

Original Article

Informed consent in elective surgical procedures: “What do the patients think?”

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Abstract

Objective: To analyze the patients' perspective of the process of informed consent in a tertiary care hospital setting.

Methods: A cross sectional survey was carried out at a tertiary care teaching hospital Islamabad and 200 patients were included who responded to the questionnaire. The study extended from March to May 2008. Patients were interviewed by trained personnel. Patients undergoing emergency surgery, minors and medical professionals were excluded from the study. Data was entered and frequencies and percentages were analyzed on SPSS 14.

Results: A total of 98% of patients admitted that informed consent was taken, however, only 81 (40.5%) patients understood the information provided. Patients reporting that their decision to proceed with surgery was actually influenced by other people including the treating doctor numbered 112 (56%). Only 58 (29%) signed their own consent form, the rest of them were signed by relatives. Only 96 (48%) patients admitted having been informed about possible complications of surgery as against 156 (78%) who were informed of sequelae of not having the surgery done. Signatures taken by the paramedics were 138 (69%). Despite a poor understanding of the process of informed consent, 187 (93.5%) still felt satisfied with the process of informed consent.

Conclusion: There is a lack of proper understanding by the population and inadequate system of informed consent in our setting. However, majority of the people still feel satisfied with the information provided. There is a unique family system where decision-making is shared within the family (JPMA 59:679; 2009).

Introduction

Informed consent, under the bioethical principle of autonomy, has become a major issue with medicolegal and ethical implications in healthcare around the world. All the institutions are required to take informed consent prior to

any intervention or procedure done on the patient, but studies raise the question whether informed consent is being implemented in true spirit or it is being adhered to as a medico legal formality.¹ There are five major components of informed consent i.e., voluntariness or autonomy,

adequate disclosure of all the relevant information about the procedure, understanding of information by the patient, competence of the patient to grant consent and finally consent itself.² The ultimate ethical objective should be the evolution of a process of informed consent which covers all aspects relevant to the patients' individual rights and preference and yet is not redundant in order to ensure better understanding on the patient's behalf. There are many assumed myths regarding informed consent that have not been formally explored and documented.³ Since the medico legal requirement concerns the doctor's interest more than the information component it is feared that doctors may secure documentation of informed consent without genuinely ensuring that the patient has received and understood the relevant information.⁴ It is also assumed that telling the patient about possible complications would discourage the patient from going ahead with surgery.³ Keeping these factors in mind it is essential to formally explore the relationship of informed consent procedure with the patients thought processes.⁵

Lastly, the effectiveness of the informed consent process in satisfying the patients' needs and rights and the patients' own perception, of how the process should be, is an essential, yet often ignored, element in the evolution of this process.⁶ While the topic is being researched on a global scale, two important studies have been done in Pakistan. One study assessed status of informed consent in patients presenting to the family medicine setting⁷ and the second study assessed status of informed consent in patients who had undergone surgery in a tertiary care hospital.⁸ Both studies indicated a very poor status of informed consent.

The present study was done to find out the patients' perceptions and thought processes about various components of informed consent taken at a tertiary care teaching hospital.

Patients and Methods

A Cross sectional study with a standardized interview-based questionnaire was conducted over a period of three months from March 2008 through May 2008. Patients were randomly selected from the wards at Shifa International Hospital Islamabad, a tertiary care multi-disciplinary hospital. Approval was taken from the Shifa Ethics Review Committee before starting the study. Two data collectors, after going through a training session, collected data from 200 patients who had undergone elective procedures. The data collectors interviewed the patients in Urdu (National language) and other local languages, if needed, such as Punjabi, Pushto, Hindko and English, in order to fill out the questionnaire. Wherever required, patients were asked further explanatory and

supplemental questions to get a better in-sight into their thought processes. Similar technique was used when the patients were asked if they understood the informed consent process and its information. Any patient who claimed to have understood the information was asked the relevant questions such as if he/she could describe the nature of his/her illness, the type of treatment he/she was offered and if he could name alternative options of treatment. Patients having emergency surgical procedures, minors (consent not valid), patients belonging to a medical profession and patients who refused to participate in the study were not included in the study. Data was analysed for frequencies and percentages of positive responses using SPSS 14.

Results

A total of 200 patients (93 males, 107 females) with mean age of 37 ± 3.5 years (range 18-75 years) were interviewed for the study (Table-1).

Table-1: Age group distribution of the patients included in the study.

Age group	Patients N= 200
18-25 yrs	45 (22.5 %)
26-35 yrs	43 (21.5 %)
35-50 years	50 (25 %)
51-65 yrs	45 (22.5 %)
> 65 years	17 (8.5 %)

While charts documented that informed consent was taken from all 200 patients, 4 (2%) patients denied that the said process was completed. Only 81 (40.5%) patients said that they understood the information provided. The educational status correlated poorly with the level of understanding by the patients (Table-2).

Table-2: The correlation of educational status of patients with the understanding of informed consent.

Educational status	Did you understand the information provided?		Total
	Yes	No	
None	22 (27.1%)	29 (24.3%)	51 (25.5%)
Primary	6 (7.4%)	25 (21%)	31 (15.5%)
High School	26 (32.1%)	34 (28.6%)	60 (30%)
Graduate	14 (17.3%)	19 (15.9%)	33 (16.5%)
Post-Graduate	13 (16 %)	12 (10.1%)	25 (12.5%)
Total	81 (40.5%)	119 (59.5%)	200 (100%)

Another finding was of the involvement of friends and relatives of the patient in the decision making process. 112 (56%) patients reported that their decision to proceed with surgery was actually influenced by other people including the treating doctor. In all 58 (29%) patients signed their own forms while the rest of the forms were signed by husbands (N=29, 14.5%), parents (N=20, 10%), children

(N=35, 17.5%) and other relatives (N= 58, 29%).

Only 96 patients (48%) admitted having been informed about possible complications of surgery as against 156 (78%) who were informed of complications or sequelae of not having the surgery done. With regards to what they wanted to know about the complications of surgery, patients were most interested in knowing major complications (N=72, 36%) followed by minor (N=22, 11%), cosmetic (N=15, 7.5%) and common (N=11, 5.5%) complications. One hundred and thirty seven (68.5%) patients thought that the informed consent process as a whole encouraged them to make the decision for going ahead with the surgery even though the effect of mentioning possible complications had some discouraging effect.

Although 183 (91.5%) patients were verbally informed by the treating surgeon or his assistant about the nature and indications for surgery, however, written consent was taken by paramedical staff (N=138, 69%) followed by

Table-3: The positive responses of the patients to the questions used in the standardized Questionnaire. (Figures in parentheses represent percentages).

Questions	Patients' response N = 200 (%)
1. Was an informed consent taken?	196 (98)
2. Did you understand the information provided?	81(40.5)
3. Were you informed of the nature of surgery?	183 (91.5)
4. Were you informed of the indication for surgery?	189 (94.5)
5. Were you informed of the possible complications of surgery?	96 (48)
6. Were you informed of the alternatives to surgery?	153 (76.5)
7. Were you informed of possible complications if surgery is not done?	152 (76)
8. Were you informed of expected benefits of surgery?	167 (83.5)
9. Were you informed of the type of Anaesthesia?	132 (66)
10. Were you given an opportunity to have your questions answered?	187 (93.5)
11. Did the informed consent influence your decision to go for surgery?	137 (68.5)
12. Were you influenced by any one to proceed for surgery?	112 (56)
13. Are you in favour of the process of informed consent?	174 (87)
14. Is there any medico-legal significance of informed consent?	99 (49.5)
15. Were you satisfied with the info provided?	187 (93.5)

residents (N=21, 10.5%) and only 17 (8.5%) by the consultant him or herself. Twenty four (12%) patients could not recall who took the consent from them. Most of the patients (N=187, 93.5%) felt satisfied with the process of informed consent. The positive responses of the study population to most of the questions are given in Table-3.

Discussion

The present study has shown some interesting trends

in the patients' perceptions and values about informed consent being taken at our institute. Majority of the patients (N=196, 98%) acknowledged that informed consent was taken from them before going for surgery. However, there is extensive involvement of family members (especially in case of females) and friends in the decision making process (N=158, 79%). A similar trend has also been reported in national studies.^{9,10} In a significant number of cases, even the treating physician is given the role of a family member.¹¹⁻¹³ This is in sharp contrast to the established norms of the western hemisphere where the patients' personal autonomy is kept preserved at all cost.¹⁴

The review of national^{7,8,15} as well as international literature^{1,3,16} highlights the importance of informed consent and the need for more specific information related to the surgery and its complications. Patients feel more confident and satisfied if the treating surgeon prior to surgery shares important and relevant information with them.^{17,18} The poor understanding of the process exists despite the patients being given opportunity to have their questions answered (N=187, 93.5%). This paradox is depicted in many other studies as well, where despite being educated, the patients fail to understand the medical terminology often used by the physicians in verbal interactions or written forms.¹⁹⁻²¹ For our patients in particular, the medical terminologies mostly used in English are not comprehensible even if they are formally educated.

Other than low literacy rates, a review article²² identified factors in the poor understanding and the delivery of the process of informed consent such as inefficient healthcare system, no concept of individual rights, unwillingness to hear bad news and inhibition in the presence of treating physicians who enjoy much higher status in their eyes. The present study also highlighted lack of awareness amongst the population for their individual rights e.g. almost half of the patients did not know that the informed consent process had a medicolegal significance.¹³³ (66%) patients did not read the consent form, 58% (N=116) did not sign their consent forms while the remaining signed their forms without reading. It is, therefore, important for the healthcare provider, who is having the informed consent form signed, to emphasize the ethical as well as medico-legal significance of the document. As reported in the European studies, the majority of patients sign the consent form as a medico-legal requirement.^{23,24}

The issue 'Who takes the consent?' is also highlighted in literature. Usually the patients are informed about the various aspects of the procedure by the treating surgeon or members of his team and then the consent signatures are taken by the junior members of the team or by the paramedics.²⁵ Similar trend was observed in our study

where majority of signatures were taken by paramedical staff followed by residents. In the published series the patients and the junior doctors had similar perceptions of being less informed if the consent was taken by the junior doctors or the paramedic staff. The junior doctors felt that they had less than adequate knowledge about the complex surgical procedures to explain the patients and satisfy their queries properly.²⁶ Another study highlighted the need for more education of the senior as well junior surgical faculty in obtaining proper informed consent from the more knowledgeable patients of today.²⁷

The study also mapped out a particular pattern of information that was given preferentially over other information. More patients were informed of the possible complications if surgery was not done as opposed to complications of the surgery itself. The patients, too, felt discouraged on mentioning of possible risks of the procedure. However, as reported earlier,²⁸ majority of the patients in the present study perceived that, at the end of complete discussion, they had a feeling of being involved in their treatment and more confidence to go for surgery. Despite poor understanding of the information and other inadequacies, majority of the patients (N= 187, 93.5%) still felt satisfied with the process of informed consent. Similar trend has been reported in national^{8,13} and international literature.²² The patients' perception of satisfaction appears to be dependent upon engagement in the discussion and decision-making rather than complete understanding of the information being provided.^{19,21} This area needs to be further explored with targeted and specific studies. The present study appears limited in respect of a quantitative rather than qualitative analysis of the perceptions of the patients which are affected by, and dependent upon, multiple personal, family and social setup-related factors.

Conclusion

Results of our study indicate that the current practice of informed consent adequately addresses issues like indication and nature of surgery, alternatives of surgery, possible outcome of surgery, and complications if surgery is not done and majority of the patients in our set up are satisfied with the process of informed consent in our hospitals.

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