

Informed consent: Is it really understood?

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Abstract:

Pre-operative counselling is an important part of the care that we give to our patients undergoing surgery. It ensures that the patients understand about their disease and the procedure that they are undergoing. This study was done with the objective of finding whether or not the patients do actually understand what has been explained to them. This is a prospective study done in the form of a survey with a set questionnaire in two hospitals in Kathmandu namely Patan hospital and Tribhuvan University Teaching Hospital. The patients surveyed were those who were admitted for elective surgery after counselling has been done and consent forms signed. The result showed that the level of understanding was poor in 11%, unsatisfactory in 33%, satisfactory in 37% and excellent in 19%. The level of understanding was affected by the education level of the patients. To conclude, the level of understanding was unsatisfactory in nearly half the patients. Only 19% had optimal understanding. This may reflect the education level of the many of our patients but it clearly points out that the medical profession needs to make more effort to make the patients understand more about their disease process. This can be said to be a reflection of our quality of care.

Key words: informed consent, autonomy, understanding, and education level

Informed consent is a legal documentation whereby patients / relatives give a written consent for treatment of operation upon an appreciation and understanding of the fact and implication of any such activities.

Pre-operative counselling is an important part of the care that we give to our patients undergoing surgery. It ensures that the patient understands about the disease that they have and the procedure that they are undergoing. Signing of the consent form is a documentation that a proper pre-operative counselling has been done and patient has understood about the disease and procedure and has opted willingly for the procedure. It ensures patient autonomy. General Medical Council, UK states that "*Successful relationships between doctors and patients depend on trust. To establish that trust you must respect patients' autonomy—their right to decide whether or not to undergo any medical intervention . . . (They) . . . must be given sufficient information, in a way that they can understand, in order to enable them to make informed decisions about their care.*"¹ The fact that the patients have been informed does not necessarily mean that they have understood. Some studies show that the patients do not comprehend the information about the disease,

its prognosis and complications to actually make an informed decision². Another study involving 59 primary care physicians and 65 General and orthopaedic surgeons showed that only 9% met the criteria for completeness of informed decision³. The lack of comprehension can be due to various factors like educational level and social background⁴ or to the poor communication skills of doctors⁵.

There are no studies done in Nepal to look at the level of understanding of the patients about their disease or the surgical procedure that they are about to have after the doctor has counselled them, hence the rationale for this study.

This study was done with the objective of finding whether or not the patients do actually understand what has been explained to them and what were the various factors that influenced their level of understanding.

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Method

This is a prospective study done in the form of a survey with a set questionnaire. Patients admitted to Department of Surgery in two hospitals in Kathmandu namely Patan and Tribhuvan University Teaching Hospital with the intent of having elective surgery were included in the study. The survey was done by a single surgical resident. However, if the surveyor himself did the pre-operative counselling, that particular patient was excluded. Other exclusion criteria were patients who have had similar surgery in the past.

The survey was done after the patient had been counselled regarding surgery and had signed their consent forms, usually in the evening before surgery.

The method of survey was interview using set questionnaire, which included the patients' age, sex education level. It asked question regarding the disease for which the patient was admitted, about the surgical procedure, information about anaesthesia, pain control, and recurrence and post op measures. Points were allocated to their answers; 5 points if they understood well, 3 if they had some understanding and 0 if they had no understanding. The points were added to give their total points. If patient obtained a score of less than 25% of the total score, he was said to have a poor understanding. Similarly, a score of 25-49% was judged as unsatisfactory; 50 -74% as satisfactory and any score of 75% or above was judged to be good.

Statistical analysis

The groups were compared with F test. P value of <0.05 is taken to be significant.

Result

There were total of 72 patients with 36 patients in each hospital. Male to female ratio was 1:1. Age varied from 15-83 with a mean age of 40. 33% of the patients had no formal education; 33% had gone to school but had not completed the school leaving certificate (SLC) and 33% had higher education. Twenty four patients were from Kathmandu while the remaining was from outside Kathmandu. Of these patients 30 were from the hilly region and 18 were from Terai.

Level of Education	No of Respondents	Level of understanding	p-Value
Illiterate	24	44%	<0.01
Primary	24	46%	
Higher	24	68%	

The level of understanding was similar in male and female (53.6% in male and 52.6% in female, $p > 0.05$). According to the level of education, those who were illiterate had a mean score of 44.6%, those who had primary education only had a mean score of 46.6% and those who were educated had a mean score of 68.2%, (p value < 0.01). Looking at the values the level of understanding is not different between those who had a primary level of education and those who did not had formal education, but it was significantly better in those who had higher education.

The origin of the patient also had a significant effect with patient from urban areas (Kathmandu: 58%, terai: 57%) having higher level of understanding compared to those from rural area (hilly region 46%) (p value < 0.01). Overall the level of understanding was poor in 11%, unsatisfactory in 33%, satisfactory in 37% and excellent in 19%.

Discussion

Patient autonomy is now ingrained into medical practice in the more developed countries. In Nepal the status of patient autonomy was what it was in United Kingdom or US in sixties'. A survey in US in 1961 had shown that only 10% of the doctors informed patients of cancer⁶. In contrast similar survey twenty years later showed complete reversal of the trend with 97% of the doctors informing the patients⁷. There seems to be a change in the trend even in Nepal. A survey here showed that 97% of the patients wanted to know their diagnosis and 87% wanting to know all aspects of the disease including the possibility of death⁸.

Informed consent is one important aspect of patient autonomy. Signing the consent form does allow an opportunity for interaction between patients and the doctor so that some information can be given to the patients and some questions that the patients or family might have may be answered. It also prevents coercion. It, undoubtedly, is a good medical practice.

The communication between the doctor and the patient reflects the quality of care. The level of understanding of the patient about their disease process and the procedure that they are likely to undergo is a reflection of communication.

This study shows that the level of understanding of patients is unsatisfactory in nearly half the patients. In 37 % although the understanding was satisfactory there was ample room for improvement. Only in 19% of patients was the understanding what we would like to be.

The level of education is an important factor that affects the level of understanding of patients. In patients who had higher education, i.e. had finished schooling and gone to college, the level of understanding was significantly better. This study does not address the 'doctor' factor for the poor comprehension by the patients. Studies have shown that the clinicians are themselves poor communicators. It is believed that poor communication is one of the key factors leading to increase in litigation. The problem of litigation in Nepal is not very high but recently there seems to be an increasing trend in this direction. It is our belief that proper informed consent and good communication should be the norm not only because it reduces legal problems but because it is a part of a good medical practice.

This study also shows that more effort has to be made to make the uneducated patients understand about their disease. More research needs to be done in this area to find the means for making the uneducated people understand about the disease.

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