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Original Article

Obstetrics and Gynaecology Section

# Assessment of Adequacy of Informed Consent Process before Caesarean Section: A Cross-sectional Study

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## ABSTRACT

**Introduction:** Caesarean section is the most common surgery performed in obstetrics. Legitimate informed consent should be obtained from the patient or her guardian before a caesarean section.

**Aim:** To assess the adequacy of the informed consent process and to understand the reasons for any inadequacy in obtaining informed consent.

**Materials and Methods:** A cross-sectional study was conducted in the Department of Obstetrics and Gynaecology at Saraswathi Institute of Medical Sciences, Hapur, Uttar Pradesh, India from January 2022 to December 2022. The study included all patients undergoing caesarean sections. A total of 460 patients were included after obtaining prior legitimate consent. A pretested and pre-validated questionnaire was adopted for the study, consisting of 16 questions related to details of the informed consent process for the surgery performed and the anaesthesia. The responses were recorded on a five-point Likert scale. Responses of "strongly agree" (1) and "agree" (2) were considered adequate, while responses of "neutral" (3), "disagree" (4), and "strongly disagree" (5) were regarded as inadequate. Data from the questionnaires were collected and entered into a Microsoft Excel sheet and analysed using Statistical Packages of Social Sciences (SPSS) software.

**Results:** Out of 460 patients, 242 (52.6%) were aged 18 to 25 years. Most of the women, 424 (92.2%), were literate. Additionally, 263 (57.2%) had undergone repeat caesarean sections, and 364 (79.1%) had emergency caesarean sections. A majority of the women, 414 (90%), were aware of the benefits of caesarean sections, and 394 (85.7%) were informed about the major risks involved in the surgery. Most respondents, 395 (85.9%), also received information regarding possible complications during their surgery. Information about the need for blood transfusion was provided to most respondents, 402 (87.4%). Furthermore, 388 (84.3%) of them were aware of the type of anaesthesia, but only a few patients, 27 (5.9%), were explained about the risks associated with anaesthesia. The effect of caesarean section on future pregnancy was not explained to 368 (80%) of the respondents.

**Conclusion:** Although most patients were well informed about the procedure and the associated risks and complications, some elements of the consent process were inadequately addressed, indicating a need for improvement.


**Keywords:** Emergency caesarean, Ethical, Medicolegal

## INTRODUCTION

Informed consent is an ethical and essential legal requirement that must be obtained before all surgical procedures. The concept of informed consent originated from the legal rights of patients to decide what happens to their bodies, as well as the duty of physicians to facilitate healthcare decisions for their patients [1].

Informed consent may be defined as "the legal term describing a patient's voluntary agreement to a doctor operating, arranging drug treatment, or carrying out diagnostic tests" [2,3].

A caesarean section is a surgical procedure to deliver a baby through an incision in the abdominal wall and uterus. It is the most common obstetric surgery and can be performed either electively or in emergencies. All caesarean sections can be associated with risks and unforeseen complications. These might include: (a) Infection; (b) Loss of blood or haemorrhage; (c) A blood clot that may break off and enter the bloodstream (thromboembolism); (d) Injury to the bowel or bladder; (e) A scar that might weaken the uterine wall; (f) Abnormalities of the placenta in future pregnancies; (g) Risks from general anaesthesia; and (h) Foetal injury [4].

Legitimate informed consent must be obtained from the patient or her guardian before a caesarean section. Ethically, it should be a voluntary, uncoerced decision made by a competent person on the basis of the information provided to her. It is a process in which a healthcare provider educates a patient about the risks, benefits, and alternatives of a given procedure or intervention in an understandable manner [5].

Ideally, informed consent for a caesarean section should include: an explanation of the procedure; a description of expected symptoms or discomfort; the risks involved; a possibility of blood loss and the need for a blood transfusion; a description of any benefits that can reasonably be expected; a disclosure of any appropriate alternative procedures that might be advantageous to the patient; possible delayed effects of the procedure; anaesthesia options; the duration of hospital stay; the approximate cost of treatment; and information that the patient is free to refuse or withdraw her consent.

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 recognised as essential legal requirements for any medicolegal litigation [6].

The World Health Organisation (WHO) has projected a target that the caesarean section rate should be upto 15% [7]. In recent times, the rate of caesarean sections has increased multifold due to various reasons, such as the availability of trained surgeons, blood transfusion facilities, safe anaesthetic options, and an increasing number of patients opting for caesarean sections [8-10].

As the rate of caesarean sections rises in tertiary care centres in India, concerns have emerged regarding the active participation of patients in the decision-making process related to the choice

of operative procedures, and how much information is actually provided to them. It is unclear to what extent current consenting practices allow patients to make informed and judicious decisions.

Therefore, the present study was planned to assess the proportion of patients receiving adequate informed consent before undergoing a caesarean section.

## MATERIALS AND METHODS

The present cross-sectional study was conducted in the Department of Obstetrics and Gynaecology at Saraswathi Institute of Medical Sciences, Hapur, from January 2022 to December 2022 {total deliveries: 1,929; Lower Segment Caesarean Section (LSCS): 495}. A total of 460 patients consented to participate in the study. Institutional Ethical Committee approval was obtained (IEC - SIMS/FMT/ETHI/13/2021 dated 08/07/2021).

**Inclusion and Exclusion criteria:** All patients who underwent elective and emergency caesarean sections in the hospital and were aged over 18 years were included. Patients who did not give consent to participate in the study were excluded from the study.

### Study Procedure

A predesigned questionnaire was adopted and modified as per the need [11]. Women were interviewed using a questionnaire, which was explained in the local language, and the information provided was checked for reliability and recorded. The first part of the questionnaire described the demographic profile of the patient and included information regarding age, literacy status, rural or urban background, and details of previous pregnancies. The second part contained questions regarding the name of the procedure performed, its indication, benefits and risks of caesarean section surgery, risks associated with denying the surgery, effects on future pregnancies, type and risks of anaesthesia, possibility of blood transfusion, cost of surgery, and other aspects of informed consent. The responses were recorded on a five-point Likert scale. Responses of "strongly agree" and "agree" were considered adequate, while responses of "neutral," "disagree," and "strongly disagree" were regarded as inadequate.

## STATISTICAL ANALYSIS

The data from the questionnaires were collected and entered into a Microsoft Excel sheet, then analysed using SPSS software. The results were presented in terms of percentage and mean.

## RESULTS

Out of the total 460 patients who consented to participate in the study, the majority of women 242 (52.6%) were in the age group of 18 to 25 years, with a mean age of 24.2 years. Most of the women were literate (92.2%), and the largest proportion had studied up to high school (61.5%) [Table/Fig-1]. A total of 263 patients (57.2%) had undergone repeat caesarean sections, while 197 (42.8%) had primary caesarean sections [Table/Fig-2]. Only 96 (20.9%) had elective caesarean sections, while 364 (79.1%) had emergency caesarean sections.

| Demographic characteristics | n (%) |
|---|---|
| **Age (in years)** | |
| 18-25 | 242 (52.6) |
| >25-35 | 143 (31.1) |
| >35 | 75 (16.3) |
| **Religion** | |
| Hindu | 215 (46.7) |
| Muslim | 212 (46.1) |
| Other | 33 (7.2) |
| Rural | 202 (43.9) |
| Urban | 258 (56.1) |
| **Parity** | |
| 0 | 151 (32.8) |
| 1 | 102 (22.2) |
| 2 | 118 (25.7) |
| 3 | 57 (12.4) |
| 4≤4 | 32 (6.9) |
| **Education** | |
| Illiterate | 36 (7.8) |
| Primary | 72 (15.7) |
| High school | 283 (61.5) |
| Graduate | 51 (11.1) |
| Postgraduate | 18 (3.9) |

**[Table/Fig-1]:** Demographic characteristics of the study group (N=460).

| Type of caesarean section | n (%) |
|---|---|
| Primary caesarean | 197 (42.8) |
| Repeat caesarean | 263 (57.2) |

**[Table/Fig-2]:** Type of caesarean sections of the study group (N=460).

All 460 participants were counselled in their local language about the procedure they were undergoing. A total of 85.7% of consent forms were complete, and the majority of the forms were filled out by junior residents (63.9%) [Table/Fig-3a,b]. As expected, consent forms for elective procedures were more complete (90/96=93.8%) than those for emergencies (304/364=83.5%). The majority of the consent forms (423, or 92%) did not bear the full signature of the doctor obtaining the consent, and 111 (24.1%) did not contain the signature of a witness.

| Details of consent forms | n (%) |
|---|---|
| Consent forms complete | 394 (85.7) |
| Consent forms incomplete | 66 (14.3) |

**[Table/Fig-3a]:** Details of consent forms, whether complete or incomplete (N=460).

| Details of consent forms | n (%) |
|---|---|
| By Junior resident | 294 (63.9) |
| By Senior resident | 116 (25.2) |
| By Faculty | 50 (10.9) |

**[Table/Fig-3b]:** Details of filled consent forms (N=460).

Most women (97.4%) reported that they received information about the name of the surgery, while 2.6% had no idea what the name of the surgery was. The majority of women (95.9%) were aware of the indication for undergoing the caesarean section. A significant proportion (90%) of the women were knowledgeable about the benefits of caesarean sections, and 85.7% also knew about the major risks of the surgery, but only 25.7% were informed about the minor risks. Only 22.6% of respondents were provided with details of the procedure. Most respondents (85.9%) received information regarding the possible complications associated with their surgery [Table/Fig-4].

| Questionnaire | Adequate response n (%) | Inadequate response n (%) |
|---|---|---|
| Name of the surgery | 448 (97.4%) | 12 (2.6%) |
| Indication of the surgery | 441 (95.9) | 19 (4.1) |
| Benefit of the surgery | 414 (90) | 46 (10) |
| Risks of the surgery – major | 394 (85.7) | 66 (14.3) |
| Risks of the surgery – minor | 118 (25.7) | 342 (74.3) |
| Details of the procedure | 104 (22.6) | 356 (77.4) |
| Complications | 395 (85.9) | 65 (14.1) |
| Type of anaesthesia | 388 (84.3) | 72 (15.7) |
| Risk of anaesthesia | 27 (5.9) | 433 (94.1) |

| | | |
|---|---|---|
| Need for blood transfusion | 402 (87.4) | 58 (12.6) |
| Cost of surgery | 430 (93.5) | 30 (6.5) |
| Duration of stay in hospital | 376 (81.7) | 84 (18.3) |
| Risk of denying the surgery | 234 (50.9) | 226 (49.1) |
| Effect of surgery on future pregnancy | 92 (20) | 368 (80) |
| Any alternate procedure | 43 (9.3) | 417 (90.7) |
| Information about right to refuse | 36 (7.8) | 424 (92.2) |

**[Table/Fig-4]:** Responses of the participants to the questionnaire.

## DISCUSSION

A caesarean section can be associated with risks and complications. Patient education and active participation are important for the consent process. There is an increase in medicolegal issues due to incorrect or inadequate information provided to patients or their relatives [10].

In a study by Kirane AG et al., it was found that 71% of the total women had knowledge about the indications for caesarean delivery [10]. Of these, only one-third were properly informed about the procedure and its complications. This contrasts with present study, where 95.9% of patients knew about the indications for undergoing a caesarean section, while the level of education among the patients in this study (7% illiterate) was similar to present study (7.8% illiterate). In present study, the majority (79.1%) had undergone emergency caesarean sections, which is similar to the study by Kirane AG et al., where 84% had emergency caesarean sections [10].

In a similar study by Tripathy S et al., 91.3% of patients knew about the indications for caesarean section, and 83.1% of patients were able to name the surgical procedure [11].

In the study by Tejaswi VP et al., out of 200 participants, the majority (197, or 98.5%) were counselled in their local language about the procedure they were undergoing. Most women 195 (97.5%) reported that they received information about the indication for undergoing LSCS, while 5 (2.5%) had no idea why they were being taken for a caesarean section [12]. Similarly, in present study, most women (97.4%) reported that they received information about the name of the surgery, and only 2.6% of patients had no idea what the name of the surgery was.

In the present study, 77.4% of patients were not explained the procedure in detail, which is similar to the study by Tejaswi VP et al., where 171 (85.5%) were not informed in detail about the procedure. Furthermore, most respondents 164 (82%) did not receive any information regarding the possible complications of their surgery [12]. This contrasts with present study, where 85.7% received information regarding the possible complications. In a study by Latika L et al., about 93% were adequately informed about the name of the procedure, 98% had adequate knowledge about the nature of the operation, and 85% of patients had adequate knowledge about the indications for the procedure [13].

In a similar study by Tripathy S et al., 95.6% and 94.6% of patients understood the benefits and risks related to surgery, respectively. This contrasts with present study, where 90% knew about the benefits of surgery, while only 85.7% of patients were aware of the risks associated with the surgery [11].

In another study by Latika L et al., it was shown that 80% of the patients were not informed about the type of anaesthesia, and 87% of patients were not given the option to choose the type of anaesthesia [13]. In contrast, in present study, 84.3% were informed about the type of anaesthesia, but none were given the opportunity to choose it. In a study by Tejaswi VP et al., only a few patients 34 (17%) were explained about the type of anaesthesia to be administered [12]. Before undergoing any surgical procedure, patients must be informed about the type of anaesthesia to be administered, and they should be allowed to discuss the procedure in detail with the anaesthetist before surgery [14].

In present study, only 9.3% of patients were informed about alternative procedures. In most other studies, a smaller number of patients were informed about the availability of alternative procedures; for instance, a study by Tripathy S et al., found that only 23.95% of patients were informed about the availability of alternative procedures [11]. In yet another study, only 26.3% of patients were informed about alternative procedures [15].

The right to refuse or decline the intervention is another important aspect of the informed consent process. A study conducted in Zambia showed that 50% of patients were informed about their right to decline the intervention [16], while in present study, only 7.8% of patients were aware that they had the right to refuse.

In present study, the majority of consent forms for caesarean sections were completed by junior residents (63.9%), compared to 78% in the study by Glennon K et al., [17].

Most of the patients (80%) in present study were not adequately informed about the effects of surgery on future pregnancies. Therefore, present study concludes that while most aspects of the informed consent process were carried out adequately, a few areas still need to be addressed and improved.

Regarding counselling about the risks and complications of caesarean sections, patients and their relatives can be informed about the procedure during antenatal visits, particularly if the obstetrician anticipates any likelihood of a caesarean section. This is important because, during emergencies, immediate action is often required, which may not provide sufficient time for proper counselling of patients or their relatives during the antenatal check-up in the near term. By providing counselling with enough time to explain everything and address any queries, patients and their relatives can participate in the decision-making process during the consent phase, even in emergency situations.

### Limitation(s)

In present study, the sample size was small, as both emergency and elective caesarean patients were included. Respondents who underwent emergency caesareans would likely be less informed due to time constraints and the stressful nature of the situation, compared to those undergoing elective caesareans. Additionally, there were a few confounding variables, and the cases were not matched—both booked and unbooked antenatal women were included.

## CONCLUSION(S)

The process of obtaining informed consent, especially during emergency caesarean sections, should be improved. Implementing a checklist and providing regular training for healthcare professionals and residents involved in the consent process can enhance the adequacy of this process. Periodic studies should be conducted in every tertiary hospital, both in government and private settings, to promote a better understanding of informed consent for patients undergoing caesarean sections. This will help to build trust and improve the doctor-patient relationship. In turn, this is likely to reduce the number of litigations and medicolegal issues.

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