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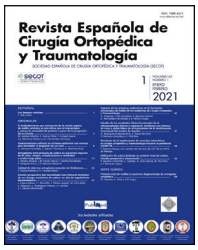

LETTER TO THE EDITOR

[Translated article] Is informed consent just a signature on a piece of paper?

¿El consentimiento informado es solo una firma en un papel?

I don't know if this has happened to you with patients you see in consultations, you explain the surgery to them, they sign an informed consent form, and after the surgery they ask ''Doctor, what did you do to me in the end?'' This is the subject of a recent article published in the European Spine Journal entitled: ''Autonomy with Responsibility: Is informed consent just a signature on a paper?''.[1] The objective of this article was to assess the information that patients undergoing surgery actually receive and assimilate after signing their informed consent.

In current medical practice, informed consent is an ethical requirement established by law. No elective surgical procedure can now be performed without patients signing their informed consent.[2] However, the main finding of this study was that about 40% of patients undergo surgery without having read the informed consent form they sign. This finding is important, because the opportunity to read contracts preserves autonomy. However, it has also been reported that people rarely read what they sign.[1]

Informed consent is based on the 4 basic principles of bioethics: autonomy, non-maleficence, beneficence, and justice, the patient being free to decide whether or not to undergo a given procedure. A patient who signs a consent form must also meet three basic requirements: they must be competent, free from coercion, and well-informed.[3] The informed consent process must therefore ensure that patients are properly informed, that their expectations are managed, and that their autonomy is respected, hence the importance that they read their consent form, and that it is not only explained to them verbally. It is also important to ensure that all participants have a copy of their consent form.

Informed consent should not be confused as offering the clinician protection, or as a contract to ensure that they will not be liable for any complications, after the patient has signed the form.[4] The informed consent process should be seen as an opportunity to forge a therapeutic alliance between patient and clinician. However, if patients do not read their informed consent form, it is unlikely that they will be able to understand what they are agreeing to or be in a position to make an autonomous informed decision, especially in the context of elective surgery.

Another important finding of this study was that 39.1% of patients were unaware of the surgical risks inherent to their procedure. While it is true that some patients would rather trust their surgeon than be informed of all the ways in which their operation could go wrong, trust in the doctor cannot override the patient's right to decide what health risks they are willing to take.[1] Based on the decision of the Montgomery vs. Lanarkshire Health Board case in the United Kingdom, where a lawsuit was brought by Nadine Montgomery, the mother of a child born with cerebral palsy due to a lack of oxygen during delivery.[5] The lawsuit was directed at Lanarkshire Health Board, alleging lack of information about the risks of childbirth. Ms Montgomery argued that, had she received full information about the risks, she would have made a different decision about when and how to give birth, which would have reduced the chances of harm to her child. In 2015, the UK Supreme Court ruled in favor of Ms Montgomery. The court ruled that patients should be regarded as consumers exercising choice and with the ability to decide on their own treatment, and no longer as passive recipients of care. Therefore, it is important to ensure that patients understand the risks inherent to surgical procedures. For it to function correctly, informed consent must be comprehensible, and patient focussed.[1,6]

Only younger and more educated patients would seek additional information about their surgery. We must bear in mind that, in the 21st century, patients can obtain a wide range of information about their disease and its treatment from the Internet. In 1957, when the concept of informed consent was born, it was impossible to expect patients to seek information about their disease management options, as medical information was very restricted and could only be found in medical libraries. Today, however, health problems are approached in a completely different way.[6] Patients today are more involved in the decision-making process than a few decades ago, when they primarily relied on the opinion of their doctor. Today's medicine is no longer paternalistic, and shared decisions between doctor and patient are sought. Therefore, one might ask: what responsibility does the clinician bear in operating on someone who does not

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understand their surgery? And also, what responsibility does the patient bear to seek to understand their surgery and what they are signing on their informed consent form? In the end, good communication requires a good transmitter and a good receiver.

In conclusion, it is important that both clinicians and patients make an effort to improve the informed consent process, which should specify not only the rights but also the responsibilities of each.

Level of evidence

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J.H. Núñez[a,b,*], B. Escudero-Cisneros[a], M.J. Jimenez-Jimenez[a], D. Bosch-García[a]

[a] *Unidad de Columna Vertebral, Servicio de Traumatología y Cirugía Ortopédica, Hospital Universitario de Mutua Terrassa, Terrassa, Barcelona, Spain*
[b] *Unidad de Columna, Artro-Esport, Centro Médico Teknon, Barcelona, Spain*

* Corresponding author.
E-mail address: hassan2803med@gmail.com (J.H. Núñez).