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Study designs and research methodology in the field of otolaryngology

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Abstract

Background: Scientific studies require a well-prepared cascade of steps starting from the idea and formulating a research question passing through collecting data and analysis of the results to proper writing a good article and publication. The methodology section is the core of any scientific article.

Main body: Study designs in otolaryngology can be classified as "observational studies," "experimental (interventional) studies," and "meta-analysis—systematic review." There may be a huge range in quality between kinds of studies. To standardize the method of reporting the quality of studies and include all important aspects in the evaluation process, a team of scientists created the reporting guidelines checklists.

Conclusions: In this article, we give a comprehensive review that can help authors to understand study designs in otolaryngology along with the appropriate reporting guidelines used in each study.

Keywords: Study design, Methods, Otolaryngology, Meta-analysis, Randomized clinical trials, Reporting guidelines

Background

Scientific studies are "planned and systematic effort based on evidence for the solution of any health problems using data with a high degree of accuracy". They require a prepared cascade of steps starting from the idea and formulating a research question passing through collecting data and analysis of the results to proper writing a good article and publication [1].

Main text

The "methodology" section is the core of a scientific article, and it is the first part to be written as it is the practical part done by the author and consequently it is the easiest part in writing [1].

In this article, we give a comprehensive review that can help authors to study designs in otolaryngology along with the appropriate reporting guidelines used in each study [1].

Studies can be classified as "observational studies," "experimental (interventional) studies," and "meta-analysis—systematic review," [1] as shown in Fig. 1.

Observational studies

In observational studies, authors do not entail interventions or experiments in their methods [2]. Investigated factors are not controlled; repetition of events is not generally possible, and randomization facilities are limited in these studies. However, their results are largely consistent with real life. They can be classified as descriptive or analytical [3].

Descriptive studies

These studies tend to describe health problems or events. They answer the following questions: "What is it?", "Where is it seen?", "When is it seen?", and "Who are observed?";

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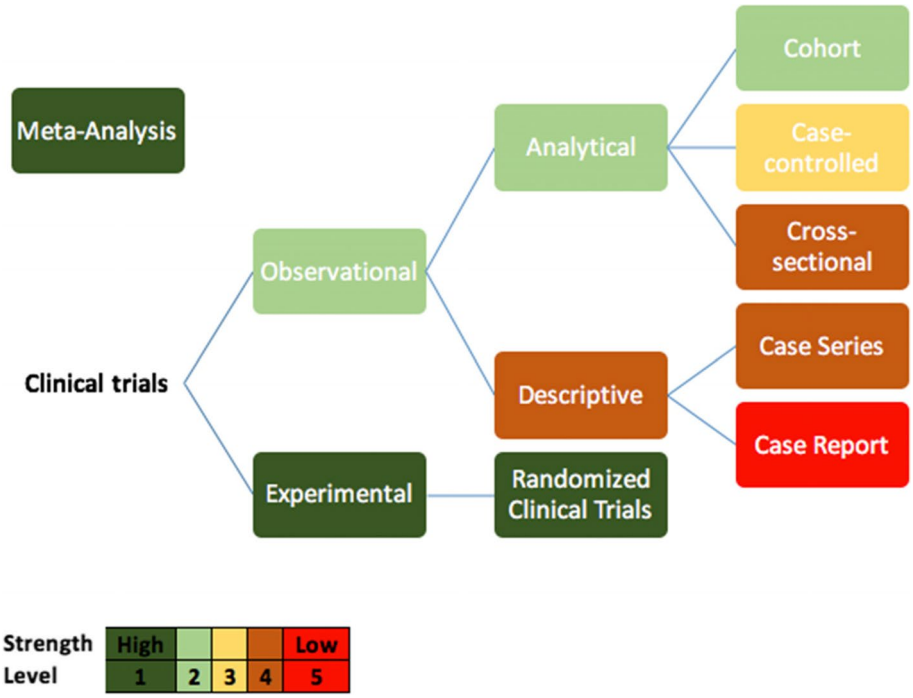

Fig. 1 Study designs

these studies entail the description of criteria like epidemiology of a disease or a character in the target population [4].

Descriptive observational studies include *case-report, case series,* and *cross-sectional studies (descriptive or prevalence)* [4].

Case report and case series

These are the simplest research types and do not contain a control group. They describe an interesting or a remarkable or even a rare finding in a patient. They are usually used by ENT surgeons. When the number of cases is exceeding two cases, this is called a "case series"; otherwise, it is called a "case report." [5]

The case report studies got transparent and more precise by using *CARE (Case REport)* statement in the publication [5].

Cross-sectional studies (descriptive or prevalence) are called studies of prevalence as it entails epidemiology or a specific character in a disease or study population [4].

Analytical studies

Cross-sectional studies

As if cross-sectional studies are classified as descriptive studies, some authors consider cross-sectional studies analytical studies which carried out in a specific time and try to analyze the link between a specific disease and a specific result in a specific time [4]. As shown in Fig. 2, these kinds of studies are supported by the STROBE statement at publication [1].

Case-control study

Case-control studies are studies of comparing; it compares a specific factor or outcome between a group of the study population and normal or healthy individuals [4]. As shown in Fig. 3. These studies are powered by *the STROBE statement* that guides authors in reporting this study design [1].

Cohort study

These are prospective studies that include the target population of a specific disease or factors to be exposed to the same method (e.g., drug or surgery). Population individuals are followed, and researchers assess exposure and outcome during follow-up [6].

Cohort studies produce the most reliable clinical evidence among the observational studies because they identify clinical or health outcomes based on exposure [4]. As shown in Fig. 4. The *STROBE statement* guides the authors in reporting cohort studies [1].

Experimental studies

In these kinds of studies, the authors compare the new drug or surgery to the traditional ones, and the target population should be divided into 2 groups randomly to group of the new drug or surgery and the control group of the traditional ones; this study could be done in four stages [7].

Fig. 2 Cross-sectional study design

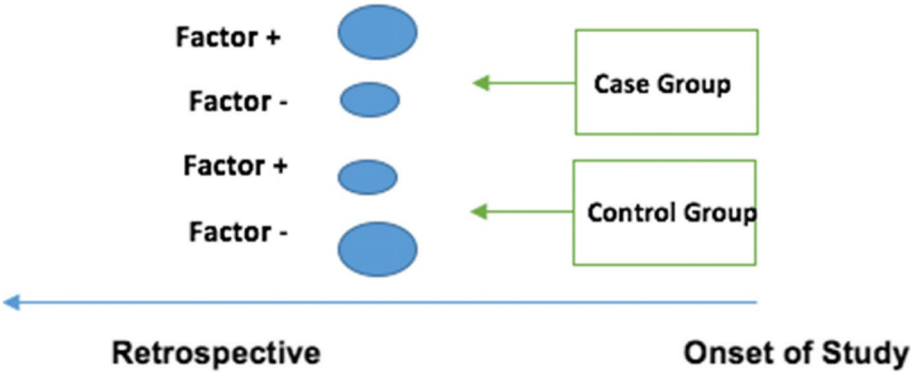

Fig. 3 Case-controlled study design

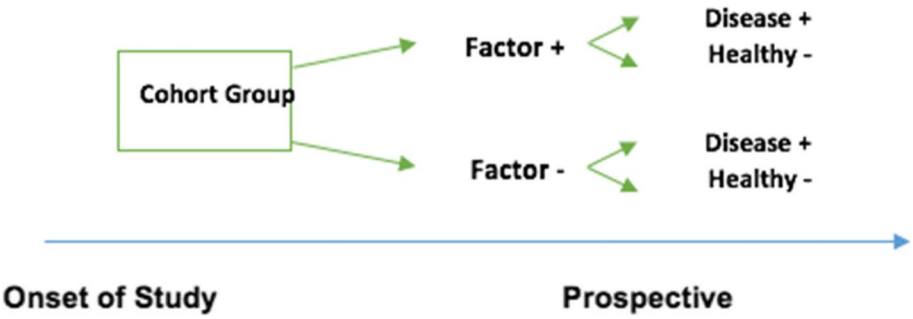

Fig. 4 Cohort study design

Stage 1: on a small number of population (30–70 individuals), it aims to evaluate the safety of the drug to the traditional one

Stage 2: on a larger number of individuals (70–300), it aims to evaluate the effectiveness and efficacy of the new drug to the traditional one

Stage 3: on a larger number of individuals (1000–3000), it aims to detect if the new drug is better than the traditional one

Stage 4: post-marketing stage, it is conducted on individuals in daily life. They evaluate the adverse effect of the new drug [7, 8].

Randomized controlled trial (RCT)

Considered the most powerful experimental study as an individual are randomly placed in 2 groups; randomization removes the allocation bias and gives more precise

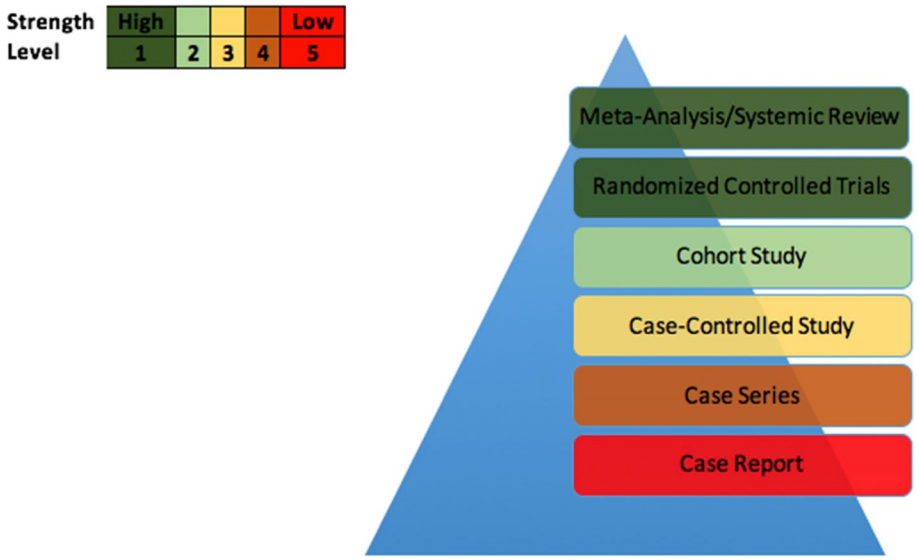

Fig. 5 Evidence pyramid

statistical results [9]. The *CONSORT statement* is used by the authors in these studies for publication [9].

Meta-analysis and systematic review

Meta-analysis are retrospective studies; it combines the different statistical results from different journals all over the world in a specific topic [10]. This is powered by the *PRISMA statement* in publication [1].

Systematic review also combines the authors' evidence in a specific topic, but it does not entail the statistical issue; both meta-analysis and systematic review are at the top level of evidence [10].

Evidence level of medical studies

Figure 5 shows the strength level of evidence of the different study designs; systematic review and meta-analysis are considered the most powerful study design and give better chance for publication, followed by a randomized controlled trial, while the weakest study design regarding evidence is the case report [1].

Reporting quality guidelines

The reporting guideline checklists have been created to standardize the system of reporting different study designs' quality all over the world [6].

- *CONSORT statement* for RCTs
- *ARRIVE* for animal experiments
- *STROBE statement* for cross-sectional, case-control, and cohort studies
- *CARE statement* for case report
- *PRISMA statement* for meta-analysis

The checklist is a diagram of a cascade of steps that include all phases of the research, for example, study design, randomization, blinding, and results. It is considered the most acceptable system for reporting quality [1] provided by the equator network [6].

Conclusions

In this article, we entailed all types of study designs, when to use, and how to use. We also discussed the strength of evidence of each. Also, this article gives an idea on the new reporting guideline system which is recently used to evaluate the quality of publications.

Abbreviations

CARE: CAse REport; STROBE: STrengthening the Reporting of OBservational studies in Epidemiology; RCT: Randomized controlled trials; CONSORT: Consolidated Standards of Reporting Trials; PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses; ARRIVE: Animal ResearchReporting of in vivo experiments.

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Authors' contributions

SM contributed with sharing in writing the paper and submission and correspondence. MA and AA contributed with application of the idea, steps of the methods and supervising the study work. OA, MH, MS, HD, LE, MF, MS, ME and HE supervised the work. HS contributed with data collection and writing the paper. All authors have read and approved the manuscript.

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Availability of data and materials

Data are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
This study has been approved by ethical committee of ENT department, Cairo University. Reference number: not applicable in our institute. Consent to participate is not applicable.

Consent for publication
Not applicable.

Competing interests
Prof Ahmed Atef is a co-author of this study and Editor-in-Chief for the journal and Prof Mosaad Abdel-Aziz is a co-author of this study and editorial board member of the journal. Both declare competing interest for this submission. Both have not handled this manuscript. The rest of the authors have no conflict of interest to declare.

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