



Original Research Article

Informed consent process before caesarean section: A study of patient's perspective regarding adequacy of consent process

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ABSTRACT

Aim: Informed consent is an ethical and legal requirement and is practiced before all the surgical procedures. Caesarean section is the commonest obstetrics surgery and there is increased rate of C-section due to better diagnosis and early referral. A legitimate consent should be taken from the patient or her guardian before caesarean section. So this study was aimed to assess the adequacy of informed consent process and the understanding of information obtained by the patient.

Materials and Methods: A cross sectional study was done with patients aged more than 18 years and who underwent elective or emergency caesarean section. Based on inclusion and exclusion criteria, a total of ninety three patients were included. A pretested and pre validated questionnaire was adopted for the study. The data were analyzed and expressed as percentage of proportion.

Result: The average age of the participants was 26.11 ± 3.97 years. About 70.96% of the participants underwent emergency caesarean section and 29.07% underwent elective section. About 91.3% of participants knew the necessity of the cesarean section, 94.62% were informed about the risk of surgery and 95.6% were informed about the benefits of C-section. About 98.92% of participants didn't know about the type of anesthesia to be used and almost all patients were not informed about their right to refuse the procedure.

Conclusion: The patients were well informed about the procedure, the risks and benefits involved in C-section. Still some elements of consent process needs to be improved which can be done by proper awareness and training of the health care professionals.

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1. Introduction

Informed consent is defined as permission granted in full knowledge of the possible consequences, typically that which is given by a patient to a doctor for treatment with knowledge of the possible risks and benefits. It is a process in which a health care provider educates a patient about the risks, benefits, and alternatives of a given procedure or intervention.¹ Informed consent provides information to the patient in an understandable manner without coercion. This allows the patient to make an informed decision about his/her health. The consent helps the patient to take a decision whether to accept or reject any examination or

treatment. This helps in building a relationship between the physician and the patient. The physician must provide all the necessary information during the consent process. The concept of informed consent originated from the legal rights of the patients to decide what happens to their body and from the duty of the physician to necessitate the healthcare decision to the patient.² Various factors like urbanization, education level, family size, health care finance options and religious practices also influence the consent practices.³ The informed consent process should include the nature, name, risks and benefits of the procedure or intervention, availability of alternative procedure, compensation for injury if related to the intervention.

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Caesarean section is one of the commonest operation performed by obstetricians worldwide. In recent times the rate of caesarean section has increased many times due to various reasons. The world health organization has projected a target that caesarean section should be up to 15%.⁴ Previously, all the patients who had undergone caesarean section were subjected to elective caesarean section for their subsequent deliveries.⁵ But in recent times, the practice has changed and vaginal birth after caesarean section has become an acceptable alternative.⁶ Other factors like availability of trained surgeon, blood transfusion facilities, and safe anaesthetic facilities affect the decision of opting for caesarean section.^{7,8} Many studies have proven that caesarean delivery has greater morbidity and mortality than normal vaginal delivery. Even if most of the caesarean section are done in good faith, it does not escape the purview of consumer awareness and protection. Because of increasing knowledge about ethics and rights, issues on consent process have become one of the frequent grounds for litigation and malpractice cases. As the rate of caesarean section are increasing in tertiary care hospitals in India, there are concerns regarding the active participation of patients in decision making of the choice of operative interventions. The bigger question is “How much the patient is informed?”. It is not clear that to what extent the current consenting practice offers the patient to make an informed judgment.

Therefore the study was planned to be undertaken at a tertiary care teaching hospital catering population from semi urban and rural area to find out the level of understanding of the patients undergoing caesarean section delivery regarding the indication, procedure and various aspects which are essentials. This study was carried out with an aim to provide insight in to the adequacy of the consenting process before caesarean section. The objective of this study was to assess the proportion of patient receiving adequate informed consent before caesarean section.

2. Materials and Methods

This cross sectional study was conducted in the department of Obstetrics and Gynaecology, SRM Medical college Hospital and Research Centre, India. The study population was chosen from patients who had undergone elective and emergency caesarean section in the hospital. The patients who were more than eighteen years old and who gave verbal consent to participate in the study were included. The procedures which were planned for and performed before labor were defined as elective caesarean sections. And the surgeries which were unplanned and were performed during labor and after complications arose were defined as emergency caesarean sections. Patients who were less than eighteen years of age and who didn't give verbal consent to participate in the study were excluded from the study. A pre tested questionnaire was adopted and modified as per the

local need of the study. The questionnaire had two parts. The first part described the demographic profile and the second part contained questions regarding the procedure performed and other aspects of informed consent. In the second part of the questionnaire, the responses were recorded in a five point likert scale. The responses for strongly agree and agree were considered as adequate and the responses for neutral, disagree, and strongly disagree were considered as inadequate. The data were collected and entered into the microsoft excel sheet and the data base was created which was analyzed by the SPSS software version 19.0. The study was approved by the institutional ethics committee.

3. Results

A total of ninty three participants were selected for the study based on the inclusion and exclusion criteria. Among the participants, about 77.4% were in the age group of 21-30 years. Only 16.1% patients were in the age group of above 30 years. The average age of the participants was 26.1 ± 3.97 years. Regarding the educational status of the participants, it was found that 47.3% were graduate or above graduate. About 23.7% were studied up to 10th standard and 5.4% were illiterate (Figure 1). About 70.96% patients had undergone emergency caesarean section and 29.04% patients had undergone elective caesarean section. In the second part, there were questions to elicit responses from the participants to find their knowledge. The responses were recorded in to two different category; adequate and inadequate. Most of the patients were informed regarding the name, indications, risks, benefits and cost of the surgery adequately (Figure 2). But the patients were not informed about the availability of alternative procedure, requirement and type of anesthesia, and right to refuse the procedure properly (Figure 3).

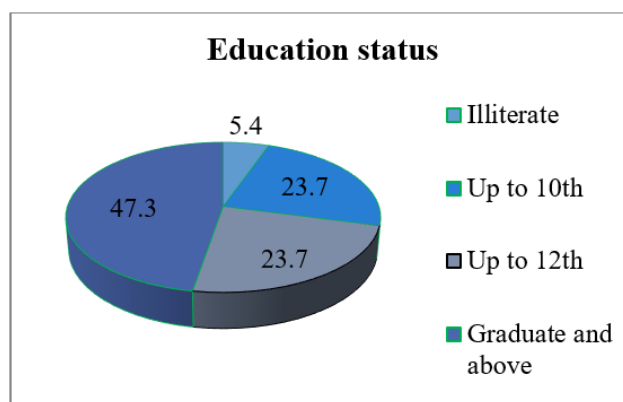


Fig. 1: Educational status of the participants (Data are expressed as percentage (%))

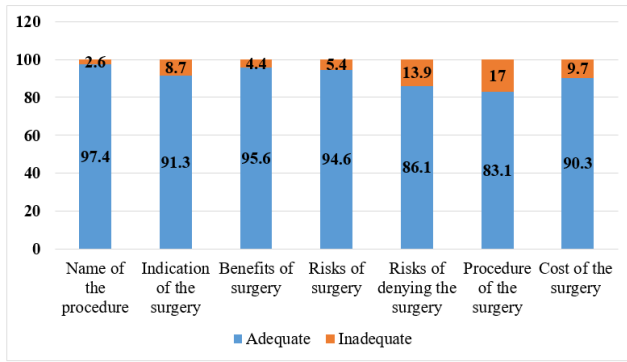


Fig. 2: Responses of the participants to the questionnaire (Data are expressed as percentage (%))

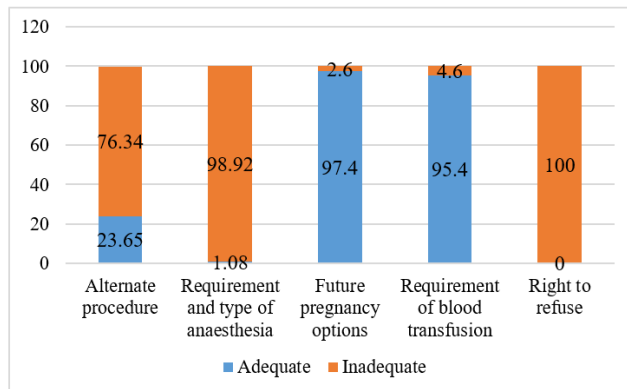


Fig. 3: Responses of the participants to the questionnaire (Data are expressed as percentage (%))

4. Discussion

There are various national health schemes which run both in government as well as private institutions. There is a significant rise in institutional deliveries because of increased awareness about health facilities and increased referral facilities. In Tamilnadu, India, the institutional delivery is 99.2% in urban area as compared with 98.7% in rural area.⁹ Among this, the birth delivered by caesarean section in urban and rural area are 36.1% and 32.3% respectively.⁹ As there is an increased load of deliveries in the institutions, the responsibility lies on the health care providers to improve and maintain the quality of health care.

Peri operative and post-operative counselling of patients undergoing casearean sections is an important and integral part of maternal care. The obstetrics patients present multiple challenges to the health care providers at the time of informed consent process. Patient education and active participation are important for consent process. There is increase in medico legal problems due to wrong or inadequate information provided to the patients or relatives.¹⁰ In most of the emergency caesarean deliveries, the informed consent forms are signed by the relatives

instead of the patients. The result of our study indicates that many of the patients and their relatives were informed adequately before the surgical intervention. These patients were selected irrespective of the elective or emergency caesarean section. Majority of the patients were literate i.e, about 94.6% were above 10th standard. This high literacy rate among our patients shows that there is a better understanding of the informed consent process. As per our study, 97.4% patients were able to name the procedure that they had to undergo and 91.3% patients were able to tell the indications of the surgery. About 95.6% and 94.6% of patients were able to understand the benefits and risks of surgery respectively. And about 83.1% of patients were able to know the procedure of the surgery. So these high percentage of adequacy regarding the informed consent process in our study indicates that the patients were literate to understand the process. Even this shows that the health care professionals were able to provide a better understanding of the informed consent process before the caesarean sections. Similar study done by Latika CC et al. shows that about 93% were adequately informed about the name of the procedure, 98% had adequate knowledge about the nature of the operation and 85% patients had adequate knowledge about the indications of the procedure.¹¹ Another study has shown that 71% patients had knowledge about the indications of the cesarean section but only 25% of patients were able to explain the procedure and complications.¹⁰ So this indicates that there is lack of information during the consent process. Many a times, the patients are explained about the indications, while procedure and risks, benefits of the surgery are not communicated properly. This can lead to legal problem if the patient has any complication intra operatively or post operatively. In our study it was found that majority of the patients (98.92%) were not informed about the requirement and type of anaesthesia during the procedure. A similar study has shown that 80% of the patients were not informed about the type of anesthesia and 87% of patients were not given the chance to choose the anesthesia.¹¹ Where possible, the woman must be aware of the form of anaesthesia planned and should be given an opportunity to discuss in detail with the anaesthesist before surgery.¹² With obesity, there is an increased risks of both surgical and anaesthetic. In our study only 23.95% patients were informed about the availability of alternate procedure. In another study it was concluded that only 26.3% of patients were informed about the alterative procedure.¹³ Another important aspect of informed consent process, i.e the right to refuse or decline the intervention was totally ignored in our study. But a study done in Zambia has shown that about 50% of the patients were informed about the rights to decline the intervention.¹⁴ An well informed, competent woman may choose the no treatment option; that is she may refuse to caesarean section, even when this may be detrimental to

her own health or the wellbeing of her fetus.¹³ Most of the patients were informed adequately about the options for future pregnancy and majority of them (79.5%) preferred to go for vaginal delivery than caesarean section. But the risks involved in future pregnancies like increased risk of uterine rupture (2-7/1000 women), antepartum stillbirth (1-4/1000 women) and placenta praevia and placenta accreta (4-8/1000 women) should be well informed.¹² This study shows that patients who are literate can question the need and justification of carrying out a caesarean section if not properly explained and counseled.

So our study finds that most of the aspects of informed consent process are carried out adequately but still there are some aspects which are to be focused and taken care of. Some factors may be shown to be associated with the quality of the informed consent process. Factors like age of the patients, education status, gestational age of the patient at the time of delivery, the type of caesarean section whether emergency or elective, the counselling and explanation provided by health care professional are important to maintain the quality of consent process. So for caesarean section, the patient education and proper counselling regarding the peri-operative and post-operative complications are indispensable. Many times, emergent indications need immediate action which might not provide enough time for proper counselling of patients or her relatives. Regarding the awareness about the risks and complications of caesarean section, the patients and relatives should be counseled during antenatal visits. If the obstetrician foresee any chance of caesarean section during the antenatal checkup near the term, he/she should start counseling. This will help the patients or the relatives to participate in taking a decision during the consent process even during an emergency situation.

5. Conclusion

Most of the caesarean sections are performed with some emergency indications. Most of the time the patients are well informed about the procedure and the risks of the procedure. But still few aspects are not covered during the process due to inadequate time or situation. This can be improved by creating a proper proforma or checklist as well as training the health care professionals who are involved in the consent process. Similar studies should be carried out in tertiary care hospitals at regular intervals. The results of such studies will help to improve further on the informed process and maintain a good doctor- patient relationship with less medicolegal litigations.

6. Source of Funding

None.

7. Conflict of Interest

None.

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