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

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اجراءات الإذن الطبي (الموافقة المستنيرة) قبل الجراحة القيصرية: دراسة لآراء المريضات حول كفاية إجراءات الموافقة

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Abstract:
Background: Surgical informed consent is defined as a process of communication between a patient undergoing surgery and the physician performing the procedure, resulting in the patient's agreement to undergo surgical procedure. This study aimed to assess patients' perception towards surgical informed consent in Obstetrics, Gynecology and Surgical Procedures at Benghazi Medical Center. Methods: Across-sectional study of all adult surgical patients who signed informed consent and underwent surgery from June to August 2023. **Results:** Out of a total of 285 questionnaires distributed to eligible patients, 178 usable questionnaires were returned fully completed. Approximately half of the respondents (50.6%) were between 31 and 40 years of age, while more than one third (36%) were younger than 30 years. Of the 178 women surveyed, 47.2% underwent emergency surgeries while 52.8% had elective surgeries. Only 10 (5.6%) of patients actually signed the consent forms themselves. In the remaining cases, consent was signed either by the family members. The majority of respondents (88.8%, n=158) thought that signing the consent form was a legal requirement prior to undergoing surgery. The majority of patients (82%) indicated full agreement with the form's contents. Over three quarters of patients (79.3%) reported signing the form primarily to proceed with their surgery and 76.4% considered the act of signing to be an important. Conclusion: This study highlights the insufficient understanding of informed consent among gynecological patients therefore practical recommendations involve enhancing preoperative information, verifying voluntariness, and including the patient in the signing decision..

Keywords: Informed Consent, Surgery, Caesarean Section, Patients' Perspective, Consent Process.

الملخص
الخلفية: تُعرَّف الموافقة الطبية للعمليات الجراحية بأنها عملية اتصال بين المريض المقبل على الجراحة والطبيب المعالج، تنتهي بقبول المريضة إجراء التداخل الجراحي. هدفت هذه الدراسة إلى تقييم تصورات المريضات تجاه الموافقة قبل القيام باي اجراء جراحي في قسم النساء والتوليد بمركز بنغازي الطبي. المنهجية: أُجريت دراسة مقطعية شملت جميع المريضات البالغات اللواتي وقّعن على نماذج الموافقة المستنيرة وخضعن لعمليات جراحية خلال الفترة من يونيو إلى أغسطس 2023. النتائج: من أصل 285 استبانة وُزعت على المريضات مستوفيات شروط الخضوع للدراسة، تم استرجاع 178 استبانة صالحة ومكتملة لتحليل وأظهرت البيانات أن حوالي نصف المستجيبات (50.6%) كن في الفئة العمرية 31-40 سنة، في

حين أن أكثر من الثلث (36%) كن دون سن الثلاثين ومن إجمالي العينة، خضعت 47.2% لجراحات إسعافيه طارئة، بينما خضعت 52.8% لعمليات جراحية مجدولة (اختيارية).. وتبين أن 10 مريضات فقط (5.6%) قمن بالتوقيع على النماذج بأنفسهن، بينما تم التوقيع في بقية الحالات بواسطة ذويهن., ورأت الغالبية العظمى (88.8%، العدد=158) أن التوقيع على النموذج التزام قانوني يسبق الجراحة. كما أعربت غالبية المريضات (82%) عن قبولهن الكامل لمضمون النموذج، وأفاد أكثر من ثلاثة أرباعهن (79.3%) بأن الدافع الرئيسي للتوقيع كان لاستكمال إجراءات الجراحة، بينما عدّت 76.4% منهن التوقيع أمراً ذا أهمية. الاستنتاج: خلصت الدراسة إلى وجود قصور في إدراك مريضات النساء لمفهوم الموافقة المستنيرة، مما يستدعي تحسين التثقيف قبل الجراحة، والتأكد من مبدأ الطوعية، وضمان مشاركة المريضة شخصياً في التوقيع على الإقرار.

الكلمات المفتاحية: الموافقة المستنيرة، الجراحة، الولادة القيصرية، وجهة نظر المريضات، عملية الموافقة.

Introduction

Surgical informed consent (SIC) is defined as a process of communication between a patient undergoing surgery and the physician performing the procedure, resulting in the patient's agreement to undergo a specific medical or surgical procedure. [1] It is broadly recognized as a voluntary, unforced decision made by an adequately competent, autonomous individual based on sufficient information and consideration to accept rather than reject a proposed course of action .[1,2]

The main purpose of informed consent is to protect patients against coercion, deception, abuse, and exploitation. [3] Moreover, the SIC is not only to "protect patients, respect their rights, and improve patient safety," but also aims to transform the relationship between medical professionals and patients into a genuine partnership where both parties have the opportunity to make decisions and share responsibility for the outcomes [4,5]. Informed consent in surgery, from both ethical and legal perspectives, depends on providing patients with sufficient information .[6,7]

In addition, Obstetric surgeries, including cesarean section, surgical procedures for obstetric hemorrhage, and gynecological surgeries, have specific characteristics that are different from general surgeries. [6] These procedures are often performed on patients who may be emotionally overwhelmed or temporarily unable to participate in the decision-making process regarding the procedure. For that reason, the Informed Consent procedure should reflect this, particularly by including sufficient information about the procedure's benefits, risks, and alternatives. [6] Numerous studies in developing countries have pinpointed key factors shaping patients' views toward surgical informed consent, including cultural beliefs, literacy, socioeconomic status, religious beliefs, and language barriers. Additional influences involve lengthy consent procedures, limited patient–physician interaction, inconsistent language on consent forms, and mistrust in the health-care system. [4,6,7,8,9] The findings from study in sub-Saharan Africa indicated that while awareness of informed consent is high among obstetric patients, there is a significant gap between awareness and full comprehension and application of the consent process .[6]

The findings of another study to assess patients' comprehension of informed consent show that understanding is frequently limited, and in some cases, obtaining consent is perceived as merely obtaining a signature. Among participants who gave written consent, several reported not reading or understanding the document. [10] Additionally, research in several countries indicates varying perceptions of informed consent. In Saudi Arabia, 23.7% of participants had a poor perception of informed consent; in Rwanda, 23% reported a poor perception, while 50% exhibited a moderate level of perception toward surgical informed consent. [11]

Despite previous studies having reported limited knowledge and various misconceptions regarding the SIC process in surgical patients, little is known or studied about it in several developing countries, including Libya. Therefore, the purpose of this study is to assess patients' perception towards surgical informed consent in Obstetrics, Gynecology, and Surgical Procedures at Benghazi Teaching Hospital.

Material and methods

Study design, period and setting:

A quantitative, cross-sectional study was conducted at Benghazi Medical Center (BMC), a major public referral and teaching hospital situated in Benghazi, Libya. The center has a bed capacity of 1,200 beds, serving the population from the northeastern part of the country. It was conducted within a period of 3 months from June till August 2023.

Study population:
The study population consisted of surgical patients attending services in the department of obstetrics and gynecology in BMC during the data collection period.

Eligibility criteria:
All adult patients admitted to the obstetric and gynecological surgical wards after undergoing surgery or invasive procedures were prospectively enrolled. Exclusion criteria were repeated surgery during the same admission, critical illness and not fully conscious.

Sample size:
1080 patients underwent obstetric and gynecological-related surgery within the past three months before data collection period to assist prediction of the sample size. Sample size determination and technique was calculated using Krejcie and Morgan tables. The estimated sample size for participants was for the recruitment of 285 participants and 178 questionnaires were returned fully completed. Using a convenience sampling technique recruited patients who met the predefined inclusion criteria and were in health status allowed to fill the questionnaire.

Study tool:
The questionnaire consisted of two sections. The first section collected general information on participants' (age, educational status, occupation and marital status). Second section questions "Informed Consent", questions regarding ethical issues of the study were listed. Data was collected using a structured questionnaire adapted from a previously validated instrument developed by Akkad et al. Study [11]

It consisted of 2 parts namely: Part (A) of the instrument elicited general data which captured the personal descriptive data of participations like age, marital status, education and employment.

Part (B) consisted of 19 items focused on various dimensions of informed consent. 6 statements assessed participant's understanding of the legal implications associated with signing the consent form, 5 statements regarding patient's views on the scope of the consent form. These items were answered using the response format ("Yes," "No," or "Do not know").

The remaining 8 statements employed a five-point Likert scale to evaluate participants' agreement with statements concerning the value and function of the consent form. Each question was varied in response from disagree, disagree, neutral, agree and strongly agree. The original questionnaire was designed in English and subsequently translated into Arabic, the local language. To ensure linguistic and conceptual consistency, a back-translation into English was performed. Prior to the data collection, pilot study was conducted on ten gynecological patients to ensure reliability and feasibility of questionnaire. The reliability of the tool was confirmed using Cronbach's Alpha, which was .791.

Ethical consideration:
Prior to administering the questionnaire, approval for the study was attained from the hospital administration, and from the unit chiefs of obstetrics and gynecology ward. Informed consent was obtained from the patients before participating in the study and after explanation of the study objectives. Confidentiality was kept throughout the study.

Data analysis: After data collection, all completed questionnaires were revised for completeness and logical consistency. Data were analyzed using IBM SPSS Statistics (version 21) software. Data were presented as frequencies and percentages in a tabulated format.

Results and discussion:-

Out of a total of two hundred eighty-five questionnaires distributed to eligible patients, One hundred seventy-eight usable questionnaires were returned fully completed and usable for analysis.

The information data pertain to female inpatients admitted to the department of obstetrics and gynecology. Regarding age distribution, approximately half of the respondents (50.6%) were between 31 and 40 years of age, while more than one third (36%) were younger than 30 years. The vast majority of participants were married (92.7%, n=165) and over half (59%, n=105) identified as housewives. Educational level varied which (7.3%) were illiterate, (22.1%) had completed at least secondary education, (25.8%) held a diploma and (34.8%, n=62) held a bachelors' degree.

Of the 178 women surveyed, 47.2% underwent emergency surgeries while 52.8% had elective surgeries. Informed consent was predominantly obtained by physicians (68.6%, n=121), followed by nurses (12.9%, n=23) whereas, (18.5%, n=33) of them were unaware of the professional designation of the person who obtained their consent.

Only 10 (5.6%) of patients actually signed the consent forms themselves. In the remaining cases, consent was signed either by the family members including husband (79.2%), father (3.4%), brother (4.5%) or others (7.3%).

Consent was taken the day before the surgery for approximately half of the inpatients (47.7%, n=85), while the remaining received it on the day of the surgery (37.6%), a few minutes before the surgery (12.9%), or postoperatively (1.7%).

Table (1) patients' perceptions regarding the legal implications of signing the informed consent form

Statement	Yes	No	Do not know
Signing the consent form is a legal requirement	158 (88.8)	3 (1.7)	17 (9.6)
Signing the consent form removes your right to compensation	92 (51.7)	61 (34.3)	25 (14)
You have the right to change your mind after signing the consent form	103 (57.9)	48 (27)	27 (15.3)
If you are not able to sign the consent form, the operation cannot take place, even if this means you could die	101 (56.7)	45 (25.3)	32 (18)
If you refuse to sign the consent form, the operation cannot take place, even if this means you could die	101 (56.7)	40 (22.5)	35 (19.7)
If you can't sign the consent form, your next of kin can sign on your behalf	126 (70.8)	17 (9.6)	35 (19.7)

The majority of respondents (88.8%, n=158) thought that signing the consent form was a legal requirement prior to undergoing surgery. Approximately half of them (51.7%, n=92) believed that signing the consent form would remove their right to seek compensation. Meanwhile, (27%, n=48) assumed they could not change their decision after signing, while (57.9%, n=103) believed they had the right to withdraw consent.

A similar proportion of patients under study (56.7% for each) expressed concern that refusal or inability to sign the consent form might result in being denied life-saving treatment. Furthermore, most respondents (70.8%, n=126) were aware that a legally authorized next of kin could sign the consent form on their behalf in cases of incapacity. Additional details were provided in table 1.

Table (2) Patients' views on the scope of the consent form.

By signing the consent form I thought I agreed ...	Yes	No	Do not know
to exactly what was on the form	146 (82)	23 (12.9)	9 (5.1)
that the physician may do something different from what was on the form if he/she thinks it is best for me	126 (70.8)	36 (20.2)	16 (9)
that I understood what was going to happen	129 (72.5)	28 (15.7)	21 (11.8)
that I understood that there are risks involved in having the operation	122 (68.5)	34 (19.1)	22 (12.4)
not really sure what I was agreeing to	85 (47.8)	69 (38.8)	24 (13.5)

The majority of patients (82%) indicated full agreement with the form's contents. Most respondents (72.5%) affirmed that their signature reflected an understanding procedure and risks involved in having surgery (68.5%). Additionally, 70.8% believed that the physician would act in the patient's best interest—even if the course of action deviated from what was stated in the form. (Table 2)

Table (3) Patients' agreement with statements on the value and function of the consent form.

Statement	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
The consent form was important to me	13 (7.3)	4 (2.2)	25 (14)	90 (50.6)	46 (25.8)
The consent form made it clear what was going to happen	15 (8.4)	20 (11.2)	41 (23)	91 (51.1)	11 (6.2)

The consent form made me aware of the risks of the operation	16 (9)	21 (11.8)	41 (23)	82 (46.1)	18 (10.1)
The consent form was just another piece of paper and a waste of time	64 (36)	62 (34.8)	11 (6.2)	35 (19.7)	6 (3.4)
The consent form prevents mix-ups during the operation	18 (10.1)	24 (13.5)	58 (32.6)	69 (38.8)	9 (5.1)
I just signed the consent form so I could have the operation	13 (7.3)	5 (2.8)	19 (10.7)	111 (62.4)	30 (16.9)
Signing the consent form was mainly to protect the hospital	10 (5.6)	7 (3.9)	47 (26.4)	87 (48.9)	27 (15.2)
The consent form gave the doctors control over what happened	19 (10.7)	11 (6.2)	37 (20.8)	90 (50.6)	21 (11.8)

Over three quarters of patients (79.3%) reported signing the form primarily to proceed with their surgery and 76.4% considered the act of signing to be important. More than half of the participants perceived the main function of the form as protecting the hospital (64.1%), followed by the belief that it granted physicians authority over what happened (62.4%).

Furthermore, 57.3% of patients felt the form clarified what would happen during the procedure, followed by 56.2% believed that it helped them understand the potential risks involved. While 43.9% viewed the form as a safeguard against mix ups during the operation, and only 23.1% saw the consent form as just another piece of paper and a waste of time.

Discussion: -

Informed consent is a basic ethical and legal requirement for surgical procedures. It ensures that patients can make their own decisions about treatments based on clear information about risks, benefits, and alternatives. This study aimed to examine gynaecological patients' understanding of the legal implications and the status and function of informed consent. In this study, the proportion of elective surgeries (47.2%) aligned with findings from a previous study in Nigeria. [9]

Regarding the timing of informed consent, less than half of the participants signed the form the day preceding surgery, allowing them extra time to ask questions. The rest signed the consent on the day of the surgery, which may not have enough time for clarification. This differs from a study in Ethiopia, where 74.5% of surgical cases were emergency surgeries and most patients signed consent forms on the day of surgery. [1] To ensure the validity of informed consent, it should not be obtained under pressure. Singing it on the day of surgery can put patients in stressful situation and affect their decision-making ability. [13, 14] Spending more time during the surgical consent process increased patient satisfaction and helped reduce anxiety by clarifying procedures and risks .[1]

The current study found that only a small number of gynecology patients signed the consent from themselves. This result was similar to findings by Arshad M. et al. (2021) in Pakistan, where self-signature rates were also low. [15] However, this contrasted with studies from Nigeria and two studies in Ethiopia, where most patients signed their own informed consent forms. [3,9,15] Another study indicated that the patient's husband often signed the consent, which was consistent with the current findings. [16] Patient relatives particularly husband played a significant role in the deciding who signed the regarding the informed consent. More than half of participants' revealed that the surgeon requested them to sign the informed consent form. This finding was in line with a study conducted in Cameroon, where 65.3% of gynecologists obtained the informed consent. [17] Medical professionals play a critical role in reducing patient anxiety by providing clear information about the reasons for surgery and its potential risks. [18]

The findings of this study reflected that many patients' misunderstood the nature and implications of informed consent, as a large majority of patients considered that signing the consent form was a legal requirement, and nearly half thought it signing the form removed their right to compensation. This belief showed a lack of understanding of legal protections and patient rights. Comparable findings with a study conducted by Mbonera and Chironda, (2018), where 31.3% of participants felt signing the consent form was a legal requirement and 28.6% thought it limited their right to compensation. [19]

Most participants indicated that their relatives or next of kin could sign the consent form for them, aligning with findings from a study in Kuwait. [20] This might reflect cultural norms of many societies where family members involved in medical decisions making to support patient. [21]

Additionally, more than half of participants felt they retained the right to withdraw consent after signing. In a study conducted in Rwanda, 37.4% of participants recognized their right to change their decision after singing. [19] Over half of participants asserted that the surgery could not proceed if they were unable or refused to sign the form, even in life-threatening circumstances .

Most patients agreed they clearly understood the consent form content, including the planned procedure and its associated risks. Compared to another study in 2023 by Verma and Rajaratnam, which reported that most patients adequate understood the procedure's name, nature, and indication, although a considerable proportion reported not being informed about the surgical risks. [22] Most patient acknowledged that the physician could deviate from the specified procedure if deemed it was the best of patients.

The majority of patients viewed the consent form as important, similar to finding by Akkad et al and higher than that reported by Mbonera and Chironda, where 46.9% of patients reported the consent form as necessary. [19, 23] Almost half of the patients were aware of the planned surgical procedure and operation risks, reflecting a lower proportion than in Akkad's study. [23] This study found that most patients perceived informed consent as more than a mere piece of paper, recognizing its importance in clinical care. More than half perceived that signing the consent form mainly protected the hospital from litigation and granted physicians greater control over medical decision-making. The present study had several limitations. Firstly, it was conducted in a single public hospital, and it would be difficult to generalize the findings to other healthcare institutions in Libya. Additionally, the sample size was relatively small and focused only on women who underwent obstetrics and gynecological surgeries, which might not be representative to the overall surgical environment in hospital. Future studies should include different surgical departments across both public and private hospitals.

Conclusion:-

This study highlights the complex and insufficient understanding of informed consent among gynecological patients. While it is clear that many participants recognized the importance of informed consent, a considerable number viewed it as merely a legal requirement or a physician/hospital prerogative, rather than a fundamental patient right and protective measure. Timing emerged as a critical factor: signing on the day of surgery limits opportunities for clarification and may compromise truly informed decision-making, compared with settings that allow more time before procedures. The prevalence of day-of-surgery signing underscores the need for clearer communication and additional time to protect patient autonomy and decrease anxiety. Practical recommendations involve enhancing preoperative information, verifying voluntariness, and including the patient in the signing decision. Future research should confirm these findings in multicenter, multidisciplinary surgical departments to provide balanced, generalizable evidence for policy-making.

Compliance with ethical standards

Disclosure of conflict of interest

The authors declare that they have no conflict of interest.

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