A survey on current practice of informed consent process in surgical specialties of a tertiary teaching hospital center: What is the state of play?

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Research Article

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Abstract

Background

Informed consent is essential in current medical practice and should be a global standard to be sought at all instances when doctors interact with patients. The aim of this study was to evaluate compliance to the guidelines of the Portuguese health entity regarding the correct filling process of informed consent.

Methods

A prospective observational survey was conducted upon arrival of the patient at the operating room of a tertiary teaching hospital center in Portugal, in march 2021, to verify the presence of informed consent in the clinical process. A sample of 202 clinical files was randomly collected.

Results

Only 47% of the patients had the informed consent document in the clinic process and only 45% of the total clinical files had the informed consent signed by the patient. Merely 21.8% of the informed consents respected all the items recommended by the guidelines of the Portugal health entity. Most of the surgical informed consent (SIC) had only basic information and only a lower percentage had reports about the surgical procedure, information regarding the treatment, possible consequences of a missed treatment or complications and possible treatment alternatives. Those results didn't conform to the standard regulations of the Portuguese health guidelines regarding SIC.

Conclusion

Even though improvements in SIC were attained in recent years, our study suggests that the implementation of SIC is still suboptimal in surgical practice. It is important to raise awareness for the obtention of SIC by the healthcare team, because complete information before an invasive procedure is an ethical requirement.

Key Message

- Given the considerable deficiencies in doctors adherence to surgical informed consent, it's necessary to make them aware of the negative impact of these gaps on the overall well-being of their patients.
- Obtaining adequate surgical informed consent is critical to improving communication, increasing patient satisfaction and reducing misunderstandings within the surgical team.
- Create strategies to improve the process of obtaining SIC.

Background

Daily surgical practice is characterized by an increased in the difficulty level of the operative procedures, associated with the increased patients proposed for surgery [1]. Furthermore, currently, the patient tends to demand more extensive information from their doctors [1].

Informed consent

is essential in current medical practice, and should be a global standard to be achieved in all instances when doctors interact with patients [2]. It is common practice to give patients the opportunity to consent to a surgical procedure. In addition, a surgical informed consent process (SIC) is considered a mainstay of standard surgical patient care [1].

The three pillars of SIC include preconditions, information and written consent [1, 3]. Preconditions for proper SIC include the patient's competence and willingness to undergo the procedure; the provided information must be adequate and understandable; finally, the written consent signed by the patient authorizes the procedure to be performed [2].

A properly conducted SIC process is an interactive and structured process, resulting in fully informed patients (or their legal guardian), truly able to make an informed decision considering the risks and benefits of the treatment, alternative treatment options and even postponing surgery or possibility of cancellation. On the other and, an inadequate SIC compromises patient's autonomy, creates risks and potential complications for the patient, reduces his satisfaction and trust in his surgeon and therefore, impairs the doctor-patient relationship. In addition, violation of the SIC may lead to a disciplinary court, assault or battery actions [4].

Surgical informed consent is critical for many reasons including: the acute and particularly vulnerable condition of patients, the urgency of the process, the high technological level of the procedure and the multitude of critical points in the process that can cause serious harm to the patient. Consequently, it becomes more difficulty for the patient to understand all the aspects and decide which ones include considerations of any alternative surgery [5].

Despite major developments in the law, information technology and patient's wishes, the procedural aspects of SIC have not changed sufficiently in the recent decades in most hospitals. Surgeons prepare their patients without adequate individualization, and the quality of information is likely to be very different [1].

This study was held at a tertiary university hospital center, covering different surgical specialties that serve a population of almost half a million and is also a reference hospital center for 2,2 million people. Collectively, 39750 surgeries are performed annually at this hospital center (32475 elective cases and 7275 urgent cases) [6].

The aim of this study was to evaluate compliance to the guidelines of the Portuguese health entity regarding the correct filling process of informed consent forms.

Methods

A prospective observational survey was conducted upon arrival of the patient at the operating theatre of a tertiary teaching hospital center in Portugal, in march 2021, to verify the presence of informed consent in the clinical process.

All methods were carried out in accordance with relevant guideline and regulations of Coimbra University Hospital Center.

Clinical processes of different surgical specialties were randomly selected from patients that met the following inclusions factors: age over 18 years and with mental capability, that were to be subjected to an elective or emergency surgery in the hospital's main operating room. The objective was to verify the presence and filling of the informed consent, and if it followed the guidelines of the health entity. Patients with any medical condition that disallowed giving the informed consented were excluded.

The consent forms were reviewed and the following information were collected: full filling of the consent, patient signature; diagnosis and description of clinical situation; description of the procedure and its nature and goal, potential benefits, complications and risks associated, reliable and scientifically recognized alternative acts/interventions, risk of non-treatment, as recommended in the guidelines of the national health entity.

Statistical analysis:

All data were collected in an online database. Statistical analyses were performed using version 23 SPSS©, Chicago, Illinois, USA. Descriptive statistics were used to analyze the data.

Results

Through the observational analysis, an instrument of internal clinical audit was applied. A sample of 202 clinical files was randomly collected from patients undergoing surgery of different specialties in march 2021. Among those patients, 49% were female and 51% males, with a mean age of 61.7 years +/- 11 years.

Only 47% of the patients had the informed consent forms in the clinic process and 45% of the total clinical files included an informed consent signed by the patient. Only 21.8% of the informed consent forms included all the items recommended by the guidelines of the Portugal health entity (Table 1). The results of this study regarding surgical specialty and elective vs emergency surgery are presented in the Table 2 and 3, respectively.

Table 1
Results of the survey informed consent (n=202).

Information present in the informed consent	Nº processes in compliance	Compliance proceeding (%)	Non-compliance proceedings (%)
Institution identification	95	47	53
Doctor identification	93	46	54
Procedure identification	95	47	53
Diagnostic and description of clinical situation	47	23.3	76.7
Description of the procedure and this nature and goal	47	23.3	76.7
Potential benefits	46	22.7	77.3
Complications and risks associated	47	23.3	76.7
Realible and scientifically recognized alternative acts/interventions	44	21.8	78.2
Risk of non-treatment	44	21.8	78.2
Patient signature	91	45	55

Table 2
Result of the survey by surgical specialty (n=202).

Specialty	Total	SIC Present	SIC Absent
Urology	39	25	14
Plastic	4	4	0
Vascular	12	6	6
Gynecology	16	14	2
Neurosurgery	23	12	11
Orthopedic	32	10	22
General surgery	76	24	52
Total	**202**	**95**	**107**

Table 3
Results of the survey by elective/emergency surgery (n=202)

	Signature SIC	No Signature SIC	Total
Elective surgery	78	90	168
Emergency surgery	13	21	34
Total	**91**	**111**	**202**

Discussion

Informed consent

is a process by which a physician interacts with a patient, allowing him to make an informed decision about the treatment of his illness [5]. In this process, communication plays a central role [7] and helps the physicians to establish a stronger relationship with the patient, which is considered by some to be a prerequisite for well-founded decision making [5]. Furthermore, two distinct but interrelated components characterize SIC: information about the risk, benefits and alternatives and the written consent [5].

Few studies have been carried out in Portugal about the obtainment of the SIC. Their results suggested that the application of informed consent in different health units was very heterogeneous, independently of their size. They also found that even in health units submitted to an international accreditation process, the interpretation of informed consent was very diverse and many practices were frankly deficient in regard to their application [7].

The aim of this project was to assess our conducts regarding informed consenting and then use the results to optimize the entire process. We analyzed the compliance to the process of obtaining the SIC (physical presence, information and signature) and identified considerable deficiencies in that process. Most of the SIC only included basic information (identification of the procedure, doctor/institution and patient's signature). Only a small percentage of the SIC mentioned important information regarding the treatment, such as prognosis, consequences of a missed treatment, possible complications and treatment alternatives. Those results didn't conform to the standard regulations of Portugal's health authorities regarding SIC.

A probable cause for this is that in our hospital culture, physicians consider SIC to be a mere legal formality, while more importance is given to oral information. Other possible reason is the short period of time available for consultation and discussion of the clinical situation.

Difficulties and limitations when obtaining the SIC are described, for instance the noise that can be established in communication. This obstacle can be originated from the lack of time to discuss the disease with the patient, which can easily be seen in the face of productivity pressure made in health structures. The relationship of authority and fear that can be established between doctor and patient, in

view of social contexts, that overestimate the role of doctors in society, and that can be transposed to the clinical relationship, is other obstacle in this process. The insufficient development of communication skills throughout the process of training doctors; the existence of language barriers between doctors and patients and the occurrence of stressful situations can create difficulties in communication [7].

The results of this study imply that there is a significant risk of litigation due to our current practice. Studies show that most legal cases are not due to treatment failures but due to poor communication and discrepancies between expected and achieved results (55%) and incorrect information (30%) are the main reasons for patient complaints. Contrary to what would be expect, most complaints are generated after smallr elective operations (70%) [1].

According to Portuguese law, the duty to inform is provided in several documents, such as the Basic Health Law: “Base XIV, nº 1 - Users have the right to be informed about their situation, possible treatment alternatives and the probable evolution of his/her condition” and in article nº 157 of the Penal Code: “For the purposes of the previous article, consent is only effective when the patient has been properly informed about the diagnosis and the nature, scope and possible consequences of the intervention or treatment (...) ” [7]. In addition, the general health entity rule nº 015/2013 serves as a guideline [8]. In this document, written informed consent is not mandatory for most of the surgical procedures. Although there is no legal requirement in a specific way for the effectiveness of consent, its formalization appears, however, as the only mean of realizing the right to clarification, particularly when medical interventions are involved, such as diagnostic or surgical procedures that pose a serious risk to the patient's life or health. The existence of a form seems to be the simplest, clearest and easiest way to provide and obtain consent [7].

In legal terms, the existence of excellent quality forms does not ensure that procedures associated with the filling process will occur properly. Several foreign court decisions are known to have denied legal validity to these documents, because they were convinced that the signature had been reduced to a simple formality, lacking real information. The best way of demonstrate that the doctrine of informed consent is implanted in the Hospital, is the institution adopt strategies that demonstrates a structured organization with established protocols for obtaining consent.

It is important to share the results of this audit with the surgical team to raise awareness of current failures in clinical practices and thereby to create strategies to modify and improve the obtaining of SIC.

Different strategies must be carried out as team training and development of program that training and improved non-technical skills [1, 9]. Effective communication is recognized as a core non-technical skill. It is crucial for delivering high-quality healthcare. The awareness of the ethical aspects of surgical practice that involve non-technical skills stimulated the increase of the focus on education of this skills, such as communication and interpersonal relationships while continuing to strive for technical excellence of procedures and patient care [9].

Other strategy maybe it’s the use an integrated interactive computer program to fill the recommended items of the informed consent form, but there is some resistance because of equipment issues and time consuming in consult [1]. Currently, for simplicity, it is available an online model type, by the Portuguese Health Authority, with editable fields for including general and personalized information.

Another strategy will be for the surgical services to organize and create a database of pre-elaborated surgical consents for the different surgeries, in order to make it faster to fill in the different items on the form. However, this strategy may jeopardize the individualization of SIC, so it is important don’t forget to individualize the consent for each patient when filling out the form.

The creation of information leaflets that explain the surgical acts with the availability of support numbers, may allow patients to reflect on the clinical situation without the pressure of the doctor's presence and the short consultation time and make a more thoughtful decision, always having a contact to clarify any doubts that may arise.

Despite the fact that the majority of the population undergoing surgery is of a high age, it will be important to develop strategies that also reach a younger population, with greater ease in obtaining information. It is imperative to adapt our clinical practice to the new information technologies, making information available through new communication channels (ex: apps, podcast, among others).

One last suggestion would be to reinforce the existence of a checklist, that prevent the arrival of patients to the operation room without the informed consent filled in and signed.

The limitations of the study were the patient’s sample, that was collected randomly rather than the whole population being studied over an extended period of time. In addition, this has been collected data of different surgical specialty which represented a mixed cohort of patient of different ages, diagnosis and pathologies.

Conclusions

Even though improvements in SIC were attained in recent years, like other studies, our study suggests that the implementation of SIC is still suboptimal in surgical practice. It is important to create awareness for the obtention of SIC by the health professional team. Complete information before an invasive procedure is an ethical requirement, even as a well-informed patient is generally more satisfied.

Declarations

Ethical approval and consent to participate: Not applicable.

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Availability of data and materials: The dataset supporting the conclusions of this study is available from the corresponding author upon request at vet.anavieira@gmail.com

Authors' contributions: AV and CI were responsible for the study conception and design. AV, CI, SS and MA participated heavily in data collection, data analysis/interpretation and writing the manuscript. CF participated in critical revision/final approval of the submitted manuscript. All the authors read and approved the final manuscript.

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