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Original Research Article

Exploring the adequacy of informed consent for caesarean section at a tertiary care center

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ABSTRACT

Background: The objective was to study adequacy of valid informed consent in caesarean section and to quantify the proportion of patients who receive a proper informed consent before undergoing caesarean section.

Methods: A cross-sectional questionnaire-based study involving 200 registered antenatal women undergoing caesarean section for various reasons both as elective or emergency basis, and data was analyzed.

Results: Among the study group, 98.5% patients were informed about the said procedure in their own local language and consent was taken, in 3 (1.5%) patients informed consent was not taken. Detailed procedure was explained to only 29 patients (14.5%) whereas 171 patients (85.5%) had no clue about the detailed nature of the procedure. 193 patients (96.5%) were satisfied with the given informed patients; 7 patients (3.5%) were not satisfied.

Conclusions: Women need consistent and adequate information for consent. Sessions should be held regarding the procedure, its risks and benefits; in this way patient will undergo the procedure with proper knowledge, awareness and confidence.

Keywords: Informed consent, Caesarean section

INTRODUCTION

Caesarean section is one of the commonest operations done in obstetrics worldwide. It could be on an emergency or elective basis. Rates of caesarean section are on the rise.

With the development of the Nuremberg code (1947), The World Medical Association's Helsinki declaration (1964) and Belmont report (1978) rights of human subjects was put into issue.

Then the emphasis was on the need for voluntary consent in research, treatment, confidentiality, protection from harm, freedom of withdrawal and the protection of vulnerable groups came into focus with the concept of informed consent.¹

Informed consent may be defined as the "the legal term describing a patients voluntary agreement to a doctor performing an operation, arranging drug treatment or carrying out diagnostic tests".²⁻⁴

In the informed consent process the concerned doctors, patient and the patient attenders are involved. Ethically it should be a voluntary, uncoerced decision made by a sufficiently competent, autonomous person (patient) on the basis of the information provided to her.

Ideally, an informed consent for a caesarean section include: explanation of the procedure, description of any attendant discomfort and risks expected, description of any benefit that can be reasonably be expected, disclosure of any appropriate alternative procedures that might be advantageous to the patient, anesthesia options, duration of

hospital stay, approximate costs of treatment, and instruction that the patient is free to accept/ withdraw her consent, depending on her wish.

This informed consent must be signed by the patient and witnessed by a relative or any third party for it to be legally valid. Issues of informed consent and adequate documentation are now recognized as the legal requirements of any medico-legal litigations.⁵

Routine practice of informed consent in Obstetrics will improve the quality of care, wherein the physician patient relationship or a contractual agreement is established. Adequate time and use of simple local language will facilitate patient's comprehension and prevent errors.⁶

Lack of consent amounts to negligence of the surgeon to disclose necessary information to patient's. In our Indian scenario, most often the patient's attenders take the responsibility to listen to the consent process and agree to it.⁷

Patient is often a passive listener to the decision made by the husband or the relatives. Lack of education, low socioeconomic status are some factors which could make the decision a passive one.

This study is designed to explore the adequacy of the consenting process for caesarean section. It explores the patient's role in the perception of the consent process and their understanding of the consent. Informed consent is an ethical and legal requirement.

METHODS

Cross sectional study was undertaken in the Department of Obstetrics and Gynecology at S.S Institute of Medical Sciences and Research Centre, Davangere for the period of two months during June 2019- July 2019. Patient undergoing elective/ emergency caesarean section who were willing to participate in the study were included. The participants were above 18 years of age. 200 registered antenatal women were included. The survey was carried out using a pre-tested questionnaire from the study done by Lubansa which was modified slightly by the researchers as per the audit standards contained within the Royal Colleges of Obstetrics Gynecology (RCOG) were used.⁸ Questionnaire was handed over to the participants within 24 hours of caesarean section. Questionnaire was both in English language and Kannada language (local mother tongue). The respondents were asked to read and tick the questionnaire during a short-allotted time of 30 minutes. On behalf of illiterate patients the questionnaire was ticked by the interviewer. Any doubts the patient had; was cleared by the investigator concerned.

Study period

The study was conducted for 2 months from June 2019- July 2019.

Ethical clearance was obtained from the institute ethical committee and informed consent was obtained from the patients before participating in the study.

Statistical analysis

Data was analysed using chi square test and Fischer's test. Statistical package for social sciences (SPSS) version 20.0 was used and $p < 0.05$ was considered significant.

RESULTS

Amongst the 200 women, majority 111 (55.5%) were primigravida and 89 (44.5%) were multigravida. Out of the total 200 participants; majority were 185 (92.5) booked cases and 15 (7.5%) patients were unbooked cases and presented as emergency cases.

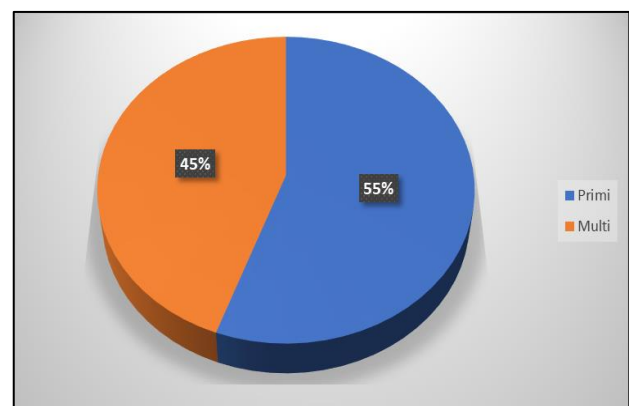


Figure 1: Primigravida and multigravida patients.

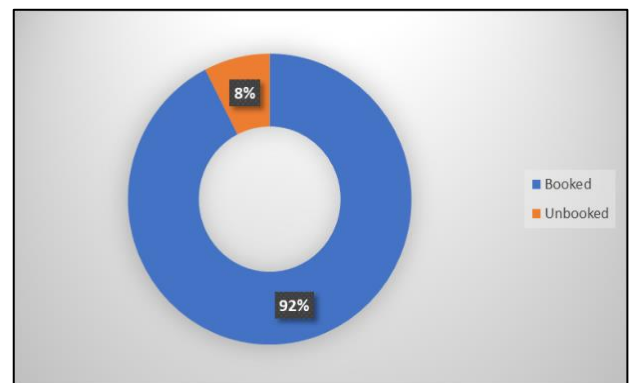


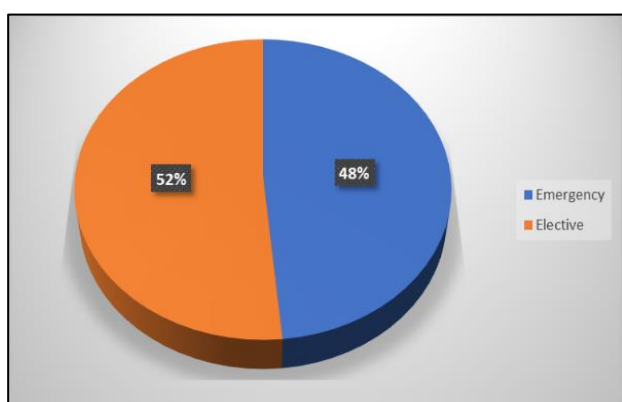
Figure 2: Booked and unbooked cases.

A total of 97 (48.5%) women out of 200 participants underwent emergency Lower segment cesarean section (LSCS) and remaining 103 (51.5%) underwent elective LSCS.

The number of women undergoing elective and emergency LSCS were almost similar and it did not depend upon whether they were booked cases or unbooked cases.

Table 1: Components of the informed consent which were put forth during consent taking.

Components of informed consent	Yes		No		Total	
	N	%	N	%	N	%
Consent explained in local language?	197	98.5	3	1.5	200	100.0
Did patient have idea about indication?	195	97.5	5	2.5	200	100.0
Detailed procedure explained?	29	14.5	171	85.5	200	100.0
Complications of procedure explained?	36	18.0	164	82.0	200	100.0
Alternative options explained?	32	16.0	168	84.0	200	100.0
Costs of surgery explained?	30	15.0	170	85.0	200	100.0
Duration of hospital stay explained?	43	21.5	157	78.5	200	100.0
Type of anesthesia explained?	34	17.0	166	83.0	200	100.0
Need for blood transfusion explained?	100	50.0	100	50.0	200	100.0
Is patient satisfied with information?	193	96.5	7	3.5	200	100.0
Did doctor sign consent?	10	5.0	190	95.0	200	100.0

**Figure 3: Emergency and elective cases.**

A total 197 (98.5%) patients were informed about the said procedure in their own local language and consent was taken, remaining 3 (1.5%) patients informed consent was not taken. Out of the 200 participants; majority 197 (98.5%) were counselled in their local language about the procedure they were undergoing. Most women 195 (97.5%) reported that they received the information about the indication for undergoing LSCS and 5 (2.5%) had no idea as to why they were taken up for caesarean section. Only 29 (14.5%) respondents were explained about the details of the procedure, 171 (85.5%) were not explained in detail about the said procedure. Most respondents 164 (82%) did not receive any information regarding the possible complications regarding their surgery.

Majority of the women 168 (84%) were not informed about possible alternatives to surgical intervention. More than three fourth of the study participants were not explained about the costs of the surgery that they will bear 70 (85%); and duration of hospital stay 157 (78.5%). Only few patients 34 (17%) were explained about the type of anesthesia to be administered. Need for blood transfusion was explained in nearly 50% (100) of the respondents. Nearly all the patients 193 (96.5%) reported that they were satisfied with the information provided. Majority of the

consent forms 190 (95%) were not signed by the doctor takin the consent.

DISCUSSION

Pre-operative and post-operative counselling constitutes an integral part in maternal care. The more experienced the surgeon, better they are at administrating informed consent. Consent procedure must be properly handled to avoid related medico-legal issues. Situation, timing of taking consent and the circumstances all matter in taking informed consent and probably are the factors that affect while taking consent in an elective and emergency caesarean section.⁹ Adequate communication with the patient and alleviating all their questions is essential in all aspects of medicine and will go a long way in avoiding medico-legal complications.¹⁰

In our study a total of 200 antenatal women were included out of which 185 (92.5%) patients were booked cases and 15 (7.5%) patients were unbooked cases. 97 (48.5%) women underwent emergency LSCS and remaining 103 (51.5%) underwent elective LSCS.

In a study conducted by Latika et al, found that majority of patients were in the age group of 21-30 years and 71% were from rural areas. 25% had studied till middle standard followed by those 21.4% who had read till matric standard. 90% cases the outcome of caesarean section was term live births and majority of them were emergency caesarean section.¹¹ Majority of caesarean sections were performed due to some emergency indications.

Latika et al has reported that 93% were adequately informed about the name of the procedure.¹¹ 75% were correctly informed about the indication and 25% were not correctly informed and counseled regarding indication for C-section as compared to our study where 197 (98.5%) patients were informed about the said procedure in their own local language and consent was taken, remaining 3 (1.5%) patients informed consent was not taken. 26.3% patients knew alternative to the procedure, 36.3% knew at

least one complication and 15% knew an option or complication of anesthesia. Overall patients were well informed about procedure and related consequences.

Kirane et al in their study found out that amongst the study group of 220 women; 7% women were illiterate and 93% were literate.¹² 71% had knowledge about indication and need to do cesarean section and one-third were properly explained about procedure and complications. 85% patients thought that there was more risk in cesarean delivery while 15% thought that there was more risk in normal vaginal delivery. They also observed that 81% wanted vaginal delivery, 13% wanted cesarean delivery and 6% did not have any preference. In their study they had not counseled the patients properly regarding the anesthesia used; as compared to our study where type of anesthesia which will be given to the patient and complications associated with it were explained to only 34 patients (17%) and 166 patients (83%) were unaware of it.

In 2017, study conducted by Rajgire et al found that 130 women were found eligible according to inclusion criteria.¹³ 20 patients declined consent. 28% knew benefits of surgery, 29% were aware of risks, 87% of women knew the need to do cesarean delivery. 57% knew the procedure options, and 93% were aware of the procedure of C-section. 100% knew they had the right to change their mind including after signing the consent form.

At the end of our study we found that 193 patients (96.5%) were satisfied with the given 7 patients (3.5%) were not satisfied. High patient satisfaction rate noted could be due to the fact that majority were booked cases (92%). Although the patient satisfaction rate was high, detailed procedure was explained to only 29 patients (14.5%) whereas 11 patients (85.5%) had no clue about detailed nature of the procedure.

At a tertiary care centre, the junior doctors or the senior residents often take consent and the operating surgeon is never seen at the scenario. Many facts may not be unveiled by junior doctors. In emergency situations, time constraints may emerge leading to hurrying in consenting process.

The possible limitations of the study: both emergency and elective LSCS patients were included. Emergency LSCS respondents probably would be less informed than elective LSCS considering the stress involved and time constraints in emergency procedures; small sample size; some confounding variables were not controlled for and cases were not matched- both booked and unbooked antenatal women were included in the study; if the consent taking process was uniformed the outcomes would be more uniformed; most often consent taking was done by duty house surgeons or junior post-graduate students which could lead in inadequate dissemination of information.

CONCLUSION

Adequate and proper information before caesarean section is crucial in maintaining good doctor patient relationship which directly influences medico legal litigations. The principles of autonomy, beneficence and justice which are basic to all ethical issues should be the key components of informed consent. Thus in conclusion, the process of informed consent can be improved by forming proper proforma, and training the healthcare professionals in the consenting process.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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