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RESEARCH LETTER

Association of Women Authors With Women Enrollment in Clinical Trials of Atrial Fibrillation

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Atrial fibrillation (AF) is one of the most common arrhythmias in clinical practice and is strongly interlinked with sex.[1] Women with AF have more devastating complications, such as stroke, than men.[1] Data are concerning about suboptimal representation of women in cardiovascular randomized clinical trials.[2] Identifying the mechanisms forming the basis of gender disparity in science has been a focus of discussion.

Authorship on trial publications, particularly for pivotal positions such as the first and last author positions, generally represent trial leadership structure. A recent study showed that a higher representation of women authors was independently associated with better enrollment of women participants in heart failure trials.[2] Herein, we investigated if the gender-based disparities in cardiology also exist in the authorship of AF randomized controlled trials and whether promoting inclusivity of women in authorship can influence women's participation in trials.

The data included in this meta-analysis are publicly available from published studies; our analyses can be shared upon request. Because publicly available data were used, institutional board review approval was not required. The study search, selection, and data abstraction process have been reported previously.[3] Briefly, we searched MEDLINE and ClinicalTrials.gov from January 1985 to April 2019 using search terms (*Atrial fibrillation OR *AF) AND (*Rate control therapy OR *Rhythm control therapy OR *Ablation OR *Cardioversion OR *Anticoagulation OR *Treatment) to identify randomized controlled trials of AF with a follow-up duration of ≥3 months. We extracted the number of women participants in the trials, the total number of women authors, and women in the first or senior (ie, last) author position. We identified women authors following prior strategy, including using the Genderize (https://genderize.io; Roskilde, Denmark) database by confirming the first name with self-identification on institutional websites, social media accounts, and other search engines with photographs, biological paragraphs, or publications listed.[2] We used a multivariable linear regression model to assess the association between women authors' proportion in each trial and women enrollment per trial after adjusting for trial characteristics (trial's intervention, publication year, region, and funding mechanism).

Of 136 trials (n=149 162), the median number of participants per trial was 205 (quartile [Q]1–Q3, 74–676), and the median number of women participants per trial was 71 (Q1–Q3, 27–218). Overall representation of women participants in trials was (n=52 477/149 162) 35.1% (95% CI, 32.6%–37.6%), which did not improve

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significantly over time (*P*=0.10). The total number of authors was 1568; the median number of authors per trial was 10 (Q1–Q3, 7–10), and the number of women authors per trial was 1 (Q1–Q3, 0–3). The overall proportion of women authors was (n=213/1568) 14% (95% CI, 12%–15%), which was consistently low irrespective of the journal, intervention, region, and funding mechanism (Figure). Among 136 trials, 127 trials had men as first authors (93%), and 125 had men as senior (92%) authors. Only 7% (n=9/136) of trials had women as the first author, and 8% of trials (n=11/136) had women in senior author positions, which did not improve significantly over time (*P*=0.07). The proportion of women authors per trial was independently significantly associated with greater women participant enrollment (β=0.19, *P*=0.02).

Our study highlights the underrepresentation of women authors in AF clinical trial leadership. This trend is not isolated to AF trials, because the gender gap in authorship across cardiology subspecialties and many noncardiovascular specialties have also been reported. Women authors comprised <20% of lipid-lowering therapy trials between 1994 and 2018.[4] The median proportion of women authors per publication was 20% in United States heart failure guidelines, 14% in European heart failure guidelines, and 11% in heart failure trials.[2] In gastroenterology, <30% of women were first authors, and <15% served as a senior author between 1992 and 2012.[5]

Equal opportunity promotes fairness, human diversity, and leads to a higher quality of work. Women's presence advocates for different views at the senior level and confronts male bias in decision making. More importantly, the lack of women participating in academic research could bias the research results, and thus the generalizability of results to clinical practice. We noted that women's participation in AF trials increased significantly with the increased representation of women in the author panel. That said, although a higher percentage of women authors may be a metric for quantifying progress, it does not necessarily translate into improvement in enrollment rates for women.

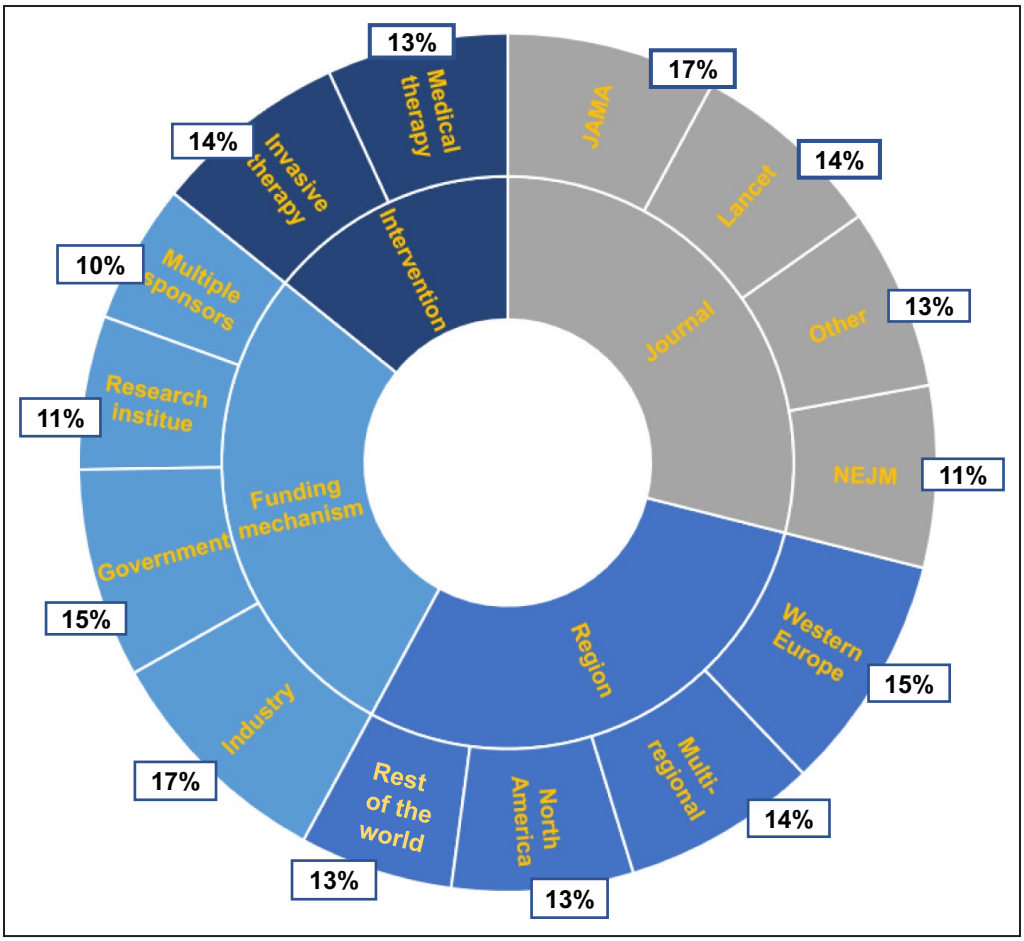

Figure 1. Representation of women authors in randomized controlled trials of atrial fibrillation stratified by journal, intervention type, region, and funding mechanism.
JAMA indicates *Journal of the American Medical Association*; and NEJM, *New England Journal of Medicine*.

Ensuring that more women are promoted as principal investigators and other key personnel at study sites may attract potential women who see women in leadership roles. Promoting gender diversity at an organizational scale and devising action plans to allow women's full participation in leadership roles can reduce sex- and gender-related disparities in clinical research.

Limitations of our study include the potential error in gender recognition and the inability to identify nonbinary gender identity. In addition, we could not abstract co-authorship (first or senior) roles; nevertheless, because women authors were consistently low overall, women were underrepresented regardless of authorship position.

In summary, this study adds to the growing evidence in cardiovascular research that promoting women in trial leadership can confront gender bias, improve diversity and inclusivity, and reduce sex- and gender-related inequalities in science.

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