Adequacy of information provided in the informed consent to patients undergoing surgery at a tertiary care hospital

Arabind Joshi[1], Shital Bhandary[2], Rony Maharjan[3], Mukesh Kumar Sah[4],
[1]Lecturer, [3]Fellow Resident, [4]Resident, Dept. of General Practice and Emergency, [2]Assoc. Prof. Dept. of Community Medicine and Public Health, Patan Academy of Health Sciences, Lalitpur, Nepal

ABSTRACT

Introduction: Informed consent gives patient assurance and faith by providing information on diagnostic and therapeutic methods, risks, cost, complications, and alternative treatment options. This study aims to determine the adequacy of information provided in preoperative informed consent in everyday practice.

Method: A cross sectional study was conducted among 388 patients undergoing surgery at Patan Hospital from November, 2016 to April, 2017. Respondents' characteristics with Adequacy of information scale (AOI scale) were evaluated. Frequency, percentage, mean and standard deviation were calculated for descriptive study while Student t-test and ANOVA test was applied for assessing association between categorical variables. P value less than 0.05 was considered statistically significant.

Result: Among participants 52.6% were females and 47.4% males with mean age of 40.69 years. Most of the patients were literate and with higher education. Male patients, exhibit a statistically significant higher AOI scale (p value <0.001) then females. Illiterates and people with higher education had statistically significant lower mean AOI scales (p value <0.001) compared to literates. A high mean AOI scale was associated with active involvement of both the surgeon and the patient in the decision-making process (p value <0.0001). Even among patients satisfied with consent process mean AOI scale was low (4.30=53.75%). The mean AOI scale did not differ significantly amongst patients of different ages, marital status, religion or caste.

Conclusion: There is a need of improving the preoperative informed consent process as adequacy of information provided is still lacking.

Keywords: Adequacy of information scale (AOI scale), informed consent, Patan Hospital, patient satisfaction

CORRESPONDENCE
Dr. Arabind Joshi
Dept. of General Practice and Emergency, Patan Hospital, Patan Academy of Health Sciences, Lalitpur, Nepal
Email: arabindjoshi@pahs.edu.np

INTRODUCTION

Informed consent is permission to do something following a discussion and comprehension of the indication, alternative treatment options, potential adverse effects, and problems.[1] This assists patients in making decision by understanding accurate, realistic, and updated information.[2,3,4] This gives the patient confidence and trust that they are not being duped or intervened forcefully. The importance to take informed consent before any procedure is increasing.[5,6,7] Legally in Nepal it has been stated that *"consent has to be obtained for treatment or operation by certified physician and in case there is no one to give consent and if the certified physician feels that it is for the benefit of the patient, he or she can proceed without consent"(Muluki Ain –Ilaj Garne ko)*.[8] The doctor should present information in a straightforward, logical, and understandable manner, and ensure that the patient's concerns are adequately addressed. Regardless, the patient has the choice to choose whether or not to get medical treatment.[4] Mostly information provided to the patient is relatively limited in our part due to differing cultural values than in the west.[5]

This study aims to determine the adequacy of information provided in informed surgical consent and understanding the current practices and gaps.

METHOD

Study Design, Study Population and Sample Size

A cross sectional analytical study was conducted at Patan Hospital, a tertiary care teaching hospital after taking ethical clearance from Institutional Review Board; National Academy of Medical Sciences "IRB-NAMS". The minimum sample size determined was 384(estimated with standard prevalence 50 percent for parameter of unknown prevalence) using formula $n=z^2p(1-p)/e^2$, where n=sample size, z=confidence interval (1.96 confidence interval of 95%), p=estimated prevalence & e=margin of error(5%=0.05). Total 388 patients receiving procedures at Patan Hospital from November, 2016 to April, 2017 was included. Patient with nonsurgical problem, age below 18 and above 65 years were excluded. Convenient sampling was used for data collection and written consent was taken for the study by the researchers before the study. Confidentiality of patient information was assured by maintaining privacy and not recording personal information. The response was evaluated by respondents' characteristics with AOI scale, which was based on pre-validated standard tool. A researcher tailored questionnaire which was used by M Jawaid, M Farhan, Z Masood and SMN Husnain in a similar study was used. The tool was forward translated into Nepali with the help of a bilingual expert, and then back translated by another bilingual expert. The original and back translated tools were discussed and required adjustments made, establishing the preliminary content validity. Pretesting was conducted among 8 patients at the Department of Surgery, Patan Hospital, and required tool modifications were made as needed to establish face and content validity. The patients of pretesting were excluded in main study. Summated score of pre-validated 8 interrelated questions is termed AOI scale and yes, no response was assessed. The possibility of maximum and minimum number of answering yes is 8 and 0 respectively. The data were entered in the Microsoft excel and analyzed using IBM SPSS statistics software version 20. Frequency, percentage, mean and standard deviation were calculated for descriptive study while Student t-test (for two categories) and ANOVA (more than two categories) test was applied for assessing association between categorical variables. P value less than 0.05 was considered statistically significant.

Patients were classified as male and female within age group 18-30, 31-50 and 51-65. Religion was classified as Hindu, Buddhist, Christian and others whereas caste was classified as Brahmin/Chhetri, Dalit, Janajati and others. Illiterate, literate, school leaving certificate level and higher education were the educational categories. Married, single and widow(er) were the marital status.

RESULT

Out of the total 388 respondents nearly half were in the age group 31-50 whereas nearly a quarter lies in 18-30 and 51-65. There is uniform distribution of female and male patients. Majority of the respondents' were Hindus. Brahmin and Janajati constitute nearly 90% respondents. More than half of the population can read and write. Majority of the respondents are married.

We got the variable response from different patients. There were maximum number of the patients who have response score of 2, 3 & 4 accounting for nearly 61%, where as low frequency was found in extreme of question response score.

The distribution of AOI scale follows the normal distribution curve with similar Mean, Median and Mode of question response score of the respondent and they are 3.67, 3.00, and 3.00 respectively.

There is no significant relationship between respondent age (p=0.531). However, mean AOI score of females and males is 3.24 and 4.15 with SD of 2.04 and 2.03 respectively (p<0.001). Religion (p=0.083), caste (p=0.075) and marital status (p=0.0150) have no statistically significant association with the respondents' adequacy of information. The respondents' education is statistically significant when it comes to adequacy of information (p<0.001). Further, post hoc test demonstrates illiterate patients and those with higher educational degree had considerably lower levels of mean adequacy of information. High level of mean AOI scale is seen in patients if consent is obtained at the time of admission in OPD with mean AOI 4.80(SD=1.85), (p<0.001). This was further confirmed by post hoc test. Consent taken by surgeon had higher mean AOI scale as compared to other healthcare workers (p<0.001), which was confirmed after applying post-hoc (Tukey) test. Also mean AOI scale is sufficiently higher when patients are involved in consent process versus when it is signed by both patients and relatives or near kin alone (p<0.0001) as evidenced by post hoc test analysis. Finally, respondents' satisfaction with consent process was compared with mean AOI scale which shows higher mean AOI scale is associated with high patient satisfaction and vice versa (mean 2.18 vs 4.34, p<0.0001).

Table 1. Demographic characteristics of respondents

Characteristics	Frequency (%)	Characteristics	Frequency (%)
Age Distribution		**Religion**	
18-30	103(26.6)	Hindu	334(86.1)
31-50	186(47.9)	Buddhist	54(13.9)
51-65	99(25.5)	**Education**	
Gender		Illiterate	61(15.7)
Female	204(52.6)	Literate	189(48.7)
Male	184(47.4)	School Leaving Certificate (SLC)	100(25.8)
Caste		Higher Education	38(9.8)
Brahmin / Chhettri	156(40.2)	**Marital Status**	
Dalit	15(3.9)	Unmarried	23(5.9)
Janajati	210(54.1)	Married	357(92.0)
Others	7(1.8)	Widow/Widower	8(2.1)

Table 2. Distribution of AOI categories in the sample

Question Response Score	Frequency (%)	Question Response Score	Frequency (%)
0	24(6.2)	5	30(7.7)
1	16(4.1)	6	7(1.8)
2	82(21.1)	7	66(17.0)
3	93(24.0)	8	8(2.1)
4	62(16.0)		
Total			**388(100)**

Table 3. Descriptive statistics of AOI scale

Total	Mean	Median	Mode	Standard Deviation	Minimum	Maximum
388	3.67	3.00	3.00	2.09	0.00	8.00

DISCUSSION

Adequacy of information scale was statistically non significant among the different age groups (p= 0.531) marital status (p=0.15), religion (p=0.083) and caste (p=0.075). Male patients have statistically significant higher mean AOI scale than females (4.15 vs 3.24). . This difference is similar to that observed in a study done by Jawaid M, et.al.[5] So more focused, clear and simple explanation needs to be done whenever female patients are supposed to have preoperative informed consent.

There was a statistically significant relationship between educational level and mean AOI scale in this study, with lower educational level being associated with lower mean AOI scale(p<0.001). This was consistent with many of the studies around the world.[3,5] This could be due to a lack of comprehension of the information as well as questions. Patients with a higher educational level had a lower AOI scale than those who are just literate to below graduation, which could be related to a high demand for information and a desire to know more. As a result, anytime preoperative consent is sought, it should be given in a straightforward, easy-to-understand manner with specifics after the patient's comprehension has been assessed.

Table 4. Comparison of adequacy of information scale with respondent's characteristics

Respondents' Characteristics	N	Mean	Standard Deviation	p value
Age Distribution				
18-30	103	3.53	2.17	0.531**
31-50	186	3.79	1.87	
51-65	99	3.58	2.37	
Gender				
Female	204	3.24	2.04	**<0.001***
Male	184	4.15	2.03	
Religion				
Hindu	334	3.59	1.98	0.083*
Buddhist	54	4.13	2.61	
Caste				
Brahmin/ Chhettri	156	3.89	1.98	0.075**
Dalit	15	3.80	3.09	
Indigenous people	210	3.56	2.08	
Others	7	2.00	0.00	
Education				
Illiterate	61	1.69	1.47	**<0.0001****
Literate	189	3.89	1.95	
School Leaving Certificate (SLC)	100	4.44	1.99	
Higher Education	38	3.71	1.94	
Marital Status				
Unmarried	23	3.34	0.49	0.15**
Married	357	3.67	2.16	
Widow(er)	8	5.00	0.00	
Timing of consent				
At Admission	105	4.80	1.85	**<0.0001****
One Day Before Surgery	134	3.14	2.03	
In the morning of Surgery day	119	3.34	2.00	
In Operation Room (OR)	30	3.43	2.04	
Consent taken by				
Surgeon	45	5.93	1.89	**<0.0001****
Other on duty doctors	96	4.47	1.79	
Intern or other health care workers	48	4.83	1.69	
Don't Know	199	2.49	1.53	
Consent signed person				
Patient	24	4.67	3.37	**<0.001****
Near Kin	39	1.93	1.88	
Patient and Near Kin	325	3.81	1.88	
Satisfied with Consent Process				
No	115	2.18	1.44	**<0.001**
Yes	273	4.30	1.99	

*=T-test and ** = One-way ANOVA; **Bold** signifies statistically significant, p<0.05

Statistically significant higher mean AOI scale was obtained if consent was taken at the time of admission. There is no statistically significant difference in mean AOI scale afterwards. This may be due to detail discussion that takes place in our OPD before admission with diagrammatic explanation about the disease condition. So it is preferable to obtain consent in an outpatient environment whenever possible which is backed up by studies by Jawaid M, et al. and Berry MG, et al.[5,9] Many of the patients were unaware that they might change their minds after signing the consent form.[5,10] This could be the reason for the skewed results.

Though surgeons were involved less frequently (45 of 388, 11.59%) in consent process, mean AOI was significantly higher when the consent is take by the operating surgeon (p<0.0001). These findings may be attributable in part to the surgeon's technical and academic competency and deeper understanding of the subject, method, and experience communicating with patients in simple and plain language in contrast to other junior doctors.

There was not a single operation performed without signature on the consent form, however patient alone was involved only in minority of

cases (N=24, 6.18%). In contrast the majority of the time it is either the patient or close relatives (N=325, 83.7%) or the near kin alone (N=39, 10.05%). This could be due to cultural norms and a long-held view that it is preferable for elder family members to participate in decision-making. Due to strong family values, a younger or female member's decision may be overruled by the elders, posing a challenge to the concept of voluntarism, as evidenced by a study conducted by Jawaid M, et al. Renshaw A, et al.[5,11] We find sufficiently higher mean AOI when patients are involved in consent process versus when it is signed by both patients and relatives or near kin alone (4.67 vs 3.81 vs 1.93, p<0.0001) as evidenced by post hoc test analysis. This discrepancy could be owing to the fact that the primary decision maker is someone else in the family, or it could be due to the patient's lack of understanding. As a result, it is preferable to obtain agreement from the patient or from a close relative who can grasp the explanation, rather than from the near relative alone. As a result, this study strongly recommends that the patient be actively involved in the consent process, which satisfies the principle of informed consent, and to protect the patient's privacy.

Finally, Adequacy of information scale was compared with satisfaction of overall consent process using T test. Out of 388 patients, 273 (70.36%) are satisfied with the consent process, whereas 115 (29.64%) are dissatisfied. Higher mean AOI scale with statistical significance (p < 0.0001) was seen on the satisfied group when compared to non satisfied group, 4.30 (53.75%) versus 2.19 (27.37 %).

From this research, it is found that a major cause of preoperative consent procedure dissatisfaction is a lack of information offered before surgery, and vice versa. This study reveals that over two-thirds of patients are satisfied with the consent process, despite the fact that the mean AOI scale in the happy group was only approximately 54%. As a result, there is a larger need to improve patient comprehension. Because doctor considerations were not taken into account, and patients with higher academic backgrounds were underrepresented in the study, the results could differ if they were included in a larger number.

Since our cultural background, social norms and traditional beliefs differ from those of the western world, more open discussion of consent process and associated factors need to be done.

This was single centered study so that the generalization of the result should be done with caution. Since the interview was conducted after an operation or procedure, the respondent may have forgotten some details during the interview, resulting in memory bias

CONCLUSION

There is a need of improving the preoperative informed consent process as adequacy of information provided is still lacking.

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Conflict of Interests

The authors declare that they have no conflict of interests.

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Author Contribution

Joshi A conceived, conceptualized, and designed the study. Data analysis was done by Bhandari S. Maharjan R; and Sah MK drafted manuscript for publication. All authors critically read the manuscript, and agreed to its submission and publication.

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