



The effects of short-term back extensor strength training in postmenopausal osteoporotic women with vertebral fractures: comparison of supervised and home exercise program

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Received: 4 February 2019 / Accepted: 11 July 2019

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Abstract

Summary This study explores the effect of supervised back extensor strength training on spinal pain, back extensor muscle strength, trunk-arm endurance, kyphosis, functional mobility, and quality of life (QoL) among sixty postmenopausal women with vertebral osteoporotic fractures.

Purpose To compare the effects of a 6-week supervised or home-based program of back-strengthening exercise on spinal pain, back extensor strength, trunk-arm endurance, kyphosis, functional mobility, and QoL in osteoporotic postmenopausal women with vertebral fractures.

Methods The study was designed as a randomized controlled clinical trial. Sixty osteoporotic postmenopausal women with vertebral fracture (mean age 60.3 ± 9.3 years) were included in the study. Subjects were randomly assigned into three groups (supervised program, home-based program, or control), each consisting of 20 subjects. The subjects underwent the 6-week exercise program which included strengthening exercise for the back extensor muscles. They performed three sets of 8, 10, or 12 repetitions for each of the exercises, biweekly ascending, three times per week. Spinal pain, back extensor strength, trunk and arm endurance, kyphosis, functional mobility, and QoL were measured at baseline and at the end of the exercise program.

Results Statistically significant improvements were demonstrated on spinal pain, muscle strength and endurance, functional mobility, and QoL for the supervised exercise program compared with control and home-based exercise groups ($p < 0.01$). Home-based exercise program did not provide a significant improvement compared with the control group except for mobility parameters of QoL.

Conclusions Six-week supervised back extensor strengthening training is superior to home-based program in terms of spinal pain, back extensor muscle strength, trunk endurance, functional mobility, and QoL for postmenopausal osteoporotic women with vertebral fractures.

Keywords Osteoporosis · Vertebral fractures · Rehabilitation · Exercise

Introduction

Osteoporosis is a skeletal disorder characterized by compromised bone strength predisposing a person to an increased risk

of fracture [1]. Vertebral fractures, the most common osteoporotic fractures, result in a deterioration of the health-related quality of life mainly through back pain, reduced physical capability, perceived poor general health, and emotional status (e.g., fear of falling, lack of independence, limitation of activity and social interactions) [2]. Although the positive effects of strengthening exercise on back pain, muscle strength, endurance, functional mobility, and quality of life (QoL) was stated in patients with osteoporotic vertebral fractures, there is no conclusion regarding the frequency, intensity, type of exercise, and mode of application (supervised or home based) [3–6]. To our knowledge, there is no study in the literature comparing the effects of supervised or home-based back extensor strengthening exercises on back pain, muscle strength, endurance, degree of kyphosis, functional mobility, and QoL in

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postmenopausal women with osteoporotic vertebral fractures. We hypothesized that supervised extensor strengthening exercises are more effective than home-based exercises because of supervision may affect adherence.

The aim of this study was to compare the effects of a 6-week supervised or home-based program of back-strengthening exercise on spinal pain, back extensor strength, trunk and arm endurance, kyphosis, functional mobility, and QoL in osteoporotic postmenopausal women with vertebral fractures.

Materials and methods

Design overview

The study was prospective randomized controlled clinical trial.

Setting and participants

Eighty-one postmenopausal severely osteoporotic women aged between 40 and 75 and who were admitted to the Department of Physical Medicine and Rehabilitation of Pamukkale University were screened for eligibility. The inclusion criteria included established osteoporosis by means of dual-energy X-ray absorptiometry using WHO criteria for osteoporosis [7] and a history of one or more vertebral fractures verified by radiography, aged 40–75 years old, to be in menopause at least 1 year, to take regular drug therapy for osteoporosis at least 6 months. The patients underwent anteroposterior and lateral radiography of the thoracic and lumbar spine at baseline. All radiographs (T-4 through L-5) were reviewed by a radiologists (NSA) independently for evidence of compression fractures in the spine and graded each vertebrae as normal (i.e., normal height) or as mildly, moderately, or severely deformed (i.e., a decrease in height of approximately 20 to 25%, 26 to 40%, or more than 40% respectively) by using the Genant semiquantitative technique [8]. Exclusion criteria were cognitive impairments (Mini-Mental State Examination score ≤ 23 points), the presence of secondary causes of osteoporosis, the presence of musculoskeletal or systemic disease barriers to exercise, failure to lie in prone position, the presence of new fractures which occurred in the last 6 months, the presence of acute back pain defined as back pain lasting less than 3 months and radicular pain, malignancy, women with 25(OH) vitamin D level < 30 ng/ml. The Regional Ethics Committee for Medical Research approved the study, and the subjects gave their written informed consent to participate in the study.

Randomization and intervention

The subjects were randomly assigned by a computer-generated list to three groups, supervised exercise (SE), home-based exercise (HE), and control (C). A researcher who was not involved in the study performed the randomization. On the other hand, patients and researcher delivering the intervention were not blind to group allocation. Patients included in the study were assessed at baseline and at 6 weeks by a physiatrist blinded to group allocation. The information about the definition of osteoporosis and its importance, risk factors, and prevention was presented by a physiatrist to the patients in each group at baseline.

Exercise program As the first warm-up exercise, the patients lie on the ground face down by putting a cushion under their abdomen while their bodies are slightly flexed and by using the power of their arms they need to bring their bodies to a neutral position and repeat this exercise for 10 times. After warm-up, back extensor strengthening exercises (in the prone position: trunk extension, alternate arm raises, opposing arm and leg raises; on the hands and knees position: opposing arm and leg raises) were given for 6 weeks. Exercises were performed 3 times per week, 3 sets of 8 repetitions for the first 2 weeks, 3 sets of 10 repetitions for the 2nd 2 weeks, and 3 sets of 12 repetitions for the 3rd 2 weeks.

While 20 patients in the SE group attended in supervised and group (consisting of 5 participants) exercise program in a clinic under the full supervision of physiatrist, 20 patients in the HE group were given an instructional booklet and asked to apply the program at home. All of the participants completed the program in 6 weeks. All of the patients in HE group received specific written instructions in the form of a booklet with descriptions and pictures of each exercise; then, exercises were demonstrated and performed one time at the hospital together with supervision. All patients in the HE group were instructed to perform exercises and wanted to mark a chart if the exercises were performed. A diary was used to monitor adherence with the HE program. Both SE and HE groups adhered to their exercise regimens well. Compliance during the rehabilitation program was excellent in the SE group, as all of the patients completed the exercises with full compliance for repetition, sessions, and time. The attendance rate at the home-based exercises averaged over 85% for HE group. The control group was asked to continue their daily life activities. They did not receive any additional therapy or exercise training during 6 weeks of the study. Physical activity measurement was assessed only in terms of group homogeneity before intervention, and no data were collected during the intervention.

Outcome measures

Spinal pain was evaluated by Visual Analogue Scale (VAS) to measure pain intensity on activity in the previous week and pain intensity at rest in the previous week. It consists of a 10-cm line, the ends of which are labeled “no pain” and “pain as bad as it could be.”

Back extensor muscle strength was measured by a hand-held dynamometer (Commander Muscle Tester Power Track II, JTech, USA) fixated with a tripod and a belt system as described in patients with osteoporotic vertebral fractures by Valentin et al. [9]. The measured isometric peak extension force value was recorded as newtons.

Trunk muscle endurance was measured using the Timed Loaded Standing test. It is a reliable and valid test assessing combined trunk and arm endurance in people with vertebral osteoporosis [10]. The test measures the time a person can stand while holding a two-pound dumbbell in each hand with the arms at 90 degrees of shoulder flexion and the elbows extended.

Thoracic kyphosis was measured using a digital inclinometer (Dualer IQ Pro Digital Inclinometer, JTech, USA). Each subject was instructed to stand without shoes on and with weight equally distributed on both feet, with the examiner standing facing the side of the subject. For measuring the degree of thoracic kyphosis, the dual inclinometer in static mode was placed over the T1 and T12 spinous process on the spine. Degrees of kyphosis were recorded directly from the scale of the inclinometer.

Functional mobility was evaluated using the “Timed Up and Go” (TUG) test. The subject was instructed to rise from a chair with a seat, walk 3 m, turn around, return, and sit down again, wearing ordinary footwear and using customary walking aids if necessary. The time (second) to complete the test was used as an outcome of this test [11].

Health-related quality of life was evaluated by the “Quality of Life Questionnaire issued by the European Foundation for Osteoporosis” (QUALEFFO-41). QUALEFFO-41, which is a disease-specific questionnaire, is self-administered and contains questions in five domains: pain, ability to perform physical functions, social functioning, general health perception, and mental performance. These five domains can be evaluated individually or be represented in a total score. All scores are expressed in values ranging from 0 to 100, where 0 represents the best and 100 the worst. The Turkish version of the QUALEFFO-41 was demonstrated to be a reliable and valid scale [12].

Statistics

Sample size was calculated as 60 patients to determine the VAS score difference between groups with a power 80% or above according to the data obtained from the other studies.

SPSS 22.0 software (SPSS, Chicago, IL, USA) was used for the statistical analysis. In each group, measurable parameters were tested with the Kolmogorov Smirnov test for the evaluation of normal distribution. Because the distributions were not normal, nonparametric tests were used in statistical evaluation. The difference between groups in terms of baseline sociodemographic and clinical characteristics was evaluated by Kruskal–Wallis test for parametric variables and the chi-square test for qualitative variables. In all groups, the significance of improvements was assessed using the Wilcoxon test between pretreatment and post-treatment evaluation for intragroup comparisons. The Kruskal–Wallis variance analysis and analysis of variance with the post-hoc Bonferroni correction (Mann–Whitney U test) were used for intergroup comparisons. p values less than 0.05 were considered as statistically significant. In analysis with Bonferroni correction, p values less than 0.0167 were considered to be statistically significant.

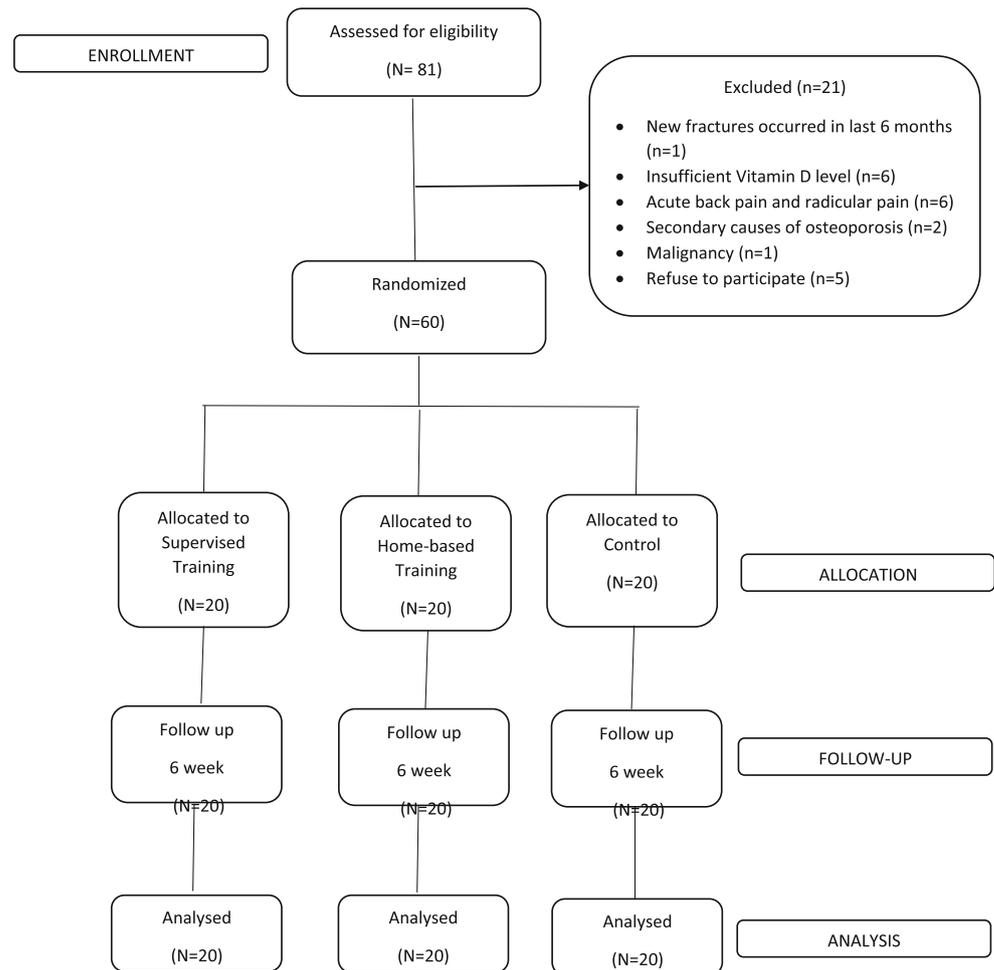
Results

A total of 81 postmenopausal severely osteoporotic women were eligible for this study; 21 of whom had to be excluded from the study, one of them due to the presence of new fractures occurred in last 6 months, six of them due to the insufficient vitamin D levels, six of them due to the presence of acute back pain or radicular pain, two of them due to the presence of secondary causes of osteoporosis, one of them due to having malignancy, and five of them due to the refusing to participate the study as shown in flow diagram (Fig. 1). Therefore, a total of 60 postmenopausal severely osteoporotic women were included in this prospective randomized controlled study. All patients in the exercise groups and control completed the 6-week follow-up period. A total of 60 patients completed the study (20 in the SE group, 20 in the HE group, and 20 control) as shown in Fig. 1.

Baseline characteristics of the participants are presented in Table 1. There was no significant difference among the groups at baseline in terms of age, body mass index (BMI), Mini-Mental State Examination, level of physical activity, and number and grades of vertebral fractures. Also, there were no significant differences in values of VAS rest, VAS activity, back extensor strength, trunk endurance, degree of kyphosis, functional mobility, and QUALEFFO-41 among groups at baseline (Table 2).

In both exercise groups (SE and HE), significant improvements in the VAS rest, back extensor strength, trunk endurance, degree of kyphosis, functional mobility, and QUALEFFO-41 scores were detected at 6 weeks compared with baseline ($p < 0.01$). In the SE group, additionally, a

Fig. 1 The flowchart of participants through each stage of the trial



significant improvement in the VAS activity scores was observed compared with baseline ($p < 0.01$). In the control group, only trunk and arm endurance increased significantly at 6 weeks compared with baseline. SE group had significantly better results in terms of VAS rest, VAS activity, back extensor strength, trunk endurance, functional

mobility, and QUALEFFO-41 scores compared with the HE and control groups at 6 weeks. There was no statistically significant difference between the HE group and the control group in all parameters evaluated at the end of the treatment except mobility scores of physical functioning domain of QUALEFFO-41 (Table 3).

Table 1 Baseline characteristics of the participants in all groups

	SE ($n = 20$; mean \pm SD)	HE ($n = 20$; mean \pm SD)	Control ($n = 20$; mean \pm SD)	p value
Age	58.90 \pm 4.70	60.20 \pm 7.57	59.65 \pm 6.45	0.679
BMI (kg/m^2)	28.46 \pm 6.06	29.87 \pm 4.97	27.49 \pm 4.11	0.225
MMSE	28.4 \pm 1.23	28.15 \pm 1.95	28.15 \pm 1.69	0.972
Physical activity (MET-min/week)	403.87 \pm 190.11	339.12 \pm 205.05	323.75 \pm 181.96	0.361
Number of vertebral fractures	1.3 \pm 0.47	1.45 \pm 0.75	1.45 \pm 0.82	0.956
Grades of vertebral fractures				
Grade I	4(70%)	14(70%)	13(65%)	
Grade II	6(30%)	5(25%)	7(35%)	
Grade III	0	1(5%)	0	0.666

SE, supervised exercise; HE, home-based exercise; BMI, body mass index; MMSE, Mini-Mental State Examination

Table 2 Baseline values of outcome measurements in all groups

	SE (<i>n</i> = 20; mean ± SD)	HE (<i>n</i> = 20; mean ± SD)	Control (<i>n</i> = 20; mean ± SD)	<i>p</i> value
VAS rest	6.40 ± 1.27	6.15 ± 1.34	5.55 ± 1.63	0.202
VAS activity	6.45 ± 1.09	6.20 ± 0.95	6.20 ± 1.57	0.621
TUG test (second)	11.57 ± 2.47	12.92 ± 2.93	12.55 ± 2.03	0.233
Back extensor strength (N)	29.30 ± 5.67	33.85 ± 6.22	34.50 ± 5.74	0.061
Trunk endurance (second)	49.10 ± 16.69	44.70 ± 18.98	44.50 ± 18.18	0.385
Thoracic kyphosis degree	46.35 ± 8.79	42.10 ± 7.15	42.55 ± 6.68	0.152
QUALEFFO-41 (score/100)				
Pain	45.25 ± 11.41	44.75 ± 7.85	44.75 ± 14.18	0.809
Activities of daily living	30.62 ± 9.27	27.50 ± 13.96	34.06 ± 9.82	0.063
Jobs around the house	33.00 ± 9.78	31.50 ± 15.73	33.50 ± 7.62	0.193
Mobility	31.25 ± 6.80	31.25 ± 7.38	31.25 ± 3.51	0.138
Physical function	31.62 ± 6.83	30.08 ± 11.10	32.94 ± 5.31	0.052
Social function	65.98 ± 13.88	74.02 ± 11.56	68.75 ± 17.10	0.203
General health	62.5 ± 10.29	65.00 ± 13.40	64.16 ± 11.50	0.833
Mental health	40.69 ± 9.63	45.13 ± 13.78	43.05 ± 12.20	0.673
Total score	41.56 ± 7.31	45.45 ± 8.98	45.29 ± 7.53	0.179

SE, supervised exercise; HE, home-based exercise; VAS, Visual Analogue Scale; TUG, Timed Up and Go; QUALEFFO-41, Quality of Life Questionnaire issued by the European Foundation for Osteoporosis

Discussion

In this prospective randomized controlled study, we compared the effects of a 6-week supervised or home-based program of back-strengthening exercise on spinal pain, back extensor strength, trunk and arm endurance, kyphosis, functional mobility, and QoL in osteoporotic postmenopausal women with vertebral fractures. Results of the present study revealed that a 6-week supervised back extensor strengthening training improved pain at rest, pain in activity, back extensor muscle strength, trunk-arm muscle endurance, functional mobility, and QoL significantly more than home-based back extensor strengthening training and control in postmenopausal women with osteoporotic vertebral fractures.

Chronic back pain in patients with osteoporotic vertebral fracture may cause muscle spasm, guarded movement, and fear of increased pain, and may all lead to physical deconditioning and disability. The strengthening of back extensors may lead to better posture, reduce pain, and subsequently increase mobility and improve the patient's QoL [13].

There is no study in the literature comparing the effects of supervised or home-based back extensor strengthening exercises on back pain, muscle strength, endurance, degree of kyphosis, functional mobility, and QoL in postmenopausal women with osteoporotic vertebral fractures. In a randomized control study, it was reported that 1-month supervised exercise program including strengthening, posture, and balance exercises was superior to home-based program in terms of spinal pain, functional mobility, and QoL in patients with postmenopausal osteoporosis without vertebral fractures [14].

In another randomized control study, it was demonstrated that supervised back muscle extensor strengthening program twice weekly for 4 months improves back strength in postmenopausal osteoporotic women with vertebral fractures [15]. In Bergström's study, progressively increasing strengthening training focused on back muscle using elastic bands (therabands) or the woman's body weight as resistance. However, in our study, we achieved similar results in a shorter period of 6-week training of progressively increasing isotonic back extension strengthening exercises using woman's body weight. In accordance with Bergström's study, no effect of training on kyphosis was seen in our study. Similarly, in accordance with our study, Malmros et al. reported that 10-week supervised training including trunk strengthening, stretching, and balance exercises gave rise to significant improvements in pain and QoL scores in women with osteoporotic vertebral fractures when compared with the control group at weeks 10 and 22. In contrast to our study, no significant difference was found in back extensor strength and function of daily living [16]. The difference in muscle strength may be due to training of progressively increasing isotonic back extension strengthening exercises in our study. Evstigneeva et al. [4] reported that a supervised 12-month physical exercise program including strengthening exercises for the lower extremities, abdomen, and back extensors, and exercises for thoracic mobility and posture improved quality of life, functional mobility, and balance in postmenopausal women with vertebral fractures. Gold et al. showed that 6-month supervised group exercise program including progressive strengthening exercises for trunk extensors, trapezius, rhomboids, hip abductors, and hip extensors,

Table 3 Comparison of outcome measurements of patients among groups

		SE (<i>n</i> = 20; mean ± SD)	HE (<i>n</i> = 20; mean ± SD)	Control (<i>n</i> = 20; mean ± SD)	<i>p</i> value
VAS rest	Baseline	6.40 ± 1.27	6.15 ± 1.34	5.55 ± 1.63	< 0.001 ^{ab}
	6 weeks	2.80 ± 1.57*	5.15 ± 1.56*	5.75 ± 1.61	
VAS activity	Baseline	6.45 ± 1.09	6.20 ± 0.95	6.20 ± 1.57	< 0.001 ^{ab}
	6 weeks	2.75 ± 1.65*	5.85 ± 1.42	6.30 ± 1.49	
TUG test (second)	Baseline	11.57 ± 2.47	12.92 ± 2.93	12.55 ± 2.03	< 0.001 ^{ab}
	6 weeks	8.5 ± 1.31*	12.10 ± 2.84*	12.40 ± 2.06	
Back extensor strength (N)	Baseline	29.30 ± 5.67	33.85 ± 6.22	34.50 ± 5.74	< 0.001 ^{ab}
	6 weeks	45.2 ± 7.15*	38.50 ± 6.63*	34.75 ± 5.80	
Trunk endurance (second)	Baseline	49.10 ± 16.69	44.70 ± 18.98	44.50 ± 18.18	< 0.001 ^{ab}
	6 weeks	108.05 ± 17.4*	56.80 ± 22.27*	47.10 ± 21.11**	
Thoracic kyphosis degree	Baseline	46.35 ± 8.79	42.10 ± 7.15	42.55 ± 6.68	0.546
	6 weeks	41.3 ± 7.23*	40.70 ± 6.13*	42.90 ± 6.63	
QUALEFFO-41					
Pain	Baseline	45.25 ± 11.41	44.75 ± 7.85	44.75 ± 14.18	< 0.001 ^{ab}
	6 weeks	26.00 ± 12.41*	42.5 ± 8.95*	42.50 ± 13.32**	
Activities of daily living	Baseline	30.62 ± 9.27	27.50 ± 13.96	34.06 ± 9.82	< 0.001 ^{ab}
	6 weeks	15.31 ± 10.03*	24.37 ± 13.28**	32.18 ± 9.57**	
Jobs around the house	Baseline	33.00 ± 9.78	31.50 ± 15.73	33.50 ± 7.62	< 0.001 ^{ab}
	6 weeks	15.75 ± 10.54*	28.75 ± 18.05**	33.25 ± 8.31	
Mobility	Baseline	31.25 ± 6.80	31.25 ± 7.38	31.25 ± 3.51	< 0.001 ^{abc}
	6 weeks	20.46 ± 6.91*	29.53 ± 6.76**	31.72 ± 3.40	
Physical function	Baseline	31.62 ± 6.83	30.08 ± 11.10	32.94 ± 5.31	< 0.001 ^{ab}
	6 weeks	17.18 ± 7.43*	27.55 ± 10.85**	32.39 ± 5.02	
Social function	Baseline	65.98 ± 13.88	74.00 ± 9.89	68.75 ± 17.10	< 0.001 ^{ab}
	6 weeks	59.14 ± 14.35*	74.02 ± 11.56	68.38 ± 17.45	
General health	Baseline	62.50 ± 10.29	65.00 ± 13.40	64.16 ± 11.50	< 0.001 ^{ab}
	6 weeks	49.16 ± 8.92*	63.33 ± 13.62**	65.41 ± 9.85	
Mental health	Baseline	40.69 ± 9.63	45.13 ± 13.78	43.05 ± 12.20	< 0.001 ^{ab}
	6 weeks	35.41 ± 9.48*	45.00 ± 12.57	44.16 ± 12.58	
Total score	Baseline	41.56 ± 7.41	45.45 ± 8.98	45.29 ± 7.53	< 0.001 ^{ab}
	6 weeks	32.48 ± 7.31*	44.32 ± 8.17**	45.44 ± 7.76	

Significant change within the group: **p* < 0.01, ***p* < 0.05

SE, supervised exercise; HE, home-based exercise; VAS, Visual Analogue Scale; TUG: Timed Up and Go; QUALEFFO-41, Quality of Life Questionnaire issued by the European Foundation for Osteoporosis

^a SE > HE

^b SE > control

^c HE > control

and stretching improved trunk strength and psychological status in older women with vertebral fractures; nevertheless, it did not reduce activity pain. In their study, pain was measured by a subscale of the “Functional Status Index,” which was designed to measure arthritis disability, not osteoporotic pain [17]. Yang et al. reported that a supervised four-week exercise program including isometric contractions of low back muscles in supine, bridging, supine to stand, waist flexion, extension, and rotation in sitting or standing was ineffective on pain in osteoporotic patients with vertebral fracture. However, patients in both intervention and control groups received other treatments, such as calcitonin, pulsed electromagnetic field therapy, which may lead to a decrease in pain [18].

In contrast to our study, Papaioannou et al. reported that a home-based 12-month exercise program including stretching, strength training, and aerobics improved QoL in postmenopausal women with vertebral fractures. Unlike their study, patients applied only 6-week back extensor strengthening exercises and did not practice aerobic exercise in our study [19]. Bennell reported that a 10-week program of combined supervised and home-based multi-modal physical therapy intervention including manual therapy, massage, taping, and particularly strengthening exercises concentrated specifically on the back extensor and posterior trunk postural muscles similarly our study was effective in reducing pain and improving physical function and back muscle endurance in osteoporotic patients with a history of vertebral fracture [20]. In this

randomized controlled study, there was no difference in kyphosis scores compared with controls as in our study. However, the multi-modal intervention including manual therapy, massage, taping, and exercises may have had interactive effects. Hongo et al. investigated the effects of 16-week home-based low intensity back extensor strengthening exercises on back extensor muscle strength, spinal mobility, and QoL in postmenopausal women with osteoporosis either with or without prevalent vertebral fractures. In the exercise group, an increase in back extensor muscle strength and improvement in QoL were observed and there was no change in spinal mobility [21]. Unlike this study, we did not find any statistically significant difference between the home-based group and the control group in back extensor muscle strength and QoL in postmenopausal women with osteoporosis with prevalent vertebral fractures at the end of the treatment except mobility scores of physical functioning domain of QUALEFFO-41. A period of 6 weeks for home-based back extensor strengthening may not have been long enough to observe any changes in muscle strength and QoL for postmenopausal women with vertebral osteoporotic fractures in our study.

Our study has some limitations. Although all participants were fully compliant in the supervised exercise group, compliance to exercise was not clearly defined in the home-based exercise group due to the lack of follow-up of patients with a phone call or message in HE group about compliance for repetition, sessions, and time. The effect of compliance to exercise on the results in HE group could not be studied. Therefore, the study does not give an idea as to whether the improvements are dose dependent. Another limitation of our study is the lack of long-term follow-up results. The long-term efficacy of both supervised and home-based back exercise may differ in postmenopausal osteoporotic women with vertebral fractures. Further longitudinal, prospective studies are warranted to evaluate the long-term results of the supervised back extensor strengthening training in postmenopausal osteoporotic women with vertebral fractures, with a long-term follow-up.

In conclusion, this study demonstrated that short-term supervised back extensor strengthening training is superior to home-based program in terms of spinal pain, back extensor muscle strength, trunk endurance, functional mobility, and QoL for postmenopausal osteoporotic women with vertebral fractures.

Compliance with ethical standards

The Regional Ethics Committee for Medical Research approved the study, and the subjects gave their written informed consent to participate in the study.

Conflict of interest None.

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