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on Bone Mass in Premenopausal Military Women Protocol 8

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The attainment of peak bone mass during the premenopausal years is critical in preventing osteoporosis later in life. The purpose of this study is to determine if peak bone mass can be improved after age 20, the age at which peak bone mass is usually reached, and to compare the effects of region-specific resistance exercise with aerobic exercise. Thus far, 82 subjects have been enrolled and randomized and begun on their exercise programs. Since dropouts are anticipated, it is hoped that 60 subjects will complete the protocol. Entry data have been tabulated but not yet analyzed. Longitudinal data is currently being collected.

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Michael T O'McDermott 16 Aug 95
PI - Signature Date

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Introduction

Postmenopausal osteoporosis is a growing health concern in the United States ultimately generating \$10 billion annually in health care costs. Development of osteoporosis in later life is known to reflect lack of bone health in early life. Peak bone mass is achieved between ages 18 and 35 and becomes the reserve upon which further aging and menopause will draw over the remainder of an individual's life.

Prevention of postmenopausal osteoporosis is recognized to be dependent on calcium intake, physical activity and genetics, as these factors determine the maximum peak bone mass in young women. Skeletal effects of exercise have been the subject of extensive recent literature reviews⁽¹⁻³⁾. Cross-sectional studies have suggested higher bone mass developing in regions of specific bone loading exercises. However, these studies were flawed by self selection and many inconsistencies which have rendered the overall results inconclusive. Prospective longitudinal studies have shown benefit of vigorous aerobic and resistance exercises especially in the loaded areas. These benefits appear to be true for both premenopausal and postmenopausal women. These studies were flawed, however, by inadequate randomization. One cross-sectional study of premenopausal women showed weight training to be more effective than aerobic⁽⁴⁾. However, four well designed prospective studies on pre- and postmenopausal women have shown varying results which include an increase⁽⁵⁾, minimal change⁽⁶⁾, no change⁽⁷⁾, and a decrease⁽⁸⁾ of bone mass in the loaded regions.

The protocol for this study calls for the prospective randomized trial of 60 premenopausal women ages 18-40 to be enrolled for a one year period in either a Nautilus exercise group or an aerobic group.

Individuals enrolled in the Nautilus group will perform exercises specifically designed to strengthen the lower back, abdomen, hips and arms in three 30 minute sessions per week. All individuals in the study complete a questionnaire on calcium intake and are given calcium supplements or increase dietary calcium intake to fulfill current recommendations for calcium intake of 1000 mg/day in premenopausal women. Bone density determinations are done on entry into the study and at six months and at one year for the lumbar spine, hip and radius which are the areas most likely to be affected by osteoporotic fractures.

The study will help answer the question of whether resistance exercise is more beneficial in premenopausal women than aerobic. It will also further clarify whether region specific exercises are beneficial in increasing bone mass and will have application for physicians recommending exercise programs for young women.

Body

The response of volunteers for this study has been excellent with 82 premenopausal ages 18-40 having been enrolled and calcium intake and baseline laboratory data having been collected. The individuals have been assigned to the exercise or Nautilus study groups according to individual preference for the type of exercise being done with 44 being in the Nautilus group and 38 in the aerobic group. Baseline demographic data on the two groups is provided on Table 1 for height, weight, daily calcium intake and scapular skin fold measures. Bone density determinations have been obtained on 78 subjects. Four subjects failed to complete a bone density determination and have been lost to the study. All individuals in the study have been instructed on the types of exercises to be done and are given log sheets to record the exercises done with individual notation for each session done including weight lifted, repetitions and duration of the exercise sessions. A calcium intake assessment has been completed on all subjects and those taking less than 1000 mg/day have been given prescriptions for supplemental calcium or have agreed to increase dietary calcium intake to the recommended level. Study volunteers are now returning with three month reports on their exercises done. Follow up bone density determinations are pending for the six month and twelve month determinations and therefore no data analysis as to the affect of the exercises can be completed at this point. As the response of volunteers has been high and enthusiastic, it is anticipated that the study will

be easily completed with 60 or more participants as outlined in the protocol. Methods for data collection have followed the methods described in the protocol and therefore it is fully anticipated that reliable results will be obtained from the study to complete the study objectives.

An additional parameter has been added to the data collection to obtain bioelectric impedance testing of body fat content on all individuals. This addition has been approved through appropriate channels and has been obtained after the patients have been properly counseled and signed a separate consent form.

Delays in the protocol approval process resulted in a six month delay in starting this study and therefore an application for an extension of the study period was recommended by the on site reviewers. The application for this extension is in progress.

Conclusions

As data collection is in progress no meaningful analysis of data can be undertaken at this time. The study will be continued with 6 and 12 month bone density determinations as described above. Exercise data on all participants will be collected on quarterly basis and entered into the data pool. An application for extension of the study period is in progress as noted above. It is fully anticipated that more than 60 participants will complete the one year study by the end of June 1996.

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Appendix

Exercise Study

	Aerobic (n=38)	Nautilus (n=44)
Daily calcium intake	835 mg \pm 99	780 mg \pm 66
Height	64.7 in. \pm 0.41	65.3 in. \pm 0.39
Weight	144.1 lbs \pm 4.1	143.3 lbs \pm 3.2
Scapular skin fold	16.2 mm \pm 0.98	14.3 mm \pm 0.65