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Evaluation of preoperative informed consent procedure in obstetrics and gynaecological surgeries

Saubhagya Kumar Jena*

Basanta Kumar Behera**

Soumya Samal***

Mousumi Sen****

Manoj Kumar Mohanty*****

Anugya Aparajita Behera******

ABSTRACT

Background: Informed consent is a two-way communication process by which the patients/parents/guardians are provided the relevant and necessary information regarding the diagnosis and treatment. In the present study an attempt was made to find out the process (How, Who, Where & When) of obtaining informed consent in Obstetrical & Gynaecological surgeries. **Materials & Methods:** This cross-sectional observational study was carried out in the Department of Obstetrics and Gynaecology at SVMCH & RC, Ariyur, Puducherry. Randomly, 132 post-operative cases were interviewed by a pre-designed, pre-tested and structured questionnaire from 1st October 2011 to 31st December 2011. **Results:** In 21.2% of cases consent was not given by the patient and in majority (72.7%) of cases consent was taken by the nurse. In 75.8% of cases consent was taken on previous day or prior to it, consent was taken in ward in 92.5% of cases and duration of explanation was from more than five to fifteen minutes in 65.2% of cases. In 48.5% of cases nurses witnessed the consent process, but in 24.2% of cases consent was not taken in patients' own language. All the components of informed consent were explained to the patients in majority of cases. **Conclusion:** The process of obtaining informed consent still has to be improved.

Keywords: Informed consent; Gynaecological Surgery; Operative procedures.

INTRODUCTION

At the start of their career, medical professionals are bound by an Oath to promote and safeguard the health of the patients. As go the words of 'Declaration of Geneva' of the World Medical Association - "The health of my patient will be my first consideration"[1]. With increasing awareness among the consumers regarding their rights, the medical fraternity needs to be more vigilant while dealing with patient care. Respecting the well being of the patient in clinical practice is the need of the hour.

The decision as to what has to be done with his/her body is in the complete autonomy of the patient[2]. The physician has to negotiate rather than dictate what has to be done with the patient's body. It is at the patient's complete discretion whether he/she agrees to or rejects the physician's advice. For centuries, doctors have been granted with the right to decide in the best interest of the people through the Hippocratic Oath[3]. During the twentieth century, because of increasing consumer awareness, this right of doctors has been conflicted. So, it in the best interest of the

Authors affiliation: *Associate Professor, Department of Obstetrics & Gynaecology, **MD, Associate Professor, Department of Community Medicine, ***DNB, Assistant Professor, Department of Anaesthesiology, ****MD, Assistant Professor, Department of Forensic Medicine, *****MD, Professor & Head, Department of Forensic Medicine, ******M. Sc (Medical Physiology), Tutor, Department of Physiology, Sri Venkateshwaraa Medical College Hospital & Research Centre, Ariyur, Puducherry – 605102, India.

Reprints requests: Dr. Manoj Kumar Mohanty, MD, Professor & Head, Department of Forensic Medicine, Sri Venkateshwaraa Medical College Hospital & Research Centre, Ariyur, Puducherry – 605102, India.

E-mail: manmohanty@yahoo.com

physicians to avoid non-consensual medical treatment.

'Informed consent' is the basic essence of consensual medical treatment. The Indian scenario of doctor-patient relationship is governed more by trust. Here, the physician is given authoritative position which is due to the huge proportion of illiterate population who are less aware about consumer rights. Notion of informed consent was practically non-existent until COPRA (Consumer Protection Act) came to the forefront to safeguard consumer rights in health services[4].

Like all other surgical procedures, informed consent should be taken in both major and minor obstetrics and gynaecological surgeries. As all patients are female, while taking consent specific care must be taken. Consent given by the lady is rarely real. Many a times, owing to the dominant role played by the husband during decision-making in household matters, he or his family members take the upper hand in deciding what is best for the female patient. She merely puts a signature on the consent form obliging to her husband. "Consent", as per section 13 of Indian Contract Act, is defined as 'two or more persons are said to consent when they agree upon the same thing in the same sense'[5]. Consent taken is valid when its essential components are practiced/ considered, which includes voluntariness (willingness of a patient to undergo treatment), capacity (patient is able to understand the nature of treatment), knowledge (sufficient information as to the nature of treatment disclosed to patient) and decision making.

A doctor examining or treating a patient without *valid consent* can be liable for 'battery' or 'assault'[6]. Even now, taking informed consent is more of a legal necessity than an ethical moral obligation seen on the part of a doctor towards his patient[7 & 8]. Improper method of taking consent and withholding complete information from the patient are the important aspects of several medical consumer litigations which need to be addressed.

However, there are limited studies on this issue in the literature despite the importance of the subject to the health care providers.

The present study was conducted

1. To find out the processes by which patients/parents are given information about their complaint, treatment and treatment options.

2. To determine whether the decision is informed or not.

3. To find out whether the patient knows and understands details of the procedure, its complications, risks and possible alternatives to the treatment.

MATERIALS & METHODS

This hospital based cross-sectional observational study was carried out in the Department of Obstetrics and Gynaecology at Sri Venkateshwara Medical College Hospital and Research Centre, Ariyur, Pondicherry. The study period was from 1st October 2011 to 31st December 2011. The study population consisted of post operative cases of Obstetrics and Gynaecological surgeries. A total of 132 cases were selected for the study by systematic random sampling. Study tool was a pre-designed, pre-tested and structured questionnaire. Participants were interviewed face-to-face on the day of discharge. During interview data was collected about informed consent. Emphasis was given on type of operation which they had undergone, how and where the informed consent was taken, who had taken, whether adequate time was given to the patient before taking consent. The anonymity of the responses was maintained. Permission from the institutional ethical committee was obtained. All post operative cases that underwent elective or emergency surgeries in the Department of Obstetrics & Gynaecology were included in the study after taking their consent. The patients who were operated by the investigator, who were not in a condition to give consent, or who had delegated the power of consent to another person were excluded from the study. Patients were interviewed by the investigators personally to collect the information. The data

collected were entered in MS-Excel spread sheet, analyzed and interpreted.

RESULTS

In the present study all 132 cases were above 18 years of age. Total of 106 cases undergone elective surgery and remaining 26 cases had undergone emergency surgeries. Out of 132 cases, 54 had undergone obstetrical surgery and 78 cases gynaecological surgery. In 21.2% of cases, consent was not given by the patient and in majority of cases the consent was taken by the nurse (Table 1). The concerned surgeon had taken consent in 15.09% of cases in elective surgery and 30.76% of cases in emergency surgery. In most of the cases, the duration of explanation was 5 to 15 minutes and consent was taken more than one day prior to surgery (Table 2). In 3% of cases consent was taken in and around operation theatre (Table 3). In 91% of cases nurse and patient attendants witnessed the consent procedure (Table 4). Out of all the components of informed consent, the consent was not taken in patient's own language in one-fourth of cases (24.2%), whereas the diagnosis of the disease was explained in almost all cases (98.5%). All other components of informed consent were explained to the patients in more than 80% of cases (Table 5). Only two (1.5%) patients were not able to identify or name the operating surgeon when asked to give the identity of the operating surgeon. Paternalism was found in 14 out of 132 (10.6%) cases.

Table 1. Persons involved in consent (n=132)

Consent Given By	**Consent Taken By**				**Total**
	Surgeon	Assistant	Resident	Nurse	
Patient	20	08	02	70	100 (75.8%)
Husband	0	0	0	04	04 (3%)
Relative	02	02	0	20	24 (18.2%)
Both Patient & Relative	02	0	0	02	04 (3%)
Total	**24 (18.2%)**	**10 (7.6%)**	**02 (1.5%)**	**96 (72.7%)**	**132**

Table 2. Time of Consent (n=132)

Time between consent & surgery	**Duration of Explanation**				**Total**
	= 5 minutes	>5 to 15 minutes	>15 to 30 minutes	Not sure	
>One day	04	60	14	02	80 (60.6%)
Previous Day	02	10	08	0	20 (15.2%)
Same Day	0	08	10	0	18 (13.6%)
Just Before Surgery	02	08	02	02	14 (10.6%)
Total	**08 (6%)**	**86 (65.2%)**	**34 (25.8%)**	**04 (3%)**	**132**

Table 3. Place of Consent

Place	Number (n=132)	Percentage
Ward	122	92.5
OPD	06	4.5
Pre Operative Room	02	1.5
Operation Theatre	02	1.5

Table 4. Witness & Consent (n=132)

Witness	Number (n=132)	Percentage
Patient's Attendant	56	42.4
Another Doctor	02	1.5
Nurse	64	48.5
Attendant & Nurse	08	6.1
Not Sure	02	1.5

Table 5. Components of Informed Consent (n=132)

Questionnaire	Yes		No	
	Number	%	Number	%
Whether diagnosis of the disease has been explained?	130	98.5	02	1.5
Whether operative procedure has been explained?	124	94	08	6
Whether alternative modalities of treatment have been explained?	110	83.3	22	16.7
Whether explanation about type of anesthesia given?	116	87.9	16	12.1
Whether risks/complications of the procedure explained?	110	83.3	22	16.7
Whether potential benefits of the procedure explained?	128	97	04	3
Whether prognosis with or without the proposed procedure explained?	114	86.4	18	13.6
Whether costs of the proposed procedure approximate explained?	116	87.9	16	12.1
Whether the success & failure rate of the proposed procedure explained?	108	81.8	24	18.2
Whether consent was taken in patient's own language?	100	75.8	32	24.2
Whether consent was explained in patient's own language?	130	98.5	02	1.5

DISCUSSION

Improper consent and withholding complete information from the patient is an important medico-legal concern. The Supreme Court of India has given the following guidelines on informed consent: "A doctor must seek and secure the consent of the patient before starting treatment. The consent so obtained should be real and valid. The information should include the nature and procedure of the treatment and its purpose, benefits and effect, alternative treatment if any available, an outline of the substantial risks and the adverse consequences of refusing treatment". The Supreme Court judgment emphasized the need for specificity of consent. Consent given for a specific procedure will not be valid for conducting another procedure. The nature and extent of

information to be furnished by the doctor to the patient to secure the consent should be acceptable as normal and proper by a body of medical men skilled and experienced in the particular field[9].

Empowering the patient will mean that the patient is part of the team in control of his medical health. This will make it much easier for the doctor to communicate risk information to him. Informed consent is not simply the patient signing a consent form, but, more importantly, is a process of detailed discussion between the doctor and his patient. Informed consent is enforced by both medial ethics and the common law. The common law places a medical duty on doctors to inform and warn. Failure to communicate is a failure in duty thus resulting in a breach of the medical standard of care. But in an emergency situation where a patient is unable to give consent due to unconsciousness, a doctor may perform emergency treatment based on the doctrine of necessity or implied consent to save life.

A person who has the capacity and competence can consent to her treatment. A person is said to have 'capacity' when she can understand the necessary information, retain that information, use it for decision making and communicate the decision by appropriate means[10]. It also depends on what is being consented; more the risk of the treatment offered, greater the capacity required to understand and comprehend[11]. There are fixed guidelines outlining the exact age of consent for medical or surgical treatment. In India, 'majority' is achieved at an age of 18 years and considered a legal age for giving a valid consent for treatment as per Indian Majority Act, Guardian and Wards Act, and Indian Contract Act[12]. In the present study, all 132 cases were above 18 years, but in nearly one-fifth of the cases surgeries were done without consent, the patient being a major & mentally sound person. Other studies have reported that around 26.7% of patients had not signed the consent form[13].

Ideally, consent may be obtained by a person who is capable of communicating all the necessary information required to make a decision regarding their health care. The physician rendering the care may obtain the consent himself/herself[14]. It remains unclear whether a house surgeon/intern can obtain an informed consent or not[15]. Staff nurses or other health care providers are not entitled to obtain the consent although they can bridge the communication gap between the surgeon and the patient. Nursing staff that has been trained in a particular speciality can educate, empathize and prepare the patients before the anticipated formal meeting of doctor and patient. This may improve the communication between the physician and patient and allay the fears and barrier pertaining to the desired procedure/ treatment[16]. In this study only in 18.2% of cases the concerned surgeon had taken the consent. Different studies in literature show different results in this regard. In the study by Dharmanada V[13] the surgeon explained the consent form in 23.4% of cases, whereas in studies by Andrea A et al[17] & SA Shittu et al[18] consent was taken by the concerned surgeon in 47% & 48% of cases respectively. In the study by Dharmanada V[13] the nurse explained the consent form in 3.3% of patients whereas in this study nurses explained the consent form in about 72.2% of cases. Consent is a contract between the doctor and the patient, and the doctor himself must give the information to the patient. In the study by Dharmanda V[13] 23.3% of cases were not sure about who had explained the consent, and almost similar finding (26.8%) was reported by Andrea A et al[17] but in our study such findings were not observed.

The literature is little regarding timing of consent and, in fact, some believe there is no right answer about ideal time and place to sign consent; each unit should determine the best local practice. However, it is important that patient be given sufficient chance to absorb the information necessary for them to make the decision. Also, if significant time has elapsed

between time of consent and the time of the procedure, it is important to reaffirm that the patient has not changed her mind[19,20].

Consent was taken in ward in 92.5% cases in this study; but a study in Australia reported consent was taken in the ward in 60% of cases[13]. In 75.8% of cases the consent was taken previous day or prior to it in this study. However, this is in contrast to the other studies[13,17]. The present study reveals that in 32 cases, patients gave consent either on the day of operation or just before surgery. During this time patients may not have a right frame of mind to take decision. Another study in district hospital shows 81.5% of patients consented within 24 hours of surgery[18]. The duration of explanation was more than 5 to 15 minutes in majority of cases, but it was 10 to 15 minutes in 40% of cases in other study[13]. Many controversies or legal complications can be reduced by adequate communication and proper dialogue at proper timing.

Obtaining an informed consent must be considered a process rather than a point which ends once the patient signs the consent form. It is a continuous two-way communication and must proceed as frequently as possible during the entire treatment of the patient. In general, the consent process provides an opportunity for the treating surgeon to create a good patient-doctor relationship by communicating with the patient regarding the details of the treatment, tailoring the information to the specific needs and understanding of the patient. It also allows for the patient to express her opinion and concerns. This can build patients trust and confidence in the doctors as they feel that they are in control of the decisions in their treatment. In the present study all the components of informed consent were explained to the patients properly in majority of cases. Similar findings were also observed by other studies[11,21].

In the present study, in 48.5 % of cases the nurses witnessed at the process of consent but in the study by Dharmananda V[13] it was 23.4% cases only. Duly witnessed and signed by uninterested third parties are more dependable legally, as the parties concerned cannot subsequently deny execution. There is no conclusive judgment mandating a witness by an uninterested third person while consenting to medical treatment. However, it is realized that the importance of a third person witness improves, especially when the consenting patients are illiterate and have consented by placing a thumb impression[22]. In our study 98.5% of patients were able to identify the operating surgeon whereas only 40% of patients could do so in other study[13]. In 24.2% of cases the consent was not taken in patient's own language.

A consent form in developed nations is expected to be readable by 8th grade level, but there are no guidelines developed in India[23]. It was observed that the consent form given to the patients often has plenty of tough medical terminology and often is not legible and scribbled in a poor handwriting[24,25]. The consent forms need to be comprehensible and written/typed legibly. It would be advisable to use short sentences with simple vocabulary and use of non-medical terminology as far as possible. The consent forms written in patients own language might improve the comprehension and understanding[26]. In cases where the same language is not possible a good interpreter should be provided. The consent form should be signed by all parties concerned (Patients/guardian/doctor/witness) to make it a valid document[22]. India is a multilingual country where every state has its own language. So people of one area cannot communicate with others in local languages. English is a universal language for Indians; however, most patients from rural India know only the local language. Urban patients may know both English and local language as schools in these areas teach both the languages. If consent is not taken in the language with which the patient is familiar, it becomes difficult to communicate. Though, till date, no literature is available regarding paternalism, this study recorded 14 cases (10.6%) of paternalism. Doctor should avoid abusing his/her power at all cost & should respect the choice

of patient which she wishes to follow while undergoing any form of treatment.

Limitations

The conclusions of this study cannot be generalized to other surgical specialities as it was done for the Department of Obstetrics & Gynaecolgy.

CONCLUSION

The importance of consent before obstetrics & gynaecological surgery cannot be over emphasized. It is believed that the best arguments in favour of informed consent are moral rather than legal. In the present study, though all the components of informed consent were explained to the patients in their own language, it was not done by the concerned surgeon. In some cases the consent was not written in patient's own language. To overcome these problems, the use of operation – specific consent form or proforma in patient's own language will ensure accurate and comprehensive discussion and documentation of serious and frequently occurring risks of surgical procedures, particularly the operation-specific ones. Also, emphasis must be given in undergraduate & postgraduate training on legal jurisprudence and legal medicine. Future studies can also be carried out in other specialities and comparison of elective and emergency procedures can be made. The effective procurement of informed consent promotes patient autonomy, engenders trust and confidence in medical professionals and reduces the risk of unnecessary legal claims premised on incorrect assumptions regarding appropriate medical care.

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