ORIGINAL ARTICLE

Gender Reporting in Radiology Human Subjects Research

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Abstract

Purpose: The aim of this report was to study the presence and extent of gender bias and reporting in radiology human subjects research.

Methods: For this bibliometric analysis, the authors reviewed all articles published between January 1, 2016, and June 30, 2016, in seven of the most cited general radiology journals. From each original research article studying human subjects, the number and gender of participants and whether gender-based results were reported were manually extracted. Articles evaluating gender-specific body parts were excluded. Article-level subject gender matching percentages were calculated and descriptive statistics reported.

Results: Of all 1,065 target journal articles during the study window, 522 met the human subjects research inclusion criteria. Of these, 48 (9.2%) made no mention at all of research subjects' gender. Of the 473 articles mentioning gender, 147 (31.1%) had more female and 308 (65.1%) more male subjects. But in aggregate, 105,763 of 254,102 (41.6%) of all subjects were male and 142,069 (55.9%) were female. By quartile distribution, subject gender matching was very variable (12.9% of articles with <25% match, 23.7% with 25%-50%, 29.4% with 50%-75%, and 34.0% with ≥75%). Of articles including subjects of both genders, however, only 27.5% (126 of 458) reported any gender-based results.

Conclusions: In human subjects research published in the most cited general radiology journals, the gender of human subjects is a poorly controlled, and frequently neglected, variable. In an emerging era of personalized medicine, initiatives to ensure transparent reporting of gender-specific results may help catalyze otherwise overlooked discoveries to advance the health of all.

Key Words: Research bias, gender bias, radiology research, disparities

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PURPOSE

Despite abundant data to the contrary, women have often historically been considered suboptimal research subjects given inherent hormonal and reproductive differences from men and perceived challenges in recruiting [1]. For example, to prevent unintended fetal consequences, the FDA in 1977 excluded women of childbearing potential from participating in clinical studies until safety and efficacy were further evaluated [2]. Accordingly, women have traditionally been underrepresented in clinical trials, thus contributing to a paucity of meaningful data for women and their health care providers regarding gender-specific risks and benefits of certain treatments and diagnostic procedures. In response to these concerns, the National Institutes of Health (NIH) Revitalization Act of 1993 mandated the inclusion of women in clinical trials. In 2010, the Institute of Medicine's Committee on Women's Health Research brought further attention to this issue when it released a report regarding the consequences of neglecting gender differences in the design, analysis, and reporting of research studies [3]. Nonetheless, several recent studies in medical fields other than radiology have shown that gender bias persists in both basic and clinical research and that gender remains a poorly controlled variable in many trials [1,4-12].

As in nonradiology research [5-9,12], controlling for gender in radiology human subjects research is important because many medical conditions present differently in women than men. Such differences can be

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secondary to intrinsic factors (eg, gender-specific physiology, genetics, hormones, body shape), extrinsic factors (eg, diet, sociocultural issues, environment), or a combination of both. Additionally, sociodemographic characteristics such as gender, ethnicity, and age are associated with certain medical conditions and thus ideally should all be considered during study recruitment and reported in study results. And, often unique to medical imaging, characteristics associated with the female gender (eg, size, age, comorbidities, past pregnancies) may be responsible for differences in the quality or accuracy of examinations. For instance, women undergoing nuclear medicine cardiac stress testing more frequently require attenuation correction to prevent false-positive results from breast tissue attenuation artifact.

Despite increasing attention to gender reporting in human subjects research more broadly, the topic has received little attention in the radiology literature. The purpose of our study was thus to assess the presence and extent of gender bias and reporting in radiology human subjects research.

METHODS

Our study entailed reviewing and abstracting previously published peer-reviewed literature that was already de-identified and publicly available. As such, our work did not constitute human subjects research and did not require oversight by our institutional review board.

Data Collection

For this bibliometric analysis, we individually and manually reviewed all articles published between January 1, 2016, and June 30, 2016, in the seven most cited general radiology journals as determined by the 2015 Thomson Reuters Journal Citation Index. These journals were (in descending order of Impact Factor) *Radiology*, *Investigative Radiology*, *European Radiology*, the *Journal of the American College of Radiology*, the *American Journal of Roentgenology*, the *European Journal of Radiology*, and *Clinical Radiology*. Despite its high citation index, we excluded one journal (*RadioGraphics*) given that the vast majority of its published articles were educational and literature review (ie, not original research) in nature.

Focusing on human subjects research, we excluded 344 articles that did not constitute original research (eg, review articles, meta-analyses, editorials, commentaries) and 77 research articles that did not involve human subjects (eg, animal, phantom, device, or equipment focused). As with a similar study outside of radiology [6], we excluded human subjects research studies that evaluated gender-specific body parts or conditions (breast [n = 75], prostate [n = 22], uterus [n = 4], cervix [n = 3], pregnancy [n = 3], testicle [n = 3], ovary [n = 2], and vagina [n = 1]), as these would involve no expectation of gender balance. All other original research articles studying human subjects were included and individually reviewed by at least one member of our study team (AJ, BLV, or TRM, all then fourth-year medical students, under the guidance of CCM, a board-certified senior faculty radiologist) to manually extract the number and gender of participants (if specified), and ascertain whether any gender-based results were reported. We classified articles as reporting any gender-based results if they included any analysis at all of data by gender in their results sections.

Matching of Study Subjects by Gender

For each article, we calculated the percentage of gender matching for subjects by dividing the number of subjects of the lesser sampled gender (whether male or female) by the number of the greater sampled gender. For example, a study involving 50 male and 50 female subjects would have a 100% gender match ([50/50] × 100 = 100%), whereas one involving 25 male and 50 female subjects would have a 50% gender match ([25/50] × 100 = 50%), and one involving 200 male and 60 female subjects would have a 30% gender match ([60/200] × 100 = 30%). Gender matching distributions were calculated by quartile.

Outcome Measures

Our primary outcome measures were the percentage of articles specifying the gender of participants, the percentage of study subjects' gender (male, female, or unspecified), the percentage of studies reporting gender-based results, and the quartile distribution of study participants' gender matching percentage. Secondarily, we evaluated the percentage of articles specifying the gender of participants, the percentage of study subjects' gender, and the percentage of studies reporting gender-based results by the seven selected most cited general radiology journals.

RESULTS

Of all 1,065 articles published in the seven selected most cited general radiology journals during our study period, 522 met the inclusion criteria (Fig. 1). Of these, 48 (9.2%) made no mention at all of their research subjects' gender. The percentage of articles specifying