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Unexpected term NICU admissions: a marker of obstetrical care quality?

Check for updates

TO THE EDITORS: We want to comment on the terminology used to describe the study design of the recent paper, Unexpected term NICU admissions: a marker of obstetrical care quality, which analyzed data from the Consortium for Safe Labor.[1] The study abstract identifies the study as a retrospective cross-sectional study. The defining feature of cross-sectional studies is that they do not have a temporal direction (ie, retrospective, prospective, or ambidirectional). This is because they involve data collection at just 1 point in time about things that may exist in the past or present, and study eligibility is not based on whether a study outcome has already occurred.[2]

The term, retrospective cross-sectional study, is thus an oxymoron. The word retrospective lacks a consensus definition in epidemiology,[3,4] but it has been used at various times to mean the following: (1) de novo collection of exposure data after outcome occurrence; (2) the case-control study design in general; or (3) the feature of historical cohort studies that distinguishes them from other cohort studies: the temporal ordering of follow-up of exposed and unexposed individuals before initiation of research (ie, in the past).[2,4] In the current situation, we suspect that the term retrospective was intended to mean a study in which preexisting data were used to address a question not specifically envisioned at the time the data were collected.

The distinction between prospective and retrospective was clearer in the era when information on exposures and confounders was usually collected by direct interview of participants. However, it has become blurred in the present era of widely available electronic records of clinical interactions, insurance claims, vital records, environmental monitoring, etc, particularly when those records can be linked at the individual level. Therefore, in the current era, these terms "do not readily convey a clear message about the study" (page 96).[2]

Because of the substantial challenges in accurately applying study design categories to modern data resources, when study design distinctions must be made, we advocate dividing only between experimental and observational studies. Even this distinction is not simple and is vulnerable to classification error: for instance, when randomized controlled trials are analyzed for secondary purposes to study only exposures that were not randomized, they are effectively observational studies. However, focusing on this distinction might provide the most crucial information while also enabling accurate designation of study designs and, in turn, facilitate the identification of potentially important biases. ■

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Generalizability from well-designed RCTs underpin their scientific strength

Check for updates

TO THE EDITORS: A recent commentary by Nezhat et al[1] attempts to draw conclusions regarding the results of a prospective randomized study (Laparoscopic Approach to Cervical Cancer trial) that demonstrated lower disease-free survival in patients who undergo minimally invasive radical hysterectomy compared with the open approach.[2] In response, we aim to highlight how the fundamental principles of study design and analysis have been overlooked by Nezhat et al. The design strength of randomization in a well-conducted clinical study ensures that all factors, both measured and unmeasured, are balanced among the groups being compared and guarantees that comparisons give unbiased and consistent estimates of the true underlying differences.[3] Heterogeneity in surgical experience is inevitable; while being controlled for by randomization, it also preserves the generalizability of the result. Surgical volume, although potentially impacting on outcome, would, by randomization, be balanced between the groups and add strength to the external validity of the results, particularly because, contrary to the implication in the commentary, the volume was not uniformly distributed across the participating surgeons. Additionally, the Laparoscopic Approach to Cervical Cancer trial was indeed stratified by site (a surrogate for surgeon) and stage of disease.

The suggested multilevel adjustment by Nezhat et al[1] would be an exercise in statistical acrobatics that would provide a limited and confusing interpretation of the resulting analyses. Limitations include (1) the results being anchored to the choice of model(s) selected, the appropriateness of which are never evaluated, (2) the distribution of factors being adjusted in the trial having little resemblance to the distribution in the wider surgical population, (3) the assumption (incorrect) that all heterogeneity can be explained by statistical adjustment, (4) potential numeric non-convergence/instability in the fitting process, and (5) introduction of missing values in the analyses when some of the factors being adjusted for are missing.

A further advantage of randomization, aside from the scientific rigor in study design, is the ability to perform unadjusted analyses that rely only on minimal assumptions. Although this may provide conservative estimates, it is underpinned by a robust design and strong scientific principles and provides a clear interpretation of the study results. The suggested post-hoc adjusted analysis is 1 of many possible approaches and, as with multiple comparisons, the risk of the selection of that method of adjustment that would support preconceived views is always present. The basic principle of clinical research dictates that new standards of care and changes in patterns of practice should be supported by well-conducted and adequately powered randomized trials. ■

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REPLY

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There is nothing scientific about surgical randomized controlled trials (RCTs) when investigators do not take into consideration differences in surgical skills in the performance of a new complex procedure and adjust for it or if they cannot ensure that the new procedure was performed appropriately.