

Informed consent in ENT. Patient's judgement about a specific consensus form

Il consenso informato in ORL. Il giudizio dei pazienti su un modello di consenso specifico

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Parole chiave

Consenso informato • Responsabilità del medico • Medicina legale in ORL

Summary

The concept of informed consent was first used in the 60's. The meaning of this term is the need of a preliminary and valid consensus that places the doctor in an authorised condition whereby he is able to carry out his work. Notwithstanding the importance and delicacy of this topic and the potentially serious consequences, there is not, as yet, universal behaviour, on the part of doctors, regarding the mode of information and documentation on how the patient be informed. In a previous article, the authors outlined the best approach, on the part of the doctor in regard to the patient, in order to obtain valid informed consent. In particular, the specific information for each disease was proposed and this was not limited only to aspects related to type of treatment and possible risks, but thorough, with regard to adhering to the logical course (case history, objective tests, instrumental diagnosis carried out, etc.) that led the doctor to a certain diagnosis and a description of the proposed treatment possibilities as well as the treatment modalities excluded, with relative reasons. The study was designed in such a way as to define the degree of acceptance that this informative method has on the patients. This was achieved by means of a questionnaire filled in by 254 patients hospitalised in our department, about to undergo surgery. Judgement was substantially positive, in that, > 70% of patients agreed that the information was quite or very good, and 90% considered it sufficient or better. This demonstrates that even those subjects who received little information, were, in fact, satisfied with that given. The patient/doctor relationship was also judged positive. The patients felt that it was important to be kept informed about their condition, regardless of the form (written or spoken). In conclusion, the outcome of the questionnaire demonstrates the appreciation, on the part of the patients, regarding the procedure of information used in seeking consensus.

Riassunto

Il concetto di consenso informato è stato introdotto negli anni '60 intendendo con tale termine la necessità dell'esistenza di un preliminare e valido consenso quale condizione necessaria affinché il medico possa essere autorizzato a svolgere la propria opera. Nonostante l'importanza e la delicatezza dell'argomento, e le sue potenziali gravissime conseguenze, non esiste ancora oggi un comportamento univoco da parte dei medici nelle modalità informative e di documentazione dell'avvenuta informazione al paziente. In un precedente articolo gli Autori hanno ipotizzato quello che dovrebbe essere il comportamento ottimale da parte del medico nei confronti del paziente al fine di ottenere un valido consenso informato. In particolare era stata proposta un'informazione specifica per patologia, non limitata ai soli aspetti connessi con la tipologia di intervento terapeutico ed ai rischi connessi, ma anche esaustiva per quanto attiene il cammino logico (anamnesi, esame obiettivo, diagnostica strumentale seguita, ecc.) che ha portato il medico a formulare una certa diagnosi e la descrizione delle opzioni terapeutiche proposte e scartate, con le relative motivazioni. Lo studio è stato disegnato al fine di definire il grado di accettazione che una tale metodologia di informazione ha sul paziente mediante questionario autocompilato somministrato ad un gruppo di 254 pazienti ricoverati presso il nostro reparto per essere sottoposti ad intervento chirurgico di elezione. Il giudizio è stato sostanzialmente positivo in quanto oltre il 70% dei pazienti ha giudicato l'informazione abbastanza buona o molto buona ed il grado di soddisfazione è risultato essere sufficiente o elevato in oltre il 90% dei casi a dimostrazione del fatto che anche i soggetti che hanno ritenuto le informazioni poco sufficienti in realtà erano soddisfatti delle informazioni ricevute. Positivo è stato anche il giudizio fornito sul rapporto con il medico. I pazienti hanno ritenuto importante essere al corrente delle informazioni sulla propria patologia, mentre non sembrano prediligere una forma specifica di informazione (scritta o orale). In conclusione l'esito del questionario sembra dimostrare un sostanziale apprezzamento da parte dei pazienti nella procedura di informazione per il consenso da noi seguita.

Introduction

One of the most critical aspects, in the relationship between doctor and patient, concerns the information given by the physician, in order to obtain the so-called informed consent. This is seen as the lawful requirement of the medical profession derived from the patient's explicit consent to undergo a particular medical procedure, once they have been adequately informed¹⁻⁴. If consent is lacking, then the medical action becomes an act against the patient's physical integrity which can be considered personal violence (art. 610 p.c.), if one holds that consent governs only the subject's moral freedom, or, as is more commonly accepted by law, voluntary personal injury (art. 582 p.c. and following), up to premeditated murder, in the case of the patient's death. However, crime is considered to have taken place even though the medical action was conducted perfectly, without any traceable fault on the part of the physician⁵. The interpretation of the crime as intentional can, however, mean that there will be no payment of damages by the physician's insurance company because, according to the contract, it answers only to the guilt of the physician.

In a previous article⁶, we advanced the hypothesis of an informative course, destined to offer adequate information to the patient and, at the same time, safeguard the doctor from possible legal action. On that occasion, it was suggested that information be specific, i.e., referring to the nature of the disease affecting the patient and/or the kind of treatment to be carried out. Once again, according to this hypothesis, information given should follow a logical course (case history, objective tests, instrumental diagnosis, etc.) that lead the doctor to a certain diagnosis or to request a certain test, as well as treatment indications, features and consistency of the treatment, foreseeable results, possible options, risks and possible complications of the various types of treatment⁷. In this type of working model, the patient is made aware of the foreseeable, but improbable and probable, risks⁸, whereas if not specifically requested, the atypical, exceptional, unpreventable and unforeseeable risks are not contemplated. This is in order not to fall into psychological terrorism which would have the reverse effect on the patient's health and is more inspired by a medical defence than a therapeutic alliance⁸⁻¹⁰.

The information must be comprehensible, simple, given in an easily understandable language, directed to a person who has no specific technical knowledge of the topic in hand, personalised, at the same cultural level as the person being spoken to, thorough, attentive to the patient's requests, approached in depth, in a humane way, not hastily, serene, truthful but, however, inspired to trust and hope⁶.

Consent must also be authentic, that is, given by the undersigned of the right of a personal choice, whereas the family consent has no importance^{11,12}, free, autonomous, convinced, responsible and not conditioned by third parties or succumbing to the wishes of others, amenable to cancellation¹³.

As far as concerns the consent of a minor, a not unusual situation in ENT, besides a rigid application of paternal authority, with the obligation of informing and obtaining parent's or guardian's consent, even greater importance is focused on the patient's wishes, especially when the child is at an age when he/she is able to understand what is being proposed¹⁴. It is difficult to establish precise limits to this proposal, whereas it would be worthwhile evaluating the young patient's capacity, case by case, in giving his/her own consent; indeed, it is now held that patients between the age of 14 and 18 could, and should, take part in the meeting with the physician and be invited to express his/her own consent¹⁴.

The mode of informing the patient could be either written or spoken. Acceptance of the medical action, by the patient, could be done in the same way. In Italy, there is no legal obligation regarding formalization of consent to health treatment, in a written form, except in the case of experimentation. In agreement with the new deontological code, the attitude of those who wish to have a written document of given consent in all cases, judging them as indispensable as a safeguard in the event of possible legal disputes, is to be shared⁴.

The best approach must be aimed at creating a good doctor/patient relationship; following this logic, in the previous article, we formulated the subsequent course: at the time when the patient is examined by the doctor, he/she should explain the clinical and therapeutic problems according to a so-called average standard of information, i.e., information suited to the patient's social-cultural level, without exceeding in technicalities or being too detached^{10,11}, after the interview, the patient is given a printed form with all the points previously explained orally, in terms that were understood by everyone; upon hospitalisation, the patient is requested to sign a form, counter signed by the physician and, if possible, in the presence of a witness, who certifies that information has been given orally, the patient has read and understood the written information and accepted the medical practices to be used.

Aim of this present study was to evaluate the results of a questionnaire, given to a group of patients, in our Department, for ENT diseases requiring surgery, referring to the appraisal and understanding of the information received.

Materials and methods

The study was carried out in the following phases: *During the outpatient examination*, the diagnosis and therapeutic indications (in our case, of a surgical type) were explained, the patient was told, by the physician, about their disease, the risks and benefits of the surgery proposed, the alternatives and the diagnostic course followed in order to reach the ultimate decision.

At the end of the visit, an informative document was given to the patient, specific for each disease, that outlined the points already explained orally. Some of these forms were described in our previous article ⁶.

Upon hospitalisation, the patient was asked to fill-in a questionnaire in which the following aspects were examined:

- 1) comprehensiveness and thoroughness of information received;
- 2) comprehensiveness and correctness of presentation mode;
- 3) suggestions to improve the informative form.

A copy of the evaluated form is reproduced herein (attachment 1).

The following pathological conditions/surgical operations were taken into consideration:

- Adenoiditis and tonsillitis/Adenoidectomy and Tonsillectomy;
- Nasal septum deviation/Septoplasty;
- Laryngeal neoplasia/Total or conservative laryngectomy;
- Chronic otitis/Tympanoplasty-Myringoplasty;
- Otosclerosis/Stapedotomy;
- Benign disorders of the larynx/Laryngoscopy under narcosis;
- Sinus disorders/Functional surgery of paranasal sinus.

A blind evaluation of the results was carried out on anonymous forms, with no possibility of knowing the identity of the patient. The patients were notified at the end of the analysis about anonymity in order not to influence them.

The following aspects of the informative course were evaluated:

- information supplied by the doctor;
- relationship with the doctor;
- consent given by the patient;
- opinion and attitude concerning informed consent.

Results

The study was carried out on subjects seen at our department and then hospitalised to undergo surgery. All patients hospitalised through the emergency department were excluded.

Results were obtained from a sample of 245 subjects, 140 (55%) male, 114 (45%) female, age range 5-75 years (mean 45). The various age groups were homogeneously represented.

To make the analysis of the results easier, the pathological disorders-surgery were divided as follows:

- Adeno-tonsillitis/Adeno-tonsillectomy (39 cases, 15.4% of sample);
- Nasal septum deviation/Septoplasty (38 cases, 15%);
- Chronic otitis-otosclerosis/Tympanoplasty-myringoplasty-stapedotomy (38 cases, 15%);
- Other (139 cases, 54.7%).

Results can be summarised as follows.

The questionnaire was filled in completely by 241 subjects (94.9%). Incomplete answers were provided more frequently by males, 6% as compared to 3% of females, and by subjects younger than 20, 12% as compared to 2% and 4% in the other age groups. As far as this point is concerned, it should not be forgotten that in the group of younger patients, many were minors and, therefore, the questionnaire was filled in by parents.

With regard to comprehensiveness and thoroughness of the information received, the patient was requested to judge the various aspects that characterised the information, as mentioned in the Introduction (Table I).

No significant difference was seen in the distribution of answers in correlation to age, sex and type of pathology/surgery.

Table I. Numbers and percentages (in brackets) of patients' answers in judgement of comprehensiveness and thoroughness of informative model concerning aspects of pathology, diagnosis and treatment possibilities.

	Not at all	A little	Enough	Very much
Nature of disease	18 (7%)	21 (8%)	87 (34%)	128 (50%)
Diagnostic course	17 (7%)	21 (8%)	86 (34%)	130 (51%)
Treatment	20 (8%)	14 (5%)	89 (35%)	131 (51%)
Foreseeable results	25 (10%)	23 (9%)	79 (31%)	127 (50%)
Treatment alternatives	36 (14%)	30 (12%)	67 (26%)	121 (48%)
Possible risks and complications	31 (12%)	22 (9%)	75 (29%)	126 (50%)

Table II. Numbers and percentages (in brackets) of answers given in judgement of doctor/ patient relationship.

	Yes	No
Clarity	252 (99%)	2 (1%)
Thoroughness	240 (95%)	14 (5%)
Enough time dedicated to information	250 (98%)	4 (2%)
Respect for patient	254 (100%)	0 (0%)
Humaneness	252 (99%)	1 (1%)

The level of information received was judged to be very low by 1 patient (0.5%), low by 3 (1%), sufficient by 51 (20%), discreet by 111 (44%) and high by 88 patients (35%).

This shows how, despite the quite high number of subjects (about 15%) who felt the information to be rather incomprehensible or not very thorough, there is an extremely low number of patients who felt, in general, that the information was only slightly satisfying. This demonstrates how a fringe group of patients show very little interest in more thorough information.

In Table II, evaluation of the relationship with the physician is reported in expressions of clarity, thoroughness of information, time dedicated to speaking with the patient, respect for the patient and humaneness.

These data show how, independently of the judgement on the consent form, the doctor/patient relationship is of high trust. Moreover, according to the patients, the doctor, by giving this information, instilled trust and hope in almost 80% of cases. Therefore, the information given did not give rise to worry. This aspect is particularly important in the case of a diagnosis of neoplastic lesions, that were also taken into consideration by us.

Over 80% of patients were convinced of the consent given and more than 80% felt that the influence of health workers and relatives, in giving their consent to the operation, was negligible. This demonstrates that, in most cases, undergoing surgery, after having listened and understood all the necessary information, was a choice that was very marginally influenced by external people.

Most patients (over 80%), however, felt that having had the various points on the informed consent explained to them (Table I), was important.

Fifty percent of the subjects interviewed were indifferent to the modality with which they were informed whereas 20% preferred a written, and 30% an oral, mode.

Finally, 65% of subjects felt that it was important for the patient to participate in the choice of treatment, 30% that participation is only partially useful and 5% that it was not useful to be informed.

Discussion

The results were obtained from a sufficiently numerous sample to be able to draw useful indications regarding the quality of informed course routinely followed by us⁶. The sample studied appears to be numerically well distributed regarding type of pathological conditions, considering the age of the subjects.

Above all, judgement was substantially positive (over 70% of subjects judged the information quite or very good) regarding comprehensiveness and thoroughness of the information given by the health worker, nature of the pathological condition, logical diagnostic course followed, suggested treatment, foreseeable results, possible therapeutic alternatives, possible risks and complications. In particular, the degree of satisfaction was sufficient to high, in over 90% of cases; thus showing that even those subjects who felt that the information was insufficient, were, in reality, satisfied with that given. The information that was felt to be less adequate was the possible results of treatment, possible alternatives, risks and complications.

Judgement on patient/doctor relationship was always seen as positive, in the various aspects investigated on the questionnaire (clarity, thoroughness of information given, time dedicated to the patient, respect for the patient and humanity, help given and involvement demonstrated). These aspects were not specifically referred to in the questionnaire but were aimed at informing us whether the patient/doctor relationship, used by us, is appreciated or needed to be changed.

All patients confirmed that the consent given came from a deep conviction and was not influenced by other people even by those close to them, such as family and relatives. The doctor's intervention also appeared to be more informative than forcing in obtaining consent, this was in accordance with the fact that the physician must inform the patient, but that it is he/she who must decide.

However, the patients felt it important to be informed about their condition, whereas it seemed that the form (written or oral) in which it was given was unimportant.

In conclusion, briefly, the model we used to obtain informed consent was based on the following points:

- visits;
- interviews with the patients concerning all aspects of the pathological condition and treatment options, including risks and alternatives;
- the preparation of a written informative form, for each pathological condition and relatively detailed concerning the diagnostic aspects;
- confirmation of informed consent upon hospitalisation, without any further interviews, with a signature on the appropriate form, only as documentary evidence.

This study can be classified as satisfactory in guaranteeing correct and suitable information for the patient and a safeguard for the physician in the event of possible legal actions on the part of the patient^{15 16}.

Some slight changes and/or additions, regarding the information about the possible risks of the proposed treatment, possible alternatives, risks and complications, appear necessary.

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Attachment 1. Questionnaire given to patient during hospitalisation.

Age of patient.
Sex.
Disease

A. Information supplied by physician

- Have you received information about your illness from the physician?
Yes _1 Partly _2 No _3 → go to 8
- Written or spoken form?
Spoken _1 Written _2 Both _3
- Information received referred to:

	Yes 1	No 2
1. Nature of disease		
2. Diagnostic course		
3. Treatment		
4. Foreseeable results		
5. Treatment alternatives		
6. Possible risks and complications		
7. Other		

- How do you evaluate in terms of comprehensiveness and thoroughness the various information received?
(Use a score of 1 to 4: 1 = not at all, 2 = a little, 3 = enough, 4 = very much)

	Comprehensiveness 1	Thoroughness 2
1. Nature of pathology		
2. Diagnostic course		
3. Treatment		
4. Foreseeable results		
5. Treatment options		
6. Possible risks and complications		
7. Other		

- In general, what is your degree of satisfaction for the information received?
Very low _1 Low _2 Sufficient _3 Discreet _4 High _5

B. Doctor/Patient relationship

6. During the interview, the physician:

	Yes 1	No 2
1. Used a simple and accessible language		
2. Was exhaustive		
3. Considered your applications		
4. Devoted the time necessary		
5. Showed respect		
6. Was sensitive and "human"		
7. Helped you to understand diagnosis and treatment		
8. Succeeded in involving you in choice of treatment		
9. Other		

7. In comparison to your previous situation, speaking with the physician produced:

	+	=	-
	1	2	3
1. Worry			
2. Confusion			
3. Awareness			
4. Calm			
5. Trust			
6. Hope			
7. Other			

C. Consent given by patient

8. Has your consent been requested regarding treatment/intervention recommended by the physician?
 Yes _1 I do not remember _2 → go to 13 No _3 → go to 13

9. If yes, written or spoken form?
 Spoken _1 Written _2

10. Were you convinced about what you consented to?
 Yes, completely _1 Yes, partly _2 No _3

11. Giving your consent, do you feel free from conditioning by third parties?
 Yes, completely _1 Yes, partly _2 No _3

12. Who or what helped you in giving your consent?

	Yes 1	No 2
1. Specialist		
2. Generic physician		
3. Family		
4. Acquaintances		
5. Personal knowledge obtained from lectures, studies, etc.		
6. Knowledge obtained from experience of others		
7. Other		

D. Opinions and attitudes regarding informed consent

13. How important is it for you to be informed about:

	Very much 1	Enough 2	A little 3	Not at all 4
1. Nature of disease				
2. Diagnostic course				
3. Treatment				
4. Foreseeable results				
5. Treatment options				
6. Possible risks and complications				
7. Other				

14. Would you prefer to receive written or spoken information from the physician?

Written _1 Spoken _2 It's the same _3

15. In your opinion, is it important for the patient to take part in the choice of treatment proposed by the physician?

Yes _1 Yes, partly _2 No _3 because

16. In your opinion, is the patient also responsible for the choice made together with the physician?

Yes _1 Yes, partly _2 No _3 because

17. In your opinion, when should the patient be asked for his informed consent?

Always _1 Never _2 Only in a few cases _3: