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Research Article

Study of adequacy of informed consent in caesarean section in a tertiary care, teaching and research institute of Northern India

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ABSTRACT

Background: Informed consent consists of availing information to the patient in an understandable manner without coercion to allow the patient to make an informed decision about their healthcare. In the case of caesarean section, information must include name, nature, proposed benefits of the procedure, risks of the procedure, alternative procedures, implications on the future reproductive health and anesthetic options. Aim and objective: To study the adequacy of informed consent in patients who undergo caesarean section at PT. B. D. Sharma, PGIMS, Rohtak.
Methods: It was a cross sectional study. The study population was the group of patients who underwent emergency or elective caesarean section at PGIMS, Rohtak. A pretested questionnaire was adopted from a study carried out at School of Medicine, University of Zambia and was administered to the patients.
Results: It was found that majority of the patients were in the age group of 21-30 years and most of them (71%) were from the rural areas. In 90% of the cases the outcome of caesarean section was term live births and majority of them (84%) were emergency caesarean section. The patients were asked fourteen questions regarding various aspects of informed consent based on the five point Likert scale.
Conclusions: Majority of the caesarean sections were performed due to some emergency indications. It was found that overall patients were well informed about the procedure and the related consequences.

Keywords: Caesarean section, Informed consent

INTRODUCTION

Informed consent consists of availing information to the patient in an understandable manner without coercion to allow the patient to make an informed decision about their healthcare. Worldwide, caesarean section is one of the commonest operations to be performed by the obstetrician.[1] Decision of performing a caesarean section must be followed by a legitimate informed consent from the patient or her guardian.[2-10] In the case of caesarean section, information must include name, nature, proposed benefits of the procedure, risks of the procedure, alternative procedures, implications on the future reproductive health and anesthetic options. Informed consent is both an ethical and legal requirement. In early times, all patients who had undergone caesarean section were subjected to elective caesarean section for their subsequent deliveries.[11,12] However in current set-up the situation has changed and vaginal birth after caesarean section has become an acceptable alternative. This is also referred as trial of labour or trial of scar.[8,11-14] The World Health Organization has projected a target that caesarean section rate should be up to 15%.[15] In today's times rate of caesarean section has increased many times due to various reasons. The decision of caesarean section depends on availability of many crucial factors like presence of trained surgeon, availability of blood transfusion facilities and safe anesthesia facilities.[16,17] It is well implicit that informed consent is required for all patients posted for an elective or emergency caesarean

section. However, it is not clear that to what extent the current consenting practice at our institute offers them an opportunity to make an informed judgment.

Therefore, a study was planned at the department of Obstetrics & Gynecology, PT. B. D. Sharma, PGIMS, Rohtak for studying and assessing the understanding of information obtained by patients undergoing caesarean section and their involvement in the consenting process and hence was aimed at providing insight into the sufficiency of consenting process for caesarean sections.

Aim & objectives

Aim

1. To study the adequacy of informed consent in caesarean section at PT. B. D. Sharma, PGIMS, Rohtak

Objectives

1. To assess proportion of patients receiving adequate informed consent before caesarean section.

2. To determine the basics of informed consent provided for the caesarean section.

METHODS

The study was carried out in the department of Obstetrics and Gynecology of Pt. B. D. Sharma, PGIMS, Rohtak. This was a cross sectional study and the study population was picked up from the patients who underwent elective and emergency caesarean section. The eligibility criterion was prepared for selecting patients in the study group. The patients who were more than 18 years of age and underwent an elective/emergency caesarean section at PGIMS, Rohtak and had given consent for participation in the study were included in the study and on the other hand, patients less than 18 years and who underwent caesarean section at other hospital and who refuse to participate in the study were excluded from the study. The convenient sampling technique was used and total fifty six (56) participants were selected.

The procedure planned for and performed before labour, or any complications arose, was defined as elective caesarean section and the surgery which was unplanned for and was performed during labour or after complications arose, was defined as emergency caesarean section.

The study tool, a pretested questionnaire of some other study[18] was adopted and modified to some extent as per the local needs of the study. The questionnaire contained two parts. Part-I contained questions regarding socio demographic profile of the participant and other obstetrics details were obtained from their case files. This section had total ten questions. Part II contained statements regarding the procedure performed/anesthesia administered and various aspects of informed consent. Each statement carried five options and the patients needed to choose one of the option. This part of questionnaire carried fourteen statements.

Statistical analysis

The data was entered into the Microsoft excel sheet and the data base was created. The data was analyzed by the SPSS software. Part-II of questionnaire carried 14 different statements and each had five options based on the Likert scale. The adequacy of informed consent was assessed on the basis of reply (i.e. strongly agree/agree) of these statements i.e. name of the procedure, nature of the procedure and indications of the procedure. The Chi square test was used and p valve was calculated.

Ethical clearance

This study does not deal with the ethical issues. This study does not have any human/animal experimentation. This is a questionnaire based study and the opinions of participants were elicited through questionnaire.

RESULTS

Demographic distribution of the participants

It was found that majority (79%) of the participants were in the 21-30 years age group. Ninety five percent of the participants were married and majority of them were from the rural areas. The educational status of the participants was analyzed and it was found that most of them were educated up to middle standard (25%) followed by participants who had studied up to matriculation (21%). Majority of the participants had term live birth (91%) and eighty four (84%) of the participants were posted for emergency caesarean section (Table 1).

Analysis of different statements of participants

The part II of the questionnaire consisted of 14 different statements for eliciting the response of the participants. The response of the participants was distributed in two different categories i.e. adequate or not adequate. The bivariate analysis was done by applying chi square test on these two categories. The knowledge of participants was adequate regarding few aspects of informed consent e.g. name of operation, nature of operation and indication of procedure etc. and the difference was statistically highly significant ($P<0.001$). On the other hand, the knowledge of participants was not adequate regarding few other aspects of the informed consent e.g. option of anesthesia, debriefing regarding procedure and right to refuse or defer the procedure etc. and their difference was also statistically significant ($P<0.001$) (Table 2).

Table 1: Demographic distribution of the participants.

	Number of participants
Age (years)	
18-20	7 (12.5%)
21-30	44 (78.5%)
31-40	3 (5.3%)
Information not available	2 (3.5%)
Marital status	
Single	3 (5.4%)
Married	53 (94.6%)
Place of residence	
Rural	41 (73.2%)
Urban	15 (26.8%)
Education Level	
Up to Middle	14 (25%)
Up to Matric	12 (21.4%)
Up to 10+2	4 (7%)
Up to Graduation	11 (19.6%)
Up to Post graduation	3 (5.3%)
Iliterate	5 (8.9%)
Information not available	7 (12.5%)
Number of days since C. section	
0-3 days	25 (44.6%)
4-6 days	13 (23%)
Above 6 days	6 (10.7%)
Information not available	12 (21.4%)
Outcome of procedure	
Term live birth	51 (91%)
Preterm live birth	4 (7%)
Still birth	1 (2%)
Type of procedure	
Elective	8 (14%)
Emergency	47 (84%)
Not clear	1 (2%)

Table 2: Analysis of responses of the participants.

Parameter	Adequate	Not adequate	P value
Told the name of operation	52 (92.8%)	4 (7.14%)	P<0.001
Told about that cut on the abdomen and the baby delivered through the abdomen?	55 (98.21%)	1 (1.78%)	P<0.001
Told why a caesarean was necessary	48 (85.71%)	8 (14.28%)	P<0.001
If answer to Q (13) is a) or b) what were you told? (patient own words) Corresponds with indication in Part 1 (Q9) (as judged by the interviewer)	42 (75%)	14 (25%)	P<0.05
Understand the reason why a caesarean was necessary?	49 (87.5%)	7 (12.5%)	P<0.001
Agreed that a caesarean was necessary	48 (85.71%)	8 (14.28%)	P<0.001
Told that a caesarean section has risks of its own	18 (32.14%)	38 (67.86%)	P>0.05
Given a chance to ask questions about the intended caesarean section	15 (26.78%)	41 (73.21%)	P<0.05
Told that had the right to refuse or defer the caesarean Section decision?	25 (44.64%)	31 (55.36%)	P>0.05
Told about the options of general or regional anesthesia	11 (19.64%)	45 (80.36%)	P<0.05
Allowed to choose your anesthetic preference	7 (12.5%)	49 (87.5%)	P<0.001
Advised on your delivery options for future pregnancies	18 (32.14%)	38 (67.86%)	P<0.05
After the caesarean section a health care provider debriefed the operation	4 (7.14%)	52 (92.8%)	P<0.001
During antenatal visit, you were told about possibility of delivery by caesarean section	21 (37.5%)	35 (62.5%)	P>0.05

P<0.05 = Significant and P<0.001 = Highly significant

DISCUSSION

Obstetric patients present multiple ethical challenges to the healthcare provider at the time of informed consent regarding disclosure of information. A cross sectional study was carried out to assess the adequacy of informed consent at our institute based on responses given by participants to the questions asked, it was found that most of the participants belonged to 21-30 years age group (78.5%), were married (94.6%) and belonged to rural background (73.2%). Most of them (25%) had studied till middle standard followed by those (21.4%) who had read till matric standard. Forty five percent of patients were those who had their postoperative day 0 to postoperative day 3 of hospital stay, followed by 23% having history of LSCS 4-6 days back and eleven percent revealed history of LSCS greater than 6 days back. Majority (91%) of patients had given birth to term live babies, followed by 7% patients who had preterm live birth and 2% patients having stillbirth as outcome of their surgeries. Most of the patients (84%) had emergency LSCS, followed by patients who had elective LSCS. The part II of the questionnaire contained fourteen questions and response of patients was measured in the form of Likert scale based options. If the patient gave answer as strongly agree/agree than the response was considered as adequate, and in other options, it was considered as an inadequate response.

Majority of the patients (93%) were adequately informed about the name of the procedure, and the difference was statistically highly significant (P value <0.001). Ninety eight percent patients had adequate knowledge about the nature of the operation and eighty five percent patients had adequate knowledge of indication of the procedure. The difference was statistically significant in both the aspects (P value being <0.001). Out of total patients who knew indication of caesarean section,75% of them told the indication correctly which corresponded with their case notes, in 25% of the cases, indication told by patients didn't match with case notes (P value <0.05). On the other hand patients were not adequately informed about the risks of caesarean section as sixty eight percent had denied having been told the risks of surgery and majority of the patients (73%) were not given the chance to ask queries regarding their surgery. The difference was statistically significant in both the cases (P value <0.05). It was found that majority of the patients (80% & 87% respectively) were not adequately informed about the type of anesthesia and were not given the chance to choose their anesthetic preference (P value <0.05). Out of total participants included in study, 32.14% agreed having been told preferences for future pregnancies while 67.86% disagreed to the same (P value <0.05). In a study carried out at Nigeria (2008) on surgical procedures (including obstetric procedures) it was concluded that only 26.3% of patients knew any alternative to the procedure, 36.3% knew at least one complication of the procedure and 15% knew an option or complication of anesthesia.

In our current study ninety three percent patients refused having been adequately debriefed by healthcare provider after surgery (P value <0.001). Antenatal visit is the appropriate time to sensitize a patient about possibility of caesarean section in certain conditions in future. 37.5% agreed to the fact that they were told that they might need surgery in future during their antenatal visit, while 62.5% refused having been told so (P value >0.05). Overall most of the case files showed good documentation however consenting process can be made better by following a proper proforma/checklist which should contain all the essential elements to be covered in consent. Adisa et al. also recommend a well-structured and standardized method of obtaining informed consent from surgical patients. Ezeome and Marshall reporting on informed consent in Nigeria (2009) made recognition of individual autonomy but also that decisions were made within the family.

CONCLUSION

Majority of the caesarean sections were performed due to some emergency indications. It was found that overall patients were well informed about the procedure and the related consequences; however few elements were not covered in the consent. Thus, it can be concluded that process of informed consent can be improved by forming proper proforma/checklist and training of the healthcare professionals who are involved in consenting process.

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