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A Comparative Assessment to Evaluate Enhanced External Counter Pulsation Effect on Physical Profile and Quality of Life in Diabetic and Nondiabetic Coronary Heart Disease Patients

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ABSTRACT

This study was conducted to assess the effect of Enhanced External Counter Pulsation (EECP) on physical profile and Health-Related Quality of Life (HRQoL) in diabetic and nondiabetic Coronary Heart Disease (CHD) patients. This pretest-posttest designed prospective study was conducted among 163 diabetic and nondiabetic coronary heart disease patients in the SAAOL Heart Center, New Delhi. The physical profile of study subjects was assessed through Cooper's 12 minutes' walk test, Canadian Cardiovascular Society (CCS) angina scale and Medical Research Council (MRC) dyspnea scale. The HRQoL of subjects was assessed using SF-36 (short form) and Seattle Angina Questionnaire (SAQ) scale. A significant improvement was observed in blood pressure, heart rate, SpO_2, VO_2 max, CCS angina and MRC score in both the groups from baseline to 12 months. Significant improvement was also observed in both the scales of HRQoL after EECP treatment at 12 months follow up in all the health domains of SF-36 & SAQ scale with special reference to angina severity and angina stability improvement. In conclusion, EECP is an effective non-invasive therapy to treat diabetic and nondiabetic CHD patients. This non-invasive procedure may improve the physical functional capacity, angina, dyspnea and overall HRQoL of diabetic and nondiabetic CHD patients.

INTRODUCTION

Diabetes mellitus (DM) and coronary heart disease (CHD) has a close relationship with each other. Diabetes mellitus is an independent risk factor for CHD development (WHO, 2014). Patients with a history of diabetes are more likely to suffer from CHD compared to individuals without diabetes (Unnikrishnan *et al.*, 2016). Diabetes mellitus and CHD are a major cause of mortality and morbidity globally (Fuster *et al.*, 2010). CHD with DM patients has higher mortality rate due to uncontrolled diabetes which further causes several dysfunctions such as insulin resistance, atherosclerosis, and myocardial infarction. Indian and international registry data confirmed that 30-40 percent DM patients have CHD in India (Ali *et al*., 2010). It is documented that more than 65 percent of cardiac deaths are due to diabetes mellitus in which 75-80 percent were especially due to CHD (Xavier *et al.*, 2008; Moss *et al.*, 1991).

Coronary heart disease can be treated by pharmacotherapy, Percutaneous Transluminal Coronary Angioplasty (PTCA), Coronary Artery Bypass Grafting (CABG), lifestyle management and non-invasive therapy known as Enhanced External Counter Pulsation (EECP) (Antman *et al.*, 2008). Enhanced external counterpulsation is US-FDA approved non-invasive therapy for treatment of CHD patients, which are not suitable, unresponsive, and unwilling for PTCA and CABG procedures. Enhanced external counterpulsation therapy increases retrograde aortic blood flow during the diastolic phase of heart pumping. The mechanical device called EECP comprises sequential compression over legs, thighs, and buttocks to direct blood flow towards the heart when it is in the resting position. This treatment is recommended for 35 hours, one hour per day for 7 weeks (5 days in a week) (Arora *et al.*, 1999; Kumar *et al.*, 2017).

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Coronary heart disease and DM comorbidity deteriorate physical functional capacity and Health-Related Quality of Life (HR-QoL) of patients (Taghadosi *et al.*, 2014). Bozorgi *et al.* and Singh *et al.* studies demonstrate that EECP may significantly improve health-related quality of life and exercise tolerance in diabetic and nondiabetic coronary heart disease patients (Bozorgi *et al.*, 2014; Singh *et al.*, 2018). The 12 minutes run or walk test was developed by Kenneth H. Cooper in 1968 to assess physical functioning capacity and to estimate VO_2 max (maximum oxygen uptake). VO_2 max is the maximum volume of oxygen consumption during an intense walk or exercise. The maximal aerobic or functional capacity is defined at the point at which oxygen consumption is high (Bandyopadhyay *et al.*, 2015). Canadian Cardiovascular Society (CCS) angina scale is widely used to assess angina severity in coronary heart disease patients. This is a valid and reliable tool to evaluate angina severity, ranging from class I to class IV in CHD patients (Kaul *et al.*, 2009). Medical Research Council (MRC) scale is widely used to assess breathlessness or dyspnea status in CHD patients. This scale comprises five segments that define the entire range of respiratory infirmity from none (Grade 1) to almost a complete incapacity (Grade 5) (Bestall *et al.*, 1999).

The quality of life assessment of an individual is the status of well-being and feeling about their health and body functioning. SF-36 and SAQ are standard tools, which are used to assess general and disease specific health-related quality of life of CHD patients (Brazier *et al.*, 1992). Thompson *et al*. study provides evidence for reliability and validity of SF-36 scale used to assess the quality of life in CHD patients (Thompson *et al*., 2003). Seattle angina questionnaire (SAQ) is a disease-specific quality of life assessment tool which has been shown to be a valid, reproducible and reliable tool to evaluate the treatment or intervention effectiveness in CHD patients (Dempster *et al.*, 2000). The SAQ scale is widely used and its validity and reliability towards health status are demonstrated (Spertus *et al.*, 1995). Enhanced external counterpulsation treatment helps in glycemic control which ultimately improve the health-related quality of life of diabetic patients and studies done by Linnemeier *et al*. and Ramasamy *et al*. validates the effectiveness of EECP in diabetes patients (Linnemeier *et al*., 2003; Ramasamy *et al.*, 2015).

Our study was designed to assess the physical functioning profile and health-related quality of life of DM and CHD comorbidity patients and Non-DM CHD patients treated with EECP therapy.

MATERIALS AND METHODS

A pretest-posttest designed prospective study was done at Science and Art of Living (SAAOL) Heart Center, New Delhi among diabetic and nondiabetic CHD patients. A total of 212 subjects were enrolled in the study using consecutive sampling techniques from April 2016 to May 2017. The study subjects were divided into two groups. The first group was CHD patients with DM while the second group subjects were CHD patients without DM.

Inclusion criteria

Coronary heart disease patients with and without DM (patients having diabetes duration maximum 5 years) aged between 30 to 75 years, who did not willingly go for invasive treatments (Coronary Artery Bypass Grafting [CABG] and Percutaneous Trans Coronary Angioplasty [PTCA]) and agreed to participate in the study with valid written informed consent were enrolled.

Exclusion criteria

Patients having cardiac arrhythmia, coagulation disorder, deep vein thrombosis, vaso-occlusive disease, abnormal aortic aneurysm, cardiac valvular disorder, pregnancy, high blood pressure (higher than 180/110 mmHg), foot wounds, dialysis history and unable to give valid written consent were excluded from the study.

Study procedure

The study was initiated with the screening of diabetic and nondiabetic CHD patients from the SAAOL Heart Center, New Delhi. A total of 300 subjects were screened. Out of 300 subjects, 88 were excluded from the study because they refused to participate, refused to give written consent and not willing to adhere 12 months study follow up. Finally, 212 study subjects were enrolled as they fulfilled all study eligibility criteria and agreed to 12 months of the study follow-up. After enrollment, the study subjects were allocated in CHD patient with DM (CHD + DM group) and CHD patients without DM (CHD group). After this, the demographic profile (age, gender, etc.), clinical history and physiological (systolic blood pressure, diastolic blood pressure, heart rate) profile, was done at baseline of all study subjects. Physical functioning capacity, SpO_2 level, VO_2 max, CCS angina status, and MRC dyspnea score assessed at baseline and followed at 6 and 12 months of study. Health-related quality of life of the study subjects was also assessed at baseline and followed at 6 and 12 months through SF-36 and Seattle Angina Questionnaire (SAQ).

Measurements

Physiological profile assessment

Systolic and diastolic blood pressure were measured at baseline, 6 and 12 months. Systolic blood pressure (SBP) and diastolic blood pressure (DBP) were recorded by qualified personnel through Diamond Clock Model blood pressure monitor. Heart rate & SpO_2 of all study subjects were assessed through pulse oximeter (ChoiceMMed MD300C2D) at baseline, 6 months, and 12 months.

Physical functioning assessment

Physical functional capacity was assessed through Cooper 12-minute walk test and VO_2 max. In the Cooper 12-minute walk the study subjects were allowed to walk for 12 minutes on a flat track and a pedometer was used to measure the distance they covered within 12 minutes. VO_2 max was used to assess the aerobic capacity of study subjects. It was calculated with the standard formula:

VO_2 max (ml/kg/min) = (22.351 × distances covered in kilometers) − 11.288.

Angina status was assessed through the Canadian Cardiovascular Society (CCS) grading of angina pectoris. Breathlessness or dyspnea status was assessed by the Medical Research Council (MRC) scale.

Health-related quality of life (HRQoL) assessment

The HRQoL of study subjects was assessed by using SF-36 and SAQ. HRQoL of CHD patients with and without DM was assessed through face to face interview and subjects were responding as they experienced problems related to mobility, normal working at work, study, personal care, leisure activities, family, pain, and depression/anxiety. Answers of the patients were recorded. Short Form-36 (SF-36) a multi-item scale comprising 36 questions was used to assess the general health-related quality of life of CHD patients with and without DM in eight health domains, namely; physical functioning, physical health problems, emotional problems, energy status, emotional well-being, body pain and general health status. The score generated for each health variable was from 0 to 100, with 0 denoting the worst and 100 the best possible health outcomes. Seattle angina questionnaire was used to assess disease-specific quality of life and it measures 5 domains to assess EECP effectiveness in diabetic and nondiabetic CHD patients. SAQ domains were the physical constraint, angina stability, angina severity, treatment satisfaction, and perceived disease.

EECP treatment

The EECP, an electro-mechanical device, consists of three paired pneumatic cuffs applied to the lower leg, upper leg and buttocks. The cuffs of the device were inflated sequentially during diastole with maximum pressure 300 mmHg and returning blood from the legs to the central circulation and producing aortic diastolic augmentation. This increases both venous return and cardiac output in coronary heart disease patients. In the next step, cuffs are deflated at end-diastole with reducing peripheral resistance and providing left ventricular supply.

The ECP PSK machine having the model; P-ECP/TI was used for the treatment of diabetic and nondiabetic coronary heart disease patients. Each subject underwent one hour per day EECP treatment for 35 days for 7 weeks (5 days in a week) with 280 mmHg pressure. All study subjects were followed up for 12 months after completion of EECP therapy. Physical functional capacity through Cooper 12-minutes' walk test, SpO_2 status, VO_2 max, CCS angina severity and dyspnea score with health-related quality of life (SF-36, SAQ) were assessed at 6th and 12th months of study follow up (Bestall *et al.*, 1999; Bandyopadhyay *et al.*, 2015; Kaul *et al.*, 2009).

Ethical approval and consent

Ethical permission for this study was obtained from the Institutional Ethics Committee of SAAOL Heart Center (Ref. No-IEC/SHRF/PhD/P-02/01.05.2016), New Delhi. Written informed consent was also taken from all study subjects before initiation of the study.

Statistical analysis

A senior Biostatistician analyzed the collected data using statistical package for the social sciences (SPSS) software version 21. Demographic and socioeconomic profile of the study subjects were compared using independent t-test. Descriptive analysis of mean, SD, independent t-test and paired sample t-test with 95% confidence interval and p-value <0.05 was considered statistically significant.

RESULTS

Recruitment and response rates of the study subjects

The study was initiated with the screening of total 300 diabetic and nondiabetic coronary heart disease patients from the study site. Out of 300 patients, 88 patients were excluded from the study because 26 patients refused to participate, 33 patients refused to give written consent and 19 patients did not agree to 12 months follow up. Finally, 212 study subjects were enrolled as they fulfilled all study eligibility criteria and agreed to 12 months of study follow up. After enrollment, the study subjects were allocated to coronary heart disease patients with diabetes mellitus and coronary heart disease patients without diabetes mellitus. Total 163 patients had completed the whole study with 12 months follow up, 49 patients did not complete whole study and follow up, so they were excluded from the final data analysis because of missing and incomplete data. Out of 49 patients, 24 patients were excluded from the CHD + DM group (13 patients left the treatment and migrated to abroad and 11 patients did not complete 12 months follow up) and 25 from the CHD group (9 patients migrated to different places,16 patients did not complete 12 months follow up). Finally, the data of 163 patients were analyzed. Study outlines and response rates of the study subjects are summarized in the consort diagram (Table 1).

Baseline demographic details with the medical history of diabetic and nondiabetic CHD groups

A total of 163 diabetic and nondiabetic CHD patients completed the study (12 months follow up). Out of total 163 subjects; n = 82 subjects were in the diabetic CHD group (first group) and n = 81 subjects were in the nondiabetic CHD group (second group). The total mean age of both the group was 59.6 ± 9.5 (mean ± SD) years in which mean age of diabetic CHD subjects were 60.5 ± 9.5 (mean ± SD) and nondiabetic CHD subjects were 58.6 ± 9.6 (mean ± SD) years. The male subjects were 50.4% in diabetic CHD and 49.6% in nondiabetic CHD group. Females were much higher (53.3%) in nondiabetic CHD as compared to diabetic CHD group (46.7%). In this study, urban subjects were higher (56.4%) in the diabetic CHD group and rural subjects were higher (55.3%) in nondiabetic CHD group. A number of subjects have obesity (63.1%) in nondiabetic CHD group as compared to diabetic CHD group (36.9%). There were more hypertensive (51.6%) patients in the diabetic CHD group as compared to nondiabetic CHD group (48.4%).

The family history of heart disease (62.5%) was higher in the diabetic CHD group as compared to nondiabetic CHD group (37.5%), similarly, the family history diabetes (83.3%) was also higher in the diabetic CHD group as compared to nondiabetic CHD subjects (16.7%). The average diabetes duration in diabetic CHD group subjects was 4 years. Smoker patients were higher (51.9%) in nondiabetic CHD group as compared to diabetic CHD group (48.1%) and similarly, tobacco user was higher (83%) in nondiabetic CHD group as compared to diabetic CHD group (17%). Physical activity was higher (53.2%) in nondiabetic CHD group as compared to diabetic CHD group (46.8%). The non-vegetarian subjects were higher (53.1%) in nondiabetic CHD group

as compared to the diabetic CHD group (46.9%). Medical history, such as myocardial infarction was higher in diabetes CHD group (54.9%), similarly, the rate of PCI (62.9%) and CABG (58.7%) was also higher in diabetic CHD subjects. The history of single vessel CHD was similar in both the groups, but double vessel CHD patients were higher (62.8%) in nondiabetic CHD subjects while triple vessel CHD was higher (60%) in diabetic CHD subjects as compared to nondiabetic CHD subjects (40%). The detail of the demographic profile and medical history of diabetic and nondiabetic CHD groups is described in Table 2.

Table 1: A systematic overview of the study.

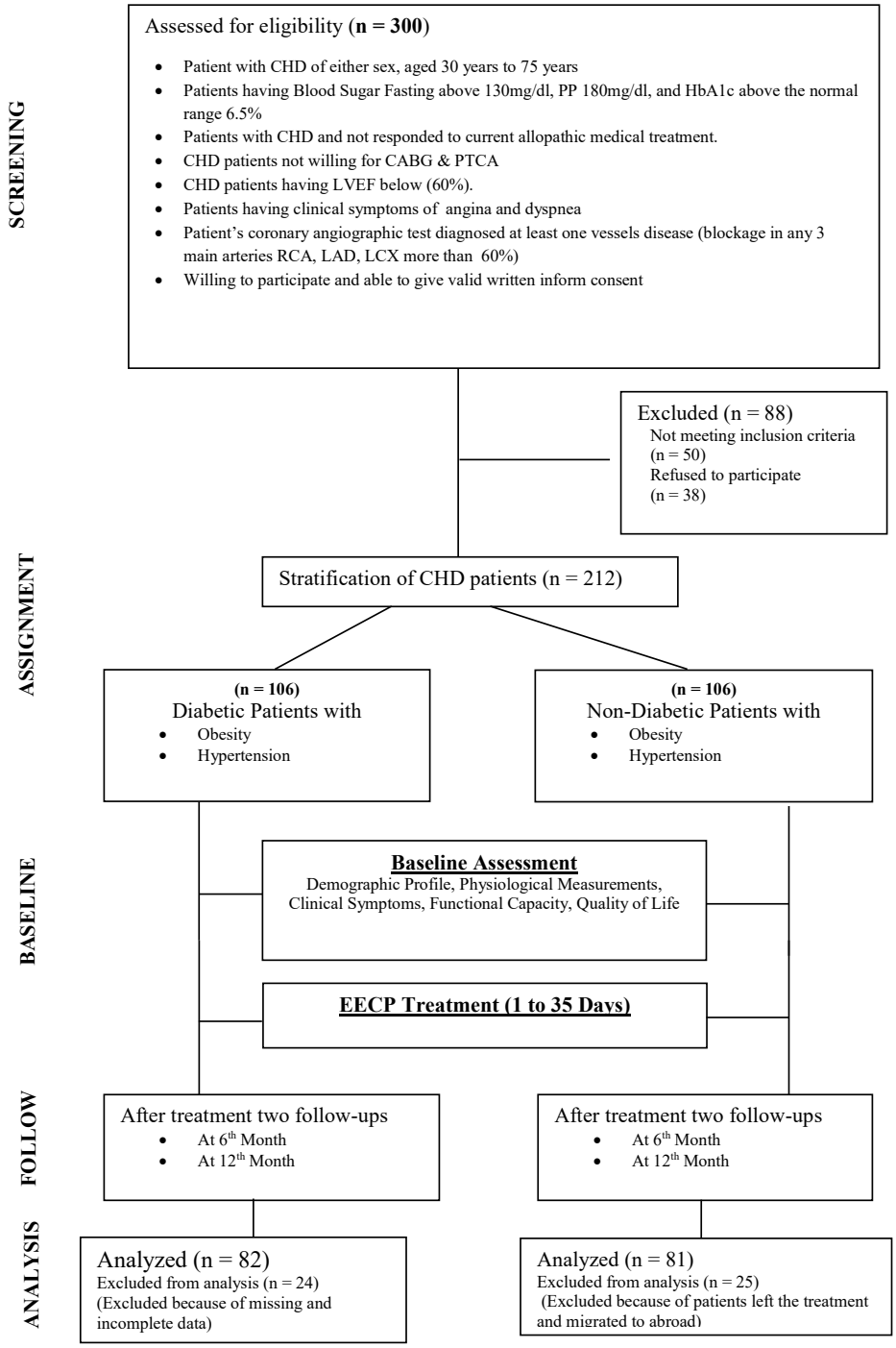

Table 2: Baseline demographic characteristics with medical history of diabetic & nondiabetic CHD patients.

Characteristics	Total (n = 163)	Diabetic CHD (n = 82)	Nondiabetic CHD (n = 81)	p-value
Age (in years)	59.6 ± 9.5	60.5 ± 9.5	58.6 ± 9.6	0.183
Gender				
Male (n)	133	67 (50.4%)	66 (49.6%)	0.714
Female (n)	30	14 (46.7%)	16 (53.3%)	
Locality				
Rural	85	38 (44.7%)	47 (55.3%)	0.135
Urban	78	44 (56.4%)	34 (43.6%)	
Obesity				
No	38	21 (55.3%)	17 (44.7%)	0.485
Yes	125	46 (36.9%)	79 (63.1%)	
Hypertension				
No	72	35 (48.6%)	37 (51.4%)	0.753
Yes	91	47 (51.6%)	44 (48.4%)	
Family History of Heart Disease				
No	115	52 (45.2%)	63 (54.8%)	0.733
Yes	48	30 (62.5%)	18 (37.5%)	
Family History of Diabetes				
No	127	52 (40.9%)	75 (59.1%)	0.973
Yes	36	30 (83.3%)	6 (16.7%)	
Smoking				
No	86	44 (51.7%)	42 (48.3%)	0.586
Yes	77	37 (48.1%)	40 (51.9%)	
Tobacco				
No	138	78 (56.5%)	60 (43.5%)	<0.0001
Yes	25	4 (17.0%)	21 (83.0%)	
Physical Activity				
No	101	53 (52.5%)	48 (47.5%)	0.480
Yes	62	29 (46.8%)	33 (53.2%)	
Stress				
Less	61	31 (50.8%)	30 (49.2%)	0.919
More	102	51 (50.0%)	51 (50.0%)	
Diet				
Veg	99	52 (52.5%)	47 (47.5%)	0.481
Non-Veg	64	30 (46.9%)	34 (53.1%)	
Acute Myocardial Infarction (MI)				
No	92	43 (46.7%)	49 (53.3%)	0.300
Yes	71	39 (54.9%)	32 (45.1%)	
Percutaneous Coronary Intervention (PCI)				
No	128	60 (46.9%)	68 (53.1%)	0.094
Yes	35	22 (62.9%)	13 (37.1%)	
Coronary Artery Bypass Graft (CABG)				
No	88	38 (43.2%)	50 (56.8%)	0.049
Yes	75	44 (58.7%)	31 (41.3%)	
Type (Vessel) of CHD				
Single	70	35 (50%)	35 (50%)	0.058
Double	43	16 (37.2%)	27 (62.8%)	
Triple	50	30 (60%)	20 (40%)	

Table 3: Baseline & follow up results of a physiological profile in diabetic & nondiabetic CHD patients.

Variables		Diabetic CHD		Nondiabetic CHD		p-value
		Mean	SD	Mean	SD	
SBP						
Baseline		131.2	15.1	132.6	16.1	0.575
6 Month		124.3	10.4	125.6	12.2	0.43
12 Month		128	12.2	129.3	14.0	0.558
p-value	Baseline - 6 Month	<0.001		<0.001		
	Baseline - 12 Month	<0.001		<0.001		
DBP						
Baseline		84.1	7.7	83.8	7.8	0.793
6 Month		79.1	6.1	78.6	6.8	0.621
12 Month		81.9	6.5	83.5	6.9	0.126
p-value	Baseline - 6 Month	<0.001		<0.001		
	Baseline - 12 Month	0.041		0.658		
Heart Rate						
Baseline		79.3	6.1	78.4	6.3	0.263
6 Month		76.7	5.0	75.5	5.1	0.257
12 Month		76.9	3.9	78.1	5.3	0.057
p-value	Baseline - 6 Month	<0.001		<0.001		
	Baseline - 12 Month	<0.001		0.934		
SpO_2 status						
Baseline		96.0	1.5	96.5	1.6	0.343
6 Month		98.2	1.7	98.4	1.8	0.938
12 Month		99.1	1.0	98.9	1.1	0.157
p-value	Baseline - 6 Month	<0.0001		<0.0001		
	Baseline - 12 Month	<0.0001		<0.0001		

Effect of EECP on physiological parameters and physical capacity in diabetic and nondiabetic CHD patients

The physiological parameters consist systolic blood pressure, diastolic blood pressure, heart rate and SpO_2 did not show any significant change between the groups from baseline to 12 months using independent t-test. A significant change has been observed in systolic blood pressure, diastolic blood pressure, heart rate and SpO_2 level from baseline to 6 months in diabetic CHD patients and similar outcomes sustained till 12 months in systolic blood pressure and SpO_2 level in both the groups. The detailed information has been given in Table 3.

A significant change was observed in dyspnea score at baseline in male using MRC scale but at 6 months and 12 months follow up no statistical change was observed. There was no significant change between the group in Cooper 12 minute walk test (walking distance), VO_2 max and CCS angina classifications were observed in diabetic and nondiabetic CHD group patients. The details of findings have been given in Table 4.

Effect of EECP on health-related quality of life (HRQoL) in diabetic and nondiabetic CHD patients

A significant improvement was observed in all SF-36 scale domains from baseline to 12 months with significant p-values <0.001. The significant changes were also observed in, energy level, social functioning, and general health after 6 months of EECP treatment between the groups but these differences did not maintain until 12 months. The difference between the groups was assessed using independent t-test. The details of SF-36 study outcomes have been given in Table 5.

All domains of SAQ scale yielded significant improvement within both (diabetic & nondiabetic CHD) groups from baseline to 12 months as assessed through paired sample t-test. Significant improvement in treatment satisfaction and disease perception after the 12 months of EECP treatment has been observed in both diabetic and nondiabetic CHD groups. There was no significant difference observed between both the groups from baseline to 6th months and 12th months of EECP treatment, assessed through the independent t-test. The details of SAQ results have been given in Table 6.

DISCUSSION

The aim of the present study was to assess the effect of EECP therapy on the physical functional status and health-related quality of life in diabetic and nondiabetic CHD patients. Our study demonstrates significant improvement in blood pressure, heart rate, and SpO_2 level after EECP treatment in both groups. Beck *et al.* and Casey *et al.* study also indicated that EECP may be useful as an adjuvant therapy for improving functional capacity in coronary heart disease patients through reductions in blood pressure and improvement in myocardial oxygen demand for better physical functioning (Beck *et al*., 2015; Casey *et al.*, 2011). Diabetic and nondiabetic CHD patients demonstrate significant improvement

in walking status, exercise tolerance with increment in VO_2 max levels after EECP therapy. Similarly, studies done by Feldman *et al.* and Urano *et al.* have supported the findings of the present study (Feldman *et al.*, 2006; Urano *et al.*, 2001).

Table 4: EECP Treatment effect on Cooper's 12-Minutes' walk test with VO_2 max, Angina & Dyspnea status at Baseline, 6th month and 12th month in CHD & DM with CHD patients.

Time	Variables	CHD (n = 81)	DM + CHD (n = 82)	p-value
Male		n = 67	n = 66	
Baseline	12 Minute test (Distance)	1449.7 ± 124.51	1491.2 ± 173.63	0.115
	VO_2 max	21.12 ± 2.72	22.05 ± 3.83	0.117
	CCS Class	2.8 ± 0.24	2.9 ± 0.16	0.678
	Dyspnea	2.8 ± 0.15	3.2 ± 0.21	0.042
6 Month	12 Minute test (Distance)	2103.2 ± 222.1	2116.9 ± 224.8	0.725
	VO_2 max	35.73 ± 4.9	36.04 ± 5.02652	0.727
	CCS Class	2.1 ± 0.12	2.2 ± 0.23	0.326
	Dyspnea	2.6 ± 0.14	2.7 ± 0.28	0.468
12 Month	12 Minute test (Distance)	2100.4 ± 384.3	2050.6 ± 413.0	0.472
	VO_2 max	35.67 ± 8.5	34.56 ± 9.2	0.474
	CCS Class	2.3 ± 0.25	2.2 ± 0.23	0.185
	Dyspnea	2.2 ± 0.23	2.1 ± 0.12	0.325
Female		n = 14	n = 16	
Baseline	12 Minute test (Distance)	1261.4 ± 107.12	1237.5 ± 57.44	0.444
	VO_2 max	16.91 ± 2.39	16.38 ± 1.28	0.464
	CCS Class	3.0 ± 0.01	2.9 ± 0.14	0.423
	Dyspnea	2.8 ± 0.14	2.9 ± 0.07	0.712
6 Month	12 Minute test (Distance)	1682.8 ± 261.45	1654.3 ± 208.29	0.742
	VO_2 max	26.33 ± 5.84	25.7 ± 4.65	0.746
	CCS Class	2.4 ± 0.28	2.1 ± 0.14	0.312
	Dyspnea	2.4 ± 0.21	2.3 ± 0.42	0.698
12 Month	12 Minute test (Distance)	1679.2 ± 389.01	1893.7 ± 367.60	0.132
	VO_2 max	26.25 ± 8.69	31.05 ± 8.21	0.134
	CCS Class	2.1 ± 0.29	2.0 ± 0.10	0.667
	Dyspnea	1.9 ± 0.05	1.5 ± 0.70	0.059

In the present study, a significant improvement was observed in the physical functional capacity in coronary heart disease patients after EECP therapy and similar findings have been reported by Rampengan *et al.* and May *et al.* in their study (Rampengan *et al.*, 2015; May *et al.*, 2015). Before EECP treatment our study subjects were mostly poor in physical functional capacity but after EECP treatment they significantly improved. A significant effect of EECP treatment on CCS angina class and dyspnea improvement has been observed in this study in diabetic and nondiabetic coronary heart disease patients. Studies done by Chung-Kuan *et al*. & Ziaeirad *et al*. (Chung-Kuan *et al.*, 2014; Ziaeirad *et al.*, 2012) have shown similar findings. The results of our study are in agreement with Petterson *et al.* and Loh *et al.* studies which have shown significant results on the effectiveness of EECP in patients with angina (Pettersson *et al.*, 2006; Loh *et al.*, 2006). Soran *et al.* study also reported similar findings in the present study (Soran *et al.*, 2006).

A significant improvement has been observed in health-related quality of life using SF-36 and SAQ scale and Arora *et al.* have reported similar findings (Arora, 1999). A significant improvement has been observed in all SAQ domains using the paired t-test to assess differences within groups from baseline to 12 months showed significant changes in both groups after EECP treatment. These results demonstrate similar outcomes in diabetic and nondiabetic CHD patients treated with EECP therapy. Our study shows improvement in the quality of life in diabetic and nondiabetic CHD patients and supported by the research done by Linnermeir *et al*. and Michaels *et al.* (Linnemeier *et al*., 2003; Michaels *et al.*, 2004).

A significant improvement was observed in the quality of life with similar clinical outcomes of Ziaeirad *et al*. in diabetic and nondiabetic coronary heart disease patients. The author reported significant improvements in quality of life of coronary heart patients in all domains of SF-36, a standard questionnaire of quality of life assessment (Ziaeirad *et al.*, 2012). SF-36 tool used by Arora *et al.* showed significant results on physical activity, general health with reduction of bodily pain and similarly Manchanda *et al.* indicated good results of EECP in respect of the improvement in the quality of life for heart patients (Manchanda *et al.*, 2007). In the present study, overall, general health status had improved, and it is supported with the data of earlier studies to demonstrate the clinical significance of EECP health-related quality of life of coronary heart disease patients (Wu *et al.*, 2012).

Table 5: SF-36 Baseline & follow up results of diabetic & nondiabetic CHD patients.

Variables		Nondiabetic CHD	Diabetic CHD	p-value
Physical Functioning				
Baseline		59.5 ± 9.6	60.1 ± 7.8	0.694
6 Month		63.3 ± 8.6	60.6 ± 10.3	0.082
12 Month		82.9 ± 6.0	82.7 ± 6.4	0.774
p-value	Baseline - 6 Month	0.020	0.702	
	Baseline - 12 Month	<0.0001	<0.0001	
Role Limitation due to physical health				
Baseline		34.8 ± 23.6	38.1 ± 26.4	0.409
6 Month		50.6 ± 27.1	43.9 ± 21.7	0.083
12 Month		62.9 ± 24.9	60.7 ± 24.1	0.543
p-value	Baseline - 6 Month	<0.0001	0.147	
	Baseline - 12 Month	<0.0001	<0.0001	
Role Limitation due to emotional problems				
Baseline		37.0 ± 29.3	37.4 ± 29.1	0.938
6 Month		44.4 ± 29.8	52.0 ± 27.7	0.095
12 Month		59.3 ± 27.9	60.2 ± 31.2	0.848
p-value	Baseline - 6 Month	0.121	0.001	
	Baseline - 12 Month	<0.0001	<0.0001	
Energy/Fatigue				
Baseline		51.2 ± 12.1	45.5 ± 9.1	0.001
6 Month		57.0 ± 12.9	52.1 ± 12.3	0.012
12 Month		65.7 ± 16.1	67.9 ± 16.8	0.393
p-value	Baseline - 6 Month	0.004	<0.0001	
	Baseline - 12 Month	<0.0001	<0.0001	
Emotional Wellbeing				
Baseline		64.6 ± 12.1	63.8 ± 11.7	0.676
6 Month		72.2 ± 20.3	68.1 ± 10.3	0.106
12 Month		73.3 ± 22.4	72.9 ± 21.6	0.875
p-value	Baseline - 6 Month	0.002	0.010	
	Baseline - 12 Month	<0.0001	0.001	
Social Functioning				
Baseline		41.7 ± 19.6	42.4 ± 13.9	0.790
6 Month		50.3 ± 15.7	44.4 ± 20.9	0.042
12 Month		84.4 ± 8.9	84.6 ± 9.1	0.979
p-value	Baseline - 6 Month	0.005	0.485	
	Baseline - 12 Month	<0.0001	<0.0001	
Bodily pain				
Baseline		66.5 ± 15.9	66.2 ± 16.7	0.909
6 Month		74.2 ± 13.4	76.4 ± 16.1	0.343
12 Month		78.5 ± 19.3	77.0 ± 12.7	0.589
p-value	Baseline - 6 Month	<0.0001	<0.0001	
	Baseline - 12 Month	<0.0001	<0.0001	
General Health				
Baseline		55.1 ± 10.4	55.3 ± 12.1	0.919
6 Month		63.8 ± 9.9	57.3 ± 9.2	<0.0001
12 Month		88.1 ± 7.3	88.3 ± 7.1	0.899
p-value	Baseline - 6 Month	<0.0001	0.257	
	Baseline - 12 Month	<0.0001	<0.0001	

Table 6: SAQ – Baseline & follow up results of diabetic & nondiabetic CHD patients.

Variables		Nondiabetic CHD	Diabetic CHD	p-value
Physical Limitation				
Baseline		23.9 ± 11.1	23.7 ± 12.7	0.911
6 Month		39.1 ± 10.7	38.4 ± 12.6	0.729
12 Month		56.2 ± 10.1	54.3 ± 10.9	0.269
p-value	Baseline - 6 Month	<0.0001	<0.0001	
	Baseline - 12 Month	<0.0001	<0.0001	
Angina Stability				
Baseline		26.4 ± 18.4	27.8 ± 20.1	0.647
6 Month		51.1 ± 18.1	52.2 ± 18.9	0.704
12 Month		74.8 ± 16.9	74.1 ± 17.2	0.807
p-value	Baseline - 6 Month	<0.0001	<0.0001	
	Baseline - 12 Month	<0.0001	<0.0001	
Angina Severity				
Baseline		25.4 ± 13.4	24.4 ± 12.2	0.604
6 Month		36.5 ± 14.4	33.6 ± 12.1	0.169
12 Month		54.8 ± 13.3	54.6 ± 13.7	0.932
p-value	Baseline - 6 Month	<0.0001	<0.0001	
	Baseline - 12 Month	<0.0001	<0.0001	
Treatment Satisfaction				
Baseline		49.7 ± 30.7	51.5 ± 23.0	0.667
6 Month		55.2 ± 26.5	52.1 ± 29.4	0.395
12 Month		76.8 ± 23.6	76.2 ± 22.5	0.861
p-value	Baseline - 6 Month	0.210	0.846	
	Baseline - 12 Month	<0.0001	<0.0001	
Disease Perception				
Baseline		51.8 ± 34.1	50.6 ± 33.7	0.816
6 Month		58.3 ± 23.9	54.2 ± 24.8	0.293
12 Month		76.5 ± 25.2	74.3 ± 26.5	0.590
p-value	Baseline - 6 Month	0.170	0.409	
	Baseline - 12 Month	<0.0001	<0.0001	

Our study showed similar results in diabetic and nondiabetic CHD patients and no major significant difference has been observed in diabetic and nondiabetic CHD group using independent t-test in physical functional capacity and health-related quality of life. Eslamian *et al.* concluded that EECP therapy can improve the angina pectoris stability and severity of disease perception (Eslamian *et al.*, 2013). Similarly, our study demonstrates that both diabetic and nondiabetic coronary heart disease patients get good results in almost all domains of SAQ quality of life assessment scale.

Enhanced external counterpulsation is an effective treatment method for diabetes management and diabetes complication including CHD. It helps in lowering blood glucose level of alerting transport of insulin into skeletal muscle and thereby help in the glycemic control and ultimately improve the health-related quality of life of diabetic CHD patients. Linnemeier *et al.*, Martin *et al.,* and Ramasamy *et al.* studies validate the effectiveness of EECP towards glycemic control in DM patients (Linnemeier *et al.*, 2003; Martin *et al.*, 2012; Ramasamy *et al.*, 2015).

Our study reveals that EECP significantly improves the health-related quality of life and remained high for the following one year in diabetic and nondiabetic CHD patients. Jorgensen *et al.* study demonstrated that the effect of EECP on quality of life sustained for three years in CHD patients (Jorgensen *et al.*, 2013). Hence, there is further need to conduct a multicentric randomized controlled trial to assess long-term effects of enhanced external counterpulsation on health-related quality of life in diabetic CHD patients.

CONCLUSIONS

The results of the present study conclude that enhanced external counterpulsation therapy may improve walking capacity, maximal oxygen uptake and peripheral capillary oxygen saturation of diabetic and nondiabetic CHD patients. This non-invasive procedure also significantly improves the clinical symptoms (angina & dyspnea) of CHD patients with and without DM. Enhanced external counterpulsation therapy may also improve overall health-related quality of life of diabetic and nondiabetic CHD patients, including angina severity, angina stability, and general health. In the summary, enhanced external counterpulsation therapy is safe, well tolerated and proved to be an effective, non-invasive therapy to treat diabetic and nondiabetic CHD patients. It may improve the physical profile and quality of life in both diabetic and nondiabetic CHD patients equally. There is further need of multicentric randomized controlled trials to assess long-term effects of enhanced external counterpulsation on health-related quality of life in a larger population of CHD with DM patients.

CONFLICT OF INTEREST

The authors of this study have no conflict of interest associated with material presented in this paper.

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