

CASE REPORT

# Clinical behavioral outcomes related to osteoporotic patients during ozone treatment.

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ABSTRACT

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Bio-oxidative therapies accelerate oxygen metabolism, stimulate the antioxidant defense system, having analgesic, anti-inflammatory and immunomodulatory properties, among others.

A quasi-experimental study was carried out with the objective of knowing the clinical behavior of osteoporosis during ozone treatment at the Provincial Center for Retinitis Pigmentosa, Camagüey (Cuba) from January - June 2006.

The Subject Population: 53 patients, 50 cases that met the inclusion criteria: patients with osteoporosis, those who agreed to participate in the study with prior informed consent and who decided to join the study by suspending or eliminating previously used therapies.

Ozone was rectally applied, 20 sessions in 2 cycles per year.

The subject selection based upon the following variables: age groups and sex, evaluation of signs and symptoms, distribution according to occupation, clinical evolution according to cycles, variation of drug treatment and social and economic impact.

The predominant ages: 31-40 and +41 years with 16 (32%) and 21 (42%) respectively, the main symptom pain 50 (100%), occupation: workers: 42 (84%). After 20 sessions of ozone, the results were: improved 38 (76%), 50 (100%) decreased the dose of medications.

Patients were incorporated into society in less time, improving their bio-psychosocial state with a cost five times lower than the standard of care treatment.

**Keywords:**

Ozone therapy, Bio-oxidative therapy, Osteoporosis.

**INTRODUCTION**

Ozone (O<sub>3</sub>) is an allotropic variety of oxygen whose existence was reported in 1785, by the Dutch chemist Marius Van Marum. In 1840, Christian Schönbein professor of physics and chemistry at the University of Basel identified it for the first time as ozone. The Austrian surgeon, Edwin Payr (born in 1871), became

acquainted with ozone and he published a book on early 1900, entitled "On Treatment with Ozone in Surgery." This was the beginning of the use of ozone in medicine as we know it today. Medical ozone was used during the First World War to treat gangrenous wounds of German soldiers. Dr. Paul Aubourg, a French physician was the first to publish a paper in 1936 on infusion of ozone rectally in the treatment of chronic colitis and fistulae. (1,2).

Bio-oxidative therapies accelerate oxygen metabolism and stimulate the release of oxygen atoms from the bloodstream to the cells. When these levels are increased, the potential for diseases decreases, as large amounts of oxygen flow into the body. At the same time healthy cells not only survive but are also capable of multiplying; as a result, a better overall immune system is achieved, (3,5).

Ozone is very toxic in its pure state (inhalation route) but it has been shown and proven to be safe and effective when applied in appropriate concentrations. Proper concentration is the basis for medical applications. Ozone is a biological modulator of oxidative stress when its administration is at an adequate and controlled dose and concentration. This is not an alternative medicine but is considered as a natural medicine, which, based on all the knowledge required by the application of gas, implements ozone treatments, regardless of the use of other specific drugs. From this point of view, it does not have collateral consequences with other treatments, it does not compete, but is random to any other medical application (6,7).

Osteoporosis is a state of reduction of bone mass per unit volume, with a normal ratio of mineral to matrix. Age, race, and sex strongly influence skeletal mass. An individual suffers from the disease if his skeletal mass is significantly lower than the particular normal value (8).

The etiology can be multiple among which are:

1- Unknown or idiopathic cause:

- Primary: (senile, post menopause).
- Juvenile: (2-3 years before puberty).

2- Endocrine abnormalities:

- Glucocorticoid excess (Cushing disease)
- Thyrotoxicosis.
- Diabetes Mellitus.
- Hypogonadism (Turner syndrome).

3- Neoplasms:

- Multiple myeloma.
- Leukemia.
- Lymphoma

4- Immobilization.

- 5- Congenital anomalies in the synthesis of bone collagen:
- Homocystinuria.
  - Ehler-Danlos syndrome.
  - Imperfect osteogenesis.

6- Heparinotherapy.

The factors responsible for idiopathic osteoporosis have not been identified to date, and multiple factors have combined to trigger the disease (9,10).

Due to the previously described benefits of bio-oxidative therapies, we made the following hypothesis: Ozone therapy could be effective in osteoporosis?

Therefore, we are motivated to know the clinical behavior of osteoporosis during ozone treatment, identify the incidence according to age groups and sex, evaluate signs and symptoms, determine occupation, assess clinical evolution and variation of drug treatment and demonstrate its social and economic effect.

## **METHODS.**

A quasi-experimental study was carried out at the Provincial Center for Retinitis Pigmentosa Dr. "Orfilio Peláez Molina" in Camagüey (Cuba) in the period from January - June 2006. A study group with 50 patients who met the inclusion criteria and who underwent conventional treatment without achieving improvement in their symptoms, from orthopedic consultations, was taken into account.

Ozone was applied rectally at a concentration of 40 mg/L and 200 mL per session, during 20 sessions in cycles of 1-2 times a year, depending on the general evolution of the patient.

Taking into account the following variables:

- 1- Age and sex.
- 2- Evaluation of symptoms and signs.
- 3- Distribution according to occupation.
- 4- Clinical evolution.
- 5- Variation of drug treatment.
- 6- Social and economic impact.

### **Inclusion criteria:**

- Patients with osteoporosis (cause 1).
- Those who agreed to participate in the study with prior signed informed consent.
- Every patient who decided to join the study must suspend all previously used therapies.

**Exclusion criteria:**

- Patients with hematological diseases and bleeding disorders.
- Those who did not agree to participate in the study.

**Study exit criteria:**

- Patients who did not meet the requirements of the study.
- Non-attendance for treatment for more than 2 occasions.
- Death of the patient.

**Operational definitions:**

- **Treatment cycles:** Each cycle consists of 20 sessions of rectal ozone, from Monday to Friday during 4 weeks, and is repeated every 6 months, as long as the patient has symptoms and signs of the disease. In each session, 200 mL of gas (oxygen-ozone) at a concentration of 40 mg/L was rectally slowly insufflated using a lubricated cannula and a 50/60 mL syringe; the gas mixture was obtained from a Cuban ozone generator (Ozomed plus).

- **Evaluation of the patient according to the treatment cycles.**

- **Improved:** All patients who eliminate the symptoms and signs with which they began treatment.

- **Slight improvement:** Those cases that reduce or eliminate some of the symptoms but others still persist.

- **Same:** Symptoms or signs remain the same as when starting treatment without reporting any change in symptoms and signs with respect to the initial condition.

**Semantic control:**

- **Osteoporosis:** Formation of abnormal spaces in the bone (pores) or the decalcification of its ducts.

- **Ozone therapy:** oxygen-ozone mixture obtained through an electrical discharge of high voltage and high frequency. This therapeutic gas at adequate concentrations produces beneficial changes to the organism.

**RESULTS.**

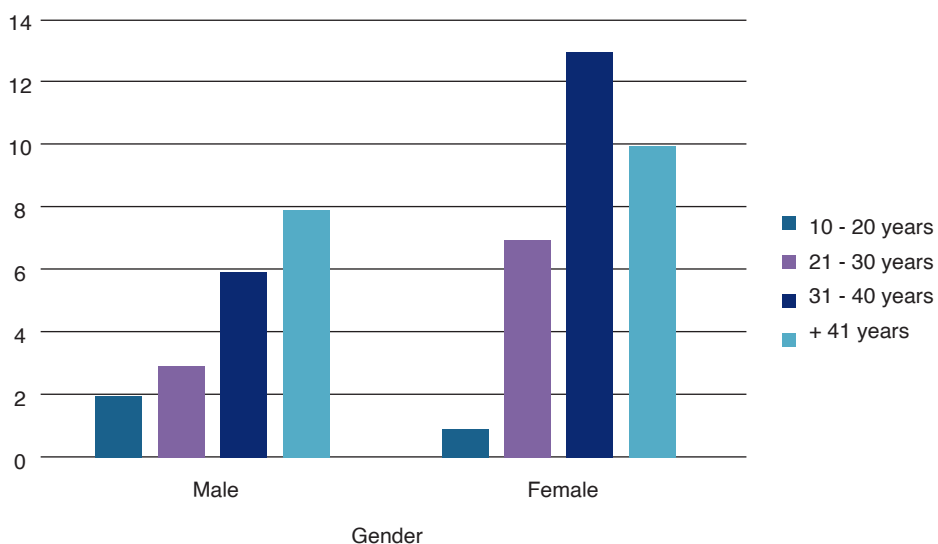
In our sample, (table and graph 1) the highest prevalence of osteoporosis were the ages between 31-40 years (16 cases - 32%) and 41 years (21 cases - 42%) and the female sex with 31 cases (62%).

**Table 1**

Age groups.  
Provincial Center for Retinitis Pigmentosa.  
January - June 2006

Age	Gender					
	Male		Female		Total	
	F	%	F	%	F	%
10-20 years	2	10.52	1	3.22	3	6
21-30 years	3	15.78	7	22.58	10	20
31-40 years	6	31.57	13	41.95	21	42
+41 years	8	42.13	10	32.25	16	32
<b>Total</b>	<b>19</b>	<b>100</b>	<b>31</b>	<b>100</b>	<b>50</b>	<b>100</b>

**Graph 1**



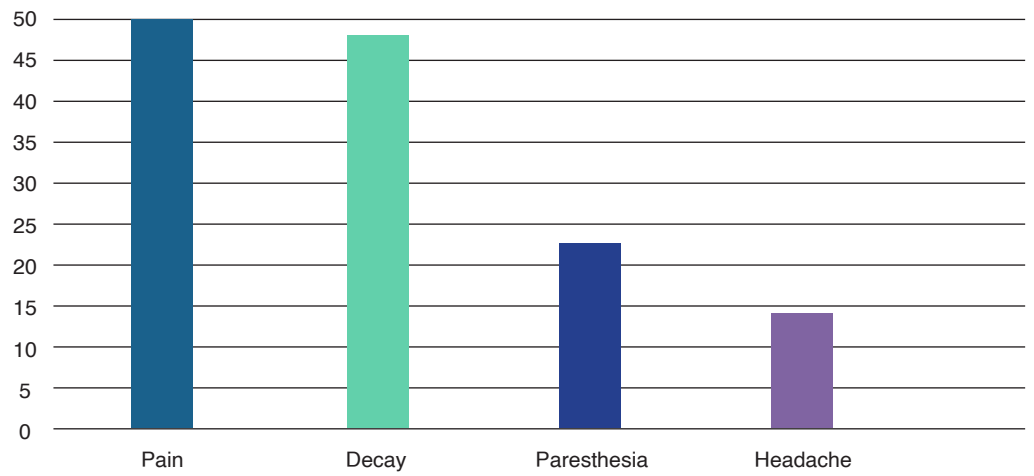
Pain was the most significant symptom (table and graph 2), present in all the patients, followed by decay in 48 patients (96%).

**Table 2**

Main signs and symptoms.

Signs and symptoms	F	%
Pain	50	100
Decay	48	96
Paresthesia	23	46
Headache	14	28

**Graph 2**



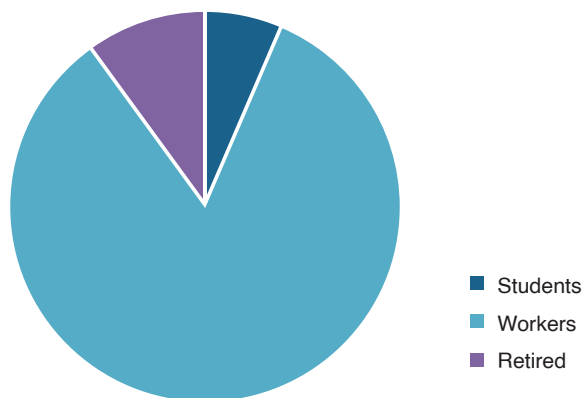
Workers had the highest incidence, 42 (84%) (table and graph 3), far from the other occupations.

**Table 3**

Distribution according to occupation:

Occupancy	F	%
Students	3	6
Workers	42	84
Pensioners	5	10
Total	50	100

**Graph 3**

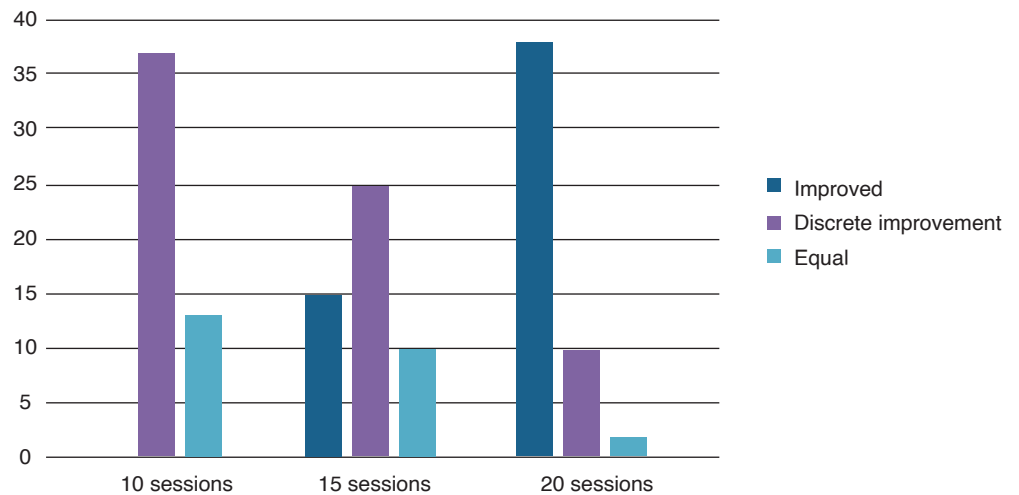


At the end of the ozone treatment, 38 cases (76%) had improved (table and graph 4) and all the patients decreased the dose of drugs (table and graph 5).

**Table 4**  
Clinical evolution.

Evolution	10 sessions		15 sessions		20 sessions	
	F	%	F	%	F	%
Improved	-	-	15	30	38	76
Discrete improvement	37	74	25	50	10	20
Equal	13	25	10	20	2	4
<b>Total</b>	<b>50</b>	<b>100</b>	<b>50</b>	<b>100</b>	<b>50</b>	<b>100</b>

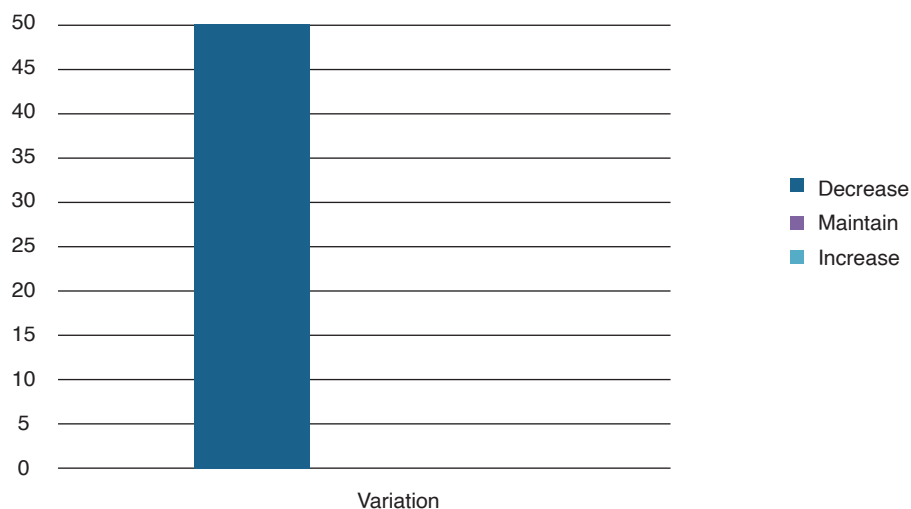
**Graph 4**



**Table 5**  
Variation of drug treatment.

Variation	F	%
Decrease	50	100
Maintain	-	-
Increase	-	-
<b>Total</b>	<b>50</b>	<b>100</b>

**Graph 5**



The cost of drugs when starting treatment rose to \$ 136.00 per patient per prescription renewal , based on the amount of drugs they have to take, their prolonged use and high cost (table 6). The cost of ozone treatment is \$ 25.00 per patient per treatment, reporting a global saving of \$ 5550.00 per year in our sample.

**Table 6**

Previous drugs.

Conventional treatment
Ibuprofen
Naproxen
Dipyron
Handle
Multivitamines
Prednisone
Vitamin B1
Vitamin B12
Vitamin B6
Vitamin D2
Calcium Carbonate
Androgenone (100 mg)
Rocaltrol
Alendronic acid (10 mg)



## DISCUSSION

Table 1 coincides with the bibliography studied, where the highest percentage of patients with osteoporosis corresponds to the female sex, preceded by menopause, accelerating after the same due to the deficit of estrogens (11,12).

Acute pain over the affected region is mainly produced by vertebral crush fractures (sometimes without trauma), prolonged exercise or excess weight (13,14).

When analyzing the occupation, workers are more exposed to predisposing factors: genetic and dietary due to their daily activity (15).

In the clinical course, patients with ozone treatment improve, since it increases oxygenation to damaged tissues (bone), diminished oxidative stress, it is an immunomodulator and has anti-inflammatory effect. Therefore, it reduces the potential for diseases, and it can be administered randomly to any other therapy by potentiating its action (16,17). Due to these properties, ozone therapy reduces the consumption of drugs (18).

As a social effect, we can say that patients who were limited by this condition without being able to go to work evolved in less time, improving their psychic sphere, eliminating or reducing the consumption of drugs without actually producing fractures in the cases studied and managing to recover the function of bone mass. We can conclude that ozone, from the bio-psycho-social point of view, increases the quality of life in a general sense of wellness in each patient. Therefore we can propose that ozone therapy constitutes a viable alternative in the current conditions of the economy of our country.

## RECOMMENDATIONS

Continue working on the use of ozone therapy in patients with osteoporosis due to the benefits of this bio-oxidative therapy, for its rapid recovery and incorporation into society, low cost to the patient and contribution to a better quality of life.

Explain to each patient the ingestion of dietary calcium greater than 1 gram per day and other fracture preventive measures.

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