Studying a Study and Testing a Test

How to read the medical literature

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Preface

Today's practicing clinicians are confronted with an enormous number of journal articles, a virtual deluge of data, and with the dilemma of how best to evaluate this information and incorporate it into their clinical practices. In order to cope with the need to keep up with the current findings of medical science, clinicians can do one of two things: they can simply memorize information, thereby adopting unquestioningly either the latest innovation or the newest technology; or they can learn how to use the techniques that are available for a more critical, and ultimately more useful, reading of the medical literature.

Unfortunately, one particular fallacy concerning the nature of scientific research often deters critical analysis. The idea has taken hold that common sense can make no contribution and that only the experts can critique the reports of medical research, an idea that robs clinicians of their most powerful prerogative—the ability to decide for themselves. This self-study, active-participation book was written to dispel this fallacy and to show clinicians how to read the medical literature thoughtfully and efficiently. The techniques that will be described do not require a specialized knowledge since they are based on the systematic use of clinical common sense.

The application of a science or a technology to any area of inquiry, however, requires the initial understanding of its assumptions, implications, and limitations. For this reason, statistical concepts are presented here, and their implications and assumptions are defined, but there is no undue emphasis on carrying out statistical manipulations. Instead, the emphasis is placed on clarifying the question that is being asked by a study, on determining whether a correct statistical test is being used, and on understanding the meaning of the results.

Any useful approach to reading the medical literature must build on, and be compatible with, clinical training. In the differential diagnosis approach to clinical problems, an organized, structured framework helps clinicians to think through a problem rapidly. Similarly, the reader of this book is given a uniform framework on which to build a critique of any research article. A checklist of questions for the reader to ask when evaluating a study also helps to develop a systematic approach that will speed up the process of analyzing articles.

Much as in learning to perform a physical examination, the reader's attention is directed initially to the individual components

of the process. Capsule summaries of hypothetical journal articles, each focused on a particular type of error, help to illustrate and crystallize the complementary parts of analysis. The time spent in learning the basic principles pays off in ability to comprehend more quickly the meaning and the limitations of any study one encounters.

The case-study method used here, which is similar to ward training or clinical/pathological conferences, provides the active "hands-on" training needed to internalize the concepts and gain proficiency in using them. At the end of each section are flaw-catching exercises—simulated articles fraught with a variety of errors—that provide practice in applying the uniform framework. A sample critique of each flaw-catching exercise allows readers to evaluate the progress they are making in analyzing the material. A flowsheet, which summarizes the various statistical methods, guides the reader through the steps involved in statistical thinking. As in clinical training, the goal is an organized analysis of the data that will provide a basis for decision-making.

The immediate aim of this book is to help clinicians assess the degree and type of uncertainty that exist in a particular piece of medical research, since the constraints on most medical research often result in data that are inconclusive. It must be stressed, however, that studies that are less than ideal do not necessarily invalidate research or relieve clinicians of their responsibility to draw clinical conclusions.

The overall objective is for clinicians to learn the kinds of questions that statistics can answer as well as the kinds of questions they must answer for themselves. Clinicians who can critically read the medical literature, and understand and accept the uncertainty that exists, are better able to draw meaningful conclusions that will help them to integrate the results of medical research into their clinical practices.

R.K.R.

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Melanie Gehen-Benedict, June Blaszkicwicz, and Ed Rovera deserve special thanks for putting together the manuscript and for contending with the revisions of the revisions. I especially thank my wife, Linda, who put herself and her enthusiasm into this project and patiently and skillfully reviewed every word.

Much of the material in Chapters 3 to 7 has been adapted from articles I wrote that first appeared in *Postgraduate Medicine,* May—September 1979, entitled "Interpreting Medical Studies: A Series."

Contents

Studying a Study PART I

The traditional course in reading the medical literature consists of "Here's the *New England Journal of Medicine.* Read it!" This approach is analogous to learning to swim by the total immersion method. Some people can learn to swim this way, of course, but a few drown and many learn to fear the water. Reading only the abstracts of medical articles is much like fearing the water.

In contrast to the method of total immersion, what will be presented here is a step-by-step, active-participation approach to a clinical review of the medical literature. With these analytical techniques, the clinician should be able to read a journal article critically and efficiently. There will be considerable emphasis on the errors that can occur in the various kinds of studies, but try to remember that every flaw is not fatal.

Before developing and illustrating the elements of critical analysis, however, let's begin with a flaw-catching exercise, a simulated journal article, and see how well you can do. Read the following study and then try to answer the accompanying questions.

A Prospective Study of Medical Screening in a Military Population

During their first year in the military service, 10,000 18-year-old privates were offered the opportunity to participate in a yearly health maintenance examination that included history, physical examination, and multiple laboratory tests. The first year 5,000 participated and 5,000 failed to participate; the 5,000 participants were selected as a study group, and the 5,000 nonparticipants were selected as a control group. The first-year participants were then offered yearly health maintenance examinations during each year of their military service.

Upon discharge from the military, each of the 5,000 study group members and each of the 5,000 control group members were given an extensive history, physical examination, and laboratory evaluation to determine whether the yearly health maintenance visits had made any difference in health and life style of the participants.

The investigators obtained the following information:

1. On the basis of their reported consumption, participants had half the rate of alcoholism as nonparticipants.

2. Participants had twice as many diagnoses made for them during military service as nonparticipants.
3. Participants had advanced an average of twice as many ranks as nonparticipants.
4. There were no statistically significant differences between the groups in the rate of myocardial infarction.
5. There were no differences between the groups in the rate of development of testicular cancer or Hodgkin's disease, the two most common cancers in young men.

The authors then drew the following conclusions:

1. Yearly screening can reduce the rate of alcoholism in the military by one-half.
2. Since participants had twice the number of diagnoses made for them, their diseases were being diagnosed at an earlier stage in the disease process, at a point where therapy is more beneficial.
3. Since participants had twice the military advancement of nonparticipants, the screening program must have contributed to the quality of their work.
4. Since there was no difference in the rate of myocardial infarction, screening and intervention for coronary risk factors should not be included in a future health maintenance screening program.
5. Since testicular cancer and Hodgkin's disease occurred with equal frequency in both groups, future health maintenance examinations should not include efforts to diagnose these conditions.

Now see if you can answer the following questions, which form the uniform framework for reviewing medical studies.

1. Was the study properly designed to answer the study questions?
2. Was the method of assignment of patients to study and control groups proper?
3. Was the assessment of the results in the study group and in the control group adequately performed?
4. Did the analysis properly compare the outcome in the study and the control groups?

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5. Was a valid interpretation drawn from the comparisons made between the study and control groups?
6. Were the extrapolations to individuals not involved in the study properly performed?

How did you do? If you feel you can answer these questions already, turn to the critique on page 87 and compare your answers. If and when you are ready, let's proceed!

Let us begin by outlining a uniform framework for analyzing clinical research articles. It will constitute the foundation for the entire process of studying a study.

The uniform framework contains the following basic components:

ASSIGNMENT Selection of individuals for a study and a control group

ASSESSMENT Determination of the results of the investigation in the study and the control groups

ANALYSIS Comparison of the results of the study and control groups

INTERPRETATION Drawing conclusions about the meaning of any differences found between the study and control groups

EXTRAPOLATION Drawing conclusions about the meaning of the study for individuals not included in the study

Figure 2-1 outlines the application of the uniform framework to a research study.

Three basic types of clinical research studies are frequently found in the medical literature: retrospective or case-control studies, prospective or cohort studies, and experimental studies or clinical trials. The uniform framework can be applied to all three types of studies with only minor modifications.

In order to illustrate the application of the uniform framework to retrospective, prospective, and experimental studies, the essential features of each type of study are outlined and then applied to the specific problem of the relationship between estrogen use and uterine cancer.

Retrospective Study (Case-control Study)

The unique feature of retrospective studies is that they begin after individuals already have developed or failed to develop the disease being investigated. They go back in time to determine the characteristics of individuals prior to the onset of disease. Retrospective studies also are called *case-control studies,* the "cases" being the individuals who have developed the disease already, and the controls

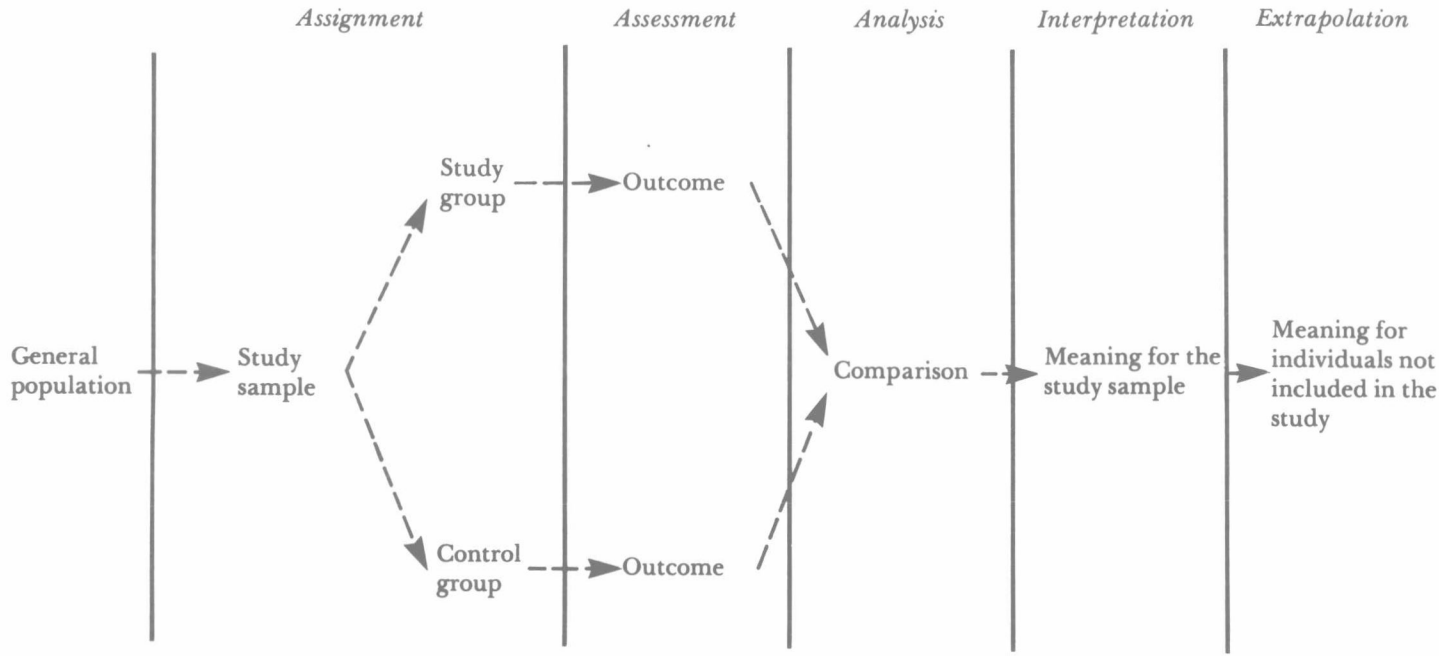

FIGURE 2-1. Uniform framework for studying a study.

being the individuals who have not developed the disease. In order to use a retrospective study to examine the relationship between estrogen use and uterine cancer, an investigator would proceed as follows.

ASSIGNMENT. Select a group of women who currently have uterine cancer (cases) and a group of otherwise similar women who do not have uterine cancer (controls). Since the development of the disease is observed to occur without the investigator's intervention, this process will be called observed assignment.

ASSESSMENT. Determine whether each woman previously took estrogens and, if so, how much she used.

ANALYSIS. Calculate the probability that the group of women with uterine cancer had been estrogen users versus the probability that the group of women without cancer had been estrogen users.

INTERPRETATION. Draw conclusions about the meaning of the differences in the probability of estrogen use by the uterine cancer study group as opposed to the control group.

EXTRAPOLATION. Draw conclusions about the meaning of estrogen use for other women not included in the study.

Figure 2-2 illustrates the application of the uniform framework to this study.

Prospective Study (Cohort Study)

The unique feature of prospective studies is that they begin *before* individuals have developed the disease that is being investigated and follow them forward in time to determine who subsequently will develop the disease. Prospective studies also are called *cohort studies,* a cohort being a group of individuals who share a common experience. Prospective or cohort studies follow a cohort that possesses the characteristic under study as well as a cohort that does not possess that particular characteristic. In order to use a prospective study to examine the relationship between estrogen use and uterine cancer, an investigator would proceed as follows.

ASSIGNMENT. Select a study group of women who are using estrogens and an otherwise similar control group of women who are not and have not been using estrogens. Since the use of estrogens is observed to occur without the investigator's intervention, this process also will be called observed assignment.

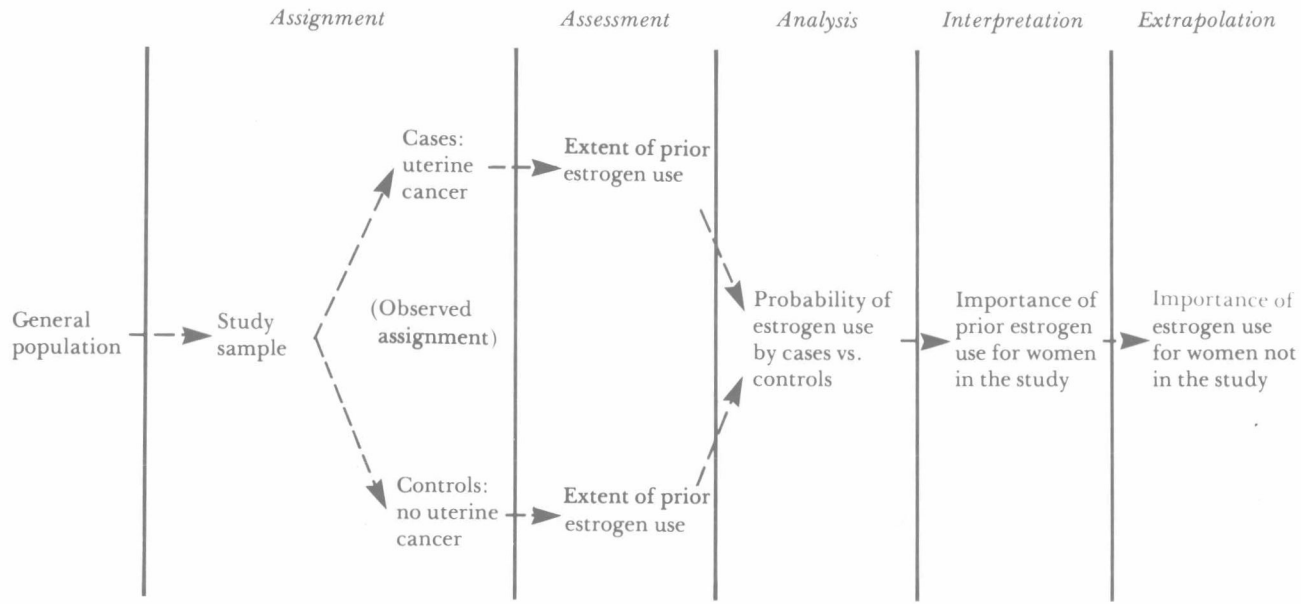

FIGURE 2-2. Application of the uniform framework to a retrospective or case-control study.

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