

How Does the Patient React After Reading the Informed Consent Form of a Gynecological Surgery? A Qualitative Study

Como o paciente reage depois de ler o termo de consentimento livre e esclarecido de uma cirurgia ginecológica? Um estudo qualitativo

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Abstract

Objective To analyze the reaction of women after reading the Informed Consent Form (ICF) before undergoing elective gynecological/urogynecological surgeries.

Methods A qualitative study with 53 women was conducted between September 2014 and May 2015. The analysis of the content was conducted after a scripted interview was made in a reserved room and transcribed verbatim. We read the ICF once more in front of the patient, and then she was interviewed according to a script of questions about emotions and reactions that occurred about the procedure and her expectations about the intra- and postoperative period.

Results The women had a mean age of 52 years, they were multiparous, and most had only a few years of schooling (54.7%). The majority (60.4%) of them had undergone urogynecological surgeries. Hysterectomy and colpoperineoplasty were the most frequent procedures. Ten women had not undergone any previous abdominal surgery. Fear (34.6%) was the feeling that emerged most frequently from the interviews after reading the ICF, followed by indifference (30.8%) and resignation (13.5%). Nine women considered their reaction unexpected after reading the ICF. Three patients did not consider the information contained in the ICF to be sufficient, and 3 had questions about the surgery after reading the document.

Conclusion Reading the ICF generates fear in most women; however, they believe this feeling did not interfere in their decision-making process.

Keywords

- qualitative study
- informed consent
- decision-making process
- elective surgical procedures

Resumo

Objetivo Analisar a reação das mulheres após lerem o Termo de Consentimento Livre e Esclarecido (TCLE) antes de se submeterem a cirurgias ginecológicas/uroginecológicas eletivas.

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Palavras-chave

- estudo qualitativo
- consentimento livre e esclarecido
- tomada de decisões
- procedimentos cirúrgicos eletivos

Métodos Um estudo qualitativo com 53 mulheres foi realizado entre setembro de 2014 e maio de 2015. A análise do conteúdo foi feita depois de uma entrevista que seguia um roteiro, que foi realizada em uma sala reservada e transcrita de forma fidedigna. Nós lemos de novo o TCLE na frente da paciente, e depois ela era entrevistada de acordo com um roteiro de questões sobre emoções e reações que ocorreram sobre o procedimento e suas expectativas sobre o período intra e pós-operatório.

Resultados As mulheres tinham uma média de 52 anos, eram multíparas, e com poucos anos de educação (54,7%). A maioria (60,4%) já havia realizado cirurgias uroginecológicas. A histerectomia e a colpoperineoplastia foram as cirurgias mais frequentes. Dez mulheres não tinham sido submetidas a nenhum procedimento. O medo (34,6%) foi o sentimento que mais emergiu das entrevistas depois da leitura do TCLE, seguido da indiferença (30,8%) e da resignação (13,5%). Nove mulheres consideraram suas reações inesperadas depois da leitura do TCLE. Três pacientes não consideraram a informação do TCLE suficiente, e outras 3 tiveram dúvidas sobre a cirurgia depois de lerem o documento.

Conclusão A leitura do TCLE desperta o medo na maioria das mulheres; contudo, elas acreditam que este sentimento não interferiu na tomada de decisão relativa ao tratamento.

Introduction

The informed consent form (ICF) is a document that should be explained and given to the patients prior to surgery so that they can decide to undergo the procedure or choose another option. Unfortunately, not all surgeons discuss what they document on consent forms; in general surgery, this represents less than half of the cases.¹ Moreover, only 40% of the patients understand the information that is provided,² and there are reports that a small percentage of patients were instructed to sign the ICF without any discussion.³ An interesting point to be highlighted is that it is already known that the comprehension of patients in trials can be good if the researchers explain the consent form in a simple and clear language, because the patients' comprehension does not differ according to their level of schooling.⁴

An English study in 2004 showed the reaction of patients that underwent elective or urgency procedures, and the researchers concluded that the ICF has a single standardized format, and that the patients' opinion regarding the surgery influenced how they viewed the act of signing the ICF.⁵ An Indian study also showed that patients were unfamiliar with the terminology employed in the ICF, and that the information provided in it was inadequate.⁶ Personal motivations are important regarding the decision-making process to undergo a gynecological surgery;⁷ therefore, they can influence in the patients' postoperative satisfaction and overall quality of life.⁸ However, little is known about the ICF in this kind of procedure and how this fulfils the objectives of signaling partnership. Another topic of concern is the ICF prior to female reconstructive pelvic surgery. Recently, there have been issues surrounding mesh use for vaginal surgery,⁹ and these issues should be addressed during the decision-making process. Thus, we aimed to study, from a qualitative point of

view, the patient's reaction after reading the ICF before undergoing an elective gynecological and/or urogynecological procedure in a tertiary hospital.

Methods

This was a prospective study performed between September 2014 and May 2015 at a gynecological surgery division of a tertiary hospital. The study project was approved by the Institutional Review Board, and the study followed all the criteria proposed by the consolidated criteria for reporting qualitative research (COREQ) guidelines on qualitative studies.¹⁰ The medical team was composed of two professors, eight attending physicians, one nurse and two nursing assistants. The patients were invited in the outpatient clinic and, after accepting to participate in the research and reading/signing the ICF, they were interviewed on another day in the same area in a private room. On that day, the patients received the ICF to read, and all questions regarding the document were explained by a medical resident, usually without the presence of a chief surgeon in the room (even though he/she were available in the office). A second consultation was scheduled to assess the patient's decision to undergo the procedure or not, and during that consultation, our interviews were performed.

Two physicians (L.G.O.B – male, and A.C.A – female) performed the interview; the former (MD, PhD) was the research coordinator, and acted as an observer of the patients' reaction during the interview to perceive their reactions throughout it. The latter (MD) was the one that actually interviewed the patients. The research coordinator had previous experience with qualitative research, and was able to conduct the study. The research team had no specific reasons to participate in the medical team, so no conflicts of

interest were attributed to this part of the study. No other participants were present in the room.

A total of 53 women were enrolled, and all of them agreed to participate. We did not perform a sample size calculation or a power calculation because we decided to use saturation as a guiding principle to collect data. As the data collection moved on, we realized that the prevailing themes were not different from the previous ones; therefore, we decided to stop enrolling women on patient number 53.¹¹ Before starting the interview, we gave the patient the same ICF as the one handed in the first consultation so that she could take a moment and read it once more. After this, the interviewers started recording the conversation in a cell phone or in a computer program (Audacity, version 1.3.12, Free Software Foundation, Boston, MA, US), and proceeded to follow a pilot-tested script (►Table 1) with 5 patients that went to consultations in the outpatient clinic. This script should have the following characteristics: it should be non-accurate, obtained through open-ended questions; it should be specific in a way that could exhibit the specific elements that determine the impact or meaning of an event; and it should be personal, with depth content demonstrated by the interviewees.¹² The questions were not copied from other studies, and they were discussed with the whole group of researchers before they were included. In the pilot phase, none of the patients suggested the inclusion or exclusion of any questions. All of the impressions of the interviewer were also part of the analysis (gestures, looks, pauses), and they were pointed out by the observer. After the participation, with the signature of the ICF and the recorded interview, the interviewer immediately transcribed the recorded data, along with the associated impressions, in a spreadsheet. Field notes were made during the interviews, which lasted ~ 90 minutes. No repeat interviews were performed. We did not return the transcripts to the participants for comments.

Content analysis was the methodological orientation;¹³ it identifies prevailing themes and subtopics in the discussions and different opinions about them, enabling the researcher to include amounts of information in groups by identifying their similar properties. The main objective is to provide a meaningful comprehension of the scenario. The first step (pre-analysis) was to choose the material to be used for analysis

and evaluate whether the document collected corresponded to our goal. As transcripts were being read, brackets were inserted when necessary to highlight the ideas that came to mind about what we had heard. The thorough reading of the texts would empower the researcher by the content, making him more able to organize ideas ("free-floating reading"). The second stage was the exploration of the material, in which several subcategories extracted from words, sentences, paragraphs were created. The third and final stage of the analysis process was the treatment of the results obtained and their interpretation. We have also used another software (ATLAS.ti, version 6.2, ATLAS.ti Scientific Software Development GmbH, Berlin, Germany) to code the data, and one coder modified the data. Feedback could not be provided to the patients after the end of the study because most of them had left the service before we analyzed the data.

Results

►Table 2 illustrates the data collected from the questionnaire form. The sample of women had a mean age of 52 years, they were multiparous (median = 3 pregnancies), and most had < 4 years of schooling (54.71%). Most women presented comorbidities (88.68%), and 60% of the patients underwent urogynecological surgeries. Hysterectomy and colpoperineoplasty were the most frequent procedures. Ten women had not undergone any previous abdominal surgery. The discussion categories that were built from the data were: the disease and its effects on every aspect of the patient's life; feelings (fear and indifference) that arose while reading the ICF; and coping with these feelings and moving on to the decision-making process.

The Disease and its Effects on Social, Personal and Professional Situations

Most patients were referred from the general practitioner with chronic complaints (with a mean duration of 28.16 months), and were looking for a solution for their disease. The long period they had spent waiting for a resolution between the primary, secondary, and tertiary levels of public health services was itself a reason for them to wish to be operated "as soon as possible." Most of the women reported

Table 1 Script questions for the patient interview

⇒ When did you first found out you had this disease?
⇒ How does this disease impair your life in general? What about your private life? What about your social activities? What about your professional activity?
⇒ When you read this document that we call Informed Consent Form, or when the physician read it to you, and you realized the possible risks concerning your surgery, what did you feel? What have you done regarding this feeling?
⇒ Why did you act like that? If you did something (or reacted) in a way that you had never thought you would do (or react), why do you think you have acted like that?
⇒ What do you expect from the surgery?
⇒ How do you rate the amount of information the physician has provided you? Why did you rate it like this? If there was anything missing, what was it?
⇒ What do you think it is going to happen after surgery?
⇒ What do you feel about deciding (or not) to undergo the surgery?

Table 2 General characteristics of the interviewed patients

Variables	Mean $\pm$ SD / n (%)
Age	52.70 $\pm$ 13.85
Number of pregnancies	3.13 $\pm$ 2.43
Number of births	2.81 $\pm$ 2.07
Schooling (years)	
<4	29 (54.72)
5–8	22 (41.51)
> 9	2 (3.77)
Marital status	
In a steady relationship	8 (15.09)
No partner	45 (84.91)
Comorbidities	
Yes	47 (88.68)
No	6 (11.32)
Type of surgery	
Gynecological	21 (39.62)
Urogynecological	32 (60.38)
Proposed surgeries*	
Colpoperineoplasty	12 (22.64)
Abdominal hysterectomy	9 (16.98)
Vaginal hysterectomy	3 (5.66)
Cystoscopy	8 (15.09)
Hysteroscopy	3 (5.66)
Myomectomy	3 (5.66)
Sling	7 (13.21)
Other abdominal procedure	8 (15.09)
Other vaginal procedure	4 (7.55)
Anterior abdominopelvic surgery	
Yes	10 (18.87)
No	43 (81.13)

Abbreviation: SD, standard deviation.

Note: *Some patients underwent more than one surgery

that the disease disrupted their lives as a whole; however, the percentage of negative points was lower when we stratified their points of view regarding the social, personal and/or professional spheres. During the analysis of the content of the interviews, the overall picture regarding their lives is a negative one. Patients with pelvic pain and abnormal bleeding are those who appeared to have greater impairment in their quality of life (–Table 3).

Excerpt from Patient with Urinary Incontinence

It disturbs like that, the pee, it bothers you to get wet, or to have to change every time you get wet, or the absorbent (sic) that turned into a diaper because of the volume of urine I lose [...]. we are ashamed, see? There's that ball down there, inside, when I'm going to pee sometimes I cannot do everything, I also have a problem to evacuate, but only sometimes. And then I started peeing while I was having a relationship (sic) with my husband. I'll tell you that I have (sic) a bit of shame, but then I started to think that I'm not doing it on purpose: it's a problem and I'm going to the doctor to treat it, running (sic) to solve it. (Patient 30, 59 years old)

Excerpt from Patient with Pelvic Pain

Oh, imagine a pain that never improves? Everything you use as a medicine is no good. Well, the doctor does not have a solution [...], we end up getting boring (sic) in the day-to-day, you know? I already had this problem of endometriosis and I had a surgery for that 4 years ago or so [...] I also have these veins that people have told me that they are sore and that there is no way to solve them. So, I underwent a procedure for these varicose veins, I think that was why they ended up disappearing, I do not remember the name [...], when I came down (sic), because now I'm not menstruating anymore, right? But when it came down (sic) it got worse and it throbbed the vagina too sic) [...], it gave some bad stitches [...]. I took those normal pain killers, sometimes I took anti-inflammatories, and it improved a little bit, but

Table 3 Impact of the disease and reaction after reading the ICF before surgery

Impact of the disease	Yes (n%)	No (n%)
Disrupts the overall life	51 (96.2%)	2 (3.8%)
Disrupts the personal life	27 (50.9%)	26 (49.1%)
Disrupts the social life	21 (42%)	26 (58%)
Disrupts the professional life	10 (22.2%)	35 (77.8%)
Reaction after reading the informed consent form	n (%)	
Fear	18/53 (33.9%)	
Indifference	17/53 (32.1%)	
Satisfaction	8/53 (15.1%)	
Resignation	7/53 (13.3%)	
Anxiety	2/53 (3.8%)	
Surprise	1/53 (1.8%)	

when the effect went away, it came back all over again. I do not want to live like this, you know ... (Patient 31, 29 years old)

Excerpt from Patient with Labia Minora Hypertrophy

It's bad to wear clothes, because it rubs and it hurts. There are some tight clothes that if it likes that a larger volume appears. And it is also bad to have sexual relations, because it has to rearrange my vulva, otherwise it also hurts. And I'm ashamed, because it's ugly. I'm ashamed to be naked in front of the people, my boyfriend. That's it. (Patient 35, 21 years old)

Fear and Indifference - The Prevailing Feelings When Reading the ICF

The feeling that most emerged during the reading of the ICF was the fear of the risks of the procedure. ► **Table 3** shows the distribution of the feelings that emerged during the interview with these women. Some patients cried ($n = 9$), interrupting the interview, when they recalled the moment when they became aware of all the risks resulting from the surgery. We noticed that the impact of being aware of the complexity of the surgery was associated with the degree of fear or surprise when they were reading of the ICF, as well as with the presence of signs and symptoms related to the proposed surgery.

When she started to say that it was a simple surgery, it was fine, but then she said, every surgery has risks, and such, and she was saying what was written in that paper, gave me a thrill (sic) to get up and leave [...]. I couldn't. I felt really scared! (Patient 1, 49 years old)

Ah, if I felt cold in my belly? I do not think I knew that surgery had such a risk. If you do so much surgery these days, you realize that it is the best way to treat any disease. But then, when it happens to you, it's another stuff. There's a lot going on in our heads. I was afraid to die, it must be the fear that most of women do, right? Then I thought I may not die, but some of those complications could happen and I would have to live with some sequels (sic) afterwards. Then I thought how it would be like if I died, you know? I thought of my family, I thought about my daughters [...], then I thought about the scar, if it was getting too ugly ... I thought I'm going to have no uterus [...]. I have to admit, it gave me a bad feeling [...], but as the doctor explained to me, those thoughts would be probably disappearing. (Patient 5, 50 years old)

Indifference and resignation were feelings that arose as well. In the case of indifference, we attempted to assess whether this feeling was not due to a difficulty to admit a hidden fear of surgery or anesthesia, but the women said that they simply did not care. Many said that this was because they had had previous surgeries, and they knew the routine of the explanation of the procedure; others said they felt

indifferent because they had been waiting for that moment for such a long time that they had ceased to worry about every possible (good and bad) surgical outcome. As for resignation, many women said they felt fear, but that the need for resolution gave room for resilience to settle in, and resignation became the final overall feeling.

Knowing about everything after reading that paper... well... I didn't change my mind, in fact. I continued happy to do. But it put me more into the real world. I spoke about this with my husband after the consultation. (Patient 6, 26 years old)

No, I did not change. I'm not afraid of surgery, I've done enough surgeries and it's always been okay. And if I'm at risk of something, I'd rather not to know. I prefer to think that if I go there, I will do the surgery and I'm already home for a few days. I believe in God and nothing wrong will happen to me (Patient 7, 58 years old)

I've been through two surgeries like this, the risks the doctor read are the same, I think I've used to it, and I did not find it very different this time. (Patient 21, 38 years old)

Dealing with the Decision to Undergo Surgery

Only five women had questions and/or concerns about the surgery. Among 51 women, 48 considered the information contained on the ICF adequate and sufficient. Although fear was the preponderant feeling among these women, it seems that this fear did not impact the decision-making process of undergoing the surgery. The speeches were filled with sentences such as: "despite our fears, this is what is best for us." Most women seemed to consider the ICF enlightening, and they had no doubts, but that did not hinder them from expressing their feelings of fear. Nevertheless, 35 women out of 45 reported that the decision to undergo the surgery was easy. In our analysis of the patients' reaction about the physician, we found no cases in which the patient expressed they felt coerced or compelled by the physician in any manner; however, three women reported that the doctor only read the ICF and did not give them the time (which would have been necessary) they thought it would be sufficient for them to reflect and decide what they felt would be the best for them. Some patients complained about not receiving information regarding the anesthesia that they would be willing to receive.

When you feel it bothers you, it's not cool; you just want the doctor to decide, no matter what he wants to do. In my case, I didn't have any other option, so you do not even have to decide. If you have surgery as the only option, you must think about whether you want to resolve it or not, and if you want to solve it, then it's the surgery. (Patient 27, 68 years old)

Interviewer: "What do you think of the information the doctor has given to you? Was it enough or something was missing?"

Patient: "Well, if he did not say something he should have said, I would not know, right? From what he said, I think it was enough. Well... I thought I did not have information about the anesthesia. They know nothing of what you ask about this, they say: 'you know it is the anesthesiologist who will do the procedure that will talk to you. That's complicate.'"

Interviewer: "What did you want to know they did not answer?"

Patient: "Ah [...] they do not talk much about the anesthesia they're going to do, they say when the time comes they decide what's best... these things..." (Patient 33, 45 years old)

Discussion

In the present study, we have concluded that fear was the most common feeling reported by the women after they read the ICF. However, they believed that the fear did not impact the decision-making process about undergoing the surgery, and this is probably related to the negative impact of their gynecological/urogynecological disease. After the interview, we followed the patients until the day of their scheduled surgery, and none of them had given up undergoing the elective procedure. Maybe this is related to the idea of the ICF as a ritualistic procedure, as a protocol devoid of the purpose of really informing the patient and giving her the necessary autonomy to make a decision. Moreover, this idea could be merged with a situation of countering paternalism that is difficult to stratify during an interview. However, it is important to approach the patients about the preoperative fear because this is a risk factor for major personal and socioeconomic burdens.¹⁴

Akkad et al¹⁵ verified that patients undergoing gynecological and obstetrical procedures have limited knowledge about the fact that the ICF is a legal requirement. The most interesting aspect of that specific study was that the patients did not believe that the ICF was an expression of autonomy, a fact proven in the analysis of what the patients said. An analysis of 25 British women using Pierre Bourdieu's theories combined with the social interactionist theory¹⁶ found that women have a reduced capacity for decision and action within a hospital structure, which has socially imposed rules of conduct that leave them only with the possibility of obeying what is requested. Perhaps this may be associated with what has been discussed before, about the patients inability to understand the legal significance of the ICF. Our study did not focus on the perceived knowledge of the interviewed women regarding the ICF, but we noticed a lack of information regarding the importance of this document. Maybe there was some sort of selection bias, because most of the interviewed women had low levels of schooling. Nevertheless, we already know that the comprehension of the ICF is not impacted by the level of schooling or the socioeconomic status.⁴

Furthermore, we did not include emergency procedures, as we know that they have a different meaning for the patients, and the situation of giving consent changes, because sometimes the mental status is impaired in these patients during an emergency.⁵

All ICFs were supervised by medical residents in the first consultation. It is already known from the literature that junior physicians feel less prepared and unable to provide patients with the correct descriptions of the risks, benefits and alternatives.¹⁷ This is an important point to be discussed, because maybe the medical resident is afraid to over-influence the patient, and this could prompt her to decide not to undergo the procedure.¹⁸ Thus, an enhanced autonomy model would be interesting for the decision-making process because it encourages patients and physicians to exchange ideas and to empower this moment of decision.

Another point that was not specifically addressed, but that probably influenced the results, are the difficulties to get access in a more complex health care institution. Most patients in the public health care system in Brazil face many barriers to undergo surgery,¹⁹ and this has already been described in another study about the motivational factors to undergo a gynecological surgery.⁷ These are problems that cannot be resolved from a local institution; however, attempts to make the patients more prone to understand the ICF may be performed; some data suggests that the ICF should be taken in a two-step process, so that patients could be reassessed in a second stage with their questions and concerns.³

An interesting fact of the present study is that in some interviews we noticed a lack of understanding of the explanations about the anesthesia to be provided in the operating room. In our service, the pre-anesthetic evaluation is not performed by the same professional who will perform the anesthetic procedure in the operating room, which probably limits the information about the probable type of anesthetic procedure that will be performed.

The advantages of having performed the present study with a qualitative design were: the ability to be able to comprehend the reactions of the women facing the decision to undergo different gynecological and urogynecological elective procedures; to seek for cultural backgrounds or reasons that could differ their responses when comparing to studies from different countries; and the exclusion of emergency procedures and/or obstetrical procedures, which have a different meaning to the patients. As for the limitations, the fact that the interviewers were part of the surgical group that would be operating these women may have caused an impact during their report.

Conclusion

In conclusion, we believe that women react with fear in most of the situations after reading the ICF; however, they deal with this feeling with their personal motivations, specifically with the negative impact of the symptoms of the disease as an important reason to undergo surgery. Studies focusing on the preparation of the surgical team regarding this step are needed to empower patients in the decision-making process, and to avoid litigations in the future.

Conflict of Interests

The authors have no conflicts of interest to disclose.

Contributions

Amorim AC, Santos LGT, Poli-Neto OB and Brito LGO contributed with project and interpretation of data, writing of the article, critical review of the intellectual content and final approval of the version to be published.

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