Original Article

Model of informed consent in plastic surgery with evaluation and attestation of the transferred information

Consentimento informado em cirurgia plástica: avaliação da transferência de informação

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ABSTRACT
Background: Informed consent is an indispensable tool in the doctor-patient relationship. Aims broadly and unrestrictedly clarify the patient about the procedure, which he/she will be submitted, including all stages of treatment and possible complications. As for the professional who will perform the procedure it's importance goes beyond the precise information to the patient, and also relevance in the legal scope for any grievances that may arise from the committed act. However for the purpose of consent is reached, one should do it in a way in which the physician has the conviction that his informations and explanations about all stages of treatment were in fact understood by the patient. Method: In order to confirm the transfer of information for the informed consent in an objective manner the authors have developed a method using a test administered to the patient after the clarification on the procedure**. Results:** We observed a greater satisfaction by patients regarding explanations because they felt more secure about the treatment's knowledge to be carried out, taking the chance of further clarification if necessary **Conclusions:** This model of consent present itself as evidence that the information about the procedure was conveyed unequivocally, ensuring tranquility and safety for the patient and the professional.
Keywords: Informed Consent. Mental Competency. Surgery, Plastic.

RESUMO
Introdução: O consentimento informado é uma ferramenta indispensável na relação médico-paciente. Tem como objetivo o esclarecimento amplo e irrestrito pelo paciente a respeito do procedimento ao qual será submetido, incluindo todas as etapas do tratamento, bem como as possíveis complicações. Já para o profissional que executará o procedimento, sua importância vai além da informação precisa ao paciente, tendo também relevância no escopo jurídico por eventuais insatisfações que possam advir do ato praticado. Contudo, para que o objetivo do consentimento seja atingido, há de se fazê-lo de uma forma na qual o médico tenha convicção de que suas informações e explicações sobre todas as etapas do tratamento foram de fato compreendidas pelo paciente.

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Método: Com o objetivo de confirmar a transferência de informação do consentimento informado de forma objetiva, os autores desenvolveram um método que utiliza um teste aplicado ao paciente após os esclarecimentos sobre o procedimento. **Resultados:** Foi observada satisfação maior pelos pacientes, pois, estes se sentiram mais seguros quanto ao entendimento das explicações realizadas pelo médico, tendo a chance de novos esclarecimentos caso necessário, eliminando a alegação de desconhecimento do ato a ser praticado, inclusive provando de forma objetiva, na possibilidade de demanda judicial, a transferência inequívoca de informação. **Conclusão:** Este modelo de consentimento é uma opção mais didática no esclarecimento de dúvidas pelos pacientes, além de eliminar a dúvida do profissional em relação à compreensão que o paciente teve de suas explicações sobre o procedimento a ser realizado.
Descritores: Consentimento informado. Competência mental. Cirurgia Plástica.

INTRODUCTION

Informed consent is a process whereby a transfer of adequate information leading to an agreement from the patient concerning the performance of a medical proceeding is assured. It cannot be reduced to the simple act of signing a piece of paper[1].

According to de Sousa: "An adequate conception of the consent should respect the objective value of the human being, taking into consideration the principles of autonomy and freedom that go beyond the inter-subjective contract between doctor-patient."[2] Therefore, the informed consent respects the principle of human dignity stated in Art.1*, subsection III of the Constitution of the Federative Republic of Brazil from 1988.

Since medieval times, doctors have used a document exempting them from future responsibilities in case of adverse effects. These documents were used mainly in Italy, France, and Eastern Europe in the 14th century and are considered the precursors of informed consent, even though their exclusive aim was to protect the doctor[3].

Nowadays, the increase in legal actions related to medical procedures of both low and high complexity has made informed consent compulsory in the doctor-patient relationship. It has become a legal tool that can be used in cases demanding the verification of the doctor's professional liability In some specialties where the legal consensus concerning the requirement of results has yet to be established, such as plastic surgery, this tendency is particularly relevant.

One of the fundamental characteristics of objective informed consent is the adequacy of the information provided to the patient; in particular, there is the need to ensure that the patient understands all of the information transmitted by the doctor even if the patient does not possess any technical knowledge about the procedure. The patient's signature is not enough, if in the future patients are able to allege that they signed without full understanding due to reasons related to lack of technical competency, or because the doctor was not clear enough in the explanations. In those circumstances, the document can lose its utility as a proof, as well as be deprived of its main aim, which is to fully clarify the procedure to the patient. Ultimately, being informed does not necessarily mean to be properly informed. In these cases, the doctor-patient relationship may be compromised due to accusations that the doctor's ethical duty of informing the patient was allegedly omitted.

Usually, the general competence of the patient is considered appropriate if the communication with that patient is normal. For those cases where incompetence is legally established, a legal representative can receive the information and take responsibilities over consent for the procedure[4].

Some studies, however, show that patients who are objectively competent can be ignorant. Frequently, these patients do not understand the process behind informed consent, are not aware of their rights, and have erroneous ideas concerning the results. Only 40% of patients think that informed consent clarifies their concerns towards the procedure[5], though most of the time they do not feel the need for more information on the risks and benefits of the procedure. When asked about the possibility of obtaining additional information, patients replied that they wished they could have had received more information than they actually received[6].

Some Brazilian courts consider cases where there is no adequate information provided to the patient, either due to failure to inform or due to incapacity to understand the information, as negligence and the professional can undergo civil law actions.

Informed consent requires three essential elements: information, free consent, and capacity of understanding and deciding. The latter is the

most difficult to evaluate in an objective manner.

This work presents an objective alternative so that professionals can be sure that patients understand informed consent. It uses a specific test that follows the medical appointment, in which the professional has the duty to explain all aspects of the procedure to be performed.

METHODS

The authors established a protocol for transfer of information that has been used for the past year to aid the adequate understanding of the procedures to be performed, as well as the possible results, complications, evolution, and post-surgery care. This allows the patient to decide after objective confirmation that the entire explanation was truly understood.

During the medical appointment, there is the transfer of all information and clarifications that both the professional and the patient consider relevant and necessaryAfter that, the patient answers a questionnaire named "Test for candidates to plastic surgeryAs the name suggests, the "candidate" will be submitted to an evaluation by means of a "test" that will confirm suitability to decide about being subjected to the procedure.

This questionnaire instructs the patients on its purpose, on the way it should be completed, and on the implications arising from not completing the questionnaire. The questions are presented in the form of statements which the patient answers as correct or incorrect; the statements are general (events that can occur in any surgical procedure) and specific for each type of surgery. A maximum of 20 questions was defined, as these seemed enough to clarify the patients' understanding without becoming too tiring; up to that number, any number of questions can be used, as long as they are considered necessary.

At the end of the questionnaire it is stated that the patient answered the test alone and without any help, and finally a space is saved for the patient's and examiner's signatures.

The test can be conducted by an assistant or by the surgeon themselves in a room where the patient is alone or with their accompanying person. After completion, the questionnaire is corrected and in the case of incorrect answers, the patient meets with the surgeon again for additional clarifications until all doubts are elucidated and the patient is qualified to repeat the test; only when all answers are correct is the patient able to decide willingness to submit to the procedure.

The questionnaires are explained by the surgeon, are specific for each type of procedure, and contain questions that, according to the surgeon, cover aspects of the procedure of which patients should be awareIn appendix I, there is an example of a questionnaire given to patients awaiting breast augmentation surgery.

After surgery, all patients tested were verbally asked about the importance of the informed consent, its capacity to clarify doubts, the negative aspects associated, and any other relevant observations .

RESULTS

This model of informed consent was used from February of 2009 to September of 2011 for all 1,500 patients undergoing surgical procedures in this clinic. All patients reported that the test stimulated a more careful consideration of aspects related to the surgery that might have been underestimated during the medical appointment. Additionally, patients reported that their doubts originated when they had to answer the questions in the questionnaire.This improvement in the transfer of information is also reassuring to the doctor when considering the possibility of legal actions, as the questionnaire helps conclude that the information was effectively transmitted. Moreover, the degree to which the patient understands the procedure and its associated aspects is established, and so procedures are not performed when doubt subsists, and future allegations of lack of information in cases of dissatisfaction, or when the results are not the ones expected, are avoided.

DISCUSSION

Recently, there has been a significant increase in the number of legal actions involving plastic surgery, and in the majority of the cases, patients have alleged lack of knowledge about the final result due to absent or insufficient information. . Information can be defined as the exposing of situations or facts concerning people, things, or relations. Information presumes the existence of a message, a messenger, a recipient, and communication between the messenger and the recipient. The aim is to amplify knowledge in cases where it is insufficient[7].

In Brazilian law, information is a proper right/duty; however, that right/duty is not restricted to information provided to satisfy the wish for knowledge. In fact, information is considered an instrument that prepares for the occurrence of a specific primary interest[8]. As such, the recipient should identify instruments that objectively show the adequacy of the transfer of information.

Informed consent is a fundamental tool in the relationship established between the plastic surgeon and patient, as this is a specialty that deals with expectations. The establishment of post-surgery consensus concerning the quality of the expected results is objectively difficult. The classical descriptive informed consent is used for this purpose; however, patients can still allege their technical incapacity in understanding the contents of the consent.

The model of informed consent presented here is effective in the transfer of information, not only by consolidating the clarification of the patient's doubts related to the results of the surgery, its limitations, the surgical procedure used, and the associated complications, but also by protecting the professional legally in case of a future disagreement. This consent objectively confirms that all doubts were clarified through the questionnaire and the questions it contained, thus eliminating the possibility of alleging lack of information on the subject, or even the accusation that the surgeon had not provided adequate information on a particular aspect of the procedure.

CONCLUSION

This model of informed consent is a more didactic option in the clarifying the doubts of the patients, in addition to eliminating the doubt that the professional may have concerning the fact that the patient may, or may not, have understood the explanations of the procedure to be performed. From the legal point of view, this method excludes allegations of lack of information or lack of understanding of the explanations provided as the answers to the questionnaire are assessed afterwards and, in the case of incorrect answers, new clarifications take place and the questionnaire is repeated.

APPENDIX 1. Consent form

PATIENT _____ DATE __/ __/ __

TEST FOR CANDIDATES TO BREAST AUGMENTATION SURGERY

The aim of this test is to show your surgeon that you have understood the information discussed during your appointment. If you answer any question incorrectly, your surgeon will review the subject and discuss it with you again and you will repeat the test when your surgeon is convinced that you have understood the explanation. In case you repeat the test using the same questionnaire, please sign and write the date next to the answers that you have changed.

All questions are Correct/ Incorrect. Please mark the correct answer only.

1 – Blood clots in the legs or pelvis can be a consequence of any surgical procedure, including this one. They can detach and migrate to the lungs, causing shortness of breath and chest pain, with possibility of death.
Correct ( ) Incorrect ( )

2 – The human body is asymmetric and the asymmetries cannot always be totally corrected with surgery.
Correct ( ) Incorrect ( )

3 – Occasionally, abnormal bleeding can occur post-surgery, which may require draining or another surgery.
Correct ( ) Incorrect ( )

4 – All surgical procedures are life threatening; pre-surgery exams are important and ELIMINATE the risks associated with surgery.
Correct ( ) Incorrect ( )

5 – All prostheses CAN lead to, at any time in life, a phenomenon named capsular contracture or "rejection," which will require the removal and substitution of the implant.
Correct ( ) Incorrect ( )

6 – A seroma is the accumulation of liquid at the site of surgery that can eventually extravasate through the surgical incision or require drainage by puncture in case of large amounts.
Correct ( ) Incorrect ( )

7 – THERE IS NO risk associated with a surgery, independent of the type of surgery.
Correct ( ) Incorrect ( )

8 – THERE ARE NO ways or methods (prophylactic) of preventing 100% of the formation of blood clots that can lead to embolism.
Correct ( ) Incorrect ( )

9 – It is fundamental that you undergo surgery with your desired weight. Post-surgery weight changes (gain or loss) will harm (compromise) the surgery's final result.
Correct ( ) Incorrect ( )

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