

THE UNIVERSITY Evaluation of Racial Disparities in Clinical Trials on Peripartum Cardiomyopathy

Banner Medicine

Introduction

Cardiovascular disease, specifically peripartum cardiomyopathy (PPCM), is a significant cause of morbidity and mortality across the globe, disproportionately affecting Black populations [1]. Underrepresentation of Black patients within cardiovascular clinical trials remains an issue [2]. With precision medicine on the uprise, the need for an indepth understanding of subpopulation-specific pathophysiology and pharmacodynamics plays an important role in maximizing efficacy of the care provided. This review sought out to synthesize a quantitative overview of the representation of Black adults in trials studying peripartum cardiomyopathy.

Methods

An extensive search was done with multiple databases using keywords ((peripartum [mesh] OR peripartum [tiab]) AND (cardiomyopathy [mesh] OR cardiomyopathy [tiab])) yielding 1,540 studies. Inclusion criteria included clinical trials on peripartum cardiomyopathy that reported ethnicities of their enrolled patients. Exclusion criteria included studies that enrolled patients with non-PPCM. Studies were independently evaluated by two independent physicians. After an extensive screening process, 5 studies were included. A total of 362 patients across multi-centers and countries were identified. Preferred Reporting Items for Systematic reviews was used for the basis of constructing a review protocol. Pooled outcomes were synthesized using Microsoft Excel. Continuous variables were reported as absolute values and respective percentages. Identification Records from multiple databases identified 1,540 studies Records screened Records excluded (n = 8) (n = 3)Reports sought for Reports not retrieved retrieval Screening (n = 0)(n = 5)Reports assessed for eligibility Reports excluded: 0 (n = 5) Included Studies included in review (n = 5)

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Total Patients	Caucasian	Black	Hispanic	Other (not specified)	Location of Stud
40	40	0	0	0	Germany
63	62	1	0	0	Germany
100	0	88	0	12	Nigeria
100	0	30	15	55	USA
59	0	59	0	0	South Africa
	Total Patients 40 63 100 100 59	Total Patients Caucasian 40 40 63 62 100 0 100 0 59 0	Total Patients Caucasian Black 40 40 0 63 62 1 100 0 88 100 0 30 59 0 59	Total Patients Caucasian Black Hispanic 40 40 0 0 63 62 1 0 100 0 88 0 100 0 30 15 59 0 59 0	Total Patients Caucasian Black Hispanic Other (not specified) 40 40 0 0 0 63 62 1 0 0 100 0 88 0 12 100 0 30 15 55 59 0 59 0 0

Participation to Prevalence Ratio

PPR = Prevalence in disease population (%) / Percentage of patients of interest among disease population

Results

5 clinical trials with a total of 362 patients were included. Within these trials, 102 patients (28.2%) were identified as Caucasian, 178 patients (49.2%) were Black, 15 patients (4.1%) were Hispanic, and 67 patients (18.5%) did not have an ethnicity noted in the manuscripts. The participation to prevalence ratio (PPR) for Black adults was measured to be 1.53 using data from the largest population-based PPCM study [3].

Conclusion

A significant ethnic disparity, characterized by

underrepresentation of Black adults, remains a crucial issue in the literature, often the result of enrollment biases [2]. However, this disparity cannot be extrapolated to clinical trials on PPCM. The PPR in our study showed overestimation of Black adults in PPCM trials. Significant limitations include the limited availability of PPCM clinical trials and population-based studies on prevalence of Black adults with PPCM, and the small sample sizes in these studies. Nonetheless, further need for recruitment research still remains to mitigate this disparity in cardiovascular trials. Future direction includes greater efforts to allow black inclusion as a priority during trial design, enhanced transparency, and recruitment by healthcare providers.

References

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