

Preoperative Information & informed consent in Patients undergoing Elective Surgery at Isra University Hospital, Hyderabad

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ABSTRACT

Objective: The purpose of this study was to assess the patient's awareness of informed consent and to evaluate the current practice of obtaining informed consent from patients proposed for elective surgery in tertiary care hospital.

Study Design: Cross sectional survey

Place and Duration of Study: This study was conducted in Isra University Hospital, Hyderabad, Sindh from 2nd April 2012 to 3rd March 2013.

Materials and Methods: This study was designed as an observational investigation and no interference was made regarding the informed consent process to the patient. The selection criteria for the patients who were interviewed were convenience sampling. All adult patients of >18 years, who were undergoing various surgical procedures were interviewed after taking verbal informed consent on the second postoperative day, when they were comfortable to answer the questions. While all those patients who were uncomfortable due to pain or other reason and were unwilling to answer the questions were excluded from the study.

All the patients were asked predesigned questions related to the information they were provided before the surgery as part of standard informed consent practice.

Questions were asked in local language which includes the demographic data, operative details, risk, benefit, complications of surgery, type of anesthesia and alternative treatment options etc. The data was entered on SPSS version 16. Frequency & percentages were calculated to show the results.

Results: Mean age of the patients was $34.95 \pm SD 14.256$ years. 220 patients were included in the study. 183(83.18%) patients were told about the indications of surgery while 136 (61.81%) patients were not told about any complication of Surgery. Type of anesthesia was discussed in only 25(11.36%) of patients while complications of anesthesia were discussed in only 18(8.18%) of patients. 165(75%) patients were not given time to ask the questions regarding their disease or surgery. Consent by the consultants was taken in only 63(28.63%) patients.

Conclusion: The majority of the patients knew the indication of surgery but very few were informed about the possible complications and risk of the surgery and anesthesia..

Key Words: Informed Consent, Complications, Surgery, Anesthesia.

INTRODUCTION

Medical ethics is often defined as "the disciplined study of morality in medicine"¹. It gives right to the patient to have full access to the information pertaining to his medical condition so as to be able to understand the possible course of the illness and the various implications it may have on his health. The health care providers must respect this right of the patient and offer them all possible opportunities to explain in detail about the disease and treatment options so that patients can take part in decision making and can voluntarily choose the form of health care for themselves^{2,3}.

Surgery and its possible complications can lead to medicolegal problems and litigation with patient alleging that they were not informed; whereas in our society, it is often presumed that telling the patient about possible complications and risks would discourage them from going ahead with the surgery⁴. A paradigm shift has been observed in the west whereby

majority of patients want to be completely informed about the surgical procedure⁵.

This requires that the patients be provided with all the relevant information pertaining to their case and to discuss with them all the available options including the possible complications and risks of surgery and anesthesia. It should actually be a joint decision making between the patient and the surgeon whereby a sort of agreement can be reached upon the optimum possible course to adopt in the best interests of the patient. Therefore, providing such an information and obtaining voluntary informed consent is an important and integral part of the medical practice⁶ and is now universally recognized as an essential safeguard to ensure the preservation of individual rights⁷.

Paternalism as well as coercion exercised during this process are unethical^{1,3}, contrary to the very concept of informed consent and should be avoided. It is also necessary that the patient understand the information provided⁸ and that consent given is voluntary⁹.

Moreover, the information provided should be in lay person language and should be clearly comprehensible. This study was undertaken to assess the patient's awareness of informed consent and to evaluate the current practice of obtaining informed consent from patients proposed for elective surgery in tertiary care hospital.

MATERIALS AND METHODS

This cross sectional survey was conducted in IUH from 2nd April 2012 to 3rd March 2013. This study was designed as an observational investigation and no interference was made regarding the informed consent process to the patient. The selection criteria for the patients who were interviewed were convenience sampling. All adult patients of >18 years, who were undergoing various surgical procedures were interviewed after taking verbal informed consent on the second postoperative day, when they were comfortable to answer the questions. While all those patients who were uncomfortable due to pain or other reason and were unwilling to answer the questions were excluded from the study.

All the patients were asked predesigned questions related to the information they were provided before the surgery as part of standard informed consent practice. Privacy and confidentiality was ensured throughout interview and response to individual question was only marked after reconfirming from the patient that the question has been clearly understood.

Questions were asked in local language so that they can understand easily. Questionnaire includes the demographic data, operative details, risk, benefit, complications of surgery, type of anesthesia and alternative treatment options etc. The data was entered on SPSS version 16. Frequency & percentages were calculated to show the results.

RESULTS

A total of 220 patients were included in the study. Their mean age was $34.95 \pm SD14.236$. Minimum age was 20 years and maximum was 85 year with age range of 65 years. 157(71.4%) patients were males while 63(28.6%) patients were females. Fifty seven (25.90%) patients were illiterate whereas 33(15%) were graduates. Thirty three (15%) patients belonged to upper socioeconomic class, 96(43.63%) to middle class, whereas 91(41.36%) belonged to poor socioeconomic class. (Table 1). One hundred eighty three (83.18%) patients were told about the indications of surgery while 136 (61.81%) patients were not told about any complication of surgery. Type of anesthesia was discussed in only 25(11.36%) of patients, while complications of anesthesia was discussed in only 18(8.18%) patients. 165(75%) patients were not given time to ask the questions regarding their disease or surgery (Table 2). Consent by the consultants was taken in only 63(28.63%) patients.

Majority of the consents 121(55%) were given by relatives instead of patients themselves. (Table 3).

Table No.1: Demographic Data

| Variables | Numbers | Percentages |
|------------------------|---------|-------------|
| Age < 30 years | 97 | 44.1 |
| 30-40 years | 64 | 29.1 |
| 41-51 years | 28 | 12.7 |
| > 51 years | 31 | 14.1 |
| Education . illiterate | 57 | 25.90 |
| Primary | 60 | 27.27 |
| Middle | 70 | 31.81 |
| Graduate | 33 | 15 |
| S.E.C. poor | 91 | 41.36 |
| Middle | 96 | 43.63 |
| Upper | 33 | 15 |

Table No.2: Questions asked from the patients

| Questions asked from patients | Numbers (percentages) yes | Numbers (percentages) NO |
|---|---------------------------|--------------------------|
| Have you told about nature of proposed surgical procedure | 64(29.09) | 156(70.9) |
| Other treatment options were discussed or not. | 85(38.63) | 135(61.36) |
| Have you told about complications of surgery | 84(38.18) | 136(61.81) |
| Was Choice of anesthesia discussed | 25(11.36) | 195(88.63) |
| Was Complications of anesthesia discussed | 18(8.18) | 202(91.81) |
| Have you told about hospital stay | 66(30) | 154(70) |
| Was time given to ask questions | 55(25) | 165(75) |
| Are you satisfied by the information provided to you | 47(21.36) | 173(78.63) |
| Did you read consent form | 64(29.0) | 156(70.9) |
| Is there any medicolegal significance of consent | 87(39.54) | 133(60.45) |
| Benefits of surgery were told to you | 143(65) | 77(35) |
| Did you understand the information | 123(55.9) | 97(44) |
| Did you told about the indication of surgery | 183(83.18) | 37(16.81) |
| Was written consent taken before surgery | 220 (100) | 00(00) |

Table No.3: Consent taken and given by:

| Variable | Numbers (percentages) |
|--|-----------------------|
| 1. Written consent was taken by consultant | 63 (28.63) |
| Staff nurse | 66 (30) |
| Medical officer/ house officers | 91 (41.36) |
| 2. Consent given by Patient herself/ himself | 89(40.45) |
| Relatives | 121 (55) |
| Friends | 10(4.54) |

DISCUSSION

The results of this study showed that although 83.18% patients knew about the indication of surgery but only 29.0% patients were told about the nature of proposed surgical procedure. Similar results are seen in the study conducted by M Jawaid et al¹⁰. 61.81% patients in our study were not given any information about the complications of surgical procedure. The results of the study conducted by Siddiqui FG et al also revealed that 79.2% patients had not received any information about complications of surgery¹¹. In another study, 69.3% patients reported receiving no information about the risk of surgical procedure¹².

Similar results are seen in the study conducted by Mc Keague et al in Auckland¹³ and Kay R¹⁴.

The anesthetists are obligated to explain to the patients, the proposed type of anesthesia and relevant risk & complications. Ideally, this information should be provided to the patient by the anesthetist directly but more often than not it is the surgeon who explains to them some of the information pertaining to the anesthetic procedure. In our study, 11.36% patients were told about the type of anesthesia and only 8.18% patients had received the information about the complications of anesthesia. Similar results are seen in the study conducted by Amin et al, whose results showed that only 15% patients received information about anesthesia complications¹⁵. While results of another study conducted by Siddiqui FG showed that although 66% patients were informed about the type of anesthesia, but no patient was informed about complication of anesthesia¹¹. Similar results are seen in the study conducted by Moores A et al.¹⁶

Ideally, the consent should be taken by the surgeon himself/ herself who is performing the surgery, because they are the best persons to answer the patients questions but unfortunately usually the consent is taken by medical officers, junior residents, staff nurses or even technicians who have limited knowledge and who think that just taking a signature or thumb impression over consent form is enough to dispense with the formalities¹⁷. In this study, consent was taken by consultants in only 28.63% of patients, while in rest of patients it was taken by the staff nurse, technicians &

residents. Similar scenario is seen in the study conducted by M Jawaid,¹⁰ where in majority of cases, consent was taken by the duty doctors and paramedic staff.

Same is seen in Scottish study, whose results showed that patients acquired most of the information from junior doctors.¹⁸

In our study, 40.45% patients gave consent themselves while in rest of patients, consent was given by their family members or friends. Similar observation has been expressed in the study conducted by Jawaid M¹⁰, where only 58.3% patients gave consent themselves & in rest of cases it was given by family members and friends. In our culture, where family values are high, the wishes of the elders may prevail and in many instances influence the decision of younger member. Moreover, usually major decisions are taken by the male head of the family. This may be the reason that usually consent is obtained/volunteered from (mostly the male) family members instead of the patients themselves, although this is challenging to the very concept of volunteerism¹⁹.

Informed consent has been defined as an expression of active participation of the patients in the decision making process^{20,21} and it gives them the right to decide whether to receive or refuse the treatment. The health care provider is obliged to disclose all the necessary information to the patient including the type of the treatment, its benefits and possible risks and complications to help them make this decision²². They feel more satisfied and confident if the treating surgeon provides relevant information to them prior to surgery^{17,13}. The review of national^{23,15,24} & international literature^{25,4,26} also highlights the importance of informed consent related to the surgery & its complications.

But in our study, one very interesting and important aspect disclosed is that while information in variable degree was provided to the patients, they were not encouraged or even afforded enough opportunity to ask questions themselves pertaining to their disease or surgery as is evident from our results which show that only 25% of the patients interacted with the interviewer and asked questions regarding their ailment. This is contrary to the very concept and spirit of joint decision making process which is often advocated in various studies.

There are some limitations of our study. As the interview was conducted in the postoperative period, so there are chances that some of the information given preoperatively might have been forgotten by the patients, preoperative interview on the other hand carries with the risk of interference with the process of care. This study was conducted in one private sector hospital. More hospitals especially public sector hospitals should be involved in the study to see the difference.

In conclusion our study has highlighted the deficiencies in many areas; hence improvements are needed to upgrade the quality of preoperative informed consent process both at patient level and health care professional level.

CONCLUSION

The majority of the patients, in our study, knew the indication of surgery but very few patients knew the different treatment options, benefit, risk and complications of surgery and anesthesia. Not all the patients were given chance to ask questions from doctor to clear up various ambiguities concerning their treatment plans.

REFERENCES

1. McCullough LB, Chervenak FA. Informed consent. *Clin Perinatol* 2007;34:275-85.
2. Nasilowsky W. Patient's consent to treatment with reference to the development of medical ethics. *Wiad Lek* 2007;60:198-200.
3. Del Carmen MG, Joffe S. Informed consent for medical treatment and research: a review. *Oncologist* 2005;10:636-41.
4. Burger I, Schill K, Goodman S. Disclosure of individual surgeon's performance rates during informed consent: ethical and epidemiological considerations. *Ann Surg* 2007; 245: 507-13.
5. Quadrelli S, Colt HG, Lyons G, Cohen D. Respect for autonomy. How much do patients want to know in order to make decisions? *Medicina* 2008; 68(3):198-204.
6. Molnar J. Consent in the 90s. *Med Law* 1997; 16:567-79.
7. Jafarey AM. Informed consent in research and clinical situations. *J Pak Med Assoc* 2003;53: 171-2.
8. Applebaum PS, Grisso T. Assessing patient's capacities to consent to treatment. *N Engl J Med* 1988;99:539-43.
9. Laura WR. Informed Consent and the Capacity for Voluntarism. *Am J Psychiatr* 2002;159:705-12.
10. M Jawaid, M farhan, Z Masood, SMN Husnain. Preoperative informed consent: is it truly informed? *Iranian J Publ Health* 2012;41;9:25-30.
11. Siddiqui FG, Shaikh JM, Memon MM. An audit of informed consent in surgical patients at a university hospital. *J Ayub Med Coll Abbottabad* 2010;22(1). 133-135.
12. Perez-Moreno JA, Perez Carceles MD, Osuna E, Luna A. Preoperative information and informed consent in surgically treated patients. *Rev Esp Anestesiol Reanim* 1998;45(4):130-5.
13. McKeague M, Windsor J. Patients perception of the adequacy of informed consent: a pilot study of elective general surgical patients in Auckland. *NZ Med J* 2003; 116. (Online) Available from URL: <http://www.nzma.org.nz/journal/116-1170/355>.
14. Kay R, Siriwardena AK. The process of informed consent for urgent abdominal surgery. *J Med Ethics* 2001;27:157-61.
15. Amin MF, Jawaid M, Rehman S, Mudassir, Hina, Zakai SB. An audit of information provided during preoperative informed consent. *Pak J Med Sci* 2006;22: 10-3.
16. Moores A, Pace NA. The information requested by patients prior to giving consent to anesthesia. *J Anaesthesia* 2003;58(7):703-6.
17. Houghton DJ, Williams S, Bennett JD, Back G, Jones AS. Informed consent: patients' and junior doctors' perceptions of the consent procedure. *Clin Otolaryngol Allied Sci* 1997; 22: 515.
18. Lavelle- Jones C, Byrne DJ, Rice P, Cuschieri A. Factors affecting quality of informed consent. *BMJ* 1993;306:885-90.
19. Renshaw A, Clarke A, Diver AJ, Ashcroft RE, Butler PE. Informed consent for facial transplantation. *Transpl Int* 2006;19(11):861-7.
20. Wears S. Informed consent: patient autonomy and physician beneficence within clinical medicine. Dordrecht: Kluwer Academic Publishers; 1993.
21. Beauchamp TL, Childress JF. Principles of biomedical ethics. New York: Oxford University Press; 1994.
22. pleat JM, Dunkin CS, Tyler MP. Communication of risk in breast augmentation. *Plast Reconstr Surg* 2003;111:2104.
23. Bhurgri H, Qidwai W. Awareness of the process of informed consent among family practice patients in Karachi. *J Pak Med Assoc* 2004; 54: 398-401.
24. Haq T, Ahmad B, Akhtar W, Naseer G, Mosharraf F, Munir K. National Survey for Practice of 'Informed Consent' in the Radiology Departments *J Pak Med Assoc* 2003; 53: 172-6.
25. Mazur DJ. What should patients be told prior to a medical procedure? Ethical and legal perspectives on medical informed consent. *Am J Med* 1986; 81: 1051-4.
26. Whitney SN, McGuire AL, McCullough LB. A Typology of Shared Decision Making, Informed Consent, and Simple Consent. *Ann Intern Med* 2003;140:54-9.

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