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Informed consent in robotic surgery: quality of information and patient perception

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Abstract: Introduction. Obtaining a valid informed consent in the medical and surgical field is a long debated issue in the literature. In robotic surgery we believe in the necessity to follow three arrangements to make the informed consent more complete.

Material and methods This study presents correlations and descriptions based on forensic medicine concepts research, literature review, and the proposal of an integration in the classic concept of informed consent.

Conclusion. In robotic surgery we believe in the necessity to follow three arrangements to make the IC more complete. Integrate the information already present in the informed consent with data on the surgeon's experience in RS, the number of procedures of the department and the regional map of expertises by procedure.

Keywords: Informed consent, Surgery, Robotic surgery

Highlights

- Obtaining a valid informed consent in the medical and surgical field is a long debated issue in the literature
- Considering patients, some factors affect the IC comprehension like: demographic and familiar context, socio-economical aspects, clinical history and listening attitude
- The advent of robotic surgery confronted all surgical specialists with the problem of the old consents suitability
- In robotic surgery we believe in the necessity to follow three arrangements to make the informated consent more complete with data on the surgeon's experience in RS, the number of procedures of the department and the regional map of expertises by procedure

Abbreviations

IC: Informed Consent
RS: Robotic Surgery
LC: Learning Curve
EBM: Evidence Based Medicine
RT: Robotic Technique

1 Introduction

Obtaining a valid informed consent in the medical and surgical field is a long debated issue in the literature. In daily clinical practice surgeons have to ensure to their patients maximum understanding of the upcoming procedures.

Over the years, technology development and the creation of new high-complexity aids, made the correct obtaining of IC more difficult for two reasons: the intrinsic complexity of surgery, and the difficulty in explaining it in a comprehensible form for the patient.

The advent of robotic surgery confronted all surgical specialists with the problem of the old consents suitability. Despite the fact that surgical patients are indirectly protected by clinical trials and strict ethical rules, surgical specialists remain concerned.

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Gynaecologists were the first to write about the issue; then the problem was discussed by cardiac surgeons and urologists, and eventually by digestive surgeons. International surgical societies involved in the robotic field suggested an open discussion with the patient about technical innovations of the procedures, but they didn't define which are the essential aspects to explain so that an IC can be considered valid [1].

This study presents correlations and descriptions based on forensic medicine concepts research, literature review, and the proposal of an integration in the classic concept of IC. The aim is to evaluate the need for introducing a specific IC for complex high-technology surgery, like robotic, to participate in the "informed debate" on the role of informative standards in surgery.

2 The informed consent

The concept of IC boasts a long history. Its origins lie at the ancient Egyptians times, when doctors believed that their medicines had to benefit their patients while not being detrimental. The current concept of IC developed on this basic principle: the fundamental element of doctor-patient relationship is based on the patient's free choice to undergo the proposed medical procedure. Procedures themselves must follow the international societies standards of care.

Considering patients, some factors affect the IC comprehension like: demographic and familiar context, socio-economical aspects, clinical history and listening attitude [2,3].

According to recent literature data, however, patients show a poor comprehension of ICs, regardless their different characteristics. They try to focus on the diagnosis and on the understanding of the organ that will be affected by the procedure. In addition, not every patient looks for the same degree of detail, so the surgeon should calibrate the information in accordance to the request [4].

More data from literature show that patients require the doctor to be informed about all possible complications (which is by the way impossible) but it is shown that in the end he doesn't use this information to decide whether or not to undergo the procedure, but just to have a better idea of what to expect [5].

Considering the surgeon, we know that the setting in which the discussion takes place has a major influence, from the moment when IC is obtained, to who the explaining doctor is.

This aspect is covered in Hagihara's 2006 paper [6], indicating as factors influencing patients information perception: doctor's age, gender and years of experience, duration of the explanation, exposition clarity and the training level (estimated by patients sensations) of the doctor.

3 Robotic surgery

Minimal invasive robot-assisted surgery enters the history of surgery in the mid 2000s and experienced a rapid growth in the last decade. Data form 2010 estimate that only from 2007 to 2009 the number of Da Vinci robotic Systems sold has nearly doubled, from 800 to more than 1400 only in the United States, and a growth from 200 to 400 outside the US. Numbers are still increasing.

The first surgeons using this system were Gynaecologists and Urologists. As regards digestive surgery, robotic technology application had a substantial growth in the last 5 years, reaching a prominent position for the treatment of benign and malignant gastrointestinal pathologies [7].

As a result of the advent of a real technologic revolution, we are witnessing a remodelling of both surgical and legal aspects.

4 Robotic concepts and legal implications

4.1 Learning curve and definition of expert robotic surgeon

4.1.1 General considerations

The two main issues still characterising robotic surgery, in all disciplines, are the absence of a defined learning curve (LC) and of an agreement on the adequate certification needed to be considered robotic surgeons.

The LC for a given intervention is the number of procedures that a surgeon has to perform to reach an acceptable level of error in line with the literature. Once this number is reached, the surgeon can be considered an expert in that procedure.

Robotic surgery LC takes into account another aspect: the proper use of the machine. Unlike the concept of LC in laparoscopic surgery, that maintains intrinsic the knowledge of laparoscopic instruments, in robotic surgery the

experience of the surgeon must be tested also as regards fluency in devices use, knowledge of instruments, robotic units mobilization and capability in resolving technical problems of the system.

This need emerged when some literature reviews defined the lack of technical competence as one of the major causes of mistakes in high technology based surgery [8].

Food and Drugs Administration defines as a minimal standard to call themselves a robotic surgeon a 1-2 days course with the use of the robotic platform simulator, achieving a diploma [9].

Other authors declare that to obtain this certification, beyond the basic course, the performance of at least 4 surgeries as first operator at the console is required.

Despite these indications, however, each surgical speciality tends to suggest different LCs; the process is also influenced by surgeons previous abilities, therefore it's not easy to standardise an universally recognised number of procedures [10].

4.1.2 Legal implications

With the IC surgeons should be able to inform patients about the minimum number of procedures a surgeon should perform to avoid errors in an acceptable way. In robotic surgery this is non yet possible. During the IC obtaining the patient should be informed about this concept, even at the expense of a more significant concern of the patient himself. In RS, moreover, the knowledge of the procedure should be integrated with the knowledge of the system.

To ensure the proper development of RT maintaining as ultimate goal patients safety, international surgical societies established three fundamental concepts: the role of the simulator, precepting and proctoring concepts.

4.2 The importance of robotic simulator

Simulators maintain the relevance that it had in laparoscopic surgery, but its usage becomes easier because it comes down to a software applicable to the robotic console. Every operative robot can therefore become a simulator when they are unused. This is essential because it allows a surgeon to make mistakes without any consequence on a patient. Moreover, having the opportunity to use the same system used in the operating room, surgeons acquire the complete knowledge of instruments, perspective and surgical setting.

During the IC acquisition, directly or by information brochures, patients should be informed about pre-operative preparation through simulations.

4.3 Definition and role of preceptor and proctor

4.3.1 General considerations

In an interesting Zorn et al. 2009 paper, the definition and role of the two supervisors in robotic surgery is established: "preceptor" and "proctor". The first one is the teacher responsible for the operation; preceptors responsibly observe the procedure, give advice and must intervene if the operator gestures are inadequate or the patient is generally at risk.

The second one, the *proctor*, validates a surgeon competence; he gives to the hospital recommendations about the surgeon's results based on his observation in the operating room. Basing on these indications the hospital will recommend to the surgeon a preceptor, or will allow privileges or restrictions about procedures a surgeon can or can not perform [11]. According to US authors a distinction between these two figures is essential, because a different role during the operation leads to a different role in the procedures legal responsibilities.

While the proctor, as a pure observer, maintains a position that is free of direct responsibilities, the preceptor is directly involved in all the decision making process during the procedure, being the surgical tutor.

Lastly, the proctor should be associated to every robotic surgeon, expert and non-expert, to test the evolution of their competence, while the preceptor is only associated to non-expert surgeons until they complete their LC.

When problems of a classic IC acquisition add up to those arising from new technologies introduction and new figures involved in the procedure, it creates an instability in information with relevant legal implications.

4.3.2 Legal implications

As we said, the Tutor or Preceptor is directly involved in robotic surgery legal aspects. But a question arises about the real Proctor's involvement for a complication during surgery: is he really exempted from all responsibility? There is no clear answer to this question but in the literature we find some examples where in lawsuits Proctors had no legal implications.

In the literature is also emphasised Proctors heterogeneity, due to non restrictive requisites to gain this role (20 procedures performed), EBM rules laid down by the machine manufacturers [12].

The definition of Preceptor is easier to understand but is not regulated by any written rule. He is the typical expert surgeon teaching a less expert colleague a procedure.

So despite the first operator is responsible and shall be accountable for his actions, the tutor remains the first responsible for the procedure. The transfer of responsibility is based on the same concept as some legal causes where the surgeon performing an operation for a neoplastic lesion, diagnosed by biopsy but not found in the final post-operative histology, is cleared to the detriment of the pathologist that signed the initial diagnosis [13].

In fact procedures responsibility (like diagnosis responsibility in the pathologists case) is borne by the person that can change the course of the procedure thanks to his experience.

During the IC obtaining for robotic surgery, therefore, the presence of Preceptor and Proctor should be indicated and responsibilities must be made clear for both surgeon and patient .

5 Legal concepts and implications in robotic surgery

5.1 Negligence and causal link

5.1.1 General considerations

For a doctor to be accused of negligence 4 elements of guilt must be proven: non-compliance to duty of care, deviation from standards of care, lesion evidence, causal link between the lesion and the lack of care [14].

So the lesion on the patient has to be proven, along with the doctor's deviation from standards of care: moreover a link must exist between the damage suffered by the patient and the strategy adopted by his doctor, for the case to exist. These possible damages must be explained to the patient during the IC acquisition; however there is no rule making clear the level of information owed to a patient.

We report some legal measures based on an IC lack of explanations on some possible complications, resolved in favour of the accused doctor and finding answers in the knowledge of the causal link.

For example in the judgment Chappel Vs Hart, it looks like the surgeon didn't let the patient know a particular complication that happened during surgery [15]. The judgment underlines the difficult concept that the damage to a patient has to be related to negligence and not to lack of information. For a better understanding, the authors suggest asking ourselves some questions like: is the damage occurred because of the lack of information, or did this preclude the patient the possibility of choosing a better treatment, or did it expose the patient to a greater risk? Or even: if, aware of the possibility of that complication, the patient would postpone the surgery, would the risk diminish? The answer could be simple, but in our opinion the security of non-guilt with an incomplete IC is not so granted.

5.1.2 Implications in robotics

The 4 principles for negligence persecution are universal and apply in RS like in classical or laparoscopic surgery.

The standard of care is an universal concept too with no specific varying in RS. However, there is no unanimity about robotic surgery as a Gold Standard for any specific procedure; there are no clear data in the literature.

When obtaining an IC in RS we should make explicit the possible implication of this technique on complications, if the technique increases the risk of improper manoeuvres or if it makes them easier.

5.2 Standard of care and loss of chance

5.2.1 General considerations

The standard of care is the reasonable way to cure, based on EBM (evidence based medicine), on guidelines, and ensures patients the correct management of the disease, keeping the error probability in an acceptable range.

The concept of loss of chance is based on the right of the patient to undergo a procedure relying on the most expert surgeon. The surgeon anyway operates in the standard of care like the other specialists, but a patient must be able to choose which specialist will take care of his problem.

In the case mentioned before [15], for better understanding the fail of these two concepts, the questions would be: knowing the degree of risk of this complication defined in the literature, is the risk increased if the procedure is performed by this surgeon? If the answer is no, the case doesn't exist. Laws about negligence, in fact, are

necessary to whom who suffered a damage because of a deviation from the standard of care, but they don't compensate people who received an intervention according to the standard of care even if it could have been better performed by another surgeon.

In other words, laws must compensate people who lost the possibility to be cared for in an optimal way, but not who lost the possibility to be cared for in a better way (in the standard of care limits). This apparently relieves the burden of the IC acquisition, but legal wrangling on this topic is still increasing.

Lobina et al. in 2007 published an interesting paper on the assessment of the real IC understanding by the surgeon [5]. Aim of this work was to test the preparation and the knowledge of surgeons themselves about basic legal concepts related to the IC obtaining. Authors declare in conclusion that, despite the median level of preparation of surgeons was high, the legal aspect of ICs is rarely reached in clinical practice.

Surgeons should educate patients, as well as about the standards of care that are often implicitly expressed, also about the concept of chance, stating the level of experience of the surgical equipe and the possibility of a more suitable specialist in the territory.

5.2.2 Implications in robotics

The concept of loss of chance could possibly turn against traditional surgery in the coming years, if data about less discomfort and better oncological results in RS will be confirmed. Legal dictates state that, during the informative conversation, surgeons should inform about the possibility to perform the same SP with another technique with better results, even if this will redirect the patient towards another colleague.

Second implication in RS is the failure to declare the surgeon's skills.

Especially in high complexity procedures the need is felt to declare the capacities and the experience of the surgeon, to clarify and make patients choice easier and more correct. This problem could be avoided by preparing a "catalogue" system of all surgeons, following the US scheme, produced by hospitals.

Actually this aspect could create three problems: first, limits on number of procedures to perform to become (and remain) a reference surgeon for a given procedure should be established; second, hospitals should publish their results, and third they should ensure that patients read and interpret these results correctly.

So the complexity of structuring this standard of control is clear, as the difficulty in standardising the concept among all typologies of patients.

In our reality it is currently inapplicable; therefore it becomes even more necessary, especially in complex procedures, discussing these aspects directly with the patient during the obtaining of the IC.

6 Discussion

There are different ways to consider the IC. For many years it was based on the concept of "beneficiality" of medical and surgical procedures, so that a surgeon's actions were always justified whatever the results, because they were useful for the protection of the patient.

In the years following, with surgical procedures increasing and the evolution of surgeons and devices, concluding contracts of trust between doctor and patient became necessary. By the way, clear rules never existed about what to say exactly during a informative talk, which information provide, which complications talk about, and what information is necessary for an universal validation of the consent itself [16].

Even most legal medicine specialists don't recognize an universal concept of information-based consent; some of them in fact have been advocating for years that for an ill patient whose last chance of cure is a surgical operation, the procedure itself is not a digression at all, but the natural evolvement of the history of the disease. Therefore it wouldn't need a consent, but on the other hand the decision not to undergo the procedure should be certified as a "reasoned refusal".

In 1936 the vice-principal of Harvard faculty of Medicine stated that in an ideal society the only foundation for a consent should be trust, and that "*a written consent should make a patient suspicious and result in a request for clarifications to elucidate the reasons behind such a formality*". Well aware that we don't live in an ideal reality, and motivated by an increasingly rapid technology development and by the increasing number of legal sanctions, surgical societies with legal medicine institutes established some rules to regulate doctor-patient relationships, and expressed the need for a written disclosure that will accompany each invasive procedure on an human being. This should include not only procedure related variables but also all the possible alternatives to that procedure, that surgeon or that timing.

We bring as an example the "Martin Salgo case" discussed in 1957, whose judgment confirms the obligation to

give a global information comprising each eventuality, in line with the concept of "*smart consent*" .

As previously stated, a "lacking consent" is mainly due to a patient's inability to figure out the information and to a doctor's poor ability in explaining the proposed procedure [17]. In RS technical complexity increases, and therefore some authors state that patient's difficulties in understanding increase too; even for the surgeon there can be difficulties in clarifying a complex procedure.

Because of this technological development, many authors began to express a concrete need for a specific IC regulation, and in 2012 Susan J. Lee Char et al suggested a scheme to follow for a correct IC acquisition based on a survey of N° patients [18]. It considered the generic procedure description with technical details, potential risks, experience and outcomes of the surgeon, and in the end how much the procedure was appealing and effective in the eyes of the surgeon himself.

Some authors declare that currently, thanks to more precise rules, to the potential use of devices and to the higher level of education in the average population, we can observe a settling in information perception that is positively influenced by an increased efficacy of surgeons and patients greater will to understand [19]. Other authors claim that patient's procedures comprehension is not compromised by robotic complexity in itself. More studies however state that any new notion about difficult techniques inevitably leads to an increasing struggle in understanding.

A more complete and standardised IC, and above all the knowledge of the complex process needed for technology application in surgery, are essential factors to deal with the remaining problems and to limit subsequent legal implications.

6.1 Limitations of the study

This is a purely observational study based on the literature, and we didn't directly compare surgeons and patients populations on these concerns.

We based our work on experiences found in the literature coming from different surgical specialities and about different surgical operations. So it's not necessarily true that our conclusions could be standardised to all surgical fields.

7 Conclusions

Currently the IC is influenced by many factors that led to an acquisition not just based on the concept of correct care, but also on the avoidance of legal sanctions. Therefore, applying a defensive medicine, the concept of informed consent is shifting towards a more appropriate concept of defensive-informed consent.

In robotic surgery we believe in the necessity to follow three arrangements to make the IC more complete. Integrate the information already present in the IC (causes of the disease, consequences of the disease if not treated, focus on the proposed technique, possible consequences if treated and risk of reintervention with related consequences) with data on the surgeon's experience in RS, the number of procedures of the department and the regional map of expertises by procedure.

It would be helpful to inform patients about the figures of Proctor, Preceptor and assistant, with their usefulness and their responsibilities in robotic surgery.

Finally, it is incumbent to ask the surgical societies to produce RS guidelines to give to patients, to define LCs of the main procedures and to consider a constant training on simulators using the figures of tutors and proctors.

All of this should happen in order to improve patients educational process in robotic surgery, supporting technology evolution without putting aside the correct interpretation and acquisition of the informed consent.

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