Eh Khaing

Cardiovascular Research Team member

UNMC Internal Medicine Department of Cardiology

Omaha

ehkhaing246@gmail.com

(402) 671-8869

Meta-analysis or systematic review

Title: Woman Representation in Atrial Fibrillation Ablation Clinical Randomized Controlled Trials

Woman Representation in Atrial Fibrillation Ablation Randomized Controlled Trials

Eh Khaing, BS[a], Nmair Alziadin, MBBS[b], Samuel Frankel, BS[c], Ahmad Aroudaky, MD[d], Danielle Dircks, MD[c], Benjamin Hollenberg, BS[e], James Aguto, BS HCB HLA[d], William Schleifer, MD[d], Jason Payne, MD[d], Arthur Easley, MD[d], Faris Khan, MD[d], John Windle, MD[d], Shane Tsai, MD, MBA[d], Daniel Anderson, MD, PhD[d], Gleb Haynatzki, PhD, DSc[f], Thoetchai Peeraphatdit, MD, MS[f], Niyada Naksuk, MD[d]

[a]University of Nebraska Omaha,
[b]HCA Healthcare/Tufts University School of Medicine: Portsmouth Regional Hospital Internal Medicine Residency Program,
[c]College of Medicine, University of Nebraska
[d]Division of Cardiovascular Medicine, University of Nebraska Medical Center,
[e]Washington State University
[f] Department of Biostatistics, University of Nebraska Medical Center, Omaha, Nebraska

Background: Despite advancement in catheter ablation for treatment of atrial fibrillation (AF), women experiencing AF may have poorer outcomes, as compared to men with AF.
Objective: To examine the proportion of women enrolled in AF randomized controlled trials (RCTs) and outcomes of AF ablation when subgroup analysis of women was available.
Methods: We systematically searched PubMed and EMBASE for AF ablation RCTs published between 01/01/2015 to 05/31/2022. Of 148 eligible RCTs, 147 ~~trials~~ reported the proportion of women and were included in this study. Characteristics of participants were examined and compared among the trials with higher woman enrollment and those with less. Results categorized by gender were reviewed.
Results: Of 147 AF RCTs with 30,055 participants, only 10 trials (6.80%) enrolled women ≥~~more than or equal to~~ half of the total study; 42 (28.57%) trials excluded women based on pregnant or breastfeeding status and additional 6 (4.08%) trials excluded reproductive age women without an adequate birth-controlled method. Overall, woman representation in AF trials varied from 9.00%-71.00% (median 31.50%, interquartile 24.65-39.00%) with stable trends over the study period (Figure). Trials with greater woman representation were likely to enroll older participants and higher CHADSVAS score, but less prevalence of persistent AF with smaller LA (P<0.05 for all). Gender was evaluated as ~~one of~~a potential risks in 19 (12.9%) RCTs and in ~~pre-specified~~ subgroup analysis in 10 (6.8%) RCTs; 10.71% of these found women as an independent risk of the trial outcomes.

Conclusion: Women were underrepresented and unanalyzed in contemporary AF ablation RCTs, limiting applicability of the results to women with AF. Additionally, women who were enrolled in the trials were likely to have higher comorbidities, but less advanced AF as compared to men.

Formatted: Font: (Default) Times New Roman, 11 pt, Font color: Auto

Figure: Proportion of women participants in atrial fibrillation catheter ablation randomized controlled trials based on publication year (P=0.593)