

RESEARCH LETTER

Representation of Women Authors in Trials of Lipid-Lowering Therapy

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Women are underrepresented in leadership roles in academic science.¹ Compared with men, women have fewer first and senior author publications, are awarded fewer grants by the National Institute of Health, and less likely to be promoted.^{2,3} In a recent study, women constituted only 10% of cardiovascular disease clinical trial leadership committees, and more than half of these trials' leadership was entirely devoid of women investigators.⁴ Only 1 in 10 studies had a female investigator in the first, senior, and overall authorship position.⁴

Addressing authorship inequity in the cardiovascular field requires extensive literature review across clinical settings, drugs and devices, funding mechanisms of the trials, and regional differences. However, providing deeper insights on authorship across individual cardiology domains would be more helpful in identifying and addressing the inequity. For instance, a recent study focused on heart failure trials to demonstrate that the median proportion of women authors was only 11% per trial, and only 16% of publications had women as first or senior authors.³

Lipid-lowering therapies (LLT) are the mainstay for the prevention and treatment of atherosclerotic cardiovascular disease. We sought to investigate if these gender-based disparities in academia, cardiology, and clinical trials also exist in the authorship of publications of clinical trials of LLT.

The data included in this meta-analysis are publicly available from published studies and the analyses can be shared upon request. The process of our study search, selection, and data abstraction was

reported previously.⁵ Briefly, we selected randomized controlled trials of LLT having a sample size of ≥ 1000 participants, follow-up duration ≥ 1 year, and published between 1994 and 2018. As this was a trial-level meta-analysis of published studies, institutional review board approval was not required. We abstracted the total number of authors, women authors, and women in the first or senior (ie, last) author position. We identified women following prior strategy, including using the Genderize 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.³ We pooled study-level estimates for proportion of women authors (number of women authors/total number of authors per article) using the DerSimonian and Laird random-effects model. Subgroup analyses explored potential sources of heterogeneity.

Of 3150 articles screened, 59 trials (485 409 participants) met inclusion criteria. The median number of men and women participants in the trials was 3733 (interquartile range, 2009–7420) and 1516 (711–4208). The median number of men and women authors were 10 (9–16) and 2 (1–3), respectively. Overall, the proportion of women as authors was 19.2% (95% CI, 15.3–23.8%). The proportions of women as first and senior authors were 17% each. The proportion of women authors did not significantly change over time and did not vary according to the journal, disease state, setting, sponsor, drug, or region (Table).

Women comprised $<20\%$ of authorship of large randomized controlled trials of LLT published between 1994 and 2018. We also found the proportion of women

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Table 1. Representation of Women Authors in Clinical Trials of Lipid-Lowering Therapy

Category	No. of Trials	% Women Authors (95% CI)	P Value
Overall	59	19.2 (15.3–23.8)	
Journal			
<i>New England Journal of Medicine</i>	30	19.5 (14.3–26.1)	0.71
<i>Journal of the American Medical Association</i>	6	23.8 (12.0–41.7)	
<i>Lancet</i>	13	15.5 (9.5–24.1)	
Others	10	20.6 (11.2–34.9)	
Disease			
Atherosclerotic cardiovascular disease	32	18.5 (14.2–23.7)	
Hypercholesteremia	12	26.1 (15.2–41.2)	0.44
Heart failure	3	14.0 (6.4–27.9)	
Diabetes mellitus	6	23.6 (14.1–36.7)	
Chronic kidney disease	4	12.8 (6.5–23.6)	
Cardiovascular risk factors	2	12.1 (2.6–41.9)	
Setting			
Primary prevention	27	20.2 (14.2–28.0)	0.61
Secondary prevention	32	18.2 (14.0–23.2)	
Drug class			
Statin	31	15.7 (11.1–21.7)	
Ezetimibe	3	17.3 (10.7–26.8)	0.10
Proprotein convertase subtilisin/kexin type 9 inhibitor	6	11.3 (6.0–20.4)	
Niacin	2	39.5 (18.6–65.1)	
Fibrate	5	20.4 (11.6–33.5)	
Omega-3 fatty acid	12	29.3 (17.1–45.4)	
Sponsor			
Government	8	20.9 (12.3–33.1)	0.27
Industry	31	18.0 (12.9–24.5)	
Research institute	3	18.2 (8.6–34.6)	
Multiple sponsors	17	19.5 (12.0–30.2)	
Region			
North America	15	18.0 (12.5–25.1)	
Western Europe	19	19.1 (13.3–26.7)	0.42
Rest of the world	8	13.2 (6.7–24.1)	
Multiregion	17	24.3 (15.9–35.2)	

authorship in LLT trials did not change over time. In contrast, other specialties, such as gastroenterology, have shown a significant increase in women first and senior authors, although women remain underrepresented overall.⁶ Women as first author increased from 9.1% in 1992 to 29.3% in 2012, and as senior author increased from 4.8% in 1992 to 14.5% in 2012, in the gastroenterology literature.⁶ Similarly, women authors increased in pediatrics, obstetrics/gynecology, and dermatology literature.⁷

One potential explanation is that cardiology continues to have the lowest proportion of women among medical specialties.⁴ Second, women in academia may be judged by a higher standard than their

male counterparts, leading to more rigorous criteria for promotion and leadership consideration, including clinical trial leadership.^{3,4} Equal opportunity practices must be implemented to promote fairness and represent human diversity because this could lead to higher quality work production, as previous research suggests.¹ A greater prominence of women in clinical trial leadership positions can also attract more female investigators to participate in cardiovascular clinical trials.⁴ Cardiology articles with women as senior authors are more likely to have women as first or middle authors, reflecting a positive influence of women role models.^{2,3} The inverse is also true, where a vicious cycle has been observed for women in academic

medicine, with the exclusion of women leading to further exclusion and lack of recognition.⁴ Additionally, women participants may be more likely to enroll in trials conducted by women, and women authors may be able to design trials that are more accommodating to women participants.³

Limitations include the potential for error in gender identification and the inability to determine nonbinary gender identity. We did not capture coauthorship (first or senior); however, an overall lesser number of women authors and similarly low proportion of first or senior author positions suggest an overall low representation of women regardless of authorship position.

Given that women's representation in LLT trials has lagged significantly,⁵ the results of this study highlight an opportunity to bring about the much-needed change in gender disparities in trial authorship.

ARTICLE INFORMATION

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