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The Role of Observational Studies in the Surgical Area

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Abstract

Background: *In randomized controlled trials, due to the randomization process the covariates are equally distributed between the groups. For these reason at the end of the study the researcher can assume that the outcomes happens only because of interventions. This strict control of bias leads the randomized controlled trials to become the gold standard in clinical research. However in some cases, like in surgical studies, it is very difficult to run a randomized controlled trial. Observational studies have some strengths and can play an important role in studies of surgical specialties.*

Discussion: *Observational studies are very commonly used nowadays, once that they are easy to conduct, needs less time and budget than randomized controlled trials. It is also a great design to test new hypothesis that could be developed in future studies. Observational design could be an excellent option to surgical research when randomized controlled trials have an ethical or feasibility issue. Besides the ethical and feasibility issues the research could have a rare outcome that is difficult to assess and measure. To all this issues observational study offers a solution.*

Keywords: *Observational, study, surgery*

1. Introduction

Since the 1940s, randomized clinical trials have been widely applied[1]. The evolution and development of scientific methodology and medical statistics oriented to understanding study designs and the influence of bias in study outcomes has allowed randomized trials to become the gold standard in clinical investigations and comparison reference for other studies[2,3].

In the setting of random assignment of participants, the samples are formed and evenly distributed in a way that the differences between the intervention groups are balanced out and that any known or unknown factors do not interfere with the result[4].

Therefore, beyond providing internal and external validity for outcomes, it can be argued that each participant has an equal chance of receiving the intervention.

Furthermore, in pharmaceutical area different countries have made randomized trials mandatory through regulatory requirements.

Nevertheless, studies and literature stresses the limitations and difficulties of implementing this design in surgical interventions[5,8].

Comparisons between randomized and nonrandomized studies show that findings may be of different magnitude[9].

However, evaluation of meta-analyzes of randomized trials and cohort studies or case-control published in five major medical journals showed that good observational studies didn't overestimated the results of treatment effects when comparison with the results of RCTs on the same topic[10].

So we want to discuss the role of observational studies in surgical area.

2. Discussion

Observational studies frequently are used to describe outcomes of new treatments. In the importance of evidence, it means level III. However, observational studies represent a very important amount of clinical research in medical world literature.

The great advantage is that observational studies are feasible study designs, facility to conduct the trial, and the research needs less time and financial supports than in randomized-controlled trials, case-control, or cohort studies.

There are a lot of criteria that can exist in a very good quality observational study, for instance, a research with an expressive objective/question, a well-defined study protocol, a clear inclusion and exclusion criteria for the sample participants, a specified time interval for patient

recruitment, objective patient enrollment, relevant outcomes, very dedicated prospective outcome data collection and intensive follow-up rate. Such criteria is respected on the present study design[11,12].

Findings can be used to generate hypotheses which sending a specific results of studies and consequently in a reliable design. It is interesting in refining new techniques or treatment protocols before these are taken to more advanced trials. Thus observational studies offer an interesting alternative for a surgeon's research when ethics or feasibility difficulties preclude the execution of randomized clinical trials.

Observational studies (OS) oppose to experimental studies (ES). The most important differences are:

1. ES: Randomized controlled Trial (RCT) – Research under the effects of exposure, which exposure is assigning in a randomized sample of patients.
2. OS : Just for observation the effect on the study of the treatments on patients; don't have action on the role of assigning exposure to the sample.
3. ES : Less methodological events (RCTs are considered better to proving causality).
4. OS : Vulnerable to methodological problems.

We can state that not all studies are experimental. One of the reasons being that sometimes not all the research questions are viable for an experimental study design. Some experimental studies, diagnostic tests trials, and treatments are highly suited for experimental studies (*e.g.* drug effects studies in a group of patients with a specific disorder and studies on the prognostic effects on a disease).

In experiments where researchers have no control over the assignment of subjects in the treatment and control group, the observational study design is a worthwhile and indicated option (*e.g.* randomized control trials, in which subjects are allocated at random to the treatment and control group). For studies that are not concerned treatments for the patient, the observational tool is not a valid method.

A variety of reasons can indicate that the study shouldn't be randomized:

- Violation of Ethical Principles. When there are doubts about the violation of ethical standards (e.g. studies on the influence of pregnancy on breast cancer. This study includes investigating the abortion and it´s benefits in treating breast cancer. In a control study there would have to be a large sample of pregnant women, randomized into the treatment group (receiving induced abortions) and a control group (that will give birth). Regular treatment of cancer would be applied to both groups. The violations of common ethical principles are clear enough. It is impossible to conduct this study as a blind experiment. This study generally starts off with a group of women who already had an abortion, therefore, patients in this group are not under the control of investigators and is formed after the surgery has been assigned[1].
- The lack of power of the researcher to establish the rules given sampling location. Due to regulation and laws in some communities, where the sample of the research will be chosen. Should this occur, there will not be a random allocation of the sampling. In an observational study, the investigator will start off with a surgical treatment group consisting of those in communities where he can apply the surgical technique, which is proposed in his study.
- A randomized surgical treatment may be impractical. A randomized surgical treatment may be impractical as a model of research. For instance, during a study for show a link between a surgical treatment for obesity and rare signs and symptoms of Diabetes Mellitus type 2 begin after surgery, characterizing a possible a side effect. Without any ethical considerations, a randomized experiment would be impractical because of the rarity of the effect. There may not be a large occurrence and sample enough for the symptoms to be observed in at least one treated subject. An observational study would normally start with a group of symptomatic subjects and making a work backwards to find those who were submitted to surgery and later developed the symptoms. This way, a subset of the surgical group was determined based on the occurrence of symptoms, instead of by random assignment.

As Dr. Richard Nahin wrote in his publication: "Although observational studies cannot provide definitive evidence of safety, efficacy, or effectiveness, they can: 1) provide information on the "real world" use and practice; 2) detect signals about the benefits and risks of complementary therapies used in the general population; 3) help formulate hypotheses to be tested in subsequent experiments; 4) provide part of the community-level data needed to design more informative pragmatic clinical trials; and 5) inform clinical practice" [13].

In the surgical literature on trials, type II Error or the problem with sample-size requirement has been recognized as an important issue. The sample-size definition is affected by the events of interest in the study or even by the frequency of it. Because of the low frequencies, the number of subjects is exponentially increased to be able to find statistically significant differences. One type of observational study, perhaps, should be appropriated in cases like Prevalence Survey or Cross-sectional Study[14].

Cross-sectional studies: Characterized individuals by hypothesized risk factors and a disease in question at one specific point in time, and used to avail the assessed in relation of the magnitude of a disease in the population

or to determine the prevalence of risk factors for a disease.

One of the main advantages of a cross-sectional tool is that it can be carried out in a temporary fashion. With the intention to validate the results, a second major advantage of cross-sectional study is, in fact, two conditions; the lack of appropriate controls and uncertainty about whether risk factors precede the onset of disease.

Case-control studies: Is a testing tool which the researcher needs a control or comparison group, but in this case, patients are assembled according to the occurrence or not of the outcome.

In literature, this kind of study has sometimes been referred as case-referent studies, case-comparison studies or, simply retrospective-study.

Despite the advantages such as the convenience to organize the study and the likeliness brevity of the study, the critical issue concerning the identification of suitable control continues to be problem.

In a surgical study, the use of short-term outcomes is favorable to methodological toll as cohort comparations. A multicenter cohort study is feasible in this case.[15]

3. Summary

Due to the balance of covariates by the randomization process RCTs are considered the gold standard in medical research. Nevertheless in studies in the surgical field RCTs could lead to ethical and feasibility issues that compromise all the study. Some of these issues are the random allocation process and the rarity of an outcome. Observational studies represent a way to overcome some of these issues.

List of abbreviations

RCTs	Randomized Controlled Trials
OS	Observational Studies
ES	Experimental Studies

Competing interests

The authors declare that they have no competing interests

Authors' contributions

EHP participated in the conception and design and drafted the manuscript. ALGS participated in the design and drafted the manuscript. FJCP participated in the design and drafted the manuscript. FPGR participated in the design and drafted the manuscript. FF participated in the design and drafted the manuscript. All authors read and approved the final manuscript.

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