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INFORMED CONSENT IN ANESTHESIOLOGY: AN EXPLORATORY STUDY

Bárbara Fontes[1], Sílvia Marina[2], Diana Andrade[3], Sofia Dias[3], Miguel Ricou[2]

Abstract: In the literature Informed consent (IC) assumptions is well established. However, the different stages and the conditions under which the IC for anesthetic practices is obtained, is scarce. The aim of the present study is to explore the phases and conditions of IC in anesthesiology. Anonymized clinical records of 325 patients submitted to anesthetic procedures at the Institute of Oncology of Porto were analyzed. A total agreement between the anesthetic techniques established in the IC and those performed, was reach with 270 patients. The importance of IC in clinical practice is discussed and an ideal process for IC is argued.

Keywords: informed consent, ethics, anesthesiology, anesthesia techniques, exploratory study

El consentimiento informado en anestesiología: un estudio exploratorio

Resumen: El consentimiento informado (CI) está bien establecido en la literatura. Sin embargo, la información sobre las diferentes fases y condiciones en las que se obtiene el CI para las prácticas anestésicas es escasa. El objetivo del presente estudio es explorar las fases y condiciones de obtención de la CI en anestesiología. Se analizaron las historias clínicas anónimas de 325 pacientes sometidos a procedimientos anestésicos en el Instituto de Oncología de Oporto. Se alcanzó una concordancia total entre las técnicas de anestesia establecidas en el CI y las realizadas con 270 pacientes. Se defiende la importancia del CI en la práctica clínica y se discute un proceso ideal para obtenerlo.

Palabras clave: consentimiento informado, ética, anestesiología, técnicas anestésicas, estudio exploratorio

Consentimento informado em anestesiologia: um estudo exploratório

Resumo: Na literatura o Consentimento Informado (CI) é bem estabelecido. Contudo, a informação sobre as diferentes fases e as condições em que o CI para práticas anestésicas é obtido, é escassa. O objetivo do presente estudo é explorar as fases e condições da obtenção do CI em anestesiologia. Foram analisados os registos clínicos anónimos de 325 pacientes submetidos a procedimentos anestésicos no Instituto de Oncologia do Porto. Foi alcançado um acordo total entre as técnicas anestésicas estabelecidas no CI e as realizadas, com 270 pacientes. A importância do CI na prática clínica é defendida e discute-se um processo ideal para a obtenção do CI.

Palavras-chave: consentimento informado, ética, anestesiologia, técnicas anestésicas, estudo exploratório

[1] Department of Community Medicine, Information and Decision in Health of the Faculty of Medicine of the University of Porto, Porto, Portugal.

[2] Department of Community Medicine, Information and Decision in Health of the Faculty of Medicine of the University of Porto, Porto, Portugal; Center for Health Technology and Services Research, Porto, Portugal.
Correspondence: mricou@med.up.pt

[3] Portuguese Institute for Oncology of Porto, Porto, Portugal.

Informed consent (IC), in general, is the accepted mechanism for sharing information regarding the therapeutic proposals appropriate to the patient*(1)*. Thus, a doctor-patient interaction is proposed, recognizing the latter's ability to make decisions about his/her health*(3,4)*. The IC results from a free and enlightened weighting - based on the consciousness and values of the patient - after clarification about the objectives and nature of the intervention, as well as the associated risks and benefits*(5)*. It is important to note that IC is only valid if the patient shows discernment and can be revoked at any time*(4,6)*. In what concerns anesthetic acts, the IC must be obtained by the anesthesiologist. Just this professional will have the necessary competence and knowledge to provide the necessary clarifications about the anesthetic plan*(7,8)*.

The IC intends to promote the doctor-patient relationship and not to be a signature that meets legal requirements at a specific moment in time*(1,6)*. However, the IC does not seem to be being valued as it should be*(9)*. In fact, almost all patients agree with the recommendations proposed by doctors, giving little relevance to the acts of obtaining and implementing the IC*(3,10)*. This lower value can arise from the IC being sometimes interpreted as a mere signature of a paper, and not as an opportunity to build a relationship of trust between doctor and patient.

It seems to be of undoubted importance to provide clear and objective information to the patient regarding the possible therapeutic proposals. However, many doctors report difficulties in sharing and exposing information, even though they are confident about the information that should be transmitted*(1,8)*. In other words, the biggest problem seems to be in the transposition of this information to the doctor-patient relationship. In fact, the way information is given is important for the patient's understanding and consequent decision making. Besides information, to make a decision the patient must be confident that the doctor will welcome his opinions/decisions*(10,12,13)*.

Considering the importance of the IC, it is necessary to look for better ways to implement it and to make professionals aware of its importance in the success of their interventions. This study intends to contribute to this purpose.

Obtaining informed consent in anesthesia is well established*(4)*, since the self-determination of anesthesiology as a differentiated specialty, between 1949 and 1955 (14). Before that, the anesthetic practice was considered implicit in relation to the surgical practice*(3,7,11)*. Since the risks inherent to the anesthetic practice are not neglectable, this option proved to be wrong*(15)*.

In the literature, there are several studies that have been carried out within the IC for anaesthetic practices*(2,8,15,16)*. There are some difficulties in establishing the type and volume of information to be transmitted*(8)*, and the ideal time to obtain consent*(1)*. Very often, the first meeting between the anesthesiologist and the patient is on the day of surgery. The overload of the National Health System (NHS) and the lack of time of professionals appear to be the main reasons for that*(1,7)*. This can hinder the construction of any kind of relationship. Informed consent on anesthetic procedures should be obtained in advance*(1)*, offering the patient enough time for the organization and exposure of questions and/or doubts about what has been proposed(8,15). Thus, although understandable, it cannot be defensible to obtain the IC in the surgery room, that is, on the very day of surgery*(8,15)*. Moreover, the professional who obtains the IC is not always the same one who will perform the anesthetic technique (1). In these cases, the anesthesiologist who obtains the IC may not emphasize certain points that the one who will perform the technique would consider as essential and vice versa*(17)*. This could hinder the procedure and undermine the relationship of trust established with the IC.

It seems to be common practice to obtain a broad IC*(18)* allowing greater flexibility in the performance of the anesthesiologist. For example, if it is necessary to convert a laparoscopy into an open surgery during the intervention*(3)*, due to the occurrence of complications not expected before the surgery, a broad IC can be a better solution than a presumed consent*(4)*. In this way, there will be the opportunity to discuss all possibilities with the patient and thus obtain the corresponding IC. Nevertheless, there seems to be a generalization of the broad consents that may be connected to

obtaining the IC by another anesthesiologist than the one who will perform the intervention*(1)*.

Given the importance of IC in anesthetic practices and considering the literature in this field, we felt the need to deepen the knowledge about the process of obtaining IC in anesthesiology. The aim of this study is to explore the process of obtaining IC, with a view to defining what would be an ideal process of obtaining IC in anesthetic practices.

Materials and Methods

Participants

The study sample consists of 325 patients undergoing anesthetic procedures at the Instituto Português de Oncologia (IPO) in Oporto. The age of the patients is between 21 and 95 years (M=62.3; SD=13.4). Most patients are female (n=196), and the remaining 129 are male. Of the 325 patients, 322 underwent a pre-anesthetic consultation where informed consent was obtained. The remain 3 patients gave consent outside the consultation for the anesthetic procedures.

Materials and procedures

The data were obtained from the clinical records of all patients submitted to at least one anesthetic technique of any kind at the IPO in Oporto during one month of the last quarter of 2019. These data were collected from the clinical information registration platform Mural-D, which was implemented by Glintt at the Oporto IPO. The data were collected by anesthesiologists of the IPO, who were collaborators of this research, after receiving approval of the respective ethics committee. The data were provided for analysis duly anonymised.

Considering the purposes of the study, a protocol was defined for the collection of relevant data upon obtaining IC for anesthetic acts. The data collected were those regarding (a) age; (b) gender; (c) surgical procedure; (d) existence of preanesthesia consultation; (e) anesthetic technique enshrined in IC coincides with the anesthetic technique implemented at the time of the intervention; (f) moment of obtaining IC and the (g) anesthesiologist who obtained IC is the one who carried out the anesthetic technique.

Subsequently, the data were categorised and input into a database built for this purpose using the SPSS statistics software.

All the ethical procedures have been performed in accordance with Helsinki Declaration. The anonymisation of data, were accomplished, and it was not possible to reconstruct the path that allows the identification of the holder. The study protocol was submitted to the Ethics Commitee of the IPOPorto (Instituto Português de Oncologia do Porto FG, EPE), and a favourable opinion was obtained from it.

Data analysis

Descriptive statistical analyses were performed, including measures of central tendency (mean, mode, median) and measures of dispersion (minimum, maximum and standard deviation) in the case of the variable age as well as frequencies for the remaining variables.

In this study, the variables are ordinal or nominal, so the relationship between them was analyzed through the Chi-square independence test, performing a crossover between the variables. Specifically, and taking into account one of the purposes of this study, the relationship between the variables was analyzed for the anesthesiologist who obtained the IC is the same one who performed the anesthetic technique (yes, no) and the variable anesthetic technique established in the IC coinciding with the anesthetic technique implemented (does not coincide, partially coincides, totally coincides).

We also considered the value of the Fisher test as well as the analysis of the standardized adjusted residues between the observed values and the expected values of the contingency table.

The analyses were performed with the SPSS Statistics Software (v.25; IBM SPSS), considering statistically significance as p-value values lower or equal to 0.05.

Results

Table 1 shows the distribution of the anesthetic techniques established in the IC for the 325 patients. Only General Anesthesia (GA), was proposed for 213 patients (65.5%). In addition to GA, other possible anesthetic techniques were considered when the IC was obtained. These techniques were coded as described: GA+/epidural, in which in addition to the consent for GA, the possible epidural blockage (n = 65; 20%) is added, i.e., GA with (+) or without (-) epidural blockage. GA+/-TAP (n = 1; 0.3%), in which in addition to the consent for GA, the possible transversus abdominis plane (TAP) is added, that is, GA with (+) or without (-) transversus abdominis plane. With 22 patients (6.8%) the IC was obtained for GA+/-LR, i.e., GA with (+) or without (-) locoregional blockage (LR). With 3 patients (0.9%), the established IC techniques included GA+/-SA, i.e., one GA with (+) or without (-) spinal anesthesia. With 6 patients (1.8%) the IC was obtained for GA or SA, that is, only one of these - or GA, or SA - could be performed. In the same previous premise, with 14 patients (4.3%) the IC was obtained for AG or LR, i.e. only one of the techniques - or AG, or LR - was performed. Sedation was considered for only 1 patient (0.3%).

The agreement between the anesthetic techniques for which IC was obtained and the anesthetic techniques performed, it was found that with 270 patients (83.3%) the congruence was total, i.e., the technique established in IC was the same one that was performed (Table 2). In 52 patients (16%), the anesthetic techniques for which the IC was obtained partially coincide with the one that was implemented. In 3 patients (0.9%), there was no agreement between the anesthetic techniques performed and those established in the IC (Table 2).

Table 3 presents the results in relation to the anesthesiologist who obtained the IC have been the same who implemented the anesthetic technique. The anesthesiologist who obtained the IC with 29 patients (8.9%) was the one who performed the technique. In most cases (90.8%), the anesthesiologist who performed the anesthetic is different from that one who obtained the IC (Table 3).

Taking into account the potential moments in time to obtain IC, it was found that IC was obtained with 324 patients (99.7%) in the day before surgery. With 1 patient (0.3%) was obtained in the same day of surgery (Table 4).

The relationship between the anesthetic technique established in the IC coinciding with the anesthetic technique implemented (does not coincide, partially coincides, totally coincides) and the the anesthesiologist is the same or not, was no statistically significant (X^2 = 0.08; p = 0.77) (Table 5). The absence of significance is confirmed by

Table 1. Frequency of anaesthetic techniques enshrined in informed consent

Enshrined technique	n	%
GA	213	65.5
GA+/-Epidural	65	20
GA+/-TAP	1	0.3
GA+/-LR	22	6.8
GA+/-SA	3	0.9
GA or SA	6	1.8
GA or LR	14	4.3
Sedation	1	0.3
Total	325	100

Note: GA, general anesthesia; TAP, transversus abdominis plane blockage; LR, locoregional blockage; SA, spinal anesthesia.

Table 2. Concordance between anaesthetic techniques enshrined in informed consent and anaesthetic techniques performed

Anesthetic technique performed coincides with the one enshrined in the IC	n	%
Coincide totally	270	83.1
Coincide partially	52	16.0
No coincide	3	0.9
Total	325	100

Table 3. Information about the anesthesiologist who obtained the informed consent and the one who performed the anesthetic technique

The anesthesiology who obtained IC was the same who performed technique	n	%
Yes	29	8.9
No	295	90.8

Table 4. Moments in the time to obtain IC

Time of obtaining IC	n	%
The day before	324	99.7
On the same day	1	0.3
Total	325	100

Table 5. Analysis of relationship between the variables technique coincides with that obtained in the IC and anesthesiologist be the same: Pearson Chi-Square

Technique coincides with that obtained in the IC* Anesthesiologist obtained IC and performed technique was the same	p
Pearson Chi-Square (X^2) .08	.774
Fisher's Exact Test	.51

Fisher's exact test (p = 0.51).

Discussion

In this study, the IC for anesthetic acts seems to be well established*(6)*. In a society increasingly autonomous in its choices, it is a practice that has been assumed as desirable and mandatory. In this study, all anesthetic techniques had an underlying IC.

The majority of patients in this sample (65.5%) consented to a GA, which is in line with what would be expected. GA is usually requested in the IC, either for prevention and/or safety in anesthetic plans*(19)*. Although it may not be the first option, it is likely to be used if the clinical situation of the patient requires it. Regarding the other patients in this sample, they were distributed by broader anesthetic proposals, allowing greater flexibility, considering that the proposals may or may not be performed in their entirety. GAs were proposed to twenty percent of the participants, with or without epidural blockage, depending on

the need (GA+/-Epidural). Similarly, with 8% of patients, three more possible proposals were considered: GA+/-TAP, GA+/LR and GA+/-SA. Finally, with 6.1% of the patients, the following anesthetic techniques were proposed in the IC: GA or SA (1.8%) and GA or LR (4.3%), in which the implementation of one excluded the other. It seems that there is some excess of pragmatism in ICs, since it is intended to be broad, allowing the anesthesiologist more freedom during the procedure. It cannot be said that obtaining a broad IC is by principle wrong. In fact, if the motivations for this greater scope are discussed with the patients, the risk is mitigated and related to the complexity of the proposals, which may diminish the understanding of the consent and decrease the confidence in the procedure. It seems clear simpler ICs correspond with greater potential for understanding by the patient. It should be clear that this is the main purpose of informed consent, regardless of compliance with a legal assumption. A broad IC facilitates the fulfillment of the legal goal of the IC, since it decreases the probability of performing a medical act without consent, but it can make it difficult for the patient to understand the importance and relevance of therapeutic proposals. The basis of IC is the necessary anesthetic proposal and the result of an active consideration of all possible proposals, aiming at a balance between the risks and benefits of the patient's ultimate condition. It will be important to actively involve the patient in the decision about the intervention, which may increase their satisfaction*(17)*. Consent in the face of uncertainty may call into question the principles that the IC intends to safeguard.

Professionals should reflect on two options, neither of which is ideal: they may obtain a broader IC, knowing that they may be penalizing the patient's understanding, or they may obtain a more specific IC and rescue themselves from the presumption of consent in situations that are forced to change the anesthetic technique. These possibilities may, or should, be discussed with patients, and the choice of one or the other should depend on the greater or lesser probability of the initially proposed technique having to be changed.

In this sample, however, a high congruence was obtained between the technique proposed in the IC and that which was actually performed. In fact, in 83.1% of the participants, there was total congruence in this matter, which shows concern for the accuracy in the process of obtaining the IC. Nevertheless, in 16% of the patients, the congruence between the practice enshrined in the IC and the one performed was partial, that is, what was proposed in the IC to the patient was not fully performed. In these cases, a broad anesthetic proposal was started, but only a portion of the proposed techniques was applied.

It may also be wondered whether the obtaining of a broad IC results from the need to guarantee consent for any of the anaesthetic techniques that may be applied or whether the fact that the anaesthesiologist who obtained the IC is not always the same one who will apply the procedure also contributes.

One of the most relevant results obtained in this study was that the anesthesiologist who obtained the IC was, for the most part, not the same one who performed the technique. In 90.8% of the patients, the professional involved in obtaining IC was different from the one who performed the anesthetic technique.

It is known well in advance that the patient-doctor relationship represents the basis of trust for making decisions about the procedures necessary for the patient. The fact that professionals are different may limit the scope for building a positive relationship. In other words, the relationship of trust built up in the pre-anesthetic visit, where informed consent is obtained, may be compromised when the patient meets a different professional on the day of the intervention. In fact, one of the great goals of obtaining IC in advance is to allow the patient to have time to reflect about what was proposed to him/her*(4)*, typically being given on the day before the procedure in this study (99.8% of the cases). Doubts may arise later, so the patient may question the professional before the procedure. The fact that the doctor is another person may limit the possibility of the patient asking the clinician in this regard. This may limit the patient's confidence in the procedure, with possible implications for patient satisfaction*(18)*.

Considering the high number of consents obtained by another professional than the anaesthe-

siologist applying the technique, the question has arisen as to whether this could contribute to an increase in the number of broad consents. It was therefore attempted to establish whether there was a connection between the existence of a partial compliance with the consent and change of the professional. This means that if the anesthesiologist did not change, there would be a greater probability of full compliance with the IC. If so, one of the explanations for the existence of broad consents could be to give a maneuvering action to the doctor who will perform the intervention. In fact, it is natural that the technique that the anesthesiologist of the pre-anesthetic visit believes to be the most appropriate may differ from that chosen by the anesthesiologist who will perform the procedure. However, this relationship has not turned out to be positive, so there seems to be no connection between these two variables. In this sense, it cannot be concluded that more wide-ranging consents stem from the fact that, in most cases, the anaesthesiologist who obtains the consent is different from the one who carries out the procedure. In reality, the percentage of broad consents is not that high, even though we have not found data in the literature that support a reference value for this type of procedure in anesthesiology. Upcoming studies will be useful to gage this dimension.

The authors' opinion that it would be important that the anesthesiologist who performs the pre-anesthetic evaluation where the IC is obtained be the same one to perform the procedure, according to the variables already discussed throughout this article. Accepting that the motivations for this reality may be based on the need to organize the service, it is clear that this reality will be preferable to the non-existence of IC or its collection by the surgeon doctor or nurses involved in the surgical process*(3,9)*.

Finally, with 3 patients, there was no congruence between the techniques established in the IC and those performed. Although they constitute a small percentage (0.3%), these 3 cases reveal that the patient consented to a different procedure from the one that was performed. This situation is hard to justify in the light of the principle of respect for patient autonomy*(20)*. It is possible that, in these cases, a totally unexpected situation may have arisen and that, according with the beneficence principle, the doctor may have presumed the patient's consent, which at the moment they are incapable of deciding, in conformity with the Code of Ethics of the Portuguese Medical Association*(6)*.

In a descriptive and an exploratory approach to IC in anesthetic intervention, the present study highlights the importance to ensure the elements recommended to obtain the IC in professional practice. As discussed in this work, the absence of these premises may act as a barrier to the establishment of a relationship of trust with the patient, which is fundamental for the whole process of obtaining IC.

Some suggestions for further investigation are considered. A study at the national level would be relevant to provide a country-wide overview in Portugal. This could be useful to foster the development of strategies for improving the quality of services. Similarly, it would be interesting to understand the best reference practices for obtaining broad consents in anaesthesiology and their relationship to the presumed consent alternative, which does not appear to be common practice in this study. Further research focusing on the perceptions of anaesthesiologists in identifying needs and barriers to the process of obtaining IC would also be useful to develop strategies to enhance an increasingly clarified and therefore free consent.

Conclusion

The results of this study indicate that there is a concern to obtain IC in the observed cases, with a total congruence between what is enshrined in the IC and what is effectively accomplished. Even in the circumstances in which obtaining the IC and the implementation of the technique was carried out by different doctors, there was no greater inconsistency between what was defined and what was intervened. It was found that the IC obtained for the anesthetic techniques is often broad, with several anesthetic proposals being included at the time of obtaining the IC. Therefore, the technique implemented will have a high probability of being included in those established in the IC. The main rationale seems to avoid presumed consent for anaesthetic acts. While the presence of different physicians in obtaining IC and in performing the procedure does not seem to cause major

inconsistencies in the techniques applied, it may compromise the relationship of trust between the physician and patient, which is a fundamental purpose of obtaining IC.

In short, ideally, the process of obtaining IC should be as objective as possible in order to promote the patient's understanding. For that, a minimum period of time should be taken in order to ensure a period of reflection. Considering the assumptions explored about the relationship of trust between the patient and doctor, it would be favorable for the implementation of the technique to be performed by the physician that obtains the IC.

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Not applied

Declaration of Conflicting Interests

The authors declare that there is no conflict of interest.

Data Availability Statement

The authors confirm that the data supporting the findings of this study are available within the article.

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