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Cardiovascular surgery trials in the United States: representation of women and minorities

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Introduction

Cardiovascular disease remains a leading cause of death in the United States, and increasing evidence supports that outcomes may differ between men and women (1). However, women remain underrepresented in cardiovascular clinical trials, and the current standard of care is based upon results of studies from a primarily male patient population (2). Furthermore, as the diversity of the patient population in the United States continues to increase, it is vital that the standard of care is established based upon the patient population served. In this viewpoint article, we highlight the current status of women and minorities in various aspects of cardiovascular surgery trials including trial patient enrollment, leadership, and authorship. In addition, we discuss potential solutions for how to eliminate these disparities in the future.

Women and minorities in cardiovascular surgery trial patient enrollment, leadership, and authorship

In a recent study, disparities in sex, race, and ethnicity were identified among 230,000 patients enrolled in cardiovascular trials in the United States over the span of two decades (3). Participation-to-prevalence ratios (PPRs) were calculated, and values of 0.8 to 1.2 were considered to reflect similar representation. Among all trials, women composed only 28.3% of the enrolled patients, and

minorities were significantly underrepresented (11.2% Hispanic/Latino, 4.0% African American, 10.4% Asian, and 2.3% other). Furthermore, when the patient population was stratified by disease category, such as patients undergoing coronary artery bypass grafting surgery, the PPR for women remained low. In another study with similar methodology, sex disparities were identified among principal investigators in cardiac surgery trials in the United States (1). Among a total of 266 principal investigator positions assigned to adult cardiac surgeons, only 6 were assigned to women (9.5% of the entire pool of women, PPR 0.37), whereas 260 were assigned to men (26.6% of the pool of men, PPR 1.04) ($P=0.004$). Similarly, a cross-sectional study with a focus on clinical trial leadership for cardiovascular surgery trials conducted during the last two decades (2) showed women cardiac surgeons constituted only 1.2% of all clinical trial authors (surgeons and non-surgeons combined) and no women were listed as authors in 29.3% of randomized clinical trials.

Future directions

In recognition of the sex disparities that exist among patients enrolled in clinical trials, the United States Congress passed the National Institutes of Health Revitalization Act of 1993 to encourage the increased recruitment and enrollment of women and minorities (3). Despite these efforts, insufficient progress has been made towards improving the enrollment

of women and minorities in cardiovascular trials over the last two decades (3). Moreover, the representation of women in clinical trial leadership and authorship has remained low.

Potential targeted solutions to improve the enrollment of women in cardiovascular surgery clinical trials include the planned continuation of trial enrollment until sufficient statistical power is achieved for the generation of minority-specific data. This approach may effectively increase enrollment of women and underrepresented minorities in future clinical trials and is currently being employed in the Randomized comparison of the Outcomes of single *vs.* Multiple Arterial grafts in Women trial (ROMA: Women; NCT04124120), which is the first cardiac surgery randomized clinical trial dedicated to women undergoing cardiac surgery (2). Other solutions include working towards the equal representation of women and minorities in clinical trial leadership, authorship, and societal involvement, which was previously shown to be associated with the enrollment of more diverse participants (4). Furthermore, other strategies include use of open processes and objective criteria to select leadership, increasing opportunities and research funding allocation, and prioritizing trials with objectives that are most aligned with the increased recruitment and enrollment of women and minorities (4).

Ultimately, diversity in clinical trial leadership can help broaden the focus of research questions and address the unique concerns of women and underrepresented minority participants. Furthermore, it may help with implementing novel trial designs that may not only improve the recruitment of women and minorities, but also generate meaningful data that can be used to meet patient-specific needs.

Conclusions

With an increasingly diverse patient population in the United States, the standard of care must be established based upon the patient population served. Here, we have provided an overview of the current status of women and minorities in cardiovascular surgery trial patient enrollment, leadership, and authorship, and we have discussed suggestions for solutions to increase the diversity and external validity of trials in the future.

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Footnote

Conflicts of Interest: Dr. OP serves as a consultant for W. L. Gore, Terumo Aortic, and Abiomed. The other authors have no conflicts of interest to declare.

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