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Current Concepts

# A Statistics Primer

## Types of Studies in the Medical Literature

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When we review the orthopaedic literature, we find that there are many different types of studies and study designs. For example, some studies are based on description, while others are more analytical. When researchers design a study, the type of study as well as the study design determine the statistical tests that can be used and the validity of the conclusions that can be drawn. When reviewing the literature, it is important to recognize the type of study that is being presented, and to be aware of its strengths and limitations before incorporating the information contained in the study into your clinical practice.

### DESCRIPTIVE STUDIES

Descriptive studies organize data in a novel and informative way. Such studies are often less expensive and less time-consuming than analytical studies. Descriptive studies may show possible associations between a disease or injury and specific variables, but cannot demonstrate cause-and-effect relationships, and as such, the findings are not as useful in drawing conclusions. Instead, the associations that arise from these studies are used to develop research hypotheses for testing experimentally. In the orthopaedic literature, descriptive studies are very common. Case reports, case series, correlation studies, and cross-sectional studies are examples of descriptive studies.

#### Case Reports and Case Series

Case reports are descriptions of a disease or condition and present information about one patient, while case series present information on a series of patients. Case reports and series are useful in identifying injury or disease patterns and possible associations, but lack controls, and do not give information regarding frequencies of occurrences of the particular disorder. For the clinician, these cases demonstrate patterns, but one should not draw general conclusions from them because the associations and findings raised in these series are usually speculative; further study of an appropriate hypothesis is required.

#### Correlational Studies

Correlational studies are descriptive studies that use very large samples to identify associations between disease or injury occurrences and other variables of interest. These studies are not common in the sports medicine literature because they frequently assess populations on a geographic scale. For example, a team of researchers might investigate the incidence of slipped capital femoral epiphysis in different countries around the world. If the data from this study demonstrated a lower incidence of slipped capital femoral epiphysis near the equator, then they might suggest that exposure to sunlight and increased vitamin D production is protective. The association may be plausible, but a cause-and-effect relationship has not been established. There are a number of other variables that may have an effect on this association. Therefore, like other descriptive studies, correlational studies may demonstrate associations but should be used cautiously when drawing conclusions. The best use of correlational studies is in their ability to generate research hypotheses worthy of testing.

#### Cross-Sectional Studies

In the cross-sectional study, a group of patients is evaluated at one specific point in time. Particular disease states and exposures to risk factors for acquiring the disease are then described. This is somewhat like taking a "snapshot"

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of a population, and then deriving associations. Cross-sectional studies may be used to describe the distribution of a condition in a population, or may be used to determine associations of disease with other variables. A magnetic resonance imaging study that assesses acromial spurring and rotator cuff tears in a population would be an example of a cross-sectional study. Because the exposure and disease are evaluated at the same point in time, cross-sectional studies cannot reliably determine cause and effect. The researchers in this example cannot conclude that an acromion with a spur causes rotator cuff tears, as the rotator cuff tear might cause the spurred acromion. Unlike the spurred acromion in this example, some variables remain constant over time, such as sex or ethnic heritage. In these cases, cross-sectional studies can be used to derive statistically meaningful conclusions. Although cross-sectional studies may suggest causal links between a disease and a particular variable, they generally cannot be used to draw definite conclusions. Instead they are more useful in generating hypotheses for testing.

## ANALYTICAL STUDIES

Analytical studies, in contrast to descriptive studies, allow for hypothesis testing and statistical analysis, and are designed to compare exposures to risk factors and disease states. The conclusions drawn from analytical studies may have statistical and clinical significance. Analytical studies can be divided into two types, cohort studies and experimental studies. In cohort studies, the researcher does not manipulate the conditions of the group, as in a clinical trial, but instead records exposures or injuries as they occur. Cohort studies can be done retrospectively by reviewing the data collected previously for a cohort of patients, or prospectively, by following a group into the future. Experimental clinical studies differ in that the researchers have an active role, and manipulate the conditions of the group and then observe the outcome.

### Case-Control Studies

The case-control study is a type of cohort study in which the participants are selected on the basis of their injury or disease status. Their past history is then evaluated to identify previous exposures and risks for developing an injury or disease. For example, a sample of patients with ACL tears may be identified, as can a control group without ACL tears matched for age and sex. The participants in both groups are then interviewed with regard to their athletic activity to determine if a specific risk factor was present antedating the interview or time of injury, for example, if they played on artificial or natural turf. The retrospective nature of this type of study is a source of bias in that the exposures to specific risk factors may not be recorded or remembered by the participants. Nevertheless, a well-designed case-control study can provide clinically relevant information and is usually more easily completed than a prospective study. Case-control studies can be performed relatively rapidly and inexpensively. These studies are advantageous because they may be used to analyze rare diseases, and multiple variables related to the outcome of interest can be examined at one time. On the other hand, case-control studies are not useful to assess rare exposure events, cannot directly measure incidence, and may be subject to selection and recall bias.

### Prospective Cohort Studies

In the prospective cohort study, a group of healthy persons is identified first, then followed over time, with exposures and the onset of the disease or injury documented as they occur. Controls are an inherent part of this type of study because they are the subjects in the population who do not develop the injury or disease. An example would be a group of healthy collegiate athletes followed over time to determine the incidence of an ACL tear. The exposures to specific hypothesized risk factors—for example, natural or artificial turf—could be accurately documented.

A prospective cohort study is thought to be more informative than a retrospective study because the temporal relationships between exposures and the disease are known and accurately documented. In addition, prospective studies allow the investigator to specify the hypothesis and variables to be studied before the experiment begins. Specifying the data to be collected and how it is to be analyzed before the study begins minimizes potential bias and increases the strength of the study's conclusions.

### Outcomes Research

Outcomes research has become a commonly used phrase in clinical research. It is, however, not new, but rather a novel approach to improve clinical research. Outcomes research places emphasis on the patient's perception of his or her health after an intervention and reports data in a manner that allows comparisons to other investigators' work. Outcomes research has developed from the impression that too much money is being spent on health care in the United States. Research performed in the 1970s and 1980s demonstrated that there is significant regional variation in the use of certain medical services. This implies that in high-use areas unnecessary or inefficient services are being provided, and that in low-use areas, patients may not be receiving adequate medical care. Frequently, cost-effectiveness analyses and decision analyses are important components of outcome studies. Outcomes research is usually completed using a prospective cohort study or an intervention study. An example might be the evaluation of the effectiveness of a home physical therapy program compared with standard physical therapy services for patients who have undergone ACL reconstruction. This study would use a standard measure of patient outcome such as the International Knee Documentation Committee evaluation. In addition to outcome measures, this study would most assuredly comment on the costs involved as well.

Data standardization is an important feature of outcome studies. Studies using the same standardized data collection techniques may be comparable. This type of research is time- and resource-intensive because it re-

quires the use of validated and sensitive outcome measurement tools.

### Intervention Studies

The interventional study, or clinical trial, is markedly different from a cohort study. In a clinical trial, an intervention to treat or prevent an injury or disease is tested. Well-designed interventional studies are prospective, that is, the experiment has been designed before data has been collected. These studies use randomization so that each patient has a known chance of being assigned to either the treatment or control group. Patients and researchers in intervention studies may also be blinded, or masked; this means that they are unaware of the specific treatment assignment during the study. The patient or treating physician *alone* may be blinded (single-blinded study), or *both* the patient and the treating physician may be blinded (double-blinded study). An example of an interventional study could be the evaluation of an analgesic effect on postoperative pain after knee arthroscopy. The hypothesis, the experimental design including statistical analysis, and the outcomes with regard to assessing pain relief would be known and established before beginning the experiment. Age- and gender-matched patients could be randomized to receive the medication or a placebo. Neither the patient nor the evaluating physician would know which treatment was given to which patient.

Interventional studies are carefully designed to reduce the effect of bias and confounding.[1] In addition, the outcome should be precisely defined as should the specific type of data collected. A study designed in this manner is thought to be the most accurate and precise way of evaluating the effectiveness of a treatment regimen, yet it is expensive, time-consuming, and may require an evaluation of ethical concerns. Nevertheless, the prospective, randomized, blinded clinical trial is thought to be the best type of study from which to draw conclusions.

In summary, when the physician reviews the medical literature and decides which studies should affect his or her practice, it is important to recognize the strengths and weaknesses of the various types of studies in the literature. The results of descriptive studies should be interpreted cautiously. The conclusions of well-designed analytical studies, on the other hand, generally have more merit; the prospective, randomized, and blinded studies are the most helpful type of study from which conclusions can be drawn and applied to your practice.

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## REFERENCES

1. Greenfield ML, Kuhn JE, Wojtys EM: A statistics primer. *Am J Sports Med 24:* 393–395, 1996