

Perceptions and Perspectives of Patients regarding process of informed consent in a tertiary care hospital

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ABSTRACT

Aim: To analyze the patient's perceptions and perceive about different components and procedure of taking informed consent in a tertiary care hospital

Methods: This was a cross sectional study conducted with a predesigned interview based questionnaire form. 150 patients who underwent cesarean section, were randomly selected for study at Jinnah Hospital, Lahore, which is a tertiary care multidisciplinary hospital. Patients who had some emergency surgical procedures, patients who belonged to a medical profession and the patients who refused to be interviewed were excluded from the study. Data was analyzed in SPSS Ver:17.0. Frequencies and percentages were calculated for demographic and perception process regarding informed consent.

Results: A total of 150 patients were included in the study. Age range of the patients, who were interviewed was 18-44 years. Majority of the patients were primipara 89(59.3%). Out of all cases, 64(42.7%) of patients were from rural areas and 88 patients (58.7%) belonged to poor socioeconomic class. Almost half of the patients 77(57.3%) were uneducated. It was observed that husbands, parents in law and patient's own parents were somehow or other were involved in the decision making process. In 107 cases (71.3%), the consent form was signed by the husband. The other forms were signed by mother in law 12(8%) and by patient's own parents 31(20.7%), surprisingly none of the patients signed her own consent form as primary consenting person though they were told about the reasons for cesarean section (n=134, 89.3%) by the signatory.

Conclusion: Majority of the patients in our set-up were satisfied with the process of informed consent, though at times, some of them were not fully aware about indications, risks and benefits of the surgery.

Keywords: Informed consent, Medical ethics, perceptions.

INTRODUCTION

Consent before a procedure is an ethical and legal necessity that has to be fulfilled before any minor/major surgery is carried out. But the different studies have highlighted the fact, that the practice of obtaining informed consent is not implemented in its true spirit¹.

In view of increasing litigation practices in medical field, informed consent procedure has become even more sophisticated and involves much more than just completing a form. The five important components of taking written informed consent include, patient's voluntariness or autonomy, patient having the right to know all the relevant facts and details about the procedure, comprehensive understanding of information by the patient (which then needs to be checked by asking questions from patient), competence of the patient to give consent and then finally the consent itself².

The significant ethical objective of obtaining an informed consent and the evolution of its process is that it should cover all aspects relevant to the patients' individual rights and preferences. Moreover it should ensure better understanding by patient as regards to all information given to him/her. In fact, generally we do not know how the patients perceive about and understand information delivered to them while taking consent. Moreover they are not aware of significance of the consent form. Many

patients feel anxious and frightened, while giving written consent and many times they do not even read the consent form, nor they understand the information, thus not meeting the essential requirement of process of informed consent^{3,4}.

The doctors are concerned and interested more with the medico legal requirement of a consent process rather than the type of information given to patient. So there are chances that doctors may get the consent form signed by patient without genuinely ensuring that the patient has actually understood the relevant information⁵. During the informed consent process, many times it is also assumed that if the patient is told about possible procedure related complications, the patient might refuse to go ahead with the surgery⁶. So keeping these factors in mind, it is essential that the consent process should match with the patient's level of understanding and intellect so that it doesn't differ much from patients' thought process⁷.

As a matter of fact the process of informed consent should cover all important aspects and components so as to satisfy the patients' needs and rights and the patients' own understanding of essential facts and that how the process should be. This of course, is an essential, yet often ignored, element in the evolution of this process⁸.

This present study was conducted at a tertiary care teaching hospital, to review the patients' perception, attitude and how they think about various components of informed consent.

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PATIENTS AND METHODS

This was a cross sectional study and the subjects were interviewed according to a predesigned questionnaire proforma. Permission was granted from the Ethical Committee. Patients were selected randomly from post-operative ward of department of obstetrics and gynecology at Jinnah Hospital. Data of 150 patients was collected. All of these patients underwent cesarean sections. Wherever required, patients were asked specific probing questions to further explore their thought processes. Patients who claimed to be satisfied with the information provided in consent form and to have understood those information, were asked the relevant questions to describe the nature of indication of surgery and alternate management options. Patients who underwent emergency surgical procedures, patients who belonged to medical profession and patients who refused to be interviewed were excluded from the study. Data was analyzed for frequencies and percentage.

RESULTS

A total of 150 patients were interviewed. Age range of subjects interviewed was 18-44 years (Table-1). Most of the patients were primipara 89(59.3%). Out of 150 patients 64 (42.7%) came from rural areas and 88 patients (58.7%) belonged to poor socioeconomic class. Almost half of the patients 77(51.3%) were illiterate but the level of understanding of consent information by the patients correlated poorly with their educational status (table- II).

Another finding was of the involvement of husband, parents in law and patients, own parents in the decision making process. In 107 cases (71.3%), the consent form was signed by the husband. All other forms were signed by mother in law 12(8%) and by patients' own parents 31(20.7%). Surprisingly none of the patients signed her own consent form though they were told about the reasons for cesarean section 134(89.3%).

In only 19 cases (12.7%), the patients were not fully convinced with the reason of cesarean section which they were told about. Though 111(74%) patients agreed that they were informed about the risks and benefits of surgery but out of these, 62 patients (41.3%) denied that they were fully aware about the risks and benefits of c-section.

Though all of the patients in this study were informed verbally about the nature and indications for surgery by the treating surgeon themselves, but the written consent was taken by the nursing staff in almost 40% of cases (N=60), which may leave a gap in dissemination and understanding of important information. The table-III illustrates the answers of respondents to most of the questions.

Table-1 Distribution of age group (n=150)

Age (years)	n	%age
Less than 20	8	5.3
21-30	124	82.7
31-40	9	6
More than 40	9	6

Table-II: Correlation of education with patients, understanding

Educational status	Positive understanding	%age
Illiterate	40	26.7
Middle / Matric	55	36.7
Graduate	3	2

Table III: Patient' response to questions (n=150)

Questions	Patients, response Yes	%age
Awareness about reasons for cesarean section	134	89.3
Satisfaction with reasons for cesarean section	121	80.7
Information (given by doctor) about risks/ benefits of surgery	111	74
Full understanding about risks/ benefits of surgery	88	58.7
Risks of alternate options explained	116	77.3
Required more information about surgery	38	25.3

DISCUSSION

This current study has highlighted some interesting facts and trends about the patient's perception about informed consent and their practical role in consenting for a surgery. It was surprising to note that 16 out of 150 patients (10.7%) were not even aware of the reason for cesarean section. This shows loopholes in communication with the patients and in obtaining a valid informed written consent, as 29 patients (19.3%) were not satisfied with the reason for their surgery.

The poor understanding of consent exists despite detailed discussion. This paradox is explained by other studies as well, as in many cases the patient fail to understand medical terminology^{9,10}. The other reason for failure to understand is low literacy rate. The Patient is more satisfied and understand the information better if the treating surgeon him/herself talks to them and shares with them important and relevant informations¹¹.

The present study highlights the dominant role of husband (in a male dominant society) in decision making (107, 71.3%). Moreover there was extensive involvement of other family members in decision making process. A similar trend has also been observed in other national studies^{12,13}. In many cases, when patient's family member are not available or are incompetent for consent process, even the treating physician has to play the role of a family member^{14,15}. This is contradictory to the established norms of the western society, where a lot of emphasis is upon preserving the patient's confidentiality and personal autonomy at all cost¹⁶.

A Pakistani review article identified several factors which leads to poor understanding of consent process and the poor delivery of information, such as faulty and inefficient healthcare system, where patient's individual rights are not looked after and the patients are not mentally ready to hear bad news¹⁷. This current study similarly highlights that the patients are usually unaware of their individual rights, that is why none of the patients signed their own consent form for surgery. Even the parents and husbands were unaware of importance of information and consent process and thus signed the forms without actually knowing it's contents. So it is very important that the healthcare providers should educate the patients and their relatives about the ethical as well as medico legal significance of this document. As reported in different European studies, the majority of patients know

the significance of consent form and sign it with full understanding as a medico legal requirement¹⁸.

In this study, though the patients did not fully understand the information delivered to them and that there were other limitations and inadequacies in the consent process, yet the majority of the patients 121(80.7%) felt satisfied with the reason of surgery. Similar observations have been reported in national¹⁹ and international literature. How the patient perceive the consent process and how much she is satisfied with the information delivered to her, is mainly dependent upon how much the patient is engaged in the discussion and decision making process. This process is compromised if there is unilateral delivery of the informations²⁰.

The inherent weaknesses in consent process needs to be evaluated further. For this purpose, targeted and specific studies should be conducted. The present study had certain limitations. This was a quantitative rather than qualitative analysis of the perceptions of the patients, so the ultimate results of the study are biased by, and are dependent upon, multiple personal, family and social set-up related confounding factors.

CONCLUSION

This study reflects disparity between the protocol of the consent process, as depicted in the bioethical model and how it is perceived and experienced by the patients who are not even aware of their rights to give consent for their surgery. The common practice of informed consent focuses on issues like indications and type of surgery and complications if surgery is not done and to some extent the alternate options of surgery and the possible outcome. Majority of the patients, are however satisfied with the process of informed consent despite few shortcomings in our hospitals.

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