

## THE EFFECT OF CALCIUM SUPPLEMENTATION ON BONE DENSITY DURING LACTATION AND AFTER WEANING

HEIDI J. KALKWARF, PH.D., BONNY L. SPECKER, PH.D., DONNA C. BIANCHI, M.ED., JULIE RANZ, R.N., AND MONA HO, M.S.

### ABSTRACT

**Background** Women may lose bone during lactation because of calcium lost in breast milk. We studied whether calcium supplementation prevents bone loss during lactation or augments bone gain after weaning.

**Methods** We conducted two randomized, placebo-controlled trials of calcium supplementation (1 g per day) in postpartum women. In one trial (the study of lactation), 97 lactating and 99 nonlactating women were enrolled a mean ( $\pm$ SD) of  $16\pm 2$  days post partum. In the second trial (the study of weaning), 95 lactating women who weaned their infants in the 2 months after enrollment and 92 nonlactating women were enrolled  $5.6\pm 0.8$  months post partum. The bone density of the total body, lumbar spine, and forearm was measured at enrollment and after three and six months.

**Results** The bone density of the lumbar spine decreased by 4.2 percent in the lactating women receiving calcium and by 4.9 percent in those receiving placebo and increased by 2.2 and 0.4 percent, respectively, in the nonlactating women ( $P < 0.001$  for the effect of lactation;  $P = 0.01$  for the effect of calcium). After weaning, the bone density of the lumbar spine increased by 5.9 percent in the lactating women receiving calcium and by 4.4 percent in those receiving placebo; it increased by 2.5 and 1.6 percent, respectively, in the nonlactating women ( $P < 0.001$  for the effects of lactation and calcium). There was no effect of either lactation or calcium supplementation on bone density in the forearm, and there was no effect of calcium supplementation on the calcium concentration in breast milk.

**Conclusions** Calcium supplementation does not prevent bone loss during lactation and only slightly enhances the gain in bone density after weaning. (N Engl J Med 1997;337:523-8.)

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LACTATING women may require additional dietary calcium to compensate for the calcium secreted in breast milk, and the current recommended dietary allowance of calcium is increased by 400 mg per day in these women.<sup>1</sup> This recommendation assumes that calcium balance can be achieved during lactation by increasing the intake of calcium. One approach to testing this assumption is to study the effects on bone of various intakes of calcium. Bone density decreases by 4 to 7 percent in the lumbar spine and hip among

women who lactate for six months.<sup>2-6</sup> Although bone density increases after weaning, it is not clear whether it is completely restored.<sup>3-8</sup> A few studies have found that repeated or prolonged lactation is associated with lower bone density many years later,<sup>9,10</sup> but most studies have not found this effect.<sup>11-18</sup>

The extent to which calcium supplementation minimizes bone loss during lactation is not known. Two randomized trials of such supplementation have been conducted in lactating women, neither of which found an effect on either bone mass or bone density.<sup>19,20</sup> However, one of these studies, conducted in the United States, involved only 15 women, and their mean base-line calcium intake was high (1300 mg per day).<sup>19</sup> The other study was conducted in Gambian women whose calcium intake was very low (283 mg per day), but only bone density in the distal forearm was measured.<sup>20</sup> Neither study included a nonlactating postpartum group to evaluate whether the responses to supplementation differed between lactating and nonlactating women. We sought to determine whether calcium supplementation prevents bone loss during lactation or augments bone gain after weaning and whether the response to supplementation is greater among lactating than among nonlactating postpartum women, both during lactation and after weaning.

### METHODS

#### Subjects

This randomized, double-blind, placebo-controlled trial of calcium supplementation was conducted in two groups of postpartum women with low-to-moderate base-line intake of calcium ( $\leq 800$  mg per day), as determined by a food-frequency questionnaire administered during the three months preceding enrollment.<sup>21</sup> Our findings with regard to the effects of lactation and weaning on bone density, without respect to calcium supplementation, have been reported previously for the first half of the group to complete the study.<sup>3</sup> Two groups of women defined according to the time since delivery were studied in order to examine the effects of calcium supplementation during lactation and weaning, with control for the time since delivery. None of the women had any disorders that affected their metabolism of calcium or bone, none were regularly taking medications or using hormonal contraceptives, and all had had singleton pregnancies lasting 37 weeks or more and had taken vitamins during their pregnancies.

From the Department of Pediatrics, Children's Hospital Medical Center, Cincinnati. Address reprint requests to Dr. Kalkwarf at the Department of Pediatrics, University of Cincinnati College of Medicine, 231 Bethesda Ave., Cincinnati, OH 45267-0541.

The subjects in the study of lactation, among whom 97 were lactating and 99 were nonlactating, were enrolled a mean ( $\pm$ SD) of  $16\pm 2$  days post partum and were followed for 6 months. The lactating women intended to breast-feed for at least six months and to provide no more than one feeding of formula per day, and the nonlactating women fed their infants exclusively with formula from the time of their births.

The subjects in the study of weaning, among whom 95 were lactating and 92 were nonlactating, were enrolled  $5.6\pm 0.8$  months post partum and were followed for 6 months. The lactating women were breast-feeding their infants  $5.5\pm 1.1$  times per day at enrollment and weaned their infants during the next 2 months ( $7\pm 4$  weeks). Among the nonlactating women, 86 had not breast-fed their infants at all, and the remaining 6 had breast-fed for two weeks or less.

### Study Procedures

The women in each study were randomly assigned to receive 1 g of elemental calcium per day as calcium carbonate (Os-Cal, Marion Merrell Dow, Kansas City, Mo.) or placebo (primarily lactose). The randomization was stratified according to age group (20 to 25, 26 to 30, 31 to 35, and 36 or more years), race, and lactation status. The calcium supplement was provided as two 500-mg tablets, and the women were instructed to consume one tablet with the morning meal and the other with the evening meal. Compliance was assessed by pill counts every three months.

The women in the study of lactation were given a daily multivitamin with iron that contained 400 IU of vitamin D (Dayalets, Abbott Laboratories, North Chicago, Ill.) to optimize their vitamin D status, and the women in the study of weaning received the same multivitamin without iron. Throughout the study, the women kept daily logs to record the frequency of feeding with infant formula (in the study of lactation) or breast-feeding (in the study of weaning) and the occurrence of menses. The women completed three-day records of food consumption and seven-day records of physical activity during the week before the second measurement of bone density and the week before the third measurement, to estimate their average daily dietary intake of calcium and their physical activity during the study. Calcium intake was calculated with use of the Nutrition Data System (Nutrition Coordinating Center, University of Minnesota, Minneapolis).

The bone mineral content of the total body and the bone mineral density of the lumbar spine (from L2 to L4), the ultradistal radius (proximal to the end plate), and the distal third of the radial shaft of the left arm were measured at enrollment and after 3 and 6 months ( $\pm 1$  week) by dual-energy x-ray absorptiometry (model QDR 1000W or 2000, Hologic, Waltham, Mass.). All the measurements in a given woman were performed with the same machine. The calibration of the absorptiometers was checked daily; the long-term precision was within 0.2 percent.

A subgroup of the women provided samples of breast milk on the day before each bone-density measurement. The calcium content of the milk was determined by atomic-absorption spectroscopy (model AA3030, Perkin-Elmer, Norwalk, Conn.). The breast-milk samples were collected beginning in the last year of the study; thus, samples were obtained for only some of the women.

The study design was approved by the institutional review board of Children's Hospital Medical Center, Cincinnati, and written informed consent was obtained from all the women.

### Statistical Analysis

Descriptive characteristics were compared between groups by the t-test or the Wilcoxon rank-sum test. An analysis of covariance was used to test the effects of calcium supplementation and lactation on changes in bone density. Analyses were conducted in which the results were expressed as both absolute changes and percent changes from base line. The results of the two types of analysis were similar; only the percent changes are presented. The hypotheses of interest included tests of the main effects of lacta-

tion (and weaning) and calcium supplementation and the effects of the interaction between these factors on bone changes post partum. Base-line characteristics that differed among the groups were included in the statistical models to prevent potential bias in the estimates of effects. Two-tailed tests were used in all the analyses.

## RESULTS

Of the 383 women enrolled, 326 completed the six-month study successfully. The reasons for discontinuing the study were loss of interest (in 8 women), illness or a need for medication or iron supplementation (in 13), the initiation of contraception with hormones (in 5), a change of residence or loss to follow-up (in 6), pregnancy (in 11), inability to swallow pills (in 1), early weaning (in 4 women in the study of lactation), and no weaning within three months after enrollment (9 women in the study of weaning). In the study of lactation, 15 women in the calcium group and 13 in the placebo group discontinued the study; in the study of weaning, the respective numbers were 12 and 17.

The base-line characteristics of the women in the two studies are shown in Table 1. There were small differences between the lactating and the nonlactating women in body weight, height, initial bone mass of the total body, density of the lumbar spine, and the amount of time spent in hard-to-very-hard physical activity. The lactating women in the study of lactation had higher calcium intakes before and during the study than the nonlactating women. In the study of weaning, the lactating women had a higher calcium intake at base line but not after weaning. The lactating women were more likely to have amenorrhea six months post partum than the nonlactating women. The degree of compliance with calcium supplementation, as determined by pill counts, was high: 92 percent of the women took at least 80 percent of their pills, and 73 percent took at least 90 percent.

The effects of calcium supplementation, lactation, and weaning on changes in bone mineral content and density during the two six-month study periods are shown in Table 2. All the mean percent changes in bone mineral content and density were adjusted for initial bone mass or density, height, weight, change in weight, dietary calcium intake, and physical activity, although these adjustments had little effect on the results.

### Study of Lactation

In the study of lactation, the lactating women lost significantly more bone mass from the total body and bone density in the lumbar spine than the nonlactating women. Bone density in the lumbar spine was decreased by three months post partum, with little further change at six months (Fig. 1). Overall, calcium supplementation had a significant positive effect on lumbar-spine mineral density. Among the

TABLE 1. CHARACTERISTICS OF THE WOMEN IN THE STUDIES OF LACTATION AND WEANING.\*

CHARACTERISTIC	STUDY OF LACTATION		STUDY OF WEANING	
	LACTATING WOMEN (N=87)	NONLACTATING WOMEN (N=81)	LACTATING WOMEN (N=76)	NONLACTATING WOMEN (N=82)
Age — yr	30±3	30±4	31±3	31±3
Parity	2±1	2±1	2±1	2±1
Height — cm	163.5±5.8	165.4±5.5†	163.8±6.8	164.8±6.4
Weight — kg	66.4±10.3	68.0±10.4	61.1±12.4	65.8±11.1†
Weight change during study — kg	-2.0±3.6	-2.9±3.7	-0.1±2.2	-0.9±3.0
Race or ethnic group — no. of women				
Black	3	2	2	3
White	84	79	72	78
Asian	0	0	2	1
Dietary calcium intake — mg/day				
Base line	614 (472, 753)	510 (371, 644)†	699 (571, 792)	578 (478, 704)†
During study	821 (680, 1029)	650 (522, 781)†	706 (582, 867)	683 (565, 826)
Level of physical activity — hr/week				
Moderate to hard	30.0 (20.3, 42.8)	34.0 (26.3, 50.0)	34.4 (25.6, 47.3)	34.3 (19.0, 45.8)
Hard to very hard	4.5 (2.3, 8.0)	5.8 (2.6, 12.0)†	6.0 (2.5, 10.1)	5.3 (2.3, 9.8)
Compliance with medication — % of women				
Took ≥80% of pills	94.3	92.6	93.4	86.6
Took ≥90% of pills	78.2	82.7	69.7‡	61.0
Resumption of menses — % of women				
By 6 mo post partum	25.3	100.0†	—	—
At enrollment§	—	—	14.5	98.8†
Initial bone measurements				
Total-body bone mass — g	2348±312	2459±347†	2201±392	2335±307†
Bone density — g/cm <sup>2</sup>				
Lumbar spine	1.078±0.121	1.118±0.116†	1.022±0.142	1.092±0.104†
Ultradistal radius	0.433±0.041	0.434±0.043	0.423±0.047	0.440±0.48†
Distal third of radius	0.685±0.034	0.687±0.048	0.678±0.043	0.687±0.043

\*Plus-minus values are means ±SD. Values followed by values in parentheses are medians followed by the 25th and 75th percentiles.

†P<0.05 for the comparison with the lactating women in the same study.

‡P<0.01 for the comparison with the study of lactation.

§The women in the study of weaning were enrolled 5.6±0.8 months post partum.

nonlactating women, this effect was statistically significant ( $P<0.01$ ), whereas among the lactating women it was not ( $P=0.38$ ). However, there was no statistical interaction between the lactation group and the calcium group, an indication that calcium supplementation was no more beneficial in one group than in the other (Fig. 1). Neither lactation nor calcium supplementation affected the bone mineral density of the radius. Among the 22 lactating women whose menses had resumed by six months post partum, the mean ( $\pm$ SE) deficit in mineral density in the lumbar spine was less than the deficit in the 65 lactating women whose menses had not resumed ( $2.0\pm0.7$  percent vs.  $5.0\pm0.4$  percent,  $P<0.001$ ). The effects of calcium supplementation did not differ according to menstrual status at the end of the study among the lactating women ( $P=0.29$ ).

The calcium concentration in breast milk decreased significantly during the first six months post partum among the lactating women in both the calcium and the placebo groups (Table 3). There were no differ-

ences between these groups at any time in the calcium concentration of breast milk.

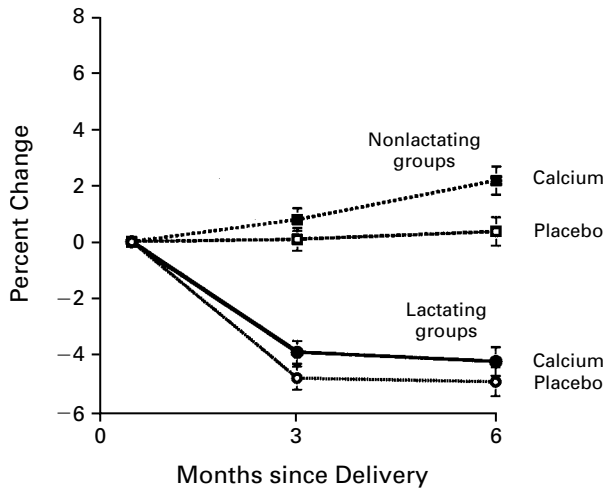
#### Study of Weaning

After weaning, there were significant increases in bone density in the lumbar spine among both the nonlactating and the lactating women, and the increases were independent of calcium supplementation (Table 2). The increases were evident 9 months after delivery and were greater at 12 months (Fig. 2). Bone density in the lumbar spine increased significantly more in the two calcium groups than in the two placebo groups. This effect was statistically significant ( $P<0.05$ ) among both lactating and nonlactating women, and there was no interaction between the lactation group and the calcium group. There was a weak interaction between these groups with respect to the total bone mass in the body: this value increased in the calcium-treated women who had not lactated, but it decreased in those who had lactated. There were no differences in the changes in

**TABLE 2. MEAN PERCENT CHANGES IN BONE MASS AND BONE DENSITY ACCORDING TO THE PRESENCE OR ABSENCE OF CALCIUM SUPPLEMENTATION, LACTATION STATUS, AND TIME SINCE DELIVERY.\***

	LACTATING WOMEN		NONLACTATING WOMEN		P VALUE		
	CALCIUM	PLACEBO	CALCIUM	PLACEBO	EFFECT OF LACTATION	EFFECT OF CALCIUM	INTERACTION OF BOTH
<b>Study of lactation (0–6 mo post partum)</b>							
No. of women	45	42	41	40			
	percent change						
Total-body bone mass	-2.4±0.3	-3.4±0.3	-1.7±0.3	-1.2±0.4	<0.001	0.51	0.20
Bone mineral density							
Lumbar spine	-4.2±0.5	-4.9±0.5	2.2±0.5	0.4±0.5	<0.001	0.01	0.23
Ultradistal radius	0.5±0.5	-0.5±0.5	0.4±0.5	-0.1±0.5	0.73	0.12	0.56
Distal third of radius	-0.3±0.3	-0.1±0.3	0±0.4	-0.6±0.4	0.73	0.54	0.27
<b>Study of weaning (6–12 mo post partum)</b>							
No. of women	38	38	40	42			
	percent change						
Total-body bone mass	-0.2±0.3	0.2±0.3	0.4±0.2	-0.2±0.3	0.67	0.72	0.04
Bone mineral density							
Lumbar spine	5.9±0.3	4.4±0.3	2.5±0.3	1.6±0.3	<0.001	<0.001	0.36
Ultradistal radius	0±0.5	-0.5±0.5	0.3±0.5	0.3±0.5	0.31	0.61	0.58
Distal third of radius	-0.8±0.3	-0.4±0.3	-0.2±0.3	-0.1±0.3	0.10	0.50	0.67

\*Values are least-square means (±SE) after adjustment for base-line bone density, height, weight, change in weight, dietary calcium intake, and level of physical activity.



**Figure 1.** Effects of Calcium Supplementation and Lactation on the Mean (±SE) Percent Change in the Bone Mineral Density of the Lumbar Spine during the First Six Months Post Partum. Values are adjusted for base-line bone mineral density, height, weight, change in weight, dietary intake of calcium, and level of physical activity. P=0.01 for the effect of calcium; P<0.001 for the effect of lactation; and P=0.23 for the interaction between calcium supplementation and lactation.

the bone mineral density of the radius, either between the calcium groups and the placebo groups or between the lactating groups and the nonlactating groups. Among the 65 lactating women whose menses had not resumed before enrollment, earlier return of menstruation was not associated with greater increases in bone density after weaning (P=0.17).

**DISCUSSION**

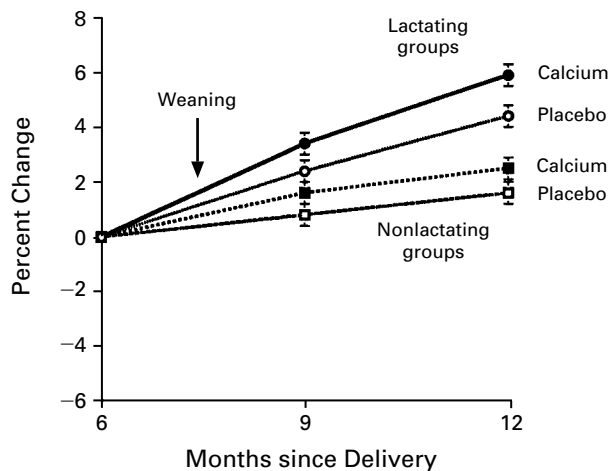
In this trial we tested the hypotheses that supplemental calcium would diminish bone loss during lactation, augment bone gain after weaning, and be more beneficial in lactating women than in nonlactating women. We found that calcium supplementation resulted in either less bone loss or increased density of the lumbar spine in postpartum women but that it was not more beneficial in lactating women than in nonlactating women, even though lactating women lost approximately 210 mg of calcium per day in breast milk. Calcium supplementation had no overall effect on the total bone mass of the body or on radial bone mineral density.

Our findings are consistent with those in other reports of calcium supplementation during lactation, in that such supplementation had a minimal effect on bone loss during lactation. In a study of 60 lactating women in the Gambia who had a very low calcium intake (mean, 283 mg per day), the bone mineral content of the midradius decreased by 1.1 percent after 13 weeks of lactation, and calcium sup-

**TABLE 3. CALCIUM CONCENTRATIONS IN BREAST MILK ACCORDING TO THE TIME SINCE DELIVERY IN THE WOMEN ASSIGNED TO CALCIUM SUPPLEMENTATION OR PLACEBO.\***

VARIABLE	TIME SINCE DELIVERY		
	0.5 MO	3 MO	6 MO
Calcium group			
No. studied	8	9	16
Calcium (mg/dl)	30±3	27±5	24±4
Placebo group			
No. studied	9	11	16
Calcium (mg/dl)	28±4	28±4	24±4

\*The calcium concentrations decreased significantly over time ( $P<0.001$ ), but there were no significant differences between groups. Plus-minus values are means  $\pm$ SD. To convert values for calcium to millimoles per liter, multiply by 0.25.



**Figure 2.** Effects of Calcium Supplementation and Lactation on the Mean ( $\pm$ SE) Percent Change in the Bone Mineral Density of the Lumbar Spine during the Second Six Months Post Partum.

Values are adjusted for base-line bone mineral density, height, weight, change in weight, dietary intake of calcium, and level of physical activity.  $P<0.001$  for the effect of calcium;  $P<0.001$  for the effect of weaning; and  $P=0.36$  for the interaction between calcium supplementation and weaning. The lactating women were fully breast-feeding at base line, and the arrow indicates the average time at which breast-feeding was completely ended.

plementation had no effect on that loss.<sup>20</sup> Among 15 lactating women in the United States whose baseline calcium intake averaged 1300 mg per day, calcium supplementation (1 g per day) for three months had no effect on the density of the lumbar spine or radius.<sup>19</sup> Two observational studies also found no relation between reported dietary intake of calcium and bone loss in the lumbar spine and femur during lactation.<sup>5,8</sup>

The small effect of calcium supplementation on bone loss that we found suggests that other factors have a greater effect on bone changes during lactation. That approximately 6 percent of bone in the lumbar spine is lost over a six-month period in lactating women with a calcium intake of approximately 1770 mg per day is consistent with this suggestion.<sup>2,6</sup> The regulation of bone loss during lactation probably involves many factors. We and others have shown that the return of ovarian function may be one such factor, because lactating women whose menses resumed early have smaller bone deficits six months post partum than lactating women who continue to have amenorrhea.<sup>4,22</sup> Recently, parathyroid hormone-related peptide has been proposed to have a role in mediating bone loss during lactation,<sup>22,23</sup> but its relative importance is controversial.<sup>24</sup>

The recovery after weaning of bone lost during lactation may be influenced by dietary calcium. Intestinal calcium absorption and renal retention of calcium both increase after weaning,<sup>7,25</sup> which should increase the accretion of bone and provide a mechanism by which lactating women may benefit from increased calcium intake more than nonlactating women. We found that after weaning both nonlactating and lactating women gained bone density in the lumbar spine in response to calcium supplementation, and the gain in both groups was similar. However, the lactating women might have gained more bone if they had received supplemental calcium longer.

The lack of effect of calcium supplementation on calcium concentrations in breast milk confirms the results of previous studies.<sup>20,26,27</sup> We think such confirmation is important, because changes in the calcium concentration of breast milk could have been nutritionally important to the infants.

In summary, postpartum women with moderate dietary calcium intake benefit slightly from supplemental calcium with regard to bone mineral density in the lumbar spine. However, supplemental calcium does not prevent bone loss during lactation and does not benefit lactating women more than nonlactating women. Bone density increases after weaning both in women who receive calcium supplementation and in those who do not.

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