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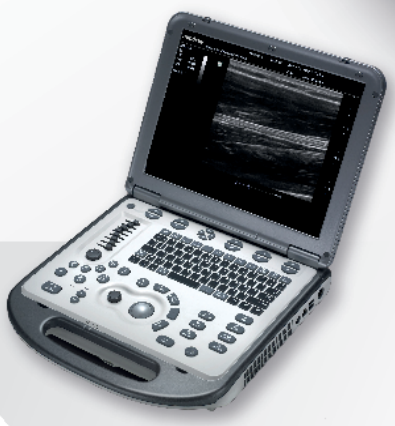

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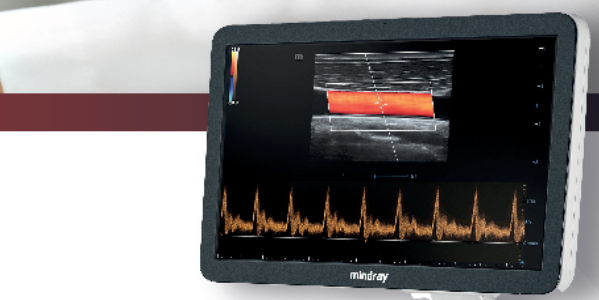

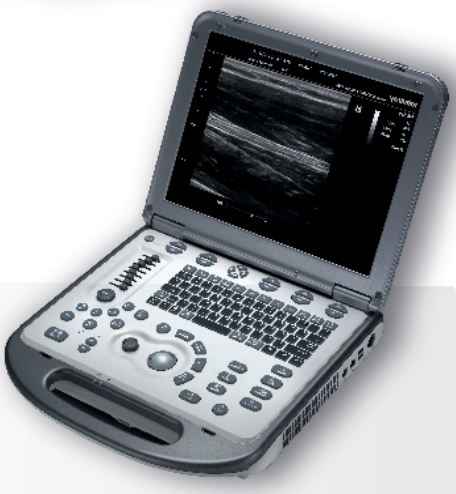

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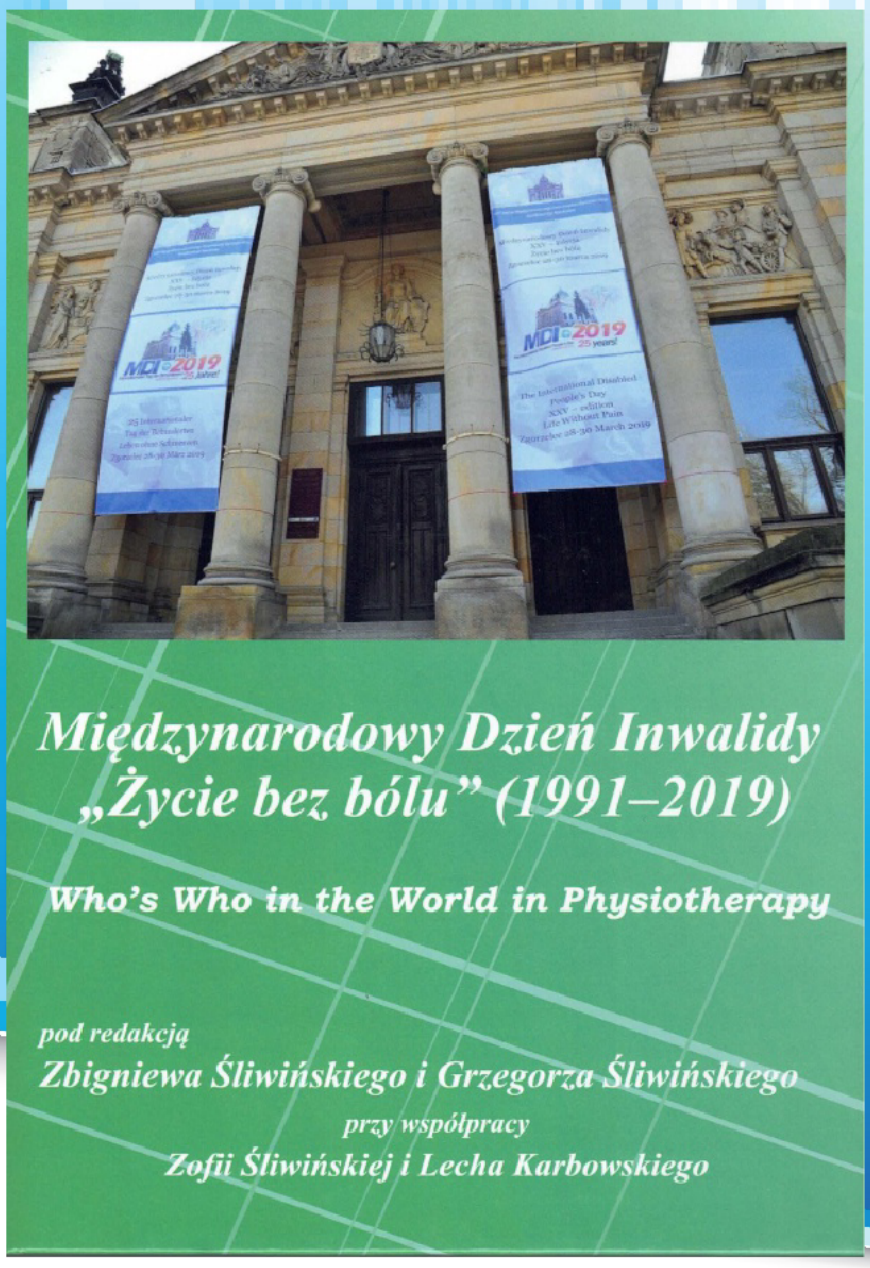

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nr 5/2021 (21)

Long term effect of physical therapy program in refractory anginal patients: A randomized controlled trial

Długoterminowy efekt programu fizjoterapii u pacjentów z oporną na leczenie dławicą piersiową: randomizowane badanie kontrolowane

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Abstract

Background. Despite number of effective pharmacological treatments and the success of interventional cardiology, many patients still experience resistive symptoms, or what is called Refractory Angina (RA), that markedly impairs quality of life (QoL). Aim. to investigate the effect of exercise training (ET) program in addition to TENS on endothelial function, QoL and physical work capacity (PWC) in patients with RA. Methods. forty male patients, suffering from chronic RA were randomly assigned into two equal groups. Group (A) received conventional TENS program in addition to ET program for five months, while group (B) subjected to only TENS for five months. Assessment was performed before treatment (pre), after 8 weeks (post I), after treatment (post II), and after more 4 weeks for both groups (post III). Outcome assessment included: endothelial function using flow-mediated dilation (FMD), QoL using The Seattle Angina Questionnaire (SAQ) and PWC using the 6-minute walk test (6MWT). Results. there was a significant improvement of the FMD in group (A) with no significant difference in group (B). Comparing between both groups showed that SAQ scores and 6MWT improved significantly in both groups with greater improvements in group (A) than group (B). Conclusion. The addition of ET program to TENS resulted in more improvement in endothelial function, PWC, and QoL in patients with RA.

Key words:

refractory angina, exercise training, TENS, endothelial function, quality of life

Streszczenie

Informacje wprowadzające. Pomimo wielu skutecznych metod leczenia farmakologicznego i sukcesu kardiologii interwencyjnej, wielu pacjentów nadal doświadcza objawów opornościowych, czyli tzw. opornej na leczenie dławicy piersiowej, która znacząco pogarsza jakość życia. Cel. Zbadanie wpływu programu treningu wysiłkowego oraz TENS na funkcję śródbłonka, jakość życia i wydolność fizyczną u pacjentów z dławicą piersiową. Metody. Czterdziestu pacjentów płci męskiej cierpiących na przewlekłą dławicę piersiową zostało losowo przydzielonych do dwóch równych grup. Grupa (A) była poddawana konwencjonalnemu programowi TENS jako uzupełnieniu programu treningu wysiłkowego przez pięć miesięcy, podczas gdy grupa (B) poddawana była wyłącznie programowi TENS przez pięć miesięcy. Ocenę przeprowadzono przed leczeniem (pre), po 8 tygodniach (post I), po leczeniu (post II) i po kolejnych 4 tygodniach (po III) dla obu grup. Ocena wyników obejmowała: czynność śródbłonka za pomocą dylatacji zależnej od przepływu (FMD), jakość życia za pomocą kwestionariusza Seattle Angina Questionnaire (SAQ) oraz wydolność fizyczną za pomocą testu 6-minutowego marszu (6MWT). Wyniki. Nastąpiła znaczna poprawa w zakresie FMD w grupie (A) bez istotnej różnicy w grupie (B). Porównanie między obiema grupami wykazało, że wyniki SAQ i 6MWT uległy znacznej poprawie w obu grupach, z większą poprawą w grupie (A) niż w grupie (B). Wniosek. Dodanie programu treningu wysiłkowego do programu TENS spowodowało większą poprawę funkcji śródbłonka, wydolności fizycznej i jakości życia u pacjentów z dławicą piersiową.

Słowa kluczowe

oporna na leczenie dławica piersiowa, trening wysiłkowy, TENS, funkcja śródbłonka, jakość życia

Introduction

Coronary artery disease (CAD) is the main cause of death worldwide. In recent decades, the evolution of medical therapy and revascularization procedures has significantly reduced the morbidity and mortality in CAD patients. However, 5–10% of CAD patients remain symptomatic despite optimal therapy referred to as 'refractory angina (RA)' [1]. This condition is defined as a 'chronic condition (> 3 months) characterized by diffuse CAD with proven ischaemia, which is not amendable to a combination of medical therapy and revascularization. Patients with RA are severely restricted in performing daily activities by debilitating angina complaints that adversely affects well-being, causing functional disability; depression, severely impairing quality of life (QoL). Additional treatment modalities for RA are therefore needed [2].

The cornerstone of treating RA is tight cardiovascular risk factor management. Therapies addressing advanced RA management are: (a) late sodium current inhibition (b) metabolic modulation (c) non-pharmacological interventions such as enhanced external counter-pulsation (EECP), Neuromodulation techniques, extracorporeal shockwave, coronary sinus reduction intervention (CSR), and gene therapy [3].

To date, electrical neuromodulation, independent of the applied modality is one of the best adjunct therapies to consider in patients with RA. It has shown to reduce complaints of angina, to enhance exercise capacity, to improve QoL and to employ anti-ischemic effects [2, 4].

Exercise in CAD patients improves myocardial perfusion, reduces angina symptoms, cardiovascular events and mortality. In 'no-option' patients, short-term exercise, improves coronary collateral blood flow, functional capacity and ischemic threshold which in turn improves QoL [5]. Growing evidence supports that Exercise training (ET) regardless of its modality, length and intensity enhances endothelial function [6].

It is clear that relieving angina via effective therapies has a powerful beneficial impact on patient functional recovery, QoL and psychological status. Consequently, interventions able to improve anginal symptoms and QoL are attractive [7]. The first neuromodulation technique used in the treatment of RA was Transcutaneous Electrical Nerve Stimulation (TENS). It was found to be safe non-invasive method with antianginal effect. However, using TENS is still underestimated in the treatment of RA [8]. The benefits of ET on symptoms, QoL, exercise capacity; mortality and morbidity have been confirmed in anginal patients. However, in spite of, the unquestionable benefits its role has been less extensively explored in the context of RA and this may relate to concerns regarding adverse events in high risk patients. Unfortunately, this paucity of data prohibits patients from participating in a potentially beneficial treatment program [7, 9]. Therefore, this study was designed to investigate the effect of ET program combined with TENS in patients with RA.

Materials and Methods

Trial design

A randomized controlled trial was conducted in physiotherapy department of National Heart Institute (NHI), Cairo, Egypt. The research protocol was approved by the Ethics committee of Scientific Research, Faculty of Physical Therapy at Cairo University [No: P.T.REC/012/00276].

Participants

Forty male patients with chronic refractory angina (RA) secondary to coronary artery disease CAD were referred by the cardiologist from the outpatient clinic of NHI. Inclusion criteria were male patients with RA diagnosis confirmed by Angiogram and/or thallium studies, were not candidates for revascularization, their ages between 45-65 years old, ejection fraction > 40%, Canadian Cardiovascular Society functional class III or IV, body mass index (BMI): 25-34.9, and they were on optimal medical treatment. Patients were excluded if they have recent myocardial infarction (MI) < 3 months, have unstable angina pectoris, have Bundle-branch block, or have any cerebrovascular or musculoskeletal disease prevented exercise training.

Randomization

Eligible patients were randomly assigned by a computerized system in a 1:1 ratio (permuted block randomization) to either group (A), 20 patients; who received TENS in addition to an ET program or group (B), 20 patients; who received only TENS. All patients remained on their prescribed medical treatment.

Interventions

- Group (A): Patients have a conditioning program for 8 weeks consisted of calisthenics exercises 30min/ 3 times a week. Calisthenics are simple movements, generally without using equipment intended to increase strength, endurance and flexibility [10]. Bending, twisting, squatting and standing leg left were of the used calisthenics forms. After 8 weeks, Symptom limited exercise test was used to determine Maximum Heart Rate for ET program, with patients first pedaled at work rate of 10 W followed by increases of 25 watts/3min until the patient could no longer maintain the required pedal cadence and then the HR max was recorded [11].

Patients then started a supervised ET program, 3 times/ week for 12 weeks. Each session involved aerobic training and resistance training. Aerobic training in the form of cycle ergometer and treadmill walking for 60 minutes with each session started with 10 minutes of warming-up in form of slow cycling exercise or quite walking and ended with a 10 minutes cool-down. Patients were trained in the target heart rate range as: Training HR = rest HR + 0.60% to 0.75% (HRmax – rest HR) and this formula is the most accurate one [12]. The training heart rate started at 50%, and increased gradually according to each patient's response till reaching 60–75% at the end of 12 weeks. All participants were closely monitored using ECG telemetry during the session.

The resistance training consisted of exercises for 8 large muscle groups (shoulder, elbow, hip and knee flexors and extensors). Resistive training intensity started at low intensity, 30-40% of pre-training maximum voluntary contraction determined using the one repetition maximum test, which was the highest weight, can be lifted once correctly in complete range of motion [13], and when the patients became confident with the exercise, they proceeded to a higher intensity (40–60%).

Progression of exercise was achieved through increasing repetitions, number of exercise circuits from one to three, followed by increasing intensity.

TENS: In addition to the ET program patients in group (A) have received conventional TENS for 30 minutes, 4 days/ week for 5 months. During application, patients were asked to sit in a comfortable position and 4 electrodes were placed over the area of anginal pain on the chest. Using the continuous stimulation mode at a frequency of 100 HZ, the intensity was gradually increased and settled at low level just above threshold.

- Group (B): Patients were subjected to conventional TENS for 30 minutes, 4 days per week for 5 months in the same manner as described for group (A).

Outcome Measurements

Assessment of all measurements was performed before treatment program (pre), after 8 weeks (post I), after termination of the program (post II), and after another 4 weeks for both groups (post III)

Endothelial Function was assessed through brachial flow mediated dilatation (FMD) testing using duplex ultrasound device (Eosatamy Lab 60 – made in Italy) according to the guidelines of Thijssen et al. [14]. The recordings were done 4.5 cm above the antecubital fosse before inflation of a pneumatic cuff on the upper arm to 250 mmHg for 5min, and repeated at 30-60 sec and 2 min after cuff release. FMD was expressed as percentage of change in diameter from baseline to peak diameter after cuff release [15, 16].

PWC was assessed by the 6MWT which is easy, better tolerated, and more reflective of daily living activities than the other walk tests [17]. Patient was instructed to walk as far as possible for 6 min without jogging along a 30-meters track; patient was permitted to slow down and/or to stop and rest on a chair if necessary, but he was instructed to resume walking as soon as he could. Post-test: the total distance walked was recorded.

QoL was measured by using The SAQ which is valid, reliable, and prognostically important disease-specific instrument. It comprises 19 questions that quantify 5 clinically relevant domains of CAD: physical limitation, anginal stability, anginal frequency, treatment satisfaction and disease perception/QoL [18]. Each scale score was transformed to a 0:100 range by subtracting the lowest possible scale score, dividing by the range of the scale and multiplying by 100, with higher scores indicated better health status. Because each scale monitors a unique dimension of CAD, no summated score was generated [19].

Statistical analysis

The test of normality in Shapiro-Wilk test of data revealed that the data was normally distributed ($P > 0.05$), and SPSS version 25 for Windows (SPSS, Inc., Chicago, IL) was used for results analysis. The following statistical procedures were conducted: Quantitative descriptive statistics (mean and standard deviation) for demographic data and measured variables, Independent (unpaired) t-test to compare between both groups for demographic data variables, and Two way mixed design MANOVA-test used to compare the tested variables at different groups and measuring periods. All statistical analyses were significant at 0.05 level of probability ($P \leq 0.05$).

Results

Comparing the general characteristics of the patients between both groups by independent t-test revealed that there were no statistical significant differences in the mean age, weight, height and BMI (Table 1).

Table 1. Patients demographic data in both groups

	Group A	Group B	t-value	P-value
Age [Year], Mean ± SD	53.95 ± 5.81	54.30 ± 6.59	0.178	0.860
Weight [kg], Mean ± SD	87.70 ± 8.75	86.75 ± 11.25	0.298	0.767
Height [cm], Mean ± SD	173.10 ± 4.49	170.30 ± 6.42	1.598	0.118
BMI [kg/m2], Mean ± SD	29.27 ± 2.33	29.91 ± 2.98	0.726	0.472

BMI: Body Mass Index; Level of significance at $P \leq 0.05$.

- FMD: Multiple pairwise comparison tests (Post hoc tests) revealed a statistical significant increase in FMD at post treatment-I, II, and III ($P < 0.05$) compared to pre-treatment in group (A) and no significant difference in group (B) at post treatment-I, II, and III ($P < 0.05$) compared to pre-treatment. Comparison between both groups confirmed that significant increase in post-treatment FMD favor of group (A) than group (B) (Table 2).

- SAQ: Multiple pairwise comparison tests (Post hoc tests) revealed a statistical significant increase in all SAQ domains (physical limitation, anginal stability, anginal frequency, treatment satisfaction and disease perception) scores at post treatment-I, II, and III ($P < 0.05$) compared to pre-treatment in group (A) and group (B). However, comparison between both groups confirmed that significant increase in post-treatment scores favor of group (A) than group (B) (Table 2).

- 6MWT: Multiple pairwise comparison tests (Post hoc tests) revealed a statistical significant increase in in 6MWT distance at post treatment-I, II, and III ($P < 0.05$) compared to pre-treatment in both groups. However, comparison between both groups confirmed that significant increase in post-treatment 6MWT distance favor of group (A) than group (B) (Table 2).

Table 2. multiple pairwise comparison of for all clinical measured outcome variables pre and post rehabilitation between study group and control group

Items		Pre	Post I	Post II	Post III
Flow mediated dilatation (FMD)	Group A	10.59 ± 1.40	13.40 ± 1.47	19.01 ± 1.55	18.45 ± 1.87
	Group B	10.18 ± 1.18	10.55 ± 1.29	10.91 ± 1.57	10.73 ± 1.56
	P-value	0.325	0.0001*	0.0001*	0.0001*
Physical limitation	Group A	15.20 ± 3.77	35.60 ± 5.65	77.95 ± 6.14	74.85 ± 5.65
	Group B	16.00 ± 4.62	27.45 ± 4.97	45.80 ± 5.38	42.05 ± 5.59
	P-value	0.553	0.0001*	0.0001*	0.0001*
Angina stability	Group A	15.00 ± 4.95	42.50 ± 14.28	83.75 ± 12.23	82.50 ± 11.75
	Group B	12.50 ± 2.82	30.00 ± 10.26	61.25 ± 12.76	57.50 ± 11.75
	P-value	0.574	0.003*	0.0001*	0.0001*
Angina frequency	Group A	12.10 ± 5.05	34.75 ± 9.38	72.65 ± 9.64	70.55 ± 11.45
	Group B	12.65 ± 4.48	22.65 ± 8.48	52.65 ± 9.64	47.90 ± 7.66
	P-value	0.848	0.0001*	0.0001*	0.0001*
Treatment satisfaction	Group A	14.90 ± 3.75	41.05 ± 8.37	73.55 ± 9.98	71.45 ± 9.35
	Group B	16.00 ± 1.39	29.35 ± 10.93	51.75 ± 11.16	48.50 ± 9.70
	P-value	0.755	0.001*	0.0001*	0.0001*
Disease perception	Group A	9.30 ± 2.30	38.70 ± 10.26	74.95 ± 9.27	72.90 ± 9.30
	Group B	8.10 ± 3.16	23.35 ± 8.47	48.40 ± 9.58	43.75 ± 8.87
	P-value	0.649	0.0001*	0.0001*	0.0001*
6MWT	Group A	209.10 ± 48.35	264.45 ± 54.98	353.70 ± 59.74	348.65 ± 59.65
	Group B	215.55 ± 62.41	247.05 ± 64.27	291.20 ± 65.55	280.75 ± 64.99
	P-value	0.717	0.036*	0.003*	0.001*

*Data are expressed as mean ± standard deviation, P-value: probability value, * = Significant*

Discussion

The aim of the present work was to determine the potential effects of ET program in addition to TENS on endothelial function [using FMD], QoL [using The SAQ], and PWC [using 6MWT] in patients with RA. The results of this study revealed a significant improvement of QoL, and PWC in both groups with a significant difference between both groups in favor to group [A] who received ET program in addition to conventional TENS application. However, FMD showed a significant improvement in group [A] with no significant difference in group [B].

Many previous studies supported the current results, Luk et al. [20] and Kim et al. [21] confirmed the improvement in FMD testing and PWC after ET program in CAD patients. Also Conraads et al. [22] in the SAINTEX study confirmed the significant improvement in PWC, endothelial function, cardiovascular risk factors, and QoL in 200 CAD patients who were randomized to a supervised 12-week of either aerobic interval or continuous training. Improvements were equal for both training interventions. Pattyn et al. [23] concluded that these improvements observed in the SAINTEX study are sustained after a 1-year follow-up. A systemic review by Kissel et al. [24] included 8 studies, concluded that ET is beneficial in anginal patients, causing improvement in PWC, oxygen uptake, and QoL and reducing severity of symptoms and myocardial perfusion defects.

The significant improvement of endothelial function in the present data may be attributed to the increase in blood flow, which augments shear stresses on the endothelium, leading to increased nitric oxide [NO] synthesis and bioavailability and thus vasodilatation. ET may help to restore the function of endothelial progenitor cells [EPCs], promoting endothelial repair and facilitating vascular angiogenesis subsequently [25].

ET induced improvements in functional capacity and the associated reduction in symptoms [lessening of angina, dyspnea and fatigue] can enhance cardiac patient's QoL and help older adults to live independently [26]. These preferable effects could be explained through the ability of regular ET to develop submaximal work tolerance through reducing cardiac work and myocardial oxygen demand at any given absolute workload. In addition, it enhances hemodynamic responses such as resting and maximum systolic and diastolic blood pressure, and heart rate [27, 11].

Neuromodulation beneficial effects on the symptoms of RA, PWC, and QoL could be explained through the ability of electrical neuro-stimulation to: reduce pain perception, reduce myocardial oxygen demand, improve coronary microcirculatory blood flow, and reduce afterload by systemic vasodilatation possibly through efferent sympathetic activity reduction [2, 4].

To the best of our knowledge, regarding the FMD results, this is study the first to investigate the effect of neuro-modulation techniques either TENS or SCS on endothelial function in CAD patients.

However, regarding the significant improvement of PWC and QoL after conventional TENS application the results of this study was supported by many studies. Eldabe et al. [28] confirmed positive effect of SCS on SAQ scores, exercise capacity and anginal symptoms in 29 patients suffering from RA.
Cheng et al. [29] also reported a fewer angina attacks, nitroglycerin consumption, improved CCS class and QoL [SAQ], up to one-year follow-up in RA patients received SCS. Two meta-analysis by Imran et al. [30] and Pan et al. [31] concluded that SCS was associated with an improvement in symptoms, nitrate consumption, exercise capacity and QoL in RA patients when compared with 'no-stimulation'. SCS also showed beneficial effects on increasing exercise time and clinically significant decrease of 2 or more CCS classes. In a recent study by Vervat et al. [1] SCS in 89 RA patients showed a significant improvement in SAQ with lower cardiovascular [1.1%] and all-cause mortality [3.4%].

Limitations

The major limitation of this study was the lack of blindness by the assessor; efforts were made to standardize diagnostic and evaluational procedures to minimize any possible bias caused by lack of blindness. Secondly, no follow up was conducted to know the long lasting effect and recurrence of symptoms.

Conclusion

The results of this study confirmed that the addition of exercise training program to TENS application is very effective physical therapy modalities for significant improvement of endothelial function, PWC, and QoL in patients with chronic RA.

Clinical relevance for physiotherapy practice

These results suggested that exercise training is well tolerated and safe to be involved in the physiotherapy program for refractory anginal patients.

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