

ORIGINAL ARTICLE

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Longitudinal evaluation of supervised versus unsupervised exercise programs for the treatment of osteoporosis

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Abstract The efficacy of an exercise program was investigated in a study of 89 post-menopausal women with osteoporosis over a 5-year follow-up period. The study attempted to examine and compare potential differences in bone mineral density (BMD), incidence of fracture, and loss of height, between a group of patients ($n = 42$) who attended the supervised exercise program in the hospital, and a group ($n = 47$) who exercised at home. Habitual physical activity, as estimated using the Harvard Alumni Questionnaire, and a Physical Activity Index were combined to obtain an estimate of overall weekly caloric expenditure over the 5-year period. The exercise program involved weight-bearing aerobic activities of moderate intensity, and muscle strengthening exercise using free weights. The mean percentage change for the lumbar BMD was +4.4% in the hospital group and +3.4% in the home group while for the femoral neck BMD was +1.1% in the hospital group and -0.9% in the home group. There was a significant reduction in the number of fractures and no significant loss of height over the 5-year follow-up period for both groups. As the correlation between BMD and weekly caloric expenditure of the subjects was not significant, no conclusion can be drawn as to the minimum level of caloric expenditure necessary in order to retard bone loss. It was concluded that for the post-menopausal women with osteoporosis who participated in the program it was possible to stabilize their height and the

BMD of the lumbar site, and to reduce fractures over the 5-year study period regardless if they exercised in a supervised or in an unsupervised setting.

Key words Bone mineral density · Cross-efficacy · Energy expenditure · Fractures · Physical activity

Introduction

Osteoporosis is a widespread bone condition that affects one in four women over the age of 50, characterized by a reduction in bone mineral density (BMD). Currently, BMD of >2.5 standard deviations below the mean density for young adults is the standard criterion used by physicians to diagnose osteoporosis (Katz and Sherman 1998). This reduction in BMD compromises the integrity of bone microstructure, enhances fragility, and increases the risk of fracture (Poubelle and Brown 1997). Failure to reach an adequate bone mass by the fourth decade of life and/or an imbalance in the coupled processes of bone formation and resorption are predisposing factors for osteoporosis (Lindsay and Cosman 1995). Starting around the fourth decade of life until the menopause, women lose bone mass at a rate of approximately 1% per year; after menopause and the loss of estrogen, bone loss and deterioration accelerate markedly for about 10 years and then level off (Katz and Sherman 1998). According to Katz and Sherman (1998), the average woman loses 15% of her bone mass within 5 years of the menopause while with prolonged bed rest the loss can increase to 40%.

While the effect of exercise on osteoporosis has received attention in the last few decades, it has only recently become self-evident that physical activity benefits the skeleton. Evidence from basic bone biology (Lanyon 1992), various exercise studies (Chilibeck et al. 1995; Shimegi et al. 1994), and large epidemiological studies (Uusirasi et al. 1994) indicates that physical activity is an important factor concerning the maintenance of bone mass and the prevention of osteoporosis.

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Clinical trials have used a variety of exercise programs to demonstrate the effects of physical activity on osteoporosis. Weight-bearing activities, such as walking and jogging, appear to have a favourable influence on weight-bearing as well as non-weight-bearing bone in post-menopausal women (Krall and Dawson-Hughes 1994). This type of exercise produces a mechanical loading, which, combined with the force of gravity, creates electrical charges in the bone that can stimulate bone formation (Chow 1995). Strength-training programs have also been found to have a positive effect on regional bone density in post-menopausal women (Nelson et al. 1994; Kerr et al. 1996). Kerr et al. (1996) showed that the most significant gains in bone mass can be achieved from a program that employs a heavy load with fewer repetitions. Furthermore, after reviewing several contributions to the osteoporosis and exercise literature, Sheth (1999) suggests that the ideal exercise for stimulating bone density involves progressive resistive training using several slow repetitions and that walking alone is probably not enough stimulus for BMD changes.

Most of these studies, however, involve only healthy post-menopausal women. Few studies have looked at the ability of women diagnosed with osteoporosis to improve their BMD and reduce fractures through an exercise-training program. One controlled trial involving post-menopausal women who had a bone loss of at least 30% demonstrated that BMD did not change in the strength-training group, but fell significantly in the control group (Hartard et al. 1996). If the results of all prospective trials of exercise and BMD are averaged, the net increase is 1% per year (Drinkwater 1994). Also, according to the results of Oyster et al. (1984), physical activity, in conjunction with other variables, is indeed a factor in the retardation of osteoporosis, but its effects without the influence of estrogen need further investigation.

These facts demonstrate that exercise can be beneficial in the treatment of osteoporosis, but there remain many unanswered questions regarding the specificity, intensity, and duration of the exercise, which might be optimal for the prevention and treatment of bone loss. No data are available regarding the minimum level of weekly caloric expenditure required to positively affect bone mass. Questions remain as to whether women remain compliant with a prescribed exercise program for a prolonged period of longer than 2 years. It is also unclear whether it is necessary for women to attend a supervised exercise program, or whether the same benefits can be accrued by following a program at home.

The purpose of the present study was to determine if patients enrolled in the Queen Elizabeth Hospital Program for the Prevention and Rehabilitation of Osteoporosis (PRO) maintained, or improved, their BMD over a 5-year period. This program was introduced at the Queen Elizabeth Hospital in 1983. The objective of the PRO program was to develop an exercise program that improved fitness, was acceptable to patients, and

that did not increase the risk of fracture. In 1997, the Queen Elizabeth Hospital, along with several other rehabilitation institutions, was renamed the Rehabilitation Institute of Toronto (RIT). Currently, there are 800 participants enrolled in the RIT osteoporosis program. The present study evaluates this program and examines and compares potential differences in clinical outcomes including: (1) bone mineral measurements, (2) incidence of fracture, and (3) loss of height, between a group of patients who attended a supervised exercise program and a group who chose to exercise on their own at home. A correlation between reported weekly caloric expenditure and BMD was also investigated.

Methods

Subjects

Of the 94 active patients enrolled in the PRO program for 5 years and more, only 42 were reachable and attended the program 40 times per year (average once per week). Also, among the 94 patients that had an annual physician assessment and exercised at home, only 47 returned the survey and had sufficient data in their hospital chart for analysis. Hence, the final 5-year comparison was made on a total of 89 patients – 42 of the hospital group and 47 identified as the home group.

All patients were referred from their primary physician to the PRO program with the diagnosis of osteoporosis based on spinal BMD below the normal range (i.e., > 2.5 SD below the norm). The subjects completed a consent form to allow information in their hospital chart to be included in the study.

Variables

The study was retrospective in nature, with data being obtained from a detailed review of each patient's hospital chart. All patients had an annual clinical assessment, including radiographs and bone mass measurements. Data were collected at study entry (T1), and periodically via the annual assessment throughout the 5-year period (T2). At T1 bone mineral content was measured by Dual Photon Absorptiometry, using a Lunar DPA3 (Kanis et al. 1994). The reliability of Lunar DPA3 has been reported as 1% and its precision as 2% for the spine (L2–L4) and 3% for the femur (Mazess 1987). At T2 BMD was measured by dual energy X-ray absorptiometry (DEXA) using the Lunar DPX densitometer. DEXA instruments provide high precision and assess total body BMD with coefficients of variation between 0.6 and 1.2% for short- and long-term measurements (Economas et al. 1996). Given that the BMD was assessed by two different techniques, the bone density was expressed as a percentage of that observed in young adults. Therefore, the percent BMD at the L2–L4 site (L-BMD), and the percent bone mass at the femoral neck site (Fn-BMD) were compared at T1 and T2. Furthermore, previous studies have reported very strong correlations ($P < 0.001$) between DPA and DEXA measurements in both osteoporosis patients and normal adult subjects (Nuti et al. 1991; Pouilles et al. 1991). Nuti et al. (1991) found significant correlation ($r = 0.94$ – 0.98 , $P < 0.001$) between DEXA and DPA measurements of total-body BMD and major anatomical areas including the spine. Particularly for spinal and femoral osteoporosis, the results of Pouilles et al. (1991) using the two techniques were also highly correlated ($r > 0.9$, $SEE = 0.02$ – 0.04 g/cm²). According to these studies, the small SEE could, therefore, allow the comparison of DPA with DEXA results in individual cases (Nuti et al. 1991).

Clinical symptoms, history of fracture, loss of height and frequency of exercise were recorded. Spinal radiographs of all participants were taken at both T1 and T2 to assess for vertebral

deformities. In addition, new fractures were also diagnosed through radiographs. Fractures that occurred in the year prior to the initial physician assessment were recorded at T1 while those that occurred over the 5-year study period were recorded at T2. Confounding variables, such as the number of post-menopause years, the use of estrogen, calcium, vitamin D or other medications known to affect bone homeostasis, were entered as yes/no variables.

Habitual physical activity was also estimated for each subject using the Harvard Alumni Questionnaire in order to determine weekly activity levels in both groups. This questionnaire has been validated for use in studies of post-menopausal women (Ainsworth et al. 1993). For analysis purposes, a flight of stairs climbed per day was equated to 28 kcal/week energy expenditure, and a city block walked per day was considered to constitute an expenditure of 56 kcal/week (Paffenbarger et al. 1978). The number of hours per week was used to classify the physical activity as either "light" or "strenuous". A list of approximately 80 kinds of physical activity was compiled, and those activities deemed to be light were rated at 5 kcal/min while those of a more strenuous nature were rated at 10 kcal/min. Further, a Physical Activity Index was calculated and expressed in kcal/week. This was a composite estimate of energy expenditure from the number of stairs climbed, blocks walked and sports played (Paffenbarger et al. 1978). This index was compared to the frequency of exercise obtained from the patients' hospital charts. The two sources of information were combined to obtain an estimate of overall weekly caloric expenditure over the 5-year period.

Exercise protocol

All patients were prescribed an exercise program, which was modified to meet individual requirements and were encouraged either to attend the hospital exercise program twice per week, or to exercise on their own twice per week. The hospital program consisted of a 20-min low-load strength training session and 30 min of aerobic activities. The "home" group patients were given an instructional booklet with the description of the exercise program for them to follow. An introductory lesson was given to them regarding all exercises included in the booklet. During the lesson, they were also provided with the choreography and the music of the "dancercise" routines to follow. The exercises and choreographies in this booklet were the same as those used in the hospital program.

The estimated caloric expenditure of completing the prescribed program was 150 kcal/session. The major muscle groups of the upper and lower extremities were strengthened using free weights ranging from 0.45–2.3 kg (1–5 lbs). Initially, the patients performed 1 set of 10 repetitions for each muscle group and they were instructed to gradually increase the number of repetitions until they could perform 1 set of 15. When this could be completed, they were instructed to increase the number of sets to 2 gradually increasing the number of repetitions. After they could safely perform 2 sets of 15 repetitions for each muscle group, they were instructed to increase the amount of weight. Thus, they were instructed on the principle of progressive resistance training.

The aerobic activities consisted of walking and various "dancercise" routines, choreographed to music. In order to ensure

that the patient achieved the target heart rate (70–80% of the age-predicted maximum heart rate), heart rates were recorded every 10 min during the 30-min aerobic sessions.

Statistical analysis

All data were analysed using SPSS (version 6.0). Initially, cross-tabulation analysis was used to determine whether changes in estrogen and/or other medications could be used as independent variables. No differences in the distribution of any medication were found at T1, but the analysis of medication use at T2 did indicate a change in distribution with the exemption of estrogen. Changes in estrogen use could not be used in the analysis since it never changed for 82% of the subjects. As too few subjects were found to be in the "yes" category for fractures at T2, the fractures at T1 were identified as an independent variable. A repeated-measures, multivariate analysis of variance (ANOVA) was then carried out using as dependent variables: L-BMD, Fn-BMD and height, and as independent variables: exercise program, medication use at T2 and fractures at T1.

Results

The descriptive characteristics of both groups are shown in Table 1. No significant differences were detected between the groups regarding these variables either at T1 or T2. Both groups demonstrated an average decrease in height of approximately 1 cm over the 5-year follow-up period.

The two groups were also similar with respect to calcium intake, estrogen usage, and other medications known to affect bone metabolism at T1 and T2 (Table 2). Interestingly, all of the women who were taking estrogen at the start of the study remained on estrogen over the 5-year follow-up period. The subset of women taking estrogen at T2 was analysed to determine the change in BMD during the course of the study. In the hospital group, 17 of the 19 women taking estrogen demonstrated an average improvement of 7.4% in the lumbar site BMD while 2 of them had a decrease of an average of 4.6% in the lumbar BMD. These 2 subjects were 25 and 34 years post-menopausal, respectively. Sixteen of the women had an average increase of 2.8% in Fn-BMD, while 3 had an average decrease of 3.3%. In the home group, of the 20 women taking estrogen, 18 demonstrated an average increase of 5.4% in L-BMD. Ten of them had an average increase of 4.0% and the other 10 had an average decrease of 4.0% in Fn-BMD.

Table 1 Descriptive characteristics for both groups at study entry (T1) and at study conclusion (T2)

	Hospital group (<i>n</i> = 42)				Home group (<i>n</i> = 47)			
	T1		T2		T1		T2	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Average age (years)	63.2	4.3	68.2	4.3	60.3	3.8	66.3	3.8
Average years post-menopausal	18.4	7.8	23.4	7.6	16.2	9.4	21.2	9.6
Average height (cm)	157.6	6.7	156.6	6.8	160.6	6.1	159.5	6.3
Number of fractures	11		2		11		2	

Table 2 Number of patients who have used estrogen, calcium and other relevant medications at study entry (T1) and at study conclusion (T2)

Group	Medication usage	Number of subjects	
		T1	T2
Hospital group	Calcium	36	42
	No calcium	6	0
Home group	Calcium	42	49
	No calcium	7	0
Hospital group	Estrogen	11	19
	No estrogen	31	23
Home group	Estrogen	12	20
	No estrogen	37	29
Hospital group	Other medications	7	13
	No other medications	35	29
Home group	Other medications	7	16
	No other medications	42	33

An important shift in both study groups occurred in the use of “other” medications. Because of the recent shift in the use of bisphosphonates, this information was analysed separately but collectively for the two groups due to the small sample size in each group. The 12 women taking didronel for the 5-year period had an average improvement of 4% in the L-BMD without significant change in the Fn-BMD. Fosamax was not available as a treatment option for osteoporosis at

study entry, as it had not received federal approval. However, 17 subjects from both groups had been taking fosamax for an average of 14.3 months at study conclusion. These women had an average improvement of 6.6% in the lumbar spine and 4.5% in the femoral neck.

In general, an average percentage increase was observed for lumbar and Fn-BMD in both the hospital and home groups. The average percentage change in L-BMD and Fn-BMD over the 5-year study is summarized in Table 3. The percentage of individuals, either taking or not taking estrogen, in each group that exhibited a change in BMD is summarized in Fig. 1 for L-BMD and in Fig. 2 for Fn-BMD. These results, however, must be interpreted with caution in light of the fact that DPA and DEXA differ slightly in their precision of measurement. Furthermore, the correlation between BMD and weekly caloric expenditure of the subjects in the present study was not significant.

The incidence of fracture was reduced over the course of the study period. At T1, 11 subjects in each group reported having had at least one fracture in the previous 12 months while only 4 of the subjects (2 in each group) reported having had a fracture over the 5-year period. Height remained almost stable for both groups, and both groups reported having increased their caloric expenditure during their time in the program.

Table 3 Average percent BMD for both groups [mean (SD)] as measured by DPA at study entry (T1) and as measured by DEXA at study conclusion (T2)

Group – site	% BMD			
	T1		T2	
Hospital group – lumbar (<i>n</i> = 42)	73.7	11.8	78.1	13.1
Home group – lumbar (<i>n</i> = 47)	74.1	10.4	77.5	12.1
Hospital group – femoral neck (<i>n</i> = 42)	74.0	12.0	75.1	11.3
Home group – femoral neck (<i>n</i> = 47)	74.7	8.4	73.8	9.7

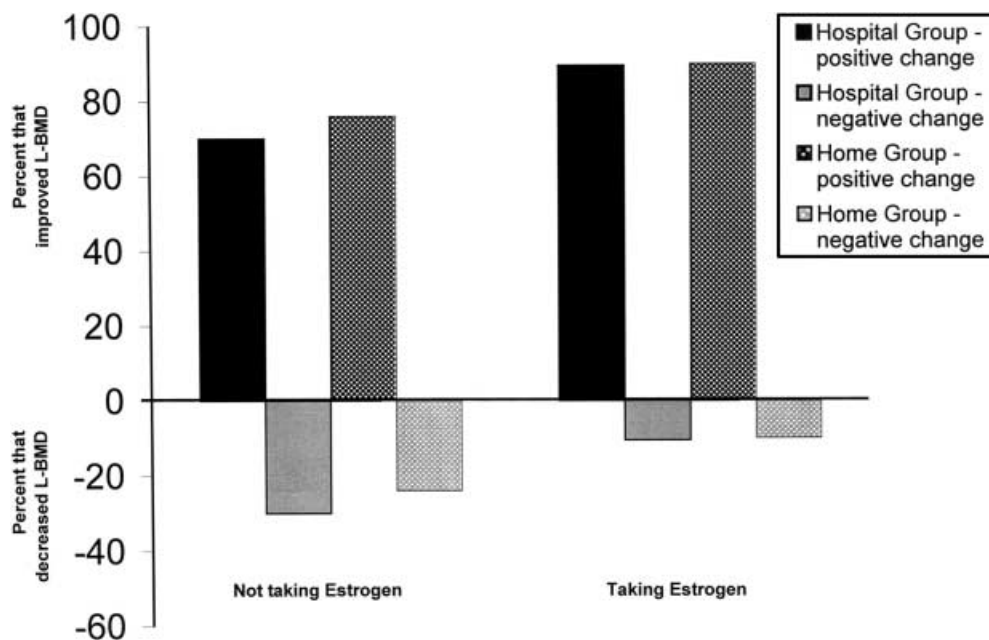
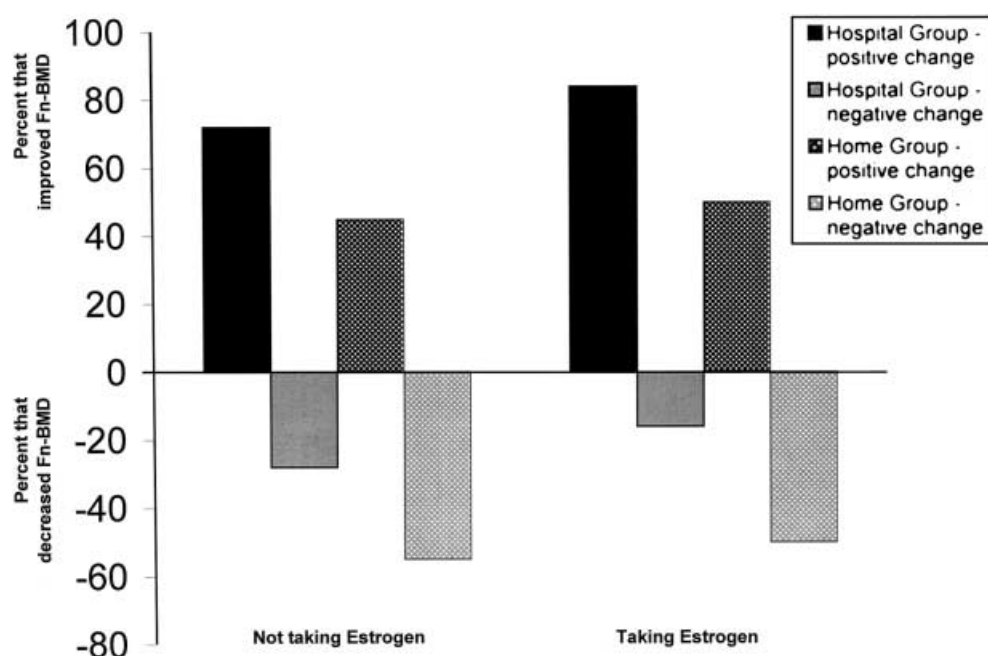
Fig. 1 Percentage of subjects not taking estrogen and percentage of subjects taking estrogen in each group whose lumbar bone mineral density (L-BMD) changed over the 5-year period of study

Fig. 2 Percentage of subjects not taking estrogen and percentage of subjects taking estrogen in each group whose femoral neck BMD (*Fn-BMD*) changed over the 5-year period of study



In terms of comparison, the two groups did not differ significantly in any of the clinical outcomes: L-BMD, Fn-BMD and height. The effects tested for in the ANOVA included: main effects of group, other medication at T2 and fractures at T1. The interactions between group and medication at T2, group and fractures at T1, fractures at T1 and medications at T2, and all interactions between the time factor and the above effects were also evaluated. There was no evidence that any of these factors was important in distinguishing the levels of significance of the independent variables.

Discussion

The effect of regular exercise on the osteoporotic process is difficult to establish. In the elderly, the value of exercise in improving bone mass to a clinically useful level is uncertain. The optimal or the minimal level of exercise necessary to retard or ameliorate bone loss has yet to be determined. According to a longitudinal study by Orwoll et al. (1996) of more than 7000 ambulatory women, general activity level and muscle strength were associated with an increased BMD. Cross-sectional studies have also found a greater lumbar BMD in exercisers than in non-exercisers (Smith et al. 1989; Notelovitz et al. 1991). However, the majority of these studies have examined long-term habitual exercisers engaged in intense activities. In the current study, the exercise program was of moderate intensity, in that there were no high impact activities. Both groups employed an exercise regime consisting of weight-bearing aerobic exercise at 70–80% of the maximal predicted heart rate for a continuous 20 min, and muscle-strengthening exercise. The results indicate that for the post-menopausal women with

osteoporosis who participated in the program, it was possible to stabilize the BMD of the lumbar site over the 5-year study period. This is in accordance with the results of Grove and Londeree (1992) who found no significant difference in BMD between low and high impact exercise programs in post-menopausal women. According to the authors, 20 min of moderate, low impact exercise, 3 days per week, for 1 year was effective in maintaining BMD in early post-menopausal women.

In a recent 2-year study of elderly athletes, reductions in exercise habits were associated with a significant decline in BMD, while continuation of the exercise program at a given level appeared to offer protection from rapid bone loss (Michel et al. 1991). The present study supports this concept, as the weekly caloric expenditure was similar between the two groups at study entry, increased slightly in both at study conclusion, and both groups exhibited a maintained lumbar BMD. On the other hand, the correlation between BMD and weekly caloric expenditure of the subjects in the present study was not significant; therefore, no conclusion can be drawn as to the minimum level of caloric expenditure necessary for retarding bone loss. In addition, the results fail to support the relationship that is believed to exist between weight gain and BMD improvement due to a local mechanical effect (Dawson-Hughes et al. 1987). Although both groups had a similar improvement in lumbar BMD, the home group gained, on average, 6.2 kg while the hospital group gained only 1.6 kg over the course of the 5-year follow-up period.

The study group that participated in the supervised exercise program was also found to sustain the BMD of the femoral neck site, while the home exercise group had a slight decrease in the Fn-BMD. According to Delee (1984), mechanical factors do not seem to have a great

effect on Ward's triangle because it lacks muscle attachments. This is probably why most hip fractures occur at the femoral neck and at an earlier age than those at other sites (Delee 1984).

In a study by Kohrt et al. (1995), a 1-year intervention trial involving weight-bearing exercises was proved to cause a significant improvement in the BMD of the lumbar spine, hip and femur in 32 subjects with an average age of 66. Similarly, Caplan et al. (1993) assessed the effects of twice-weekly aerobic weight-bearing exercise on BMD in post-menopausal women. The mean percentage change in the L-BMD was -0.8% in exercisers and -3.8% in controls while the trochanteric BMD was $+9.6\%$ in exercisers and -4.4% in controls. In the current study, the mean percentage change in L-BMD was $+4.4\%$ in the hospital group and $+3.4\%$ in the home group, while that for Fn-BMD was $+1.1\%$ in the hospital group and -0.9% in the home group. In most cross-sectional studies, however, the difference in bone mass demonstrated between exercisers and controls may be attributed to either the exercise or to selection differences. In the current study, a repeated-measures design was used to overcome this problem, so differences noted in BMD between groups could not be attributed to selection differences. Compatibility between study groups has also been a problem in many of the previous studies. In this study, groups were matched based on years post-menopause, average height, average BMD and medication status.

Many studies have demonstrated a relationship between physical activity and bone density (Orwoll et al. 1996), but it is important to use reliable and valid methods to draw meaningful conclusions. The validity and reproducibility of the Physical Activity Index from the College Alumnus Questionnaire was recently determined in a study of 78 men and women with a broad range of physical activity habits (Ainsworth et al. 1993). The results suggest that this questionnaire is a moderately good instrument for classifying people according to their habitual activity levels, and that it has acceptable reproducibility. These results are consistent with earlier validation studies that showed statistically significant associations among the Physical Activity Index and other measures of cardiorespiratory fitness (Siconolfi et al. 1985).

Black-Sandler et al. (1982) also defined exercise in terms of weekly caloric expenditure using the Paffenbarger questionnaire, and found no significant correlation between kcal/week expended and bone mineral content. In their study, however, the time frame for assessing physical activity was only 3 days. It is likely that bone mass is dependent upon long-term physical activity, as the effects of activity on bone are cumulative. The longitudinal nature of the present study allowed observations to be made over a 5-year follow-up period. However, a potential difficulty also exists with retrospective measurement of physical activity. When relying on memory, biased estimates of activity often occur. The subject's ability to recall activity and weekly seasonal

variations in activity patterns can have an impact on the results. In an attempt to control for this, the hospital attendance records, the physician assessments, and the physical activity questionnaire were equally consulted to obtain the best possible picture of the weekly caloric expenditure.

The present results suggest that a home training program can be as effective as a supervised hospital program for preventing bone loss. The benefits of supervised versus unsupervised exercise programs have just recently been addressed. To date, two studies have investigated this issue in bypass patients discharged from the exercise rehabilitation program, and have presented widely different results. Casperson et al. (1985) found no significant difference between supervised and unsupervised exercise in improving exercise capacity in their post-bypass sample, whereas Stevens and Hanson (1984) found supervised exercise to be significantly more vigorous and more beneficial. However, the follow-up period for both studies was short, lasting 10–12 weeks.

A potential side-effect could be associated with self-selection. Patients who are capable of working independently and successfully on their own may choose the home exercise program, while patients who recognize their need for supervision and group support in order to comply to an exercise program may choose the hospital group program. As a result of this self-selection, it is possible that one type of exercise program, undertaken by a particular subject, produces different results than would occur with random assignment. However, individual differences should be considered when patients are prescribed an exercise training program. Finally, the quality of the performance of the exercise program has not been recorded for the patients who exercised at home but, if patients can actually achieve equitable and safe results in an unsupervised or minimally supervised program, considerable benefits could be actualized in terms of the potential diminished morbidity associated with the initiation of an exercise program.

Even in the absence of any significant improvement in bone mass, regular exercise may be beneficial in many other ways. Regular exercise undertaken by the elderly individual has been reported to have beneficial effect on various psychological factors and a general sense of well-being (Dishman 1994). Furthermore, good muscle tone should reduce the probability of falls that results from unsteadiness. As was indicated in a recent study, even low-load, low-dosage exercise can improve risk factors for falling and balance confidence in elderly women (Kimura et al. 1999). Hence, focusing solely on improving BMD is addressing only part of the problem: prevention of falls is likely to contribute substantially to reducing fracture rates. While the current study did not record the number of falls, there was a significant reduction in the number of fractures over the 5-year follow-up period. This is in agreement with the results of a 2-year study of 92 older women (mean age 64.4) following a weight-bearing exercise protocol (McMurdo et al. 1997). According to these results only two frac-

tures were recorded during the 2-year study period. They found that the study group taking calcium and engaging in exercise experienced fewer falls than the women taking calcium only. This supports the view that improving balance, strength and flexibility through exercise may reduce the falls in osteoporosis patients (Province et al. 1995). The majority of women participating in the present study indicated that their mobility and balance improved as a result of the exercise program. They also reported an improvement in their co-ordination and an overall decrease in pain from osteoporosis. Based on the encouragement of their fellow patients, many found that, with perseverance, they were able to carry out progressively more vigorous exercises without pain. This could give each individual the confidence to return to more energetic and interesting activities, and greatly improve their quality of life.

In conclusion, the results from the current study clearly demonstrate that the patients received a significant benefit as a result of their participation in the PRO program regardless of whether they exercised in a supervised program or in an unsupervised environment. However, more research is needed in this area in order to clarify if it is a combination of medical therapy and the exercise programs that leads to a significant improvement in lumbar BMD in osteoporosis patients.

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