Review

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Ethical issues and doubts surrounding the acceptability of sham surgery

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Abstract

Sham surgery omits the intended therapeutic procedure and aims instead to isolate the specific effects of a surgical treatment as opposed to any incidental effects, thus neutralizing the placebo effect. Sham controls have been used in many surgical trials: bilateral internal mammary artery ligation, arthroscopic procedures and transplantation of human embryonic stem cell-derived neurons in patients with Parkinson's disease. However, this experimental approach poses considerable problems for medical ethics and codes of professional conduct. Exposure to an invasive sham procedure is not without risk and can cause pain and suffering, without offering any of the advantages associated with the treatment. Moreover, what does freely given informed consent entail for patients who agree to participate in such trials? The ethical validity of placebo-controlled clinical trials is still under discussion in the international scientific community. In this paper, we argue that the use of sham surgery is unacceptable because it is invasive and dangerous and may cause physical and psychological harm. ***Clin Ter 2025; 176 (6):826-829 doi: 10.7417/CT.2025.5304***

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Introduction

Many factors contribute to the outcome of surgery beyond the specific effects of the surgical procedure: the patient's expectations, the surrounding environment, the surgeon's personality, the anesthetic and the incision. Patient expectations are influenced by: the experiences of friends and other patients; disease duration; levels of pain; and media accounts of surgery. For this reason, objective evaluation of a surgical procedure, as in the testing of drugs, cannot overlook the placebo effect (1).

Randomized double-blind placebo-controlled trials provide reliable evidence and are considered the gold standard of scientific research (2). Consequently, in order to isolate the specific effects of a surgical treatment as opposed to any incidental (placebo) effects, researchers use sham surgery as a way of objectively evaluating the outcomes of surgical procedures. Thus, sham surgery omits the intended therapeutic procedure without providing research participants with the expected benefits of the actual therapeutic intervention.

However, while placebo surgery in surgical trials is methodologically efficient, the enrollment of participants in placebo-controlled surgical studies in the arm of a sham surgical procedure has necessarily produced a lively debate on its ethical acceptability (3). Moreover, what does freely given informed consent entail for a patient agreeing to participate? Many studies have addressed the ethical implications of sham surgery, and the issue remains controversial (4–10). Our contribution first examines four of the most important surgical trials in which sham surgery has been performed; then it offers some considerations concerning the ethical implications of sham surgery.

Three representative cases of sham surgery

The first surgical trials in which sham surgery was performed date back to 1959 and 1960 with the publication of two independent double-blind placebo-controlled studies on cardiac patients suffering from severe angina pectoris (11,12). The assumption of both trials was that anastomosis between the internal mammary arteries and the coronary arteries would facilitate blood supply to the ischemic heart. In these studies, internal mammary artery ligation was performed on a group of patients, while only a skin incision was made (no arterial ligation) in a second group. The result was remarkable. A significant clinical improvement was detected not only in patients who had undergone internal mammary artery ligation, but also in a significant percentage of the placebo group (skin incision only). After the publication of these results, internal mammary artery ligation as a treatment

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for refractory angina pectoris in coronary artery disease was abandoned.

Another important double-blind controlled study was conducted on 180 patients with knee pain (13). One group of patients received arthroscopic debridement, a second group underwent arthroscopic lavage, and a third group underwent simulated debridement without insertion of the arthroscope (only small incisions were made). Neither of the intervention groups reported better knee function or less pain than the placebo group: in other words, arthroscopic lavage and debridement were shown to be no more effective than sham surgery.

An even more controversial study was published in 2001 concerning the transplantation of human embryonic stem cells in the brains of patients with Parkinson's disease (14). The trial was based on the theory that the placebo effect in neurological diseases is mediated by dopamine-related compensatory mechanisms (15). The patients of the control group were given a placebo treatment consisting of skull trepanning (like the patients who received the real treatment), and a stereotactic frame was attached to the skull. They underwent PET-MRI exams, general anesthesia, antibiotic therapy and six months of immunosuppressive therapy but they did not receive a transplant. The results of the study showed some benefit in younger patients because of the survival of transplanted neurons, but no benefit in older ones; however, no significant differences were found between the treatment and placebo groups, even in the case of adverse events.

According to some researchers, this 2001 study provided evidence to support the hypothesis of a mind-body correlation in patients with Parkinson's disease (16). Patients who were convinced they had received a transplant reported better quality of life and neurological function after a year compared to those who thought they had undergone sham surgery.

Arguments for and against sham surgery

Is sham surgery ethically acceptable? This issue remains highly controversial. Some authors are in favour of sham surgery because (a) the risks to subjects may be deemed "reasonable" in relation to the possible benefits; (b) double-blind randomized trials with a placebo arm are the only experimental methodology able to exclude any benefits related to the placebo effect or experimental biases; and (c) some surgical procedures (such as cell transplantation) have more in common with drug therapies than with traditional surgery (17).

On the other hand, other authors, including Macklin, consider sham surgery unethical because (a) the protection of human life cannot be exclusively based on the acquisition of informed consent and (b) patients involved in such trials are deceived (18). It is interesting to note that some guidelines and European legislation protect the interests of participants in medical research without actually condemning sham surgery (19–22).

In 2002, the American Medical Association put forward ethical criteria for the use of placebo controls in surgical trials. According to these guidelines, sham surgery should only be used if (a) no other experimental design will produce the necessary data; (b) it is accompanied by a meticulous informed consent process (possibly by involving a neutral third party); (c) careful consideration is given to the risk-benefit ratio; (d) the disease under study is susceptible to the placebo effect, and (e) the risks to the subject are low (23).

Albin has suggested that sham surgery is justified only if the following criteria are met: (a) the general standards of ethical conduct in clinical research are all fulfilled (validity and scientific value, fair subject selection, favourable benefit-risk ratio, independent review, informed consent, and respectful treatment of the participants); (b) there is no alternative (less harmful) research design; (c) the dangers are minimized; (d) the least possible number of people are involved in the study, and (6) the trial is supervised by an independent board (24).

Discussion

In our opinion, the use of sham surgery in surgical trials is very questionable because it undermines the principle of beneficence. In sham surgery a patient is subjected to the risks of a surgical procedure without obtaining any real benefit, unless the placebo is considered paradoxically as a benefit.

Therefore, in our view, sham surgery does not adhere to the basic goal of medicine, which is to act for the benefit of the patient. While there is no doubt that sham surgery has proven certain surgical and therapeutic practices to be unnecessary, to the good of scientific progress, it is equally true that the ends do not always justify the means: a human being must not be exposed to the risks of a surgical procedure without this entailing a desirable benefit. Otherwise, the human being becomes a mere instrument to test the scientific validity of a procedure and its possible outcomes. Instead, any clinical trial involving patients must always centre on a therapeutic act aimed at improving the health of the patient, and only at a later stage can experimenters think about the positive impact on all other patients who might benefit from the new scientific evidence. This corresponds to the general ethical principle that no research should be conducted without acting in the best interest of the participant.

Secondly, the principle of respect for autonomy is undermined in sham surgical trials. The patient's decision to participate may be conditioned by desperation for treatment. The potential for significant benefits goes hand in hand with exposure to risk of temporary and/or permanent injury and the possibility of no therapeutic benefit other than the placebo effect. Therefore, patient consent can only ever be partially informed.

Thirdly, contrary to Freeman et al.'s claims, we do not recognize an equivalence between the testing of some surgical procedures, such as the transplantation of embryonic stem cells in patients with Parkinson's disease, and drug testing: it is evident that the former is more invasive and dangerous than the latter. The integrity of a patient should never be affected by the use of invasive procedures which are not essential and not for therapeutic purposes, in compliance with the principle of non-maleficence (duty to not inflict harm), which is the other side of the coin to the principle of beneficence (duty to do good).

Furthermore, we believe that even if an experimental study is valid (regardless of who carries out the research, where it is conducted, the consent procedure and the documentation provided) and of value in itself (because of its usefulness in the formulation of a hypothesis, taking into consideration all presumptive and exogenous factors such as costs, priority, etc.), it is not necessarily ethically acceptable. If it is true that "bad" science is science which is unethical in itself, this does not entail that "good" science is in itself ethically acceptable.

For these reasons, we believe that physicians involved in clinical and surgical trials should not uncritically adopt the experimental methodology of double-blind placebo-controlled studies. While such designs guarantee an "evidence-based" methodology, they do not guarantee that ethical standards of healthcare have been upheld in relation to the individual patient.

Although scientific knowledge is important, it will not necessarily be valued by today's modern society if it is achieved in ways deemed inappropriate (25). Altruism exercised in the participation of experimental clinical trials for the sake of general progress can compromise a person's physical integrity and it is widely agreed in the medical community that this can only be accepted if levels of risk and suffering are minimized.

As stated previously, those who defend sham surgery highlight that the risks of a sham procedure must be reasonable. However, the question of whether the risks and/or harms (not only physical but also psychological) to the individual are proportional to the benefits to science and society is difficult to answer because there is no standard to decide when an intervention has enough social value (26). The severity and prevalence of the disease are aspects to consider in this regard, but the concept of "benefits to society" is often vague, indeterminate and uncertain (27). Some sham procedures do not pose substantial risk or harm, because they only involve a minimally invasive intervention such as an intravenous or intra-articular injection. For other more invasive sham procedures, the risks are much higher (28). Furthermore, with the advent of new interventional technologies, the liabilities of the different actors involved in medical malpractice cases are not yet clearly defined, especially when artificial intelligence is involved in the decision-making process (29). This raises new and important ethical issues in the field of sham surgery.

What has been discussed so far takes on considerable relevance if we consider that strong doubts have been expressed about the reliability of placebo effects, and it has been suggested that the reported effects of placebo treatments in various studies could simply be artifacts of inadequate research methods altering the results (30). In addition, confounding factors can modify the strength of (or even reverse) the causal association between exposure and outcome (geographical origin, sex, age, pre-existing pathologies, etc.) (31). Furthermore, to date there is no clearly defined neuropsychological profile that experimenters can use as a prerequisite for patient participation in studies assessing the placebo effect (32).

Conclusions

Randomized double-blind placebo-controlled trials are considered to be the gold standard of scientific research in the medical field. Since surgery (like the administration of drugs) may elicit a placebo effect, researchers perform sham surgery in many surgical trials to objectively evaluate the outcome of surgical procedures. However, this experimental methodology has posed ethical and deontological problems for the scientific community, which remains divided over the question of whether sham surgery is ethically acceptable. Among international organizations, only the American Medical Association has considered the matter by suggesting some criteria for the adoption of sham surgery (33). In our opinion, sham surgery is ethically unacceptable because (a) it undermines the principle of beneficence since the patient is subjected to the risks of a surgical procedure without obtaining any benefit; (b) the principle of respect for autonomy is undermined as the patient, who cannot know whether or not they will receive an actual surgical treatment, can express only partially informed consent; (c) the relationship of trust between doctor and patient is distorted, because the doctor may have doubts about whether the intervention is in the patient's best interest; (d) it is not equivalent to the use of placebos in drug testing, because some surgical procedures, such as the transplantation of embryonic stem cells in patients with Parkinson's disease, are particularly invasive and dangerous.

In conclusion, trials involving sham surgery are methodologically correct and pursue the dictates of evidence-based medicine, combining validity and scientific value, but this is not enough. A clinical trial "with" and not just "on" a patient must have incontrovertible ethical value in itself without violating the inalienable rights of the human being. The study must have an authentic therapeutic principle and social significance.

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