

The Practice of Obtaining Informed Consent for Elective Surgery and Anesthesia from Patients' Perspective: An Institutional based Cross-Sectional Study

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Abstract

Background : Informed consent is a body of shared decision making process and voluntary authorization of patients to receive medical or surgical intervention. There are limited studies conducted so far to examine the practice of informed consent in Ethiopia. The aim of the study was to assess the practice of informed consent for surgery and Anesthesia from patients' perspective.

Method: An institutional-based cross-sectional study was conducted from March to May 2019. The data were collected using an interviewer-administered structured questionnaire and entered and analyzed using Microsoft Excel and SPSS version 23.

Results: A total of 139 patients were interviewed in this study. Most 42(30.2%) of patients were in the age group of 29-38 years. The majority 74(53.2%) of the population were females and most 85 (61.2%) were from a rural residence. Nearly half 68 (48.9%) of the patients were informed of the benefits of the surgical procedure and 78(56.1%) of the patients were informed on the type of anesthesia to be administered while 65 (46.8%) were not informed on any complications related to the anesthesia. About 66 (47.5%) of the patients interviewed were informed on alternatives to the surgery done. Of these patients, 39(59%) were not informed of any benefits and possible risks associated with the alternative modes of treatment. More than half 75 (54%) of the patients reported as they were understood the information provided during the pre-operative counseling and about 114 (82%) of the patients interviewed satisfied with the current process of obtaining informed consent.

Conclusions and recommendation: The current practice of obtaining informed consent addressed only certain aspects of the informed consent component which reflects that patients were inadequately informed on complications related to surgery and anesthesia, alternative forms of treatment and their risks and benefits.

Background

Informed consent is an essential requirement in the health care practice which considers the patient's capacity to be involved in the decision making process concerning their care which ensures the care received reflects their goals, preferences, and values. Currently, the importance of obtaining informed consent before any surgical procedure is well established in all hospitals. However, the practice and understanding of informed consent process are not uniform among health professionals and patients. It is stated that any adult patient with the capability of making decisions concerning his/her own body has the right to get adequate information and there should be a shared decision on the proposed treatment(1). It is an ethical obligation of health care professionals to uphold patients' autonomy and let them decide on the proposed medical, surgical or other health care and research interventions(2).

Therefore, health professionals must provide appropriate information for patients to the level of the patient's understanding and decision-making skills. In other words, it does not mean to the single moment

of an agreement, but to the whole complex process of gaining information, shared decision and consenting.

A patient's decision to consent to a surgical procedure needs to be grounded on an adequate and relevant information. Without such explanation, a patient's decision to consent to surgery and anesthesia is not effective informed consent. The effectiveness of the informed consent process in satisfying the patients' needs and rights and the patients' perception of how the process should be, is an essential element in the process of obtaining informed consent(3).

Currently, patient education and patient-oriented care are important topics, thus for a clinical activity like high-risk clinical procedures (surgical interventions). It is better to assess the status of informed consent and health literacy among patients and direct service providers. The health sector transformation plan of Ethiopia has set an ambitious goal to improve equity, coverage, and utilization of health care services at all levels of the health system. The ministry of health of Ethiopia has launched a training package and establishing Compassionate, Respectful and Caring health professionals for the health taskforce (CRC) to improve the health care service provided. There is a growing body of evidence showing that compassionate care has been associated with improved health outcomes, increased patient satisfaction, and better adherence to treatment recommendations, fewer malpractice claims and reduced healthcare expenditure (4). Medical ethics and informed consent are an integral part of CRC package.

The adequacy of the information provided to patients in satisfying the patients 'needs and rights is not assessed yet. There has been no published study done at the Public and private hospital of Ethiopia to assess the practice of obtaining informed consent for surgical procedures. Evidence-based information regarding the practice of obtaining informed consent is lacking in the study area.

Therefore we aimed to assess the practice of taking informed consent because the information obtained from this research could help patients, clinicians, health system leaders, and policymakers and thereby improve the quality of health care services towards the medical ethics and informed consent for surgery and Anesthesia. The study also tries to probe health care providers to implement the standard requirements of informed consent and patient safety practice and to keep the ethical norm of informed consent. It will not only strengthen efforts in improving the process of obtaining informed consent, but also provide a basis for further studies, and practical ways of improving the current informed consent process in the hospitals.

Methods

Study Design and Population

An institutional-based cross-sectional study was conducted. All elective surgical patients aged above 18 years who underwent major surgical procedures as elective surgery and who had given consent were involved. Patients who were undergoing elective surgeries but who were considered too ill to consent for

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ients were excluded. The sample size was determined by

taking the following assumption: since there is no previous study in the area we assumed the proportion as 50%, confidence interval of 95% and margin of error to be tolerated 0.05. The sample size taken for the study was determined using a single population formula. By applying a finite population correction formula, the final sample size was determined as,

$$N_f = n / (1 + n/N)$$

Whereas, N_f = the minimum sample size

n = sample size

N = the number of elective cases in the study area for January, February and March 2019 was 200 excluding pediatric elective cases and emergency cases. $N_f = 132$ we are obtained by adding a 5% non-respondent rate and gave the final $n = 132 + 7 = 139$; therefore, the total sample size of 139 elective surgical patients participated in this study.

Sampling Technique And Data Collection Procedure

All patients who underwent elective surgery during the data collection period were involved. The data was collected using a structured questionnaire after obtaining informed consent. Data was collected by assigned nurses at the workplace, supervised by one responsible senior anesthetist. Information on the socio-demographic and clinical characteristics of patients and the practice of informed consent were taken from the participants.

Operational Definition

Adult patient: a patient who has the age of 18 years and above.

Pediatric patient: a patient who is below the age of 18 years.

Informed consent: the practices of providing the necessary information that allows the informed person to make autonomous authorization.

Data Quality Assurance and Analysis Procedures

Microsoft excels and Statistical Package for Social Sciences (SPSS) version 23 was used to analyze the data. Descriptive analysis using frequency and other summary measures were used to analyze the data. Tables, figures and text narrations were used to present the findings. To maintain the quality of data, a questionnaire was developed in a simple and easily understandable and in the local language. The training was given for two days for data collectors before the actual data collection. Then the questionnaire was checked for its accuracy, clarity, and consistency. The data collectors were nurses who
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supervision were done during the data collection period by the supervisors and the completeness of the data was checked daily.

Results

Socio-demographic Characteristics of Patients

Respondents of this research were adult patients scheduled for elective surgery in the study area. A total of 139 patients were interviewed. The majority 74(53.2%) of the participants were females and about 114(82.8%) are orthodox religious followers. Most 85 (61.2%) of the patients were from rural areas.

Most 42(30.2%) patients are were in the 29-38 year age group. Regarding the level of education of the respondents,41(29.5%) had unable to read and write while 37(26.6%) had attended college and above (table -1).

Table 1
Socio-demographic characteristics of elective surgical patients in the study area, 2019

Variables	Category	Frequency (n = 139)	Present (%)
Sex	Male	65	46.8
	Female	74	53.2
Religion	Orthodox	114	82.80
	Muslim	19	13.7
	Protestant	6	4.3
Place	Rural	85	61.2
	Urban	54	38.8
Educational status	Unable to read and write	41	29.5
	Attend primary school	30	21.6
	Attend secondary school	31	22.3
	Attend college and above	37	26.6
Age category	18–28	10	7.2
	29–38	42	30.2
	39–48	30	21.6
	49–58	34	24.5
	≥ 59	23	16.5

The following figure (Figure-1) showed that 69(49.6%) of the patients underwent elective general surgery while the least, 18(12.9%) of the study participants underwent urology procedures.

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Regarding preoperative counseling/informed consent for surgery and anesthesia, 127 (91.4%) of the patients had got their preoperative counseling in the admission ward and 12 (8.6%) in the clinic 122(87.8%) of the study participants could not recall who conducted the counseling and 9(6.5%) of the study participants had counseled by nursing officer and 8(5.8%) had received counseling by anesthetist (figure-2).

About 68(48.9%) and 78(56.1%) of the study participants have got information on the benefits of surgery and benefits of anesthesia respectively. Only 51 (36.7%) of the patients have got counseling on possible complications of anesthesia and 78(56.1%) of the patients have got counseling on the possible

During pre-operative counseling, 51(36.7%) of the patients were given an opportunity to ask questions prior to the signing of the consent. More than half 75 (54%) of the study participants understood well the information provided to them prior to signing the consent form while 80 (46%) of them partially understood the information. Following the pre-operative counseling sessions and signing of the consent form, about 114 (82%) of the patients reported as they are satisfied with the process of obtaining informed consent for elective surgery.

Discussion

During this study, 139 patients were interviewed, with the percentage of female patients being higher than male patients, which is consistent with the fact that there are more female surgical patients in the hospital than male patients. The study participants were aged between 18 years to over 59 years with the highest percentage of patients being between 29-38 years (30.2%). This could be attributed to the respondents in the study area who were undergoing surgery in four units or departments (General surgery, Gynecology, obstetrics, and urology). A similar trend was observed in a study done by Mohammed Amir et al on surgical informed consent where the majority of the patients were aged between 25-35 years, therefore, the majority of surgical patients are in the younger age group (22).

The majority of the patients had varying levels of formal education and 29.5% of the patients had no formal education. Establishing the literacy level of patients during pre-operative counseling is important as patients may fail to understand the medical terminology often used by the physicians and anesthetists. If the patient has had little or no formal education, reading the written consent form may be difficult and this curtails on the patient's autonomy. Besides patients with less formal education are likely to be influenced by other people when deciding whether to proceed with the surgery or not, regardless of their knowledge of the procedure. A study by Mohammed Amir et al found that 81(58%) of patients did not read the consent form due to low literacy levels (22).

Regarding the type of surgical procedure, the majority of the patients interviewed were scheduled to undergo general surgery procedures 69(49.6%) while the least number of patients were scheduled to undergo urology procedures 18(12.9%). About 9 (6.5%) had their pre-operative counseling for surgery conducted by nursing staff in surgery. Health care professionals should introduce their name and role before taking the informed consent. However, about 122 (87.8%) of the patients did not know the medical practitioner who provided pre-operative counselling.

In our study setting, students and senior staffs may conduct pre-anesthetic counseling. When students conduct the informed consent, they are required to consult with the senior anesthetist supervising them.

A study that looked at the surgeons' and anesthetists' attitudes towards informed consent in the United Kingdom found that 97% of the surgeons agreed on informing the patient on the surgery, its risks and benefits and educating the patient on alternative treatment options (20). In the current study, about 68(48.9%) of the patients interviewed were informed of the benefits of surgery but only 78(56.1%) of the Loading [MathJax]/jax/output/CommonHTML/jax.js applications that may arise following surgery. 65(46.8%) of the

patients were not informed of the possible complications associated with the type of anesthesia to be administered. This may be due to the fear that disclosure of complications related to the procedure and anesthesia may increase the patients' anxiety levels and dissuade them from the surgery or the health care professional carrying out the counseling may be inadequately informed on what is required to be told to the patient.

A study on the surgeons' and anesthetists' attitudes towards informed consent conducted in the United Kingdom found that 50% of the surgeons and anesthetists felt that major risks with an incidence of >1 in 1000 or more should be disclosed to patients as part of the consent process. Seventy percent of both surgeons and anesthetists felt that minor risks with an incidence of >1 in 20 should be disclosed to the patient when obtaining consent (24).

During pre-operative counseling, patients should be informed on alternative forms of treatment, their risks, and benefits in addition to the proposed surgical procedure or type of anesthesia to be administered by the surgeon or anesthetist respectively. In this study, 66(47.5%) of the patients were informed of alternative forms of treatment for the elective surgery to be done. Of these patients, only 23 (16.5%) were informed about the benefits and possible complications of the alternative forms of treatment.

A study on the surgical informed consent in the Royal Sussex County Hospital in the United Kingdom by White and Walton et al showed that the factors that affect the amount of information conveyed to the patient during the consent process included patient's age, level of education, inquisitiveness and complexity of the procedure (24).

Once information regarding the proposed form of treatment has been relayed, patients should be accorded the opportunity to have their questions answered. This also helps in assessing the patient's level of understanding of the information provided and also assesses the patient's level of satisfaction with the consent process. In this study, the patients' perception of satisfaction appears to be dependent upon engagement in the discussion and decision-making rather than a complete understanding of the information being provided.

In our study, about 75 (54%) of the patients stated that they understood all the information provided and 114(82%) of the patients stated that they were satisfied with the consent process. A similar trend was observed in a study conducted in Pakistan on informed consent for surgical patient where despite the poor understanding of the information and other inadequacies, the majority of the patients 130 (93.5%) still felt satisfied with the process of informed consent (22).

This study is the first study in the area in providing information on the practice of obtaining informed consent, although the study has certain limitations like smaller sample size and a single-institution study.

Conclusion

In conclusion, the current practice of obtaining informed consent only addresses certain aspects of informed consent such as nature and indication for surgery and the type of anesthesia to be administered. Patients are inadequately informed on the complications related to surgery and anesthesia, alternative forms of treatment, risks, and benefits. Besides, the study revealed that majority of patients did not know the health professional conducting the informed consent. The study showed that the process of informed consent in the study period did not address the key aspects of anesthesia such as benefits, type of anesthesia to be used, the possible complications related to anesthesia and alternative forms of anesthesia. In this study, most of patients are not fully satisfied with the current practice of informed consent process. The detailed informed consent form that addresses all the key aspects of informed consent which include the nature of the procedure, its benefits and possible risks, reasonable alternatives to the proposed intervention, as well as relevant risks and benefits related to each alternative, should be developed and well communicated with patients.

A written consent form for anesthesia that fully outlines the anesthesia, its possible risks and benefits as well as alternatives to the proposed form of anesthesia should also be developed. The health caregiver should introduce themselves and sign the consent form once the patient has consented to the proposed surgery and anesthesia. The departments of surgery and anesthesia should develop standards of practice for obtaining informed consent for surgery and anesthesia.

Abbreviations/ Acronyms

CRC: Compassionate, Respectful and Caring

WHO: World Health Organization

Declarations

Ethical Approval and Consent to Participate

Ethical clearance was obtained from a Research Ethics Committee of College of Health Sciences, Debre Tabor University. The permission and agreement consent was taken from Debre Tabor General hospital before the study and written consent was taken from patients after a brief explanation of the purpose of the study.

Consent for Publication

Not applicable

Availability of Data and Materials

The datasets are obtained from the corresponding author upon reasonable request

Competing Interests

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The authors declared as there is no competing of interest

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Authors contributions

Mr. Tadese T and Mr. Aragaw T were involved in write up of the proposal, data entry, data analysis and final manuscript write up. The final manuscript is read and approved by both authors.

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Figures

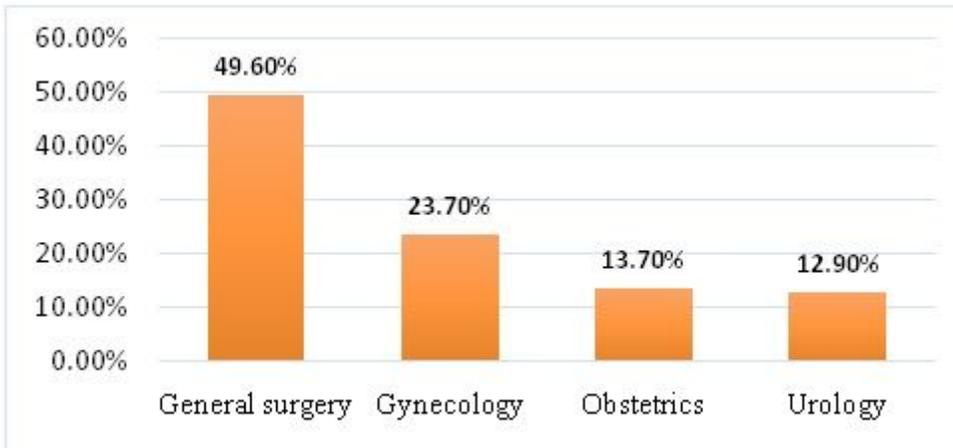


Figure 1

The type of elective surgical procedure among elective surgical patients from January to May 2019 in the study area

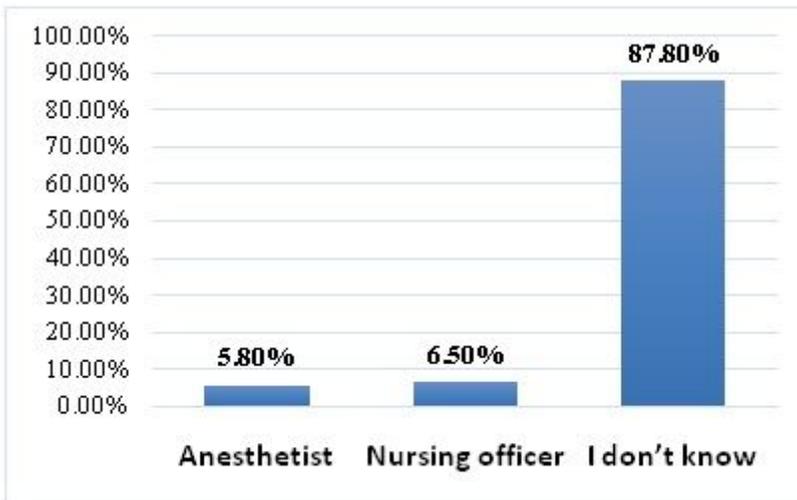


Figure 2

Pre-anesthetic counseling among elective surgical patients from January to May, 2019 in the study area

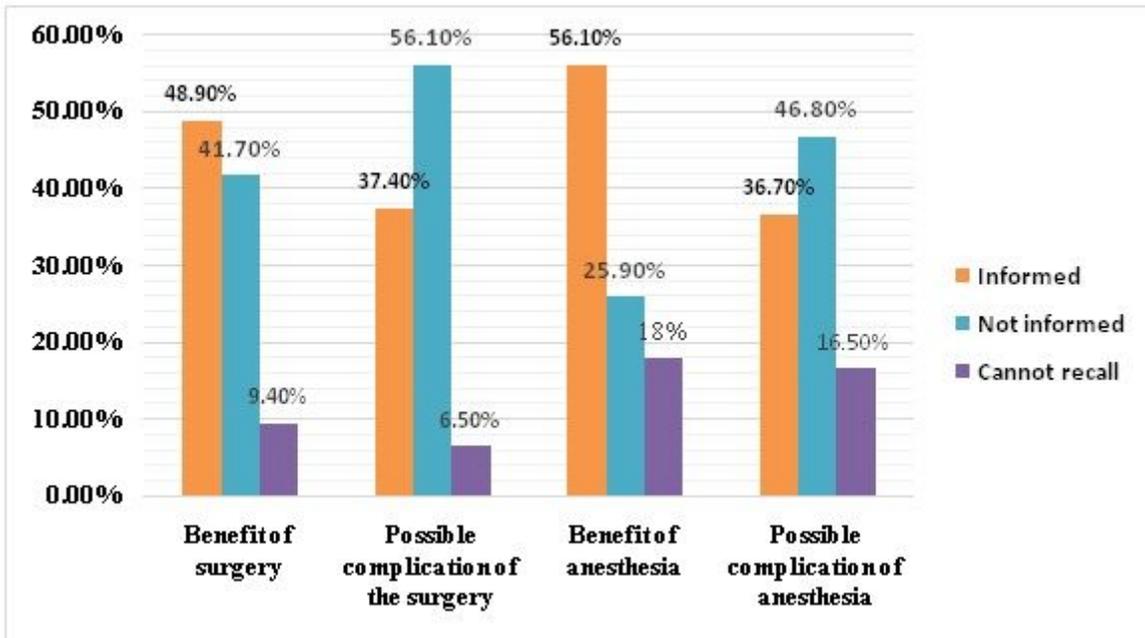


Figure 3

Elective surgical patients who got information on benefits and complications associated with the elective Procedure and anesthesia in the study area, 2019