Original Article

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Assessment of Surgery and Anesthesia Services and Patients' Attitude Towards Informed Consent: The Case of a Specialized and Comprehensive University Hospital in Northern Ethiopia

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Abstract:

Objective: Healthcare providers need to establish close relationships with patients planning to undergo major elective surgery as this helps produce positive patient outcomes. This study aimed at investigating surgery and anesthesia services and patients' attitude toward informed consent at Ayder comprehensive specialized university hospital, in Northern Ethiopia.

Material and Methods: A facility-based cross-sectional study was conducted in the biggest health facility in Northern Ethiopia. Four hundred ten patients with major elective surgery were recruited. A structured questionnaire was used to collect socio-demographics, anesthesia and surgery services and the attitude of patients toward informed consent. Descriptive results were presented using frequencies and tables. Regression analysis was accompanied by an odds ratio and a 95% confidence interval was run to identify factors associated with the outcome variable.

Results: Study participants' mean age was 36.1±11.7. Around two-thirds (71.7%) and one-fourth (26.6%) of the study participants were informed about their proposed surgical procedure and its possible complications, respectively. Two hundred ninety four (66.8%) and 88 (21.5%) were made aware of the type of anesthesia that was going to be administered and possible complications. About half (50.7%) had expressed a positive attitude towards informed consent. Rural residents have about twice (AOR=1.9; 95% CI: 1.06-2.73) higher odds of expressing a positive attitude towards the informed consent than their counterparts.

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Conclusion: The study revealed that the proportion of patients who were informed about their anesthesia-surgery services was moderate. Besides, patients' attitude toward informed consent was poor. The residence was a good predictor of positive patients' attitudes toward informed consent. Thus, healthcare professionals in the surgery department should establish clear and transparent communication with patients about surgery and anesthesia-related services.

Keywords: anesthesia, ayder, consent, patients, services, surgery

Introduction

Surgical care is a fundamental component of hospital services[1]. Major elective surgery, is a medical procedure planned ahead of time as it does not require emergency action[2-4]. Global estimates indicated that as high as eight million people undergo surgery in a year, and developing nations take the lion's share[5].

During the early period of anesthesia, it was being done in such a way that patients with were firmly fixed via rope or held down. This resulted in deaths even though the anesthesia service was in place. Moreover, septic conditions were causing unexpected deaths of patients undergoing surgery. As a result, the patients perceived level of fear of surgical procedures was raised up[3,5,6].

In Ethiopia, it is usual to notice that patients or a member of their family are shocked when a surgeon declares that a medical surgical procedure will be performed. Though anxiety and fear are expected events, patients simply remain highly worried even for simple surgeries.[7] Sometimes, they refuse to do the proposed procedure as they believe that it could be the end of their life and this hinders patients from having a discussion on possible alternatives and expectations with their surgeon[5,8].

In the last two decades, even though the Ethiopian government introduced different health service improvement strategies, less attention has been given to the most sensitive service areas such as surgery and anesthesia related services[6,9] though the patient has the right to obtain detailed information regarding his/her surgical procedure options. Healthcare providers are aware that every patient should be well informed about any proposed anesthesia and surgical procedure as this is a critical step[10-12]. In addition, it is practical that all surgical procedures require a written informed medical consent as it helps clarify probable outcomes plus legal aspects[13-15]. With all the above ideas in mind, pre-operative patient assessment is a vital task because it assists the anesthetist to know their client well which in turn helps choose the anesthesia of choice and the medical equipment necessary to conduct the proposed procedure[16,17].

Despite all the preceding realities, putting surgical patients at the center of the proposed anesthesia and surgical procedure is being ignored. Starting from the day the hospital has commenced rendering medical services, it remained unclear whether healthcare workers provide sufficient information on surgical procedures and anesthesia-related activities to their patients. Hence, this study was proposed to assess anesthesia, surgery services and patients' attitude toward informed consent in Ayder Comprehensive Specialized hospital.

Method and Materials

Study area, study period and design

This study was conducted from November 11 to February 30, 2020 in Ayder comprehensive specialized university hospital. This hospital is located in Mekelle, the largest city in Northern Ethiopia. The hospital has been serving around eight million people in Northern Ethiopia since 2008. Ayder comprehensive specialized university hospital, currently being used as a teaching hospital for the college of health sciences at Mekelle University, is the second largest hospital in Ethiopia and has a 500-bed capacity.

Currently, its operation department has seven active operation beds, 27 anesthetists 55 surgeons, and 53 nurses.

Study population and eligibility criteria

Sampled patients who had had major elective surgical procedures in the hospital were the study population. Patients with major elective surgery and aged 18 years and above were involved in the study. Emergency patients, those with minor surgery and mothers who came for cesarean section were excluded from participating in the study. Overall, four hundred ten patients with major elective surgery were selected using a systematic sampling method.

Study variables

Patients' attitude towards informed consent, dichotomized as 'positive attitude' and 'negative attitude' was the primary outcome variable of interest. Socio-demographic variables such as age, marital status, educational status, residence; previous history of operation and anesthesia and patient type were the independent variables of this study.

Outcome variable (patients' attitude towards the informed consent) measurement

The attitude of study participants towards informed consent was assessed using a tool which contained 16 positively and negatively worded items. Items were scored using a five-point scale reflecting the agreement rate on a five-point frequency scale (including a neutral category). The percentage of positive responses (strongly agree and disagree) for each item was calculated. Negatively worded items were reversed when computing percentages of positive responses. To make the analysis not complex, the outcome variable was dichotomized by collapsing its levels ('Strongly disagree', 'disagree' and 'neutral' are regarded as levels referring to negative attitude; Strongly agree and agree are regarded as levels referring to positive attitude).

Data collection tool

Data were collected using a structured questionnaire developed by considering the inputs taken from different studies[2,3,8,14,17]. The data collection tool was developed in English and was administered by the research assistants. For further enrichment of the structured questionnaire, pre-test was done at a different hospital two weeks ahead of the main study. The questionnaire was designed to address information on socio-demographic variables, anesthesia and surgery services, and patients' attitude towards informed consent.

Operational definition

Adult patient: Adult patient refers to those aged 18 years and above.

Patients' attitude: This refers to the outlook of patients in terms of the sixteen items/questions to the informed consent administered before the major elective surgery takes place.

Anesthesia and surgery services: This denotes the transfer of information to a patient with proposed major elective surgery and includes the anesthesia procedure and its complications, type of anesthesia to be administered, idea of anesthesiology, surgery procedure and its complications and the informed consent.

Healthcare providers: This refers to the surgeons, anesthetists and nurses in the operation room who perform the proposed anesthesia and surgery procedure of patients. The judgment matrix for the outcome and other measurable variables in this study is as follows: High >85; Moderate: 70-85; Low: <70

Data quality and analysis

Data quality was enhanced by training data collectors on the overall purpose of the study, the way the questionnaire has to be administered and issues of data confidentiality. The data collectors were nurses

holding a Bachelor of Science degree from a recognized higher education institution. At the end of each day's data collection activity, members of the research team took the responsibility to review 5% of the completed questionnaires and necessary feedback was given to the data collectors in the next morning.

The data was cleared, coded and entered into Epi Data version 3.5.1 and the SPSS version 21 software was used for the purpose of analysis. Data were described using frequency tables and narratives. Bivariate analysis of independent variables with the outcome variable was done and those with 'p-value' less than 0.05 were noted and analyzed using multivariable regression analysis. The magnitude of association was measured using an adjusted odds ratio and a 95% confidence interval.

Ethical considerations

The study was compliant to the Helsinki declaration on research ethics and written informed consent was taken from each patient. Furthermore, patients were made aware of the purpose of the study, anticipated benefits and risks and the data collection process. Patients' full right to refuse, withdraw or completely reject the study was also in place. In addition, patient information was kept confidential by removing the coding system from the questionnaire. Ethical clearance approval was secured from Mekelle University, College of Health Sciences' Institutional Review Board with a documented registration number of MU-IRB 1820/2020.

Results

Socio-demographic characteristics of the study's participants

A total of 410 patients with major elective surgery were recruited in this study. Of the 410 study participants, 160 (39.0%) were in the age category 26-35 year. Three-fourths (74.1%) of the study participants were married and almost all 382 (93.2%) were Orthodox Christians. In regards to educational status, 105 (25.6%) and 109 (26.6%) completed informal education and primary school, respectively. About two-fourths (51.0%) of the study subjects were rural area residents. More than three-fourths of the study subjects were farmers and employees,152 (37.1%) and 172 (42.0%), respectively. At least three-fourths (79%) were new patients (Table 1).

Table 1 Socio-demographic characteristics of study subjects with major elective surgery in Ayder comprehensive specialized university hospital, 2020 (n=410).

Variable	Frequency	Percent
Age in years		
18-25	72	17.6
26-35	160	39.0
36-45	106	25.9
>45	72	17.6
Marital status		
Married	304	74.1
Single	91	22.2
Others*	15	3.7
Religion		
Orthodox	382	93.2
Muslim	14	3.4
Others**	14	14
Educational status		
No formal education (can read and write)	105	25.6
Primary school	109	26.6
Secondary school	104	2.4
Tertiary (Diploma and above)	92	22.4
Residence		
Urban	201	49.0
Rural	209	51.0
Occupation		
Farmer	152	37.0
Employed	172	42.0
Others***	86	21.0
Payment status of patient		
Paying	134	32.7
Free	276	67.3
Visit status of patient		
New	324	79
Repeat	86	21
Previous history of surgery		
Yes	72	17.6
No	338	82.4

Other *Catholic and Protestant; **Divorced and widowed; ***House wife, student, merchant

Anesthesia and surgery services

Among the 410 study participants with major elective surgery, those who had had obstetrics and gynecology related operations 169 (41.2%) were the most, followed by general surgery 119 (29.0%). Around three-fourths (71.7%) of the study participants received a proper explanation about their proposed anesthesia and surgical procedure. One-fourth (26.6%) had an explanation about surgery related complications such as surgical site infections, 51 (12.4%) and bleeding, 45 (11.0%) were the commonly mentioned ones. Pre-anesthesia evaluation was done for 221 (53.9%) of the study subjects and clarification about the type of anesthesia to be administered was given to 274 (66.8%). Only 88 (21.5%) were informed of anesthesia related complications. With regard to anesthesia related complications, breathing problems were the major ones mentioned by 88 (10.7%) of the study subjects. Most of the study subjects (82.4%) did not have know-how on the preparation and optimization of surgical patients for surgery and anesthesia (Table 2).

Table 2 Anesthesia and surgery related services of patients with major elective surgery in Ayder comprehensive specialized university hospital, 2020 (n=410).

Variable	Frequency	Percent
Discipline of surgery		
Orthopedic	104	25.4
General	119	29.0
Obstetrics and gynecology	169	41.2
Ear, Neck and Throat (ENT)	18	4.4
Did health care professional explained to you about the proposed surgery?		
Yes	294	71.7
No	116	28.3
Did health care professionals explain surgery related complication?		
Yes	109	26.6
No	301	73.4
What type of surgery related complications were explained?		
Bleeding	45	11.0
Surgical site infection	51	12.4
Others	13	3.1
Who explained the surgery related complications?		
Surgeon	106	25.9
Other	4	1.0
Did any health care provider perform pre-anesthesia evaluation?		
Yes	221	53.9
No	189	46.1
Did any health care provider explain type of anesthesia to be used?		
Yes	274	66.8
No	136	33.2
Did health care provider explain anesthesia related complications that might occur?		
Yes	88	21.5
No	322	78.5
What anesthesia related complications were you told?		
Pain	13	3.2
Nausea and vomiting	31	7.6
Breathing problem	44	10.7
Who explained anesthesia related complications?		
Surgeon	62	15.1
Anesthesia	26	6.3
Which ideas of anesthesiology do you know?		
Making area numb	7	1.7
Putting to sleep	10	2.4
Making unconscious	55	13.4
No idea	338	82.4

Patient's attitude towards the informed consent

Of the 410 study subjects enrolled in this study, 304 (98.5%) indicated that dealing with a consent form was just a formality and for almost all (99.6%), signing the consent form was perceived as a legal requirement to undergo surgery. Only 138 (33.7%) believe that the consent form removes patients' rights to compensation. A majority (92.9%) indicated their agreement that the consent form confirms that the proposed operation has been explained to the patient. One hundred forty-two (34.7%) believe that patients do not have the right to change their minds after written informed consent was taken by the healthcare provider. At least one-fourth (29.0%) of the study participants have the belief that what has been written in the consent form is not put in simple and clear language and enough time was not given to clarify questions for 244 (59.5%) of the patients. About half (50.7%) indicated a positive attitude toward informed consent (Table 3).

The bivariate analysis showed that the variables age, residence and occupation were correlated (p-value< 0.005) with patients' attitudes toward informed consent (Table 4).

Table 3 Patients' attitude towards the informed consent at Ayder comprehensive specialized university hospital, 2020 (n=410).

Variable	Attitude, n (%)				
	Positive attitude		Negative attitude		
	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
Consent form was just a formality	149 (36.3)	255 (62.2)	3 (0.7)	3 (0.7)	0 (0.0)
Signing the consent form is a legal requirement	147 (35.9)	261 (63.7)	0 (0.0)	2 (0.5)	0 (0.0)
Consent form removes your right to compensation	11 (2.7)	127 (31.0)	22 (5.4)	223 (54.4)	27 (6.6)
Consent form protects the doctor against being sued	35 (8.5)	201 (49.0)	29 (7.1)	139 (33.9)	6 (1.5)
Consent protects the patient's rights	45 (11.0)	323 (78.8)	19 (4.6)	23 (5.6)	0 (0.0)
Consent form confirms that operation has been explained	74 (18.0)	307 (74.9)	11(2.7)	18 (4.4)	0 (0.0)
Consent is a must for undergoing operative surgery	116 (28.3)	264 (64.4)	5 (1.2)	25 (6.1)	0 (0.0)
It is the right of the patient to change mind after signing the consent form	26 (6.3)	210 (51.2)	32 (7.8)	118 (28.8)	24 (5.9)
Relatives can sign the consent form on behalf of you	47 (11.5)	306 (74.6)	10 (2.4)	47 (11.5)	0 (0.0)
Operations cannot take place without informed consent	119 (29.0)	227 (55.4)	5 (1.2)	59 (14.4)	0 (0.0)
Information on the consent form was understood and written in simple and clear language	23 (5.6)	222 (54.1)	46 (11.2)	118 (28.8)	1 (0.2)
Questions were clarified	15 (3.7)	260 (63.4)	25 (6.1)	110 (26.8)	0 (0.0)
There was enough time to clarify questions	8 (2.0)	118 (28.8)	40 (9.8)	199 (48.5)	45 (11.0)
I felt afraid of the professional who communicated me about the informed consent	6 (1.5)	257 (62.7)	20 (4.9)	127 (31.0)	0 (0.0)
I received a copy of the informed consent form	7 (1.7)	233 (56.8)	0 (0.0)	151 (36.8)	19 (4.6)
Only signature was requested without explanation of the consent form	52 (12.7)	156 (38.0)	43 (10.5)	144 (35.1)	15 (3.7)

Table 4 Patients' attitude towards the informant consent versus socio-demographic variables, 2021 (n=410)

Variables	Patients' attitude towards health care workers management approach of the informed consent form, n (row %)		p-value
	Positive attitude n (%)	Negative attitude n (%)	
Age in years			0.001
18-25 (ref)	36 (50.0)	36 (50.0)	
26-35	96 (60.0)	64 (40.0)	
36-45	49 (46.2)	57 (53.8)	
>45	21 (30.6)	51 (69.4)	
Marital status			0.370
Married	158 (51.9)	146 (48.1)	
Single	45 (49.5)	46 (50.5)	
Others*	5 (33.3)	10 (66.7)	
Religion			0.003
Orthodox	202 (71.6)	180 (28.4)	
Others**	6 (21.4)	22 (78.6)	
Educational status			0.459
No formal education	64 (61.0)	41 (39.0)	
Primary education	59 (54.1)	50 (45.9)	
Secondary education	42 (40.4)	62 (59.6)	
Tertiary education	43 (46.7)	49 (53.3)	
Residence			0.000
Urban	80 (39.8)	121 (60.2)	
Rural	128 (61.2)	81 (38.8)	
Occupation			0.030
Farmer	92 (60.5)	60 (39.5)	
Employed	83 (48.3)	89 (51.7)	
Others***	33 (38.4)	53 (61.6)	
Payment status of patient			0.436
Paying	64 (47.8)	70 (52.2)	
Free	144 (52.2)	132 (47.8)	
Visit status of patient			0.565
New	162 (50.0)	162 (50.0)	
Repeat	46 (53.5)	40 (46.5)	
Previous history of surgery			0.902
Yes	37 (51.4)	35 (48.6)	
No	171 (50.6)	167 (49.4)	

Other *Catholic and protestant; **Divorced and widowed; ***House wife, student, merchant

To control confounders, the three variables were then taken to the last model, the multivariable analysis. In the multivariable analysis, age and residence were found to be independent predictors of positive attitudes toward informed consent. Rural residents had about twice (AOR=1.98; 95% CI: 1.06-2.73) more chance of reflecting a positive attitude towards informed consent than urban residents. Subjects older than 45 years had lower odds (AOR=0.45; 95% CI: 0.20-0.99) of producing positive attitudes towards the informed consent than those aged 18-25 years (Table 5).

Table 5 Multivariable analysis of socio-demographic and related variables with the dependent variable 'Patients' attitude towards health care workers management approach of the informant consent', 2021 (n=410)

Variables	Patients' attitude towards health care workers management approach of the informant consent, n (row %)		COR (95% CI)	AOR (95% CI)
	Positive attitude n (%)	Negative attitude n (%)		
Age in years				
18-25	36 (98.8)	36 (8.8)	1	1
26-35	96 (23.4)	64 (15.7)	1.500 [0.857-2.626]	1.398 [0.768-2.543]
36-45	49 (12.0)	57 (13.6)	0.860 [0.472-1.565]	0.820 [0.432-1.557]
>45	21 (5.1)	51 (12.4)	0.412 [0.207-0.818]*	0.445 [0.199-0.997]**
Marital status				
Married	158 (51.9)	146 (48.1)	1	
Single	45 (49.5)	46 (50.5)	1.106 [0.692-1.767]	
Others*	5 (33.3)	10 (66.7)	2.164 [0.723-6.482]	
Residence				
Urban	121(29.5)	80 (19.5)	1	1
Rural	81(19.8)	128 (31.2)	2.39 [1.281-3.32]*	1.98 [1.06-2.73]**
Occupation				
Farmer	60 (14.6)	92 (22.4)	1	
Employed	89 (21.7)	83 (20.2)	1.644 [1.057-2.558]	
Others*	53 (13.0)	33 (8.1)	2.463 [1.431-4.238]	
Educational status				
No formal education	64 (61.0)	41 (39.0)	1	1
Primary education	59 (54.1)	50 (45.9)	1.323 [0.768-2.279]	0.804 [0.426-1.520]
Secondary education	42 (40.4)	62 (59.6)	2.304 [1.324-4.011]*	0.938 [0.448-1.966]
Tertiary education	43 (46.7)	49 (53.3)	1.779 [1.009-3.136]*	0.544 [0.243-1.220]
Payment status of patient				
Paying	64 (47.8)	70 (52.2)	1	
Free	144 (52.2)	132 (47.8)	0.838 [0.554-1.267]	
Visit status of patient				
New	162 (50.0)	162 (50.0)	1	
Repeat	46 (53.5)	40 (46.5)	0.870 [0.540-1.400]	
Previous history of anesthesia and surgery				
Yes	37 (51.4)	35 (48.6)	1	
No	171 (50.6)	167 (49.4)	1.032 [0.621-1.717]	

Other *Catholic and Protestant; **Divorced and widowed; ***House wife, student, merchant
COR=crude odds ratio, AOR=adjusted odds ratio, CI=confidence interval

Discussion

Our study, which included 410 patients who underwent elective major surgery at Ayder comprehensive specialized university hospital, in Northern Ethiopia showed that 294 (71.7%) of the study subjects were made aware of their proposed anesthesia and surgery procedure. This finding is lower than the finding done in Pakistan[18] where the score is 87.7%. The reason for the inconsistency could be due to the difference in the health care system of the two countries in that Pakistan, a country whose developmental progress is far better than Ethiopia, might have introduced patient-centered care in its health service provision. However, the finding from the current study is better than that of the Nigerian study[19] where only 46.25% got their procedure explained. This could probably be due to the fact that the Nigerian study was conducted at least a

decade ago during which the Nigerian health system's focus on patient-centered care was far from the recommended standards.

In regards to surgery-related complications, this study indicated that only 26.6% of the study subjects who underwent major elective surgery were informed of the possible complications of their procedure. This is a much higher score as compared to the Pakistani[18] score in which only 3.4% of the study subjects got explanation about the possible risks and complications of their proposed surgical procedure.

This study showed that 53.9%, 66.8% and 21.5% of study subjects were briefed about the anesthesia procedure, type of anesthesia to be used and complications associated with it, respectively. This result is not in line with the result from a Colombian study[20] where the finding was 9.1%, 23.2% and 22.7%, respectively. Such deviations could indicate that the role of anesthesia professionals is masked by the surgeons and that the perception of the community about the role of anesthesiologists is poor. Moreover, as per the study results from Brazil[21], 40.9% were well aware of the idea of anesthesiology, unlike the current study in which only 17.6% have the necessary awareness which implies that the patient-anesthesia professional relationship is poor.

In relation to patients' attitudes towards the written informed consent taken from the study subjects, this study showed 50.7% of the study subjects reflected positive attitudes towards the informed consent administered to the patient with major elective surgery or to its legal guardian. Moreover, 59.7% and 67.1% of the study participants declared that the information on the written informed consent was clear and further doubts were clarified, respectively. Such findings are in line with the findings from Brazil and Uganda[22,23]. But, an Italian study[24] indicated that 90.9% and 65.6% of the patients claimed that written informed consent presented to them for signature was written in a clear language and was accompanied by proper explanations, respectively. The higher scores in the Italian study could go to the stable and advanced health care delivery system in the country and due attention is given to health ethics by the professionals in the surgery and anesthesia departments. In addition, the Italian health care system gives due emphasis to the physician-patient interaction which encourages patients to be concerned for their rights to get the required information about their proposed anesthesia and surgical procedure.

The independent variable 'residence' was found to have a statistically significant association with patients' attitudes toward informed consent. Surgical patients from rural areas have about twice as more chance of expressing a positive attitude than their counterparts. This implies that the principle of equity is in place and that the health care delivery system is giving more emphasis to patients from rural areas as it is believed that they deserve more interaction with the health care provider due to their lower educational achievement and therefore lower information about the health care delivery system of the country, Ethiopia.

Subjects older than 45 years had lower odds of expressing positive attitudes towards informed consent than those aged 25 years and below. This could really indicate that younger patients are good at protecting their rights to information, that is, younger patients' desire to establish a smooth relationship with healthcare providers is good enough.

Clinical implication and recommendation

The finding of this study pinpointed that those healthcare professionals in the operation room are poor at describing anesthesia and surgery-related complications. This could imply that healthcare professionals themselves may have fear that if patients are informed of the complications, they will experience anxiety and disturbance. Moreover, the low score of patients' positive attitude towards

informed consent could mean they communicate poorly and that could result in negative outcomes.

Strengths and limitation

The sample size is taken, which we believe is too much for a single health facility, is the strength of this study. Our finding showed that having a rural residency is a statistically supported predictor of rural resident surgical patients' positive attitude toward informed consent. This could suggest that surgical patients from the rural area could be afraid not to be implicated and became positive. Another limitation of this study is that the knowledge surgical patients towards anesthesia and surgery services, and attitudes toward informed consent were not assessed.

Conclusion

The proportion of patients who were informed of their surgery and anesthesia procedure and related complications was judged as 'moderate' and 'low.' Besides, surgical patients' attitude toward written informed consent is low. Residence of patients is found to be an independent predictor of patients 'positive attitudes toward informed consent. Thus, establishing a good surgical patient–healthcare provider interaction which enhances symmetrical information flow between the two stakeholders should be put in place.

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