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Original Research Article

The relationship between knowledge and perception of patients regarding informed consent in surgical procedures in Rwanda

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ABSTRACT

Background: Lack of patient's knowledge on surgical informed consent increase the likelihood of a patient safety incident, patient anxiety and result in postoperative dissatisfaction. The aim of the study was to examine the relationship between knowledge and perception of patients regarding informed consent process for surgical procedures.
Methods: A descriptive correlation design was conducted. Using Probability Stratified sampling technique, a sample size of 147 surgical patients was selected. Data was collected using an interview schedule and analyzed using descriptive and inferential statistics.
Results: Eighty-three per cent (83%) had low knowledge, 12% moderate and only 5% had high level of knowledge. Twenty-three per cent (23%) had low perception, 50% moderate and 31% had high level of perception towards informed consent for surgical procedures. A weak significant positive correlation [($r = 0.487$), ($-1 \leq r \leq 1$), $p<0.00$)] between patient's knowledge and perception towards informed consent for surgical procedures was found with knowledge contributing variance 23.7% (R Square=0.237).
Conclusions: This study revealed that the patient's knowledge towards informed consent for surgical procedures is limited and their perception towards informed consent is poor. Therefore, there is need to devise strategies that increases the knowledge levels of patients so that they will be able to positively alter their perceptions towards informed consent of surgical procedures.

Keywords: Informed consent process, Knowledge, Perceptions, Surgical procedures

INTRODUCTION

One of the legal, professional and ethical principal of surgical procedures is the aspect of informed consent. The patient has the right to obtain enough information regarding surgical procedures options.[1,2] In the twentieth century, the informed consent had been recognized as an issue in surgical health care services.[3] Informed consent is built on patient competence to understand information and making a deliberate decision to undergo a specific surgical procedure and is valid until the patient' disease has not been changed or no new findings that may change the planned procedure are revealed.[4]

Patient's self-reflection should be empowered as it enables them to take treatment decisions themselves. Nevertheless, poor patient's perception to informed consent compromises their autonomy and self-

determination, therefore they feel powerless and unaccountable for their treatment.[4] The study done in Saudi Arabia revealed 48% of patients believing that they sign the consent because they thought the surgery would not be performed without signing and 42% thought they would destroy their relationship with their physician.[5]

A survey conducted in Uganda at three university teaching hospitals has shown that patients 'knowledge towards informed consent are diverse and limited because some patients do not know even the identity of the surgeon or the reason for surgery.[6] Lack of patient's knowledge 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.[7]

The knowledge of patients was poor in 17%, unsatisfactory in 33%, satisfactory in 32% and excellent in 18% of the patients.[8] Although studies show that surgical informed consent leads to positive postoperative outcome, study conducted in Nigeria showed that the patients had a positive attitude and know the informed consent as they are aware of it at 97.5% and stated that the patient understanding during informed consent process is highly related to the patient knowledge, religious beliefs and sociocultural factors as educated one are conscious of their rights and need to know what is being done on their body.[5] Educated patients are aware of their rights and are more likely to understand information provided in surgical informed consent process than uneducated patients.[5,9]

Moreover, many patients do not fully understand their health diagnosis, treatment and possible risks because of limited knowledge, personal stress and cultural beliefs.[10] A study conducted on the role of education in the informed consent process revealed that as the patient's level of education increases the requirement of disclosing everything on the surgical process decreases representing 64.7% of patients with no formal education and 56% of patients with university level.[11]

The study highlighted the impact of knowledge on patient's perceptions towards informed consent whereby patients with no formal education were unable to understand the information provided during informed consent process and 24% of patients with secondary level knew that they have the right to know the risks, benefits and are allowed to take the decision regarding their treatment at their own.[11]

Other study have revealed poor perception of patient to surgical informed consent as highly associated with limited knowledge, religious beliefs and sociocultural factors.[8]

In Rwandan hospitals, poor perception and limited knowledge regarding surgical informed consent among patients undergoing surgical procedures has been observed but not documented in literature. Furthermore, previous studies have implicated a relationship between knowledge and perceptions of surgical patients with regards to informed consent procedure. However, this relationship has never been examined in Rwanda context. Hence the need to examine the relationship between knowledge and perceptions of surgical patients concerning the informed consent.

The purpose of this study was to examine the relationship between patient's knowledge and perceptions towards informed consent for surgical procedures at selected referral hospital in Rwanda.

The objectives of the study were to determine the level of knowledge of patients towards informed consent for surgical procedures in Selected Referral hospital in Rwanda and to characterize the patient' perception towards informed consent for surgical procedures in Selected Referral hospital in Rwanda. To establish the relationship between knowledge and perception of patients regarding informed consent for surgical procedures in Selected Referral hospital in Rwanda.

METHODS

Research approach

Quantitative approach was used to assess the patient's knowledge and perception towards informed consent for surgical procedures in Selected Referral hospital in Rwanda.

Research design

This research used descriptive correlational design. The researcher described the patient's level of knowledge and perception towards informed consent for surgical procedures in the Rwanda military hospital. Thereafter, a relationship between knowledge and perception of patients regarding informed consent for surgical procedures was established.

Research setting

The study was conducted in Rwanda military hospital. It is a referral hospital located in Kicukiro district, Kigali city. This hospital receives patients from different surgical specialties.

Study population

The study population was described in terms of entre, target and accessible population. The entire population were all surgical patients admitted in Rwanda hospitals. The target population were all surgical patients in the Rwanda military hospital. The accessible population was all consented surgical patients that were available at the time of the study.

Sampling strategy

Probability Stratified sampling was used as sampling strategy. The researcher divided surgical patients into different strata according to the surgical specialties (general surgery, orthopedic, obstetrics and gynecology, urology, ENT, maxilla facial and plastic surgery stratum). Simple random sampling technique was used to determine the sample in each stratum and the researcher took different sampling fraction of patients across strata in order to achieve homogeneity.[12]

Sample size

The sample size implies the number of units that make the study sample.[13] In this study, the sample size was calculated by the formula:

N = z2pq/d2 where[13]

N stands for is the minimum sample size,
Z is the standard normal deviate set at 95% and the confidence limit is at 1.96,
P is the prevalence of surgical procedures that required informed consent equal to 0, 5 (50%),
q = 1-p (complementary probability) =1-0.5=0.5,
d is the degree of precision (the margin of error) usually at 5% =0.05.

Therefore, N = (1.96) 2 × 0.5 × 0.5/ (0.05) 2

= 3.8416 × 0.25/0.0025
= 0.9604/0.0025
= 384.16

According to Mugenda, if the population is less than 10 000, the following formula is applied[15]

Nf =n/1+ (n/N)

Where;
Nf is desired sample for population less than 10000,
n desired sample size for population greater than 10 000,
N is estimate of the population size equal to140,
Therefore, the desired sample size is 384/1 (384/140)
Nf= 384/ (1+2.74)
Nf =384/3.74
Nf =102

The researcher applied a 20% attrition rate to calculated sample size to make it 122. Twenty-five more participants were added to improve the power and the validity of the study. Therefore, the sample size for this study became 147 patients.

Data collection instruments

Data will be collected using closed ended interview schedule consisting of bibliographical data, knowledge and perception to surgical informed consent. After getting the permission from the author for article titled Knowledge, attitude and perception of patients towards informed consent in obstetric surgical procedures at Aminukano teaching hospital; the researcher adopted the tool from Sulaiman et al. The research instruments consisted of 3 sections namely: Section A of the instrument elicited demographic data which will capture the personal descriptive data of participations. Section B assessed the level of knowledge of patients towards informed consent for surgical procedures. The minimum possible total score for level of knowledge was 13 and the maximum possible score will be 49. Dividing the attained score on this section by the maximum possible attainable score (49) and multiplying by a hundred came up with a percentage calculated knowledge of informed consent with surgical procedures. Knowledge of informed consent of 80% to 100 % was classified as high, 70% to 79% was classified as moderate and of below 70% was considered as low.

Section C assessed the level of perceptions of patients towards informed consent for surgical procedures in the Rwanda military hospital. The minimum possible total score for level of knowledge was 11 and the maximum possible score was 33. Dividing the attained score on this section by the maximum possible attainable score (33) and multiplying by a hundred came up with a percentage calculated level of perceptions towards informed consent with surgical procedures. A perception of informed consent of 80% to 100 % was classified as high, 70% to 99% was classified as moderate and of below 70% was considered as low. The validity of the instrument was determined in terms of face, content and construct validity.

RESULTS

Demographic data of the research subjects

Descriptive statistics in the form of graphs and tables was used to analyze demographic data. Table 1 reveals the demographic data of research subject. One hundred forty-seven patients were recruited for the study. Regarding age, 54 (36.7%) of respondents were between 31 and 40years, 49 (33.3%) were between 18 and 30years, 22 (15%) were between 41 and 50years, 10 (6.8%) were between 51 and 60years and 12 (8.2%) were greater than 60years. Eighty-one (55.1%) of respondents was male and 66 (44.9%) were female. One hundred and seven (72.8%) of respondents were married; 31 (21.1%) of respondents were single; 7 (4.8%) were separated and 2 (1.4%) of respondents were divorced. The majority of the respondents were Christians 123 (83.7.4%) while 19 (12.9%) were Muslims and 5 (3.4%) are from traditional religion.

Fifty-two per cent (52.4%) had grade one level to grade 6 level, 44 (29.9%) had senior one to senior six, 16 (10.6%) had university level and 10 (6.8%) were below primary level. Sixty-eight (46.3%) were semi-skilled; 57 (38.8%)

unemployed and 22 (15%) were skilled. Of 147 patients 38 (25.9%) were from general surgery; 29 (19.7%) from orthopedics 25 (17%) were from obstetrics and gynecology; 13 (10.9%) were from plastic surgery; 13 (8.8%) were from maxilla facial; 13 (8.8%) ENT; and 13 (8.8%) were from urology.

Table 1: Demographic data of the research subjects (n=147).

Variable	Frequency	% frequency
Age in years		
18-30 years	49	33.3
31-40 years	54	36.7
41-50 years	22	15.0
51-60 years	10	6.8
Greater than 60 years	12	8.2
Gender		
Male	81	51.1
Female	66	44.9
Marital status		
Married	107	72.8
Single	31	21.1
Separated	7	4.8
Divorced	2	1.4
Religion		
Christianity	123	83.7
Islam	19	12.9
Traditional	5	3.4
Education		
Below primary level	10	6.8
Primary level	77	52.4
Secondary level	44	29.9
University/college level	16	10.9
Surgery discipline		
Orthopedic	29	19.7
General surgery	38	25.9
Obstetrics and gynaecology	25	17.0
Urology	16	10.9
Plastic	13	8.8
Mfs	13	8.8
Ent	13	8.8
Residential area		
Rural	63	42.9
Urban	84	57.1
Occupation Skilled	22	15.0
Semi-skilled	68	46.3
Unemployed	57	38.8

Results on research subject knowledge towards informed consent for surgical procedures

Table 2 displays the patient's knowledge towards informed consent for surgical procedures.

The majority 82 (55.8%) agreed that they want to know the reason for operation; 28 (19%) strongly agree, 23 (15.6%) disagree and only14 (6.5%) strongly disagree.

Table 2: Research subject knowledge towards informed consent for surgical procedure (N=147).

Variable	Frequency	% frequency
Reason for operation		
Strongly disagree	14	6.5
Disagree	23	15.6
Agree	82	55.8
Strongly agree	28	19.0
What will be during the operation		
Strongly disagree	27	18.4
Disagree	41	27.9
Agree	57	38.8
Strongly agree	22	15.0
Cost for the operation		
Strongly disagree	21	14.3
Disagree	42	28.6
Agree	73	49.7
Strongly agree	11	7.5
Risks and complications		
Strongly disagree	6	4.1
Disagree	40	27.2
Agree	83	56.5
Strongly agree	18	12.2
Postop care information		
Strongly disagree	10	6.8
Disagree	34	23.1
Agree	83	56.5
Strongly agree	20	13.6
After how many days you should resume your work		
Strongly disagree	15	10.2
Disagree	71	48.3
Agree	51	34.7
Strongly agree	10	6.8
Successful result of the operation		
Strongly disagree	3	2.0
Disagree	32	21.8
Agree	88	59.9
Strongly agree	24	16.3
Special precaution to be taken after operation		
Strongly disagree	7	4.8
Disagree	51	34.7
Agree	75	51.0
Strongly agree	14	9.5

57 (38.8%) of patients want to know what will be during the operation while 41 (27.9%) do not want. 73 (49.7%) agreed that they want to know the cost for the operation while 42 (28.6%) do not want to know. 83 (56.5%) of patients agreed that they want to be aware of risks and complications of the procedure, 40 (27.2%) disagree, 18 (12.2%) strongly agree and only 6 (4.1%) strongly disagree.

83 (56.5%) agreed that they need to know postoperative care information, 34 (23.1%) disagree, 20 (13.6%) strongly agree and 10 (6.8%) strongly disagree.

Forty-eight per cent 71 (48.3%) of patients do not want to know after how many days they should resume their work, 51 (34.7%) agreed that they want to know and 10 (6.8%) strongly agreed. The majority, [88 (60%)] of patients agreed that the want to be knowledgeable on successful result of the operation while 32 (21.8%) do not. 75 (51%) want to know special precaution to be taken after operation and 51 (34.7%) do not.

Table 3: Research subject knowledge towards informed consent for surgical procedure (N=147).

Variable	Frequency	% Frequency
Special dietary consideration to be considered after operation		
Strongly disagree	13	8.8
Disagree	59	40.1
Agree	66	44.9
Strongly agree	9	6.1
Following doctor s recommendation		
Do not know	23	15.6
Disagree	65	44.2
Agree	59	40.1
I want to know about my treatment		
Do not know	22	15.0
Disagree	64	43.5
Agree	61	41.5
Patient makes a final decision		
Do not know	22	15.0
Disagree	46	31.3
Agree	79	53.7

Table 2b continues to reveal results on knowledge of patients with regards to informed consent procedures. Forty five percent 66 (44.9%) need to be informed on special dietary consideration to be considered after operation while 59 (40.1%) disagreed. Regarding the patient role in the decision making about the procedure, 65 (44.2%) of patients disagreed on following the doctor s recommendation while 40.1% agree to follow the doctor's recommendation. agree to follow. Forty-three points five (43.5%) of patients allow doctors to determine their treatment but they want to know about their treatment while 61 (41.5%) agree. Fifty-three points seven (53.7%) of patient need to make a final decision regarding their treatment and 46 (31.3%) do not want.

Table 3 displays the total research subject knowledge score towards informed consent for surgical procedures. The mean, median and the modal score was 30. The knowledge score ranged from 24 to 45 out of possible score of 49. Eighty-three per cent (83%) had low knowledge, 12% moderate knowledge and only 5% of the patients had high level of knowledge.

Table 4: Total research subject knowledge score towards informed consent for surgical procedures (N=147).

Knowledge score out of 49	Percentage knowledge score	Level of knowledge	Frequency	% frequency
24	49	Low	2	1.4
25	51	Low	5	3.4
26	53	Low	9	6.1
27	55	Low	17	11.6
28	57	Low	15	10.2
29	59	Low	14	9.5
30	61	Low	18	12.2
31	63	Low	18	12.2
32	65	Low	11	7.5
33	67	Low	9	6.1
34	69	Low	5	3.4
35	71	Moderate	3	2.0
36	73	Moderate	4	2.7
37	76	Moderate	4	2.7
38	78	Moderate	6	4.1
39	80	High	5	3.4
40	87	High	1	0.7
45	92	High	1	0.7

Results on research subject perceptions towards informed consent for surgical procedures

Table 4 displays the perceptions towards informed consent for surgical procedures. Forty eight percent of the patients did not perceive informed consent as formal document. However, 52 (35.4%) took it as formal and 24 (16.3%) did not know neither formal nor not. 57 (38.8%) did not believe that signing the consent form is a legal requirement while 46 (31.3%) did. 65 (44.2%) of the patients thought that signing the consent form will not remove their right to compensation. 63 (42.9%) did not believe that informed consent protects the doctor against being sued while 55(37.4%) did. Fifty-six per cent 83(56.5%) of patients stated that informed consent protects their rights.

The majority, [92 (62.6%)] believed that informed consent confirms that operation have been explained while 48 (32.7%) thought that informed consent does not necessary mean the operation has been explained. 57.1% took the informed consent as a must for undergoing operative procedure while 39.5% believed it is not.

68 (46.3%) thought they have no right to change their mind after signing the informed consent and 55 (37.4%) believed they have right. 69 (46.9%) stated that their relatives can sign the consent form on their behalf and 58 (39.5%) did not think so. 64 (43.5%) of patients believed that the operation cannot take place without informed consent while 62 (42.2%) believed that it can. 68 (46.3%) stated that informed consent is necessary and 52 (35.4%) mentioned that they are not.

Table 5: Presentation of the research subject perceptions towards informed consent for surgical procedures (N=147).

Variable	Frequency	% of frequency
Consent forms are just a formality		
Do not know	24	16.3
No	71	48.3
Yes	52	35.4
Signing the consent form is a legal requirement		
Do not know	44	29.9
No	57	38.8
Yes	46	31.3
Consent form removes your right to compensation		
Do not know	40	27.2
No	65	44.2
Yes	42	28.6
Protect the doctor against being sued		
Do not know	29	19.7
No	63	42.9
Yes	55	37.4
Consent form is to protect the patient's rights.		
Do not know	20	13.6
No	44	29.9
Yes	83	56.5
Informed consent confirms that operation have been explained		
Do not know	7	4.8
No	48	32.7
Yes	92	62.6
The consent form is a must for undergoing operative procedure		
Do not know	5	3.4
No	39.5	39.5
Yes	57.1	57.1
Right to change your mind after signing the consent form		
Do not know	24	16.3
No	68	46.3
Yes	55	37.4
Your relative can sign the consent form on your behalf		
Do not know	20	13.6
No	58	39.5
Yes	69	46.9
The operation cannot take place without informed consent		
Do not know	21	14.3
No	62	42.2
Yes	64	43.5
Consent forms are necessary		
Do not know	27	18.4
No	52	35.4
Yes	68	46.3

Table 5 shows the total perception score towards informed consent for surgical procedures among patients. The mean and median were both 25 and the modal score was 26.00. The lowest score and the highest score was 17 and 32 respectively out of 33.

Twenty-three per cent (23%) had low perception, 46% moderate and 31% of the patients had high level of perception towards informed consent for surgical procedures. Presentation of relationship between research

subject knowledge and perception of patients towards informed consent for surgical procedures.

Table 6: Total research subject perception score towards informed consent for surgical procedures (N=147).

Perception score out of 33	Percentage perception score	Level of perception	Frequency	% of frequency
17	52	Low	1	0.7
18	55	Low	3	2.0
19	58	Low	5	3.4
20	61	Low	6	4.1
21	64	Low	9	6.1
22	67	Low	10	6.8
23	70	Moderate	12	8.2
24	73	Moderate	16	10.9
25	76	Moderate	16	10.9
26	79	Moderate	20	13.6
27	82	High	13	8.8
28	85	High	11	7.5
29	88	High	9	6.1
30	91	High	9	6.1
31	94	High	6	4.1
32	97	High	1	0.7

Table 6 reveals the results for the relationship between the subject knowledge and perception towards informed consent for surgical procedures. There was a significant weak positive correlation between patient's knowledge and perception of patients towards informed consent for surgical procedures (r = .487), (-1≤ r ≤1, p=.00). The correlation was significant at 0.01 meaning that 99 percent of the results were correct and there was only one percent chance that the results were incorrect.

Table 7: Correlation between subject knowledge and perception towards informed consent for surgical procedures.

Variables		Knowledge	Perception
Total knowledge	Pearson correlation	1	0.487**
	Sig. (2-tailed)		0.000
	N	147	147
Total perception	Pearson correlation	0.487**	1
	Sig. (2-tailed)	0.000	
	N	147	147

**. Correlation is significant at the 0.01 level (2-tailed).

Table 8: Regression analysis of knowledge.

Model	R	R square	Adjusted R square	Change statistics		
				F change	Degrees of freedom	Sig. F change
1	0.487[a]	0.237	0.232	45.145	1	0.000

a-Predictors: (constant), knowledge

Table 7 reveals the regression analysis of the contribution of the independent variable (Knowledge) to the dependent variable (perceptions) regarding informed consent for surgical procedures.

The results show knowledge contributing 23.7% to increased perception (R Square =0.237) towards informed consent for surgical procedures. The significant F-test (45.145, P=00) indicated a linear relationship and that R Square was significant.

DISCUSSION

The purpose of the study was to examine the relationship between knowledge and perceptions of patients regarding informed consent process prior to surgical procedures.

Generally, the findings of this study displayed that eighty three per cent had low knowledge, 12% had moderate knowledge and 5% of the patients had high level of knowledge which are different from Singh et al study findings where general the level of knowledge towards informed consent was poor in 17%, unsatisfactory in 33%, moderate in 32% and excellent in 18% of the patients.[8] With regards to patient's knowledge towards informed consent for surgical procedures, more than half of the respondents wanted to know the reason for operation which is similar to study conducted where 55.2% of the patient needed to know reason for operation.[8] Thirty eight point eight per cent of patients were interested on what will be during the operation which is contrary to findings of Singh whereby 63.6% of respondents were not bothered to know what will be done during the operation provided they were made better.[8]

A significant number (56.5%) of respondents wanted to be aware of risks and complications of the surgery. However, the findings from a study done in Saudi Arabia revealed a large number of approximately 94% of respondents needing information regarding risks and complications regarding the procedure.[5] Contrary to Siddiqui et al study result where seventy percent of respondents were not interested on information about the risks and complications.[16] Fifty-six per cent (56.5%) of respondents needed information regarding postoperative care management which is somehow similar to Singh et al. study findings where (43%) wanted post-operative care information.[8] The majority (60%) of respondents wanted to be knowledgeable on successful result of the operation and this is congruent to results of Olaboyede et al who revealed the need for a greater number of participants to recognize the importance of informed consent like being aware of surgery outcome.[17]

Fifty one percent of respondents (51%) wanted to know special precaution to be taken after operation which a large number comparatively to results is found by Singh et al result was only 25.6% needed to be informed on special precautions after surgery.[8] Fifty three percent (53.7%) of patients needed to make a final decision regarding their treatment. However according to Agu et al, the majority (69.2%) of the respondent were happy to allow doctors to determine their treatment but they wanted to know about their condition, the treatment and the important side effects.[11]

The level of perception of patients towards informed consent process for surgical procedures was also established from the study results. Forty eight percent of the patients did not perceive informed consent as formal document which is different from Singh et al. study findings where 55 % of respondents took informed consent as a formal document.[8] Thirty one percent (31%) believed that signing the consent form is a legal requirement and (28.6%) of the patients thought that signing the consent form will remove their right to compensation. However, Olaboyede et al study results revealed that almost all participants (91.5%) agreed that signing of consent form is a legal requirement before surgery while nearly a half 110 (47%)of the patients believed that signing the consent form will prevent them claiming their rights to compensation.[17]

Thirty seven percent of respondents believed that informed consent protect the doctor against being sued which is different from findings by Agu et al which revealed nearly half of respondent believing to protects the hospital and doctors against litigation.[11] More than half of the respondent (57.1%) took the informed consent as a must for undergoing operative procedure and this is contrary to findings where they were number of doubts about the implications of signing or not signing the consent form and they wondered if surgery can proceed when consent form is not signed.[17] Forty six percent thought they have no right to change their mind after signing the informed consent and 37.4% believed they have right and this is similar to findings by Sulaiman et al.[5] Contrary, the findings are different from Singh et al. which revealed 88% of the patients having no right to change their minds after signing the consent.[8]

Forty-six per cent (46.9%) stated that their relatives can sign the consent form on their behalf and (43.5%) of patients believed that the operation cannot take place without informed consent. These results were different from Hammami et al where nearly all participants (95.7%) were aware that their next of kin could sign on their behalf.[4] The results of this study revealed that there is a significant weak positive correlation between patient's knowledge and perception of patients towards informed consent for surgical procedures ($r = 0.487$), ($-1 \leq r \leq 1$, $p=0.00$). This means that as the patient' knowledge increases the perception also increases towards informed consent for surgical procedures.

Moreover, the patient level of education, occupation influences significantly the knowledge and perception towards informed consent for surgical procedures which is similar to Agu et al findings.[11] Similarly findings were also revealed by Singh et al who stated that the level of understanding of informed consent was significantly better in those who had higher education.[8]

CONCLUSION

In conclusion, the study revealed that the patient's knowledge towards informed consent for surgical procedures is limited and their perception towards informed consent is poor. Moreover, the relationship between patient's knowledge and perception towards informed consent was established whereby as the patients with high level of education had a positive perception towards informed consent and understood quickly information provided during informed consent process. Therefore, enough time should provide to low educated patients to obtain the informed consent and their comprehension should be assessed.

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