

Knowledge and perception of surgical informed consent and associated factors among adult surgical patients in Gondar University Comprehensive and Specialized Hospital, Ethiopia

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Abstract

Introduction: there are many studies regarding informed consent in clinical trials, however, only few studies have assessed adult patient's knowledge and perception of surgical informed consent in clinical practice. Therefore, the purpose of this study was to assess knowledge and perception of surgical informed consent and associated factors among adult surgical patients in Gondar University Comprehensive and Specialized Hospital, Northwest Ethiopia, 2018

Methods: responses from 312 postoperative adult surgical patients was taken using pretested structured interviewer administered questionnaires for one month.

Result: there were a total of 302 respondents, (40% males and 60% females). More than half, 178 (59%) were in age groups of 31-43 years. Of the study participants, 193(63.91%) of them had poor knowledge and 155(51.3%) had poor perception about surgical informed consent in the study area. On the other hand, living in urban, being higher educational status and having past history of surgery were positively associated with good knowledge of patients towards surgical informed consent while being urban, higher education, being ophthalmologic patient & receiving consent from physician were positively associated with perception of patients regarding surgical informed consent.

Conclusion: majority of the study participants had limited knowledge and poor perception about surgical informed consent. Adequate preoperative health education for patients should improve patients' knowledge and perception.

Keywords: Gondar University Comprehensive Specialized Hospital, Knowledge, patient perception, surgical informed consent

Background

Surgical informed consent is the process whereby patients are informed of all the necessary information about health care and subsequent treatment plans, risk, and alternatives. An informed consent is built by competent patient to make decision about his/her surgical procedure with enough information which is clear and understandable and valid unless the patient's disease has not been changed, and or no new findings that may change the planned procedure are revealed(1). Whatever it is, the patient has still full right to refuse the treatment, called informed refusal, but the reality is not true in clinical practice (2, 3).

Informed consent is an ethical and legal obligation for the physicians to communicate to the patient and results in the patient's agreement to undergo a medical procedure. It is taken as a safety tool for both patient and the surgical team and Informed consent originated from legal and ethical principles ;this is done by improving patients' knowledge and perception about informed consent process that enables the patient to decide on their surgical procedure freely and intentionally without enforcement(4).

However, now a day (starting from 20th Century) informed consent had been recognized as an issue in surgical health care services (5). Evidence shows that Patients often feel powerless and vulnerable and it is a proven fact that patient's awareness of legal and ethical issues related to the consent process is often limited. The informed consent process should be seen as an invitation to him to participate in his health care decisions(6).

Patients' perceptions of what constitutes informed consent are diverse and many patients undergo surgery without knowledge of even the identity of the surgeon or the reason for the surgery. Based on this literature poor knowledge and perception about surgical informed consent process leads to poor patients' participation in informed decision making leads to loss of patient autonomy(7).

Signing a surgical informed consent has many benefits including increase patient cooperation, protects patient's autonomy thus minimizing surgical complications and increasing the chances of successful defense against possible medico-legal cases (7-9). However, a systemic review on surgical informed consent revealed that substantial weaknesses and omissions of SIC are evident and the current elements of the SIC process are largely neglected in daily practice. Based on this evidence preconditions are ignored, information is incomplete, and the consent itself is not an accurate reflection of the patient's

authorization; in the media surgeons are blamed for making mistakes and people are encouraged to “sue for every fault their surgeons make,” leading to an increase in medico legal claims. However, it should be realized that most legal cases are not due to failures in treatment but due to failure in communication during consent before surgery is undertaken(10).

Some literatures stated that patients had poor knowledge and perception about surgical informed consent process and they have to be informed of the reason for operation, success of the operation, alternatives of the treatment, what would happen during the operation, for how much the operation would take, precautions after the operation and information on post treatment/post-operative/ care and free and willingness of the overall consent before consent is signed (11, 12).

Lack of patient’s knowledge and poor perception on surgical informed consent compromise shared decision making between the physician and the patient, increase the likelihood of a patient safety incident, patient anxiety and generally result in postoperative patient dissatisfaction(13).

Literature shows that patients with no formal education are unable to understand the information provided during informed consent process this indicates the presence of gap in health education during consent process(4). Even though evidence suggested that every surgical patient should be informed by the surgeon about the proposed surgery prior to obtaining consent form, but still patients are not aware and the reality is not true in clinical set up especially in developing countries(14).

Therefore, informed consent for surgery is expected to be more detailed as compared to general medical care and the appropriate pre-operative counselling during informed consent process fills the gap of patients’ knowledge & perception towards consent and this will not only help to strengthen the patient-doctor relationship but also protect the doctor against medico-legal risks(8, 15).

According to Ethiopian guidelines developed in Addis Ababa in April, 2016 of Medical Ethics for doctors in Ethiopia, under article 26, recommends that “It is the duty of the doctor to inform the patient about the treatment (Including surgical procedures), she/he intends to carry out. The doctor is always obliged to obtain a written consent of the patient before carrying out procedures. In the case of minors or persons who are unconscious or of unsound mind, the necessary consent should be obtained from parents or legal guardians, if there is no other legal provision”(16), but in practice, patients are not well informed about their overall treatments as result of suspicion of health care workers about patients against consent if their treatment risks were informed as result of poor knowledge and perception about informed consent.

In the study area there is poor perception and limited knowledge regarding surgical informed consent among patients, during the clinical practice, that patients sign the informed consent as a medical obligation for surgery and thought that the decision making regarding their treatment is the physician deal rather than their own rights.

Although studies showed that an informed consent during a surgical procedure leads to positive postoperative outcome, but to the researcher, the patient’s knowledge and perception and factors towards the surgical informed consent is not known in Ethiopia. Therefore, this study will assess patient’s knowledge and perception towards informed consent for surgical procedures in Gondar University Referral comprehensive and specialized hospital.

Methods

The study was carried out in Gondar University Comprehensive Specialized Hospital, found in Gondar, Ethiopia. Gondar is one of the ancient city in Ethiopia, located 750 km Northwest of Addis Ababa. According to the 2007 Ethiopian census report, it has a total population of 206,987 and more than half (108,902) of them were female(31). The town is divided in to 12 administrative areas; there are two hospitals (1 referral and 1 defense hospital), eight health centers and one NGO clinic. The study was conducted at Gondar University Comprehensive and Specialized Hospital (GUCSH) (surgical ward, orthopedics ward, trauma unit, ophthalmology unit, Fistula center and Gynecologic (Maternity) wards). The Hospital is a referral and teaching hospital found in Gondar town, Ethiopia.

The source population were all adult surgical patients in Gondar University Comprehensive Specialized Hospital, Northwest Ethiopia, 2018. While the study population were all adult post-surgical patients admitted in Gondar University Comprehensive and Specialized Hospital surgery wards during the data collection period.

All adult post-surgical patients available in GUCSH surgery wards during the study period was included in the study; and patients who are not fully conscious at a time of data collection and patients with post-operative complication at a time of data collection were excluded from the study.

The actual sample size for the study was determined using single population proportion formula taking assumption 50% proportion to maximize the sample size (and since this study is new and the first time in the area even in Ethiopia); with 95% confidence interval (1.96); $\alpha=0.05$;5% marginal of error (5%).

- $n = (Z_{\alpha/2})^2 \cdot p(1-p)$; Therefore, $n=384$

$$d^2$$

Reports on annual surgical operations of the institution on Gondar University Comprehensive and specialized Hospital (GUCSH) information and statistics center shows that as a summary 4,632 surgeries were done per year in the year of 2017. When this value evenly distributed in months, on average **1,110 (N)** surgical patients undergone major surgery in the Hospital within one month.

As $N=1,110$, which is $<10,000$, then we could apply reduction formula, $Nf=n/[1+(n/N)] = nf = 384 / (1+384/1,110) = 284$; by adding 10%(28) non-response rate the final sample size became **312**.

Stratified sampling technique was used as sampling strategy and the study participants were divided into different strata according to the surgical specialties. By allocating the sample size proportionally in each surgery wards of GUCSH (surgical, orthopedic, obstetrics and gynecology, Fistula, ophthalmology and trauma unit), a Systematic random sampling technique was used as sampling strategy to collect the study participants in each ward by calculating a constant 'k' skip interval. Therefore, every surgical patient would have equal chance of being selected in the study

Good knowledge about surgical informed consent if s/he answered knowledge questions with a median of $\geq 12.5\%$ otherwise having poor knowledge(2, 32); good perception about surgical informed consent if s/he answers perception questions with a mean score $\geq 62.04\%$ and otherwise they were considered as having poor perception towards surgical informed consent(2, 32).

A pretested structured interviewer administered questionnaires adapted from Ahmed S. et al in Egypt (32) was used as a standard tool. The reliability coefficient (Cronbach alpha) analysis of the research instrument was calculated to keep internal consistency (for knowledge=0.82; perception=0.79)

The questionnaire has 5 sections: -

Section A: sociodemographic data: which includes the personal descriptive data of participations.

Section B: - Knowledge questions. The response was rated on yes/No question whereby the one who answers yes was considered as correct and had good knowledge otherwise poor knowledge. The overall score was calculated in percentage.

Section C: - Perception Questions, the response was rated on a Likert scale whereby the most favorable answer gets a higher score and less favorable a lower score and the overall score was calculated in percentage. The minimum possible total score for level of perception will be 10 and the maximum possible score is 40.

Section D: -Clinical related factor questions

Section E: -information and health care worker related factors

Data was collected by using a pretested structured interviewer administered questionnaire in surgical ward, orthopedics ward, trauma ward, Gynecologic & obstetrics ward, Fistula center and ophthalmology unit at GUCSH. A total of three clinical Nurses were participated for data collection in the study and was supervised by one Bsc nurse.

To ensure quality of data, the questionnaire was prepared in English and translate in to Amharic and then back to English to maintain consistency. To achieve the reliability, a closed ended questionnaire with the same words, same structure and same format for each participant, was used to ensure consistency and accuracy of data. Two-day training was given for data collectors and supervisor on data collection technique. Pretest was done on 5%(16) of sample size outside study area at Debarq Hospital. The data collection process was supervised by supervisor and principal investigator daily.

Data was cleaned manually, entered by EPI INFO version 7 and was exported to SPSS version 20 for further analysis. The result was expressed by number, percentage, mean and standard deviation. Descriptive statistics were presented by table, graph (pie chart) and text. Bivariable analysis was used primarily to check which variable have association with the dependent variable and variables found to have p value of < 0.2 was entered into multivariable analysis for controlling the possible effects of confounders. The adjusted Odds ratios together with their 95% CI and p-value were computed to measure the association b/n the dependent and independent variables. Finally, in multivariable analysis, a p-value ≤ 0.05 was considered as statistically significant in this study.

Ethical clearance was obtained from school of nursing, College of medicine and Health Sciences, and University of Gondar ethical review committee. Permission letter was obtained from Gondar University Comprehensive and Specialized Hospital. The purpose and the importance of the study were explained and informed consent was secured.

Confidentiality was maintained at all level of the study. Participants' involvement in the study were on voluntary bases and that they could withdraw at any time if they want. All the information given by the respondents was used for research purposes only.

Results

A total of 312 post-surgical patients were involved in this study with 302(97%) response rate. Out of the total of respondents, more than half, 181(60%), of them were females. On the other hand, 178 (59%) were 31-43 years and only 44(15%) of patients were age ≥ 57 years. One hundred and ninety-nine (65.9%) of patients were married and 61(20.2%) were single. more than half, 157(52%) were came from urban area. Regarding the educational status of the study participants, 138(45.7%) of patients were illiterates (Table 1)

When we see knowledge of study participants, 238(78.8%) of them responded that signing an informed consent is a legal requirement for every surgical procedure. On the other hand, 230(76.2%) of patients responded that signing surgical informed consent means waving their rights to any compensation. Similarly, 245(81.1%) of the study participants responded that they have no right to change their mind after signing the consent. (Table2)

In general, 193(64%) of patients had poor knowledge regarding surgical informed consent with the median of $12.5\% \pm 25$ IQR, mean 19% and SD of 26.071%

According to these study, 130(43%) of patients perceived that consent form was important to them; 80(26.5%) strongly disagree that the consent form made clear what was going to happen to them while 73(24.2%) strongly agree. One hundred and sixteen (38.4%) of participants strongly disagreed that consent form made them aware of the risk of the operation whereas 70(23.2%) strongly agreed as they were aware of risk of their operation. The result also showed that 89(29.5%) patients strongly disagreed that consent form made their wishes known.

Almost more than half, 178(58.9%), of patients perceived that consent form gave the doctors control over what they are going to do. On the other hand, 174(47.7%) of them perceived as signing a consent did not as such time consuming process to be prepared for surgery. (Table3)

In general, almost more than half 155(51.32%) of patients had Poor perception about surgical informed consent with a median of 60% and mean score $62.04\% \pm 17.83\%$ of SD. The minimum & maximum percentage score was 25% and 100% respectively.

Bivariable and Multivariable analysis

Bivariable and Multivariable analysis were done between knowledge of adult surgical patients about surgical informed consent and independent variables. Bivariable logistic regression was performed to assess the association of each independent variable with knowledge of surgical informed consent. Variables that have $p < 0.2$ were added to multivariable regression model to control the effect of confounding.

Applying Bivariable analysis, the result of these finding showed that 7 variables (marital status, residence, education, occupation, past surgical history of the participants, source of information, & time given for explaining consent process) remains associated with knowledge of surgical informed consent. In the multivariable analysis, by adjusting variables, a total of three variables (residence, educational status of the participant and past surgical history of the patient) were significantly associated with knowledge of adult surgical patients towards surgical informed consent. Surgical patients who were at educational status of college and above were four times [AOR=4.25 ; (95%CI=1.06, 5.10); $p=0.042$] more likely knowledgeable than illiterates. On the other hand, participants at preparatory educational level were nearly four times [AOR=3.76; 95%CI (1.94, 5.04); $p=0.039$] more knowledgeable as compared to illiterates (Table 4).

Regarding factors which affects perception of post-surgical patients towards surgical informed consent, applying a Bivariable analysis, (9 variables): residence, education, occupation, type of surgery, past surgical history, having information about SIC, from where the participant gets information, from whom they had taken surgical consent process, and the time given for consent process were associated with perception of surgical informed consent at $p < 0.2$. When these variables were adjusted by using a multivariable analysis, to avoid the confounding effect of variables, a total of four variables (residence, educational status of patients, type of surgery and HCWs who gives consent process) were statistically associated with the outcome variable. Based on these result, study participants living in urban area were two times [AOR=2.07; (95%CI (1.06, 4.04); $p=0.033$] more likely having Good perception than rural dwellers. (Table 5)

A result of this study's binary logistic regression analysis also showed that a study participant who had completed a secondary (grades 9-10) school had two times [AOR=2.06 ; (95% CI (1.70, 3.95); $p=0.004$] more likely good perception about SIC than illiterate participants. On the other hand, patients having an educational status of college and above level were almost nine [AOR=8.9 ; (95%CI (8.25, 9.82); $p=0.000$] times more likely have good perception than illiterates.

The odds of having good perception regarding surgical informed in orthopedic patients were decreased by 91% [AOR=0.09 ; (0.03, 0.3); $p=0.000$] as compared to ophthalmologic patients. Similarly, the odds of having good perception about surgical informed consent(SIC) in patients who had taken SIC process from intern practitioners were decreased by 55% [AOR=0.45; (95%CI (0.26,0.96); $p=0.024$] than patients received from a senior physician. (Table 5)

Discussion

This study was done to assess knowledge and perception of surgical informed consent and associated factors among adult post-surgical patients in Gondar University Comprehensive and Specialized Hospital, Northwest Ethiopia. Knowing gap of knowledge and perception about surgical informed consent and then identifying those factors that affect will have its own contribution to strength decision making ability of the patient in surgical informed consent regarding their surgical procedure.

In this study, we demonstrated that 36.1% (95% CI (30.8, 41.4)) of post-surgical patients had good knowledge about surgical informed consent. This finding was higher than the study done in Cairo University Hospital, Egypt where 27.3% of surgical patients were knowledgeable about surgical informed consent(17). This variation might be differences in educational status

of the study participants that unlike this study majority of participants (61%) in the above study were illiterate. Our finding was also different from the study done in Rwanda by Mbonera F. et al(15) such that eighty-three percent (83%) had low knowledge, 12% had moderate and only 5% had high level of knowledge towards informed consent in surgical procedures. The possible explanation for this difference might be the difference in study setting and sample size (147) difference. This result was lower than study's done in Nigeria by Sulaiman A. et al(2), where knowledge of patients about surgical informed consent in Nigeria was high (97.5%). The reason behind these difference might be difference in study setting, population difference and majority of the respondents (89.4%) had formal education in the above study.

Findings of this result was also different from the studies done in Croatia, by Vucemilo L. et al(20) and England studied by Akkad A. et al(13), in which half of study population were knowledgeable about surgical informed consent. The reason for this difference might be sample size (3329) and all study participants were literate in Vucemilo's study, sociodemographic variation might also be a possible explanation for this difference with studies at England; in India by Singh A. et al(14) where the overall understanding was poor in 17%, unsatisfactory in 33%, satisfactory in 32%, and good in 18% of the patients. This difference might be as a result of differences in sociodemographic characteristics (educational status 20% illiterate) as compared to our study setting) and or variation in sample size (n=582). On the other hand, the findings of this study regarding knowledge of patients about surgical informed consent was higher than the study done in south Africa by Kalala T. et al(6) such that the general knowledge of patients about components of a valid informed consent was only 8%. Time might be the possible explanation for these difference as it was studied in 2008 and sample size (98)

During evaluation of perception of patients towards surgical informed consent, about half of post-surgical patients, 48.68% (95% CI (47.7, 54.6)), had good perception about surgical informed consent. this result is different from the study in Rwanda by Mbonera F. et al(15)., where 23% had low perception, 50% moderate and 31% of them had high level of perception towards informed consent in surgical procedures. The possible explanation for this difference might be differences in sociodemographic factors, the models they used (ordinal logistic) and sample size difference (147). On the other hand, this was different from the study reported by Sulaiman. Et al(2) in Nigerian Obstetric patients in which there was documented as high perception of patients about surgical informed consent in Amino kano teaching Hospital. The difference might be sampling technique difference which was non-probability type of purposive sampling. Unlike this study, most of the study participants (89.4%) were educated and this might also be another thing that makes perception difference in two study areas. On the other hand, the result of this finding was consistent with studies done in Egypt, by Ahmed S. et al(32), and England by Akkad A. et al(13). Stated that patients in their study areas had a great deal of poor perceptions regarding informed consent in surgical procedures.

Regarding perception of patients towards surgical informed consent, the result of this study showed that about more than half, 59.6% (95% CI= (59.4, 66.3), of post-surgical patients perceived as consent form did not made them aware of the risk of the operation during consent process. When we compare this result with other studies, it was consistent with finds by Ahmed S. et al in Egypt(32) where 62.66% of them did not be informed risk of their operation; different from studies in Nigeria by Atanda O.et al.(18)(21.3%) and in England by Akkad A. et al.(13)(12%) of them were perceived as risk of their operation couldn't be informed during informed consent process. This implies that patients are not well informed about their operation before surgery in the study area.

Findings of this result reported that the residence of study participants was significantly associated with knowledge of surgical patients about surgical informed consent. Based on this, the odds of having good knowledge towards surgical informed consent in urban patients were 1.52 [95%CI (1.03, 3.10); p=0.016] times more likely than urban residents. This is in line with a study conducted in Nigeria by Ezeome E. et al(27), confirmed that patients came from urban areas had good knowledge about surgical informed consent and in practicing consent in surgery than rural. But this result is different from the study done in Saudi Arabia in Sohag University by EL-Nasser A. et al(11) such that living in urban or rural had no any significance (p=0.136) in patient's preoperative satisfaction and knowledge of patients regarding surgical informed consent. This difference might be sample size difference (199) and study time (2011).

Regarding the educational status of patients, the study confirmed that there was a significant association between knowledge of adult surgical patients regarding informed consent and educational level of the participants. As educational level of participants increased, so does their knowledge about surgical informed consent. Patients with an educational level of college and above were four times [AOR=4.25;95%CI (1.06,5.10); p=0.042] more likely knowledgeable than illiterate patients. (Table 5)

This is supported by findings in: - Nigeria by Sulaiman A. et al.(2) and by Agu K et al.(4) stated that educated patients are conscious of their rights and are more likely to understand consent process in surgical procedures than non-educated; in Rwanda by Mbonera F. et al(15) it was confirmed that level of education influences significantly the knowledge of patients towards informed consent for surgical procedures; in south Africa by Minnies D. et al(33) and in Melendo M. et al(24) stated as the more educated a patient, the more likely s/he was to link informed consent to the understanding of procedures during a consent process.

On the other hand, this finding was different from studies done:- in India by Rajesh A. et al.(9) and America by Fink A. et al(26) reported as looking at the values the level of understanding is not different between those who had a primary level of education and those who did not had formal education, but it was significantly better in those who had higher education. The justification for this difference might be sample size (555). A study in Saudi Arabia ,by EL-Nasser,(11) showed that education was not a predictor variable for knowledge of patients towards SIC. The possible explanation might be difference in educational status of study participants such that 62.8% of patients were illiterate in Saudi, while 45.7% in this study

This study also confirmed that there is a significant association between knowledge and past surgical history of patients. Based on this result, patients having past surgical history were nearly two times [AOR=2.2; 95%CI (1.39, 6.42); p=0.005] more likely to have good knowledge than those who didn't have. The reason behind might be due to preoperative health education in their previous surgery. This result was different from study by Kalala Tshimanga(6), in south Africa where past surgical history of study participants showed no added advantage over those without it related to patients' knowledge about informed consent. The difference might be difference in time (2008), sociodemographic factor, and difference in sample size (1768), surgical patients might not have had preoperative health education regarding informed consent.

Our study also tried to identify those factors which affects perception of patients about surgical informed consent. According to this study, the odds of having good perception towards surgical informed consent in urban patients were 2.07 [AOR=2.07;95%CI (1.06,4.04); p=0.033] times more likely than surgical patients from rural setting. This might be because of most of the time educated populations were living in urban areas in other words patients with a high educational level had relatively good perception about informed consent in surgical procedures.

Findings in this result also reported that educational status of the study participants was significantly associated with perception of patients regarding surgical informed consent. But, it was confirmed that there was no perception difference between patients with educational status of primary school, preparatory and illiterate patients. Based on this finding, those patients with educational level of college and above were nearly nine times [AOR=8.9; 95%CI (8.25, 9.82); p=0.000] more likely having good perception than illiterate participants. This finding was similar in studies done in Rwanda by Mbonera F. et al(15) and in south Africa by Kalala Tshimanga(6) where formal education had positive association with better perception of informed consent.

The type of surgery was still another factor that affects patients' perception towards surgical informed consent. Based on these finding, the odds of having good perception about surgical informed consent in orthopedic patients was decreased by 91% [AOR=0.09; 95% CI (0.03, 0.32); p=0.000] than ophthalmologic surgical patients. It might be due to difference in preoperative health education. This finding was consistent with study done in Nigeria by Sulaiman A. et al(2) Stated that there was a statistically significant association between type of surgery and patients' perception about surgical informed consent (p=0.006). On the other hand the above finding was different from studies done in:-Jerusalem, Israel by Brezis M. et al.(21) ; Rwanda by Mbonera F. et al(15) stated as there was no perception difference between different surgical disciplines of the patient. The justification for this difference might be sample size (147 for Mbonera et al.'s study), time (2008 for Brezis et. al).

The result of this finding still reported that there was a significant association between HCW profession from whom the patient had taken informed consent process and patients' perception regarding SIC (surgical informed consent). Based on this finding, the odds of having good perception about SIC in patients who had taken SIC process from intern practitioner were decreased by 55% [AOR=0.45;95%CI (0.26,0.96); p=0.024] than patients received from physicians. This is supported by studies done in Croatia by Vucemilo L.et al(22). and in Saudi Arabia by Abolfotohu M. et al(23), stated as higher quality was predicted when the physician was the one who explained the informed consent. This implies that perception of patients about surgical informed consent should increase as consent process was explained by physicians.

The strength of this study was since there were no similar studies so far in our country, therefore this study shows index of knowledge and perception of patients towards surgical informed consent in our context, and being a base line for future researchers. The study was also tried to include study participants in all surgery disciplines and as it was conducted at tertiary care Hospital, so diversity of patients was obtained.

Our study has the following limitations: Lack of triangulation (data source and methodological triangulation might provide the investigator with better insight towards knowledge of patients towards surgical informed consent among adult surgical patients if there were qualitative data); the study was conducted in a single referral hospital and Institution based study, not generalizable for the community as whole.

Conclusion

This study revealed that the patient's knowledge towards surgical informed consent for surgical procedures was limited and their perception towards informed consent was poor as compared to other literatures. Being urban, being higher educational status and having past surgical history were significantly associated with Good knowledge of surgical informed consent while, being urban, higher education, type of surgery and receiving consent explanation from the physician were statistically associated with good perception of patients about surgical informed consent

Abbreviations

CI: Confidence interval, CMHS: College of Medicine and Health Science, CS: Caesarian Section, GURH: Gondar University Referral Hospital, HCW: Health Care Workers, ICT: Information Communication Technology, NGO: Non-Governmental Organization, OR: Odds Ratio, SIC: Surgical Informed Consent, SPSS: Statistical Package for Social Sciences, TEVT: Technical Educational and Vocational Training

Declarations

Authors' contributions

AY, NN: Conceived, designed and organized the whole procedure of this article production, and performed data analysis and interpreting of findings. SM, AY: performed data analysis, interpreting of findings and coaching and mentoring, as well prepared the manuscript. AY, NN, SM, and HB: performed data analysis, interpreting of findings and coaching and mentoring, and equally prepare the manuscript. All authors read and approved the final manuscript

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Competing Interests

The authors have declared that they have no competing interests

Availability of data and materials

The datasets used and/or analyzed and in which conclusions are drawn during the current study are included in the manuscript

Consent for publication

Not applicable

Ethics approval and consent to participate

Ethical clearance was obtained from school of nursing, College of medicine and Health Sciences, and University of Gondar ethical review committee. Permission letter was obtained from Gondar University Referral Hospital. The purpose and the importance of the study were explained and informed consent was secured.

Confidentiality was maintained at all level of the study. Participants' involvement in the study were on voluntary bases and that they could withdraw at any time if they want. All the information given by the respondents was used for research purposes only. Confidentiality and privacy was maintained by omitting personal identifier of the respondents during data collection procedure

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References

1. Hammami MM, Al-Gaai EA, Al-Jawarneh Y, Amer H, Hammami MB, Eissa A, et al. Patients' perceived purpose of clinical informed consent: Mill's individual autonomy model is preferred. *BMC medical ethics*. 2014;15(1):2.
2. Sulaiman AI, Ayyuba R, Diggol IG, Haruna IU. Knowledge, attitude and perception of patients towards informed consent in obstetric surgical procedures at Aminu Kano Teaching Hospital. *Nigerian Journal of Basic and Clinical Sciences*. 2015;12(1):45.
3. Aasa A, Hovbäck M, Berterö CM. The importance of preoperative information for patient participation in colorectal surgery care. *Journal of clinical nursing*. 2013;22(11-12):1604-12.
4. Agu KA, Obi EI, Eze BI, Okenwa WO. Attitude towards informed consent practice in a developing country: a community-based assessment of the role of educational status. *BMC medical ethics*. 2014;15(1):77.
5. Marasini S, Kaiti R, Mahato RK, Gyawali R, Nepal BP. Informed consent in patients undergoing eye surgery: A qualitative study assessing their attitude, knowledge and anxiety level in a community based hospital of Nepal. *Journal of optometry*. 2013;6(3):147-53.
6. Kalala Tshimanga. Patients' perceptions and understanding of informed consent for surgical procedures 2011.

7. Ochieng J, Buwembo W, Munabi I, Ibingira C, Kiryowa H, Nzarubara G, et al. Informed consent in clinical practice: patients' experiences and perspectives following surgery. *BMC research notes*. 2015;8(1):765.
8. Faghanipour S, Joolaei S, Sobhani M. Surgical informed consent in Iran—how much is it informed? *Nursing ethics*. 2014;21(3):314-22.
9. Rajesh D, Abhishek S, Mukul C, Gaurav S, Venkateshan M, Anu B. Patient's Awareness, Attitude, Understanding and Perceptions towards Legal Nature of Informed Consent. *J Indian Acad Forensic Med*. 2013;35(1).
10. Leclercq WK, Keulers BJ, Scheltinga MR, Spauwen PH, van der Wilt G-J. A review of surgical informed consent: past, present, and future. A quest to help patients make better decisions. *World journal of surgery*. 2010;34(7):1406-15.
11. EL-Nasser GA, Mohamed N. Patient Satisfaction with Preoperative Care and Its Relationship with Patient Characteristics. *The Medical Journal of Cairo University*. 2013;81(2).
12. Agnew J, Jorgensen D. Informed consent: a study of the OR consenting process in New Zealand. *AORN journal*. 2012;95(6):763-70.
13. Akkad A, Jackson C, Kenyon S, Dixon-Woods M, Taub N, Habiba M. Patients' perceptions of written consent: questionnaire study, english hospita. *BMJ*. 2006;333(7567):528.
14. Singh A, Bhardwaj A, Jindal R, Mithra P, Siddique A, Rajesh D. A cross sectional study of the patient's awareness and understanding toward legal nature of informed consent in a dental hospital in rural Haryana. *Journal of Education and Ethics in Dentistry*. 2012;2(1):25.
15. Mbonera F, Chironda G. The relationship between knowledge and perception of patients regarding informed consent in surgical procedures in Rwanda. *International Journal of Research in Medical Sciences*. 2017;6(2):408-16.
16. Olaboyede o, Owonikoko, Musliudin K, Adeniji, Oladeni A. Pre-operative written consent in Nigeria : How informed are our patients? *International Research Journals*. 2013;4(8):307-10.
17. Galal YS. Knowledge, practice and perception towards the informed consent process among physicians and patients in General Surgical Departments at Cairo University Hospitals. *Egyptian Journal of Community Medicine*. 2016;34(2).
18. Atanda Oluseyi, Olaboyede Owonikoko, Kola Musliudin, Adeniji, Oladeni A. Pre-operative written consent in Nigeria: How informed are our patients? *International Research Journal of Medicine and Medical Sciences*. 2013;4(8).
19. Siao D, Sewell JL, Day LW. Assessment of delivery methods used in the informed consent process at a safety-net hospital. *Gastrointestinal endoscopy*. 2014;80(1):61-8.
20. Vucemilo L, Milosevic M, Babic-Bosanac S, Mustajbegovic J, Borovecki A. Is there a need to improve the informed consent procedures in Croatia-a pilot field survey on a representative sample, a food for thought? *Revista Romana de Bioetica*. 2014;12(1).
21. Brezis M, Israel S, Weinstein-Birenshtock A, Pogoda P, Sharon A, Tauber R. Quality of informed consent for invasive procedures. *International Journal for Quality in Health Care*. 2008;20(5):352-7.
22. Vučemilo L, Milošević M, Dodig D, Grabušić B, Đapić B, Borovečki A. The quality of informed consent in Croatia—a cross-sectional study and instrument development. *Patient education and counseling*. 2016;99(3):436-42.
23. Abolfotouh MA, Adlan AA. Quality of informed consent for invasive procedures in central Saudi Arabia. *International journal of general medicine*. 2012;5:269.
24. Melendo MP, Viegas K, Souza ENd, Caregnato RCA. Surgical patients' understanding of the free and informed consent form. *Acta Paulista de Enfermagem*. 2016;29(3):291-7.
25. Jukic M, Kozina S, Kardum G, Hogg R, Kvolik S. Physicians overestimate patient's knowledge of the process of informed consent: a cross-sectional study. *Med Glas*. 2011;8:39-45.
26. Fink AS, Prochazka AV, Henderson WG, Bartenfeld D, Nyirenda C, Webb A, et al. Predictors of comprehension during surgical informed consent. *Journal of the American College of Surgeons*. 2010;210(6):919-26.
27. Ezeome ER, Marshall PA. Informed consent practices in Nigeria. *Developing World Bioethics*. 2009;9(3):138-48.

28. Hanson M, Pitt D. Informed consent for surgery: risk discussion and documentation. *Canadian Journal of Surgery*. 2017;60(1):69.
29. Bhattacharyya T, Yeon H, Harris MB. The medical-legal aspects of informed consent in orthopaedic surgery. *JBJS*. 2005;87(11):2395-400.
30. Medical Ethics for doctors in Ethiopia, EMA(2016).
31. Commission PC. Summary and statistical report of the 2007 population and housing census. Population size by age and sex. 2012.
32. Ahmed SA, Dewedar S. Obstetric patient perceptions of written consent forms: A middle east hospital study. *IJAR*. 2011;3:473-76.
33. Minnies D, Hawkridge T, Hanekom W, Ehrlich R, London L, Hussey G. Evaluation of the quality of informed consent in a vaccine field trial in a developing country setting. *BMC medical ethics*. 2008;9(1):15.

Tables

Table 1: Socio-demographic characteristics of the study participants, Gondar University Comprehensive and Specialized Hospital, Northwest Ethiopia, 2018 (n=302)

Characteristics	Categories	Numbers(n=302)		Percent
Sex	Male	121		40.1
	Female	181		59.9
Age	18-30year	57		18.9
	31-43years	178		58.9
	44-56years	23		7.6
	≥57years	44		14.6
	Marital status	Single	61	20.2
		Married	199	65.9
		Divorced	25	8.3
		Widowed	17	5.6
	Religion	Orthodox	231	76.5
		Catholic	18	6
		Muslim	48	15.9
		Protestant	4	1.3
		Others	1	0.3
Residence	rural	145		48
	Urban	157		52
Education	Illiterate	138		45.7
	Primary (grade 1-8)	64		21.2
	Secondary (grade 9-10)	28		9.3
	preparatory (grade 11-12)	33		10.9
	College/TEVT	39		12.9
Occupation	Farmer	76		25.2
	Housewife	102		33.8
	Government employee	52		17.2
	Private employee	41		13.6
	Daily laborer	6		2
	Merchant	3		1
	Other	22		41.4

Table 2: Respondents Knowledge on surgical informed consent in Gondar University Comprehensive and Specialized Hospital, Northwest Ethiopia, 2018 (n=302)

Characteristics	Frequency(n=302)	Percent
Signing the consent form is a legal requirement		
Yes	238	78.8
No*	64	21.2
Signing the consent form does removes your right to compensation		
Yes	230	76.2
No*	72	23.8
Have the right to change your mind after signing a consent		
No	245	81.1
Yes*	57	18.9
If you are not able to sign the consent form, the operation couldn't take place, even if this means you could die		
Yes	249	82.5
No*	53	17.5
If you refuse to sign the consent form you could die		
Yes	239	79.1
No*	63	20.9
If you can't sign the consent form, your next of kin can sign on your behalf		
No	260	86.1
Yes*	42	13.9
After consent the doctor can do anything different from what was on the form as s/he wants.		
Yes	255	84.4
No*	47	15.6
Doctor cannot do anything different from what was on the form unless it is life saving		
No	241	79.8
Yes*	61	20.2

Table 3: Results on perception of the respondents about surgical informed consent Process, GUCSH, Northwest Ethiopia, 2018 ;(n=302)

Characteristics	Frequency (n=302)	Percent
The consent form was important to me		
strongly disagree	41	13.6
Disagree	60	19.9
Agree	71	23.5
Strongly agree	130	43.0
Consent form made it clear		
Strongly disagree	80	26.5
Disagree	69	22.8
Agree	80	26.5
Strongly agree	73	24.2
Consent form made me aware of the risks of the operation		
Strongly disagree	116	38.4
Disagree	64	21.2
Agree	52	17.2
Strongly agree	70	23.2
Consent form made my wishes known		
Strongly disagree	89	29.5
Disagree	78	25.8
Agree	53	17.5
Strongly agree	82	27.2
Consent form prevents mix-ups during the operation		
Strongly disagree	119	39.4
Disagree	83	27.5
Agree	43	14.2
Strongly agree	57	18.9
Consent form was just another piece of paper		
Strongly disagree	93	30.8
Disagree	60	19.9
Agree	47	15.6
Strongly agree	102	33.8
I just signed the consent form so I could have the operation		
strongly disagree	77	25.5
Disagree	43	14.2
Agree	33	10.9
Strongly agree	149	49.3
Signing the consent form was mainly to protect the hospital		
strongly disagree	98	32.4
Disagree	54	17.9
Agree	47	15.6
Strongly agree	103	34.1
Consent form gave the doctors control over what happen		
strongly disagree	117	38.7
Disagree	61	20.2
Agree	32	10.6
Strongly agree	92	30.5
Signing the consent form was a waste of time		
strongly disagree	104	34.4
Disagree	70	23.2
Agree	40	13.2

Table 3: Results on perception of the respondents about surgical informed consent Process, GUCSH, Northwest Ethiopia, 2018 ;(n=302)

Strongly agree	88	29.1
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Table 4: Bivariable & Multivariable logistic regression analysis for factors that affect knowledge of adult surgical patients towards surgical informed consent, GUCSH, Northwest Ethiopia, 2018; (n=302)

Variables	Categories	Knowledge		COR(95% CI)	p-value	AOR(95% CI)	p-value
		Poor	Good				
Residence	Rural	108(56%)	49(45%)	1		1	
	Urban	85(44%)	60(55%)	1.56(0.97,2.50)	0.067	1.52(1.03,3.10)	0.016*
Education	Illiterate	34(87.2%)	5(12.8%)	1		1	
	Primary	27(81.8%)	6(18.2%)	1.5(1.42,5.49)	0.10	1.46(1.37,4.15)	0.05*
	Secondary	17(60.7%)	11(39.31%)	4.4(1.31,5.7)	0.016	3.25(1.70,6.99)	0.046*
	Preparatory	80(58%)	58(42%)	4.93(1.82,6.37)	0.53	3.76(1.94,5.04)	0.039*
	College/TEVT	35(54.7%)	29(45.3%)	5.6(1.95,6.26)	0.002	4.25(1.06,5.10)	0.042*
History of surgery	No	48(78.7%)	13(21.3%)	1		1	
	Yes	145(60.2%)	96(39.8%)	2.4 (1.26,4.75)	0.008	2..2(1.39,6.42)	0.005*

[P is statistically significant at $p \leq 0.05$ level of significance. (*= statistically significant)]

Table 5: Bivariable and multivariable logistic analysis for factors associated with perception of surgical informed consent among adult surgical patients, GUCSH, Northwest Ethiopia, 2018

Variables	Categories	Perception		COR(95% CI)	p-value	AOR(95% CI)	p-value
		Poor	Good				
Residence	Rural	92	53	1		1	
	Urban	63	94	2.59(1.63,4.12)	0.000	2.07(1.06,4.04)	0.033*
Education	Illiterate	84	54	1		1	
Type of surgery	Primary	35	29	1.29(0.71,2.347)	0.407	1.27(0.61,2.66)	0.519
	Secondary	10	18	2.8(1.20,6.52)	0.017	2.06(1.70,3.95)	0.004*
	Preparatory	21	12	0.89(0.40,1.95)	0.769	0.50(0.40,1.99)	0.854
	College/TEVT	5	34	10.5(9.90,12.73)	0.000	8.9(8.25,9.82)	0.000*
Type of surgery	Ophthalmological	86	58	1		1	
	Orthopedics	24	7	0.43(0.03,0.24)	0.000	0.09(0.03,0.32)	0.000*
	Gyn & Obstetrics	10	37	5.4(0.80,5.67)	0.058	3.19(0.74,6.48)	0.063
	General surgery	27	21	1.15(1.03,2.52)	0.001	1.12(1.05,3.41)	0.037*
	Others	8	24	4.4(0.29,4.96)	0.906	2.64(0.41,6.58)	0.482
HCW Who explains SIC process	Physician	24	42	1		1	
	Intern	118	95	0.46(0.26,0.813)	0.008	0.45(0.26,0.96)	0.024*
	I don't know	13	10	0.44(0.67,1.154)	0.918	0.38(0.36,1.45)	0.357

[P is statistically significant at $p \leq 0.05$ level of significance. (* = statistically significant)]