A practical approach to evidence-based dentistry: IV

How to use an article about harm

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ABSTRACT

Background and Overview. Questions regarding harm are common in dental practice. Observational, nonrandomized studies (that is, cohort studies and case-control studies) are the designs used by investigators to answer most of these questions. A critical appraisal of these studies should include an assessment of the risk of bias, the results, and the applicability of the study. The authors provide the concepts and guidelines that dentists can apply to most effectively use articles regarding harm to guide their clinical practice.

Practical Implications. Dentists who wish to inform their clinical decisions regarding questions of harm can use these guidelines to decide what type of studies to search, define the specific question of interest to search efficiently for these studies, and critically appraise an article about harm.

Key Words. Evidence based-dentistry; harm; observational studies; critical appraisal.

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FOURTH IN A SERIES

In the 3 previous articles of this series, we introduced the process of evidence-based dentistry (EBD),[1] how to search for evidence to inform clinical practice,[2] and how to use an article about therapy.[3] In this article, we will explain how to use an article to inform clinical decisions regarding questions of harm. We will introduce and describe the basic concepts needed to understand observational studies, and we will explain how to use these concepts to critically appraise such studies. In subsequent articles in this series, we will describe how to use other types of study designs.

Supplemental material is available online.

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BOX 1

Clinical scenario.

You met with a new patient who was referred to you by his family doctor. The patient explained to you that he had been having many physical problems, such as muscular pain in his shoulders, back, arms, and legs, and that his physician told him that one of the causes might be his oral health status. While examining the patient, you noticed that he has lost many teeth. The patient asks you if this tooth loss might be related to his general health problems. You are not sure, so you decide to search for evidence from a clinical study to answer this question.

CLINICAL QUESTIONS OF HARM

Questions regarding potentially harmful exposures, either to dental treatments or external agents, are common in dental practice. Some examples of these questions are the following: Do people who live in areas where the water is fluoridated have a higher risk of having enamel defects? Does smoking increase the risk of having oral cancer? Does the dentist's use of rubber dams when placing a dental restoration increase the patient's risk of allergic reactions if the patient has a latex allergy?

The classic Population-Intervention-Comparison-Outcome (PICO) framework requires only minor modifications to address questions related to harm. The population is the patients of interest. In cases that address questions related to harm, the population is those patients who may face the potentially harmful agent. The intervention becomes the exposure, which corresponds to the harmful agent. The comparison is the reference, which is the absence of the exposure to the harmful agent. The outcome is the potential negative consequence of the exposure. Table 1 shows examples of questions related to harm and the corresponding PICO components.

WHAT STUDY DESIGN BEST ADDRESSES QUESTIONS OF HARM?

Owing to the hierarchy of evidence used to answer questions about harm, even though investigators might identify randomized controlled trials as being the best type of study design to answer these types of questions, they generally cannot use this type of study design because of ethical reasons. Therefore, at the level of a primary study, an observational study is usually the most appropriate study design to answer questions regarding harm. This is not always true, however. Note, for example, that investigators could address the question listed in Table 1 about rubber dams by using a randomized controlled trial design.

An observational study is one in which the investigator does not assign an exposure or intervention; rather, these exposures or interventions occur naturally in the study setting. Although investigators have conducted descriptive observational studies in which they recruit only one group of patients and do not compare them with any other group of patients, in this article we describe the type of observational studies in which investigators use a comparison group (which can happen because either 2 groups of patients are recruited and followed, or 1 large group of patients is divided into 2 or more, on the basis of the presence of an exposure).

Observational studies can be classified according to the direction in which the exposure or outcomes are measured.[4] The intuitive design is one in which investigators enroll participants who either are exposed or are not exposed (for example, patients living in a community that has fluoride in the water or patients living in a community that does not have fluoridated water) and follow them over a period, recording whether the outcome of interest (that is, fluorosis) does or does not occur. We call these cohort studies (Figure, Table 2[5-7]).[8]

A less intuitive design is one that involves investigators recruiting samples of study participants in whom the outcome has occurred (for example, they have had fluorosis [we call these participants "cases"]) and comparing them with similar study participants who have not had the outcome of interest (that is, no fluorosis [we call these participants "controls"]). Investigators then determine—by asking questions to participants or by looking at medical records or other information sources—whether participants in either group experienced the exposure of interest (that is, water fluoridation). We call these case-control studies (Figure, Table 2[5-7]).[9]

Investigators can use another type of design only when they can assess the exposure and the outcome at the same time. Here, the investigator looks simultaneously at the exposure (for example, the current exposure to fluoridated water) and the outcome (for example, fluorosis). We call such designs cross-sectional studies.[4]

In general, cohort studies are less susceptible to bias than are case-control studies, and case-control studies are less susceptible to bias than cross-sectional studies. Thus, if available, we would choose cohort studies as our source of evidence.

Why then would investigators bother conducting case-control studies? The reason is that if an outcome is rare or if the outcome occurs over a long period, conducting a cohort study may be challenging or not feasible at all and choosing the case-control design might be a better option.

Consider the question of whether smoking increases the risk of oral cancer. Because oral cancer is (fortunately) rare and because it develops over a long period,

ABBREVIATION KEY. **DMFT:** Decayed, missing, filled teeth. **EBD:** Evidence-based dentistry. **PICO:** Population, Intervention, Comparison, Outcome. **SSB:** Sugar-sweetened beverages.