

How Informed Is Informed Consent

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I. Introduction

Informed consent is a cornerstone of the ethics of modern medical care. In an ideal world, informed consent is a process of education – a conversation between a surgeon and a patient or family that allows the patient or family to make the best possible decision regarding care. The consent form was designed to serve as documentation of this conversation. However, in recent times, the consent form itself has become a medico legal necessity. (1)

Informed consent is an established ethical and legal requirement for surgical treatment. It has important roots in Anglo-American political theory and has been articulated in the law in a series of judicial decisions (2,3).

Informed consent also forms the ethical foundation for the modern practices of shared decision making and patient-centered care (4).

Informed consent has increasingly become a major topic of discussion and debate. While the need for client participation in healthcare decision making has been acknowledged, its implementation has been varied and individualistic.

Studies from developing countries show that patients view written consent as ritualistic and bureaucratic. Some feel frightened or pressured to give consent (5,6).

Considering the above, researchers in India are beginning to recognize the limitations of standard informed consent forms. For non-literate and semi-literate persons, this document is viewed with suspicion and one to which they are reluctant to affix their signatures or thumb impressions. In order instances, the informed consent process has become a mere formality with subject/patients simply acquiescing to whatever is required of them.

Aim: To study how informed is 'informed consent'

Objectives

- (i) To assess how much information is given to the patient before taking consent for surgery.
- (ii) To assess how efficiently consent forms were filled.
- (iii) To assess the patient perception of informed consent.

II. Material and method

Study design. This study is a cross sectional study using in depth interviews to assess the information given to patient and to assess how efficiently forms consent were filled, preoperatively.

Study setting. The study was carried out in ward of General Surgery, Neurosurgery, Plastic Surgery, Urology and Obstetrics & Gynaecology department of a 1082 bedded tertiary care hospital in a metropolitan city

Study duration. The study was conducted over a period of 12 weeks as per the following schedule:-

- (i) Defining scope of study- 2 weeks
- (ii) Selection of validated checklist- 2 weeks
- (iii) Data collection- 4 weeks
- (iv) Analysis of data- 2 weeks
- (v) Final write up- 2 weeks

Sampling method and size. The convenient sampling method was used. Sample size of 200 was calculated using statistical software by using sample size of previous related studies and taking degree of freedom as 5.

Exclusion criteria. All patients who have been operated in any other hospital and have been admitted here for further treatment have been excluded from the study.

Inclusion criteria. All patients who had undergone surgery and signed written consent form preoperatively of General Surgery, Neurosurgery, Plastic Surgery, Urology and Obstetrics and Gynaecology ward, within the study time period, were included in the study

III. Methodology

This is a prospective study with a view to assess the information given to patient before signing the consent form and to assess efficiency in filling up the consent form.

We studied numerous literatures and articles regarding informed consent in relevant journals. Validated checklist was taken from WHO website and incorporated in the study. Checklists are attached as AppxA&Appx B. Multiple visits were done to various wards and patients were identified who have undergone surgery. Only those patients who were physically fit enough to participate in interview and have given written consent were included. A team of 04 members conducted interview in Hindi/ local language and the results were transcribed in English for analysis. A frame work analytical approach was used for data analysis which involves categorical analysis of data on following 5 parameters pertaining to patients who had undergone surgery. All interviews were carried out in privacy and both patients and their relatives were assured of confidentiality.

Patients related data of name, age, sex, education, monthly income and admission date, surgery date and diagnosis were recorded from medical sheet. Then structured interview was conducted which was based on fourteen points in the checklist and marked as yes or no according to responses given by patients. These responses were calculated for each patient and inference was withdrawn from graphs, plotted for five parameters i.e. age, sex, education, type of patient and type of surgery whether elective or emergency, by using computer software minitab.

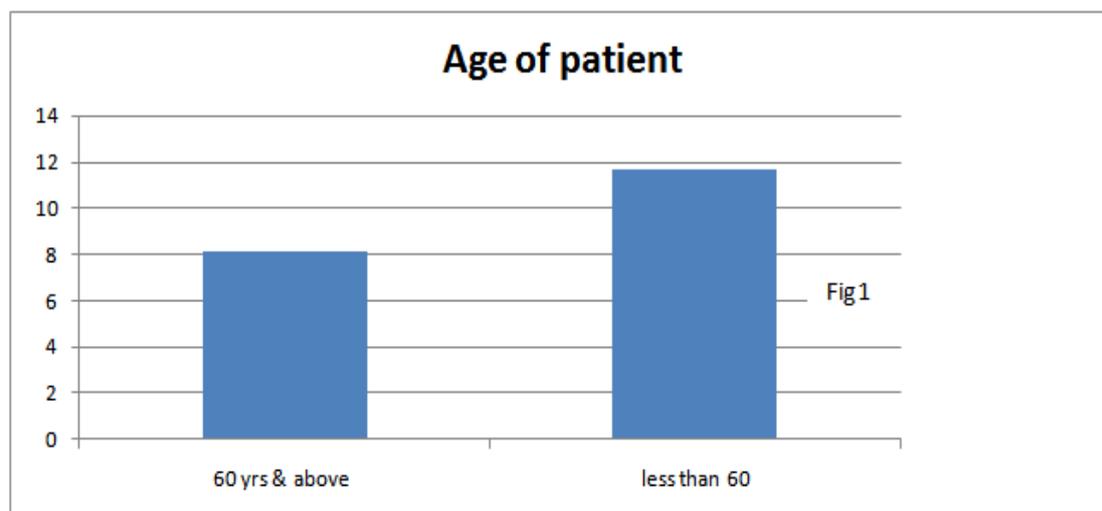
Another checklist of eight points was employed for the assessment of efficiency in filling up of informed consent forms. The responses were undertaken as Yes and No, directly from filled consent forms. These responses were calculated and inference was withdrawn. The photographs of these forms were taken for future references.

IV. Observation & Discussion

200 patients were interviewed to assess how much information was provided to them before undergoing the surgery. To put the data in quantifiable term a validated checklist was used when the patient mentioned that particular information was provided it was taken as a 'Yes' response and if patient mentioned that particular information was not provided it was taken as a 'No' response. Using the checklist, average Yes responses were calculated for each patient, patients were then categorized based on their age, sex, educational status, economic status, economic status of the patient and type of surgery whether emergency or elective.

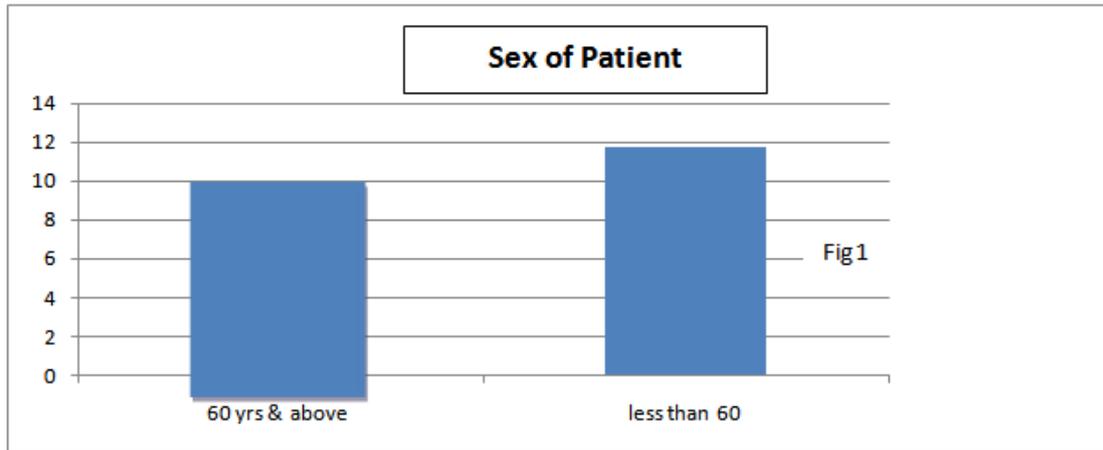
Graphical representation of the data is shown in the Fig (1,2,3,4,& 5) The graph has been plotted using category of patients on X axis and average number of 'Yes' responses in the checklist on Y axis.

(a) Age of the patient. Patients age more than 60 years (n= 32) showed an average of 8 'Yes' responses and patients below 60 years of age (n= 168) had an average of 11. In the present study it was found that patients age less than 60 years were better informed. Fig 1

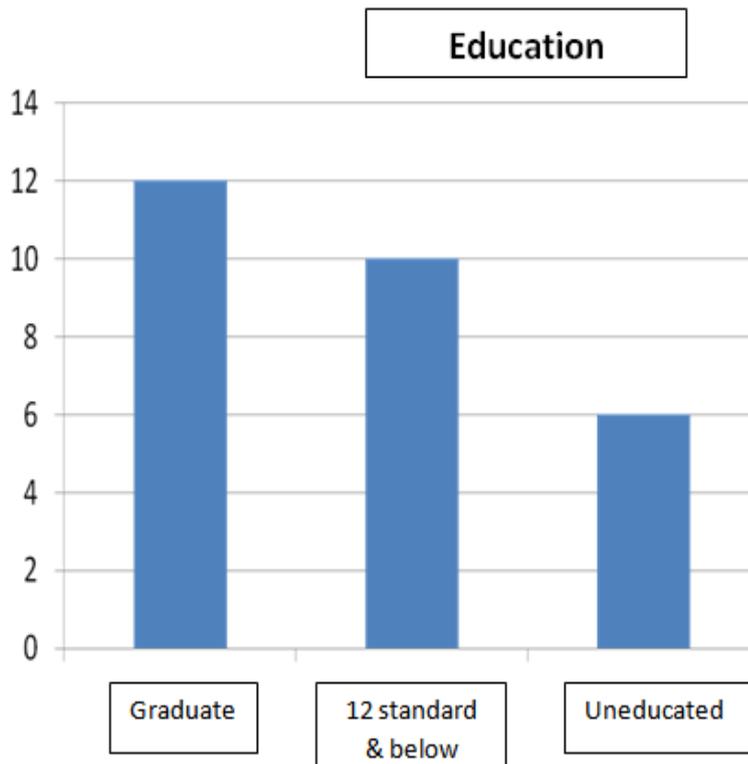


(b) Sex of the patient. Average Yes responses of male & female patients were 10.2 & 10.9 respectively. The mean scores did not differ significantly according to sex at any point of time.

Fig 2



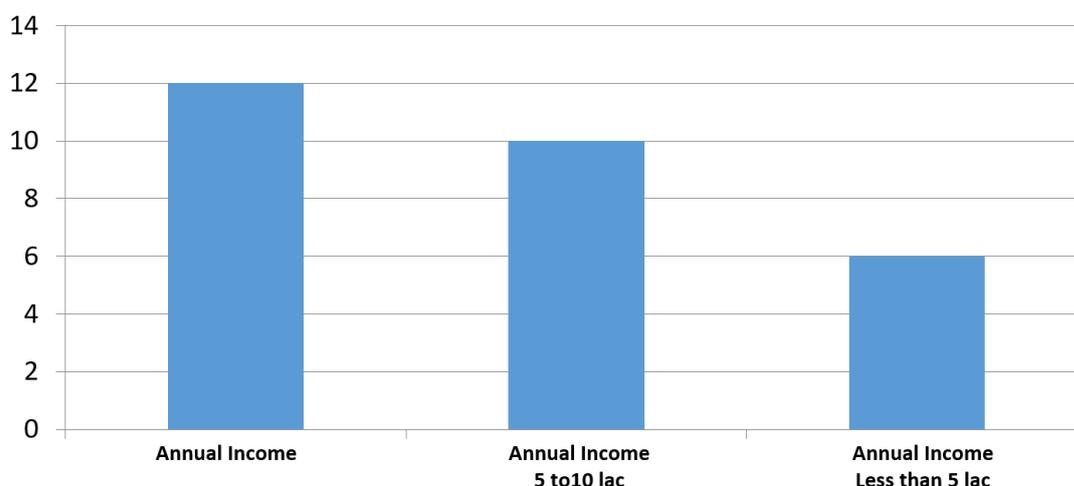
(c) The education level of patients were classified as uneducated & educated. Educated category was further divided into patients with a graduate degree and patients with education of 12th standard and below. The results obtained are shown in fig 3



Inference: In the present study we found a direct correlation between the educational status and information provided to the patient. Better the educational status better was the information provided to him/her.

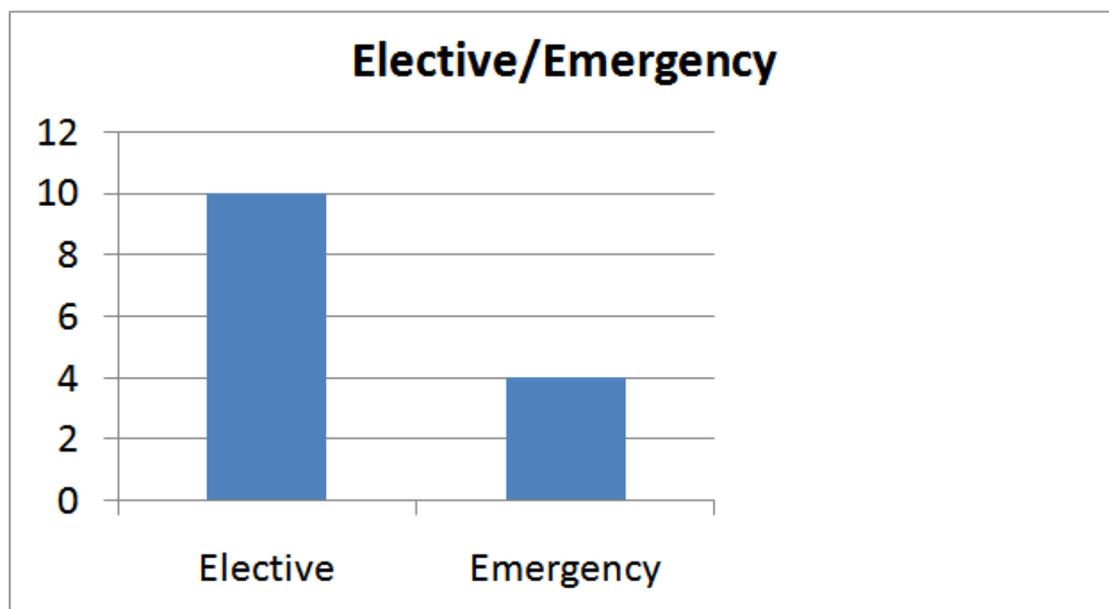
(d) Type of patients. Patients of the hospital were categorized based on economic status. Results obtained are shown in the fig 4

Fig 4
Based on economic status



Inference. It was found that patients with higher economic status category were better informed compared to other categories

(e) Type of surgery. Based on clinical condition the patients were categorized into emergency cases and elective surgery patients. The data obtained is graphically depicted in Fig 6.



The percentage of patients informed pertaining to the points in the check list are shown in table 1

Table 1

Sl No		Remark
1.	Discussed the patient's current clinical situation or problem	100 % were informed
2.	Discussed the indication for the proposed procedure	98 % were informed
3.	Discussed the purpose of a proposed treatment or procedure	96 % were informed
4.	Explained the actual procedure of the patient	84 % were informed
5.	Explained the risks involved	34 % were informed

6.	Explained the benefits of the procedure	90 % were informed
7.	Informed about the alternative options available to the patient	26 % were informed
8.	The risks and benefits of alternatives	24 % were informed
9.	Asked whether patient had any queries	94 % were informed
10.	Told the patient when he/she can resume work	60 % were informed
11.	Informed briefly about the post operative care the patient has to take	94 % were informed
12.	Addressed all queries of the patient	84 % were informed
13.	Summarized the discussion	70% were informed
14.	Rechecked that the patient was willingly giving consent	98 % were informed

The report of the assessment of informed consent forms is shown in table 2

Table 2

Sl No		Remark
1.	Name and signature of the patient, or if appropriate, legal guardian	98 % complied with
2.	Name of the hospital;	98 % complied with
3.	Name of all practitioners performing the procedure and individual significant task if more than one practitioner	0 % complied
4.	Date and time consent is obtained	42 % complied with
5.	Statement that procedure was explained to patient or guardian	100 % complied with
6.	Name of the procedure	86 % complied with
7.	Signature of professional person witnessing the consent;	54 % complied with
8.	Name and signature of person who explained the procedure to the patient or guardian.	90 % complied with

Perception of patients on Informed consent

Many of the patients interviewed in the study were not aware of the importance of Informed consent, few patients mentioned that they signed the paper just because doctor had asked them to sign it without even going through the content in the consent form. Few of the patients considered signing a consent form as a formality which they had to do before undergoing the surgery.

Why patients dont ask queries before signing consent

During the interview we were given many reasons why patients didn't ask queries regarding the surgery or their clinical condition, all the reasons given by patients could be summarized in one word i.e **TRUST**. Many patients had the belief that Doctor knows the best. This behavior was predominantly seen in patients of lower socioeconomic status and uneducated patients.

V. Recommendations

Awareness creation among doctors. To improve the process of informed consent creating awareness among doctors, taking consent is critical. In general all doctors are aware about the process and importance of consent taking but certain fine details such as what all components have to be informed to the patient have to be made clear. It was found that many a times patient was just asked to sign the consent form before the surgery and patient having faith and respect towards the doctor just signed the consent form without asking any questions. Such practices cannot be removed by introducing rules and regulation rather creating awareness of the necessity and legal implication of informed consent would improve the process of consent taking

Patient education. Certain measures could be taken to educate the patient in hospital setting such as

- (i) Prominent display of Patient Rights in patient waiting areas
- (ii) Computer based equipment which would provide information of the disease
- 1. Using audiovisual aids to explain to the patient

Medico Social worker. Doctors due to factors such as shortage of time may not be able to cater to the requirements of patients in facilitating decision making during such time availability of medico social worker would be helpful. Medico social worker along with this can cater to the emotional requirements of patients

Maintaining data base of patients who have undergone surgery in the hospital. Old patients of the hospital with their consent can be used to provide guidance to the patients. They would act as a peer group to the patients. Success stories of previous patients can guide patients in making decision.

Re-form the Informed consent form. The present informed consent form has certain deficiencies such as

- (i) There is no designated space to mention the name of all practitioners performing the procedure
- (ii) In place of signature of doctor it is mentioned signature of MO (Medical officer) so in case a specialist explains about the surgery he/she doesn't sign in the space for signature of MO.
- (iii) All the departments of the hospital do not have similar format of consent form. It is recommended to have a standard informed consent form for the entire hospital.
- (iv) An ideal consent form must have the following components
 - aa. Name & signature of the patient or if appropriate legal guardian
 - bb. Name of the hospital
 - cc. Name of all practitioners performing the procedure
 - dd. Statement that procedure was explained to patient or guardian
 - ee. Name of the procedure
 - ff. Name & Signature of the professional person witnessing the consent
 - gg. Name and signature of person who explained the procedure to the patient or guardian.

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