ORIGINAL ARTICLE

Patients' experience regarding informed consent in elective and emergency surgeries

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ABSTRACT

Aim To examine whether there are differences in the experience in giving informed consent of patients whose surgery was elective compared to emergency surgery in the same department.

Methods A prospective cross-sectional study was conducted in the Department of Gynaecology and Obstetrics of University Clinical Hospital Mostar during a 6-month period. The sample of respondents consisted of two groups of patients, 145 with elective surgery and 90 patients with emergency surgery. The study was conducted using an anonymous questionnaire.

Results Patients in both examined groups were equally satisfied with the procedure of informed consent. Most patients signed the informed consent at the request of a nurse, 195 (83%). During the process of consenting, almost all patients, regardless of whether they had elective or emergency surgery, claimed that they understood the form, which had to be signed, it was important to them, 230 (97.9%), except the patients who had elective surgery, 130 (90.3%), regularly stated that having an opportunity to ask questions was important to them. Respondents with emergency surgery more frequently agreed to sign whatever was in the form, 42 (46.7%).

Conclusion Patients who had a planned surgery and patients who had an urgent surgery, mostly declare contentment with the use of informed consent although they did not have the same experience about informed consent.

Key words: consent form, understanding of consent, patient satisfaction

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INTRODUCTION

One of the main human rights is the right of a human to be "the master of his/her own body" (1). This right becomes particularly important when medical procedures with the aim of treatment, diagnosis and prevention are undertaken.

Over the past few decades, legal, bioethical and medical circles have been using the term of informed consent or advised consent of informed approval (2). This is the term for the process by which the informed patient consents to the proposed medical procedure by manifesting his/her will freely and without coercion (3). Any invasive or medical procedure on a patient requires his/her consent (4,5). Therefore, a prerequisite for any diagnostic, therapeutic or experimental procedure is the patient's free, informed consent, and a fully and timely informed and competent patient (6).

The institute of informed consent in the Federation of Bosnia and Herzegovina entered into force upon the adoption of the Law on Rights, Obligations and Responsibilities of Patients in May 2010 (5). However, despite the adoption of the Law, patients as well as health professionals have poor knowledge of both the content and the manner of exercising this right. Therefore, a practical question comes to mind: is the adoption of the said Law only a "dead letter," or is informed consent implemented in the health care system? What is the everyday clinical practice? What are the experiences of patients? Specifically, the legitimate right of a patient is to be timely advised and informed by the doctor about the nature and severity of his/her disease, the risks and severity of the proposed type of treatment or medical procedure, alternative methods and their prospects for success, as well as the consequences of refusal of the proposed procedure (6-8).

It should be noted that an important part of informed consent is the signing of the consent form. This part is often misused, i.e. violated in medical practice, to put it mildly. However it should be kept in mind that the signed consent form itself still does not mean that the patient has given consent, it is just a proof that the procedure of obtaining informed consent has been conducted (7).

Despite legal provisions, in practice, patients often do not even read the consent form, they recall having signed "something" but they cannot recall the content. In the end, "what does it matter" when they do not understand most of it anyway, and doctor must "know what is best for the patient" and will carry out a procedure in line with rules of the profession. However, even today, after the legalization of patients' rights, a paternalistic attitude is still deeply rooted both in patients and doctors, and they give the consent formal importance instead of importance in terms of the right to autonomy (9-11). It is indisputable that signing of the consent for surgery should not be a mere formality, but a real opportunity for the patient to get clarification of all ambiguities related to the proposed surgery from the physician. In addition, for the physician it is an opportunity to protect him/herself from potential damage claims they are exposed to, particularly in the field of gynaecology and perinatology, by providing reasonable information to their patients, as defined by law (12).

The aim of this study was to evaluate the experience of patients in giving informed consent for the surgery in gynaecology and obstetrics, and to examine whether there are differences in the experience of patients who had elective or emergency surgery in the same clinic.

PATIENTS AND METHODS

Patients and study design

The survey was conducted in the Clinic of Obstetrics and Gynaecology of University Clinical Hospital Mostar during a 6-month period (between 1 March 2011 and 30 September 2011). The survey was voluntary and the written questionnaire was anonymous. The Ethics Committee of the Faculty of Health Studies in Mostar, and the Ethics Committee of University Clinical Hospital Mostar, Bosnia and Herzegovina (B&H) assessed the research as ethically acceptable.

For the purpose of testing informed consent for a surgery, two groups of respondents were examined based on the degree of surgery urgency: 145 patients who had elective surgery and 90 patients who had emergency surgery.

Methods

Patients who agreed to participate in the survey filled in the Questionnaires in the period of two to four weeks after the surgery. The study was conducted using an anonymous questionnaire specially constructed for this research.

The questionnaire contained two groups of questions. The first group of questions is made up of 12 socio-demographic and gynaecology-obstetrics questions of open and closed type. It contained information on age, education, employment, economic status, place of residence, information on previous surgeries, surgeries on the uterus, number of births, the length of stay in the hospital, as well as the urgency of the surgical procedure.

The second group of questions related to the examination of patients' experience with informed consent was developed based on a survey questionnaire (Akkad et al., 2004). For the purpose of this research, the questionnaire had been designed into three-degree Likert scale (13). The questionnaire consisted of 6 questions: the experience, the memory of signing the consent form, the reasons for not reading the consent form fully, the emotional and the physical state of the respondents when signing the consent, the importance of certain questions in the process of giving consent.

Statistical analysis

The normality of distribution of continuous variables was tested with the Kolmogorov-Smirnov Test, and for the presentation of its average value and measure of dispersion, the arithmetic mean and standard deviation was used. The χ^2 test was used for the analysis of nominal variables, while Fisher's Exact Test was used in the lack of expected frequency. The possibility of error was accepted at $\alpha<0.05$, and the differences between the groups were accepted as statistically significant at $p<0.05$.

RESULTS

In the 6-month period a total of 235 patients (145 had elective and 90 had emergency surgery) were voluntary responded to the (written) questionnaire.

The average age of respondents was 34 years. The youngest respondent was 18 and the oldest 68 years of age. Most frequently, the respondents had a high school education, 139 (59.1%); they were mostly employed, 123 (52.3%), their economic status was mostly on average, 203 (86.4%). Most respondents were more frequently married, 218 (92.8%), lived in the urban area, 133 (56.5%). There was no significant difference in the prevalence between respondents who had undergone any kind of surgery in the past, 105 (44.7%), and those who had not, 130 (55.3%) (p=0.001).

A significantly higher number of respondents did not have surgery of the uterus, 184 (78.3%) (p<0.001). Mostly, surgery was elective, in 145 (61.7%) cases; the length of stay in the hospital was mostly between 5 and 10 days in, 182 (77.4%) patients.

Relating to surgery intervention, 129 (54.9%) respondents had a Caesarean section, 54 (23.0%) hysterectomy, 26 (11.1%) conization, seven (3.0%) urogynecological intervention, six (2.6%) salpingectomy, five (2.1%) adnexectomy, four (1.7%) cystectomy, and four (1.7%) women had salpingotomy.

In the overall sample, the majority of respondents, 146 (out of 235, 62.1%), were satisfied with the process of giving consent. The respondents' satisfaction with the process of giving consent did not differ significantly depending on whether surgery was elective or emergency: 92 (out of 145, 63.4%) and 54 (60.7%), 55 (60.7%), respectively (p= 0,145).

Most of the respondents, 195 (83%), signed the consent form at the request of nurses, and only 31 (13.2%) respondents signed the consent form at the request of the operator; another doctor has given a consent form to sign in nine (3.8%) cases (p <0.001).

No significant difference was found in the respondents' answers in the process of requesting the signing of the form in relation to surgery type, e. g. elective or an emergency (p=0.576). Respondents' answers did not differ significantly concerning remembering the situation surrounding the signing of the form in relation to a surgery type (p=0.002). Although most of the respondents did not read the form fully, more frequently it happened in those who had had emergency surgery, 73 (81.1%) (Table1).

Table 1. Respondents' answers related to their memory of signing the consent form

Question	No (%) of patients		p
	Elective	Emergency	
Do you remember anything about signing the consent form?			
Yes	97 (66.9)	57 (63.3)	0.576
No	48 (33.1)	33 (36.7)	
Have you read the consent form fully?			
Yes	55 (37.9)	17 (18.9)	0.002
No	90 (62.1)	73 (81.1)	

The main reason why the respondents did not fully read the form (only one with statistical significance; p<0.001) was the feeling of illness, in women with emergency surgery, 40 (54.8%), comparing to women with elective surgery, 27 (18.9%) (Table 2).

The respondents did not differ significantly in their feeling of being frightened, pressured and

Table 2. Distribution of reasons for not fully reading the consent form aas per the degree of urgency of the surgery

Question	No (%) of patients		p
	Elective	Emergency	
She felt too ill			
Yes	17 (18.9)	40 (54.8)	2.530
No	73 (81.1)	33 (45.2)	
She did not get the opportunity			
Yes	52 (57.8)	48 (65.8)	0.002
No	38 (42.2)	25 (34.2)	
Trusting the physician			
Yes	69 (76.7)	48 (65.8)	9.972
No	21 (23.3)	25 (34.2)	
There was verbal explanation			
Yes	45 (50.0)	29 (39.7)	0.079
No	45 (50.0)	44 (60.3)	
The form was too long			
Yes	7 (7.8)	9 (12.3)	8.949
No	83 (92.2)	64 (87.7)	

relieved at the time of signing the form in relation to surgery type, e. g. elective or emergency. The respondents who had emergency surgery more frequently felt pain, illness and intoxication at the time of the signing of the form, 46 (52.9%), as opposed to respondents who had an elective surgery, 35 (24.5%) (p<0.001) (Table 3).

Table 3. Distribution of answers related to physical/emotional status at the time of signing the consent form as per the degree of urgency of the surgical procedure

Question	No (%) of patients		p
	Elective N (%)	Emergency N (%)	
The feeling of pain, illness, intoxication, fatigue and exhaustion at the time of signing of the consent form?			
Yes	35 (24.5)	46 (52.9)	<0.001
No	108 (75.5)	41 (47.1)	
The feeling of being frightened or intimidated because of the signing of the consent form			
Yes	32 (22.5)	26 (30.2)	0.196
No	110 (77.5)	60 (69.8)	
The feeling of pressure because of the signing of the consent form			
Yes	21 (14.8)	10 (11.6)	0.500
No	121 (85.2)	76 (88.4)	
The feeling of relief because of the signing of the consent form			
Yes	73 (51.4)	48 (54.5)	0.643
No	69 (142)	40 (45.5)	

The respondents did not differ significantly in evaluating the importance of understanding the signed consent form, checking the understanding of the form by a neutral person, having the form checked by a family member, obtaining detailed information about complications, and the importance of time for self-reflection before signing the consent depending on whether they had elective or emergency surgery. Among the questions relating to proper procedure giving a consent, most frequently the respondents agreed (answer 'yes') with the question about understanding what they signed, in 230 (97.9%) total cases, as well as in both groups, e.g. 142 (98.6%) and 88 (97.8%) in the elective and emergency group, respectively (p=0.632). The least frequently the respondents agreed with the question about checking the form by a family member, in 125 (53.2%) total cases, as well as in both groups, e. g. 73 (50.7%) and 52 (59.1%) in the elective and emergency group, respectively (p=0.213) (Table 4).

Table 4. Distribution of elements of the proper procedure of giving consent in respondents' opinion as per the degree of urgency of the surgical procedure

Question	No (%) of patients		p
	Elective	Emergency	
To understand what I'm going to sign			
Yes	142 (98.6)	88 (97.8)	0.632
No	2 (1.4)	2 (2.2)	
Someone to check if I understood everything before signing the consent form			
Yes	103 (71.5)	67 (76.1)	0.441
No	41 (28.5)	21 (23.9)	
Husband/family member to check the form before you sign it			
Yes	73 (50.7)	52 (59.1)	0.213
No	71 (49.3)	36(40.9)	
To have the opportunity to ask questions about the surgery			
Yes	130 (90.3)	71 (80.7)	0.037
No	14 (9.7)	17 (19.3)	
To get detailed information about complications			
Yes	129 (89.0)	80 (90.9)	0.636
No	16 (11.0)	8 (9.1)	
To have some time alone to think before signing the form			
Yes	121 (83.4)	64 (73.6)	0.070
No	24 (16.6)	23 (26.4)	

As for the overall opinion regarding the signing of the consent in relation to whether the surgery was elective or emergency, the number of respondents differed significantly (without statistical significance) only in the attitude whether they would sign whatever was in it, where the respondents with emergency surgery agreed with it more frequently, 42 (46.7%) comparing with the patients with elective surgery, 44 (30.3%) (p=0.041) (Table 5).

Table 5. Answers to the questions asked about the overall attitude regarding signing of the consent form among respondents

Question/ Answer	No (%) of patients		p
	Elective	Emergency	
I had no choice when it comes to signing the consent form			
I mostly agree	62 (42.8)	47 (52.2)	
I neither agree nor disagree	32 (22.1)	21 (23.3)	0.205
I mostly disagree	51 (35.2)	22 (24.4)	
I would have signed whatever was in it			
I mostly agree	44 (30.3)	42 (46.7)	
I neither agree nor disagree	33 (22.8)	16 (17.8)	0.041
I mostly disagree	68 (46.9)	32 (35.6)	
Signing the consent was a waste of time			
I mostly agree	12 (8.3)	6 (6.7)	
I neither agree nor disagree	36 (24.8)	31 (34.4)	0.280
I mostly disagree	97 (66.9)	53 (58.9)	
Hospitals should deal with the consent forms for the type of surgery that I had			
I mostly agree	79 (54.5)	52(57.8)	
I neither agree nor disagree	41 (28.3)	26 (28.9)	0.721
I mostly disagree	25 (17.2)	12 (13.3)	

DISCUSSION

The results of this study showed that the majority of patients (62%) were satisfied with the procedure of informed consent, regardless of whether they had elective or emergency surgery, and about 26.9% of the patients remained neutral in their response to that question. In a research conducted in the UK in 2004, 80% of patients who had a planned surgery expressed their satisfaction with the informed consent process, and 63% of the patients for emergency surgery (13).

A doctor who will perform an operational surgery must get an informed consent, based on oral and written information, and if that is impossible, then another doctor who is qualified for that procedure needs to get an informal consent (1,5). The informed consent is invalid if the nurse has obtained it for the doctor (1). The results of our research showed that most patients (83%) signed the consent form upon the nurses' request, the operator asked for the consent in 13.2% of patients, while in 3.8% of the patients another doctor received informed consent. The research results raise concern and confirm that signing of the informed consent in clinical practice is not based on legal regulations. Very often informed consents stem from the situation that nurses give a written consent form along with all other forms that the patients are required to sign upon admission to the hospital, so that the patients indiscriminately sign them without having received any information about their medical condition or medical intervention (14).

Amir et al. came across interesting data showing that almost all patients who had a planned operational procedure signed an informed consent, however only 40.5% understood given information. Half of them were aware of the risks and complications, however, despite misunderstanding of the process of informed consent, 93.5% of the patients expressed their satisfaction with the informed consent process (15).

In the research conducted by Kirane et al. 71% of the patients were aware of the indications that were the reason why Caesarean section needed to be done, while only 25% of those patients correctly explained the procedure and complications, which indicates the deficiencies in providing information and obtaining informed consents (16). On the other hand, some research show that the patient's memory of an event cannot be perfect (17). Sherlock and Browni systematically searched the literature to explore the memory and understanding of the proposed medical procedures for which a patient consent was given and found that memory and understanding of medical procedures, risks and complications depend on education and is difficult for older people, confirming that the use of written material and the use of interactive multimedia communication have led to improvements in understanding of the medical procedure (18). In our study, the majority of patients recalled the situation surrounding the signing of the consent. The patients did not differ significantly concerning the memory of signing the form regardless of whether they had elective or emergency surgery.

A high percentage of patients (81.8%) who had an emergency surgery said they had not fully read the consent form. The obtained results can be interpreted with the fact that patients are inclined to paternalistic relationship with their physicians in emergencies, as confirmed by other research (3).

Also, the data suggest that in emergency medical procedures around one quarter of patients are unable to give thier consent (19), which can be caused by pain or analgesics.

The results of our study indicated that patients who had elective surgery had not read the consent form as they received sufficient verbal information, and because they trusted their doctor. In most cases, as reasons for not having read the consent form, emergency surgery patients stated the feeling of illness, and not having been given the opportunity. The survey which was conducted by Akkad et al. in 2004 showed that a smaller number of patients who underwent emergency surgery had read and understood the consent form and felt more afraid while signing the consent in relation to patients who had elective operation. As the reasons for not having fully read the form, emergency surgery patients have in most cases claimed to trust their doctor, and to have received good verbal information (13). The results of our study indicate that at the time of signing the consent form almost none of the patients felt frightened and the majority felt no pressure over signing. A significant fact was recorded only in the group of urgent surgery patients who reported that at the time of signing the form they felt pain, sickness and intoxication, as expected. In a study conducted by Kay and Sirwaredena, 81% of patients who had emergency

surgery felt pain at the time of giving consent to the surgery, but only 34% of patients stated that pain interfered with their ability to give consent. Although 70% of patients stated that they had received painkillers before signing the consent, only 27% thought that painkillers reduced their ability to give a consent (20).

In 2006, Saunders et al. examined the practices and opinions of obstetric anaesthesiologists on the issue of informed consent for epidural analgesia in new mothers through questionnaires: 68% of anaesthesiologists considered that new mothers in labour can give informed consent for epidural analgesia, 13% recommended antenatal aesthetic consultations for pregnant women who asked for epidural analgesia (21). In contrast to these results, Black and Cynahad have obtained different findings showing the differences of regional analgesia and their attitudes towards informed consent, in 70% of cases the anaesthesiologists indicated that labour prevents women's ability to give full informed consent; verbal consent for regional analgesia was obtained in 80% of cases and in 20% of cases consent was not recorded or was not discussed (22).

It is interesting to consider the question of whether pregnant women who have already been given medication to ease labour pain, or are under the influence of sedatives, are capable of giving informed consent. Gerancher et al. found that being under opiates and sedatives does not affect the process of informed consent. There were no differences in attitudes between mothers who received opiates and those who did not receive them, in relation to the satisfaction with informed consent (23).

The results of our study have shown that almost all patients considered that in the process of giving informed consent it is essential to understand received information. Somewhat fewer patients believe that it is important to obtain detailed information about complications of the surgery. Also, majority of patients considered it to be essential to have the opportunity to ask the doctor questions about the surgery or to be familiar with possible complications during the surgery. Specifically, patients with emergency surgery considered it less important to have the opportunity to ask questions about the surgery, in which these two groups differ significantly.

This is not surprising because at the time they were asked to sign a form, most of the patients in emergency situations were in a lot of pain, which in itself is stressful. In our research, approximately half of the patients agree with the statement that they had no choice when it came to signing the consent form, while 46.7% of emergency surgery patients considered they would have signed anything that was written on the form.

In Fröhlich's survey conducted in 2011, 79% of patients considered that discomfort during childbirth influenced the ability to sign informed consent for epidural analgesia. Almost all patients believe that informed consent should be signed before giving birth (24). Some researchers imply that informing patients in detail about a suggested medical procedure can influence on reducing anxiety. This statement is supported by a study conducted on sixty women who had a planned caesarean section whom the level of anxiety was investigated before and after giving information about the caesarean section. The authors found that after informing the women they felt a lower level of anxiety (25).

In conclusion, the patients who had elective and patients who had emergency surgery do not have the same experience within formed consent. The likely reason is that more than half of the emergency patients at the time of signing the consent are in pain, and thus the credibility of the signed consent is in question. The paper revealed that the consent form for the surgery was offered by a nurse in a high number of cases. Obviously, the adoption of the said law, which was to strengthen the position of patients and health professionals, caused confusion in practice and the right to informed consent often meant "blind" signing of the consent form. Also, the results indicate that the currently valid form of consent is inappropriate, particularly because the same form of consent is used for all surgical procedures and does not provide appropriate instructions for other aspects of the process of consent that are important to patients. A new approach is necessary to take into account the preferences of the patients and recognize different needs of the patients depending on whether they had elective or emergency surgery.

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