Effect of Homeopathic Calcium on Bone Density

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Determining the effect of a homeopathic medium potency of calcium on the bone density of women as measured by bone ultrasonometry: a pilot study comprising one year

Aim

The aim of this study was to assess by objective means the effect of homeopathic calcium on the bone density of women taking the remedy over a period of one year.

Introduction

Osteoporosis is described as a progressive, generalised diminution of bone density (measured as bone mass per unit volume), causing skeletal weakness. The ratio of mineral to organic elements remains unchanged. There is, however, a decrease in both calcium and other organic minerals. There is also no abnormality in bone mineral or organic matrix. In osteoporosis, the net rate of bone resorption exceeds the rate of bone formation, resulting in a decrease of bone mass i.e. density. By contrast, in the disease osteomalacia, there is a decrease in the calcium only. The bone density of women peaks before the age of 40 and then steadily declines until, at menopause, there is a 20% decline in the first 5 years.

Osteoblasts are cells that make up the organic matrix of the bone and mineralise it. Osteoclasts are cells that resorb bone. The activities of these two are controlled by systemic hormones such as oestrogen in women, testosterone in men and parathyroid hormone (PTH), calcitonin and 25-hydroxyvitamin D. In healthy bones, the osteoblasts and osteoclasts work harmoniously to maintain a balance within the bone structure. In osteoporosis, there is more osteoclast activity, resulting in a greater rate of bone resorption and a resultant decrease in bone density.

There are two types of osteoporosis. These are:

1. Type I Osteoporosis

Occurs commonly between the ages of 51–75. This type is associated with low oestrogen levels in women and low testosterone levels in men. The disease is six times more common in women. Oestrogen loss results in elevated levels of interleukin-6 and possibly other cytokines that lead to an increase in osteoclast activity. This type of osteoporosis affects the trabecular bone and commonly results in vertebral crush fractures and Colles’ fractures (distal radius).

2. Type II Osteoporosis

This is also known as Involutional or Senile Osteoporosis. This is associated with the normal aging process. Rather than being a result of an increase in osteoclasts, this type is associated with a normal decline in osteoblast activity. Type II affects the trabecular and cortical bone and more commonly results in fractures of the femoral neck, vertebrae, proximal humerus, proximal tibia and pelvis. This type is believed to be a result of either a decrease in, or unresponsiveness of, the vitamin D receptors. In older women, it is possible to have both type I and II osteoporosis.1

The role of PTH and calcitonin

Bone maintenance involves an intricate interplay of hormonal activity. The hormones involved are Vitamin D, PTH and calcitonin.

Vitamin D

Vitamin D stimulates the absorption of calcium. Vitamin D is produced in the skin in a conversion that involves 7-dihydrocholesterol into Vitamin D (cholecalciferol). Vitamin D is then transported to the liver and converted by an enzyme (of which, interestingly, the nutrients involved in the conversion are as yet unknown) to 25-hydroxycholecalciferol (25-OHD). 25-OHD is then converted to 1,25-dihydroxycholecalciferol (1,25-(OH)D) under the action of another enzyme, this time occurring in the kidneys. It is this derivative that is the most potent.

SUMMARY

Osteoporosis is a disease that is rapidly increasing in prevalence owing to a combination of dietary influences, adverse effects of medication and a rapidly aging population. Osteoporosis is placing an increasing strain on the public health purse. Homeopathy is an inexpensive non-pharmacological alternative that may be useful to increase bone density. However, currently there is little evidence-based research on its effects. This pilot study aimed at exploring the effect of medium-potency calcium on the bone density of women over a period of one year. The majority of the women were post-menopausal. The bone density was measured before and after treatment with bone ultrasonometry. Results showed that medium potency calcium caused an increase in the bone density of eleven of the fifteen participants that completed the trial, ten of these post-menopausal. This prescription can be combined safely with allopathic drugs and is cost-effective. It is concluded that this homeopathic dose may be a viable treatment for osteoporosis but future controlled trials are needed to confirm the results.

KEYWORDS Calcium, Bone density in women, Calcarea carbonica, Calcarea phosphorica, Calcaria fluorica, Ultrasonometry, Pilot study

form of Vitamin D. There have been cases of osteoporosis treated with this form of Vitamin D.2

PTH
PTH is secreted by the parathyroid gland, situated behind the thyroid. PTH increases serum calcium levels by increasing osteoclast activity. Interestingly, PTH also decreases urinary excretion and increases intestinal absorption. PTH also increases the conversion of 25-OHD to 1,25-(OH)D. Even though PTH stimulates osteoclast activity, it may play a role in the prevention and treatment of osteoporosis as it increases urinary absorption of calcium and increases the conversion of 25-OHD to 1,25-(OH)D that will in turn stimulate the absorption of calcium. Naturally, increased serum calcium levels stimulate osteoblast activity, thereby increasing bone density. So, even though PTH initially stimulates osteoclast activity, the end result is increased osteoblast activity. There has been recent investigation into the use of low doses of PTH in the treatment of osteoporosis.3 Oestrogen deficiency possibly makes osteoclast activity more sensitive to PTH resulting in increased osteoblast activity. As serum calcium rises, PTH levels decrease, therefore the levels of potent Vitamin D falls, resulting in lowered absorption. The activity of Vitamin D as regulated by PTH in the potent 1,25-(OH)D seems to be of remarkable importance, even overriding the effects of the initial osteoclast activity.

Calcitonin
Calcitonin is secreted by the kidneys in response to high serum calcium levels. It is responsible for osteoblast activity increases. Calcitonin can be isolated from salmon bones and has been used to treat osteoporosis.4

Other factors involving low bone density
1. As we age our stomach acid naturally declines.5 As calcium absorption requires a high acid environment, calcium absorption naturally decreases with age. A large percentage of women with diagnosed osteoporosis have been found to suffer from concomitant hypochlorhydria.6
2. High intake of dietary phosphorus displaces calcium in the body and increases calcium excretion. Efficient calcium absorption requires the correct ratio of calcium to phosphorus to magnesium (1 : 1 : 2 respectively).7
3. Calcium carbonate, the most common form of calcium supplement, is well known to be poorly absorbed. The citrates and hydroxyapatites are far more assimilable.7 Since calcium carbonate is an antacid, calcium absorption is impeded also.

Of the 37 500 femoral neck fractures occurring annually in England and Wales alone, it is calculated that 1/4 of these are at least partly attributable to osteoporosis. With a mean hospital stay of 40 days and a mortality of 16%, the estimated cost for neck fractures alone is 165 million pounds annually.8

The issue of bone health is a complex one involving the interplay of many hormones and there may be numerous treatment options. It is important to both the homeopathic and allopathic community. If proven effective, homeopathic treatment could be either a conjugate treatment for osteoporosis, or even a replacement, depending on individual factors and the severity of the symptoms. Since it is safe and cost-effective, such a treatment would be most welcome for many patients suffering from this condition. The trial was located at the Australian College of Natural Medicine, Melbourne, Australia.

Literature review
Menopausal symptoms represent a huge percentage of the total interest in complementary medicine. Due to the increasing popularity of complementary medicine, it is important to review research in relation to the efficacy of alternative remedies. According to a nursing journal, more than 70 different remedies and herbs have been used with clinical success to treat menopausal symptoms.9 Again, according to another nursing journal, Kass-Anneses states that homeopathic therapies are one of the most commonly used alternative therapies for menopause.10 Whilst many trials have been conducted on popular alternative remedies, there have not been many focusing specifically on homeopathy. Considering the popularity of homeopathy, future research is needed.

Homeopathic remedies are currently prescribed to relieve symptoms of menopause. As no physical amount of the remedy is present, the remedies are a safe alternative and can also be used in conjunction with allopathic medication. As André Thurneyson reminds us, homeopathy can be used safely for the treatment of post-menopausal problems in conjunction with other treatment options.11 A review in a nursing journal concludes that homeopathic treatment can be used not only to treat physical and emotional symptoms, but can also be used safely in conjunction with Hormone Replacement Therapy (HRT) or as an alternative to HRT, for the management of menopausal symptoms.

Certain alternative remedies such as phytoestrogens, have gained much popularity and, as a result, extensive scientific research has proven that these remedies are a safe and effective for the relief of menopausal symptoms. For example, a review of phytoestrogens on bone was conducted by examining the evidence from 17 in-vitro studies of cultured bone cells, 24 in-vivo studies of animal models for postmenopausal osteoporosis, 15 human observational/epidemiologic studies, and 17 dietary intervention studies; its conclusion was that diets rich in phytoestrogens have bone-sparing effects in the long term, although the magnitude of the effect and the exact mechanism(s) of action are pres-

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3 MIMS, CMP Medica Australia Pty Ltd, Level 2, 1 Chandos St, St Leonards NSW, Australia, 2000.
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7 MIMS, CMP Medica Australia Pty Ltd, Level 2, 1 Chandos St, St Leonards NSW, Australia, 2000.
The research concluded that this particular remedii progenitabant. Two scientiﬁc studies, though, have indicated that homeopathic remedies have had positive effects on post-menopausal symptoms.

Homeopathic calcium ﬂuoride is a very commonly prescribed remedy. This is especially true, as ﬂuoride in physical doses is potentially toxic. C. Palermo et al. conducted an in-vitro study to measure the effect of homeopathically prepared calcium ﬂuoride on rat-derived osteoblasts. Homeopathic calcium ﬂuoride was shown to promote osteogenesis in-vitro in rat tibia derived osteoblasts.14 The results of this study are promising and could then be extrapolated to include the treatment of postmenopausal osteoporosis. More scientiﬁc research on effect of homeopathic calcium ﬂuoride on human osteoblasts is needed.

Another study attempted to test the effect of a homeopathically prepared substance called Feminon M (The article was in Polish so the content of the preparation is unknown; however, it is important that the preparation was homeopathically prepared) for the treatment of menopausal symptoms. Homeopathic Feminon M was used by a team of Polish researchers to decrease menopausal symptoms in women. The climacteric index, FSH, oestriodiol and cythromonal smear results were measured before and after six months of therapy. The climacteric index and FSH were signiﬁcantly lower after six months of therapy. The research concluded that this particular homeopathic preparation could reduce menopausal symptoms.15

Unfortunately, these studies reﬂect the current body of evidence. A review of the scientiﬁc literature available on the common alternative remedies for the treatment of menopausal symptoms calls for randomised, controlled trials. Standardised dosage and accurate safety and efﬁcacy labelling are required to ensure the proper use of alternative remedies.16 As homeopathic research is quite limited, any research into the effect of homeopathic medicine on bone density would beneﬁt the scientiﬁc community and allow for insight into future research.

Methods

As there is no previous literature in relation to homeopathy and osteoporosis, I decided to use a medium potency to have a regulatory effect. I prescribed the indicated lecithin remedy of either Calciare phosphorica, Calciare floriaca or Calciare carbonica, 30C, once daily for a period of one year.

Study design

The study design is a pilot study to determine the effects of homeopathically prescribed, medium-potency calcium remedies on bone density. The model is pretest/post-test.

- Obtained measurements of the dependent variable i.e. bone density as measured by bone ultrasonometry and recorded as stiffness score.
- Applied the independent variable i.e. homeopathically prescribed medium potency calcium.
- Measured the dependent variable again, i.e. bone density as measured by bone ultrasonometry and recorded as stiffness score.

Hypothesis

I expect that medium potency calcium over a period of one year will cause an increase in bone density as measured by bone ultrasonometry.

Subjects

The sample size was 21. All patients were female. The mean age was 56.5. The age range was 22–8:2. Only 2 were pre-menopausal. 19 were post-menopausal. No remuneration was received.

Recruitment

An incidental sampling method was used to easily access members of a target population. Patients were recruited by advertising in a community health section of a local paper. I advertised a trial on osteoporosis to attract post-menopausal women. A local community was canvassed with attention focusing on care facilities for senior citizens.

Inclusion criteria

Ideally subjects were post-menopausal (either naturally or surgically induced) women with a known loss of bone density either in the osteopenic or osteoporotic stage. I considered all willing participants.

Exclusion criteria

Death, permanent disability or disabling failure, to take the remedy as prescribed or the consumption of newly prescribed allopathic medicines for loss of bone mass were reasons for exclusion. Of the 21 patients, 6 dropped out over the course of one year for a variety of reasons: the remedy was too fiddly, poor remedy compliance, nightmares and change of address.

Variables

Dependent variables

An independent nurse from the Australian Bone Density Testing Centre performed a non-invasive ultrasound of the heel. Bone loss at the heel is representative of osteoporosis of other bones, in particular the hip and spine. According to the testing centre, bone ultrasonometry measures a “stiffness test” that is accurate to ±2%. The instrument measures results accurately. For example, a test result conducted at 8 am will be the same as a test result conducted at 6 pm. It takes a signiﬁcant amount of time for test results to show any change.

While dual-energy x-ray absorptiometry (DXA) is the standard criterion in identifying low bone mineral density (BMD), access is limited and the cost is prohibitive. DXA and QUS are able to predict fractures and QUS can predict independently of BMD.17 Bone ultrasonometry measures the risk of fracture in the same way that a cholesterol test predicts the risk of cardiovascular disease. The measurement of bone density is given as a “stiffness score”.

Bone stiffness score is a measurable risk factor calculated by assessing the strength of bone with the expected value of the bone of a young adult of the same sex and age.
Table 1 Homeopathic remedies and prescribing indications

<table>
<thead>
<tr>
<th>Remedy</th>
<th>Prescribing Indications</th>
<th>Worse for &lt;</th>
<th>Better for &gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcarea carbonica</td>
<td>– rheumatic pains, exposure to wet</td>
<td>– exertion, mental and physical</td>
<td>– rest, dry</td>
</tr>
<tr>
<td></td>
<td>– cold knees</td>
<td>– cold, damp and washing</td>
<td>– lying on painful side</td>
</tr>
<tr>
<td></td>
<td>– digestive complaints</td>
<td></td>
<td></td>
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<td></td>
<td>– mental dullness</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>– increased perspiration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calcarea phosphorica</td>
<td>– conditions arising from poor cellular development</td>
<td>– cold, wet, changeable</td>
<td>– warm, dry weather</td>
</tr>
<tr>
<td></td>
<td>– frequent colds</td>
<td>– damp, cold and draughts</td>
<td></td>
</tr>
<tr>
<td></td>
<td>– irritability</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calcarea fluorica</td>
<td>– conditions due to loss of elasticity of connective tissue</td>
<td>– on rising, first movement</td>
<td>– motion</td>
</tr>
<tr>
<td></td>
<td>– weak bone, enamel and tendons</td>
<td>– cold, wet weather</td>
<td>– hot applications</td>
</tr>
<tr>
<td></td>
<td>– fear of financial ruin</td>
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</tbody>
</table>

Table 2 Before and after bone stiffness score results

<table>
<thead>
<tr>
<th>Patient</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
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<tr>
<td>Test 1</td>
<td>110</td>
<td>116</td>
<td>80</td>
<td>102</td>
<td>79</td>
<td>59</td>
<td>130</td>
<td>91</td>
<td>70</td>
<td>85</td>
<td>91</td>
</tr>
<tr>
<td>Test 2</td>
<td>120</td>
<td>118</td>
<td>89</td>
<td>91</td>
<td>65</td>
<td>121</td>
<td>111</td>
<td>82</td>
<td>89</td>
<td></td>
<td></td>
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<tr>
<td>Patient</td>
<td>L</td>
<td>M</td>
<td>N</td>
<td>O</td>
<td>P</td>
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<td>R</td>
<td>S</td>
<td>T</td>
<td>U</td>
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</tr>
<tr>
<td>Test 1</td>
<td>72</td>
<td>73</td>
<td>82</td>
<td>85</td>
<td>78</td>
<td>85</td>
<td>112</td>
<td>116</td>
<td>80</td>
<td>74</td>
<td></td>
</tr>
<tr>
<td>Test 2</td>
<td>87</td>
<td>90</td>
<td>87</td>
<td></td>
<td>83</td>
<td>73</td>
<td></td>
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After 1 year, no change in stiffness score indicates bone density has stabilised. Any increase in stiffness score is a positive result and indicates an increase in bone density and a decreased risk of fracture.

**Independent variables**
Calcarea carbonica 30C prescribed once daily for a period of 1 year.

**Extraneous variables**
Exercise and diet. As weight-bearing exercise increases bone density, participants were advised not to undertake any increase in weight-bearing exercise. Patients were advised not to make changes to their current diet. Participants were also asked not to discontinue or begin any new medication or supplementing including calcium supplementation. Both the pre-test and post-test consultations included acquiring this information.

**Materials and procedures**

Bone ultrasound, also called bone ultrasonometry or quantitative ultrasonography (QUS), was performed on the heel, both before and after 1 year of treatment with homeopathic calcium.

**Homeopathic remedies**
The homeopathic remedies prescribed were from Martin and Pleasance, an Australian homeopathic manufacturer. I prescribed the calcium remedy based on individual symptoms that were unrelated to bone density and according to the law of similars. Table 1 shows the remedies prescribed and basic prescribing indications.

**Data management**
The initial bone density results were compared to the second bone density results approximately 1 year later in line with recommendations from the Australian Bone Density Testing Centre. Regular phone contact and mail correspondence with participants was maintained to assure that they were taking the remedy correctly and were experiencing no side effects. Over the course of the trial period patients were asked not to make any changes to their diet, calcium intake or medication. Patient compliance was good. The remedy was posted or personally delivered.

Of the 21 patients, 6 dropped out over the course of one year. The reasons indicated were: the remedy was too fiddly, poor remedy compliance, nightmares and change of address.

**Ethics**
At the time of the research there was no ethics committee at the Australian College of Natural Medicine. A research proposal was approved by a senior lecturer at the college. No participants suffered any harm during the course of this experiment and all gave informed consent.

**Timetable for proposed research**
The study was conducted from 12/11/2001 – 17/12/2002. I chose to conduct the study over a period of not less than one year as this is the time, recommended to me by the Bone Density Testing Centre, that is necessary to achieve significant rises in stiffness score.

**Costs**
The Australian Bone Density Testing Centre charges $40 for an individual test. As the sample size is 21, the total amount payable would normally be $1680. As the Australian Bone Density Testing Centre offered a discounted rate, the total cost to me was $1000. The homeopathic remedies were supplied by the Australian College of Natural Medicine.

**Results**
Comparison of weight, physical activity, dietary changes and the consumption of other intervening nutrients showed no significant changes throughout the study. Patient U, however, came off HRT. The following tables show before and after results for bone stiffness, change in stiffness index and age and pre/post-menopausal state.

Table 2 shows before and after results of the bone stiffness score. It is clear that some have received a higher stiffness test for the second result. This is relevant as bone density normally declines. Fig. 1 shows the same results as Table 1 in a graphical representation. The patients that...
do not record a second reading are drop-outs.

Table 3, entitled Patient Records, shows the age, post-menopausal state and change in stiffness index. The mean calculation for the change in bone stiffness score is 5.4.

**Statistical analysis**

An independent statistical analysis was conducted. Although the data for both measurements was normally distributed (KS Z ≥ .21), a nonparametric test was chosen to test the hypothesis that there was an improvement in bone density from the baseline measurement to the post-treatment measurement after one year.

As can be seen from Table 2, there were six missing data items owing to drop-out for reasons explained in the discussion. For the total data set, the mean for the first measurement was 89.05 (standard deviation [SA] 18.9, range 59 – 130), and for the second measurement 94.87 (SA 18.05, range 65 – 121).

Since comparisons between both measurements were performed only for valid data sets, the sample size was reduced to N = 15. There were virtually no changes in the distribution of the first measurement (Mean 89.47, SA 18.2, range 59 – 130). Thus, although the sample size was decreased by 28%, this did not encompass major alterations which could have affected the statistical results.

A Wilcoxon test was performed to test for a difference between the ranks of the first and second measurement. The result yielded a highly significant improvement in bone density between the two measurements (Z = – 2.33, p = .01). Thus, the hypothesis that the homeopathic treatment of patients with osteoporosis would lead to significant positive changes could be confirmed. To evaluate the size of the effect, an effect measure (Cohen’s d) was calculated according to the formula: MeanA – MeanB/Pool SA. The result showed that the effect of d = 0.30 was small according to general conventions.

**Explanation**

The results confirm the subjective impression that there was an improvement between the two tests. It is statistically highly significant, meaning that such a result would occur by chance once in a hundred measurements. This is a positive result and may warrant future research. The effect as such is small, meaning that the numerical changes were 0.3 standard deviations. In other words, although there is a statistical effect it might not be of clinical significance in the first place. This is difficult to decide because there are a number of alternative explanations that cannot be ruled out, such as regression to the mean, placebo effects, confounding variables etc.

**Discussion**

Of the 21 patients, 6 dropped out. The reasons are that the remedy was too fiddly, poor remedy compliance, one had nightmares and some lost contact. Of the 15 participants that completed the trial, 11 patients recorded an increase in bone density. Of these 11 participants, 10 were post-menopausal. The mean increase in stiffness score was 8.45. 4 patients recorded a decrease in bone density. The mean decrease in stiffness score was 3.75.

A major weakness associated with this trial was a small sample size. The sample size is non-representative and the sample is biased, which compromises external validity. The literature review is inadequate as there is so little research on homeopathy for osteoporosis. This study is not modelled on any previous study so comparison is impossible. The research strategy is inappropriate, for example there is no control. There are three homeopathic calcium remedies prescribed, which compromises internal validity. The Rosenthal, placebo and Hawthorne effects may be being observed, threatening external validity.

For the purpose of this trial, the aims and hypothesis are met. Indeed the statistical analysis has shown significant positive changes in bone density. The internal validity is strengthened as the bone ultrasonometry tester is independent and the trial was supervised. Prescribing remedies according to the law of similaris strengthens the homeopathic principles. The dependent, independent and extraneous variables are controlled to a certain degree.

This trial may assist future researchers with a correct estimation of the time needed to complete data collection, to identify, control and eliminate independent and extraneous variables and to choose an appropriate study design for future research.

**Future Research Potential**

- A randomised, double-blind, placebo-controlled study on post-menopausal women with a pre-existing osteoporotic state, using one homeopathic calcium remedy to decrease variables and increase significance.
- A randomised, double-blind, placebo-controlled study on postmenopausal women with a pre-existing osteoporotic state, using low potency PTH to stimulate an increase in PTH, thereby an increase in bone density.
- A randomised, double-blind, placebo-controlled study on post-menopausal women with a pre-existing osteoporotic or osteopenic state, using low potency vitamin D to stimulate an increase in vitamin D absorption, thereby increasing bone density.
Conclusion

The results confirm the hypothesis that medium-potency calcium over a period of one year will cause an increase in bone density. Homeopathy can therefore be indicated to increase bone density and decrease risk of fracture; future research using a larger sample size is, however, needed to establish clinical significance.

Acknowledgements

I would like to thank Dr. Rainer Schneider for his assistance with the statistical analysis.

I would also like to thank the Australian Bone Density Centre for offering a discounted rate for the bone ultrasonometry.

References

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