Women in cardiology leadership of randomized clinical trials and participation of women in late-breaking clinical trials: has the COVID-19 pandemic changed a thing or not exactly?

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Introduction: Despite considerable developments made in the representation of women in cardiology (WIC) recently, there still remain substantial disparities in the representation of women participants in clinical trials, as well as women physicians and scientists in clinical trial leadership. Under-representation of women in Randomized Clinical Trials (RCTs) remains the bane of the modern medicine, impeding the development of sex-specific guidelines in cardiovascular diseases. Female leadership in clinical trials has been shown to enhance the inclusion of women as trial participants. Furthermore, while the COVID-19 pandemic has impacted women in academia, there is no data thus far reporting the impact of the pandemic in terms of presenters and leadership of late-breaking clinical trials (LBCT) in cardiology during this period.

Purpose: We aimed to determine inclusion of WIC in LBCTs leadership and their correlation to inclusion of women in reported RCTs.

Methods: In our comprehensive analysis, we included all LBCTs presented at major international cardiovascular meetings reported over the period of January 2020 to February 2022. Data were derived from the original presentation at the meeting and/or simultaneous/ subsequent publication of manuscript. Sex of the presenter (woman or man), was assessed by either original videos of the presentation at the meeting, or based on pronoun use in the biographies derived from institutional profiles. The presence or absence of reporting of sex distribution of study participants were also recorded from original presentation at the meeting and/or published manuscript. Proportion of women included in each trial was sourced from either original publication or calculated from any similar data shown during the presentations.

Results: A total of 400 of RCTs from 19 meetings were included with a total of 400 presenters/principal investigators recorded – 32 (8%) women and 368 (92%) men. There were no significant differences between 2020 and 2021 [15 (7.2%) women in 2021 vs. 17 (19.3%) in 2020 (P=0.446)]. Proportions of women included in RCTs with WIC (37.3%) vs. non-WIC (38.7%) presenters were comparable (p=0.559), while 45% of RCTs didn't report sex distribution of participants. Except for 2 meetings (CRT 2020 and 2022), all others were virtual.

Conclusion: WIC representation as RCTs presenters was significantly low, despite the opportunity of virtual attendance afforded during the COVID-19 pandemic. Modest inclusion of women irrespective of sex of RCT leadership emphasizes multi-level problems that require more actionable solutions: i.e. implicit bias training started as early as medical school, continuing education on necessity for diversity, equity and inclusion, patient and public involvement, and comprehensive guidance on trial design, such that future RCT participants reflect the populations intended to treat.

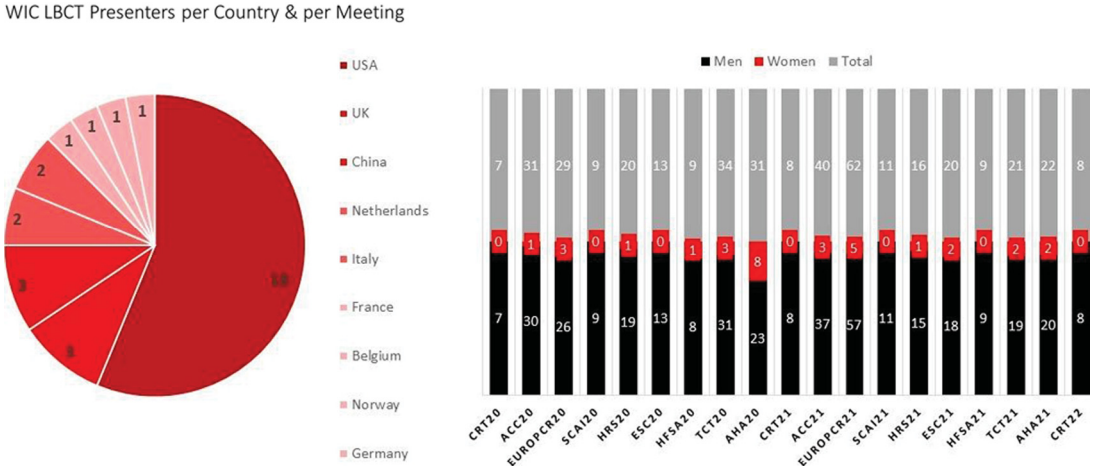

Figure 1