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A PILOT TRIAL EVALUATING STATIC POSTURAL CONTROL AFTER GYM AND POOL EXERCISES IN FEMALES TREATED FOR BREAST CANCER

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A – study design, **B** – data collection, **C** – statistical analysis, **D** – interpretation of data, **E** – manuscript preparation, **F** – literature review, **G** – sourcing of funding

ABSTRACT

Background: Breast cancer (BC) therapies can cause toxic peripheral nerve injury resulting in postural control disorders and increased risk of falling.

Aim of the study: To determine the effects of gym and pool exercises on static postural control in female BC survivors. In this regard, advanced stabilometric parameters, including center-of-foot pressure (COP) excursions, rambling, and trembling, evaluated postural control.

Material and methods: This single group pilot included 11 females (30-65 years) treated for stage II-III BC who completed chemotherapy and/or radiotherapy after breast-sparing surgery or mastectomy. The intervention consisted of two 45-minute exercise sessions in the gym and one 60-minute session in the pool at least once a week for six weeks. Static postural control measurements were recorded with participants standing with eyes open and eyes closed on a force plate, which recorded the range, root-mean-square (RMS), and mean velocity of COP, trembling, and rambling.

Results: The pre-intervention and post-intervention values of stabilometric parameters obtained with eyes closed were not significantly different. However, eyes open measurements showed significant increases in the range, mean velocity, and RMS of COP, the range and RMS of rambling, and the mean velocity of trembling in the medial-lateral direction ($P<0.05$).

Conclusions: The six-week intervention involving gym and pool exercises resulted in static postural control changes in BC survivors. However, the results of this pilot study need to be verified by high-quality randomized clinical trials.

KEYWORDS: breast cancer, physical activity, physical therapy, postural control

Background

Breast cancer (BC) is the most common malignant tumor in females and one of the primary causes of female mortality. In 2018, 2.09 million new female BC cases and 0.63 million deaths were recorded globally [1].

BC therapies involve the risk of health complications, with surgical interventions and radiotherapy leading to muscle injury, tissue necrosis, fibrosis, and scars that deteriorate motor coordination [2,3]. Moreover, chemotherapy-induced peripheral neuropathy (CIPN) disturbs proprioception, motor coordination, muscle strength, and exercise capacity [4], which impairs postural control and increases the risk of falls [5,6,7].

BC prevention and management guidelines underscore the ability of physical activity to positively modulate biological BC risk factors [8,9,10], reduce body mass and estrogenic blood concentration, and increase the level of sex hormone-binding globulin [10]. They are also known to improve adiponectin synthesis and insulin sensitivity, stimulate hepatic and muscle metabolism of fatty acids [8], reduce blood levels of glucose, glycated hemoglobin, and insulin-like growth factor-1 (IGF-1), and increase the concentrations of IGF-binding proteins [9].

Physical exercises improve postural control and reduce the risk of falls in females with BC, although studies in this area are few and use different methodologies. Indeed, only five randomized controlled trials (RCTs) [11-15] and four pilot clinical trials [16-19] have attempted to improve participants' postural control using strength exercises [11], progressive resistance training (of spine and limb muscles) [12], sensorimotor exercises [14], exercises improving postural balance, endurance [15,19], resistance to fatigue [17,18], and upper extremity flexibility [18]. However, only three studies included an all-female BC cohort [14,18,19].

Schwenk et al. [13] divided 22 patients with post-chemotherapy CIPN (only 2 [9.1%] had BC) into two equal groups, an experimental group (EG) and a control group (CG). The EG received interactive game-based balance training 45 minutes per day, twice a week for four weeks, while the CG participants exercised regularly at home. After the intervention, the authors observed significant reductions in hip, ankle, and center of mass sway during standing in a feet-closed-position with eyes open (P=0.010-0.022, except the anterior-posterior [AP] center-of-mass sway) and semi-tandem-position (P=0.008-0.035, except for ankle sway) in the EG.

Vollmers et al. [14] studied 36 females treated for BC, with the EG (n=17) performing sensorimotor exercises twice a week for 12 weeks until the end of therapy and for the following six weeks. Meanwhile, the CG (n=19) performed regular exercises of their choosing at home. Subsequent analysis of static postural control measurements in a standing position with eyes open demonstrated a significantly smaller sway area (cm^2) in a monopedal stance for the EG after chemotherapy (both legs, $P<0.001$) and six weeks later (left leg, P=0.003; right leg, $P<0.001$) than the CG. In the bipedal stance, the EG's sway area was significantly smaller than the baseline after chemotherapy compared with the CG (P=0.039).

This pilot trial aimed to determine the effect of gym and pool exercises on static postural balance measured with a force plate in BC-treated females. Similar to other studies, the movement of the center-of-foot pressure (COP) was assessed. However, stabilometric parameters such as the root-mean-square (RMS), rambling, and trembling were measured for the first time in BC survivors.

Aim of the study

The study aimed to determine the effect of gym and pool exercises on static postural control in female BC survivors. Traditional and advanced stabilometric parameters, including COP, rambling, and trembling, evaluated postural control.

Material and methods

Study design

The intervention lasted six weeks and consisted of gym and pool exercises under the supervision of a physiotherapist. The study protocol was prepared to comply with the amended 1964 Declaration of Helsinki and was approved by the Academy's Bioethics Commission. The trial was registered with the Australian-New Zealand Clinical Trials Registry: ANZCTRN12619001599167.

Setting and participants

All participants were treated at the same oncology clinic, and their trial eligibility was assessed against the following inclusion criteria: female, aged 30-65 years, stage II-III BC, underwent breast-sparing surgery or mastectomy and chemotherapy and/or radiotherapy, and consented to participate in the study. The exclusion criteria included contraindications to physical exercise, pregnancy, recurrent BC, and other malignancies and diseases, especially nervous system and musculoskeletal disorders affecting body balance.

Group allocation

The participants were enrolled in the trial by a physician and informed in writing about its purpose and design and that they could withdraw at any time without prejudice to further treatment.

Patient characteristics and cancer classification

Standard interviews, physical examinations, and medical records provided participant demographic information, and the TNM scale (primary tumor [T], condition of regional lymph nodes [N], distant metastasis [M]) assessed BC type and spread. Meanwhile, a cell proliferation marker (Ki67), estrogen and progesterone receptor status, and epidermal growth factor receptor (EGFr) expression established the biology of the tumor.

Treatment

The participants received BC treatment according to best clinical practice, accounting for the cancer stage and biology, concomitant diseases, and their general condition. Treatment was interdisciplinary and involved surgical intervention, chemotherapy, hormonotherapy, immunotherapy, and radiotherapy.

Breast cancer prevention, education, and psychotherapy

All participants received written information about BC prevention basics and were invited to participate in twelve 45-minute meetings on BC prevention and treatment, delivered twice a week over six weeks. They also participated in peer-group support sessions (eight 45-minute meetings) to reduce their stress and anxiety levels.

Physical activity

The participants exercised twice a week for 45 minutes in the gym and once a week for 60 minutes in the pool for six weeks under the supervision of a specialist cancer physiotherapist. The gym exercises aimed to stretch their chest, back, and shoulder muscles and to improve general fitness and body balance. Each gym session concluded with upper limb relaxation exercises and dynamic breathing exercises performed in standing, sitting, and lying supine positions on the unoperated side, and involved the use of balls, resistance tapes, and gym sticks. The pool exercises aimed to improve postural balance and strengthen their upper and lower limbs and torso muscles and were performed in a standing position, with participants' feet touching or not touching the bottom of the pool, depending on the depth of the water. The gym and pool exercise methodology was derived from the rehabilitation guidelines for females recovering from BC [20].

Stabilographic measurements

Stabilographic measurements utilized a force plate (AMTI, MA, USA), with participants standing quietly, barefoot, and with eyes open or closed. Forces and torques were registered with a sampling frequency of 100 Hz.

The quiet standing tests were performed before the first and after the last training session. During measurements, the participants stood with feet shoulder-width apart, arms hanging at their sides, and their gaze fixated on a mark placed three meters away at eye level. Each measurement (with eyes open and eyes closed) lasted 30 seconds and was repeated three times for reliability.

Calculations employed Matlab r2017b software (Mathworks Inc., MA, USA). The raw COP signal was computed from the registered forces and torques and processed by a low-pass-4th-order Butterworth filter with a 7 Hz cut-off frequency. The COP signal was decomposed using Zatsiorsky and Duarte's method [21] to assess rambling and trembling. The following parameters were calculated and analyzed: mean velocity (V), range (Ra), and RMS of COP, rambling, and trembling.

Outcomes

Primary outcomes

The primary study endpoint measured at week six was static balance control in participants standing with eyes closed. It was assessed based on the Ra, mean V, and RMS of COP, rambling, and trembling in the medial-lateral (ML) and AP directions.

Secondary outcomes

The secondary study endpoint was static postural control measured with eyes open after six weeks of intervention, assessed against the same set of parameters as the primary outcome.

Statistical analysis

All computations used STATISTICA v.13.1 (StatSoft, Inc., OK, USA). The Shapiro-Wilk test examined variables for normality of distribution, and most data had a non-normal distribution, perhaps due to the small sample size. Consequently, the Wilcoxon signed-rank test compared within-group results obtained pre-intervention and post-intervention. The level of significance was set at P≤0.05.

Results

Between June 1st, 2019, and November 30th, 2020, 21 females were screened for the trial, with 12 meeting the inclusion criteria for study enrollment. One female (8.33%) withdrew from the intervention due to family problems. Among the remaining 11, nine participated in all training sessions, one missed two gym sessions and one pool session, and one was absent from two sessions, one in the gym and one in the pool. Statistical analysis was performed on data obtained for the 11 participants (Figure 1).

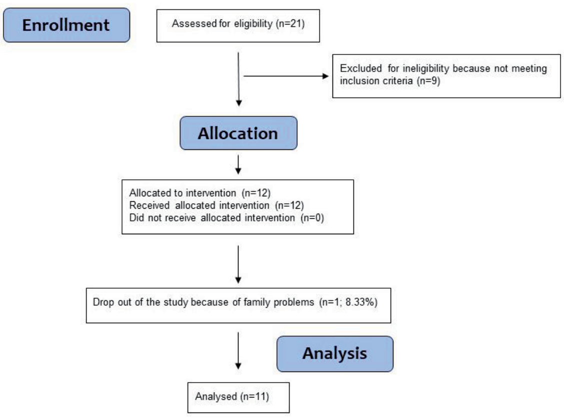

Figure 1. Diagram flow of the study

Patient baseline characteristics

Table 1 outlines the baseline characteristics of the participants. All were Caucasian with a mean age of 57.63±6.42 years (Ra of 41-69) and a mean body mass index (BMI) of 27.36±5.50 kg/m^2. Seven had stage I BC (63.6%), four (36.4%) had stage II BC, and none presented with stage III BC. All participants underwent conserving surgery for BC. Additionally, five (45.5%) had chemotherapy, 10 (90.9%) had radiotherapy, one (9.1%) had immunotherapy, and three (27.3%) had hormonotherapy.

Table 1. Patient characteristics before therapy (n=11)

Characteristics	Experimental group (n=11)
Age [years] (mean ±SD)	57.63±6.42
Range [years]	41–69
BMI [kg/m^2] (mean ±SD)	27.36±5.50
Disease stage [n]	
I	7 (63.6%)
II	4 (36.4%)
III	0 (0%)
Breast surgery type [n]	
Breast conserving surgery	11 (100%)
Chemotherapy [n]	
Yes	5 (45.4%)
No	6 (54.5%)
Time since end of chemotherapy [n]	
<6 months	2 (40%)
6–12 months	3 (60%)
>12 months	0 (0%)
Radiotherapy [n]	
Yes	10 (90.9%)
No	1 (9.1%)
Time since end of radiotherapy [n]	
<6 months	6 (60%)
6–12 months	3 (30%)
>12 months	1 (10%)
Immunotherapy [n]	
Yes	1 (9.1%)
No	10 (90.9%)
Hormonal therapy [n]	
Yes	3 (27.3%)
No	8 (72.7%)

Primary outcome

The primary study outcome was static postural control while standing with eyes closed. The post-intervention tests were not significantly different from the baseline (Table 2).

Secondary outcome

The post-intervention standing with eyes open tests revealed a statistically significant increase in the Ra COP (P=0.004), mean V COP (P=0.026), and RMS COP (P=0.008) in the ML direction. The Ra rambling (P=0.008), RMS (P=0.010), V trembling (P=0.016), and RMS (P=0.041) were also significantly higher. Other changes in the ML direction, including V rambling (P=0.213), Ra trembling (P=0.110), and parameter changes in the AP direction, were non-significant. Table 3 and Figure 2 provide detailed results.

Table 2. Assessment of static posture control with eyes closed

Parameters	Experimental group (n=11)			
	Pre-training	**Post-training**	**p (pre vs. post)**	**Effect size**
Quiet Standing Eyes Closed AP				
Ra COP(cm)	2.39 (1.89–2.65)	2.25 (2.09–2.65)	0.477	0.21
Ra rambling (cm)	1.99 (1.69–2.37)	2.08 (1.85–2.42)	0.424	0.24
Ra trembling (cm)	0.84 (0.78–1.10)	0.97 (0.70–1.36)	0.790	0.08
RMS COP (cm)	0.46 (0.35–0.51)	0.46 (0.38–0.54)	0.374	0.11
RMS rambling (cm)	0.44 (0.32–0.45)	0.41 (0.36–0.53)	0.213	0.06
RMS trembling (cm)	0.09 (0.09–0.15)	0.10 (0.09–0.16)	0.929	0.28
V COP (cm/s)	0.96 (0.82–1.17)	0.98 (0.80–1.19)	0.657	0.20
V rambling (cm/s)	0.67 (0.58–0.83)	0.73 (0.55–0.78)	0.657	0.20
V trembling (cm/s)	0.55 (0.44–0.75)	0.65 (0.41–0.74)	0.929	0.28
Quiet Standing Eyes Closed ML				
Ra COP(cm)	1.44 (0.95–1.78)	1.27 (0.88–1.52)	0.328	0.29
Ra rambling (cm)	1.38 (0.93–1.56)	1.06 (0.78–1.49)	0.248	0.35
Ra trembling (cm)	0.39 (0.30–0.60)	0.45 (0.20–0.48)	0.110	0.48
RMS COP (cm)	0.31 (0.17–0.35)	0.21 (0.16–0.36)	0.328	0.29
RMS rambling (cm)	0.30 (0.17–0.33)	0.19 (0.15–0.33)	0.248	0.35
RMS trembling (cm)	0.04 (0.03–0.07)	0.04 (0.02–0.05)	0.091	0.51
V COP (cm/s)	0.47 (0.36–0.60)	0.49 (0.31–0.59)	0.722	0.11
V rambling (cm/s)	0.37 (0.29–0.46)	0.35 (0.27–0.46)	0.929	0.03
V trembling (cm/s)	0.23 (0.14–0.34)	0.24 (0.09–0.28)	0.534	0.19

Data are presented as median (lower quartile and upper quartile); *p≤0.05; Ra – range; RMS – root-mean-square; V – velocity; COP – center-of-foot-pressure; AP – anterior-posterior; ML – medial-lateral.

Table 3. Assessment of static posture control with eyes open)

Parameters	Experimental group (n = 11)			
	Pre-training	**Post-training**	**p (pre vs. post)**	**Effect size**
Quiet Standing Eyes Open AP				
Ra COP(cm)	1.94 (1.61–2.64)	1.94 (1.39–2.08)	0.091	0.51
Ra rambling (cm)	1.83 (1.44–2.42)	1.70 (1.40–1.91)	0.155	0.43
Ra trembling (cm)	0.59 (0.52–0.80)	0.51 (0.44–0.67)	0.374	0.27
RMS COP (cm)	0.42 (0.30–0.57)	0.38 (0.29–0.44)	0.213	0.38
RMS rambling (cm)	0.41 (0.28–0.52)	0.33 (0.29–0.43)	0.248	0.35
RMS trembling (cm)	0.07 (0.05–0.09)	0.06 (0.04–0.07)	0.328	0.29
V COP (cm/s)	0.65 (0.59–0.75)	0.66 (0.55–0.87)	0.594	0.16
V rambling (cm/s)	0.49 (0.45–0.57)	0.49 (0.44–0.65)	0.534	0.19
V trembling (cm/s)	0.37 (0.25–0.46)	0.34 (0.23–0.49)	0.286	0.32
Quiet Standing Eyes Open ML				
Ra COP(cm)	0.93 (0.85–1.37)	1.30 (0.95–1.75)	0.004*	0.86
Ra rambling (cm)	0.90 (0.78–1.29)	1.14 (0.87–1.70)	0.008*	0.80
Ra trembling (cm)	0.27 (0.15–0.40)	0.44 (0.21–0.52)	0.110	0.48
RMS COP (cm)	0.18 (0.18–0.29)	0.25 (0.20–0.38)	0.008*	0.80
RMS rambling (cm)	0.17 (0.16–0.26)	0.23 (0.18–0.37)	0.010*	0.78
RMS trembling(cm)	0.03 (0.01–0.04)	0.04 (0.02–0.06)	0.041*	0.62
V COP (cm/s)	0.36 (0.27–0.44)	0.47 (0.29–0.62)	0.026*	0.67
V rambling (cm/s)	0.30 (0.23–0.36)	0.32 (0.26–0.41)	0.213	0.38
V trembling (cm/s)	0.16 (0.08–0.19)	0.21 (0.09–0.32)	0.016*	0.72

Data are presented as median (lower quartile and upper quartile); *p≤0.05; Ra – range; RMS – root-mean-square; V – velocity; COP – center-of-foot-pressure; AP – anterior-posterior; ML – medial-lateral.

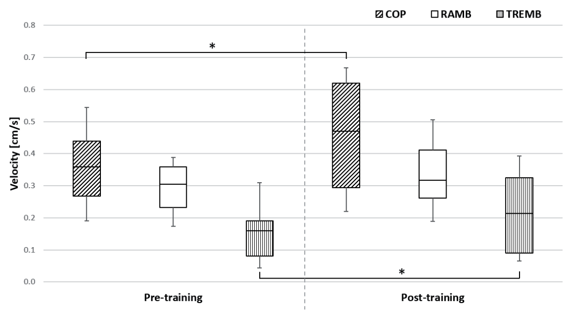

Figure 2. Pre- and post-training velocities for COP, Rambling and Trambling in ML direction

Discussion

Statement and principal findings

Force-plate stabilometry is an advanced method for assessing static and dynamic postural control in people with balance disorders, such as the elderly [22], patients with central nervous system disorders [23], and those with peripheral neuropathies of various etiologies [24,25].

Static postural control is assessed with eyes closed and eyes open, with increased postural sway attributed to the impairment of righting reflexes that need visual, vestibular, and proprioceptive information to function [26]. The cause of increased sway when standing with eyes closed is a proprioceptive rather than a vestibular balance disorder and is concomitant with peripheral neuropathies [27]. Increased postural sway carries a greater risk of a fall when uncontrolled, and controlled sway, even if strong, usually results from a postural response to various motor requirements [28,29].

Müller et al. [30] studied 35 patients with cancer (BC=89%) and 35 healthy persons and confirmed that chemotherapy leads to postural disorders. The postural control parameters did not significantly differentiate the cancer patients before chemotherapy from the controls but were markedly different within cancer patients before and after chemotherapy and between cancer patients after chemotherapy and the CG. The most serious balance problems were observed in participants standing with their eyes closed [30].

Of the three known RCTs [13-15] investigating the effects of physical exercises on static postural control in post-chemotherapy patients, only one [14] studied females treated for BC, and none used a training program similar to this study. Moreover, only one trial [15] assessed postural control using a force plate. The participants included females with CIPN symptoms following treatment for different types of cancer (BC=12 [32.4%]) divided into an EG (n=19) and a CG (n=18). They underwent moderate-intensity endurance training on a stationary bicycle below the individual anaerobic threshold for 30 minutes a day, twice a week, for 12 weeks. Additionally, those in the EG performed balance exercises for 30 minutes per day, twice a week, for 12 weeks. After the intervention, the sway path length of COP in a semi-tandem stance with eyes open was significantly shorter than the baseline in the EG (P=0.018), whereas it did not change in the CG. As a result, the difference between the groups was statistically significant (P=0.049).

Błaszczyk [31] argues that neither increased nor decreased body sway in upright standing is conclusive proof of postural control disorders. Similarly, Portnoy et al. [23] concluded that higher values of stabilometric parameters when standing with eyes open did not necessarily point to postural control problems. They measured and compared static postural control in healthy young adults (n=13; mean age of 25.4±1.1 years), healthy elderly adults (n=11; mean age of 64.5±3.5 years), and adults in a chronic post-stroke state for a period of 6 to 18 months (n=21; mean age of 61.4±10.1 years). The latter had a significantly longer COP path length in quiet standing for 10 seconds with eyes open and eyes closed than all healthy participants, as well as significantly higher maximal COP V, but only when standing with eyes closed. Interestingly, elderly healthy adults had significantly greater COP path length when standing with eyes open but not with eyes closed.

Solnik et al. [32] asked 12 volunteers (aged 28±3 years) to point to objects located in different places and at different distances while standing on a force plate. No association was found between the location of the objects and the body sway indicators, but correlations between comfort ratings and trembling values were significant. The authors [32] concluded that persons performing motor tasks with eyes open focus more on subjective comfort than the amount of postural sway.

According to studies on athletes, there is an association between sport and static postural sway [28,29]. Indeed, Negahban et al. [29] established that athletes in sports requiring dynamic balance, such as taekwondo, had significantly greater postural sway than athletes in sports emphasizing static balance, such as sport shooting. Furthermore, a study on highly-trained karate athletes and untrained physical education students demonstrated that the former had longer COP path lengths, larger rambling and trembling trajectories in the AL direction, and larger rambling trajectories in the ML direction [28].

The cited studies indicate that postural control may depend on factors independent of health disorders. For instance, studies on athletes [28,29] suggest that increased but controlled body sway in a quiet standing with eyes open position may result from adaptation to physical exercise. Similarly, increased body sway in females treated for BC in this study may signify that the intervention improved their postural control. This observation requires further clinical research to be confirmed.

Limitations

The main limitations of this pilot study were the lack of blinding, the absence of a CG, and the small sample size. In addition, the study did not assess the long-term effects of the intervention. These limitations will be addressed in future clinical trials.

Conclusions

The six-week intervention consisting of two 45-minute exercise sessions in the gym and one 60-minute exercise session in the pool per week did not influence postural control while standing with eyes closed in females treated for BC. Nonetheless, the higher values for some stabilometric parameters measured in the standing with eyes open position, including the Ra, mean V, RMS of COP, Ra rambling and RMS, and mean V of trembling, suggest their postural control may have slightly improved. This observation requires further high-quality RCTs to be confirmed. It is also important to further investigate which physical exercises improve static and dynamic postural control in females treated for BC, how they change their postural sway, and how postural sway relates to their ability to maintain postural balance and reduce the risk of falling.

Abbreviations (listed in the order in which they appear in the article)

BC – breast cancer
RMS – root-mean-square
COP – center-of-foot pressure
CIPN – chemotherapy-induced peripheral neuropathy
IGF – insulin-like growth factor
RCT – randomized controlled trial
V – velocity
Ra – range
ML – medial-lateral
AP – anterior-posterior
BMI – body mass index
EG – experimental group
CG – control group
TMN – tumor node metastasis
EGFr – epidermal growth factor receptor

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