ISSN 2394–806X (Print), ISSN 2454-5139 (Electronic)
IJHRMLP, Vol: 04 No: 02 July, 2018
Printed in India

ORIGINAL PAPER

Physicians' knowledge and patients' understanding of informed consent: challenges in clinical practice

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***Received on** March 31, 2018**; editorial approval** on June 30, 2018*

ABSTRACT

***Aim:** To assess physicians' knowledge and to find out its understanding in patients. M**ethod**: 120 physicians and 280 patients were given separate questionnaires to assess their knowledge and understanding of informed consent. **Results**: 52.3% respondents took less than 10 minutes in taking consent. There was significant difference in providing information about length of hospital stay among junior (57.1%) and senior doctors (88%). Among 266 patients who responded, 102 (28%) were illiterate (group I) and 164 (72%) were literate (group II). In the group I 13.7% knew that consent needs to be taken before the procedure, whereas in group II 50% were aware. 40.2 % among the illiterate group, and 80% of the literate group understood the contents of consent, The anxiety level after consents increased rather than decreasing. **Conclusion:** All components of consent were not communicated to the patients by the physicians. Patients' literacy level increased the understanding of consent.*

***Keywords:** Informed consent**,** physicians'knowledge, patients' understanding, patients' education, anxiety level*

INTRODUCTION

Informed consent is a process of communication between a patient and physician, for patient's authorization to undergo a specific medical intervention.[1] An informed consent is an ongoing process; it involves exchange of information and not mere signing of form. For ethical and legal reasons patients must be fully informed before deciding to undergo a major treatment and consent must be documented in writing.

The socioeconomic status, education of patients and lack of application of knowledge to practice are the main challenges in providing informed consent in developing world. The aim of our study was to assess physicians' knowledge and practice of obtaining informed consent before medical procedures. To find out patients' comprehension of the process of consent and to observe factors hindering its understanding.

METHOD

The study was conducted from January 2014 – July 2014. All authors were employed in the hospital making it easier to conduct the survey. Separate questionnaire were given to the patient and physician. Total 280 questionnaires were given to the patients admitted in the obstetrics and gynecology ward waiting for operation. 266 forms were duly filled, the patients who were illiterate got the proforma filled by husband or relative who was literate. Total 120 physicians which included senior resident, resident, consultant working in the hospital were distributed the questionnaire by the authors. The physicians present at the time of the survey filled out the questionnaire on their own and returned the completed form to the author who was in charge of the local survey. Participation in the study was voluntary and anonymous. Total 109 proforma were duly filled and returned. Results were analyzed, appropriate statistical analysis was done to compare the variables.

RESULTS

Out of total 109 questionnaires, 84 were filled by resident doctors and 25 by senior doctors of consultant level. Table 1 shows the questions asked and its response. Question number 1- 3 were regarding the doctors understanding of the process

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***Cite this article as:** Kumar Manisha, Asmita, Bhavya HU. Physicians' knowledge and patients' understanding of informed consent: challenges in clinical practice. Int J Health Res Medico Leg Prae 2018 July;4(2):88-92 DOI 10.31741/ijhrmlp.v4.i2.2018.21*

Table 1 Shows response of junior and senior doctors to the questions

S no	Questions	Total N= 109	%	Junior doctors N= 84	%	Senior doctors N=25	%	P value
1.	Attainment of higher ethical standards and organizational morale as most important reason for taking consents	77	70.6	60	71.4	17	68.0	0.468
2.	Agreed that the procedure of obtaining informed consent for treatment regulated by law	103	94.5	79	94.0	24	96.0	0.833
3.	Agreed that physician should educate the patient on the issues of providing consent for treatment	107	98,2	82	97.6	25	100	0.475
4.	Spent less than 10 min on consent	57	52.3	53	63.1	4	16.0	**0.000**
5.	Consent to be taken from patient only	39	35.8	27	32.1	12	48.0	0.398
6.	Gave information to patients about their medical condition and treatment procedures in detail	55	50.5	42	50.0	13	52.5	0.689
7.	Answered to patients' queries in detail	34	31.2	24	28.6	10	40.0	0.509
8.	Informed patients about the length of their hospital stay	70	64.2	48	57.1	22	88.0	**0.010**
9.	Patient give consent for the treatment after consulting the family	78	71.6	55	65.5	23	92.0	0.091

of consent. Total 77(70.6%) doctors considered attainment of higher ethical standards and organizational morale as the major reason for taking consents. Almost all senior and junior doctors (94.5%) knew that the process of taking informed consent is regulated by law. When asked whether it is physician or staff nurse who was supposed to provide information on consents 97/109 (89%) felt it was the responsibility of the physicians to provide the information.

Question 4-9 dealt with practical use of their understanding of process of consent. About half of the respondents (52.3%) took less than 10 minutes taking consent. The senior doctors gave significantly more time on taking consents compared to the resident doctors. Among the residents 27/84 said they would take the consents from the patients only, and 12/25 among seniors said they would take consents only from the patients, all others believed consent needs to be taken from patients as well as the relatives . When asked about giving information about the medical condition to the patients half of the doctors said they would inform patient in detail about the medical condition. Similarly patients' queries were provided in detail by only 31.2% of doctors. There was significant difference in providing information about length of hospital stay among junior (57.1%) and senior doctors (88%). 78/109(71.6%) physicians observed that patients gave consent after consulting the family rather than taking decision independently or upon coercion by physician.

Table 2 shows the questions asked to the patients and its response.Out of 266 duly filled proforma by the patients, 102 (28%) who responded were illiterate and were categorized as group I, 164 (72%) were literate and categorized as group II. In the group I 13.7% knew that consent needs to be taken from them before the procedure, whereas in group II 50% were aware of this. 40.2 % among the illiterate group, and almost 80% of the literate group understood the contents of the consent, there were more among the group I (68%) compared to group II (54.3%) who believed that less than 10 minutes were given for consent but the difference was not significant. Among first group only 7/102 (6.9%) and in

Table 2 Shows response of patients to the questions asked

S no	Questions	Total n= 266	%	Patient illiterate n=102 (group 1)	%	Patients literate N= 164 Group 2	%	P value
1	Wanted that the consent being taken from them	90	50	14	13.7	82	33.8	**0.000**
2	Were aware that the consent was taken before the procedure	237	95.7	80	78.4	157	89.1	**0.000**
3	Agreed to have understood the content of the consent	172	79.9	41	40.2	131	64.7	**0.000**
4	Agreed that < 10 min was given to take the consent	158	54.3	69	68	89	59.4	0.117
5	Had knowlcdgc about thc nature of the operation being performed	79	43.9	7	6.9	72	29.7	**0.000**
6	Had information regarding why it was performed	194	82.3	59	57.8	135	72.9	**0.001**
7	Was made aware of its complications	89	46.3	13	12.7	76	33.5	**0.000**
8	Were informed about alternative treatments and its risk	119	53.7	31	30.4	88	44.7	**0.000**
9	The anxiety level increased after the consents	116	37.2	55	53.9	61	43.6	**0.000**

group II 70/164 (43.9%) knew about the nature of operation being performed. When asked regarding reason why it was performed 59/102 in group I and 135/164 in group II knew the motive. Only 13/102 patients in group I and 76/164 in second group were more informed about the complications, whereas 31/102 and 53/164 were informed about alternative treatment in first and second group respectively . The anxiety level after consents increased rather than decreasing in 55/ 102 in group I whereas in 61/164 in group II. There was significant difference in all responses between illiterate and literate patient except in time taken in which there was no significant difference.

DISCUSSION

The present paper deals with the physicians' understanding of basic principles and purpose of consents; it also tries to find out the practical aspects, application of knowledge about different elements that constitute informed consent. In our hospital set up majority of the consents are taken by resident doctors therefore estimation of their knowledge and understanding was very important.

In our study we found that the physicians had adequate knowledge regarding the purpose of taking consents but their understanding of consents was not curriculum based therefore the junior doctors lacked the basic knowledge about from whom to take the consent from, as half of them thought consent needs to be taken from relatives as well as the patients. The consent was taken by junior doctors in most of the cases, who devoted less time than required for the consents. Therefore were not able to develop good communication and did not provide detailed information about alternative treatment, complications duration of hospital stay. Consent should be incorporated in undergraduate and postgraduate medical training so that comprehensive knowledge about consent is developed. Also there is no provision of written format of consent in government hospitals of the country, therefore many vital components of consent is missed even though consent is taken. A properly constructed and clearly formatted consent form providing clear and simple information about procedures in local language would improve patient comprehension and would lower patient anxiety levels. Repeating information to patients using various formats and modes at different times can strengthen comprehension and recall.[2]

As this hospital is a tertiary care government hospital it generally caters to lower middle and low income group patients and therefore has a mixed bag of illiterate, semi and literate patients. We tried to find out the patients' understanding of different aspects of consent and the ground reality about whether the basic purpose of consent regarding patient safety and satisfaction is fulfilled or not.

One of the basic tenets of process of consent is that the information should be comprehensible to the patient and the patient should set reasonable expectations. We found that same amount or even lesser time was given to illiterate patients probably because the attending doctor did not felt the need to convince the satisfy the patient about the various aspect of treatment given. In almost all areas the perception of an illiterate patients differed from literate patients but as no extra efforts were taken to meet the needs leading to significant difference between the understanding among illiterate and literate patients.

Although literacy level helped patients in understanding of the process of consent but it is important to educate and make people aware of their legal right to informed consent, public health programmes to create such awareness is needed. Patients should be provided information regarding complications, alternative treatment, and length of hospital stay giving them opportunity and right to choose. Physicians should make sure that their counselling about specific risks and benefits is based on current evidence.[3]

A Study done by Sanwal et al contradicted the myth that patients in India do not need to be told about their operations They are unable to understand the complexities and forget the salient facts soon afterwards however in their study they found that 70% of the patients recalled the relevant data. 98 of the 100 patients appreciated being given the information because they said it reduced their anxiety.[4]

One of the major purposes of the informed consent process is to reinforce a patient's understanding of her condition and treatment alternatives and to thoroughly review the chosen procedure with its risks and benefits. Preoperative education and discussion is a crucial part of the surgeon-patient relationship.[5] This process, which includes obtaining written consent from the patient to perform surgery, aims to ensure that the patient has an accurate understanding of her condition, the treatment alternatives, the course of recovery, and appropriate comprehension of the risks, benefits, and potential complications of the planned operative procedure.[6, 7]

A study done by Adam et al to evaluate how well women who consented to undergo sacrocolpopexy understood their planned procedure found that despite detailed preoperative discussion, women had deficiencies in their understanding of sacrocolpopexy they concluded that new methods to improve patient education and comprehension should be considered.[8] Audio and video-based presentation methods also have been used, sometimes with better results.[9]

Although the physicians had basic understanding of consent, all the components of consent process was not communicated to the patients by the physicians. There was significantly low level of understanding of the consent process by patients leading to their increase in anxiety after consent, this difference was more significant in illiterate patients .

Disclosure: None declared.

Funding: There is no funding from any source.

Ethical Clearance: Taken.

Author Declaration: We declare that this work was done by the authors named in this article and all liabilities pertaining to claims relating to the content of this article will be borne by the authors.

REFERENCES

1. American Medical Association. Informed consent. American Medical Association. April 11, 2001.
2. Hoehner PJ. Ethical aspects of informed consent in obstetric anesthesia--new challenges and solutions. J Clin Anesth 2003 Dec;15(8):587-600.
3. ACOG Committee Opinion No. 578: Elective surgery and patient choice. Obstet Gynecol 2013 Nov;122(5):1134-8.
4. Sanwal AK, Kumar S, Sahni P, Nundy S. Informed consent in Indian patients. J R Soc Med 1996 Apr;89(4):196-8.
5. Ogburn T. Making and Informed Consent for Hysterectomy. Clin Obstet Gynecol 2013 Oct 18.
6. Pape T. Legal and ethical considerations of informed consent. AORN J 1997;65:1122-7.
7. Stewart MA. Effective physician-patient communication and health outcomes: a review. CMAJ 1995;152:1423-33.
8. Adams SR, Hacker MR, Merport Modest A, Rosenblatt PL, Elkadry EA. Informed consent for sacrocolpopexy: is counseling effective in achieving patient comprehension? Female Pelvic Med Reconstr Surg 2012 Nov-Dec;18(6):352-6.
9. Hopper KD, Zajdel M, Hulse SF. Interactive method of informing patients of the risks of intravenous contrast media. Radiology 1994;192:67-71.