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Original Article

Informed Consent — A Critical Part of Modern Medical Care

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ABSTRACT

Introduction: *To assess the importance of informed consent- a critical Part of modern medical care.* ***Methods & Materials****: This study is a cross-sectional study using in depth interviews to assess the information given to patient and to assess how efficiently consent forms were filled preoperatively. The study was carried out in Dept. Of Forensic Medicine, Dhaka Medical College Hospital, Bangladesh from January to December 2022. All interviews were carried out in privacy and both patients and their relatives were assured of confidentiality.* ***Results:*** *Total 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. 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.* ***Conclusion:*** *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*

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be informed to the patient have to be made clear. 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.

Keywords: *Informed, Informed Consent, Modern Medical Care*

INTRODUCTION

Informed consent is a cornerstone of modern medical ethics. In an ideal world, informed consent would be an educational process, a conversation between the surgeon and the patient or family, empowering the patient or family to make the best decision about their treatment. A consent form was developed to document this conversation. However, more recently, consent forms themselves have become a medico-legal requirement[1]. Informed consent is a well-established ethical and legal requirement for surgical treatment. It has important roots in Anglo-American political theory and has been enshrined in law in many court decisions[2,3]. Informed consent also forms the ethical foundation of the contemporary practice of shared decision-making and patient-centred care[4]. Informed consent has become an increasingly important topic of debate and discussion. Although the need for patient involvement in medical decision-making is recognised, its implementation is variable and individual-specific. Studies in developing countries show that patients consider written consent to be ritualistic and bureaucratic. Some may fear or feel pressured to give consent[5,6-10]. In light of the above, Indian researchers are beginning to realise the limitations of standard consent forms. Illiterate and semi-literate people view the document with suspicion and hesitate to put their signature or thumbprint on it. In some cases, the informed consent process becomes a mere formality, with subjects/patients simply accepting what is asked of them.

METHODS & MATERIALS

Study Design: This study is a cross-sectional study.

Study Setting: The study was carried out in Dept. Of Forensic Medicine, Dhaka Medical College Hospital, Dhaka, Bangladesh from January to December 2022.

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 underwent surgery in another hospital and were referred here for further treatment were excluded from the study.

Inclusion Criteria

- All patients who underwent surgery within the study period and signed written informed consent from the departments of general surgery, neurosurgery, plastic surgery, urology and obstetrics and gynecology before surgery were included in the study.

This was a prospective study aimed to evaluate the information patients receive before signing the consent form and to evaluate the efficiency of completing the consent form. General literature on informed consent and relevant journal articles were reviewed. A validated checklist was adopted from the WHO website and incorporated into the study. The checklist is attached as Appendix A and Appendix B. Multiple visits to different wards were made and patients who underwent surgery were identified. Only patients who were physically fit enough to participate in the interviews and gave written consent were included.A four-member team conducted the interviews in Bengali and English and the results were transcribed in English for analysis. A framework analysis approach was used for data analysis, which involves categorical analysis of data from patients who underwent surgery based on five parameters.

All interviews were conducted confidentially and confidentiality was guaranteed to both patients and their families. Patient-related data such as name, age, sex, education, monthly income, date of admission, date of surgery, and diagnosis were recorded from medical records. A structured interview was then conducted based on 14 checklist items, which were scored as "yes" or "no" depending on the patient's responses. These responses were calculated for each patient and conclusions were drawn from graphs generated for the five parameters using Minitab computer software: h. Age, sex, education, type of patient, and type of surgery (final or emergency) were recorded. Another eight-item checklist was used to evaluate the efficiency of filling out the consent form. Responses were taken directly from the completed consent form as "yes" or "no." These answers were calculated and conclusions were withdrawn. The form was photographed for future reference.

RESULTS

Total 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 (**Figure 1,2,3,4, & 5**).

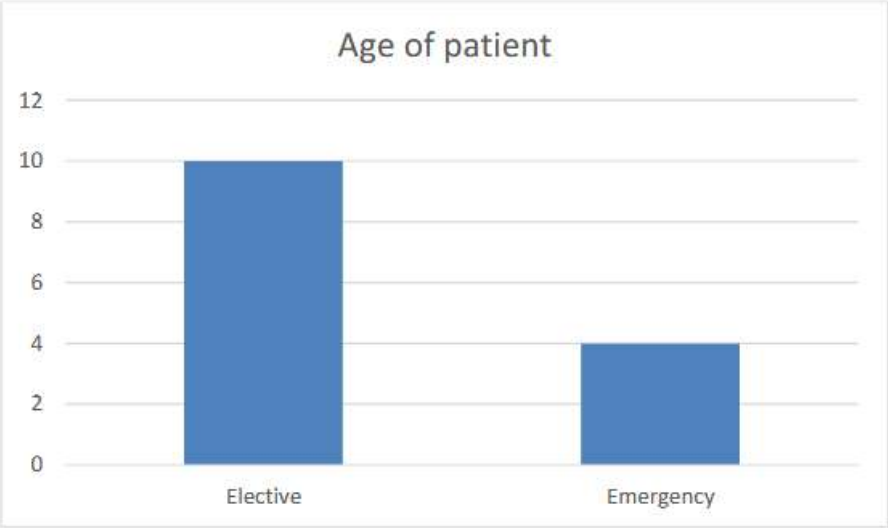

Figure – 1: Age Distribution of the Study Patients

The graph has been plotted using category of patients on X axis and average number of "Yes" responses in the checklist on Y axis. 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 (**Figure 1**).

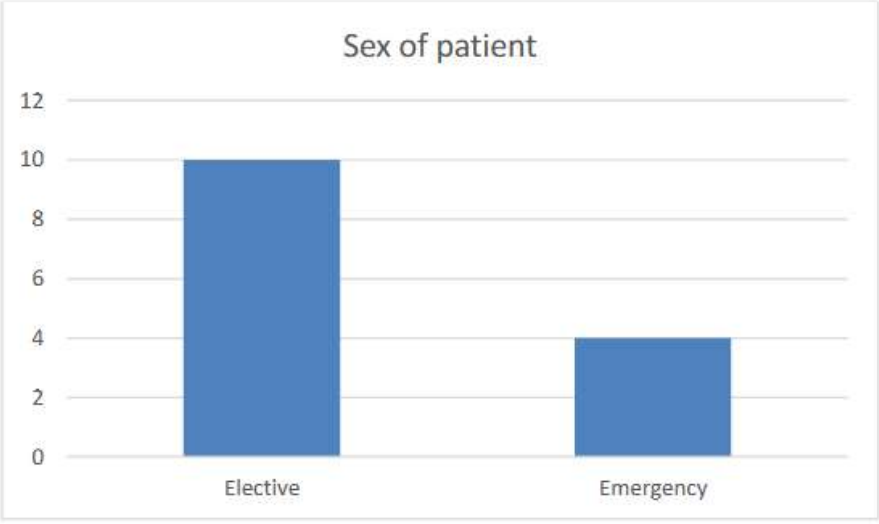

Figure – 2: Sex distribution of the study patients.

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 (**Figure 2**).

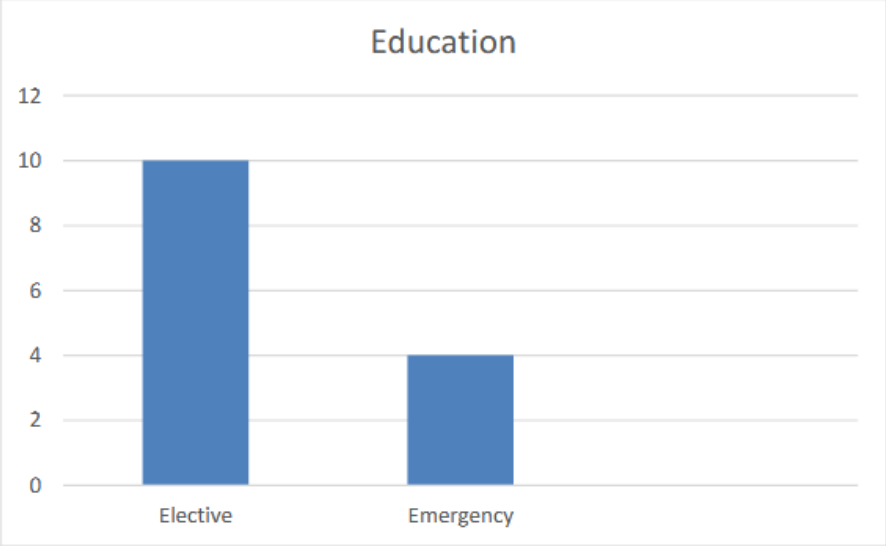

Figure – 3: Education Status of the Study Patients

The educational level of the patients was categorized as uneducated and educated. The educational category was further categorized into patients with a college degree and those with an education level of 12th grade or less. The results obtained are shown in **Figure 3**. In the present study, it was found that there was a direct correlation between educational status and the information provided to the patients. The higher the educational level, the better the information provided.

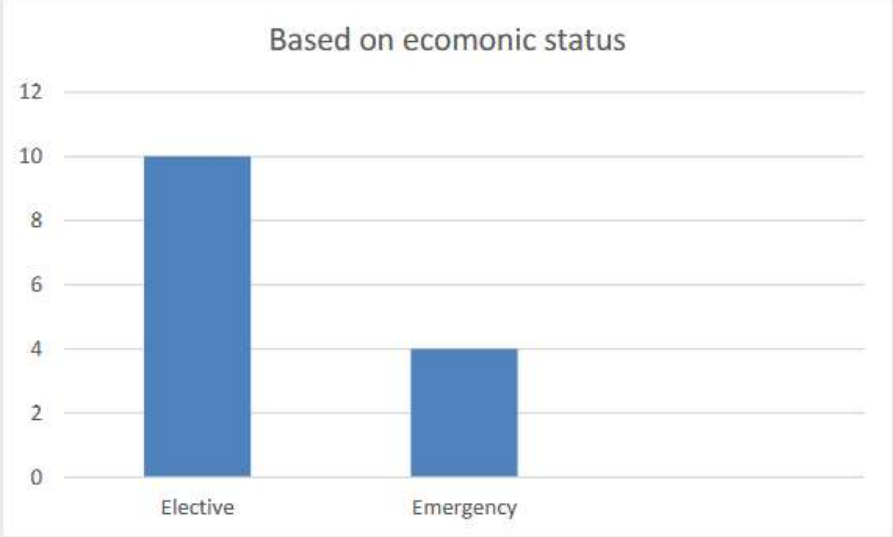

Figure – 4: Economic Status of the Study Patients

Type of patients: Patients of the hospital were categorized based on economic status. Results obtained are shown in the **Figure 4**.

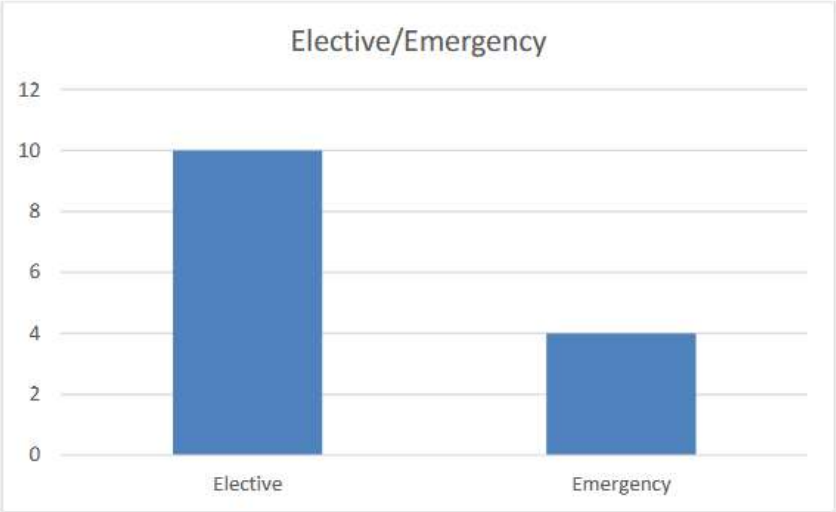

Figure – 5: Type of Surgery Study Patients

It was found that patients with higher economic status category were better informed compared to other categories 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 **Figure 5**.

Many of the sufferers interviewed withinside the take a look at had been now no longer aware about the significance of Informed consent, few sufferers referred to that they signed the paper simply due to the fact physician had requested them to signal it without even going thru the content material withinside the consent shape. Few of the sufferers taken into consideration signing a consent shape as a formality which they needed to do earlier than present process the surgery. **Table I** shows the percentage of patients informed pertaining to the points in the check list.

Table – I: The Percentage of Patients Informed Pertaining to the Points in the Check List

Sl. No.	Patients Informed	Remark
1.	Discussed the patients 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

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. **Table II** shows the report of the assessment of informed consent forms. Many patients had the belief that Doctor knows the best. This behavior was predominantly seen in patients of lower socioeconomic status and uneducated patients.

Table – II: The Report of the Assessment of Informed Consent Forms

Sl. No.	Assessment of Informed Consent Forms	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

DISCUSSION

In the literature, informed consent is described as the process by which a health care provider conveys information about the potential benefits, risks, and alternatives of treatment to a patient[11]. This makes informed consent an integral part of all levels of health

care and allows patients to be involved in decision-making. A total of 200 patients were surveyed to see how much information they were provided with before surgery. A validated checklist was used to make the data quantifiable. If the patient stated that a particular piece of information was provided, it was considered a “yes” answer, and if the patient stated that a particular piece of information was not provided, it was considered a “no” answer. This can also be interpreted in light of Article 21 of the Constitution of India, which provides for the principle of autonomy, which guarantees the right to life and personal liberty[12]. ***Searight and Barbarash***, in their paper on informed consent in family medicine, highlight that informed consent in family medicine goes far beyond clinical and legal aspects. Family doctors maintain long-term relationships with their patients. A multicenter study by Koyfman et al. compared information provided and recorded in interviews and found that certain important elements were often omitted from the interviews[13]. Similarly, our study found that, even though 100% of consent forms stated that patients were informed about the procedure, only 34% of patients reported being informed about the risks and only 26% reported being informed about possible alternatives. A study conducted in the UK by Sivanadaraja et al. on the readability of consent forms concluded that it may be difficult for the majority of patients to give informed consent due to differences in literacy levels and the information included in the consent forms[14-16]. Our study also concluded that patients' understanding of the procedure depends on their level of education, with higher levels of education allowing them to absorb more knowledge. ***Wood et al.*** examined physicians' perspectives to assess barriers to obtaining consent. Lack of time, inexperienced clinical staff, and reluctant patients were found to be major barriers[14]. The researchers found that residents were most often responsible for obtaining patient consent for procedures with which they themselves were unfamiliar. In our institute, consent is also obtained from junior physicians who have limited knowledge of risks and alternative treatments. This explains why patients have little knowledge about certain aspects of the procedure[17]. The literature states that patients avoid the consent process and place their "trust" in the doctor[15,16]. In our study, patients gave the researchers several reasons why they did not ask questions during the interview. The number one reason was "trust." The majority of patients believed that the doctor knew what was best for them. In a study by ***Akkad et al.***, conducted to compare consent for planned and emergency procedures, emergency patients were found to be less satisfied with the study information provided[17]. It was also found that patients did not read the contents of the consent form because they had received verbal explanations and trusted the doctor. Both results were comparable to those of our study.

Conclusion and Recommendations

To improve the informed consent process, it is important to raise doctors' awareness of obtaining consent. In general, all doctors are aware of the consent process and its importance, but certain nuances, such as which elements need to be communicated to patients, need to be clarified. It was found that patients are often only asked to sign a consent form before surgery, and patients who trust and respect their doctors simply sign the consent form without asking any questions. Such practices cannot be eliminated by the introduction of rules and regulations. Rather, raising awareness of the need for informed consent and its legal implications will improve the consent collection process.

Doctors may not be able to meet the needs of patients when making decisions due to lack of time or other reasons. In such cases, the presence of a medical social worker can be helpful. In addition, medical social staff can address the emotional needs of patients. They maintain a database of patients who have had surgery at the hospital. Former hospitalized patients are available to advise patients if they consent. They act as a peer group for patients. Success stories of previous patients help patients make decisions.

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Conflict of Interest

The authors declare no conflict of interest.

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