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Methodological letter

Ethics in surgical research: What we cannot miss☆

Ética en investigación quirúrgica: lo que no podemos olvidar

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Although medical ethics is classically considered to have originated in ancient Greece, surgical ethics as we know it today emerged with modern surgery in the 19th century. The atrocities committed by Nazi doctors during the Second World War led to the Declaration of Helsinki in 1964, which was the seed of ethics committees, informed consent and confidentiality of personal data[1].

Innovation is one of the most important drivers of change in surgery and therefore has a unique role in surgical ethics. While drug research is strictly regulated by the FDA or EMA, surgical innovation has historically been poorly regulated, and there has even been much debate about the transparency of informed consent in surgery[2,3].

Surgical ethics can be considered to differ from medical ethics in three important respects:

1 Informed consent, which is intimately associated with the special relationship established between the patient and the surgeon, as well as the usual absence of a prolonged period of time to establish this relationship.
2 The responsibility inherent in surgical care, with an essential human factor that is not found in medical research.
3 Surgical innovation which, not being considered experimental research, has benefited from less regulation, thus allowing important advances in the treatment of our patients. However, innovation should not make us forget our therapeutic relationship with patients.

Surgical research has been criticised in multiple forums for producing low-level evidence, in the form of case series rather than randomised clinical trials. However, conducting a surgical randomised clinical trial is inherently more difficult than similar research in the medical setting, both because of the nature of the surgical diseases and the treatment, where the variables to be taken into account are difficult to quantify, from the learning curve, surgeon experience, etc[4].

Principles of ethical conduct in research and ethics committees

Biomedical research almost always involves potential harm to the patient. This potential for harm to the individual means that the ethical principles of each research study must be reviewed before it is initiated and must therefore meet the following requirements:

1 Scientific or social value.
2 Scientific validity.
3 Reasonable inclusion criteria.
4 Favourable risk/benefit ratio.
5 Independent review.
6 Informed consent.
7 Respect for potential and already included subjects.

To ensure compliance with the aforementioned requirements, the Research Ethics Committee (REC) is formed by

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health and non-health professionals, independent of the study promoters and the researchers. The function of the RECs is to evaluate the methodological, ethical and legal aspects of biomedical research projects. All studies, both prospective and retrospective, must be assessed and approved by an REC before being carried out.

Intrinsic obstacles to ethical surgical research

The ideal study is considered to be a multicentre, randomised, double-blind study including relevant groups of patients. However, some aspects of surgical practice and culture prevent such studies from being conducted.

Compared to the standardisation of drug administration, the standardisation of surgical treatment depends on the surgeon's experience, the availability of surgical instruments, and clinical pathways in each of the centres, which raises doubts about the internal validity of multicentre studies. Moreover, studies conducted by a single surgeon lead to low generability of the results, thus decreasing the external validity of the study.

In addition, the learning curve is an intrinsic feature of surgical innovation that is not present in medical research and directly affects the internal validity of the study[5].

To overcome these problems and to be able to conduct ethical and valid surgical research, McCulloch's group described the IDEAL model for the development and evaluation of surgical innovation[6].

Informed consent

Good communication is the basis of informed consent. The potential risks and benefits of study participation need to be explained in a way that the patient can understand. If after explanation the patient is not able to explain the aims of the study and its risks, informed consent cannot be considered to have been obtained. The investigator must be honest with the patient by explaining the possible risks as well as the aims and potential benefits of the study. Patients may assume that because the technology offered is new, it is inherently superior to the previous technique. However, in surgical innovation this is not necessarily true and, in these cases, the burden of truth lies with the investigator to explain this to the patient.

Sham procedures

Sham procedures are sometimes used to maximise the scientific validity of research on invasive procedures. This sham procedure controls the placebo effect, however, unlike in pharmacological studies, where the placebo is an inert compound that does not harm the patient, sham procedures put the subject at risk for pain and complications of anaesthesia. Opponents of these procedures argue that subjects are harmed without reasonable expectation of improvement, however, proponents of these procedures counter that this also occurs in phase 1 pharmacological studies[7].

Relationship with the industry

Typically, and especially at the beginning of their use, industry representatives have more experience in the use of surgical instruments and manufactured materials than the surgeons themselves. Although the relationship with industry is important to promote innovation and clinical advances, and may be useful in defining hypotheses, economic interest has no place in the assessment of results or in defining the conclusions of a study. Disclosure of conflicts of interest with industry in presentations and publication of scientific data is now essential.

Authorship

Publication is an essential part of academic promotion and has important social and economic implications. Thus, ethical dilemmas arise when it comes to giving proper credit to each author and to avoid including as authors those members who have not contributed significantly to the article. To standardise the criteria for authorship, the *International Committee of Medical Journal Editors (ICMJE)* has defined the 4 criteria to consider someone as an author. This concept of authorship is important as it is not always determined by the contribution to the paper, but is unethically awarded based on hierarchies. Therefore, mentors should take into account power dynamics when determining authorship[8].

Conclusions

Market pressures, conflicts of interest and deregulation affect surgical research, challenging many of the ethical and methodological requirements. Despite the difficulties inherent in surgical research, frameworks, such as IDEAL, have been developed in which to conduct it in a valid and ethical manner. We must stress the importance of Research Ethics Committees, which are necessary guarantors of ethical and legal requirements, and whose approval is required for all types of surgical research projects.

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