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ORIGINAL

The benefits of adjuvant rectal ozone therapy in children with cerebral palsy

Utilidad de la ozonoterapia rectal adyuvante en niños con parálisis cerebral

Sandra Haidee Hernández García[1], Santa González Corrales[2], Yuselys de la Caridad Cordero Cabrera[1], Bárbara del Rosario Hernández Bravo[2], Aimara García Martínez[1]

[1]Universidad de Ciencias Médicas de Pinar del Río, Hospital Pediátrico Provincial Docente "Pepe Portilla". Pinar del Río, Cuba.
[2]Universidad de Ciencias Médicas de Pinar del Río, Facultad de Ciencias Médicas "Dr. Ernesto Guevara de la Serna". Pinar del Río, Cuba

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Corresponding author:
Sandra Haidee Hernández García

ABSTRACT

Introduction: cerebral palsy is the most common cause of physical disability in children. Preclinical and clinical studies support rectal ozone therapy as an adjunctive treatment to reduce spasticity and improve quality of life in children with spastic cerebral palsy.
Objective: to determine the efficacy of adjunctive rectal ozone therapy in children with cerebral palsy.
Method: a quasi-experimental before-and-after study without a control group was conducted in 49 children with cerebral palsy (GMFCS I–IV), aged 1 month to 18 years, treated in Pinar del Río, Cuba (January 2021–December 2024). Rectal ozone (15–25 µg/mL, volume based on age) was administered in 20 daily sessions every 3 months, four cycles per year.
Results: preschoolers and school-aged children predominated, indicating a delay in the initiation of treatment. Sleep, feeding, and immune patterns improved in the majority. Spasticity decreased more in younger children.
Conclusions: rectal ozone therapy as an adjunct to standard rehabilitation was safe and well-tolerated, with no serious adverse events. It was associated with clinically and statistically significant improvement in quality of life, sleep, feeding, and reduced illness.

Keywords: Medical Ozone; Rectal Ozone Therapy; Cerebral Palsy; Pediatrics; Quality of Life.

RESUMEN

Introducción: la parálisis cerebral es la causa más común de discapacidad física infantil. Estudios preclínicos y clínicos avalan la ozonoterapia rectal como terapia adyuvante para reducir la espasticidad y mejorar la calidad de vida en niños con parálisis cerebral espástica.
Objetivo: identificar la utilidad de la ozonoterapia rectal adyuvante en niños con parálisis cerebral.
Método: estudio cuasi-experimental tipo antes/después, sin grupo control, en 49 niños con parálisis cerebral (GMFCS I-IV), de 1 mes a 18 años, tratados en Pinar del Río, Cuba (enero 2021-diciembre 2024). Se administró ozono rectal (15-25 µg/ml, volumen según edad), 20 sesiones diarias cada 3 meses, cuatro ciclos al año.
Resultados: predominaron preescolares y escolares, evidenciando retraso en el inicio del tratamiento. Mejoraron los patrones de sueño, alimentación e inmunológicos en la mayoría. La espasticidad disminuyó más en los niños de menor edad.
Conclusiones: la ozonoterapia rectal como adyuvante a la rehabilitación estándar fue segura y bien tolerada, sin eventos adversos graves. Se asoció con mejoría clínica y estadísticamente relevante en calidad de vida, sueño, alimentación y reducción de enfermedades.

Palabras clave: Ozono Médico; Ozonoterapia Rectal; Parálisis Cerebral; Pediatría; Calidad de Vida.

INTRODUCTION

Cerebral palsy (CP) is a heterogeneous group of permanent movement and posture disorders that limit activity and is attributed to nonprogressive abnormalities that occur during the development of the brain of a fetus or young child. [1,2,3] These motor disorders are frequently accompanied by sensory and cognitive impairments, communication and behavioral disorders, epilepsy, and secondary musculoskeletal problems.

The global incidence of cerebral palsy ranges from 1,5 to 3 per 1 000 newborns. It has a multifactorial origin and results from various events that may occur during the prenatal, perinatal, or postnatal period. The main causes, in order of frequency, are prematurity (78 %), intrauterine growth restriction (34 %), intrauterine infection (28 %), antepartum hemorrhage (27 %), severe placental pathology (21 %), and multiple birth (20 %). [2,3,4]

Its prevalence in developed countries remains stable, but the life expectancy of these children has increased, meaning that an increasing number of children and adults with cerebral palsy (CP) will require care, with the medical, social, educational, and economic implications that this entails. [5]

The management of this condition involves various types of treatments: physical therapy, occupational therapy, medications for spasticity (such as botulinum toxin or baclofen), and surgery. [2] The use of complementary therapies aimed at improving functionality, reducing comorbidities, and enhancing the quality of life for these patients and their families is a priority. However, these interventions have limitations, such as systemic side effects, invasiveness, high cost, or the need for repeated procedures, which drives the ongoing search for safe and effective adjuvant therapies.

Ozone therapy, specifically the rectal route, is emerging as a biooxidative therapeutic modality of growing interest. Medical ozone, a mixture of oxygen and ozone in precise concentrations, exerts biological effects that are modulated through reactions with blood components and body fluids, generating reactive oxygen species (ROS) and lipid peroxidation products at therapeutic doses (ozonoids) that act as redox messengers.

As noted by Menéndez et al. [6], controlled oxidative stress induced by ozone activates cellular signaling pathways that culminate in the upregulation of endogenous antioxidant enzymes (superoxide dismutase and glutathione peroxidase) and the modulation of the inflammatory response. This mechanism, known as oxidative hormesis, is the basis for its anti-inflammatory, immunomodulatory, and analgesic properties, as well as its ability to improve energy metabolism and tissue oxygenation. The rectal route is particularly advantageous in pediatric patients because of its minimally invasive nature, good tolerability, and efficient systemic absorption of ozone through the hemorrhoidal venous plexus.

Recent studies[7,8,9] have explored its use in inflammatory bowel diseases, immunodeficiency syndromes, and as an adjunct in neurological diseases. Given the pathophysiology of CP, which includes chronic inflammatory components, oxidative stress, and alterations in muscle and neuronal metabolism, rectal ozone therapy (ROT) could theoretically intervene in these underlying processes.

Smith et al. [10] linked oxidative stress and chronic inflammation as perpetuating mechanisms in COPD. They explain why, from the perspective of the underlying pathology, an antioxidant/anti-inflammatory therapy (such as ozone) might be beneficial. In his study of complementary therapies for CP, the aforementioned author concluded that the evidence regarding ozone therapy is promising but of low methodological quality, highlighting the lack of randomized clinical trials.

On the basis of the observations of Smith et al. [10], the administration of medical rectal ozone, through improved tissue oxygenation, modulation of oxidative stress, and the release of neurotrophic factors, may create a favorable cerebral microenvironment to enhance the neuroplasticity mechanisms inherent in the developing central nervous system, which translates to clinical improvement in children with static encephalopathy.

The aim of this study was to describe the effects of adjuvant rectal ozone therapy in children with cerebral palsy.

METHOD

A quasiexperimental, before-and-after study without an equivalent control group was conducted on the results of ozone therapy in children with spastic cerebral palsy (GMFCS levels I–IV) at the "Pepe Portilla" Provincial Teaching Pediatric Hospital in Pinar del Río between January 2021 and December 2024.

The study population consisted of patients between one month and 18 years of age referred to the Ozone Therapy Clinic of the Pediatric Specialties Polyclinic at the "Pepe Portilla" Provincial Teaching Pediatric Hospital in Pinar del Río, Cuba, between January 2021 and December 2024, with a diagnosis of spastic cerebral palsy (GMFCS levels I–IV).

Patients with other types of paralysis, severe malnutrition, anemia, platelet disorders, hyperthyroidism, inflammatory bowel disease, or active anorectal pathology; glucose-6-phosphate dehydrogenase deficiency (favism); uncontrolled epileptic seizures; or who had received ozone therapy during the previous 6 months were excluded. The exclusion criteria for the study were receiving fewer than 15 treatment sessions per cycle or failing to complete 4 cycles within a year. The final sample consisted of 49 children.

An OZOMED mini device was used. Medical ozone was administered rectally. Concentrations of 15, 18, 20, and 25 µg/ml were used, with volumes adjusted according to the patient's age. Daily applications were prescribed for a total of 20 sessions every 3 months to complete four cycles within a year.

The following variables were collected: feeding patterns, weight gain, sleep patterns, clinical response regarding immune status (based on illness reports provided by parents), improvement in spasticity, and results from the PedsQL™ (*Pediatric Quality of Life Inventory*) questionnaire. [12]

To determine improvement in spasticity, changes in the modified Ashworth scale score were recorded for the adductors and calves. [11] The severity of the response was rated on a scale of 0 to 4 before starting treatment, at the end of the 4 cycles of the first

year, and at 2 years.

The data obtained were stored in a database. Descriptive statistics were used for data analysis.

Prior to the intervention, informed consent was obtained from the patient's parents or guardians. Similarly, this study stems from an institutional project approved by the medical ethics committee and the scientific council of the institution. This research complied with the principles and recommendations of the Helsinki Declaration on Biomedical Research and the recommendations for physicians in research reviewed by the 29th Assembly in Tokyo and the 35th in Vienna and ratified at the 41st World Assembly held in Hong Kong in 1991.

RESULTS

The distribution of children with CP by sex and age, as shown in Table 1, illustrates that in the sample selected for the study, no differences were found between male and female patients. The greatest number of children were in the 1–5-year-old and 6–10-year-old age groups.

Table 1. Distribution of the study sample by sex and age group

Age groups	Gender		Total	%
	Male	Female		
Under 1 year	3	1	4	8,0
1–5	12	10	22	45,0
6–10	10	11	21	43,0
11–15	1	0	1	2,0
> 15 years	0	1	1	2,0
Total	26	23	49	100

Before ozone therapy, 29 (60,0 %) children exhibited abnormal eating patterns. With respect to sleep, 48 (98,0 %) patients exhibited abnormalities. Twenty-nine (60,0 %) children had a compromised immune system.

Table 2. Distribution of dependent variables before ozone therapy

Dependent variables	Before ozone therapy	
	No.	%
Ineffective eating pattern	29	60,0
Disturbed sleep pattern	48	98,0
Impaired immune status	29	60,0

Analysis of the data in Table 3 reveals that 45 (92,0 %) of the children studied, according to the Ashworth scale—which is clinically assessed on the basis of motility, strength, tone, and muscle atrophy—exhibited spasticity. No cases were diagnosed in children under 1 year of age

Table 3. Spasticity patterns versus age in patients with CP

Age group (n= 49)	Presence of spasticity prior to ozone therapy	
	No	%
1–5	22	49,0
6–10	21	47,0
11–15	1	2,0
Over 15 years old	1	2,0
Total	45	92,0

Eating patterns gradually improved in all the children after treatment (four sessions per year) to 100 %. With respect to sleep, the results were similar. 47 (95,0 %) had improved by the fourth treatment cycle. Improvement in immune status was evident; only two patients required specialized medical care during the fourth ozone therapy treatment cycle.

Table 4. Behavior of dependent variables after four cycles of ozone therapy

Dependent variables	Cycles			
	First	Second	Third	Fourth
Feeding pattern	32 (65,3 %)	36 (73,4 %)	37 (75,5 %)	49 (100 %)
Sleep pattern	30 (61,2 %)	45 (92,0 %)	45 (92,0 %)	47 (95,0 %)
Immune status	30 (61,2 %)	40 (82,0 %)	45 (92,0 %)	47 (95,0 %)

The data in Table 5 show that there was no variation in the variables studied when the variables were evaluated two years after the start of ozone therapy treatment.

Table 5. Behavior of variables two years after ozone therapy treatment

Variables	No.	%
Dietary pattern	48	98,0
Sleep pattern	47	95,0
Immune status	45	92,0

Analysis of the data in Table 6 revealed that muscle tone improved in the children studied according to the Ashworth scale, which was clinically assessed by motility, strength, tone, and muscle atrophy; in 36 (73,5 %) cases, spasticity decreased, whereas this was not the case in older patients.

Table 6. Spasticity trends versus age in patients treated with ozone therapy

Age group	Decrease in spasticity after ozone therapy	
	No.	%
1–5 (N°- 22)	18	82,0
6–10 (N°- 21)	15	71,0
11–15 (N°- 1)	0	0
Over 15 years old	0	0
Total	33	67,3

One patient experienced mild abdominal distension, which was resolved by reducing the volume in subsequent treatment sessions.

Table 7. Adverse events during ozone therapy treatment

Adverse events	No.	%
Mild	1	2,0
No events	48	98,0
Total	49	100,0

The highest percentage of parents in the "happy" category was found in the spasticity dimension

Table 8. Quality of life assessment

Dimensions	Very unhappy	Unhappy	Neither happy / Neither happy nor unhappy	Happy	Very happy
Eating habits	0	0	3 (6,0 %)	38 (77,5 %)	8 (16,3 %)
Sleep pattern	0	0	5 (10,2 %)	24 (49,0 %)	20 (41,0 %)
Immune status	0	0	2 (4,0 %)	30 (61,2 %)	17 (3,0 %)
Spasticity	0	2 (4,0 %)	1 (2,0 %)	44 (90,0 %)	2(4,0 %)

DISCUSSION

No differences were observed in terms of sex in the study. The greatest number of children were between the ages of 1 and 10 years. The authors believe this is due to a lack of awareness of this technique in early intervention clinics. However, it is necessary to consider the child's prenatal and perinatal history, which may suggest that CP should begin rehabilitation treatment early. [13]

CP affects the development of various systems that regulate the body's vital functions, such as sucking, chewing, swallowing, and breathing, which affect the feeding processes and nutritional status of children with this condition. [14] However, these children have improved many of these functions because of reduced secretions, improved muscle tone and posture, etc. Ozone is a natural therapy that, owing to its antioxidant properties, harmonizes the body's energy and promotes metabolism. [6]

The questionnaire administered to parents or guardians explains the importance of making mealtime enjoyable—by creating a calm atmosphere, correcting the child's posture effectively and effortlessly, and letting them know what they will be eating—which helps ensure that this basic activity is carried out in the best possible way.

Sleep patterns improved during both years of treatment; this had a positive impact on their quality of life, as the child felt better and slept more soundly. After ozone treatment, people report feeling calmer, more relaxed, and better equipped to handle daily

tasks. [15] Children cannot verbally express these sensations, but their mothers perceived them and conveyed them to the researchers.

The application of ozone in neurology has been explored in stroke, multiple sclerosis, and dementia, with reports of improvement in parameters of fatigue, cognition, and functionality. In pediatrics, its use is becoming more common. A case series published by Fernández et al. [16] in *the Spanish Journal of Ozone Therapy* evaluated OTR in children with autism spectrum disorders and reported notable improvements in sleep regulation, eye contact, and food tolerance, with no significant side effects. These findings, although preliminary, open the door to research into other neurodevelopmental disorders, such as CP. The rationale for the rectal route lies in its efficacy and safety; as stated in the clinical protocol of the Spanish Society of Ozone Therapy[17], rectal insufflation is the systemic route of choice in children because of its rapid absorption, avoiding the stress of injections and carrying a minimal risk profile.

From the first treatment cycle, the children fell ill less frequently. No differences were observed in the second year; in the authors' opinion, this is due to the anti-infective properties of ozone. - Ozone therapy is a natural, safe, and feasible therapeutic modality that helps strengthen the immune system, since as it enters the body, it oxygenates cells throughout the body; this cellular oxygenation improves their function, "injecting energy" into them, which strengthens the immune system. [6]

Therapeutic ozone revitalizes cells' natural defense systems and stimulates enzymes that regulate proper cellular nutrition, thereby slowing cellular aging. [18]

Notably, ozone can be generated in vivo in activated neutrophils, as this substance plays a physiological role not only as a bactericidal agent but also as a potential component of the physiological mechanisms that amplify inflammation and activate associated genes. [19]

Díaz Luis et al. [20] administered 42 sessions of rectal ozone insufflation to 18 children with impaired phagocytosis; 94 % showed clinical improvement, as evidenced by a reduction in the number of infections, increased appetite, and resolution of the reported asthenia. These results are consistent with those obtained in the present study.

The significant reduction in intercurrent infections is consistent with strong evidence of the immunomodulatory properties of ozone. As proposed by Menéndez's model[6], ozone therapy acts as a bidirectional immunomodulator: it stimulates a weak immune response and attenuates a hyperactive response. This is particularly relevant in children with CP, who often present with relational immunosuppression due to malnutrition, reduced mobility, and chronic medication use.

Spasticity is the most common muscle tone disorder observed in patients with neurological conditions. It is characterized by a baseline increase in postural tone. It is present in 70–80 % of cases, with hypertonia (abnormal increase in muscle tone) as the primary feature of involvement of the pyramidal tract and cerebral cortex. [21] In CP, it is not a static phenomenon. It arises from an imbalance between inhibitory (primarily GABA-mediated) and excitatory pathways at the spinal and supraspinal levels, secondary to damage to the corticospinal tract. This leads to hyperexcitability of the myotatic reflex. Furthermore, the spastic muscle undergoes structural changes, such as fibrosis, increased connective tissue, and chronic ischemia due to permanent contraction, creating a vicious cycle of pain-immobility-increased spasticity.

Rectal ozone therapy could intervene at multiple levels of this pathophysiological chain:

- At the systemic/immunological level, it induces cytokine modulation, reducing the levels of proinflammatory cytokines (TNF-α, IL-1β, and IL-6) and increasing the levels of anti-inflammatory cytokines (IL-10 and TGF-β). This is crucial, as chronic inflammation sensitizes neurons in the anterior horn. A study by Bocci et al. [22] in *Mediators of Inflammation* revealed that ozone acts as a physiological immunomodulator that is capable of restoring the homeostasis of the redox system and the immune response.
- At the local muscular level, it improves tissue oxygenation through the Bohr effect (shifting of the oxyhemoglobin dissociation curve), increasing the release of O_2 in hypoxic tissues such as spastic muscle. It also reduces local acidosis and improves blood rheology, promoting perfusion.
- At the central/peripheral neurological level, the reduction in oxidative stress and the release of neurotrophic factors could affect the plasticity of residual circuits. The rectal route allows for efficient absorption through the hemorrhoidal plexus, achieving therapeutic systemic concentrations.

A Cuban quasiexperimental study by Pérez et al. [23] involving 25 children revealed that following a course of rectal ozone therapy, 84 % of patients experienced clinical improvement in muscle tone and a reduction in the use of antispastic medications. Another Mexican observational study[24] revealed a statistically significant reduction in the number of hospitalizations for pneumonia in the group treated with ozone during a one-year follow-up.

In terms of the clinical presentation of the children in this study, spasticity was the primary factor, but fortunately, their improvement was evident after the use of medical ozone, which had a positive impact on their quality of life and that of their families.

However, it is important to note that in pediatric patients with cerebral palsy, spasticity cannot be diagnosed until the child is at least two years old. It is recommended to allow for the central nervous system to mature and for functional abilities to develop in this age group prior to the diagnosis of this condition. [25]

The observed improvement in spasticity could be explained by the dual action of ozone: centrally, by modulating neuronal excitability through a reduction in oxidative stress and the release of neurotrophins; and peripherally, by improving oxygenation and the elasticity of spastic and ischemic muscle tissue. This finding is crucial, as spasticity is among the main determinants of disability and pain.

An improvement in quality of life, particularly in terms of better nutrition and sleep; fewer illnesses; and reduced spasticity, is fundamental. CP affects the entire family, and a therapy that alleviates the burden of care and the child's suffering is of immense

value. The reduction in medical care confirms the potent immunomodulatory effect of ozone reported in other diseases; this could translate into fewer interruptions in rehabilitation, less use of antibiotics, and better overall health.

Our results are consistent with the theory of oxidative hormesis and with preclinical evidence. As a recent review on oxidative therapies concludes, ozone therapy, by inducing an adaptive response to stress, can rebalance biological systems that are dysregulated in chronic diseases such as cerebral palsy. [6]

CONCLUSIONS

Rectal ozone therapy, as an adjunct to standard rehabilitation, proved to be a safe and well-tolerated intervention in children with spastic cerebral palsy, with no serious adverse events reported. The intervention was associated with a statistically and clinically significant improvement in the quality of life of the children and their families, particularly in terms of improved eating, sleep, and reduced illness.

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CONFLICT OF INTEREST

The authors declare that they have no financial or nonfinancial conflicts of interest.

AUTHORSHIP CONTRIBUTIONS

Conceptualization: Sandra Haidee Hernández García, Santa González Corrales, Yuselys de la Caridad Cordero Cabrera, Bárbara del Rosario Hernández Bravo, Aimara García Martínez.

Data curation: Sandra Haidee Hernández García, Santa González Corrales**,** Yuselys de la Caridad Cordero Cabrera, Aimara García Martínez.

Formal analysis: Sandra Haidee Hernández García, Santa González Corrales.

Research: Sandra Haidee Hernández García, Santa González Corrales**,** Yuselys de la Caridad Cordero Cabrera, Bárbara del Rosario Hernández Bravo, Aimara García Martínez.

Methodology: Sandra Haidee Hernández García, Santa González Corrales.

Administration: Sandra Haidee Hernández García, Santa González Corrales**,** Yuselys de la Caridad Cordero Cabrera, Bárbara del Rosario Hernández Bravo.

Supervision: Sandra Haidee Hernández García, Santa González Corrales.

Validation: Sandra Haidee Hernández García, Santa González Corrales, Yuselys de la Caridad Cordero Cabrera

Visualization: Sandra Haidee Hernández García, Yuselys de la Caridad Cordero Cabrera.

Drafting - original draft: Sandra Haidee Hernández García, Santa González Corrales, Yuselys de la Caridad Cordero Cabrera, Bárbara del Rosario Hernández Bravo, Aimara García Martínez.

Writing, revision, and editing: Sandra Haidee Hernández García and Santa González Corrales.

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