

Short-Term Outcomes According to Sex in a Real-World Cardiac Rehabilitation Program: A Retrospective Cohort Study

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Abstract

Background: Despite its proven benefits, cardiac rehabilitation (CR) remains markedly underutilized, particularly among eligible women. We sought to demonstrate whether women enrolled in a contemporary CR program derived similar benefits as men.

Aim of Study: In this study, we aimed to compare the changes in physical and psychosocial outcomes by sex after CR completion. We hypothesized that after participation in CR, women will demonstrate similar improvements in physical and psychological parameters to men.

Patients and Methods: Using a clinical registry of CR participants between January 2015 and February 2020 who completed a standard 12-week CR program, we analyzed changes in physical and psychosocial well-being parameters. Primary endpoint was improvement in 6-minute walking distance (6MWD). Secondary endpoints included change in exercise minutes per week (EMW 150) (only patients with more than 150 minutes per week of reported exercise are included), depression scores (PHQ9), anxiety scores (GAD7), and overall quality of life (COOP) scores (lower scores are better) [1].

Results: There were 617 patients (mean age 64 ± 12 years, 26% women) with complete pre- and post-CR data. At baseline, women had lower 6MWD, lower EMW150, higher GAD7, PHQ9, COOP, heart rate and LV EF. Women were more likely to be referred following a valvular procedure and had fewer CABG. By the end of the CR program, women had similar improvement in their 6MWD as men (women: Median (IQR): 14 [7,20] % (increase from baseline) vs. men: 13 [6,21] % (increase from baseline), p -value=0.87). Women with mild anxiety improved significantly more than men (Table 3).

Conclusions: Women who completed a CR program derive similar physical benefits as men and may have greater psychosocial well-being improvements. Efforts to increase CR participation should certainly target eligible women.

Clinical implications: Physical and psychosocial improvements observed in women completing CR are similar to men. Efforts that increase women participation in CR need to be encouraged.

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Key Words: Cardiac Rehabilitation – Sex – Gender – Females – Males – Men – Women – Coronary artery disease – Non-coronary artery disease – Heart failure – Myocardial infarction – Stable angina – Heart transplantation – Percutaneous coronary intervention – Valvular heart disease – Coronary artery bypass graft.

Introduction

CARDIAC rehabilitation (CR) is a highly effective secondary prevention measure in patients with cardiovascular disease (CVD) proven to reduce cardiovascular mortality and re-hospitalization in observational and randomized controlled studies [1].

There are known differences between men and women in several aspects of CVD, including risk factors (smoking rate is decreasing less in women), presentation (often an atypical presentation of ischemic heart disease in women), management (diagnosis of ischemic heart disease is often missed more in women), response to therapy, quality of care and outcome [2]. The use of evidence-based treatments appears to be imbalanced according to patient gender as was shown in the study by Rathore et al., [2]. For the more frequent use of cardiac catheterization in men than women.

List of Abbreviations:

6MWD	: 6-minute walking distance.
AACVPR	: American association of cardiovascular and pulmonary rehabilitation risk score.
COOP	: Overall quality of life score.
CR	: Cardiac rehabilitation.
CRF	: Cardiorespiratory fitness.
CVD	: Cardiovascular disease.
EMW 150	: Exercise minutes per week.
ETT	: Exercise tolerance test.
GAD7	: Anxiety score.
PHQ9	: Depression score.

Previous studies highlighted the underutilization of CR in women compared to men with lower rates of referral (31 vs 42%), participation (19 vs 29%) and completion (26 vs 28%) [3]. The percent of women with improved cardiorespiratory fitness (CRF)-best measured by the $\dot{V}O_2$ (peak oxygen uptake) [4] is less than men at baseline even after adjusting for age (13 vs 17%). CRF does not improve in women as much as men after CR [4]. CR is tied to behavioral or psychosocial factors in women. Some of these barriers are present for both men and women but are more prevalent in women or have a larger impact [4].

Patients and Methods

All enrolled patients in the outpatient CR program (a prospectively collected cohort) from the Brigham and Women's Hospital (BWH) database (Foxborough, Boston, MA) during the time period between January 1, 2015, and February 1, 2020 (N=848) were included in our study. Patients were grouped according to self-reported sex in medical charts.

The CR program in BWH consists of an outpatient 12-week program in Foxborough, MA. The program included two one-hour sessions per week that incorporated 30-40 minutes of cardiovascular conditioning, 5-15 minutes of resistance training, 10 minutes of warm-up and cool down, and 5 minutes of stretching or relaxation. Exercise prescription for almost all patients was based on a maximal exercise tolerance test (ETT), or an entry 6-minute walking distance (6MWD) when an ETT was not performed. The physical training was based on the peak heart rate achieved during an initial ETT. Additionally, there was one weekly 60-minute educational session that covered different prevention-related topics, such as nutrition, physical exercise, stress reduction, and medication adherence. Furthermore, five educational sessions were dedicated to heart-healthy diet and weight loss.

Among our enrolled cohort, 617 patients completed the program and had paired pre- and post-CR data.

The primary outcome was the change in the 6MWD from the start of CR to completion.

The secondary outcomes consisted of the change in: Exercise minutes per Week (EMW 150) [defined as patients who exercised more than 150 minutes per week as recommended by the American heart association (AHA)], overall health related quality of life scores determined by the Dartmouth Cooperative Functional assessment (COOP), depression

scores by Patient Health Questionnaire-9 (PHQ9) (is a 9-item questionnaire to estimate the prevalence of major depressive symptoms), and anxiety scores by General anxiety disorder-7 (GAD7) (is a 7-item questionnaire that measure anxiety frequency). Reduced scores are better in terms of depression (PHQ9), anxiety (GAD7) and overall quality of life scores (COOP). Anxiety scores were divided into clinical categories [5]: (0-4: no/minimal anxiety, 5-9: Mild anxiety, 10-14: Moderate anxiety, 15-21: Severe anxiety) and depression scores [6] (0-4: No depression, 5-9: Mild depression, 10-14: Moderate depression, 15-19: Moderately severe depression, 20-27: Severe depression). Exercise capacity was assessed by ETT and/or 6MWD.

EMW 150 was collected from patient's questionnaires. All parameters were collected at the beginning and at the end of the CR. The study protocol was approved by the Internal Review Board (IRB) at Brigham and Women's hospital.

Statistical analysis:

Values are presented as mean \pm standard deviation for normally distributed variables, median and interquartile range for non-normally distributed variables, and frequencies and percentage as appropriate. *t*-test and Wilcoxon signed rank-test were used to compare continuous variables between groups, and chi-squared test for categorical variables. Only patients with complete paired pre- and post-CR data were included.

Adjusted linear regression was used to assess the association of sex with the change in 6MWD between pre- and post-CR. The multivariable linear regression model included: Age, body mass index (BMI), sex, PHQ9, GAD7, COOP (all at baseline). A level of significance of p 0.05 was used for statistical significance. Statistical analyses were carried out using Stata statistical package (Stata 16.1).

Results

Between January 2015 and February 2020, 848 subjects were enrolled and participated in our CR program, among them 617 (73%) completed the 12-week-CR program including 159 women (26%) (Fig. 1). Compared to men, women had higher baseline: Heart rate (71 ± 12 vs. 68 ± 12 bpm, $p=0.035$), and were more likely to be enrolled in CR following non-CAD than CAD diagnoses. Men were more likely to have hypertension, diabetes mellitus, hyperlipidemia, and cardiac surgical procedures (224 (48%) vs. 60 (37%), $p=0.01$). Both groups had no statistical difference regarding

age, BMI, American association of cardiovascular and pulmonary rehabilitation risk score (AACVPR), other exercise tolerance test (ETT) parameters and waiting time before enrollment.

Baseline 6MWD was higher in men than women (median (IQR): 1540 (1296, 1760) vs. median (IQR): 1405 (1145, 1642) feet, $p=0.003$). Baseline depression, anxiety and COOP scores were low in both groups but significantly better in men. (Demographic and clinical characteristics by sex are listed in Table (1).

Tables (2,3) show that both groups improved their 6MWD ($p<0.001$) with a similar increase for women and men (women: Median (IQR): 179 [100, 247] feet or 14% [7, 20] vs. 203 [90, 298] feet, $p=0.13$ or 13% [6, 21] (increase from baseline) in men, $p=0.87$) (Fig. 2).

Psychological health scores improved significantly in each sex ($p<0.001$) proved by a reduction in GAD7, PHQ9 and COOP scores. After CR participation, there was a significant increase in the proportion of patients in the no/mild anxiety (Fig. 3) and no depression (Fig. 4) categories for both women and men, and the increase was greater in women.

The multivariable linear regression analysis showed that sex was independently correlated with the change in 6MWD (Table 4).

Table (1): Baseline clinical and demographic characteristics.

Variable name	Women (N=159; 26%)	Men (N=458; 74%)	<i>p</i> -value
<i>Demographics and cardiac risk factors:</i>			
Age, yrs	64±12	64± 11	0.85
Weight, lbs	168±40	203±38	<0.001
Height, in.	63.4±3	69.3±2.9	<0.001
BMI, kg/m ²	29±6	29±5	0.50
<i>AACVPR Risk profile:</i>			
Low	50 (31 %)	154 (33%)	0.55
Medium	56 (35%)	139 (30%)	
High	53 (33%)	162 (35%)	
<i>Pre CR markers:</i>			
Baseline HR,bpm	71 ± 12	68±12	0.035
Peak HR, bpm	122±22	125±22	0.16
Baseline SBP, mmHg.	125±18	127±17	0.25
Baseline DBP, mmHg.	71±9	74±9	0.009
Peak SBP, mmHg.	149±23	155±23	0.010
Peak DBP, mmHg.	71±10	72±9	0.19
ETT, mets	6±3	8±3	<0.001

Table (1): Count.

Variable name	Women (N=159; 26%)	Men (N=458; 74%)	<i>p</i> -value
<i>Cardiac risk factors:</i>			
Hypertension	122 (76%)	382 (83%)	0.06
Smoking	12 (7.5%)	55 (12%)	0.12
Diabetes	29 (18%)	109 (24%)	0.014
Hyperlipidemia	123 (77%)	394 (86%)	0.011
HbA1C	6± 1	6± 1	0.73
LDL-cholesterol	87±35	70±32	<0.001
Left ventricular EF	56±12	54±12	0.035
<i>Medications:</i>			
Beta blockers	137 (86%)	396 (86%)	0.92
Calcium blockers	22 (13%)	73 (15%)	0.53
ACEI	63 (39%)	236 (51%)	0.009
Statins	12 (7%)	50 (10%)	0.22
Antidepressant	62 (39%)	96 (21 %)	<0.001
Days to enrollment	36±23	37±35	0.90
<i>Enrollment diagnoses:</i>			
AMI	45 (28%)	111 (24%)	<0.001
PCI	66 (41 %)	180 (39%)	0.62
CABG	21 (13%)	151 (33%)	<0.001
Heart valve repair/ replacement	42 (26%)	90 (19%)	0.07
Heart transplant	2 (1%)	3 (0 .7%)	0.47
Heart failure	17 (10%)	33 (7%)	0.17
Stable angina	13 (8%)	27 (5 %)	0.31
Other	3 (1%)	9 (2%)	0.95
Cardiac surgical procedure	60 (37%)	224 (48%)	0.015
<i>Outcomes at baseline:</i>			
6MWD	1405 (1145, 1642)	1540 (1296,1760)	<0.001
EMW 150†	19 (12%)	98 (21%)	<0.001
GAD7 ^b	3 (1, 7)	2 (0, 4)	0.002
<i>Anxiety (GAD7)^c</i>			
- No/minimal (0-4)	94 (59%)	340 (74%)	0.003
- Mild (5-9)	38 (24%)	63 (14%)	0.17
- Mod. to severe (10)	21 (13%)	44 (10%)	
PHQ9 ^d	3 (1, 6)	2 (1, 5)	
<i>PHQ9^e</i>			
- No (0-4)	97 (61%)	319 (70%)	<0.001
- Mild (5-9)	33 (21%)	81 (18%)	
- Mod. to severe (15)	23 (15%)	48 (11%)	
COOP ^e	21 (18, 24)	18 (15, 21)	

Abbreviations: AACVPR: American association of cardiovascular and pulmonary rehabilitation; BMI: Body mass index; lbs: Pounds; HR: Heart rate; SBP: Systolic blood pressure; DBP: Diastolic blood pressure;ETT: Exercise tolerance test; AMI: Acute myocardial infarction; CR: Cardiac rehabilitation; ACEI: Angiotensin converting enzyme inhibitors; 6MWD: 6 minute-walking distance; EMW150: Exercise minutes per week if >150 minutes per week.

^aData reported as mean ± standard deviations, n (%) or median (interquartile range).

^bAnxiety scores.

^cAnxiety scores clinical interpretation: 0-4: No/minimal anxiety, 5-9: Mild anxiety, 10-14: Moderate anxiety, 15-21: Severe anxiety [7].

^dDepression scores

^eDepressionscores clinical interpretation: 0-4: No depression, 5-9: Mild depression, 10-14: Moderate depression, 15-19: Moderately severe depression, 20-27: Severe depression) [8].

^eOverall health quality.

Table (2): Clinical and demographic characteristics pre and post cardiac rehabilitation by sex.

Variable name	Women (N=159)	Men (N=458)	p-value
<i>Weight, lbs.:</i>			
Pre	168±40	203±38	<0.001
Post	166±39	200±36	<0.001
Change	-0.8±2	-1±5	0.34
Change %	0.4±1.7%	0.6±3%	0.64
<i>BMI, kg./m²:</i>			
Pre	29±6	29±5	0.50
Post	29±6	29±5	0.67
Change	-0.8±2	-1±5	0.34
<i>SBP, mmHg.:</i>			
Pre	123±21	122±18	0.90
Post	116±12	119±13	0.02
Change	-6±18	-3±16	0.05
<i>DBP, mmHg.:</i>			
Pre	69±9	70±11	0.26
Post	67±8	68±9	0.09
Change	-2±9	-2±10	0.67
<i>LDL cholesterol, mg./dl.:</i>			
Pre	87±35	70±32	<0.001
Post	76.2±31.7	64±27	<0.001
Change	-11±31	-8±31	0.39

Table (3): Primary and secondary outcomes in pre and post CR by sex.

Variable name	Women (N=159,26%)	Men (N=458,74%)	p-value
<i>6MWD, ft.:</i>			
Pre	1405 (1145, 1642)	1540 (1296, 1760)	<0.001
Post	1585 (1340, 1820)	1738 (1484, 1992)	<0.001
Change	179 [100,247]	203 [90,298]	0.13
Change %	14 [7, 20]	13 [6, 21]	0.87
<i>EMWI50, N (%) :</i>			
Pre	19 (12%)	98 (21%)	0.009
Post	99 (62%)	334 (73%)	0.011
Change	81 (51%)	240 (52%)	0.90
<i>GAD7:</i>			
Pre	3 (1, 7)	2 (0, 4)	<0.001
Post	1 (0, 3)	1 (0, 3)	0.41
Change	-1 (-4, 0)	0 (-2, 0)	<0.001
<i>PHQ9:</i>			
Pre	3 (1, 6)	2 (1, 5)	0.003
Post	1 (0, 4)	1 (0, 3)	0.13
Change	-1 (-4, 0)	-1 (-2, 0)	0.02
<i>COOP:</i>			
Pre	21 (18, 24)	18 (15, 21)	<0.001
Post	17 (13, 19)	15 (12, 18)	0.03
Change	-4 (-6, 0)	-2 (-5, 0)	<0.001

Table (4): Multivariable linear regression analysis for change in 6MWD.

6MWD change (feet)	Coef.(feet) (95% CI)	p-value
Sex†	29.65 (0.20,59.11)	0.048
Age, years	-2.18 (-3.29, -1.07)	<0.001
BMIa, kg./m ²	-2.79 (-5.17, -0.40)	0.022
GAD7 ^{ab}	0.31 (-4.01,4.65)	0.886
PHQ9 ^{ac}	-1.14 (-5.78,3.48)	0.626
COOP ^{ad}	0.77 (-2.56,4.11)	0.648

Abbreviations: BMI: Body mass index, 6MWD: 6 minute-walking distance, † Sex: One unit increase=men.

- a Values at baseline.
- b Anxiety score.
- c Depression score.
- d Quality of life score.

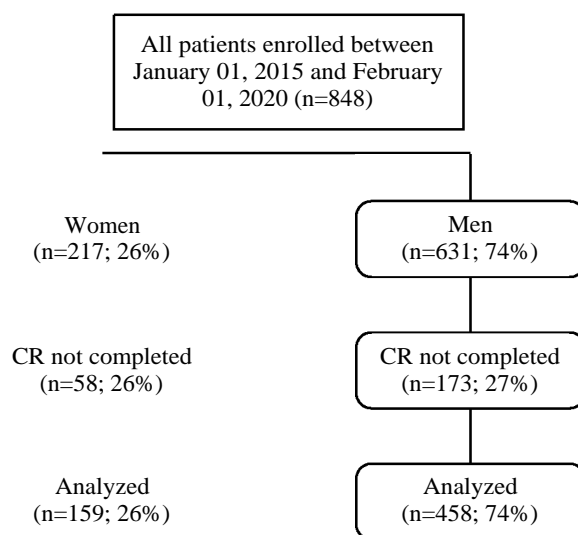


Fig. (1): Consort diagram for the study patients.

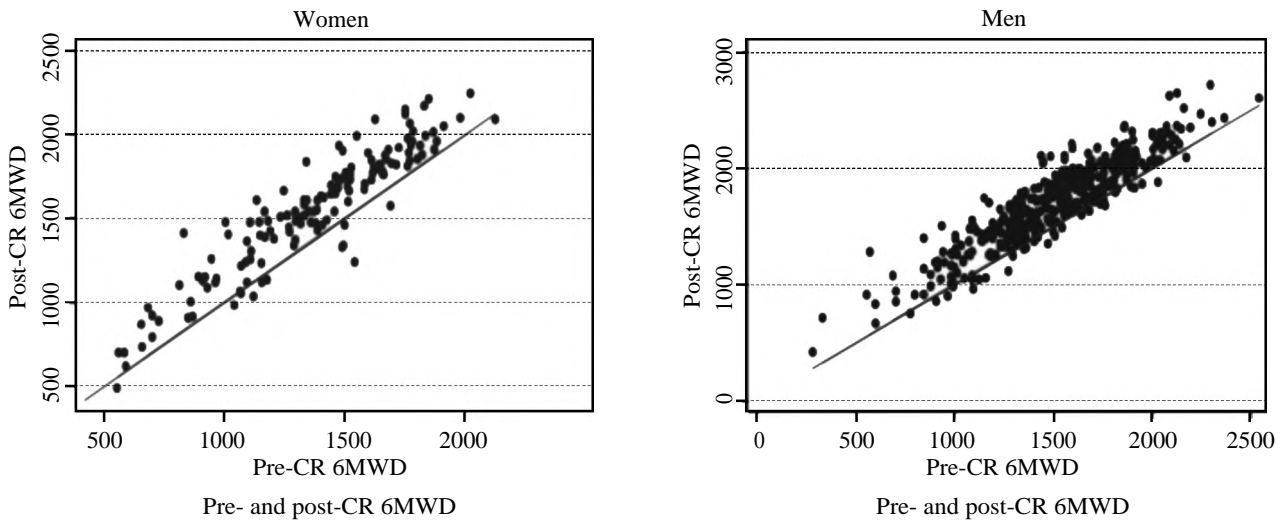


Fig. (2): Scatterplot of the 6MWD pre- and post- CR by sex.

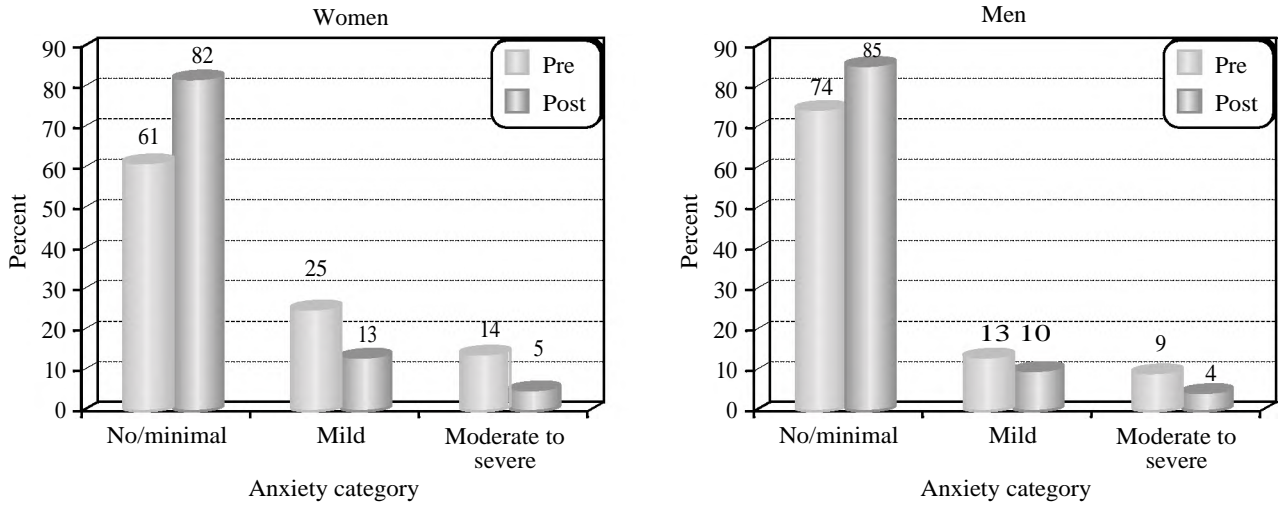


Fig. (3): GAD7 anxiety categories before and after CR by sex.

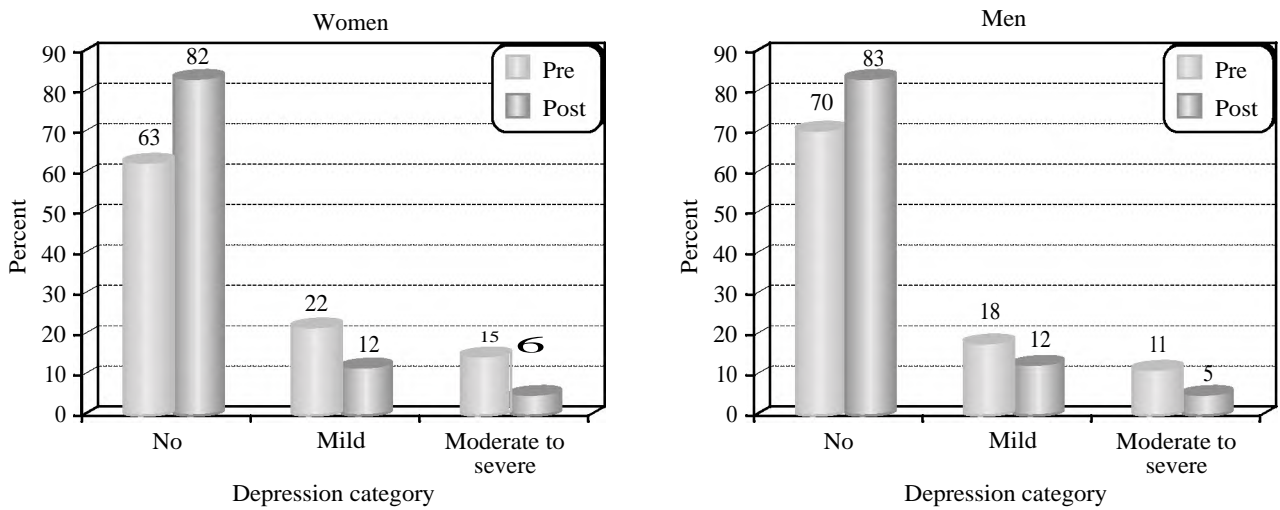


Fig. (4): PHQ9 depression categories before and after CR by sex.

Discussion

Our study demonstrates that in a large group of contemporary CR participants, improvements in physical outcomes at the end of the CR program were overall important, and similar in men and women, whereas improvements in psychosocial parameters appeared greater in women than men.

Our primary physical endpoint of change in 6MWD improved similarly in men and women.

Our study shows that women had lower percent of all studied traditional risk factors as in a study done by Izawa et al., [9]. Hypertension and obesity rates were elevated in our women cohort, with prevalence rates similar in the literature [10]. Overweight prevalence in women can be a strong factor leading to a poorer physical performance during CR.

For the referral diagnoses for CR, women were more likely to be referred following heart failure, valvular heart diseases, AMI (possibly due to less referral of women for revascularization) and less likely following CABG like it was found by the study done by DeFeo et al., [11].

Our study shows some trends in CR as a study done by Gaalema et al., [12] with an average participant's age of 64 years old and an increase in women participation up to 30%.

Verill et al., [13] found in a short study of 12 weeks a 15% improvement in the 6MWD for each sex with significant statistical difference pre- and post-CR: They found a similar finding with more baseline 6MWD in men than women (1463 ± 339 ft vs. 1243 ± 301 , $p < 0.001$) and at follow-up (1683 ± 346 vs. 1435 ± 298 ft., $p < 0.001$). Same results were found in a study by Hamilton et al., with men walking farther than women ($p < 0.01$) [14]. A plausible explanation was mentioned by Verill et al., [13] referring this difference due to men's longer stride during 6MWD, greater baseline functional capacity or both. Studies done by Lane et al., [15] and O'Farell et al., [16] concluded that men usually have higher levels of physical activity than women leading to better adherence to CR.

In the United States, Brody et al., [17] and Canuto et al., [18] found that women have twice the rate of depression than men, accordingly, the women anxiety and depression impact their participation and attendance in CR. Social relationships impacts the women more, especially, the caregiving for others [4].

Nevertheless, there are inconsistent findings on the correlation between the improvement in physical and psychosocial wellbeing in CR by sex: Results range from no correlation [11] to a strong correlation [18] to the hypothesis that the psychosocial improvement will not happen in a short-term CR [19]. Although there were better baseline GAD7, PHQ9 and COOP in men, the scores improvements were more significant in women ($p < 0.001$). However, the anxiety and depression clinical categories were only significantly improved in the mild anxiety category in women ($p < 0.01$) (Fig. 3).

Adjusting for other covariates, sex was found to be associated with the change in 6MWD post CR program. This result is in agreement with multivariable linear regression analysis of a large systematic review including eleven highly selected randomized controlled trials by Bellet et al., [20].

This study has some strengths by including real-world patients and comparing women to men as the main study group using the 6MWD as the primary outcome post CR: On one hand, The sub-maximal nature and the self-paced aspect of the 6MWD makes it a very safe evaluation, because, the test is relatively low intensity, it allows the assessment of individuals who are otherwise limited by their symptoms during an evaluation of their functional status or exercise capacity. The 6MWD has been proven to be a reliable, valid, and reproducible test of functional capacity [20]. The majority of previous studies discussing women in CR program focused on their referral, adherence and compliance [7]. However, our study has several limitations: This was an observational cohort, and our analysis included only subjects with paired data who completed the program. About 25% of patients were non completers with missing follow-up data (with similar baseline data). As it was mentioned previously, despite that our primary outcome was physical improvement in 6MWD, women improved significantly psychologically than men. In our study, significantly more women were found to be on antidepressant treatment at baseline than men which affect the generalizability of our results. The discrepancy in the enrollment diagnoses between women and men may add to the lack of generalizability of our results. Also, it has been found by the study by Mamataz et al., [8]. That women-targeted CR had better physical improvement by adopting other exercise modalities like dancing and aerobics.

Conclusion:

We demonstrate that women who participate in CR derive similar improvements in functional capacity, and possibly greater improvements in psychological wellbeing than men. Accordingly, efforts to increase referral to, and CR participation for all eligible patients should be encouraged, especially if targeting women and groups traditionally less likely to participate. A female-targeted CR may improve physical outcomes.

Declarations:**Ethics approval and consent to participate:**

The study protocol was approved by the Internal Review Board (IRB) at Brigham and Women's hospital, MA, USA and an informed consent was obtained from every participant in the study.

Consent for publication: I am the single author for this research article, and I give my consent to publish it.

Availability of data and material: All data and materials are available when requested.

Competing interests: No competing interests.

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نتائج قصيرة الأجل وفقاً للنوع البرنامج إعادة تأهيل القلب : دراسة بأثر رجعي

تمهيد : على الرغم من فوائده الثابتة، لا يزال برنامج إعادة تأهيل القلب (CR) غير مستخدم بشكل ملحوظ، لا سيما النساء المؤهلات له. لقد سعينا إلى إثبات ما إذا كانت النساء المسجلات في برنامج CR المعاصر يستفدن مثلاً لرجال.

طرق البحث : باستخدام سجل سريري للمشاركين في CR بين يناير ٢٠١٥ وفبراير ٢٠٢٠ الذين أكملوا برنامج CR مدته ١٢ أسبوعاً، قمنا بتحليل التغيرات في العوامل البدنية والنفسية والاجتماعية. كان الهدف الأساسي هو التحسن في إختبار ٦ دقائق سيراً على الأقدام (MWD6). تضمنت الأهداف الثانوية التغير في دقائق التمرين في الأسبوع (150 EMW) (يشمل المرضى الذين مارسوا أكثر من ١٥٠ دقيقة فقط في الأسبوع من التمرين)، ودرجات الاكتئاب (9PHQ)، ودرجات القلق (7GAD)، ودرجات جودة الحياة العامة (COOP) (الدرجات المنخفضة أفضل) ١.

النتائج : البحث شمل ٦١٧ مريضاً (متوسط العمر ١٢±٦٤ عاماً، ٢٦٪ من النساء) مع بيانات كاملة قبل وبعد CR. في الأساس، كان لدى النساء MWD6 أقل، وEMW ١٥٠ أقل، وأعلى 7GAD، و9PHQ، وCOOP، ومعدل ضربات القلب، وكفاءة عضلة القلب. كانت النساء أكثر عرضة للإجابة بعد إجراء الصمامات وكان لديهن عدد أقل من جراحات القلب المفتوح لترقيع الشرايين التاجية. وبحلول نهاية برنامج التأهيل، شهدت النساء تحسناً مماثلاً في MWD6 مثل الرجال (النساء : الوسيط (IQR): ١٤ (٧، ٢٠)٪ (زيادة عن الأساس) مقابل الرجال : ١٣ (٦، ٢١)٪ (زيادة عن الأساس)، (p -value=0.87). تحسنت النساء المصابات بالقلق الخفيف بشكل ملحوظ أكثر من الرجال (الجدول ٣).

الإستنتاجات : النساء اللواتي يكملن برنامج CR يستفدن فوائد بدنية مثل الرجال وقد يكون لديهن تحسن أكبر في الرفاه النفسي والاجتماعي. ومن المؤكد أن الجهود الرامية إلى زيادة المشاركة في برنامج التأهيل القلبي ينبغي أن تستهدف النساء أيضاً .

الآثار السريرية : التحسن البدني والنفسي والاجتماعي الذي لوحظ في النساء اللواتي يكملن CR يشبه الرجال. وينبغي تشجيع الجهود الرامية إلى زيادة مشاركة المرأة في إعادة التأهيل القلبي.