and no participants expressing dissatisfaction.

**Table 2: Clarity of explanation and satisfaction with consent process**

| Variable | Category | Frequency (n) | Percentage (%) |
|---|---|---|---|
| Clarity of explanation | Clear | 138 | 92.0 |
| | Partially clear | 12 | 8.0 |
| Satisfaction with the consent process | Highly satisfied | 115 | 76.9 |
| | Satisfied | 35 | 23.1 |
| | Neutral/Dissatisfied | 0 | 0.0 |

## Discussion

The findings of this study provide important insights into patients' perceptions and experiences of the informed consent process before undergoing surgical procedures. Overall, while compliance with basic ethical requirements was high, significant gaps were identified in the depth, clarity, and completeness of information provided, with potential implications for patient autonomy and shared decision-making.

With regard to awareness and comprehension, it is encouraging that all patients (100%) reported being informed about their diagnosis and the nature of the planned surgical procedure. Disclosure of diagnosis is widely regarded as the minimum ethical standard in informed consent, and this finding aligns with established ethical norms and previous international studies [1]. Comparable levels of diagnostic awareness have been reported in studies from Greece, where all participants were aware of their diagnosis [8]. However, awareness declined when patients were questioned about more nuanced aspects of consent. Only 84.6% of patients were aware of the anticipated benefits of surgery, a figure comparable to that reported in Greece (88.3%) [8] and substantially higher than reports from Addis Ababa (55.6%) [6] and Pakistan (40.6%) [9]. More concerning was the finding that only 76.7% of patients were informed about the potential consequences of refusing surgery. Failure to disclose this information undermines informed decision-making and may result in consent being based on an incomplete understanding.

In terms of risk communication, although 92% of patients reported that surgical risks were explained, a notable proportion still desired further clarification. This highlights that the effectiveness of consent depends not merely on the provision of information but on its quality and comprehensibility. International studies demonstrate wide variability in risk disclosure practices, with reported rates ranging from 26.7% in the United States to 76.6% in Greece and 60% in Israel [6,8,10]. These findings reinforce the ethical requirement that risks be communicated in clear, patient-friendly language, consistent with the principle of comprehension as a core element of valid informed consent [5].

Disclosure of alternative treatment options and patients' right to refuse treatment emerged as key areas of deficiency. Only 61.4% of respondents were informed about alternative therapeutic options, and even fewer recognised their right to decline the proposed procedure. This omission is ethically significant, as meaningful choice among available options is central to respect for autonomy [5–7]. Similar deficiencies have been reported in high-income settings, including a large audit from the United States in which only a minority of consent forms actively supported patient decision-making [7].

Evaluation of the written informed consent document revealed that, although it addressed diagnosis, benefits, risks, and anaesthesia, it lacked explicit mention of alternative treatments, estimated duration of surgery, patients' right to refuse, and sources for additional information. Such gaps mirror global trends, where consent forms often prioritise legal protection over patient understanding [7,9].

Despite these shortcomings, patient satisfaction with the consent process was relatively high. Most participants reported adequate time to review the consent form and opportunities to ask questions, reflecting a generally supportive communication environment. These findings compare favourably with studies from Ethiopia and Pakistan, where significantly lower levels of patient engagement were reported [6,9]. Nevertheless, the proportion of patients who found the explanation unclear underscores the ongoing need for simplified language, culturally sensitive communication, and tailored consent discussions, particularly for individuals with lower health literacy

## Overall Implications

The relatively high levels of patient awareness and satisfaction observed in this study may be attributed to Kerala's high literacy rate and comparatively robust healthcare infrastructure. However, these contextual advantages do not obviate the need for systematic improvements. Ensuring comprehensive coverage of all essential components of informed consent remains imperative, particularly with respect to disclosure of alternative treatment options and patients' rights. Structured training programs aimed at enhancing physicians' communication skills and standardising consent discussions are essential to improve the quality, clarity, and ethical robustness of the informed consent process.

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