

Quality of Life of the Aged: Transplant or Mechanical Support (SUSTAIN-IT): Sex Differences for Non-Enrollment

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Abstract

Introduction: Women are under-represented in heart failure (HF) trials and the reason remains unknown. This study is to evaluate sex differences in non-enrollment for a multi-center advanced HF study called Sustain-IT.

Hypothesis: Our hypothesis is women do not participate in heart failure studies for different reasons from men so we may need to change our approach to enroll more women.

Methods: 237 patients were approached and not enrolled in SUSTAIN-IT, a multi-center study comparing health-related quality of life outcomes in 60-80 year old patients implanted with left ventricular assist devices as destination therapy (DT) or who awaited heart transplantation (HT). Reasons for not enrolling and for refusing were documented. Sex differences were evaluated for the cohort and then stratified by DT vs HT.

Results: 50 women (29 DT, 21 HT) and 187 men (81 DT, 106 HT) approached did not enroll in SUSTAIN-IT. Women were more likely than men to refuse (92% vs 76%, P=0.015) and the reasons varied by sex. Women were more likely too tired, stressed, anxious, depressed, or unable to concentrate while men were mostly not interested (Table 1). When stratified by HF therapy, women were more likely to refuse when approached for HT (100% HT vs 86% DT, P=0.13), while refusal for men did not differ with HF therapy (76% HT and 77% DT). Refusal also varied by therapy with the majority of HT non-enrollers not interested (38% women, 52% men) and DT non-enrollers refusing for different reasons (women 56% symptoms; men 31% symptoms, 32% not interested).

Conclusion: Women approached who did not enroll in SUSTAIN-IT were more likely than men to refuse to participate. Reasons for refusal varied for both women and men based on type of advanced HF therapy. Our novel findings may provide tailored guidance when recruiting men and women in clinical trials

Background

Women are under-represented in clinical HF trials with reduced ejection fraction and the reason remains unknown. In an analysis by the FDA that involved 5 cardiovascular studies including 1 HF study, the percent of women and men that did not enroll were similar. The FDA concluded that more women simply need to be approached to improve enrollment. Our study was performed to further understand the sex differences in non-enrollment.

Patient Description

Inclusion: 60-80 yo HF patients with advanced HF considered for left ventricular assist device and/or heart transplantation

Exclusion: patients who do not meet criteria for heart transplant or left ventricular assist device and patients <18 yo.

Final Cohort: 237 HF patients were not enrolled in Sustain-IT

Methods

All patients approached and who did not enroll inn SUSTAIN-IT were included in the analysis. Reasons for refusing to enroll were documented. Sex differences were evaluated for the cohort and then stratified by DT vs HT

Findings

50 women (29 DT, 21 HT) and 187 men (81 DT, 106 HT) approached did not enroll in SUSTAIN-IT. Women were more likely than men to refuse (92% vs 76%, P=0.015) and the reasons varied by sex. Women were more likely too tired, stressed, anxious, depressed, or unable to concentrate while men were mostly not interested (Table 1).

Findings

When stratified by HF therapy, women were more likely to refuse when approached for HT (100% HT vs 86% DT, P=0.13), while refusal for men did not differ with HF therapy (76% HT and 77% DT). Refusal also varied by therapy with the majority of HT non-enrollers not interested (38% women, 52% men) and DT non-enrollers refusing for different reasons (women 56% symptoms; men 31% symptoms, 32% not interested).

Table 1. Sex Differences for Non-Enrollment in SUSTAIN-IT

Patient Not Enrolled by Sex (all patients)					
Variable	N	Entire Cohort (N=237)	Male (N=187)	Female (N=50)	P-value
Why Not Enrolled:, No. (%)	237				0.06
. Does Not Meet Inclusion/Exclusion Criteria		12 (5%)	12 (6%)	0 (0%)	
. Refused		189 (80%)	143 (76%)	46 (92%)	
. Enrolled In Another Study		7 (3%)	7 (4%)	0 (0%)	
. Expired Prior To Consenting		2 (1%)	1 (1%)	1 (2%)	
. Other		27 (11%)	24 (13%)	3 (6%)	
Patient Refused, No. (%)	237				0.015
. No		48 (20%)	44 (24%)	4 (8%)	
. Yes		189 (80%)	143 (76%)	46 (92%)	
Refusal Reason, No. (%)	189				0.019
. Too Sick To Participate		15 (8%)	13 (9%)	2 (4%)	
. Too Tired, Stressed, Anxious, Depressed, Or Cannot Concentrate (symptoms)		44 (23%)	26 (18%)	18 (39%)	
. Too Busy		17 (9%)	14 (10%)	3 (7%)	
. Not Interested		74 (39%)	62 (43%)	12 (26%)	
. No Reason Given		36 (19%)	27 (19%)	9 (20%)	
. Other		3 (2%)	1 (1%)	2 (4%)	

Limitations

SUSTAIN-IT study recorded limited information on why patients did not enroll but did not collect demographic information since patients did not consent to the study.

Conclusion

In a large multi-center study for HF patients with advanced disease, women were more likely than men to refuse to participate and the reasons included too tired, stressed, anxious, depressed or unable to concentrate while men mostly were not interested. Refusal also varied by therapy with women more likely to refuse when being considered for heart transplant while refusal for men did not depend on type of therapy.