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Exploring the Adequacy of Obtaining Informed Consent for Caesarean Deliveries - A Patient Perspective

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Abstract
Objectives: The objective of this study was to assess the adequacy of informed consent obtained from patients prior to caesarean delivery.
Design: Descriptive study
Setting: Tertiary level hospitals in a major South African center in Pretoria, South Africa
Subjects: Two-hundred-and-fifty patients who underwent elective and emergency caesarean deliveries
Outcome measures: The assessment of the adequacy of the informed consent was assessed via a questionnaire that the participants answered on day 2-3 post caesarean delivery.
Results: Average age of participants was 28.8 years (28.75 ± 5.92). Twenty three percent (23.2%) of the participants underwent elective and 76.8% underwent emergency caesarean deliveries. Seventy five percent (75.6%) of the participants knew the name of the procedure, although only 29.2% were aware of the associated risks, and 59.2% of participants knew of their right to refuse the procedure.
Conclusion: Adequate communication is essential to all aspects of medicine and this study has highlighted the inadequacy of the informed consent process that takes place at our institution. Information regarding risks and complications was not adequately communicated. A standardized informed consent document that healthcare professionals can use for counseling, starting antenatally, should be considered.

Keywords: Caesarean section, Informed consent

Introduction

Informed consent is a fairly new concept to the practice of medicine. In ancient medical practice a paternalistic approach was adopted. Paternalism implies that the physician makes decisions based on what he or she deems is in the best interest of the patient despite the fact that the patient is capable of making the decision themselves. This was the practice of medicine in the 19th century.[1] During the 20th century various legal decisions swung the pendulum from a paternalistic approach to a more patient-centered approach. This process includes shared decision-making about treatment options between physician and patient. It is a key component of patient-centered care and is the preferred model for communication in healthcare encounters.[1,2]

Autonomy is one of the major ethical principles which govern medicine today.[1,3,4] Autonomy can be broadly defined as a person's capacity to freely express his/her own will and freedom for action.[3,4] Patient autonomy is when patients are the decision makers who act intentionally, with understanding and without controlling influences to determine their decisions.[3] This may be complicated in difficult maternal-fetal situations where for example the fetus may benefit from caesarean section for fetal distress, but the mother has the right of informed refusal. The foundation of informed consent rests on the principle of respect for autonomy and dignity of persons, consent based on information and understanding, and the right of informed refusal.[3,4,5]

As informed consent has a legal component it forms part of patients' rights. Patients' rights vary in different countries and in different jurisdictions. Differing models of the doctor-patient relationship infer the particular rights of patients in each country.[5] Patients' rights are protected by laws that regulate the type of information that patients must be given so that they can make an informed decision regarding receiving medical care, diagnostic tests or treatment. Some countries have specific laws about certain medical situations and levels of disclosure to patients. In South Africa self- determination and the rights to bodily and psychological integrity are accepted as fundamental rights of every patient since 1996 when the new Constitution was adopted.[6]

The aim of the study was to ascertain the adequacy of the process of informed consent obtained prior to a caesarean delivery in a South African academic healthcare setting.

Methods

A descriptive study was conducted between April and August 2019 in a major South African center, which comprises three tertiary hospitals. Hospital 1 serves an estimated 2 million people, Hospital 2 is a tertiary

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referral hospital that also receives patients from neighbouring provinces, and Hospital 3 is a tertiary hospital which serves an estimated 2.5 million people mostly from informal settlements. The study population consisted of patients on day 2-3 post caesarean delivery.

A sample size of 250 patients who underwent caesarean deliveries was required. Convenience sampling was performed to include 250 patients. Proportional sampling was further used to ensure that each hospital was represented adequately in the sample size. Hospital 3 reports performance of the most caesarean section deliveries (5373/year), compared to Hospital 1 (2661/year) and Hospital 2 (1527/year). Thus 138 (55.2%) patients from Hospital 3, 71 (28.4%) patients from Hospital 1 and 41 (16.4%) patients from Hospital 2 were recruited, ensuring adequate representation of all three hospitals in the sample.

Informed consent is obtained in a dialogue between clinician and patient where the patient is informed about the nature of the operation, its associated risks and benefits, and alternative treatment modalities. [3] The adequacy of these components was assessed by a structured questionnaire, available in English. The questionnaire was divided into 2 parts, viz. the first part included patient demographic information and the second part focused on assessing the adequacy of the informed consent process. Patients were able to indicate "yes" or "no" and elaborate if they wished to do so. The first author conducted all the interviews over the study period. The interviewer was able to converse fluently in all major South African languages. Patients under the age of 18 or those with limited mental capacity were excluded from this study.

The research protocol was approved by the Health Sciences Research Ethics Committee (Protocol number 557/2018), and the respective hospitals. Informed consent was obtained from patients prior to enrolment in the study.

Results

During the study period of April-August 2019, 250 participants consented to participate in the study at the three hospitals: 71 (28.4%) patients from Hospital 1, 41 (16.4%) patients from Hospital 2, and 138 (55.2%) patients from Hospital 3. The proportion of participants that had elective and emergency caesarean delivery was 58 (23.2%) and 192 (76.8%) respectively. Indications for the 192 (76.8%) emergency caesarean deliveries are illustrated in Figure 1.

The age of participants ranged from 18 to 43 year (median 28 years, IQR 24-33 years). All 250 participants were formally educated with the highest level achieved being primary school for 5 (2.0%) participants, high school without matriculation for 82 (32.8%), 115 (46.0%) having attained matriculation and 48 (19.2%) having obtained a degree/diploma. Northern Sotho was the predominant home language with 66 (26,4%) and isiZulu coming in second at 37 (14,8%). However, English was the language in which most (n=163, 65.2%) informed consent was obtained, followed by Northern Sotho (n= 66, 26.4%). This may have been a factor accounting for the disparity in the number of patients that reported not being adequately counselled with regards to their caesarean delivery (Table 1).

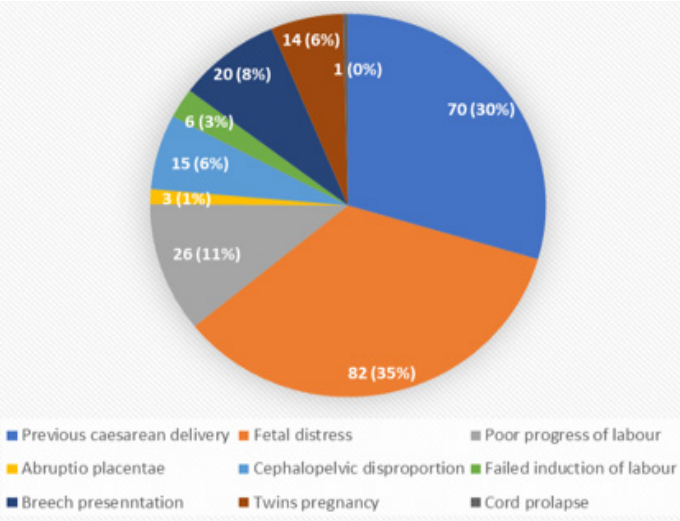

Figure 1. Indications for caesarean delivery

Responses to questions regarding the adequacy of information provided during the counselling for caesarean delivery were recorded as "yes" (adequate counseling) or "no" (inadequate counseling), according to the patient's memory. A total of 189 participants, 75,6%, reported being told the name of the operation. Information on why the operation was necessary (n=231, 92.4%), the type of anaesthesia they would receive (n=201, 80.4%) and about the possibility of a blood transfusion (n=221, 88.4%) was made available to the large majority of respondents as indicated. Fewer participants reported to have been informed regarding risks of the operation (n=73, 29.2%), benefits of the operation (n=64, 25.6%) and delivery options for future pregnancies (n=92, 36.8%).

Consent was obtained either by the nursing sister who was the registered midwife in the labour ward. (n=1, 0.4%), medical intern (n=2, 0.8%), medical officer (n=80, 32%) or obstetrics registrars\ (n=167, 66.8%). Figures 2 and 3 illustrate what was reported by the patients as extracted from the questionnaires.

Table 1. Comparison of language preferred versus language of consent (n=250)

Language (n, %)	Patients preference (n, %)	Informed consent obtained (n, %)
English	2 (0.8%)	163 (65.2%)
Afrikaans	5 (2%)	0
Setswana	16 (6.4%)	7 (2.8%)
Northern Sotho	66 (26.4%)	34 (13.6%)
Southern Sotho	24 (9.6%)	8 (3.2%)
isiXhosa	6 (2.4%)	0
isiZulu	37 (14.8%)	32 (12.8%)
Tshivenda	11 (4.4%)	3 (1.2%)
Tshitsonga	12 (4.8%)	0
Ndebele	15 (6%)	3 (1.2%)
siSwati	20 (8%)	0
Shona	19 (7.6%)	0
Other languages	17 (6.8%)	0

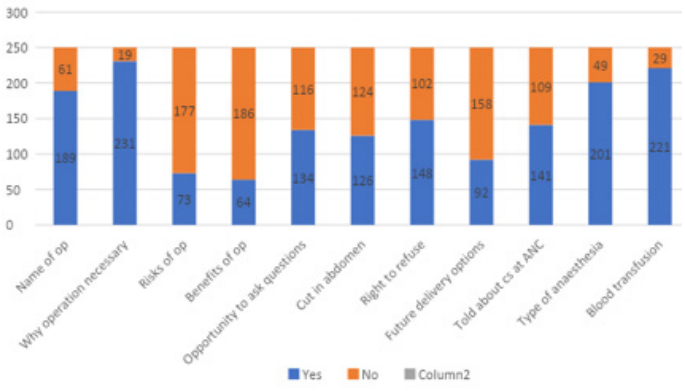

Figure 2. Patients' perception of adequacy of information received prior to caesarean delivery

Abbreviations: cs: caesarean section
ANC: Antenatal clinic

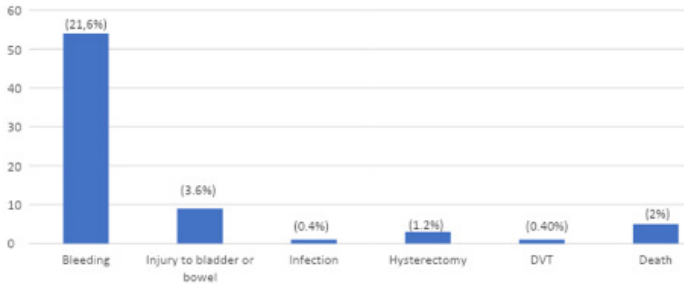

Figure 3. Patients' reported knowledge of risks associated with caesarean delivery, given as choice options

Discussion

Mutual trust provides the foundation of a good doctor-patient relationship. Patients become progressively more informed about health and diseases therefore obtaining informed consent before subjecting a patient to any test, procedure or investigation is essential.[5,7] Obstetric patients present multiple ethical challenges to the healthcare provider at the time of the informed consent process.

The literacy rate may impact on the level of understanding between the patient and doctor during the informed consent process. Although consent forms in our institution are in English some of the informed consents were taken in other South African languages such as Northern Sotho and isiZulu to further assist patients to understand and make informed decisions in a language they are comfortable in.

Clinical informed consent must at minimum include four content elements namely information about the procedure, risks, benefits and alternatives (in these cases, avoidance of caesarean section) which were all included in our questionnaire. We found that whilst the majority of patients were well counselled with regards to the name of the procedure and indication for the caesarean delivery, little information was offered to the patients regarding the risks, benefits or alternatives to caesarean delivery. This may be attributed to the majority of the caesarean deliveries being emergencies. The risk most mentioned was reported as the risk of bleeding.

Participants reported very little knowledge with regards to delivery options for future pregnancies. This is regarded as a major negative outcome of the analysis.

Participants were well counselled regarding type of anaesthesia and the possibility of blood transfusion, this could be because a separate blood consent form needs to be completed for consent to blood products prior to surgery. Participants reported to have been adequately informed regarding their right to refuse the operation which speaks to the healthcare workers understanding of patient autonomy. The results indicated that doctors were the predominant healthcare providers involved in obtaining informed consent. This is appropriate as the surgeon should ideally obtain informed consent. Overall the findings indicate that the consenting process for caesarean deliveries was not done well enough as not all the elements of the informed consent process were seemingly discussed with the participants.

Latika et al. in India (2015) and Lubansa et al. in Zambia (2010), both low-middle income countries, conducted similar studies in their respective institutions and their results were similar to our findings. The majority of their patients were adequately counselled on the name of the procedure and indication but reported poor counselling regarding the risks and complications associated with the procedure. This indicates a lack of information during the informed consent process and can have legal implications if the patient develops complications intra- or post-operatively. Latika et al. found that counselling on the right to refuse caesarean delivery was poorly delivered. Conversely, in our study and from Lubansa et al. it was noted that patients were informed of their right to refuse caesarean delivery as this forms the cornerstone of patient autonomy and should never be underestimated.[9,10]

Studies conducted in developing countries including the major economies of India and Nigeria regarding the adequacy of consent for caesarean sections showed that although patients knew the indications of their operations they were not adequately counselled regarding complications and risks. In our study patients were selected irrespective of having had an elective or emergency caesarean delivery because irrespective of indication proper counselling of the patient cannot be undermined.[10,11,12] Tripathy et al. in India (2020) and Ogunbode et al. in Nigeria (2015) recognized the importance of individual autonomy but also acknowledged that decisions were made within the family.[10,13] In their studies consent practices were also influenced by level of education and urbanization. Our study utilised individual autonomy and our consent practices were influenced by multilingualism in our institutions. While in elective procedures consent discussions could include family members, that is rarely the case in emergencies.

Ogundode et al. alluded to the fact that consent documents are written in English but a large proportion of their patients would have preferred to be counselled in their home language.[10] This can be extrapolated to the South African context where we have eleven official languages and a significant foreign population who speak their own native languages. With South Africa being a multilingual society information may possibly be lost in translation during the informed consent process. The National Health Act (2003) stipulates that healthcare workers obtaining informed consent must, where possible, counsel the patient in a language that he/she understands.[8] This is a major practical difficulty as most practitioners are able to use few languages. Language forms a major challenge to the informed consent process and this should never be disregarded as it has potential to compromise patient autonomy.

Patient comprehension is fundamental to valid informed consent. Current practices may often be limited by inadequate patient comprehension. A systematic review of 52 studies evaluating 60 interventions to improve patient comprehension in informed consent suggested that interactive informed consent interventions, particularly those that intentionally promote active patient involvement and bidirectional communication, may be superior to non-interactive interventions. Among interactive interventions, those that use test/feedback and teach-back techniques were most effective.[14]

The field of Obstetrics and Gynaecology faces special ethical considerations in the implementation of informed consent, relating to mother and fetus as patients, and because emergencies may arise rapidly and without warning in patients that the healthcare worker does not have had a rapport with.[15] Referring specifically to caesarean deliveries, it is difficult to maintain respect for patient autonomy when serious decisions must be made in the challenging situations of labour and delivery, be it an elective or emergency procedure. The key principles for informed consent to be valid are that the patient must have capacity to make an informed decision, consent must be provided voluntarily, and the patient must be properly informed of the risks and benefits of the intended procedure, which is not always adequately achieved in women who are in active labour.[2,3,4,15]

Obtaining informed consent has become the cornerstone of medical practice today yet it is not free of limitations and challenges. Broader limitations of informed consent include the fact that patients cannot give consent when they are young, very ill or mentally impaired. Informed consent cannot be used for setting up public health policies as there has to be of uniform standard whereas one needs to individualize the informed consent process.[16] Challenges more specific to the informed consent process, and illustrated in this study, include language barriers especially in a culturally diverse country like South Africa where the doctor and patient often speak different languages. The person translating

for the doctor must not be a family member as they can obscure the truth. Informed consent is designed to give patients liberty to decide on their treatment. Also, the patient's educational background plays a role in the ability of the patient to comprehend the terminology used to counsel the patient.[17]

Another factor to be considered is the patient's religious beliefs, the treatment or intervention may be contradictory to their beliefs, e.g. a Jehovah's Witness patient will decline blood transfusion due to religious reasons.[17,18] Other patient perceptions and possible misinformation must be considered when obtaining informed consent because such misconceptions may lead to misunderstandings and litigation.[17] Furthermore, some populations in South Africa still live in paternalistic communities where the husband, family or community will dictate the final decision that the patient eventually makes.[16,17]

Speculating on possible solutions to the identified problems, educational brochures should be considered. Educational brochures are an important tool for communicating information and can aid the informed consent process. Bester et al. conducted a study on the effectiveness of brochures as teaching aids for patients and they found them to be very effective in communicating information to patients.[19] Our informed consent process for caesarean deliveries could be improved by the use of standardized information and templates included in the maternity case record, that incorporates the four elements essential for informed consent according to RCOG guidelines, namely, name of proposed procedure, intended benefits, significant, unavoidable and frequently occurring risks, and extra procedures which may become necessary during the procedure such as blood transfusions.[20] This may facilitate counselling of patients regarding the possibility of caesarean deliveries already initiated during antenatal visits when the environment is relaxed and avoids the stress associated with labour pains and a busy labour ward. This emphasizes the importance of ante-natal counselling of our patients in terms of their birth plans and the need for a possible cesarean delivery.[15] Audio-visual material containing pertinent information can similarly be used in the obstetric units waiting areas.[19]

The strengths of this study included the large sample size that was distributed across three hospitals and the data collected by a single investigator. Limitations of the study included that the questionnaire was only available in English, and the lack of documentation with regards to what was actually discussed with the patient during the informed consent process, as this study used patient recall as reporting tool.

Caesarean delivery is a common procedure in obstetrics and with the rise in litigation cases makes it an ideal subject in the study of informed consent. Litigation in obstetrics may be prevented through ensuring adequate communication with and consent of patients during treatment.[21] Informed consent provides evidence that a clear, concise and structured explanation was given prior to a procedure.[18] Obstetric patients are a unique patient population that pose multiple ethical and practical challenges to the healthcare provider.[15,18] The informed consent process epitomizes sharing of information and a partnership between physician and patient. The fact that the physician has made a proper disclosure to the patient and the patient understands the limitations, the less likely the patient will abandon the confidence and trust had in the physician and initiate legal proceedings[22] especially with the current growing rate of litigation due to an inadequate informed consent process.

Conclusion

Adequate communication is essential to all aspects of medicine. This study reports on the patients' recall of inadequacy of the informed consent process prior to caesarean deliveries, especially regarding risks and complications. Thus, there is a need for improvement in the informed consent process. The introduction of a standardized informed consent document including all pertinent information in simple language should be considered. This will assist healthcare workers to start the conversation about the possibility of a caesarean delivery already in the antenatal period.

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