# Effects of Calcium Carbonate on Pain Symptoms in Third Trimester of Pregnancy and Nursing Period: a randomized clinical trial

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Received December 2007; Revised and accepted March 2008

Abstract

**Objective**: The study evaluated the efficacy of oral calcium carbonate supplement on leg pain in pregnancy and nursing period.

**Materials and methods**: A total number of 176 women at third trimester of pregnancy or nursing period till to one year after delivery with complaint of leg pain, low back pain (LBP), and posterior pelvic pain (PPP) were evaluated for distinct primary causes and were excluded, then 58 patients randomized into calcium group (n=27) treated with 500 mg calcium carbonate orally per day just for one week, and control group (n=31) received no drug. Incidence of days with leg, low back, and posterior pelvic pain per week were evaluated and compared between the two groups at 3 different weeks before, during, and after discontinuation of drug. Statistical significance was defined as $P<0.05$.

**Results**: Mean number of days with leg pain per week during calcium carbonate intake was significantly different between the study and control groups ($P<0.05$). Mean number of days with LBP and PPP was not significantly different between two groups.

**Conclusion**: The use of oral calcium supplement was associated with lower episodes of leg pain but failed to reduce the incidence of LBP and PPP in pregnancy and nursery period.

**Key words**: Leg pain, Back pain, Low back pain, Pregnancy, Nursery, Calcium

## Introduction

Approximately 80% of pregnant women experience pain of leg, low back, and posterior pelvic girdle, especially at the third trimester and nursery period (1). Some studies showed that one of each two pregnant women has pain of back and pelvis, and the pelvic pain is two times more common (2). Leg pain may be due to multiple factors and different etiologies are especially related to venous return (3) but, it is yet some frequent leg pain in pregnancy and nursery with not exactly known diagnosis after correct evaluation of common causes till to a few years after child birth. Several anatomical factors such as lower extremity mal alignments may alter the body mechanic and prone it to overuse injuries (4). Spinal disc disorders are frequent in pregnancy (5) and sacroiliac joints are responsible for considerable amount of leg and pelvic pain (6). These are frequently accompanied with mood disorders and depression and serious troubles for mothers (7- 8). Few original researches supposed different patterns of leg pain in pregnancy which are describe as "catching" instead of sacroiliac dysfunction (9). It seems to be another entity from disuse

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**Table 1:** maternal demographic and clinical characteristics at randomization

| | Calcium n=27 | Control n=31 | Change (+/-) | P-Value |
|---|---|---|---|---|
| Mother age (year) | 30.1 | 28.5 | 0.6 | NS |
| Parity (number) | 2.2 | 2.5 | 0.3 | NS |
| Gestational age (month) | 7.8 | 8.2 | 0.4 | NS |
| Child age(month) | 4.4 | 5.1 | 0.7 | NS |
| Serum Ca level (mg/dl) | 8.8 | 8.7 | 0.1 | NS |
| Leg pain (number) | 27 | 31 | 4 | NS |
| LBP (number) | 20 | 26 | 6 | NS |
| PPP (number) | 24 | 21 | 3 | NS |

LBP: low back pain , PPP: posterior pelvic pain

and mechanical factors like activity level, hence no difference was found in female athletes' leg pain during pregnancy (10) and regular exercise was found to be neither protective nor risk factor in pregnant women with lower extremity pain (11). The hypothesis of this study was that night sleep or prolonged rest position of legs induces calcium absorption from upper fibula and tibia metaphysis to restore serum calcium content and creates leg pain. So, the purpose of this study was to determine if incidence of leg pain episodes with not well known diagnoses in third trimester of pregnancy and nursing period would be reduced after intake of oral calcium supplement and relapse after discontinuing it.

## Materials and methods

This randomized clinical trial was performed in the orthopedic outpatient ward of Imam Reza (501 Army) Hospital of the Army University in Tehran, Iran, from February 2005 to March 2007. Ethics were considered to this study, hence the used drug is neither contraindicated nor a new one and is permitted in some situations during third trimester of pregnancy and the nursery period. After approval of the ethical committee of the hospital, this clinical trial was conducted. Informed written consents of all the participants were obtained.

A total number of 176 pregnant women with lower extremity pain consisted of unilateral or bilateral leg pain, low back pain (LBP), and posterior pelvic pain (PPP) were referred to the orthopedic clinic from the obstetric-gynecology department. They were examined and excluded for known musculoskeletal, infectious, metabolic, collagen vascular diseases and marked nutritional disturbances. They had no medical and obstetric-gynecologic complications related to the pregnancy and no history of oral or parenteral calcium supplementation. The patients were examined for lower extremity pain with the following especial orthopedic tests: straight leg rising (SLR), active SLR, flexion-abduction-external rotation (FABER), and Patrick test, then were checked for abdominal and anterior pelvic pain, joint stiffness and limitation of motion, neurovascular impairment, and deep vein thrombosis (signs such as skin color changes, calf tenderness, positive DVT signs, edema, and weakness of pulses). As the result 118 patients with positive findings were excluded from the study. Remainders (58 patients: 41 pregnant and 17 nursing mother) continued the study. The leg pain was constant, sharp, with cold feeling, at night or prolonged rest time, with moderate intensity but awakening from the sleep and usually relieved with awaking or walking, and not dependent to lateral decubitus position. The location of pain often was about proximal third of tibia and fibula especially at lateral side. No difference was between right or left leg. These 58 patients with defined lower extremity pain included in the study were randomized to 27 women in calcium group (19 pregnant and 8 nursing) and 31 women in control group (22 pregnant and 9 nursing) at the first visit. Computer generated random number table was used for randomization of the investigation. Group assignments were placed in sealed opaque sequentially numbered envelopes. Both groups of patients were randomly selected to receive oral calcium carbonate tablet 500 mg per day with enough water intake for the study group and no drug for control group. They received 3 table charts to mark the painful and painless days for the weeks before, during, and one week after ceasing the drug. At least one episode of pain per day was recorded as one positive day (maximum of 7 days per week). Nutritional status, physical activity level, and socioeco-

**Table 2:** Mean number of days with leg pain, low back pain, and posterior pelvis pain per week; one week before, during, and after discontinuation the drug.

| | | Mean number of days per week with | | |
|---|---|---|---|---|
| | | PPP | LBP | Leg pain |
| **One week After first visit** | control | 4.80 ± 1.70 | 3.38 ± 1.78 | 2.93 ± 1.61 |
| | study | 5.22 ± 1.33 | 2.81 ± 1.14 | 3.66 ± 1.54 |
| | significant | NS | NS | NS |
| **One week During treatment** | control | 4.93 ± 1.65 | 3.12 ± 1.80 | 3.09 ± 1.55 |
| | study | 1.40 ± 1.24 | 2.88 ± 1.39 | 3.22 ± 1.36 |
| | significant | P < 0.05 | NS | NS |
| **One week After discontinuation** | control | 5.06 ± 1.71 | 3.58 ± 1.60 | 3.03 ± 1.81 |
| | study | 4.77 ± 1.05 | 3.48 ± 1.25 | 3.81 ± 1.49 |
| | significant | NS | NS | NS |

LBP**:** low back pain , PPP: posterior pelvic pain , NS: Not Significant

nomic status of the two groups were matched. Two groups were compared for the results of mean number of painful days per week, and demographic characteristics such as age, parity, gestational age or child age, and serum calcium level. Categorical data were tested with the student t test, and fisher exact test. Statistical significance was defined as P<0.05. All patients were included in the analysis. Comparison between the mean number of painful days about leg, low back, and posterior pelvis at the weeks before, during, and one week after discontinuation of calcium tablet were recorded.

## Results

A total of 58 patients with leg pain, LBP, and PPP were included in the study. Twenty seven patients were randomly assigned to the calcium group and 31 were randomly assigned to the control group. The two groups were not statistically different with respect to age, parity, gestational age or child age, serum calcium level, patterns of unilateral or bilateral leg pain, LBP and PPP (Table 1).

Calcium group demonstrated a fewer days with leg pain both unilateral and bilaterally during drug intake for one week. This observed difference was statistically significant (P<0.05). There were not significant difference between the mean number of painful days with LBP and PPP during drug intake in the two groups. Also, there were no statistically significant difference between the two groups with leg pain, LBP and PPP before and one week after discontinue the drug (Table 2). There were no sign and symptoms of hyper or hypocalcaemia, deep vein thrombosis, internal medicine complications, fetal or maternal complications, and adverse drug effects in either groups believed to be related to calcium supplementation. Three patients were excluded from the control and 1 from the study groups (due to normal delivery and preterm labor). No significant difference was found with these obstetric complications between the two groups.

## Conclusion

This was a randomized clinical trial which evaluated the efficacy of oral calcium carbonate supplement therapy in patients with unilateral and bilateral leg pain in third trimester of pregnancy and nursery period especially the one which awakens the patient from the sleep. Calcium carbonate is a level-C drug in pregnancy and nursery period in relationship to fetal, breastfeed child, and maternal hazards but it has been found to be effective in pain relief of especial musculoskeletal disorders which doesn't act as an analgesic drug and its mechanism of effect is documented to be therapeutic. Calcium dosage up to 1500 mg per day is considered to be safe (12). In some studies calcium compounds were effective in leg pains with venous stasis (13), and Sudek atrophy (14) but in this study the origin of leg pain was described not to be related to latter pathologies. Hypocalcaemia was not found in understudy population perhaps because of lower limit undetectable transient episodes or compensation of serum calcium via bone absorption. It may be a night or prolonged rest position for skeleton especially for upper tibial and fibular metaphyseal bones which makes them prone to calcium absorption. This idea demands new investigations. Also, the marked characteristics of the studied pain with sharp, constant, with sense of cold feeling, at upper leg, and awakening type which relives with weight bearing, may desire other studies to be done to name a new described syndrome. Calcium carbonate

supplements in this study failed to reduce the episodes of LBP and PPP of the patients probably because of mechanical disturbances in these axial weight bearing joints and relaxation effects of maternal hormones on them, rather than to be sites for calcium absorption. It must be remembered that this study was not placebo controlled one. Randomized clinical trials with larger sample sizes are needed to determine whether oral calcium intake reduces the episodes of leg pain in pregnancy and nursing periods of women versus probable drug complications to both mothers and children.

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