Annals of Medicine and Surgery 79 (2022) 104104

Contents lists available at ScienceDirect

Annals of Medicine and Surgery

journal homepage: www.elsevier.com/locate/amsu

Cross-sectional Study

Patients' satisfaction and associated factors towards preoperative informed consent process: A cross-sectional study

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ARTICLE INFO

Keywords:
Anesthesia
Informed consent
Preoperative
Satisfaction
Surgery

ABSTRACT

Background: Informed consent is a process that needs time and effort to satisfy patients' desires. Patient dissatisfaction on preoperative informed consent process may be caused by multiple factors of clinical practice. This study aimed to assess patients' satisfaction and associated factors of informed consent process among elective surgical patients.

Methods: A cross-sectional study was conducted on 404 postoperative patients who signed the informed consent for elective surgery. A systematic sampling technique was applied to select the study participants. Modified Leiden perioperative patient satisfaction tool was adapted to assess patients' satisfaction with preoperative informed consent process. Data were entered in to Epi-data version 4.20 and exported to SPSS version 20 for analysis. Bivariate and multivariable logistic regression was computed to identify independent variables associated with patient satisfaction towards preoperative informed consent process. A p-value of less than 0.05 was used to declare the statistical significance.

Results: The overall satisfaction of patients with preoperative informed consent process was 70.3%. Multivariable logistic regression analysis revealed that, being male (AOR: 4.75, 95% CI: 2.47–9.16), primary school (AOR: 8.42, 95% CI: 4.74–7.55), secondary school (AOR: 2.17, 95% CI: 5.74–8.62), rural residence (AOR: 1.8, 95% CI: 2.1–3.9) and received general anesthesia (AOR: 2.92, 95% CI: 1.62–5.26) were significantly associated with patients' satisfaction with the informed consent process.

Conclusion: The overall patients' satisfaction on preoperative informed consent process was relatively low. Being male, low level of education, living in rural area, and receiving general anesthesia were significantly associated with patients' satisfaction on informed consent process. Surgeons and anesthesia professionals need to work more to improving the satisfaction of patients with preoperative informed consent process. Researchers are expected to do periodic assessment of patients' level of satisfaction and factors affecting satisfaction.

1. Introduction

Informed consent is a fundamental principle which includes the patients' capacity to be involved in the decision making concerning their care [1]. Patients must be competent to make the particular decision and should receive sufficient information to help them in making a decision [2].

Informed consent is best viewed as a process, not as an event because, it is an ongoing dialogue between patient and health care givers throughout the patient's care. It begins with a preoperative examination and continues through surgery and postoperative treatment [3–6]. Informed Consent Process (ICP) being regarded as a basic requirement of a doctor–patient relationship, no patient can be forced, directly or indirectly, to accept treatment which it may refuse, even if it is painless, beneficial, without any risk, or even life threatening [7]. Beyond the law, informed consent is the cornerstone of medical ethics and surgical practice because it empowers respecting patients' autonomy and dignity [3].

Inappropriate informed consent can win legal suits for the patient even when the claim for any negligence (7). Thus better understanding of the informed consent process protect patients and healthcare

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https://doi.org/10.1016/j.amsu.2022.104104
Received 5 May 2022; Received in revised form 25 June 2022; Accepted 25 June 2022
Available online 30 June 2022

Acronyms/abbreviations

AOR	Adjusted Odds Ratio
CI	Confidence Interval
CRC	Compassionated, Respectful and Caring
HCPs	Health Care Professionals
ICP	Informed Consent Process
POICP	Preoperative Informed Consent Process

professionals clinical care practice [7]. Currently, Compassionated, Respectful and Caring (CRC) health care practice is being advocated by ministry of health of Ethiopia. CRC is serving patients ethically with empathy and sympathy, living the professional oath and being a role model for the young professionals. Informed consent is one of the main components of compassionated care which requires appropriate information disclosure with sympathy and empathy to make informed and shared decision on treatment plans. Evidences suggest that compassionate care has been associated with improved health outcomes, increased patient satisfaction, better adherence to treatment recommendations, fewer malpractice claims and reduced health care expenditure [8]. However, the impact of CRC initiative on patients' satisfaction of health care delivery particularly in surgery and anesthesia is not investigated.

Patient dissatisfaction on preoperative informed consent process could be affected by multiple factors of clinical practice [9,10]. Experience of health care professionals and patients' level of education and health literacy, and other socio-demographic factors could influence the satisfaction of patients with preoperative informed consent process [8]. Evidences are lacking regarding the level of patients' satisfaction on preoperative informed consent process in the study setting. This study aimed to assess satisfaction and associated factors of the preoperative informed consent process among surgical inpatients.

2. Methods and materials

2.1. Study area and period

A multicenter cross-sectional study was conducted from January to March 30, 2021, in three randomly selected hospitals in South Gonder Zone, Ethiopia. On average, 4560 patients are expected to undergo major surgery in a year in these hospitals. The study was reported in line with the 2021 STROCSS criteria [11] and registered at https://www.researchregistry.com/browse-the-registry#home/with unique registry number of researchregistry7853.

2.2. Study design

A multi-center cross-sectional study.

2.3. Eligibility criteria

All elective surgical patients with the age of 18–65 years were included in the study, but critically ill patients and patients with known mental illness were excluded from the study.

2.4. Sample size and sampling technique

The sample size was calculated using single population proportion formula taking 50% Prevalence at 95% CI with 5% margin of error. By adding 10% of the calculated sample size for non-response rate, the total sample size was found to be 423 patients. A systematic sampling technique was employed to select the study participants from the selected hospitals proportionally based on the daily operation schedule lists.

2.5. Data collection technique

The structured questionnaire was adapted from Modified Leiden Perioperative Care Patient Satisfaction questionnaire (LPPSq) tool and different literatures to the local context to assess patients' satisfaction and associated factors with preoperative informed consent process and interviewer administered data collection technique was used.

2.6. Data quality assurance

The data collection tools were pretested at non selected hospital on about 5% of the total sample size. Reliability of the tool was checked with Chrombach's Alpha (0.79) and inter-item correlation (0.75) with variance of 0.1. Then the authors reviewed the data collection tool for the main data collection. Training was given for the data collectors and daily supervision of data collection process was conducted by co-investigators. Data were checked for completeness, clarity and consistency on daily basis by the principal investigator.

2.7. Data analysis

Data with complete information were entered in to Epi-data version 4.20 and exported to SPSS version 20 for analysis. Descriptive statistics and association between the factors and outcome variable were determined at 95% confidence interval. Both bivariate and multivariable logistic regression was employed to assess the predictive risk factors and strength of association between patients' satisfaction with preoperative informed consent process and explanatory variables. Adjusted Odds Ratio was used to see the strength of association. A p-value of less than 0.05 was used to declare the statistical significance.

2.8. Ethical clearance

Before conducting the study, ethical approval letter was obtained from Debre Tabor University ethical review committee with reference number of ጤሳኮ/3399/2013 and permission was obtained from each hospital administrators after providing detail information about our objectives of the study. After getting permission from hospital managers, data collectors took written informed consent from each patient. Participants were informed as they have full right to withdraw from the research process if they feel discomfort. During the data collection process norms, values and morals of patients were respected by the data collectors.

2.9. Operational definitions

Patient satisfaction is meeting the expectation of patients in the preoperative informed consent process. It was assessed using questionnaire consisting of 10 statements with five-point Likert scale responses (5 = completely satisfied, 4 = satisfied, 3 = neutral, 2 = dissatisfied and 1 = completely dissatisfied). Proportion of patients with mean score of >3 on the Likert scale questions were classified as satisfied [12–14].

3. Results

3.1. Socio demographic characteristics

A total of 404 patients with a response rate of 95.5% have participated in the current study. The mean age of the study participants was 40 years with a standard deviation of 15 years. More than half (62.4%) of study participants had a primary school educational level, and most (71.3%) of patients live in the rural areas.

3.2. Clinical characteristics and satisfaction of the study participants

In this study the majority of patients (77.2%) were operated for the

first time and more than half (58.4%) were operated under spinal anesthesia. Orthopedics surgery was common surgical procedure followed by cesarean section. The overall satisfaction of patients with preoperative informed consent process was found to be 70.3% (see Table 1).

3.3. Factors associated with satisfaction of patients with preoperative informed consent process

Both bivariate and multivariable logistic regression model were fitted in this study to identify associated factors with patients' satisfaction on informed consent process. On bivariate analysis, patients' level of education, operated as per the schedule, operated for the first time and type of anesthesia were showed statistically significant association with preoperative informed consent process. Variables with p-value < 0.25 were taken for multivariable analysis to identify independent predictors for patient satisfaction. Therefore, being male, primary and secondary education level, being rural in residency and type of anesthesia (GA) were showed statistically significant association with patients' satisfaction on informed consent process (Table 2).

4. Discussion

Patients' satisfaction towards provision of surgical and anesthesia informed consent process may vary in different clinical setup. Patient satisfaction may not be easily achieved as there are many factors that might play a role in it. Some factors are patient-related (e.g., socio-demographic features, health status, and patient-physician relationship) while others are organizational (e.g., number of beds, staff performance, and using electronic medical records (11). The other issue that could affect patients' satisfaction with service delivery could be their expectation from the healthcare service which in turn varies from society to society depending on social, cultural, economic, political and religious factors (16).

Table 1
Socio demographic characteristics of elective surgical patients in the study period, 2021.

Variables	Frequency (N = 404)	Percent
Sex		
Male	160	39.6
Female	244	60.4
Age		
18–29	116	28.7
30–39	124	30.7
40–49	84	20.8
50+	80	19.8
Marital status		
Married	360	89.1
Unmarried	20	5
Divorced	20	5
Widowed	4	1
Level of literacy		
Can read and write	204	50.5
Can read only	24	5.9
Cannot read and write	176	43.6
Level of education		
Primary school	252	62.4
Secondary school	100	24.8
Diploma	32	7.9
Degree or above	20	5
Residency		
Rural	288	71.3
Urban	116	28.7
Religion		
Orthodox	388	96
Muslim	12	3
Others	4	1
Occupation		
Farmer	256	63.4
Merchant	40	9.9
Teacher	20	5
Health professional	20	5
Student	48	11.9
Other	20	5
Residency		
South Gondar		
Yes	360	89.1
No	44	10.9

Table 2
Association of factors with preoperative informed consent among elective surgical patients, 2021.

Variables	P-value	AOR	95% CI for AOR	
			Lower	Upper
Sex (male)	.02[a]	4.75	2.47	9.16
Can read and write	.53	.79	.38	1.62
Can read only	.55	1.38	.46	4.08
Primary	.00[a]	8.42	4.74	7.55
Secondary	.00[a]	2.17	5.74	8.62
Diploma level	.51	.65	.19	2.28
Being rural residency	.00[a]	1.8	2.1	3.9
Number of operation (1st)	.16	1.57	.82	3.00
Operated on the day of surgery (***Yes***)	.77	1.11	.51	2.44
Risks explained (**Yes**)	.63	1.2	.50	3.06
Alternatives explained (**Yes**)	.91	.97	.56	1.67
Age G (18–29)	.05	.43	.18	1.00
Age G (30–39)	.07	.43	.17	1.07
Age G (40–49)	.03[a]	.39	.16	.92
Type of Anesthesia (GA)	.00[a]	2.92	1.62	5.26
Constant	.72	1.38		

[a] Denotes variables with statistically significant association, we used enter mode.

The current study revealed that, the proportion of patients who are satisfied with the information delivered and decision they made during informed consent process was 70.30%.This finding seems consistent with studies conducted in Netherland, Israel, Addis Ababa (Ethiopia) and Rwanda as reported to be (80.8%, 80%, 62.1%, and 67.4% respectively [8–10,15]. However, the finding of present study was considerably higher than the studies conducted at Jimma (Ethiopia), Djibouti and Eritrea which revealed as 43%, 48.4% & 45% respectively [12,16,17]. The possible explanation for this discrepancy might be the difference in health care service delivery quality, study population, and study period.

In the current study, multivariable analysis indicated that, male gender, primary and secondary school education level, being rural in residency, age group (40–49 years) and type of anesthesia (GA) had statistically significant association with patients' satisfaction with informed consent process. This finding is partially inline to study done by Ahmad I. et al. who found that age as a significant factor to determine the satisfaction level and Afzal et al., 2014 reported that, modest negative correlation was found between patients' years of education and satisfaction, higher level of education was associated with lower level of patient satisfaction [10]. The reason could be due to higher expectation of those patients from the health professionals. El-Nasser et al. (2013) reported that, significant correlation between patient satisfaction and married patients [18].

In contrary to our findings, a study conducted at Jimma University medical center and Eritrea showed that patients who came from urban residence were two times more likely satisfied with informed consent process as compared to respondents who came from rural residence [9]. The possible reason for this difference might be due to the difference in socio-demographic characteristics of the study participants which affect the level of understanding of the given information, and the study period.

In an observational study performed at John Hopkins University Medical School reported that preoperative satisfaction with a decision to pursue surgery is associated with understanding after an informed consent discussion, indicating overall high satisfaction with the

decision. A patient's preoperative satisfaction with their decision was strongly associated with increased knowledge of the planned surgery. In this study, there were no significant differences between the satisfied and not satisfied groups with respect to age, race, education level, anxiety score, or health literacy. The study concluded that patients' knowledge and understanding of surgery are important components of a patients' satisfaction with their decision to proceed with pelvic floor surgery. Therefore, measuring patients' understanding after informed consent discussions may help clinicians to better manage preoperative expectations, increase patient satisfaction, and improve the informed consent process [16].

Another study in Saudi Arabia on 198 patients to assess the association between patient satisfaction and the quality of the informed consent process showed that patients with children were the most satisfied patient group. The most satisfied age group was those between 56 and 65 years of age with a mean score of 85.07. Disclosure and understanding score showed a strong positive relationship with the level of satisfaction using the Pearson correlation coefficient. Fifty percent (50%) of the participants were not informed about other therapeutic options. Of those who did not understand the form, 79.6% did not actually read it. Otherwise, there were no significant differences between the other variables of the patient satisfaction questionnaire score including patient educational level [9].

5. Strength and limitation of the study

This study is the first of its kind in assessing patients' satisfaction and associated factors with preoperative informed consent process in the study setting quantitatively. However, it did not address the perceptions of patients about the adequacy of the informed consent process qualitatively which could be helpful in designing evidence based intervention.

6. Conclusion

In this study, abouttwo-third of patients were satisfied with the preoperative informed consent process. Being male, low educational level, living in a rural area, and receiving general anesthesia were significantly associated with patients' satisfaction with the informed consent process. We recommend health care providers to implement the standard requirements of the informed consent process and strengthen patient safety practices to keep the ethical norm of the informed consent process. Periodic assessment of patients' satisfaction and associated factors would be also important for the sustainability of improved patient care and safety.

Funding

The study was funded by Debre Tabor University. The funder has no role in the design, implementation, analysis, and interpretation of the study.

Availability of data and materials

The data used and/or analyzed during the current study are available from the corresponding author on request.

Registration of research studies

The research was registered on the research registry platform with a unique identification number of researchregistry7853 with a registration link of https://www.researchregistry.com/browse-the-registry#home/

Consent for publication

Verbal and written informed consents were taken from participants for publication before the data collection. The participants were informed as they have the right to discontinue participation on the study at any time without any risk.

Provenance and peer review

Not commissioned, externally peer-reviewed.

Annex

Questionnaire

Objective: To assess Satisfaction and associated factors of Elective Surgical Patients with Preoperative Informed Consent Process in South Gondar Zone Hospitals, 2021.

General information

My Name is_____; I'm here on behalf of XY, College of HS, Department of Y. The aim of this questionnaire is to assess patients' satisfaction with preoperative informed consent process and associated factors among surgical patients in XX hospitals, 2021. Currently, there is scarce information regarding satisfaction of patients with preoperative informed consent process and factors influencing satisfaction in Ethiopia, particularly in South Gondar zone hospitals.

The aim of this study is therefore, to assess patients' satisfaction with preoperative informed consent and associated factors during informed consent process from patients' perspectives. So, your honest response on the following questions is invaluable in contributing for the improvement of obtaining preoperative informed consent which in turn improves patient satisfaction with the surgical service. Your participation is voluntary. Only anonymous data will be analyzed and we strictly keep confidentiality of participants. Participating or not participating on this study will not result in any harm or benefit to you. This interview could take a maximum of 30 min. We strongly value your honest response for the questions. If you feel or face any problem regarding your participation, you can contact the principal investigator Mr. TT by xxxxx or ttttttttt.

Do you agree to participate?

1. If the participant agrees to participate, go to the next page 2. If the participant cannot agree to participate on the study, got to the next participant

Name of the data collector: _____Date: _____ Sig. _____
Name of the supervisor: _____Date: _____ Sig. _____

Questionnaire

ID of the questionnaire _____

Part I: Socio-demographic characteristics of the study participants (please encircle the choice the participant).

S/N	Question Categories	Response Categories	Remark
101	Sex	1. Male 2. Female	
102	Age	… … …	
103	Marital status	a. Married b. Unmarried c. Divorced d. Widowed	
104	Literacy level	a. Can read and write b. Read only	

(*continued on next page*)

(*continued*)

S/N	Question Categories	Response Categories	Remark
		c. Cannot read and write	
105	Level of formal education	a. Primary level b. Secondary level c. College level d. Higher Education	
106	Residency	1. Rural 2. Urban	
107	Religion	1. Orthodox 2. Muslim 3. Protestant 4. Others … …	
108	Occupation	A. Farmer B. Merchant C. Teacher D. Health professional E. Student F. Others … …	
109	Are you residing in south Gondar zone?	1. Yes 2. No	
110	What is your illness?	… … … … …	
111	How many times you had operation	1. First 2. Second 3. Third 4. Fourth and above	
112	Type of surgery	1. Abdominal 2. Cesarean section 3. Gynecologic 4. Orthopedics 5. Urologic 6. ENT 7. Neurosurgery 8. Other…	
113	Type of Anesthesia	1. GA 2. SA	

Part 2: Questions to Assess Patient Satisfaction with Preoperative Informed Consent.

Give your response as 5 means completely satisfied, 4 = satisfied, 3 = neutral, 2 = dissatisfied and 1 = completely dissatisfied.

Patient satisfaction with ICP	*Response: encircle one*				
1. I am satisfied that I was adequately informed about the issues important to my decision	5	4	3	2	1
2. The decision I made was the best decision possible for me	5	4	3	2	1
3. I am satisfied that my decision was consistent with my personal values	5	4	3	2	1
4. I am satisfied with the explanation of my operation					
5. I expected to successfully carry out (or continue to carry out) the decision I made	5	4	3	2	1
6. I am informed the amount of time I stay in operation room	5	4	3	2	1
7. I am informed the number of days to stay in hospital	5	4	3	2	1
8. I am satisfied with the time given for me to decide	5	4	3	2	1
9. I am satisfied with the information given to me	5	4	3	2	1
10. I am satisfied with the informed consent process	5	4	3	2	1
11. The staffs were attentive to my needs	5	4	3	2	1
12. The staffs were acting according to my need	5	4	3	2	1

Declaration of competing interest

The authors declared that there is no conflict of interests.

Acknowledgment

We would like to appreciate Debre Tabor University, College of health sciences, Research and Community Service office for the financial and stationary support to conduct this study. We would like to thank the study participants and data collectors for their time and cooperation. We are also grateful to the individuals who have been supporting us in data clerk, analysis and write-up of this research anonymously.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.amsu.2022.104104.

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