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ORIGINAL ARTICLE

Status of medical information and patient consent in orthopedic surgery and traumatology at the University Hospital of Burgos (period 2017-2018)☆

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Abstract
Introduction: The principle of autonomy is the basis of the informed consent concept. Informed consent is a patient´s right consisting in prior to the medical intervention being carried out on his body, he must express his agreement that it must be preceded by the proper information that allows him to decide according to his interests. In this work, our objective was to know the status of medical information and informed consent of the patient in the Traumatology and Orthopedic Surgery Service of the University Hospital of Burgos.
Material and methods: An anonymous questionnaire was prepared and distributed among 647 orthopedic surgery and trauma patients at the University Hospital of Burgos. Subsequently, a descriptive, cross-sectional, observational quantitative study was carried out. The association of sociodemographic variables with the responses to the questionnaire items was studied.
Results: Only 28.9% of the patients know that information is a right, but the majority (97.3%) expressed the need to receive information on risks and complications of the treatment and consider that the information does not increase fear or anxiety (63.4%). The majority stated that they were informed about the care performance (98.1%), understanding the explanations received (98.0%). The time used was sufficient (73.7%). In general, the information received was rated as sufficient (89.8).
Conclusions: Most of the patients felt informed and considered that the time that the doctor had had for this was sufficient.

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PALABRAS CLAVE
Derechos del paciente;
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Estado de la información médica y el consentimiento del paciente en cirugía ortopédica y traumatología en el Hospital Universitario de Burgos (periodo 2017-2018)

Resumen
Introducción: El principio de autonomía es la base del concepto de consentimiento informado. El consentimiento informado es un derecho del paciente que consiste en que éste, previamente a que se efectúe la intervención médica en su cuerpo, debe expresar su conformidad que debe ir precedida de la debida información que le permite decidir según sus intereses. En este trabajo nuestro objetivo fue conocer la situación de la información médica y del consentimiento informado del paciente en el Servicio de Traumatología y Cirugía Ortopédica del Hospital Universitario de Burgos.
Material y métodos: Se elaboró y distribuyó un cuestionario anónimo entre 647 pacientes de cirugía ortopédica y traumatología del Hospital Universitario de Burgos. Posteriormente se realizó un estudio cuantitativo observacional descriptivo de corte transversal. Se estudió la asociación de las variables sociodemográficas con las respuestas a los ítems del cuestionario.
Resultados: Solo el 28,9% de los pacientes conoce que la información es un derecho, pero la mayoría (97,3%) manifestaron la necesidad de recibir información sobre riesgos y complicaciones del tratamiento y consideran que la información no aumenta el miedo o ansiedad (63,4%). La mayoría afirmaron que fueron informados sobre la actuación asistencial (98,1%), comprendiendo las explicaciones recibidas (98,0%). El tiempo utilizado fue suficiente (73,7%). En general, la información recibida fue calificada como suficiente (89,8%).
Conclusiones: Los pacientes, en su mayoría, se sintieron informados y consideraron que el tiempo que el facultativo había tenido para ello era suficiente.

Introduction

Diagnostic as well as therapeutic medical interventions affect the integrity of the person, and persons are legal assets which enjoy protection and are safeguarded by the law.[1]

In medical activity from the moment that a patients informs the doctor of their symptoms and until they receive the prescribed treatment, the intimate and personal sphere of the patient will be involved. Human beings know of no greater limitation of freedom that the state of being ill, which reduces or even annuls the freedom to undertake major life projects, as well as perform the small actions of everyday life.[2]

The law offer patients freedom in a formal sense; this consists of the guarantee that, in spite of the aforesaid limitations and factitious restraints, everything occurs because this is what the patient desires. The legitimacy of medical care requires an act of consent; that is, an authorization or permission for something to be done, which thereby becomes a basic pillar of the doctor-patient relationship.[3]

A patient's right to informed consent consists of expressing their agreement prior to a medical intervention, based on the due information which allows them to decide according to their interests. As a correlation to this right, the obligation of the doctor arises to inform the patient and receive their consent prior to executing the medical intervention.

Informing and obtaining consent should be part of a process that promotes the fundamental values of clinical relationships: these consist of interpersonal communication, non-discriminatory treatment and respect for the right to decide on the basis of one's own beliefs and values.[4]

The principle of autonomy is the basis of the concept of information consent. Based on their autonomy, patients decide what they want regardless of medical-scientific criteria and without any external pressure. For this purpose, individuals who have no intellectual disability and whose will is not subject to dominant internal or external coercion are defined as autonomous, and they are able to take autonomous decisions.[5] The principle of respecting autonomy is not applicable to everybody, given that some people do not act autonomously as they are disabled or under coercion. This is the case for minors, older individuals with intellectual disability, mental disorders (such as psychotic disorders, severe addictions in an acute imbalanced stage or severe dependency on the consumption of substances of abuse), individuals with intellectual disability or dementia, etc. The decision whether or not an individual lacks autonomy should be reviewed at regular intervals, depending on their personal circumstances.[6]

The need for informed consent was made obligatory by art. 10 of the General Health Law 14/1986, of 25 April.[7] The

regulations have since been broadened through the Instrument for the Ratification of the Agreement for the protection of human rights and human dignity respecting the applications of Biology and Medicine, in Oviedo on 4 April 1997,[8] and Basic Law 41/2002, of 14 November, which governs patient autonomy and the rights and obligations in the field of information and clinical documentation.[9] Legislation by the Autonomous Communities has subsequently developed and complemented Law 41/2002, although some Autonomous Communities have their own law from prior to the said law. It should be pointed out that the Basque Country was the first Autonomous Community to legislate, in 1998, on patient rights.[10] Other regions had done so to define the situations when consent has to be obtained, and the forms in which this can be expressed.[10]

Informed consent is a patient right that should be respected and guaranteed by professionals and medical centres. It is a part of the "*lex artis medica*", and failure to comply with it gives rise to legal professional liability for all professionals and medical centres.

There are two sides to the interest in how information is supplied and the subsequent obtaining of patient consent. On the one hand, it is of interest to know what actually occurs, because the clinical act of informing and obtaining consent may give rise to problems that could generate enormous legal activity. On the other hand, it is of interest to know how such conflictive situations could be avoided.

Our aim in this work is to study the situation respecting medical information and informed consent in the Traumatology and Orthopaedic Department of Burgos University Hospital.

The core aim is to study how the principle of autonomy influences the doctor-patient relationship, together with how patients and users perceive this principle.

The secondary objectives are to study and analyse:

- Patient attitudes to informed consent.
- The information that is received.

Material and method

Type of study

This research involved a cross-sectional descriptive observational quantitative study, using a questionnaire with closed questions.

Participants

The study population consisted of patients who had been treated in the unit and who visited for follow-up in the Traumatology and Orthopaedic Department of Burgos University Hospital in the years 2017 and 2018, during which time 13,781 and 14,471 patients were seen, respectively. As this population could not be covered in its entirety, a sufficiently representative sample of the same had to be obtained to make it possible to extrapolate the properties of the sample to the population as a whole. Randomized sampling was used to prepare this work, and all of the patients who had not been subjected to physical intervention requiring their informed consent were excluded.

The size of the sample obtained, setting the error of estimation at 4% (below the standard level of 0.5 used in research of this type) and for a confidence level of 95.5%, was 599 patients.

Respecting the ethical aspects of this work, the Medicine Research Ethics Committee of Burgos University Hospital Complex was informed that the study would take place, and it approved the same. Fieldwork and data gathering took place under the terms of Organic Law 15/1999, of 13 December, on Personal Data Protection.

Instrument

A questionnaire containing 20 structured items divided into 3 blocks of content was prepared for data gathering. The variables studied in this survey were:

- Block 1: variables respecting attitude to informed consent.
- Block 2: variables respecting the information received.
- Block 3: respondents' sociodemographic variables.

The anonymous questionnaire was distributed and collected personally among the selected patients with the help of previously instructed nursing staff.

The reliability of the questionnaire was analysed by a pilot study using a sample of 100 participants. This test gave the result of Cronbach's alpha at 0.780, which is an acceptable value, so that no element was eliminated to improve the reliability score.

Statistical analysis

Version 20.0 of the SPSS statistical package for the Mac operating system was used for the descriptive analysis of the data, to obtain tables of frequencies and percentages of the qualitative variables, and fundamental descriptive parameters for the quantitative variables. We studied the possible relationships between the study variables, with a 95% level of significance ($P \leq .5$) using Chi-squared tests.

Results

647 questionnaires were collected, surpassing the figure of 599 obtained when calculating the sample size. There were individuals in each block of questions who failed to answer or did so wrongly in one of the questions or the block as a whole, although the number of valid questionnaires was greater than the set number of 599 patients.

The patients' average age was 58.48 years, with a standard deviation of 18.77. The youngest patients was 4 years old, and the oldest was 95.

42.3% of the patients who answered the questionnaire were men and 57.7% were women. Almost half of the respondents had a medium or high educational level, and the rest knew how to read and write or had received primary education.

Table 1 shows the valid results of the sociodemographic variables of the patients who were surveyed.

Tables 2 and 3 show the distribution of frequencies and percentages of the answers to the questions about attitude to informed consent and the information received.

Table 1 Sociodemographic characteristics of the 647 patients surveyed.

Variables	Frequency	%
Sex		
Male	267	42.3
Female	364	57.7
Age		
0-19	25	4.0
20-39	76	12.2
40-59	212	34.1
60-79	233	37.5
80 years or more	75	12.1
Educational level		
Literate	134	21.3
Primary education	191	30.3
Qualified	305	48.4

Table 4 shows the statistically significant results of associations between the sociodemographic variables and some of the variables studied in the survey. No significant differences were found in connection with the other variables.

Discussion

Almost half of the patients who answered the questionnaire had a medium or higher level of education, while the rest were literate or had received primary education. It may therefore be deduced that, with the help of trained nursing staff they were able to answer the survey.

In block 1, about attitudes to informed consent, when asked "before being informed, did they ask you if you wished to receive information about the traumatological or orthopaedic treatment?", the great majority of the patients surveyed (87.9%) stated that they were asked, while only 12.1% answered that they were not asked. This response indicates that the vast majority of traumatologists fulfil their duty of asking, as the right not to be informed also exists if the patient so decides. This result agrees with the one reported by López Arenas et al.[11]

When they were asked "if you consider it to be necessary before the intervention for you to be informed of the risks and complications of the traumatological or orthopaedic treatment that will be used", almost all of the patients surveyed (97.3%) answered yes.

This general affirmative response by the patients expresses their desire to know any possible risks and complications which may arise due to the treatment that will be used.

When asked "who do you believe should be given this information?", 47.4% stated that it should be given to the patient, while almost half (49.9%) considered that it should also be given to the family in the same way. In Spain patients do not usually visit a doctor alone, but rather go in the company of direct family members, or friends or people with whom they have an emotional tie, and they go into the surgery and take part in all of the doctor's conversation with the patient. This is why it is relevant that almost half of the patients answered that the information should be given to the patient. Therefore, when a traumatologist asks a patient into his surgery, they should ask if they wish to go in alone or in company, as this would be an indirect way of ensuring that half of the patients surveyed could proceed as they wished.

Table 2 Distribution of frequencies and percentages of the answers to the questions about attitude to informed consent.

Variables	n	% valid
Were you asked if you wished to receive information about the traumatological or orthopaedic treatment?		
Yes	560	87.9
No	77	12.1
Do you consider it necessary that you be informed of the risks and complications of the treatment before the intervention?		
Yes	622	97.3
No	17	2.7
Who do you believe should be given this information?		
The patient	304	47.4
The family	17	2.7
Both parties	320	49.9
Do you consider the information supplied increased your fear or anxiety before the medical intervention?		
Yes	234	36.6
No	478	63.4
Do you think that it would have been better for them to have said nothing?		
Yes	160	25.1
No	478	74.9
Why do you think they informed you?		
Because the law obliges them to	339	53.2
To prevent possible complications for the patient and their family	114	17.9
Because patients have a right to the information	184	28.9
Do you believe that the traumatologist has enough time to explain the intervention?		
Yes	470	73.7
No	168	26.3

When asked "if you consider the information supplied increased your fear or anxiety before the medical intervention?", approximately one third of the patients surveyed answered in the affirmative, and the other 2 thirds stated that it did not. This result may be due to the fact that on the majority of occasions this information is supplied with empathy, clearly and simply explaining the type of intervention to the patient, together with its risks and complications.

When asked "Do you think that it would have been better for them to tell you nothing?", one quarter of the patients surveyed answered in the affirmative, while the other three quarters stated that they wanted to be informed. This response indicates that the great majority of patients want to be informed, and those who answered that it would have been better not to have been informed means that they should have been told more clearly about their right not to

Table 3 Distribution of frequencies and percentages on the responses to the questions about the information received.

Variables	n	% valid
Did they inform you about what the intervention would be (surgery, close reduction, infiltration…) and if so what it would consist of?		
Yes	631	98.1
No	12	1.9
Did they inform you of the risk of the intervention?		
Yes	617	97.3
No	17	2.7
Who informed you?		
The traumatologist who diagnosed you in the surgery or the Emergency Department	541	85.5
One of the traumatologists who treated you	89	14.1
The ward nurse	3	0.5
How were you given the information?		
Orally	292	45.6
In writing	22	3.4
Orally and in writing	326	50.9
Did you understand the explanations they gave you about the intervention?		
Yes	622	98.0
No	12	2.0
Did you ask the person who informed you about anything that you did not understand?		
Yes	471	74.6
No	160	25.4
Did the person who informed you answer your questions?	507	93.4
Yes		
No	36	6.6
When informed consent was explained, did they describe the different surgical and non-surgical techniques that they could use?		
Yes	516	82.4
No	36	17.6
The risks and complications of the proposed intervention - how were they explained to you?		
Generically (in general)	449	71.5
Without much detail	64	10.2
In great detail	115	18.3
In general, how would you describe the information received?		
Sufficient	572	89.8
Insufficient	65	10.2

Table 4 Association between sample variables and patient attitudes to the informed consent process.

Variables	n	%	*P*
Did they ask you if you wanted to receive information about the treatment? [a]			
Sex	550		0.002
Men	246	92.8	
Women	304	95.1	
Why do you believe they informed you? [b]			
Sex	337		0.018
Men	143	53.8	
Women	194	54.5	
Sufficient time to explain [a]			
Sex	464		0.001
Men	216	81.2	
Women	248	68.9	
Person to be informed [c]			
Age (years)	308		
0-19	15	60.0	0.000
20-39	29	38.7	
40-59	85	40.5	
60-79	135	58.2	
80 years or more	44	59.5	
Did they ask you if you wanted to receive information about the treatment? [a]			
Educational level	549		0.002
Literate	130	97.7	
Primary education	161	85.6	
Medium level education	256	85.9	
Person to be informed [c]			
Educational level	314		0.000
Literate	72	54.1	
Primary education	105	55.5	
Medium level education	136	48.2	
Why do you believe they informed you? [b]			
Educational level	336		0.004
Literate	90	67.2	
Primary education	102	54.5	
Medium level education	142	47.6	

[a] The response is: yes.
[b] The response is: because the law obliges them to.
[c] The response is: both parties.

be informed, and the possibility of delegating this information to other trusted individuals.

When asked "why do you think they inform you?", more than half of the patients surveyed (53.2%) answered that this was because it was a legal obligation for doctors to do so. Almost a third (28.9%) stated that it is because patients have a right to this information, and the rest (17.9%) answered that it was to warn patients and their families about the risks and possible complications of the intervention. These answers imply that the majority of patients know that there is a regulation that obliges doctors to inform them, and that this is also a patient's right. The other respondents stated that this information is to warn the patient and their family. In general, these responses show that patients are learning about the right to informed consent as defined by the law. We should underline that the 28.9% datum is double the score obtained in other studies of this type.[12]

When they were asked "do you believe the traumatologist has enough time to explain the medical intervention that they will apply, together with its risks and complications, and to clarify and doubts that may have arisen?", the majority (73.7%) answered affirmatively. This agrees with the study published by Giraldo P et al.,[12] while a quarter of the patients surveyed answered that they lacked sufficient time. These answers show us that the majority of patients consider that the traumatologists who treat them inform

them and care for them. It also calls the attention to those doctors who fail to comply with the objectives of giving information in such a way that patients are able to give their properly informed consent.

Study of the relationship of dependency between answers to the questionnaire and sociodemographic variables shows that a strong association exists between some of them (Table 4). The association of sex with the following variables was therefore found to be statistically significant: "Did they ask you if you wanted to receive information about the treatment?", "why do you believe they inform you?" and "was enough time taken for the explanation?". Additionally, age was associated in a statically significant way with the "person to be informed" variable. Lastly, the educational level of the patient was found to be strongly and significantly associated with the variables: "Did they ask you if you wanted to receive information about the treatment?", "the person to be informed" and "why do you believe they inform you?"

In block 2, about the information received, the question "did they inform you of what the medical intervention would be and what it consisted of?" was answered affirmatively by almost all of the patients surveyed, and only a minority (1.9%) answered no. This shows us that the majority of traumatologists correctly fulfil their function of offering good information to patients. It is clear that training and awareness-raising measures should be adopted so that this majority becomes a totality. Our data here contrast with those obtained in a study covering all of the departments in a Spanish university hospital, where only 66% of the patients stated that they had received an explanation of what their intervention consisted of, and 11% had not received any explanations.[13]

When asked "did they inform you about the risks of the intervention?" almost all of the patients surveyed (97.3%) answered affirmatively. This answer and the one to the previous question confirms that almost all traumatologists comply with their obligation to inform patients about the possible risks involved in a medical act. Although these data are better than those from another study in Spain,[12] measures should be taken to reach the totality of cases.

When they were asked "who informed you?" almost all of the patients surveyed answered that it was the traumatologist who had diagnosed them, or one of the traumatologist who intervened. A small percentage (0.5%) answered that they are informed by the ward nurse. This answer should not be considered to be a source of information, as it is probably due to ward nurses answering questions that the patients had asked them.

When they were asked "how was the information supplied to them?", approximately half of the patients surveyed (50.9%) answered that it was given orally and in writing. A slightly smaller percentage (45.6%) were told orally, and a small number (3.4%) in writing. These answers indicate that the majority of the patients received the information properly, and the only target for corrective action would be the small percentage who were only informed in writing. This is because they were probably given a written document to be read and signed by the patient, with no spoken information. The results of other studies on this point are surprising, as the clinicians opted to only give verbal information, recording this in the clinical history.[11]

When asked if "they understood the explanations that they were given about the intervention?", almost all of the patients surveyed said that they did, while a small percentage (2.0%) answered that they did not. This confirms what we found in the previous answers, that the majority of traumatologists inform their patients properly, and that the latter understand the need for treatment, its risks and possible complications. It would be ideal if all patients attained this level of comprehension. In other studies only half of the patients admitted that they had fully understood the explanations of the risks and benefits of the intervention.[13]

When they were asked "if they asked the traumatologist to explain anything that they had not understood?", three quarters of the patients surveyed said that they had, while a quarter said they had not. Doctors here should create an empathy with the patient so that the latter trust them sufficiently to ask them about their doubts respecting the intervention they will receive. The fact that a quarter of the patients did not ask the doctor shows that there was insufficient trust within the relationship to ask for explanations.

When they were asked "did the person who informed you answer your questions?", the majority of the patients surveyed answered that they had clarified their doubts, while a minority (6.6%) said that they had not done so. This response implies that the majority of doctors offer clear and simple explanations to their patients about the intervention they will perform, together with its purpose, risks and possible complications. A minority of doctors do not do so, so they should be trained in these skills.

When asked "when informed consent was explained, did they also explain the different surgical and non-surgical techniques that could be used?", the majority of the patients surveyed answered affirmatively, while a minority (17.6%) did not. This shows and confirms the findings of previous questions, in which the majority of traumatologists explain what they are going to do to their patients, informing them sufficiently well. It also confirms that a minority of doctors should receive training so that they can acquire skills to allow them to properly fulfil their duty to inform.

When they were asked "how did they explain to you the risks and complications of the proposed intervention?", the majority of the patients surveyed answered that this was done in generic terms, while a minority (10.2%) said that the explanation contained little detail, and a higher proportion (18.3%) said that the explanation was very detailed. Traumatologist doctors should specify the information patients should be given beforehand, and the information also has to be true. This may contradict what the majority of the patients said, which is that the information is generic. An excess of information is as counterproductive as restricting it to generalities. In the first case it may cause patients to worry unnecessarily, while in the second case it would not offer them enough information to give their fully informed consent. It is therefore necessary for doctors to have received training and have experience in how to inform patients, and the only way to achieve this is for traumatologists to acquire the specific skills that are needed.

Conclusions

Our study shows that the majority of patients are aware that there is a legal regulation which obliges doctors to inform

them before obtaining their consent. They express their desire to know, and state that it is their right to be informed. The majority deny that the information supplied by doctors made them fearful or anxious.

The majority of the patients felt that they had been informed and that the doctor had spent sufficient time in doing so. They received oral information on the intervention, the procedure and its risks, and any doubts which arose were clarified. They are more appreciative of the quality of information given than they are of its quantity.

The informed consent process applied in the Orthopaedic and Traumatological Surgery Department of Burgos University Hospital complies with legal regulations and is normal, and it also satisfies the majority of patients. To fully satisfy patients a continuous training process for professionals should be implemented, making them more aware of the right to information, to overcome some of the deficiencies found by the questionnaire. We also consider it to be possible to improve the explanation patients receive about the right not to be informed, and the possibilities of delegating this right to other trusted individuals. Furthermore, traumatologists must dispose of sufficient time to offer suitable explanations in all cases, so that patients can give their informed consent in a responsible manner. The small percentage (3.4%) of traumatologists who only supplied information in writing should also be corrected.

Conflict of interests

The authors have no conflict of interests to declare. This study was not financed by any organization.

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