

## **Abstract Submission Form**

The Women's Heart Center Program Committee is accepting abstract submission forms through **August 15**, **2025**. Completed forms should be emailed to <a href="https://www.whc.ac.nih.gov/wh

Abstract submissions should be gender- and sex-specific research pertaining to one of the program topics outlined below.

The Program Committee wishes to encourage young scientific investigators and will reward up to 4 abstracts/posters submitted by presenters considered early career (definition provided below). First place will receive \$1000, second place will receive \$500, and two honorable mentions will each receive \$250.

The presenting author will be sent an email with the status of the submission by **August 22, 2025**. If your abstract is accepted, your notification will contain complete presentation information. However, please note the following:

- All human subject research must conform to the principles of the Declaration of Helsinki of the World Medical Association.
- The presenting author should be able to provide documentation of IRB approval if requested.
- The Program Committee is unable to reimburse presenters for travel, hotel, or per diem expenses.
- Submission of an abstract constitutes a commitment by the presenting author (or designee) to present inperson at the symposium on October 3, 2025, during the following times:
  - o Registration & Networking: 7:00 8:00 am
  - o Networking Lunch: 12:00 1:30 pm
  - o Poster Session Award Announcement: 4:50 5:10 pm
- All accepted abstract presenters must register for the symposium via Eventbrite and pay the applicable registration fees (trainees and invited speakers will have the registration fee waived).
- If an author wishes to withdraw an abstract, please email WHC@TheChristHospital.com.

## **Presenting Author Information** Name (First, Last, Credentials):Ishita, Tickoo, MD Institutional Affiliation: Saint Vincent Hospital, Worcester, MA Email Address:ishitatickoo@gmail.com, ishita.tickoo@stvincenthospital.com Early Career (Defined as physicians, scientists, medical students, and other healthcare providers currently in residency or fellowship programs or within three years of training)? Yes 🖂 No $\square$ **Co-author Information** Email: majmundarvidit@gmail.com Affiliation: Department of Cardiology, Name: Vidit, Majmundar, MD University of Miami, Jackson Memorial Hospital, Miami, Florida Email: amir.joshi@stvincenthospital.com Affiliation: Department of Internal Name: Amir, Joshi, MD Medicine, Saint Vincent Hospital, Worcester, MA Email: mark.kranis@stvincenthospital.com Affiliation: Division of Cardiology, Saint Name: Mark, Kranis, DO Vincent Hospital, Worcester, MA Name: Click or tap here to enter text. Email: Click or tap here to enter text. Affiliation: Click or tap here to enter text. **Disclosures:** Please list any relevant financial disclosures. None. **Abstract Topic (must be gender- or sex-specific)** ☐ Preventative cardiology ☐ General cardiology ☐ Cardio-oncology ☐ Heart failure ☐ Cardio-obstetrics ☐ Cardiovascular Imaging ☐ Electrophysiology ☐ Coronary Microvasculature ☐ Social Determinants of Health ☐ Precision Medicine ☐ Mental Health **Title:** Include the full title as it will appear on the poster.

Gender representation in Cardiovascular trials: A 10-Year Look at MI, PAD, and TAVR Trials

**Background:** In an initial paragraph, provide relevant information regarding the background and purpose of the study, preferably in no more than two to three sentences.

Historically, cardiovascular clinical trials have underrepresented women, despite cardiovascular disease being the leading cause of death in women worldwide. Moreover, while trials routinely report biological sex, gender identity remains absent mainly from trial data, leaving an essential dimension of diversity unexamined. Initiatives like the NIH Revitalization Act of 1993, the Sex as a biological variable policy, enacted in 2016, and subsequent FDA guidance emphasized the inclusion and transparent reporting of sex and gender in clinical research.

Despite these initiatives, the lack of representation of women and gender identity data remains prevalent in

cardiovascular trials. We conducted a systematic review of interventional studies in myocardial infarction (MI), peripheral artery disease (PAD), and transcatheter aortic valve replacement (TAVR) from 2015 to 2025 to evaluate trends in sex-based enrollment and the reporting of gender identity.

**Methods:** Briefly state the methods used.

We conducted a systematic review of 72 interventional trials registered on ClinicalTrials.gov between 2015 and 2025, including MI (n=32), PAD (n=34), and TAVR (n=6). Inclusion criteria were: (1) adult (> 18 years old) patient population, (2) interventional trials with disease-specific focus on MI, PAD, or TAVR, and (3) availability of participant demographic data. We also examined whether trials reported gender identity. The primary outcomes were the proportion of trials reporting participant sex and gender identity, and the sex distribution (number and percentage of male and female participants) within each disease category. Prevalence percentage proportion was calculated using Excel 16.6.7.

**Results:** Summarize the results in sufficient detail to support the conclusions.

All 72 trials reported participant sex, but none reported gender identity data. On average, women made up only 33% of enrolled participants, with individual trial values ranging from 0% to 100%. PAD trials had the lowest female representation relative to expected disease prevalence, while TAVR trials approached parity. Click or tap here to enter text.

**Conclusions:** Concisely state the conclusions reached.

Women made up only a third of participants in interventional cardiovascular trials, despite their substantial disease burden. In our review, 0% of trials reported gender identity, underscoring that cardiovascular research almost exclusively considers sex (biological characteristics) and not gender identity. This gap may obscure pivotal nuances in how treatments work for transgender or non-binary patients, a topic gaining recognition but not yet addressed in trial reporting. As emphasized by the JACC Council perspectives, overcoming enrollment and retention barriers requires multi-stakeholder strategies, including expanding trial access, improving recruitment methods, and diversifying leadership to ensure intentional inclusion, transparent reporting, and equitable cardiovascular research.<sup>1</sup>

**Tables/Figures/Graphics:** Include images that are part of your submission here. Images should be high resolution and have a file type of "gif", "jpg", or "jpeg".

Trials(n)	32	34	6	72
Category	Myocardial Infarction	PAD	TAVR	Total
Trials reporting sex (n, %)	32(100%)	34(100%)	6(100%)	72(100%)
Trials reporting gender identity (n, %)	0%	0%	0%	0%
Men (n, %)	28641(66%)	12521(71%)	524(56%)	41687(67%)
Women (n, %)	14926(34%)	5175(29%)	412(44%)	20512(33%)

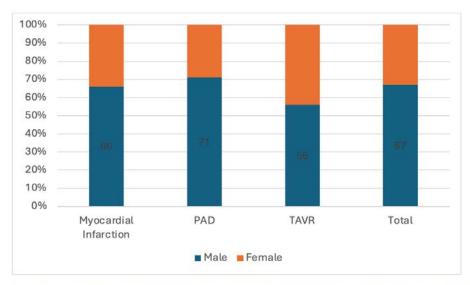


Figure 1: Sex distribution and gender identity reporting in myocardial infarction (MI), peripheral artery disease (PAD), and transcatheter aortic valve replacement (TAVR) trials (2015–2025). Bars show the proportion of men (blue) and women (orange) enrolled; all trials reported sex, none reported gender identity. Table includes absolute numbers and percentages.

## **References:**

<sup>1</sup>Cho, L, Vest, A, O'Donoghue, M. et al. Increasing Participation of Women in Cardiovascular Trials: JACC Council Perspectives. JACC. 2021 Aug, 78 (7) 737–751.

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