Original Article

THE STANDARD OF INFORMED CONSENT IN ELECTIVE SURGERY - AN OBSERVATIONAL STUDY FROM A TERTIARY HEALTHCARE FACILITY

Muhammad Tayyab[1], Mahmud Aurangzeb[2]

ABSTRACT

Objectives: To evaluate the practice and patient's perception of informed consent before elective surgery in Tertiary Health Care setup.

Methodology: This questionnaire based observational study was conducted in Surgical Department of Khyber Teaching Hospital Peshawar from April 2009 to August 2009. Standard questionnaires were handed over during their stay in the hospital to the patients who had undergone elective surgery. Independent variables of our study were age, educational level and socioeconomic status. Dependent variables were knowledge about the disease, treatment options, alternatives, what if no treatment, type and risk of anesthesia and postoperative complications and their management, the consent taking authority, their satisfaction about the information given and whether the consent form was signed by the patients themselves or their attendants.

Results: In our study on 37 (24.33%) patients the consent was obtained by the concerned surgeon while in 113 (75.33%) patients consent was taken by some junior doctors (trainee medical officers or house surgeons). Disease was explained to 105 (70%) patients and various treatment options to 67 (44%) patients. One hundred thirty five (90%) patients were informed about the complications of their surgical treatment. Contrary to our expectations 110 (73.33%) patients expressed their satisfaction with the information given to them about their surgical management. Informed consent was signed by all (100%) the patients.

Conclusion: The current informed consent practice in our surgical setup is deficient as far as the international, legal and ethical standard is concerned. We think further measures should be taken to involve the concerned surgeon and enhance patient's understanding of informed consent for surgery.

KEY WORDS: Informed consent, Surgical practice, Preoperative.

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1. Dr. Muhammad Tayyab, MCPS, FCPS, Medical Officer.
2. Dr. Mahmood Aurangzeb, FRCS (UK), FRCS, FRCS, Professor and Incharge.

1-2: Department of Surgery, Khyber Teaching Hospital, Peshawar Pakistan.

Correspondence:

Dr. Muhammad Tayyab, Flat No.12 (New block), Khyber Teaching Hospital, Peshawar - Pakistan.
E-mail: tayyableo@yahoo.com

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INTRODUCTION

''Every human being of adult years and sound mind has a right to determine what shall be done with his own body''.[1] Surgical management starts from counseling by the surgeon where appropriate information regarding the nature of disease, the available treatment options and alternatives, the consequences of doing nothing and the possible outcome are

explained to the patient in reasonable details so that they develop a trust that everything is done in their best interest. In fact it is good to involve the patient fully in decision making.[2] The main purpose of informed consent before an intervention is to uphold and reinforce the concept of patient autonomy. As part of the process patient must have the opportunity to say ''No'' and be presented with an alternative course of action where they exist.[3] When surgeon and patient both agree on a course of treatment that is consent art.[4,5] The shared decision making model represent the best building of surgeon expertise and patient choice.[6]

We designed our study to evaluate the current practice of informed consent so that to construct a basis for a standard for the quality of the informed consent.

METHODOLOGY

This observational study was conduced during the five months period from April 2009 to August 2009. Age, educational level and socioeconomic status were the independent variables of our study. Dependent variables of the study were consent taking authority, patient's knowledge about his disease, various treatment options, alternatives, what if no treatment, the proposed surgery, its complications and their management, anesthesia and its complications, blood transfusion and its complications, rehabilitation, patient's confidence and satisfaction and who signed the consent form.

Using structured questionnaire 150 patients were interviewed about the information given to them about their surgical management as a part of the standard informed consent practice. We visited the patients within three days of their elective surgery when they were ready for interview to take place. Memory, education level and social status of the patient were important factors to affect such interview.

RESULTS

Postoperative interview based on structured questionnaire was conducted on 150 patients randomly selected willing patients. One hundred two (68%) were males and 48 (32%) females with a male to female ratio of 2:1. Age range was from 18 to 60 years, 54% were from 18 to 40 years and 69% were in 41 to 60 years range. Patients admitted as emergency and those below 18 years and above 60 years were excluded from the study.

Consent was taken by doctor other than the concerned surgeon in 113 (75.33%) patients. The consent was taken by the operating surgeon in only 37 (24.66%) patients. Their problem was discussed in details with 105 (70%) patients and 67 (44.66%) patients were told about the various treatment options of their disease as well as other alternatives while 55 (36.66%) patients were informed about the consequences in case of no treatment. Nature of the proposed surgery and type of anesthesia as well as associated risks, benefits and complications were explained to 135 (90%) and 65 (43.33%) patients respectively. Seventy eight (52%) patients knew about blood transfusion and its complications while 35 (23.33%) patients knew about postoperative complications and their management while only 15 (10%) patients were explained about rehabilitation.

Contrary to our expectations, 110 (73.33%) patients showed their confidence and satisfaction regarding the counseling and consent taking process. The consent form was signed by all the patients by signature or thumb print.

Table-I: Independent variables of the study

Variables	*No. of patients (%)*
Gender	
Males	102 (68%)
Females	48 (32%)
Age group	
18-40 years	81 (54%)
41-60 years	69 (46%)
Education level	
Illiterate	65 (43.33%)
Primary	52 (34.66%)
Secondary and Higher	33 (22%)

Table-II: Dependent variables of the study

Variables	*Yes (Patients %)*	*No (Patients %)*
Consent taken by the concerned surgeon	37 (24.66%)	113 (75.66%)
Problem was discussed in detail	105 (70%)	45 (30%)
Various treatment options explained	67 (44.66%)	83 (55.33%)
Consequences of no treatment discussed	55 (36.66%)	95 (63.33%)
Proposed surgery and its complications explained	135 (90%)	15(10%)
Type of anesthesia and its complications discussed	65(43.33%)	85 (56.665)
Blood transfusion and it complications discussed	78 (52%)	72 (48%)
Postoperative complications and treatment discussed	35 (23.33%)	115 (76.66%)
Postoperative rehabilitation discussed	15 (10%)	135 (90%)
Patient was confident and satisfied	110 (73.33%)	40 (26.66%)
Consent form was signed by the patient	100 (100%)	0 (0%)

DISCUSSION

Our study showed that consent was taken by the junior doctors like trainee medical officer and house surgeons in most (75.33%) patients which has far reaching implications in the consent taking process because it means that the surgeons were aware of requirement as determined by the department of health for an adequate consent.[7] Emphasis has been given that senior doctors should take the consent as many members of the surgical team might not have sufficient knowledge to inform the patient properly.[8] In 53 out of 110 cases, the most junior member of the surgical team took the consent and patients were not being warned about specific complications and risks associated with surgery. So use of standardized and structured consent forms was recommended which allowed the senior staff retains responsibility for consent while improving the standard of informed consent.[9]

We found that 70% patients were informed about the disease while various treatment options and alternatives were explained to 40% patients. The proposed surgery and its complications was discussed with 90% patients while type of anesthesia and associated complications to 43.33% patients.

For consent to be valid the patient must be properly informed about the risks and benefits which require a two way transfer of information in a meaningful and accessible form. Despite these requirements and precautions, in many cases patients claim to have been inadequately provided with the information necessary to make informed consent.[10,11] In another study it was noted that no information was provided to 69.3% of patients regarding surgical risks and 75% of patients received no information on risks of anesthesia.[12] Interestingly patient confidence and satisfaction was observed in 73% patients. Many authors have found that even when the consent process satisfied administration and legal requirements, patient's needs may not be met and some patients may even consent to surgery they do not want.[13] On the other hand despite the fact that very little information was provided in informed consent but most of the patients (78%) were satisfied by the informed consent.[14] All the patients signed the consent form themselves in our study and it was exactly consistent with the study by Amin MF et al on 200 patients.[15]

Limitation of the study: Our study has following limitations: (1). We selected patients randomly, irrespective of their social class and educational level which are important factors in the perception and understanding and decision making. (2). We interviewed the patients postoperatively and after passing through a

major process of anesthesia and surgery most of our patient's attitude was found different. In addition they could not recall the exact conversation with the consent taking authority. (3). Finally we could not generalize our findings being conducted in the Tertiary Care Hospital of our province having multicultural people with low literacy rate and least information about the primary health care.

CONCLUSIONS

Surgery is technically an assault unless the patient has given expressed and dully signed permission for this to occur. The practice and quality of informed consent in our setup is definitely below standards to international and ethical acceptability. Surgeon and health care providers must be trained through pre and post-graduate education system, hospital processing and procedures as well as individual practice. Moreover patient must be made aware of the legal implications of signing or not signing the informed consent.

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