REVIEW ARTICLE

COMPARATIVE ANALYSIS OF STUDY DESIGNS IN HEALTH RESEARCH

Iftikhar Ahmad[1], Muhammad Marwat[2], Habibullah Khan[3]
Departments of [1]Community Medicine, [2]Ophthalmology and [3]Medicine, Gomal Medical College, D.I.Khan, Pakistan

ABSTRACT

A research design is a framework or guiding plan to approach the research subjects for data collection and data analysis to study a research problem. Every Research study design has its inherent strengths & weaknesses. It is the situation & the objectives that determine the suitability of a research study design for a study and not the absolute superiority of one above the other as a basis to rank different study designs. Choosing an appropriate study design is a crucial step ahead of researcher. Careful thought must be given to the appropriateness of the proposed study design, operational feasibility, information to be obtained, expected duration of the study and expenses.

KEY WORDS: Epidemiologic research design; Research design; Comparative study; Observational study; Study characteristics.

This article may be cited as: Ahmad I, Marwat M, Khan H. Comparative analysis of study designs in health research. Gomal J Med Sci 2013; 11: 242-4.

INTRODUCTION

A research design is a framework or guiding plan under which a medical or epidemiological study is conducted.[1] The history of study designs starts from Hippocrates, the First epidemiologist (460-370 BC) whose 'Humoral theory of disease' challenged the age old 'Supernatural theory of disease' (5000 BC). 'Contagion theory', 'Miasmatic theory', and 'Spontaneous generation theory' followed them in succession over the span of many centuries, till the conception of 'Germ theory' (1873) & modern theory of 'Multifactorial causation' (1819-1901). John Graunt (1620-1674 AD), Thomas Sydenham (1624-89), Willium Farr (1807-1883), John Snow, Louis Pasteur and Robert Koch (1877) were among the key figures who helped shape the discipline.[2]

Research study designs fall into two major categories; Observational (non-interventional) and Experimental (interventional) studies; based on the fact that researcher is either allowing the nature to take its course or he/ she is actively manipulating the situation.

Observational studies include Descriptive studies with no comparison groups or Analytic studies including Case control, Cohort & Comparative cross-sectional designs which have comparison groups. Experimental studies include Clinical trials, Field trials & Community trials, with participants as patients, healthy people & communities, respectively.

Descriptive studies include Case reports, Case-series, Exploratory studies, Knowledge, Attitude & Practice (KAP) studies, Opinion polls, Cross-sectional (prevalence) and Longitudinal (incidence) surveys. Case reports (or Case series) provide clues to identify a new disease.

The steps of Descriptive studies include defining population & disease under study, distribution & measurement of disease & generation of hypotheses for future testing. KAP studies provide a rapid method to measure attitudes of the people regarding health and disease including access & utilization of any health service. Cross-sectional studies are more useful in chronic disorders than acute. These serve as a useful tool for health planning & management through data generation regarding disease prevalence & identification of high risk groups. Economy, simplicity & rapidity of procedures are some of the advantages of Descriptive studies. The disadvantages of Cross-sectional surveys are; inability to estimate the natural history of disease, incidence or risk factor identification due to lack of temporality, which need longitudinal studies.

Analytical study designs attempt to test hypotheses formulated by Descriptive studies by quantifying

Corresponding Author:
Dr. Iftikhar Ahmad
Associate Professor
Department of Community Medicine
Gomal Medical College
D.I.Khan, Pakistan
e-mail: iftikharahmadgandapur@yahoo.com

the relationship between two factors, i.e. the effect of an intervention or exposure on an outcome.

Case control (retrospective) studies have patients & their matched controls who are healthy people. Their past exposure to risk factors are assessed & compared to reach on a conclusion about possible association of risk factors with the disease of interest by calculating odds ratio. Case control studies are less expensive, quick, easy, have no ethical or attrition problems; helpful in studying rare diseases and multiple causes of diseases. Selection bias, recall bias, confounding bias, berkesonian bias, interviewer's bias are the well known weaknesses of these studies.[2]

Cohort (prospective, follow up or forward looking) studies are also called longitudinal studies. The selected cohort consists of all healthy subjects, one group exposed and the other unexposed to one or more risk factors. They are followed over time to determine the frequency of disease of interest in them. Cohort studies may be either prospective (i.e., exposure is identified at the start and a follow up into the future), retrospective (or historical) in which past medical records are used for the identification of exposure or a combination of these two. Relative risk is the measure of association. Cohort study can calculate disease incidence directly. Multiple outcomes can be studied. Bias is minimum. Temporality is there. Higher validity makes it a feasible option when an experiment cannot be conducted due to any reason. Disadvantages include ethical and practical problems. They are expensive, time & resource consuming; require a large sample size; inefficient for rare outcomes; attrition problems.

Comparative cross-sectional study design compares prevalence of outcome of interest (health, disease, risk factors, disability or death) e.g. studying coronary artery disease in two communities with different diet & exercise habits.

Experimental or interventional study designs involve an active attempt to change a disease determinant, such as an exposure or a behavior, or the progress of a disease through treatment. Clinical or Randomized Control Trial (RCT) evaluates new forms of treatments in patients in health institutions are considered the 'gold standard' in medical research. It involves a treatment and a control group. Patients are randomly assigned to avoid selection bias. Double blinding means RCT in which neither physician nor the patient knows which of several possible treatments the patient is receiving. RCT can be either parallel group or crossover. Later is only relevant if the outcome is reversible with time, e.g. symptoms; where each study participant is randomised to treatment A first; at the crossover point they are then switched over to treatment B. Lack of biasness, blinding & valid statistical analysis are the advantages of RCTs. Disadvantages include; expensive regarding time and money, volunteer bias, ethical problems. RCT may be replaced by Quasi experimental study design due to ethical problems in human subjects; later may lack either randomization or a control group, but manipulation is always there.

Field trials evaluate procedures in preventing disease in healthy participants whereas Community trials include both healthy and diseased members of community.

This study was conducted with the objective to provide a brief overview of the range of study designs and to comment on the important strengths and weaknesses of these designs.

DISCUSSION

There has been a wide discussion in health literature regarding the strength of the evidence that can be obtained from observational studies and randomized clinical trials.[3] Strict adherence to research design can provide high-class evidence for rational clinical decision-making.[4] Descriptive studies such as Case reports and Case series provoke an idea about a novel phenomenon but have limited worth due to lack of comparison.[5] Randomized controlled trial (RCT) is least likely to have serious biases as compared to common observational studies.[6] RCTs are no doubt the 'gold standard' studies but observational studies may give comparable results if quality, validity, and sample size criteria are followed.[7,8] RCTs are the optimal study design to study the therapeutic/intervention effects and to establish causality; but with ethical and practical limitations such as studying the association between smoking and lung cancer.[9,10] Both observational studies and RCTs accomplish a complementary role in various fields of medical science.[11] They fulfill a valuable role in health research. Therefore observational designs are usually more useful than RCTs for non-therapeutic research.[12]

One of the most important steps before beginning research is deciding on your research design. Every Research study design has its inherent strengths & weaknesses. It is the situation & the objectives that determine the suitability of a research study design for a study and not the absolute superiority of one above the other as a basis to rank different study designs. Before employing a study, careful thought must be given to the appropriateness of the proposed study design, operational feasibility, information to be obtained, expected duration of the study and expenses.

CONCLUSION

Both observational studies and RCTs fulfill a complementary and valuable role in various fields of medicine. Generally speaking, experimental study

designs are best suited to establish causality, but have ethical and practical limitations. In summary, observational designs are usually more useful than RCTs for non-therapeutic research.

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CONFLICT OF INTEREST
Authors declare no conflict of interest.
GRANT SUPPORT AND FINANCIAL DISCLOSURE
None declared.