

# EFFECT OF A MIXTURE OF CALCIUM, VITAMIN D, INULIN AND SOY ISOFLAVONES ON CALCIUM ABSORPTION IN POST-MENOPAUSAL WOMEN: A RETROSPECTIVE ANALYSIS

PP  
407

M. Bevilacqua<sup>1</sup>, V. Righini<sup>1</sup>, D. Certan<sup>1</sup>, M. Alemanni<sup>2</sup>, G. Gandolini<sup>3</sup>

<sup>1</sup> Endocrinology and Diabetes Unit, Department of Medicine, Luigi Sacco Hospital (Vialba) - University of Milan, Milan, Italy; <sup>2</sup> Medical Affairs, Medical Department, Bayer S.p.A. - Pharmaceuticals, Milan, Italy; <sup>3</sup> IRCCS "S. Maria Nascente", Rheumatology and Bone Metabolism Unit, Don Gnocchi Foundation ONLUS, Milan, Italy

## INTRODUCTION

Recent findings strongly suggest that the concomitant supplementation of calcium and vitamin D is required for an effective prevention of bone fractures, whereas the sole supplementation of either seems to be ineffective [1-3]. However, there is a tendency in the elderly to progressively develop vitamin D resistance in the gut, thereby limiting its effectiveness in promoting an efficient calcium absorption [4,5]. Thus, there is the need to search additional ways to promote an effective calcium absorption and, consequently, bone health. By retrospectively analyzing a population of post-menopausal women, we observed that the addition of inulin and soy isoflavones to a relatively low amount of calcium and vitamin D was able to enhance calcium absorption.

## AIM OF THE STUDY

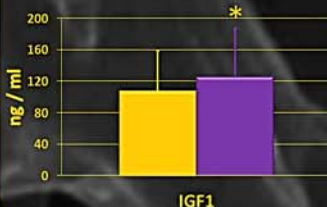
In the light of the abovementioned observations, we wanted to test whether the addition of **inulin** and **soy isoflavones** to a mixture of calcium and 25(OH) vitamin D was able also to influence **bone metabolism** in a population of otherwise healthy post-menopausal women.

## RESULTS

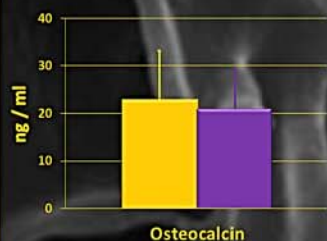
### DEMOGRAPHICS

Women, <i>n</i>	28	The study population, although small, was quite heterogeneous, in terms of age and years since menopause onset, favoring the generalizability of the observed results.
Age (range)	67 (36 – 84)	
Years at menopause (range)	51 (32 – 59)	
Years in menopause (range)	18 (4 – 43)	

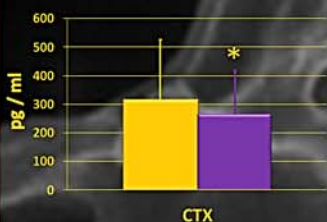
### EFFECTS ON BONE METABOLISM



The significant increase of Insulin-like Growth Factor 1 (IGF1) levels (+16%) are suggestive of an **improved bone anabolism**. Soy isoflavones are known to promote the synthesis of IGF1 [6].



A trend towards a modest reduction of osteocalcin levels was observed, but it was not statistically significant, probably because of the small sample size.



Collagen-telopeptide (CTX) levels were significantly decreased (-17%), suggesting a **decrease in bone resorption**. A positive effect of soy isoflavones on bone resorption has already been extensively characterized [7].

Data shown as mean (SD) \*  $p < 0.05$ ; 3 months of supplementation (■) vs baseline (■).

## MATERIALS AND METHODS

We retrospectively analyzed all the post-menopausal women presenting in our outpatient clinic between June 2011 and June 2012 that were treated with a product present on the Italian market, consisting in a mixture of calcium (500 mg), 25(OH) vitamin D (300 IU), inulin (3 g) and soy isoflavones (40 mg).

### INCLUSION CRITERIA

- Last menstruation at least 2 years ago
- Supplementation with the study mix for at least three months

### EXCLUSION CRITERIA

- Primary hyperparathyroidism
- Celiac disease
- Serum 25(OH) vitamin D < 10 ng/ml
- Diabetes or other systemic disease
- Concomitant therapies for osteopenia/osteoporosis

All the considered variables were derived from the clinical records of the selected patients, and consisted in hematological parameters we routinely assess in our patients in order to monitor the effectiveness of the prescribed therapies.

The effects of the study mixture on bone metabolism were evaluated by considering serum IGF1, CTX and osteocalcin levels, comparing the levels before the start of the supplementation and after three months. Additionally, daily calciuria, serum free calcium, 25(OH) vitamin D and parathormone were considered to monitor the effects of the mix on calcium absorption.

### PREVIOUS OBSERVATIONS

	Baseline	3 months
Daily calciuria - mg/day	120.86 (80.36)	193.07 (124.61) #
Ionized plasma calcium - mmol/L	1.21 (0.04)	1.21 (0.05)
25(OH) vitamin D - ng/ml	32.15 (18.65)	32.54 (18.72)
Parathormone - pg/ml	62.50 (30.95)	52.04 (20.91) *

In spite of unaltered 25(OH) vitamin D levels, **daily calciuria was markedly increased**, suggesting increased calcium absorption, and parathormone levels decreased, whereas plasma calcium was unchanged, as expected since it is the set-point for calcium balance.

Data shown as mean + SD. \*  $p < 0.05$ ; #  $p < 0.001$  vs baseline.

## CONCLUSIONS

The study mixture was able to promote intestinal calcium absorption, as shown by the marked increase in daily calciuria and by the decrease in circulating parathormone levels. Since the amount of supplemented calcium was relatively low, the starting 25(OH) vitamin D levels were above the threshold for vitamin D sufficiency and they were unchanged by the treatment, it is likely that the **addition of inulin and soy isoflavones was responsible for the improvement in calcium absorption** observed.

The observed effects on bone metabolism can also be attributed to the action of soy isoflavones [6-7] and to inulin, which is also able to promote their absorption [8]. For these reasons, the addition of inulin and soy isoflavones to the daily supplementation of calcium and 25(OH) vitamin D **represent an interesting option for both the enhancement of calcium absorption and the promotion of bone health in post-menopausal women**.

## REFERENCES

- [1] Avenell et al. *Cochrane Database Syst Rev* 2009; 2: CD000227
- [2] Rejnster. *Lancet* 2007; 370: 632-4
- [3] Schulman et al. *Curr Osteoporos Rep* 2011; 9: 184-95
- [4] Hesney et al. *J Bone Miner Res* 1989; 4: 469-75
- [5] Gallagher et al. *J Clin Endocrinol Metab* 2012; 97: 3550-6
- [6] Marini et al. *Ann Intern Med* 2007; 146: 839-47
- [7] Taku et al. *Maturitas* 2011; 70: 333-8
- [8] Piazza et al. *Am J Clin Nutr* 2007; 86: 775-80