Original Article

Elective Surgery

Preoperative Information & informed consent in Patients undergoing Elective Surgery at Isra University Hospital, Hyderabad

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ABSTRACT

Objective: The purpose of this study was to assess the patient's awareness of informed consent and to evaluate the current practice of obtaining informed consent from patients proposed for elective surgery in tertiary care hospital.

Study Design: Cross sectional survey

Place and Duration of Study: This study was conducted in Isra University Hospital, Hyderabad, Sindh from 2nd April 2012 to 3rd March 2013.

Materials and Methods: This study was designed as an observational investigation and no interference was made regarding the informed consent process to the patient. The selection criteria for the patients who were interviewed were convenience sampling. All adult patients of >18 years, who were undergoing various surgical procedures were interviewed after taking verbal informed consent on the second postoperative day, when they were comfortable to answer the questions. While all those patients who were uncomfortable due to pain or other reason and were unwilling to answer the questions were excluded from the study.

All the patients were asked predesigned questions related to the information they were provided before the surgery as part of standard informed consent practice.

Questions were asked in local language which includes the demographic data, operative details, risk, benefit, complications of surgery, type of anesthesia and alternative treatment options etc**.** The data was entered on SPSS version 16. Frequency & percentages were calculated to show the results.

Results: Mean age of the patients was 34.95± SD 14.236 years. 220 patients were included in the study. 183(83.18%) patients were told about the indications of surgery while 136 (61.81%) patients were not told about any complication of Surgery. Type of anesthesia was discussed in only 25(11.36%) of patients while complications of anesthesia were discussed in only 18(8.18%) of patients. 165(75%) patients were not given time to ask the questions regarding their disease or surgery. Consent by the consultants was taken in only 63(28.63%) patients.

Conclusion: The majority of the patients knew the indication of surgery but very few were informed about the possible complications and risk of the surgery and anesthesia..

Key Words: Informed Consent, Complications, Surgery, Anesthesia.

INTRODUCTION

Medical ethics is often defined as "the disciplined study of morality in medicine"[1]. It gives right to the patient to have full access to the information pertaining to his medical condition so as to be able to understand the possible course of the illness and the various implications it may have on his health. The health care providers must respect this right of the patient and offer them all possible opportunities to explain in detail about the disease and treatment options so that patients can take part in decision making and can voluntarily choose the form of health care for themselves [2,3].

Surgery and its possible complications can lead to medicolegal problems and litigation with patient alleging that they were not informed; whereas in our society, it is often presumed that telling the patient about possible complications and risks would discourage them from going ahead with the surgery[4]. A paradigm shift has been observed in the west whereby majority of patients want to be completely informed about the surgical procedure[5].

This requires that the patients be provided with all the relevant information pertaining to their case and to discuss with them all the available options including the possible complications and risks of surgery and anesthesia. It should actually be a joint decision making between the patient and the surgeon whereby a sort of agreement can be reached upon the optimum possible course to adopt in the best interests of the patient. Therefore, providing such an information and obtaining voluntary informed consent is an important and integral part of the medical practice [6] and is now universally recognized as an essential safeguard to ensure the preservation of individual rights[7].

Paternalism as well as coercion exercised during this process are unethical[1,3], contrary to the very concept of informed consent and should be avoided. It is also necessary that the patient understand the information provided[8] and that consent given is voluntary [9].

Moreover, the information provided should be in lay person language and should be clearly comprehensible.
This study was undertaken to assess the patient's awareness of informed consent and to evaluate the current practice of obtaining informed consent from patients proposed for elective surgery in tertiary care hospital.

MATERIALS AND METHODS

This cross sectional survey was conducted in IUH from 2nd April 2012 to 3rd March 2013. This study was designed as an observational investigation and no interference was made regarding the informed consent process to the patient. The selection criteria for the patients who were interviewed were convenience sampling. All adult patients of >18 years, who were undergoing various surgical procedures were interviewed after taking verbal informed consent on the second postoperative day, when they were comfortable to answer the questions. While all those patients who were uncomfortable due to pain or other reason and were unwilling to answer the questions were excluded from the study.
All the patients were asked predesigned questions related to the information they were provided before the surgery as part of standard informed consent practice.
Privacy and confidentiality was ensured throughout interview and response to individual question was only marked after reconfirming from the patient that the question has been clearly understood.
Questions were asked in local language so that they can understand easily. Questionnaire includes the demographic data, operative details, risk, benefit, complications of surgery, type of anesthesia and alternative treatment options etc**.** The data was entered on SPSS version 16. Frequency & percentages were calculated to show the results.

RESULTS

A total of 220 patients were included in the study. Their mean age was 34.95± SD14.236. Minimum age was 20 years and maximum was 85 year with age range of 65 years. 157(71.4%) patients were males while 63(28.6%) patients were females. Fifty seven (25.90%) patients were illiterate whereas 33(15%) were graduates. Thirty three (15%) patients belonged to upper socioeconomic class, 96(43.63%) to middle class, whereas 91(41.36%) belonged to poor socioeconomic class. (Table 1). One hundred eighty three (83.18%) patients were told about the indications of surgery while 136 (61.81%) patients were not told about any complication of surgery. Type of anesthesia was discussed in only 25(11.36%) of patients, while complications of anesthesia was discussed in only 18(8.18%) patients. 165(75%) patients were not given time to ask the questions regarding their disease or surgery (Table 2). Consent by the consultants was taken in only 63(28.63%) patients. Majority of the consents 121(55%) were given by relatives instead of patients themselves. (Table 3).

Table No.1: Demographic Data

Variables	Numbers	Percentages
Age < 30 years	97	44.1
30-40 years	64	29.1
41-51 years	28	12.7
> 51 years	31	14.1
Education . illiterate	57	25.90
Primary	60	27.27
Middle	70	31.81
Graduate	33	15
S.E.C. poor	91	41.36
Middle	96	43.63
Upper	33	15

Table No.2: Questions asked from the patients

Questions asked from patients	Numbers (percentages) yes	Numbers (percentages) NO
Have you told about nature of proposed surgical procedure	64(29.09)	156(70.9)
Other treatment options were discussed or not.	85(38.63)	135(61.36)
Have you told about complications of surgery	84(38.18)	136(61.81)
Was Choice of anesthesia discussed	25(11.36)	195(88.63)
Was Complications of anesthesia discussed	18(8.18)	202(91.81)
Have you told about hospital stay	66(30)	154(70)
Was time given to ask questions	55(25)	165(75)
Are you satisfied by the information provided to you	47(21.36)	173(78.63)
Did you read consent form	64(29.0)	156(70.9)
Is there any medicolegal significance of consent	87(39.54)	133(60.45)
Benefits of surgery were told to you	143(65)	77(35)
Did you understand the information	123(55.9)	97(44)
Did you told about the indication of surgery	183(83.18)	37(16.81)
Was written consent taken before surgery	220 (100)	00(00)

Table No.3: Consent taken and given by:

Variable	Numbers (percentages)
1. Written consent was taken by consultant	63 (28.63)
Staff nurse	66 (30)
Medical officer/ house officers	91 (41.36)
2. Consent given by Patient herself/ himself	89(40.45)
Relatives	121 (55)
Friends	10(4.54)

DISCUSSION

The results of this study showed that although 83.18% patients knew about the indication of surgery but only 29.0% patients were told about the nature of proposed surgical procedure. Similar results are seen in the study conducted by M Jawaid et al [10]. 61.81% patients in our study were not given any information about the complications of surgical procedure. The results of the study conducted by Siddiqui FG et al also revealed that 79.2% patients had not received any information about complications of surgery[11]. In another study, 69.3% patients reported receiving no information about the risk of surgical procedure [12].

Similar results are seen in the study conducted by Mc Keague et al in Auckland [13] and Kay R[14].

The anesthetists are obligated to explain to the patients, the proposed type of anesthesia and relevant risk & complications. Ideally, this information should be provided to the patient by the anesthetist directly but more often than not it is the surgeon who explains to them some of the information pertaining to the anesthetic procedure. In our study, 11.36% patients were told about the type of anesthesia and only 8.18% patients had received the information about the complications of anesthesia. Similar results are seen in the study conducted by Amin et al, whose results showed that only 15% patients received information about anesthesia complications[15]. While results of another study conducted by sidiqui FG showed that although 66% patients were informed about the type of anesthesia, but no patient was informed about complication of anesthesia[11]. Similar results are seen in the study conducted by Moores A et al. [16]

Ideally, the consent should be taken by the surgeon himself/ herself who is performing the surgery, because they are the best persons to answer the patients questions but unfortunately usually the consent is taken by medical officers, junior residents, staff nurses or even technicians who have limited knowledge and who think that just taking a signature or thumb impression over consent form is enough to dispense with the formalities[17]. In this study, consent was taken by consultants in only 28.63% of patients, while in rest of patients it was taken by the staff nurse, technicians & residents. Similar scenario is seen in the study conducted by M Jawaid, [10,] where in majority of cases, consent was taken by the duty doctors and paramedic staff.

Same is seen in Scottish study, whose results showed that patients acquired most of the information from junior doctors. [18]

In our study, 40.45% patients gave consent themselves while in rest of patients, consent was given by their family members or friends. Similar observation has been expressed in the study conducted by Jawaid M [10], where only 58.3% patients gave consent themselves & in rest of cases it was given by family members and friends. In our culture, where family values are high, the wishes of the elders may prevail and in many instances influence the decision of younger member. Moreover, usually major decisions are taken by the male head of the family. This may be the reason that usually consent is obtained/volunteered from (mostly the male) family members instead of the patients themselves, although this is challenging to the very concept of volunteerism [19.]

Informed consent has been defined as an expression of active participation of the patients in the decision making process [20,21] and it gives them the right to decide whether to receive or refuse the treatment. The health care provider is obliged to disclose all the necessary information to the patient including the type of the treatment, its benefits and possible risks and complications to help them make this decision [22]. They feel more satisfied and confident if the treating surgeon provides relevant information to them prior to surgery [17,13]. The review of national [23,15,24] & international literature[25,4,26] also highlights the importance of informed consent related to the surgery & its complications.

But in our study, one very interesting and important aspect disclosed is that while information in variable degree was provided to the patients, they were not encouraged or even afforded enough opportunity to ask questions themselves pertaining to their disease or surgery as is evident from our results which show that only 25% of the patients interacted with the interviewer and asked questions regarding their ailment. This is contrary to the very concept and spirit of joint decision making process which is often advocated in various studies.

There are some limitations of our study. As the interview was conducted in the postoperative period, so there are chances that some of the information given preoperatively might have been forgotten by the patients, preoperative interview on the other hand carries with the risk of interference with the process of care. This study was conducted in one private sector hospital. More hospitals especially public sector hospitals should be involved in the study to see the difference.

In conclusion our study has highlighted the deficiencies in many areas; hence improvements are needed to upgrade the quality of preoperative informed consent process both at patient level and health care professional level.

CONCLUSION

The majority of the patients, in our study, knew the indication of surgery but very few patients knew the different treatment options, benefit, risk and complications of surgery and anesthesia. Not all the patients were given chance to ask questions from doctor to clear up various ambiguities concerning their treatment plans.

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