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Original Article

Preoperative Informed Consent: Is It Truly Informed?

M Jawaid [1], M Farhan [2], Z Masood [3], SMN Husnain [4]

1. *Section of Surgery, Dow University of Health Sciences, Karachi, Pakistan*
2. *Cardiac Surgery, Dow University of Health Sciences, Karachi, Pakistan*
3. *Section of Surgery, Civil Hospital Karachi, Pakistan*
4. *Surgical Unit III, Civil Hospital Karachi, Pakistan*

***Corresponding Author:** Tel: +92-0300-9279786 Email: masood@masoodjawaid.com

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Abstract

Background: Pre-operative informed consent is an important aspect of surgery, yet there has been no formal training regarding it in Pakistan. This study was done to assess the preoperative informed consent practice.

Methods: After taking informed permission, a questionnaire was filled in during an interview with 350 patients, who have undergone elective surgical procedures under routine practice conditions from July to October 2010. All the patients were asked a set of standard questions which related to the information they were provided before the operation as a part of standard informed consent practice.

Results: Most i.e. 307 (87.7%) patients were informed about their condition but very few 12 (3.4%) were briefed regarding complications. Only 17 (4.9%) patients said they knew about the risks and complications of proposed anesthesia. One hundred thirty-eight (39.4%) patients said that they were allowed to ask questions while giving consent. Most of the time 196 (56%) consent was taken one day before surgery but in few 2 (0.6%) instances it was taken on the morning of surgery and on operation table in some cases 3 (0.9%) as reported by patients. The consent form was signed by the patients themselves in only 204 (58.3%) cases and by their relatives in the rest. About half the number of patients 171 (48.9%) interviewed were satisfied from the information they received as informed consent process.

Conclusion: This study highlights the poor quality of patient knowledge about surgical procedures and the inadequate information provided.

Keywords: Informed consent, Surgical ethics, Operative risks, Pakistan

Introduction

Providing information is an important aspect of doctor-patient relationship. The need to provide relevant and comprehensible information to patients before invasive procedures is continuously increasing. Nowadays, informed consent has replaced the old paternalistic notion of "the doctor knows best", with a more mutual patient-physician relationship (1). Patients expect to be informed of the risk of surgical interventions (2). Pre-operative informed consent requires that the procedures are properly explained that the patient understands the procedures and their risks, and agrees to undergo them voluntarily (3). One reason for taking informed consent is that it provides assurance that patients and others are neither deceived nor coerced (4). Hence, the process of obtaining consent is as important as the contents.

Successful surgery depends on a relationship of trust between the patient and the doctor. To

establish this, the patient's right to autonomy must be respected, even if their decision results in harm or death. Surgery is technically an assault, unless the patient has given permission for this to occur (5). However, despite these requirements; instances still arise in which patients claim to have been inadequately provided with the information necessary to make informed decisions (6).

In contrast to Western cultures, which adhere to more individually oriented philosophies, traditional Pakistani cultures place more value on the collective role of family in decision making. Due to this reason in the hospital practice of our region, most often patients are given inadequate information about their surgery before operation (7). Despite this general observation, there is limited research is available from our country about the usual practice of preoperative informed consent.

This study was designed to evaluate the current informed consent practice related to patients undergoing different surgical procedures in two large tertiary care teaching hospitals of Karachi.

Materials and Methods

The study was designed as an observational investigation, which dictated that no interference was to be made regarding the informed consent process to the patient. Study was carried out by using structured questionnaire-based interview technique by MF and ZM (both present simultaneously). After taking informed consent, patients who had undergone elective surgery at two large tertiary care teaching hospitals (Civil Hospital and Jinnah Postgraduate Medical Centre) of Karachi, were interviewed from July to October, 2010. Patients with neurological diseases and those aged under 18 or above 60 were excluded.

The selection criteria for the patients who were interviewed were convenience sampling. All the patients were asked a set of standard questions which related to the information they were provided before the operation as a part of standard informed consent practice. The second author did most of the interviews, which was on the bedside of the patients without the presence of the treating healthcare personal. Privacy and confidentiality was ensured throughout the interview and response to individual questions was only marked after reconfirming from the patient that the question had been clearly understood.

The questions were asked in the local language which was in Urdu, so that patients could easily understand and respond to the same. The questionnaire sought information in yes/no format regarding the patient's knowledge prior to surgery, operative details with risks, type of anesthesia to be given with its risks, alternate treatment options, outcome in case of no treatment. Timing of consent, designation of consent taker and who gave the consent were also enquired. All the interviews were conducted by interviewer who had no involvement in the delivery of health care, between one to four days postoperatively at the earliest time the patient is comfortable to do so. All the question asked are shown in Fig. 1.

As part of preoperative consent:
- Have you told about your condition prior to surgery?
- Have you told about details of surgery?
- Have you told about complications of surgery?
- Have you told about the type of anesthesia to be given?
- Have you told about the complications of anesthesia?
- Have you told about alternate treatment options?
- Have you told about outcome in case of no treatment?
- Was time given to you to ask questions?
- What was the timing of consent?
- Consent was taken by?
- Consent was signed/given by?
- Are you satisfied by the preoperative consent procedure?

Fig.1: Questions asked in structured interview

Results

A total of 350 patients belonging to four specialties of surgery were interviewed (Table-1). Most i.e. 307 (87.7%) of the patients were informed about their condition and the nature of surgery they were to undergo, but only some 31 (8.9%) patients said that knew the details of surgery and very few 12 (3.4%) said they knew about possible

complications. Majority of patients 254 (72.5%) said they were aware of the type of anesthesia to be given but only 17 (4.9%) said they knew about its complications. One hundred and thirty-eight (39.4%) patients said that they were allowed to ask questions while giving consent (Table-2).

Table1: Demography of patients

Age (Mean±SD)	37.44±14.46
Gender (M:F)	217:133
ASA status* (I/II)	264 / 136
Education	
Nil	126 (36.0%)
Primary	86 (24.6%)
Secondary	59 (16.9%)
Matric	72 (20.6%)
Graduate	7 (2.0%)
Hospital	
Civil Hospital Karachi	200 (57.1%)
Jinnah Postgraduate Medical Centre	150 (42.8%)
Surgical Department	
General Surgery	200 (57.1%)
Orthopaedics	50 (14.3%)
Ear Nose & Throat	50 (14.3%)
Ophthalmology	50 (14.3%)

* ASA: American Society of Anesthesia

Table 2: Affirmative (yes) responses of patients at Post-operative Interview (n=350)

Question	n (%)
Condition prior to surgery	307 (87.7)
Details of surgery	31 (8.9)
Complications of surgery	12 (3.4)
Type of anesthesia to be given	254 (72.5)
Complications of anesthesia	17 (4.9)
Alternate treatment options	11 (3.1)
Outcome in case of no treatment	15 (4.3)
Allowed to ask questions	138 (39.4)

In most 196 (56%) of the cases consent was taken one day before surgery but in few instances (0.6%) it was taken on the morning of surgery and even on the operation table in some instances (0.9%) as reported by patients. In more than half (54.6%) of cases the consent was taken by the junior duty doctor (intern/House officer) and in 42.6% by the paramedical staff (Table-3). The consent form was signed by 58.3% of patients only; but by their relatives and friends in rest of the cases 41.7% (Table-3).

Table3: Timing of Consent and personnel involved

Timing of consent	n (%)
At admission	149 (42.6)
One day before surgery	196 (56.0)
On the morning of surgery	2 (0.6)
On table in operation room	3 (0.9)
Consent taken by	
Duty Doctor	191 (54.6)
Paramedical Staff	149 (42.6)
Consultant	10 (2.9)
Consent given by	
Patient	204 (58.3)
Relative	140 (40.0)
Son	44 (12.6)
Brother	32 (9.1)
Husband	23 (6.6)
Mother	14 (4.0)
Father	11 (3.1)
Daughter	9 (2.6)
Sister	5 (1.4)
Wife	1 (0.3)
Uncle	1 (0.3)
Friend	6 (1.7)

On further analysis, there was statistical significant difference between male and female who gave the consent themselves [male 144 (67.3%); female 57 (42.9%)] chi2 test $P<0.001$. About half the number of patients (48.9%) interviewed were satisfied from the information they received as informed consent process.

Discussion

Our study showed that the current preoperative informed consent practice in large tertiary care teaching hospitals of Karachi was below international ethical acceptability standards. Even current status of the disease was not explained to all of the patients. Informed consent is not simply the signing of a consent form by the patient but more

importantly, it is a process of a detailed discussion between the doctor and the patient. This process takes time. However, for the busy health-care provider there is often the temptation to hand over the consent form to the patient for signing or delegate the responsibility to a junior doctor or even paramedics. It is important to realize that signing a consent form does not constitute informed consent (8).

Very few of our patients said that the details of surgery were explained to them. In a study about patient's perception of informed consent, 34% patients said they did not understand what the operation itself consisted of and 31% patients stated that they would have liked more information about the operation after were admitted to hospital (9). One major part of consent is adequate explanation about the possible complications of the proposed surgery. Only 3.4% patients in the present study were told about this aspect. The doctor is obliged to disclose any significant risks to the patient (10). Simply obtaining a patient's written consent does not mean that the legal duty towards a patient to explain all material risks has been fulfilled. Kay R, et al. reported that 46% patients received explanation about the potential side effects and complications of surgery before an elective abdominal procedure (11). Another study cited the similar observation in which over 1/3rd of the patients could not name a single complication of the proposed surgery (9).

Anaesthetists, like other doctors also have a duty to obtain 'informed consent' from their patients but they are not involved in this process in our setup. Even, not all patients were aware of the type of anesthesia to be given and only about 5% were told about the complications of planned anesthesia. A study regarding information requested by the patients prior to surgery showed that 66% questions were related to the nature of anaesthesia and 30% about proposed procedure (12).

Ideally, the consent should be taken be the surgeons performing the procedure, as they are usually the best person to answer the queries. However, this task is usually left to the most junior doctor of the surgical team (13). A study from Aukland revealed that house officer obtained written consent from 79% of the patients, the registrar from 6% and the consultant from 14% (9). Most patients feel that the house surgeon provides the least useful information regarding the nature, risks, benefits, and alternate options to treatment. This is in accordance with a Scottish study, which showed that the patients acquired most of the information from junior doctors during their stay in the hospital (14). In the current study also, the consent was mostly taken by house officers; even the paramedical staff took consent in many cases in our hospitals.

Pakistan is a mainly patriarchal society with the economical background dividing the population in various ill defined classes. Major decisions effecting life and other issues are mainly decided by the male head, who may or may not be the bread earner of the family. The same also takes on the responsibility of the outcome of the decision made. The individual person, even if directly affected by the circumstances surrounding the decision has minimal say especially if they are female member of the family. This is an accepted norm and doctors during their training learn to follow this cultural environment. This is the main reason and most of the time in our setup even preoperative informed consent was taken from the family member instead of patients himself/herself.

In some cultures patients prefer to hand over their decision-making to elder family members. In countries like Pakistan, where family values are high, the wishes of the elders may coerce the decision of a younger member, thereby challenging the concept of voluntarism (15). It was interesting to note that the consent was not obtained from all the patients in our study; sometimes other members of the family and even friends gave the consent for surgery on behalf of the patients (Table-3). However, we feel that it is important that the ultimate decision about whether or not to go ahead with the procedure should be made by the patient and he/she should be the one to sign the consent form.

The timing of obtaining informed consent is also very important. Patients usually prefer information about a planned surgical procedure in the out

patient clinic and final consent for surgery when admitted to the ward (16). Most patients in this study gave pre-operative consent in less than perfect circumstances, as they had already been through the admission process and were within 24 hours of surgery and even in few instances on the operating table. In these circumstances, it is difficult to imagine how a patient would feel free to refuse the proposed surgical treatment? In a study about patient's perceptions, one third of the patients did not realize that they can change their mind after they had signed the consent form (9).

It is also important to find out how much information is wanted by the patient. It is interesting to note that in one study, disclosure of 'minimal' information in a leaflet led to only 29% of patients believing the content to be too little. This however, increased to 63%, when further information was provided later (17). In other words, further disclosure of information leads to more requests on the part of patients. It is not clear; however, how much information would be considered reasonable. Osuna et al. (18) demonstrated in their study that patients were not satisfied with the information they were provided. They did sign the consent form but felt that they have not fully understood the risks involved in the surgery and anesthesia. On the other hand giving too much information has a grave potential of making the patient refuse surgery, even when told with the best of intentions (19).

A similar trend was observed in our study where although little information was provided but half of the patients were satisfied with the information received. Saw et al. concluded that 41% of their patients did not mind what happened to them provided they were made better; 54% trusted their doctor to do the right thing and did not think detailed explanation was important (20).

To increase the quality of informed consent practice in our setup, we plan to arrange small group workshops and awareness seminars for healthcare personals. We are also working on a study about what patients want to know before their surgery in our culture, so that we can work on our own guidelines and not following Western culture blindly. We believe patient's wishes in this respect may be different from Western culture because of our family values and belief in God. Also a study is in planning phase in which the quality of the informed consent is correlated with the patient's experience of the care.

Limitations of the Study

There are some limitations of our study. As the interviews were conducted in the postoperative period, hence it is possible that some of the information given preoperatively might have been forgotten by the patients; preoperatively interviews on the other hand carries with the risk of interference with the process of care. The hospitals involved in this study were public sector hospitals; things may be different in the private sector.

In conclusion our study has highlighted deficiencies in a number of areas; hence improvements are needed to upgrade the quality of pre-operative informed consent practice. Senior doctors should play a major role and provide specific information before or just after admission to hospital. The information should be simple and concise, and should highlight possible complications to enable the patient to determine whether to undergo or decline a procedure. It is equally important to confirm that the patient understands and is fully satisfied with the information provided. There is a need for formulating standard guidelines about informed consent in our country and to train health care providers in this aspect. As majority of patients in our study perceived no discussion of the potential side effects or complications of surgery it could be argued that consent was not truly informed.

Ethical considerations

Ethical issues (Including plagiarism, Informed Consent, misconduct, data fabrication and/or falsification, double publication and/or submission, redundancy, etc) have been completely observed by the authors.

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