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The effect of the first intervention in patients with low bone density

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Abstract
The osteoporosis is a progressive disease and the most frequent bone tissue pathological condition. An appropriate diet could help to prevent and manage osteoporosis by assisting in the production and maintenance of bone tissue.
The study aimed to compare the impact of nutrition, supplements and drug intake on bone tissue density. The sample of the study consisted of one hundred women between 47 and 94 years old.
T and Z score bone density tests were performed before the interventions. People with a T-score of -2.5 and above consisted the drug group and underwent a drug intervention. All others were randomly divided in two groups with a ratio of 1:1. The patients of the nutrition group were instructed by the nutritionist intaking 1200mg of dietary calcium daily and a supplement of vitamin D3 400IU twice daily. The patients of the supplement group had to intake a combined 500mg calcium and 400IU D3 supplement twice daily. T and Z score bone density tests were repeated after 12 months.
The results indicated that there were no significant differences between the nutrition and the supplements groups in mean T and Z scores before the intervention. After the treatment, there was a statistically significant increase in mean T and Z scores in both groups, but no significant differences between them. The drugs group had a significant improvement after treatment and significantly better results compared to the other two groups. In conclusion, nutrition intake and calcium-vitamin D supplements significantly reduced the T and Z scores, but with no significant difference between them, in people with osteopenia. In patients with higher initial T and Z scores, the use of drugs is more appropriate for reducing the risk of fractures.

Keywords: Osteopenia, osteoporosis, calcium, vitamin D, drugs for osteoporosis

1. Introduction
The osteoporosis is a progressive disease and the most frequent bone tissue pathological condition. The main characteristics of the osteoporosis are low bone mass and disorder of the microarchitectural bone structure resulting in reduced endurance of the bone and an increased risk of fracture [1]. There are nonmodifiable and preventable (modifiable) risk factors for osteoporosis. Nonmodifiable risk factors include age, height, weight, body mass index **(**BMI), and menopause which are not preventable. The preventable risk factors include calcium intake, exposure to sunlight, smoking, alcohol intake, exercise, underlying autoimmune disorders, steroids intake, hormone replacement therapy, etc [2].
An appropriate diet could help to prevent and manage osteoporosis by assisting in the production and maintenance of bone tissue. The most important nutrients are calcium, and vitamin D. Calcium is the primary component of the bone tissue, and vitamin D is essential for assisting calcium absorption. For this reason, the intake of nutritional supplements of calcium and vitamin D3 is another recommended treatment. Various drugs, like bisphosphonates, or parathyroid hormone or RANK ligand inhibitor (RANKL)-monoclonal antibody can also increase the density of the bone tissue [3, 4].

2. AIM
The present study aimed to investigate the differences in bone tissue density after one year of

appropriate nutrition, nutritional supplements (such as calcium and vitamin D supplements), and drugs plus nutritional supplements.

3. Material and Methods

The sample of the study consisted of one hundred women between 47 and 94 years old, who visit an orthopaedic clinic willing to examine their osteoporosis risk. To determine the bone density, the orthopaedic doctor ordered T and Z score bone density tests. The T-score compares the patient's bone density to the bone density of a healthy 30-year old adult. A score of -1 or above is normal. Values between -1 to -2 indicate low bone density, called osteopenia. A score of -2.5 or below sets the diagnosis of osteoporosis. The Z-score compares the patient's bone density to the normal score of the same age and body size individuals. A Z-score above -2.0 is normal, according to the International Society for Clinical Densitometry (ISCD). A diagnosis of osteoporosis is recommended to be based not only on one bone density test result.

The exclusion criteria of the present study were: people below 45 years old, people with thyroid gland morbidities and people who were already in osteoporosis therapy.

T and Z score tests were performed in all patients. People with a T-score of -2.5 and above consisted the drug and nutritional supplement group (group 3). They underwent in a drug intervention, such as bisphosphonates or parathyroid hormone or RANK ligand inhibitor (RANKL)-monoclonal antibody plus a nutritional complement of 500mg calcium and 400IU vitamin D3 twice daily. All others were randomly divided in two groups with a ratio of 1:1. The patients of the nutrition group (group 1) were instructed by the nutritionist intaking 1200mg of dietary calcium daily and a supplement of vitamin D3 400IU twice daily. For this purpose, every patient received a tablet with the same amount of calcium for every 100gr of various foods (Table 1).

Table 1: Calcium content per 100gr of different foods

Foods		mg Ca per 100gr	Ca per portion
Milk	3.5% fat	125	1 big glass (240ml) = 300mg
	1.5% fat	125	1 big glass (240ml) = 300mg
Yogurt	4% fat	140	1 big (220gr) = 300mg
	2% fat	140	1 big (220gr) = 300mg
Cheese white <20% fat		300	1 portion (30gr) = 90mg
yellow <20% fat		500	1 portion (30gr) = 150mg
Feta cheese		400	1 portion (30gr) = 120mg
Groovier		1000	1 portion (30gr) = 300mg
Emmental		1100	1 portion (30gr) = 330mg
Parmesan		1350	1 portion (30gr) = 400mg
Eggs		25	1 egg = 25mg
Meat		10-15	1 portion (150gr) = 15-25mg
Fish	low fat	30	1 portion (200gr) = 60mg
	Oily (omega 3)	60-380	1 portion (200gr) = 120-760mg
Bread		20-50	1 slice = 10mg
Pasta		10-20	1/3 of a cup (unboiled) = 10mg
Potatoes (boiled-fried)		15-40	1 middle sized = 10mg
Beans - chickpeas		140	½ teacup (unboiled) = 85mg
Lentils		70	½ teacup (unboiled) = 40mg
Broccoli		100	1 big salad 300mg
Spinach		80	1 big salad 250mg
Fruits	orange	30	1 orange = 45mg
	Strawberry	30	8-10 strawberries = 45mg
	Tangerine	30	2 tangerines = 45mg
Oil		0	1 teaspoon
Butter		10	1 teaspoon
Margarine		0	1 teaspoon
Hovευ		5	1 teaspoon
Orange juice		10-20	1 big glass = 25-50mg
Wine		7	1 small glass = 10mg
Beer		8-12	1 can = 25-40mg
Milk chocolate		220	

The patients of the supplement group (group 2) had to intake a combined 500mg calcium and 400IU D3 supplement twice daily.

The physician recommended to the patients of all groups moderate physical activity, daily. The T and Z score bone density tests were repeated after 12 months.

The outcomes of the study were statistically analyzed by using the IBM SPSS v.26 program. The means and standard deviations were estimated for each variable. Comparisons were made by performing T-tests. Paired-samples T-tests determined the difference in means and standard deviations from each group before the intervention and one year after. Additionally, the difference in means and standard deviations between groups were carried out for each variable, pre-treatment, and one year after, using independent samples T-test.

3.1 Ethical considerations

This study followed all fundamental ethical principles that govern the conduct of research such as full confidentiality regarding the patients' data, the safety of the material, and anonymity of the participants. Finally, the study protocol complied with the Helsinki Declaration and was approved by the Ethical Committee of the School of Health Sciences of the University of Peloponnese.

4. Results

The mean age of the sample was 71.6 ±10.53 yo.

For the nutrition group (group 1), the one year mean of T-score (T2) was found -1.83±0.68, while the initial mean score was -2.15±0.75. Similarly, the one year mean of Z-score (Z2) was -0.48±0.55, while the initial mean score was -0.67±0.58. Both T and Z scores had statistically significant differences after the intervention (Table 2).

For the supplements group (group 2), the one year mean of T-score (T2) was found -1.86±0.79, while the initial mean score was -2.21±0.70. Similarly, the one year mean of Z-score (Z2) was -0.52±0.59, while the initial mean score was -0.69±0.68. Both T and Z had statistically significant differences after the treatment (Table 2).

For the drugs and nutritional supplement group (group 3), the one year mean of T-score (T2) was found -2.56±0.75, while the initial mean score was -2.87±0.58. Similarly, the one year mean of Z-score (Z2) was -0.89±0.71, while the initial mean score was -1.18±0.82. Both T and Z had statistically significant differences after the treatment (Table 2).

a) Comparison between group 1 and group 2

There were no significant differences between the two groups in mean T and Z scores before the intervention. After the treatment, there was a statistically significant increase in mean T and Z scores in both groups, but no significant differences between them (Table 2).

b) Comparison between group 1 and group 3

There were statistically significant differences between the two groups in mean T and Z scores before the intervention explainable by the study design (ethical reasons). After the intervention, there was a statistically significant increase in mean T and Z scores in both groups. Although group 3 presented better outcomes than group 1 (p<0.001 and p=0.001 in T and Z score respectively) (Table 2).

c) Comparison between group 2 and group 3

There were statistically significant differences between the two groups in mean T and Z scores before the intervention explainable by the study design (ethical reasons). After the intervention, there was a statistically significant increase in mean T and Z scores in both groups. However, group 3 presented better outcomes than group 2 (p<0.001 and 0.041 in T and Z score respectively) (Table 2).

Table 2: Comparison within and between groups

	T1	T2	P-value*	Z1	Z2	P-value*
Group 1 mean±sd (n =27)	-2.15±0.75	-1.83±0.68	0.023	-0.67±0.58	-0.48+0.55	0.017
Group 2 mean±sd (n =26)	-2.21±0.70	-1.86±0.79	0.027	-0.69±0.68	-0.52±0.59	0.029
P-value**	0.499	0.876		0.152	0.132	
Group 1 mean±sd (n =27)	-2.15±0.75	-1.83±0.68	0.023	-0.67±0.58	-0.48+0.55	0.017
Group 3 mean±sd (n =47)	-2.87±0.58	-2.56±0.75	<0.001	-1.18±0.82	-0.89±0.71	0.001
P-value***	<0.001	<0.001		<0.001	0.001	
Group 2 mean±sd (n =26)	-2.21±0.70	-1.86±0.79	0.027	-0.69±0.68	-0.52±0.59	0.029
Group 3 mean±sd (n =47)	-2.87±0.58	-2.56±0.75	<0.001	-1.18±0.82	-0.89±0.71	0.001
P-value****	<0.001	<0.001		0.013	0.041	

*comparison within groups using Paired Samples T-tests

** comparison between nutrition group and CaD3 group using Independent Samples T-tests

*** comparison between nutrition group and drugs + CaD3 group using Independent Samples T-tests

**** comparison between CaD3 group and drugs + CaD3 group using Independent Samples T-tests

5. Discussion

Many studies investigated the potential benefits of a diet rich in calcium and vitamin D, or dietary supplements in the bone tissues density. The present study showed a significant increase in bone density, which was achieved either by appropriate nutrition or using supplements, without substantial differences between the two methods of intervention. Similarly, Murray in 1996 concluded that adequate calcium nutrition increases bone mineral density during skeletal growth and prevents bone loss and osteoporotic fractures in the elderly. He recommended that all calcium requirements be pursued through food sources. Pharmaceutical calcium supplements should be considered where dietary preferences or lactase deficiency restrict consumption of dairy foods [5]. A meta-analysis of Tang *et al*. in 2007, found that calcium, or calcium in combination with vitamin D supplementation, was effective in the preventive treatment of osteoporosis in people aged 50 years or older [6].

A review of Sunyecz concluded that although dietary sources of both nutrients calcium and vitamin D are available, most people do not receive them adequately. Therefore supplements can bridge this gap. As reviewed, there is ample evidence that calcium and vitamin D alone have the ability to prevent bone loss and reduce fractures [7].

Recent evidence indicates that a healthy diet with adequate amounts of protein, calcium, vitamin D, and nutrients could favour the metabolism of the bone tissue. A diet rich in dairy products (mainly fat-free), fruit and vegetables and adequate amounts of meat, fish and poultry is optimal [8].

According to Reid, dietary calcium intake has not been associated with adverse effects as supplements do, because it is absorbed more slowly from the gastrointestinal tract, resulting in slower gastric transit time [9]. In agreement with this conclusion, Sahni *et al*. state that dietary approaches can be an important strategy for the prevention of osteoporosis, and emerging evidence indicates the vital role in skeletal health of the diet at the level of vitamins, minerals and food groups [10].

Qaseem *et al*. showed that calcium and vitamin D might be added as dietary supplements, although it was uncleared whether the addition of the supplements was effected in the osteoporosis treatment [11].

Chiodini & Booland strongly suggest increasing the dietary calcium intake in patients with estimated low calcium intake and those treated with bone-active drugs. However, when the correct calcium intake is not achieved through a balanced diet, then the use of supplements is inevitable [12].

Jennings *et al*. affirmed that the Mediterranean-like diet, together with vitamin D3 supplements (10 µg/d) significantly reduced the rate of loss of bone at the femoral neck in individuals with osteoporosis [13].

The analysis carried out by Weaver *et al*. suggested that expanding the combined use of calcium and vitamin supplements could reduce the risk of fractures and hospital costs for osteoporosis-attributable fractures [14].

According to Chen *et al*., increasing dietary calcium should be the first consideration, and supplements could be used when it cannot be achieved adequate dietary calcium intake [15].

Muñoz-Garach *et al*. confirmed that balanced nutrient intakes are essential for the reduction of osteoporosis risk, alongside with regular physical activity. They recommended a healthy dietary pattern to decrease the risks of osteoporosis and fractures. However, they recognized the need for further research [16].

6. Conclusions

Nutrition rich in calcium plus vitamin D3 supplements seems to have the same beneficial effect on bone tissue density as the combined calcium and vitamin D3 supplement, after a year of treatment in patients with T-score above -2.5. For bone density lower than -2.5, these two treatments alone are not sufficient, and the treating physician has to consider a combination of the appropriate drugs.

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