

ORIGINAL

## Use of Rectal Ozone Therapy in Patients With Osteoarthritis

### Uso De Ozonoterapia Rectal En Pacientes Con Osteoartritis

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#### ABSTRACT

**Introduction:** ozone therapy is characterized by the simplicity of its application, high effectiveness, good tolerance and practically absence of side effects.

**Objective:** to characterize the use of rectal ozone therapy in patients with osteoarthritis treated at the ozone service of the Isabel Rubio Díaz polyclinic in the municipality of Los Palacios during 2019.

**Method:** descriptive and transversal research. The sample studied 84 patients attended in ozone therapy service in the analyzed period, according to inclusion criteria. ABSTRACT measures were used for qualitative data and chi-square.

**Results:** the predominant age group was 60 years and older (63,1 %) and female sex (77,4 %); the most affected joints were upper interphalangeal joints (100 %), followed by knees, decreasing the degree of disability at the end of treatment, which was significant; the response to treatment was satisfactory in 81 % of cases and only 4 % presented adverse reactions.

**Conclusions:** Rectal ozone therapy has demonstrated its efficacy and few adverse reactions in patients with osteoarthritis, so its use is recommended as another therapeutic option.

**Keywords:** Ozone therapy; Osteoarthritis; Therapeutics.

#### RESUMEN

**Introducción:** la ozonoterapia se caracteriza por la simplicidad de su aplicación, alta efectividad, buena tolerancia y prácticamente ausencia de efectos colaterales.

**Objetivo:** caracterizar el uso de la ozonoterapia rectal en pacientes portadores de osteoartritis atendidos en el servicio de ozono del policlínico Isabel Rubio Díaz del municipio Los Palacios durante 2019.

**Método:** investigación descriptiva y transversal. La muestra estudiada 84 pacientes atendidos en servicio de ozonoterapia en el período analizado, según criterios de inclusión. Se emplearon medidas de resúmenes para datos cualitativos y chi cuadrado.

**Resultados:** predominaron las edades de 60 años y más (63,1 %) y el sexo femenino (77,4 %); las articulaciones más afectadas fueron interfalángicas superiores (100 %), seguida de las rodillas, disminuyendo el grado de discapacidad al final del tratamiento lo que resultó significativo, la respuesta al tratamiento fue satisfactoria en el 81 % de los casos y solo el 4 % presentó reacciones adversas.

**Conclusiones:** la ozonoterapia rectal ha demostrado su eficacia y pocas reacciones adversas en pacientes con osteoartritis, por lo que se recomienda su uso como una opción terapéutica más.

**Palabras Clave:** Ozonoterapia; Osteoartritis; Terapéutica.

## INTRODUCTION

Osteoarthritis (OA) is the most prevalent form of arthritis, and its prevalence has risen by approximately 30% over the past decade. <sup>(1,2)</sup> It stands as one of the principal causes of pain and disability, marked by stiffness and progressive loss or diminishment of joint function, leading to varying degrees of functional and psychological limitations that adversely affect the quality of life. <sup>(1,2)</sup>

Medical care for musculoskeletal disorders has undergone significant changes and transformations in recent times. It no longer depends solely on the utilization of analgesics and anti-inflammatories but also has integrated a variety of therapeutic alternatives, especially within the extensive domain of natural and traditional medicine. <sup>(3)</sup>

Ozone therapy is categorized as one of the alternative or natural treatment modalities. Its underlying philosophy traces its origins to Eastern culture, which is why, for many years, a significant portion of its research findings remained under-recognized by Western medicine. Initially, this therapy was employed in medicine due to its potent bactericidal effects on anaerobic microorganisms. However, its scope rapidly expanded to various medical specialties upon the discovery of its germicidal effects on other bacteria, viruses, and fungi, as well as its positive impact on hemorheology, its application in oxidative stress treatment, and its role as an immune system modulator. At present, it ranks among the most widely adopted alternative treatments globally. <sup>(4)</sup>

Ozone therapy is distinguished by its straightforward application, high efficacy, excellent tolerance, and practically negligible side effects. As with any therapy, its effectiveness is contingent upon the dosage, and in medical practice, concentrations below toxic levels are utilized. <sup>(5)</sup> Its advantages have been substantiated in various conditions, including sepsis, cerebrovascular disease, joint diseases such as osteoarthritis, and others. <sup>(4)</sup>

Since 2003-2004, new services and technologies have been introduced targeting Primary Health Care. In February 2017, the ozone therapy service was inaugurated at the Isabel Rubio Díaz polyclinic in the Los Palacios municipality. This service has extended its application to a diverse spectrum of clinical conditions, with musculoskeletal disorders being particularly noteworthy. The objective of this research is to characterize the utilization of rectal ozone therapy in patients with osteoarthritis.

## METHODS

A descriptive cross-sectional study was conducted at the Ozone Therapy Service of the Isabel Rubio Díaz Polyclinic in San Diego de los Baños, Los Palacios, Pinar del Río, from January to December 2019.

### *Universe*

The universe included a total of 101 patients diagnosed with osteoarthritis who received care at the Ozone Therapy Service of the Isabel Rubio Díaz Polyclinic between January and December 2019.

### *Sample*

A total of 84 patients aged 40 and older (given that the presentation of the condition is more prevalent in this age group), were selected from the study population based on the inclusion criteria.

### *Inclusion criteria*

- Informed consent
- Absence of contraindications for ozone therapy.
- Age of 40 years and older.

### *Exclusion criteria*

- Failure to meet the inclusion criteria.
- Acute or decompensated chronic diseases.
- Depauperate patients with high levels of oxidative stress.
- Pregnancy.
- Anticoagulant therapy (precaution)
- Cognitive impairment that impedes cooperation with the study.

### *Variables*

Age, sex, degree of disability, treatment response and adverse reactions.

Degree of disability: assessed through the utilization of the Health Assessment Questionnaire (HAQ), which

was adapted according to the research objectives.

The HAQ score can vary from 0 (indicating no disability) to 3 (indicating maximum disability). In instances where a specific item is left unanswered, the highest value from the remaining items within the same category is assigned. If one or two complete categories lack responses, the sum of the remaining 7 or 6 categories is divided by 7 or 6, respectively, to derive the mean value, which falls within the range of zero to three [0-3].

A questionnaire with fewer than 6 completed categories is deemed invalid.

No disability: 90 % or more of items evaluated without any difficulty.

Mild disability: 75 - 89 % of items evaluated without any difficulty.

Moderate disability: 50 - 74 % of items evaluated without any difficulty.

Severe disability: less than 50 % of items evaluated without any difficulty.

#### *Treatment response*

- Satisfactory: marked improvement or complete resolution of symptoms; physical examinations and/or required complementary tests demonstrate improvement, absence of adverse reactions, no functional impairment in the affected joint, and an assessment indicating mild disability or no disability.
- Unsatisfactory: symptoms remain stable or worsen, physical examinations and/or required complementary tests do not indicate improvement, and adverse reactions may or may not be present. Functional impairment in the affected joint persists, and the assessment indicates moderate or severe disability.

#### *Techniques and procedures*

The transrectal medical ozone treatment consisted of a total of 20 sessions, administered at a rate of 5 sessions per week. It involved the rectal administration of ozone using syringes, with a volume of 150 mL and an ozone concentration of 15 µg/mL for the initial 5 sessions, 200 mL with an ozone concentration of 20 µg/mL for the subsequent 10 sessions, and 250 mL with an ozone concentration of 25 µg/mL for the final 5 sessions.

The data were extracted from patients' health records and processed using summary statistics for qualitative variables. Absolute and relative percentages were computed. Chi-square statistics were employed when assessing the presence of statistically significant associations between causal and resultant factors. A  $p$ -value  $\leq 0,05$  was considered indicative of statistical significance.

#### *Ethical aspects*

Participants were informed of their voluntary participation and the option to withdraw from the study at any point without repercussions. They were also assured that the results would be utilized anonymously for the scientific community.

## RESULTS

**Table 1.** Distribution of patients treated with ozone therapy by age and sex at the Isabel Rubio Díaz Polyclinic, 2019.

Age groups	Female		Male		Total	
40 - 49	2	3,0	1	5,2	3	3,6
50 - 59	21	32,4	7	36,9	28	33,3
60 and older	42	64,6	11	57,9	53	63,1
Total	65	77,4	19	22,6	84	100

Source: Personal health records.  $X^2 = 0,39$ ;  $P = 0,821725701$ .

The female sex exhibited a predominance (77,4 %), as did individuals aged 60 and older (63,1 %), although the latter was not significant (table 1).

**Table 2.** Distribution of patients by affected joints

Joints (n = 84)	N	%
Hands	84	100
Knees	80	95,2
Hips	62	73,8
Cervical Spine	43	51,1
Lumbar Spine	38	45,2
Other joints	26	43,3

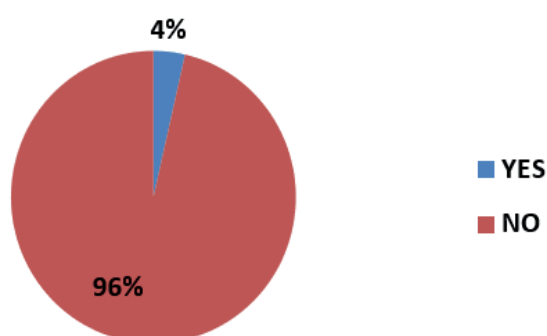
The most commonly affected joints were the hands in 100 % of cases, followed by the knees in 95,2 %. Subsequently, the hips, cervical spine, and lumbar spine were affected, in that order (table 2).

<b>Table 3.</b> Distribution of patients by degree of disability before and after treatment				
Degree of disability	Before		After	
No disability	-	-	19	22,7
Mild disability	18	21,4	49	58,3
Moderate disability	56	66,7	14	16,7
Severe disability	10	11,9	2	2,3
Total	84	100	84	100
<b>Source:</b> Personal health records. $\chi^2 = 63,88$ ; $P = 8.7222 \times 10^{-14}$				

Table 3 illustrates the distribution of patients based on their degree of disability before and after the treatment. Initially, all patients presented some level of disability, with moderate disability being the most prevalent at 66,7 %, followed by mild disability at 21,4 %. However, following the completion of the treatment, 19 patients (22,7 %) were found to have no disability, and only 2 patients still exhibited severe disability (2,3 %). These outcomes were statistically highly significant with a p-value of <0,005.

<b>Table 4.</b> Treatment response		
Response	N	%
Satisfactory	68	81,0
Unsatisfactory	16	19,0
Total	84	100

Table 4 presents a comparison of the treatment response with the patient's initial condition. The results indicate that 81,0 % of the patients exhibited a satisfactory response following the treatment.



**Figure 1.** Adverse reactions

Only 4% of the patients experienced an adverse event (figure 1).

## DISCUSSION

The predominance of certain age groups aligns with findings in the existing literature concerning the studied condition. This condition is recognized as a degenerative joint disease, and the prevalence of which escalates with advancing age. It exhibits a higher incidence in males before the age of 45, while a significant increase is observed in females after the age of 55, as is evident in the data presented in this study. It is important to note that the risk of gonarthrosis and coxarthrosis surges in women post-menopause, contributing to its ranking as the fourth leading cause of morbidity among females worldwide. <sup>(6,7,8)</sup>

Research conducted by the Ozone Research Center in Cuba <sup>(9,10)</sup> has provided evidence that ozone can serve as a therapeutic modality for numerous medical conditions. This is grounded in the physiological effects that ozone therapy elicits in the human body, including the regulation of oxidative stress associated with hundreds of diseases, enhancement of oxygen metabolism, the modulation of the immune system, and broad-spectrum germicidal properties. <sup>(11,12)</sup>

The results concerning joint preferences, particularly in the interphalangeal joints, are consistent with the literature under review <sup>(1)</sup>, which indicates that the predilection for joint involvement is prominently observed

in the proximal and distal interphalangeal joints (Bouchard's and Heberden's nodes). Nevertheless, it is worth noting that an increase in body weight, contributing to obesity, amplifies the susceptibility to osteoarthritis, especially in the knee, hip, and lumbar spine. This is primarily attributed to structural alterations in bone support leading to malalignment of the affected joints. <sup>(1,8)</sup>

The pain and stiffness experienced by these patients in their joints can reach a level of intensity that significantly impairs their activities of daily living. This can lead to the development of depressive states and sleep disorders. These disabilities exert a substantial impact on the patients' quality of life and productivity. Furthermore, from an economic standpoint, the burden imposed on both patients and healthcare systems is comparable to that associated with rheumatoid arthritis.

The treatment response outcomes were slightly lower in this study compared to the findings reported by Trujillo Pérez *et al.* <sup>(10)</sup>, who observed an improvement rate of 83,3 % in patients with ulcerative colitis treated with ozone. Conversely, Herrera Santos *et al.* <sup>(11)</sup> documented an improvement rate of 85 % in patients with herniated discs.

Concerning adverse reactions, in this case, three patients experienced minimal rectal bleeding, seemingly attributed to the manipulation of the rectal catheter in individuals with heightened sensitivity of their mucous membranes.

These results exemplify the efficacy and minimal side effects associated with ozone therapy as a therapeutic modality for a range of clinical conditions. <sup>(4)</sup> Comparable findings have been corroborated in the studies under review. <sup>(11,12)</sup>

As noted by Padilla Díaz *et al.* <sup>(13)</sup>, ozone therapy is not a panacea; it exhibits specific indications in which it demonstrates remarkable therapeutic success for certain conditions, while for others, its efficacy is moderate, and there are situations in which it is not considered useful.

Adverse reactions were reported by only three patients (mild rectal bleeding). Importantly, these reactions did not disrupt the treatment regimen, as they were promptly addressed and resolved. The underlying cause was attributed to minor mucosal traumas resulting from rectal probe manipulation, particularly in individuals with heightened rectal mucosal sensitivity. Once treated it, these adverse events did not impact the ongoing treatment.

## CONCLUSIONS

Rectal ozone therapy has exhibited its efficacy with minimal adverse reactions among osteoarthritis patients, rendering it a recommended therapeutic alternative.

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#### CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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