Letter to Editor

Importance of a Control Group in Sleep Research

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In this letter, the necessity of a control group in sleep studies is emphasized. Indeed, I believe that it is crucial to follow a correct methodological approach in sleep science studies. To make an evidence-based clinical decision, an appropriate control group is required to establish a valid association between the risk factor/treatment and the outcome of an analytical sleep study. However, defining and recruiting healthy sleepers can be challenging for sleep researchers.

A control group refers to participants who are similar to the case group in all aspects that affect the outcome, except for the risk factor/intervention in question (1). In epidemiological studies, a control group is used to establish causality by providing the ability to remove the effect of other covariates, called confounders (1). The control condition is an essential element in clinical trials, as it serves as a baseline for determining the effectiveness of the study treatment. The purpose of such a control group is to determine whether the effect of the intervention was due to the self-limiting course of the disease or a placebo effect. In addition, since a clinical trial without a control group cannot have sufficient validity, it cannot be justified from an ethical point of view (2). Similarly, in cohort and case-control studies, it is necessary to have a comparison group to achieve valid results (1).

Given the serious consequences of sleep disorders on patients' health and quality of life (QOL), investigating the risk factors and possible curative modalities is important. Hence, what methodological considerations should be taken into account in sleep research? One of the most basic considerations is how study participants are selected. Normal sleepers (control subjects) can be as critical as patients because the true effect of risk factors or the true effectiveness of a treatment can be influenced by the selection of a control group. To minimize bias in control selection, the following three basic principles are suggested for conducting case-control studies by Wacholder et al. (3); however, they are also applied for cohort studies. The aim of the first principle named "study base principle" is to sample controls from the target population in which the cases arose. The second one named "deconfounding principle" refers to the measurement and control of important confounders either in the design or in the analysis phase of the study. The third is the "comparable accuracy principle", which means that the measurement of exposure or outcome of interest in cases and controls should be equivalent.

As Beattie et al. described, there have been various criteria for defining normal sleepers (controls). They suggested four main components of normal sleep, including sleep disruption, circadian disruption, sleep disorders, and general health (4). Differences in the definitions may lead to different comparison groups among studies. Therefore, comparing the results of studies becomes problematic. Moreover, since there are several methods for diagnosing sleep disorders, such as simple self-reporting, a personal history, polysomnography (PSG), and a clinical

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interview, to prevent information bias, it is important to evaluate the outcome of interest among patients and control subjects in the same way. What is essential when reporting research results is to clarify the diagnostic criteria of the patients and controls.

In my view, understanding the role of potential risk factors of sleep disorders and assessing the effectiveness of a treatment depends not only on the case definition but also on the thoughtful selection of controls. Therefore, adequate attention should be paid when we conclude about a risk factor or a proposed treatment for sleep disorders.

Conflict of Interests

Authors have no conflict of interests.

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