

Sex bias in human surgical clinical research

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An analysis of about 1,300 peer-reviewed research articles found that few studies included men and women equally, less than one-third performed data analysis by sex, and there was wide variation in inclusion and matching of the sexes among the specialties and the journals reviewed, according to a study published online by *JAMA Surgery*.

Males and females can have different postoperative outcomes, complication rates, and readmission rates, so it is important to know if [sex](#) bias is pervasive in surgery. Adequately controlling for sex as a variable with inclusion, [data](#) reporting, and [data analysis](#) is important because data derived from clinical research are the foundation for evidence-based medicine.

Melina R. Kibbe, M.D., of the University of North Carolina at Chapel Hill (formerly of Northwestern University, Chicago), and Editor, *JAMA Surgery*, and colleagues conducted a study to determine if sex bias exists in human surgical clinical research, if data are reported and analyzed using sex as an independent variable, and to identify specialties in which the greatest and least sex biases exist. For the analysis, data were abstracted from 1,303 original peer-reviewed articles published from January 2011 through December 2012 in 5 surgery journals.

Of the 1,303 articles, 17 (1.3 percent) included males only, 41 (3.1 percent) included females only, 1,020 (78 percent) included males and females, and 225 (17 percent) did not document the sex of the participants. Although female participants represent more than 50 percent ($n = 57,688,606$) of the total number (115,377,213) included,

considerable variability existed with the number of male (46,111,818), female (58,805,665), and unspecified (10,459,730) participants included among the journals, between U.S. domestic and international studies, and between single vs multicenter studies.

For articles included in the study, 38 percent reported these data by sex, 33 percent analyzed these data by sex, and 23 percent included a discussion of sex-based results. Sex matching of the included participants in the research overall was poor, with less than half of the studies matching the inclusion of both sexes by 50 percent (e.g., 100 males to 50 females, or vice versa). During analysis of the different surgical specialties, a wide variation in sex-based inclusion, matching, and data reporting existed, with colorectal surgery having the best matching of male and female participants and cardiac surgery having the worst.

The authors write that the implications of these findings are numerous. "First, drugs, therapies, and devices may be developed that are effective for one sex. Second, for therapies and drugs that have an overall low efficacy in men and women when the data are combined, the therapy or drug may be abandoned; however, that therapy or drug may have greater efficacy in one sex vs the other. This result would be known if sex-based analysis and reporting of the data were performed. ... Third, therapies may be developed that have undesirable adverse effects in the opposite sex. For example, the odds of an [adverse drug reaction](#) in women is 50 percent greater than in men, women are more likely to be hospitalized because of an adverse drug reaction, and 80 percent of the drugs removed from the market by the FDA were because of undesirable adverse effects in women."

"Thus, whereas it is important to collect data of male and female participants, performing independent data analysis and reporting can produce findings leading to valuable contributions to the health and well-

being of males or females independently."

"Because the foundation of precision health is adjusting treatment modalities specifically for each patient, consideration of sex variability is necessary to increase successful outcomes. In addition, we need to consider sex presentation, age, ethnic background, and socioeconomic status because these factors also can determine results," write Julie A. Freischlag, M.D., and Michelle M. Silva, B.A., of the UC Davis Health System, Sacramento, in an accompanying commentary.

"Identification of all patients included in clinical trials is essential. Authors, reviewers, publishers, and funding agencies should mandate this process in any publication so that results used to provide quality care are accurate. Diversity and inclusion excellence are important in the success and greatness of academic institutions, and the same can be said for research."

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