Practices of Documentating the Pre-Operative Informed Consent in Obstetrics and Gynaecology in a Tertiary Care Hospital – An Interventional Study

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Abstract

An informed consent form plays a major role both in giving the needed information for the patient and as a legal tool for the doctor to carry out various diagnostic and therapeutic procedures. This paper was an interventional study, conducted in Department of Forensic Medicine, Sri Manakula Vinayagar Medical College and Hospital, Madagadipet, Puducherry to audit and improve the current practices of using informed consent forms by the faculties of Department of Obstetrics and Gynecology. The practice of documenting the informed consent forms obtained during the major surgeries of the concerned department was analyzed using a validated check-list. Deficiencies were identified in the documentation and an intervention was carried out to stress on the importance of documentation in the consent forms and the post-interventional consent forms were analyzed against the same validated check-list. The results of both the pre- and post-intervention data on the documentation of consent form were analyzed and compared, which showed a significant improvement in the documentation of the informed consent forms by the faculties of the Obstetrics and Gynecology Department. This study result will emphasis the role of intervention mode used to enhance the documentation of informed consent forms.

Keywords: *Informed consent form; Deficiencies; Documentation; Intervention.*

Introduction

"Consent connotes agreement, compliance or permission given voluntarily without compulsion.[1] Indian contracts act, section 13 states that "two or more person are said to consent when they agree upon the same thing in the same sense" and section 14 states that "consent is said to be free when it is not caused by coercion, undue influence, fraud, misrepresentation and mistake".[2] Initially, the information given in informed consent forms are complex and difficult for the patient to understand. In the era of 21st century, patients are becoming more aware about this consent form, as the information is available for them at fingerprints through the wide spread access of internet and media.[3] Informed consent in medical practice is based on the decision between the doctor and the patient, where the doctor has to explain and the patient must understand about the details of consent form in the same sense. This can be done by actively involving the patient in decision making process towards the surgery.[4, 5] Failing to do the above process of obtaining informed consent form, the doctor is said to commit an assault and will be liable for the damages caused to the patient as per section 351 IPC.[6] Though there are so much of strict regulations and increasing negligence cases under the consumer protection act because of the improper method of obtaining the informed consent form, still most of

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the doctors are having a careless attitude towards the informed consent form practice. So to access the current trends of obtaining the informed consent form, this study was carried out to evaluate the same with an aim to improve it by having an intervention and also carrying out a post-interventional analysis.

Materials and Methods

The study was done at Department of Forensic Medicine, Sri Manakula Vinayagar Medical College and Hospital, after obtaining approval from Institutional Ethics Committee (IEC No: 98/2016). It is a hospital based interventional study conducted for a period of 24 months from October 2016 to October 2018. The informed consent forms of the elective major and minor surgeries conducted during the study period by the Department of Obstetrics and Gynecology were taken up for the study, whereas emergency surgeries were taken as exclusion criteria. Sampling method was by using systemized random sampling method. The total sample size of the study was calculated as 690 consent forms, using "Epi Info Software Version 7.2 2.6", taking into account the improvement in practice of documenting informed consent forms from 34% based on previous study with 95% confidence interval and 90% power. Out of this 690 consent forms, 345 consent forms were analyzed during the pre-interventional period and another 345 consent forms were analyzed during the post-interventional period. A checklist proforma of the informed consent form consisting of 18 variables was prepared after going through the guidelines of MCI, Royal College of Obstetricians and Gynecologist of London on consent, consent form of the hospital and review of literature. This checklist proforma with 18 variables was scrutinized and validated by the faculties of Forensic Medicine and Obstetrics and Gynecology Department of the hospital, also for the convenience of result analysis these 18 variables were group into 3 categories. (Table No 1) Using this checklist, the 345 informed consent forms taken during the pre-interventional period were crosschecked for any deficiencies in the documentation. These data were entered and analyzed using "Epi Info Software Version 7.2 2.6". An intervention was carried out in form of a workshop for the faculties of Obstetrics and Gynecology department, aiming to emphasis on the importance of documentation of informed consent form and addressing the deficiencies found in the analysis of the pre-interventional period consent forms. Post-intervention another set of 345 informed consent forms of the major and minor elective surgeries were crosschecked using the checklist proforma and data were analyzed. "Student t test" was used to compare the data obtained from the pre and post interventional period and to find the effect of intervention on improving the documentation of the informed consent forms.

Table No 1: Checklist with variables prepared from informed consent form

Category A: Preliminary Variables	Category B: Procedure Variables	Category C: Legal Variables
1. Serial No 2. In-patient No 3. Date of Consent 4. Name of the patient 5. Age 6. Bed No 7. Ward No	8. Nature of the disease 9. Benefits of surgery 10. Risks of surgery 11. Alternative treatments 12. Type of anesthesia 13. Complications of surgery 14. Consequences of surgery	15. Patient signature 16. Doctor signature 17. Witness signature 18. Date of signature

Results

The study results showed that, on analyzing the 345 informed consent forms obtained during the pre-intervention period under category A variables (Preliminary variables), almost all the variables have been documented completely except the variables like bed no and ward no. Fortunately the post-interventional data analysis of the 345 informed consent forms showed significant improvement in these two variables, which

indicate the awareness created among the doctors while documenting every variables in the informed consent form have fulfilled its role. (Table No 2)

Table No 2: Pre and post interventional comparison of Category A – Preliminary variables

S.No.	Category A: Preliminary variables	Pre-intervention n (%)	Post-intervention n (%)	p value
1	Serial No	345 (100%)	345 (100%)	NA
2	In-patient No	345 (100%)	345 (100%)	NA
3	Date of consent form	345 (100%)	345 (100%)	NA
4	Name	344 (99.95%)	345 (100%)	NA
5	Age	342 (99.70%)	345 (100%)	NA
6	Bed No	0 (0%)	201 (58.26%)	0.005
7	Ward No	11 (3.19%)	202 (58.55%)	0.005

It was very evident that the doctors were perfect while documenting the category C: Legal variables like patient's signature, doctor's signature, witness signature and date of signature, since the analysis of the informed consent forms showed complete documentation i.e. 345 (100%), during both the pre and post intervention period which was a very significant finding.

The study showed that on analyzing the Category B: Procedural variables in the pre-interventional informed consent forms used for the patients who underwent major and minor elective surgeries didn't have the printed information about the details of the procedural variables like nature of the disease, benefits of the surgery, risks of the surgery, alternatives treatments, type of anesthesia, complications and consequences of the surgery. Later during the intervention workshop, postgraduate students of Obstetrics and Gynecology were assigned the role of developing customized informed consent forms including the details of the procedural variables for the commonly done major and minor surgeries in their department, under the guidance of one faculty for each postgraduate. Then during the post-intervention analysis of the informed consent forms, it was fortune to see that all the informed consent forms 345 (100%) had the details of procedural variables.

Discussion

In this study, informed consent forms were analyzed in the pre and post intervention period with an intervention mode, but there was a study done by O. C. Osime et al, titled "Current practices and medico-legal aspects of pre-operative consent" at University of Benin teaching hospital, Benin city, where they have done analysis of 133 informed and consent forms and also interviewed all the patients with any intervention and post intervention alanysis.[4]

A study conducted by Mabroka Alfoghi and Mohamed Ben Ramadan, titled "Clinical record keeping survey of patients admitted to Misurata centre hospital" at Department of Pediatrics, Libiya, out to 110 case records analyzed, the patients name were written in 110 (100%), age was written in 105 (96%) and bed number was written in 101 (92%) of case records, whereas in our study during both the pre and post intervention period, except bed number and ward number rest all of the preliminary variables were documented in all the

informed consent forms.[7]

Documenting the doctor's signature in the informed consent forms were done in 344 forms and 345 forms during the pre and post interventional period respectively, but there are studies like the one done by Catherine Leng and Kavitha Sharma, titled "An audit cycle of consent form completion: A useful tool to improve junior doctor training", where the percentage of documenting the doctor's signature was only 46% and 13% during the pre and post interventional period and another study done by Carter K et al, titled "Informed consent forms for vascular intervention: completing one audit loop", showed out 99 consent forms studies only 59 consent forms were signed by doctor's.[8, 9]

In this study, date of informed consent form was written in all the 345 (100%) consent forms, during both the pre and post interventional period, but a study done by Catherine Leng and Kavitha Sharma, titled "An audit cycle of consent form completion: A useful tool to improve junior doctor training", where the percentage of documenting the date was only 46 % and 13 % during the pre and post intervention period, respectively.[8]

When it comes to documentation of complications of the surgery, in this study it was found that during the pre and post interventional period, 0 % and 100 % respectively, was the percentage of documentation, but in a study done by Jennifer Isherwood, titled "Documenting informed consent in elective hip replacement surgery: a simple change in practice", the percentage of documenting the procedure specific complications was 86 out of the 100 consent forms analysed.[10]

Study done by Mark T Siddins, Elizabeth M Klinken and Lee R Vocale, titled "Adequacy of consent documentation in a speciality surgical unit: time for community debate?", it was found that out of 1280 consent forms analyzed, the need for surgery and relevant risks of the surgery were documented only in 10.1% and 4.1% of consent forms, but in our study during the post interventional period all the 345 (100%) of informed consent forms, has documented the need and relative risks of the surgery.[11]

Conclusion

The study have recorded and analyzed the existing standards of documenting informed consent form and the deficiencies were shared during the intervention workshop, which increased the awareness of the faculties on proper documentation, as evident from the post intervention analysis. This study has improved the consent practices related to surgical procedures in Obstetrics and Gynecology department of our institute by developing a structured informed consent form considering the national and international guidelines in both English and Tamil language, which was later approved and implemented in the institute. We feel there are scopes for improving the consent practices more by having day to day awareness methods on the concepts of consent practices, having more regular intervention methods and also keeping frequent post interventional analysis of the informed consent forms. Such studies have to be done in other specialties also with regular awareness programs and analysis of the consent form documentation, which in-turn benefits the patient by making them aware on the surgery details and the doctor's by acting as a better defense against negligence suits.

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