AN AUDIT OF INFORMED CONSENT IN SURGICAL PATIENTS AT A UNIVERSITY HOSPITAL

Faisal Ghani Siddiqui, Jan Mohammad Shaikh*, Mohammad Munir Memon
Department of Surgery, *Anaesthesia, Liaquat University of Medical & Health Sciences, Jamshoro, Pakistan

Background: To obtain informed consent is considered an integral part of modern clinical practice. It works as a safeguard of patient's rights and minimizes the chances of legal action against the physician in case of any complication arising from the proposed therapy. Objective was to evaluate the practice of informed consent in patients undergoing surgery in a University hospital. **Methods**: A survey was conducted at different surgical departments of a university hospital during December 2007 to March 2008. Participants were selected from patients over the age of 18 years who had undergone elective or emergency surgery. All interviews were based on structured questionnaire. The patients were asked if an informed consent was taken or not before the surgery. They were also inquired if they were given information about the diagnosis, the surgical procedure planned and risks associated with it. The patients were also asked if they were informed about the types of anaesthesia proposed. **Results**: A total of 106 patients were randomly selected for this study. In 8.5% cases, no consent was taken. Only 38% of the surveyed patients acknowledged that they actually understood the information imparted to them. 66% patients were informed about the type of anaesthesia proposed but none was given any hint about complications of anaesthesia. 11% patients actually signed the consent forms themselves. **Conclusion**: The quality of existing informed consent process in a university hospital is less than ideal. There is a great need to educate the doctors and healthcare regarding the importance of patient's autonomy and their right to the information about their medical condition and the proposed surgical procedures to ensure their participation in the decision making regarding their treatment.

Keywords: Informed consent, audit, postoperative patients

INTRODUCTION

Informed consent is a process by which a competent patient is given all the relevant information about his disease so that he can participate in choices regarding his health care. It is generally accepted that an informed consent includes discussion on the nature of the procedure, reasonable alternatives to the proposed intervention, and the relevant risks and benefits associated with the procedure.[1,2] It is necessary that the patient understands the information provided[3] and that the consent given is voluntary[4]. Comprehension on part of the patient is as important as the information provided. Consequently, the information provided should be in layperson's terms.

A paradigm shift has been observed in the west whereby increasing number of patients want to be extensively informed about procedural alternatives, risks and benefits before electing to undergo a surgical procedure.[5] Unfortunately, in hospital practice in our setup, patients and their families are mostly given very little or inadequate information. This study was designed to evaluate the current practice of taking informed consent in preoperative emergency and elective surgical procedures in a public sector tertiary care and teaching hospital.

PATIENTS AND METHODS

A survey was conducted at a tertiary care teaching hospital between December 2007 and March 2008. Participants were selected from patients over the age of 18 years who had undergone elective or emergency surgery in the departments of General Surgery, Obstetrics and Gynaecology, Orthopaedics, Urology and Neurosurgery. Permission was obtained from the unit chiefs of each ward. Patients were interviewed in the immediate postoperative period once they were deemed comfortable to answer the interviewer's questions. Patients who were unwell or uncomfortable because of pain, nasogastric tube or any other immediate postoperative complication were not interviewed. All interviews were based on structured questionnaire.

RESULTS

A total of 106 postoperative patients were randomly selected for this study. Demographic data of patients is given in Table-1. In 9 (8.5%) cases, no consent was taken with males outnumbering females with a ratio of 2:1. All cases where no informed consent was taken belonged to the department of General Surgery with more than two thirds undergoing emergency surgical procedures. All 97 (91.5%) consents were taken by junior doctors or the paramedics and included registrars and postgraduates (94 cases), interns (2 cases) and nurses (1 case). In none of the patients was the informed consent taken by the surgeon who will be performing the procedure.

Only 21 (19.8%) consents were taken in the patient's mother tongue with just 38% agreeing to the

fact that they fully understood the information parted to them. All consents were taken on a handwritten document scribbled by the person taking the consent. Only 12 (11%) patients actually signed the consent forms themselves. In rest of the cases the consent was signed either by the family members (36%), spouses (21%), siblings (18%) or friends (14%).

Majority of the patients were informed about their existing surgical condition (89.7%) and the proposed procedure (72.1%). Details regarding information about alternate treatment options, complications of the proposed surgical procedure, type of intended anaesthesia technique and complications of anaesthesia are given in Table-2.

Table-1: Demographic data

Characteristic	Number (%)
Gender	
Male	61 (57.5%)
Female	45 (42.5%)
Physical Status	
ASA I	74 (69.8%)
ASA II	26 (24.5%)
ASA III	6 (5.7%)
Type of Surgery	
General Surgery	36 (34.0%)
Urology	15 (14.1%)
Orthopaedic	19 (17.9%)
Neurosurgery	7 (6.6%)
Gyn/Obs	29 (27.4%)
Nature of Surgery	
Elective	23 (21.7%)
Emergency	83 (78.3%)

ASA=American Society of Anaesthesiologists

Table-2: Characteristics of informed consent

Characteristic	Patient Informed No. (%)	Patient Not Informed No. (%)
Alternate Treatment Options	23 (21.7%)	83 (78.3%)
Complications of Surgical Procedure	22 (20.8%)	84 (79.2%)
Type of Anaesthesia	70 (66%)	36 (34%)
Complications of anaesthesia	00	106 (100%)

DISCUSSION

Physicians are required both by law and medical ethics to obtain the informed consent of their patients before initiating treatment, including any surgical procedure.[6] It is an expression of active participation of the patients and their families in the decision-making process and a means of respecting individual patient's autonomy.[7,8] An increasing number of patients are now being involved in the decision making regarding health care provision, especially in the west. This change has come about mainly due to the increased patient knowledge about their rights, generated by the mass media and better education.

In this survey, 9 (8.5%) patients received any information regarding the diagnosis or the surgical procedures planned and were not given a chance to sign a consent form. Majority of patients who did receive this information either failed to understand what was told to them or were not given adequate information. Fifty-eight (54.7%) patients acknowledged that they did not understand the information given to them citing various reasons including discussion in non-mother tongue (74.5%) and consent being taken by junior doctors or paramedics not well-versed with the diagnosis or the procedure planned (12.2%). Majority of the patients surveyed were given no information either about the nature of their diagnosis, purpose of operation, expected benefits or potential risks attached with it. Eighty seven (89.7%) received information about their existing surgical condition while 70 (72.1%) patients were informed about the nature of the proposed surgical procedure. In a similar study conducted by Amin MF *et al,* 71.5% and 45% patients received information regarding their medical condition and the nature of the proposed intervention respectively.[9]

Seventy percent of patients in our study were not given any information about the potential side-effects or complications associated with the proposed surgical procedure. Vessey *et al*., in their study, report that although majority of patients understood why an operation was being planned, 28 out of 49 (57.1%) patients undergoing surgery for acute abdomen did not receive any information about the complications before undergoing surgery.[10] In another study, 69.3% patients reported receiving no information about the potential risks.[11] The doctor's desire to protect patients against anxiety is usually cited as the reason for not divulging the complications associated with surgery. This notion, no matter how good-intentioned, is unfounded. Marco *et al*. refute this baseless impression by reporting that none of their patients undergoing coronary artery bypass surgery (CABG) or percutaneous coronary intervention (PCI) identified any of the explained risks as a reason to reconsider having the surgery with majority (80%) of the patients wanting to be informed of all the risks of surgery.[12] It is observed that although patients are usually notified why an operation was being planned, there is a clear need for improved discussion on common and important complications.[13]

A majority of patients (66%) in our survey acknowledged receiving information about the type of proposed anaesthesia. Interestingly, none of these patients were informed about the specific risks and consequences associated with anaesthesia. Amin *et al*. report only 15% patients receiving information about the complications associated with anaesthesia.[9] In current medical practice, patients who have consented to a surgical procedure are routinely considered to have given an implied consent to

undergo anaesthesia. It is usually regarded unacceptable for doctors, other than anaesthetists, to disclose the nature of the complications when they will neither be administering it nor have adequate knowledge of what is involved. Anaesthetists, therefore, have a duty to explain to the patient the nature, purpose and material risk of the proposed anaesthetic procedure. There is a dire need for designing specific guidelines by the anaesthetic departments for the process of taking consent.

Surprisingly, none of the consents in our study were taken on a printed proforma. Documentation of informed consent is considered an integral element for the protection of both the patient and the surgeon. Not even one department of this particular university hospital had a printed consent form. All consents were handwritten in Urdu on the patient's charts and majority were affixed with a thumb-print. Though we did explore general public's perception about the importance of documentation of informed consent, a study conducted in Karachi on participant's involved in medical research indicates that up to 61% of people believe that documentation of informed consent is important.[14] It was interesting to note that only 12 (11%) consents bore patients' own signature or thumbprint while the remaining 89% consents bore signature or thumbprints of siblings (18%), husbands (21%), other family members (36%) or friends (14%).

CONCLUSION

Informed consent enjoys an irrefutable position in clinical practice as a safeguard of patient's rights. It also minimizes the chances of legal action against the treating physician if a complication arises from the proposed therapy. Yet, the quality of existing informed consent process is less than ideal in our milieu and needs to be strengthened by educating both the patients and the physicians alike. There is a dire need to alert the doctors and healthcare providers *vis-à-vis* the significance of providing appropriate information to the patients and their relatives to ensure their participation in the decision making regarding their treatment. In addition, there is a dire need for designing specific guidelines by the anaesthetic departments for the process of taking consent for anaesthesia.

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Address for Correspondence:

Dr Faisal Ghani Siddiqui, 42/142-Defence Officers' Housing Society, Hyderabad, Pakistan. **Tel:** +92-22-2780451, **Cell:** +92-321- 3050707

Email: fgsiddiqui@gmail.com