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ORIGINAL

Effectiveness of rectal ozone therapy in patients with sensorineural hearing loss

Efectividad de la ozonoterapia rectal en pacientes con Hipoacusia Neurosensorial

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ABSTRACT

Introduction: sensorineural hearing loss is defined as the loss of hearing capacity, producing a difficulty or impossibility to hear normally, where there is damage to the inner ear or the auditory nerve. Medical ozone has proven biological effects that make it very useful in this pathology, since it intervenes in the intracellular metabolism regulating its redox state.
Methods: a descriptive, prospective and longitudinal study was carried out in the Natural and Traditional Medicine Service of the Dr. "León Cuervo Rubio" Clinical and Surgical Teaching Hospital, with the Otorhinolaryngology Service of the General Hospital Abel Santamaría Cuadrado to evaluate the effectiveness of rectal ozone therapy in patients with Sensorineural Hearing Loss. The sample consisted of 35 patients who met the inclusion criteria. A traditional clinical history was taken and an audiometric evaluation by the ENT specialist was recorded before and after treatment with prior informed consent.
Results: the nosological entity was predominantly male and between 45 and 54 years of age. The most significant risk factors were arterial hypertension and diabetes mellitus, 54,20 % had good response to treatment.
Conclusions: rectal ozone therapy proved to be effective in patients with sensorineural hearing loss.

Keywords: Sensorineural Hearing Loss; Rectal Ozone Therapy.

RESUMEN

Introducción: la Hipoacusia neurosensorial se define como la pérdida de la capacidad auditiva, produciéndose una dificultad o imposibilidad para oír normalmente, donde existe daños en el oído interno o el nervio auditivo. El ozono médico posee efectos biológicos demostrados que lo hacen muy útil en esta patología, pues interviene en el metabolismo intracelular regulando su estado redox.
Métodos: se realizó un estudio descriptivo, prospectivo y longitudinal en el Servicio de Medicina Natural y tradicional del Hospital Clínico Quirúrgico Docente Dr. "León Cuervo Rubio", con el Servicio de Otorrinolaringología del Hospital General Abel Santamaría Cuadrado para evaluar la efectividad de la ozonoterapia rectal en los pacientes con Hipoacusia Neurosensorial. La muestra fue de 35 pacientes que cumplieron con los criterios de inclusión. Se les realizó historia clínica tradicional registrando valoración audiométrica del otorrino antes y después del tratamiento con previo consentimiento informado.
Resultados: la entidad nosológica predomino en el sexo masculino y las edades entre los 45 y 54 años. Los factores de riesgo más significativos fueron la hipertensión arterial y la diabetes mellitus, un 54,20 % tuvo buena respuesta al tratamiento.
Conclusiones: la ozonoterapia rectal resultó ser efectiva en pacientes con Hipoacusia neurosensorial.

Palabras clave: Hipoacusia Neurosensorial; Ozonoterapia Rectal.

INTRODUCTION

As the global population ages, there is a rising prevalence of individuals experiencing hearing impairment. The growth rate in the population aged 65 and older is anticipated to range from 18 % to 50 % during the period from 2010 to 2020 across all regions worldwide. Consequently, the prevalence of hearing loss is expected to expand in concordance with these demographic shifts.[1]

In older adults, as reported by the Pan American Health Organization, the prevalence of hearing loss varies, ranging from 30 % among those aged 65 and above to 60 % in individuals aged 85 and older. A recent review of available studies conducted by the World Health Organization (WHO) reveals the highest prevalence of disabling hearing loss in South Asia, the Asia-Pacific region, and Sub-Saharan Africa.[1] Among the elderly population in Chile, data from the National Health Survey indicates that the prevalence of hearing loss is estimated at 52,4 % in individuals aged 65 and older during the 2009-2010 survey. This figure escalates to 91,1 % among those aged 80 and above, as per the data collected in the National Health Survey of 2003.[2]

Aging in Cuba constitutes the foremost demographic challenge, with a proportion reaching 19,2 % of the population aged 60 years and above. It is anticipated that by 2025, this segment will exceed 25 % of the overall population, positioning Cuba among the Latin American nations with the most advanced aging population. Hearing loss stands as one of the most prevalent chronic conditions among the elderly, with prevalence rates ranging from 25 % to 40 % in individuals aged 65 years and older. This prevalence continues escalating with progressive aging.[1]

Hearing loss is defined as the diminishment of auditory capacity, leading to difficulty or inability to perceive sounds at a normal level. This loss can manifest unilaterally, impacting only one ear, or bilaterally, affecting both ears. The evaluation of hearing function can be conducted through straightforward audiometric tests, facilitating the assessment of the degree of auditory impairment. The severity of hearing loss is quantified in decibels (dB), representing the lowest threshold at which various sound frequencies become detectable.[3,4]

In addition to classifying hearing loss by its severity in decibels, it is typically categorized based on the anatomical site of the lesion; conductive hearing loss is caused by diseases or obstructions within the outer or middle ear, impeding the transmission of sound waves to the inner ear; this affects all sound frequencies and often exhibits a favorable response to medical or surgical interventions, as well as hearing aids, contingent upon the underlying cause.[5]

Sensorineural hearing loss, conversely, ensues when damage occurs in the inner ear or the auditory nerve, resulting in irreversible impairment with a frequent impact on specific sound frequencies. These sounds may be perceived with distortion, and depending on the degree of hearing loss, the restoration of hearing may necessitate the use of a hearing aid or cochlear implant. Mixed hearing loss, on the other hand, combines characteristics of both conductive and sensorineural hearing loss, arising from complications in both the external or middle ear and the inner ear. Lastly, central hearing loss pertains specifically to lesions within the auditory centers of the brain.[5,6]

The causes of hearing loss and deafness can be categorized as congenital or acquired. Congenital causes manifest as hearing loss either at birth or in the postnatal period. In these cases, hearing impairment may be attributed to both hereditary and non-hereditary factors, as well as perinatal and neonatal complications. Such complications may encompass maternal infections during pregnancy, such as rubella or syphilis, low birth weight, birth asphyxia (lack of oxygen during childbirth), inappropriate administration of specific medications such as aminoglycosides, cytotoxic drugs, antimalarials, and diuretics, in addition to severe neonatal jaundice that can lead to damage of the neonate's auditory nerve.[3,6]

The clinical profile of this condition can exhibit a wide spectrum, spanning from inconspicuous mild hearing loss to abrupt deafness, prompting patients to seek medical evaluation. Additional possible manifestations encompass unilateral tinnitus and a sensation of aural fullness or blockage, sometimes accompanied by peripheral vertigo. Approximately one-third of patients awaken with the condition already established.[7] For the diagnostic of hearing loss, a comprehensive audiological examination is crucial, incorporating otoscopy, pure-tone audiometry, instrumental audiometry, and electronic audiometry.

In the context of liminal tone audiometry, a simultaneous decline is noted in both auditory pathways, with intensities surpassing 30 dB at three consecutive frequencies. Supraliminal tonal testing serves as a valuable tool for topodiagnosis of lesions, while speech audiometry does not encompass the assessment of 100 % of phonemes. Furthermore, tympanometry results remain within the normal range.[3,5]

In the medication management of this condition, corticosteroids are commonly utilized, and their specific mechanisms of action are believed to encompass anti-inflammatory, neuroprotective, antioxidant, and anti-

apoptotic properties.[6]

Multiple modalities of Natural and Traditional Medicine are employed in the therapeutic approach to this condition. These modalities encompass acupuncture, moxibustion, auriculotherapy, herbal medicine, and ozone therapy.[8]

Ozone, discovered in 1785 by Dutch physicist Martinus Van Marum (1750-1837) who discerned its peculiar odor near electrostatic machines. However, it was not until May 1840 when the German chemist Cristian Friedrich Schonbein (1799-1868) synthetized it. Ozone possesses remarkable properties that render it highly valuable in the realm of biology and, fundamentally, in the field of medicine. The biological effects of ozone, when applied for therapeutic objectives, are diverse, including enhancements in oxygen metabolism, modulation of biological oxidative stress, broad-spectrum germicidal properties, immunomodulatory influences, and metabolic regulation.[9,10] This research proposes the utilization of these properties in the treatment of hearing loss, which stands as the most prevalent sensory deficit in human populations.

METHODS

Type of study

A descriptive, prospective, and longitudinal study was conducted at the Natural and Traditional Medicine Service of the Dr. "León Cuervo Rubio" Clinical Surgical Teaching Hospital, in collaboration with the Otorhinolaryngology Service of the Abel Santamaría Cuadrado General Hospital. The primary aim of this study was to assess the effectiveness of rectal ozone therapy in patients afflicted with sensorineural hearing loss, with their informed consent.

Definition of the universe and the sample

The universe comprised all patients referred for consultation with a diagnosis of Sensorineural Hearing Loss, while the sample specifically included 35 patients who met the predefined inclusion and exclusion criteria.

Inclusion criteria

- Patients older than 18 years.
- Willing patients to participate in the study.

Exclusion criteria

- Patients with glucose-6-phosphate dehydrogenase deficiency.
- Hyperthyroidism.
- Convulsions.
- Thrombocytopenia with hemorrhagic symptoms
- Cardiovascular instability.
- Intellectual disability.
- Use of anticoagulants.
- Pregnant women.
- Depauperate patients susceptible to ozone.
- Tumors.

Techniques and procedures

For data collection

At the initial patient consultation, a traditional medical history was systematically compiled for all participants, integrating the results of the conducted audiometric assessments.

Audiometry represents a subjective assessment, as it relies on the patient's active cooperation to indicate their ability to perceive the test tones. This characteristic renders audiometry particularly challenging when applied to patients with disabilities or children under the age of 3. The procedure necessitates that the patient be situated within an audiometric booth, with meticulous attention to the calibration of plugs, connections, and frequencies on the equipment, there should be no external noise interference, and the patient must not see the manipulation of the audiometer. Special consideration is needed when the patient experiences tinnitus, which calls for the application of pulsed-tone audiometry. Under these circumstances, the typical normal range fluctuates between 0 dB and 20 dB, with the red earpiece designated for the right ear and the blue earpiece for the left ear.[11]

This examination must be prefaced by otoscopy. Subsequent to the assessment, the results are graphically represented on an audiometric chart (audiogram). In this chart, the horizontal axis corresponds to frequencies measured in Hertz (Hz), while the vertical axis denotes the intensity, expressed in decibels (dB). The audiogram serves as a vital tool for the interpretation and classification of the degree of hearing loss.

During this initial consultation, patients were presented with an explanation of the therapeutic approach

being employed, which aligns with the principles set forth in the Madrid Declaration.[12] This declaration provides several recommendations to be adhered to prior to commencing rectal ozone therapy. These recommendations encompass the necessity of having a meal before the treatment, the maintenance of regular daily bowel movements, and the avoidance of specific substances, including vitamin C, vitamin E, Polivit, aspirin, other anticoagulants, and medications like glucosamine. It is advisable for patients to refrain from the consumption of tomatoes, guavas, or citrus fruits throughout the treatment regimen. The determination of the precise dosage was contingent on the consideration of contraindications and fundamental principles.

The treatments were administered employing the OZOMED PLUS apparatus, which provides an ozone concentration scale, allowing for the precise adjustment of concentrations in (mg/L), flow rates in (L/min), and module settings in correspondence with the prescribed dosage for each patient. It is imperative to have at one's disposal an oxygen tank equipped with the necessary accessories, a rectal probe, designed for insertion at a depth of 10 cm, a 50 mL syringe, an appropriate treatment table, gloves, bed linens, and a well-ventilated environment conforming to established safety standards. Furthermore, the patient's oxidative stress levels may be evaluated via the measurement of markers like malondialdehyde and catalase, among others. In cases where the assessment of these markers is not possible, the evaluation of the treatment's efficacy is predicated upon the patient's clinical condition.[13,14]

For processing and analysis

Description of the technique

The patient is positioned in the lateral decubitus position, ensuring that the prescribed dosage has been meticulously reviewed, and all requisite materials are readily prepared. Subsequently, the rectal probe is inserted to a depth of 10 cm, with the clamp being manipulated both prior to and following the administration of ozone gas. The patient must be instructed to retain the gas for the maximum duration possible.

The recommended treatment had a duration of four weeks, encompassing a total of 20 sessions to be administered continuously, thereby attaining hormesis and the desired biological effects. The prescribed ozone concentrations for each week were as follows: during the first week, 30 mg/L in 100 mL; for the second week, 35 mg/L in 150 mL; in the third week, 40 mg/L in 200 mL, and during the fourth week, 40 mg/L in 200 mL.[12]

Upon the conclusion of the treatment, the patient received guidance to undergo an evolutionary audiometry assessment, to be conducted by the otorhinolaryngologist. Additionally, a follow-up appointment was arranged for a traditional evaluation, enabling the assessment of the patient's response to the procedure. The response, as determined by the results, may be categorized as follows:

Good: Clinical improvement and positive changes in pure-tone audiometry.

Fair: Clinical improvement without changes in pure-tone audiometry.

Poor: No clinical improvement and no changes in pure-tone audiometry.

Statistical aspects

Descriptive statistics methods: all data were initially recorded in a database created in the Excel Software to ensure data reliability and simplify the creation of dynamic tables. Subsequently, the Epinfov statistical software was utilized for data processing, employing analysis and interpretation of the results through descriptive statistical methods tailored for parametric samples with percentage means in qualitative variables. The outcomes were presented in a tabular format.

Ethical aspects

The data gathered in the conducted research were exclusively employed for scientific purposes and will solely be disseminated in scientific events or publications. No health interventions, prompted by research, that could affect the well-being of the patients will be conducted. Furthermore, no animals will be utilized in the study, thereby ensuring that no adverse ecological impacts will be provoked.

In this research, strict adherence was maintained to the principles and recommendations established for physicians engaged in biomedical research involving human subjects. These principles were promulgated during the 18th World Medical Assembly in Helsinki in 1964 and were reaffirmed during the 41st World Assembly convened in Hong Kong in 1991. The ethical considerations enshrined in these principles encompass: respect for persons or autonomy, beneficence and non-maleficence, and justice. Every participant selected for this research was provided with clear and comprehensive explanations, ensuring a full understanding of the research's nature and the significance of its findings, with regard to the welfare of their families and society at large. Participants had complete freedom to decline participation in the study if they decided so.

RESULTS

Tabla 1. Distribution of patients with Sensorineural Hearing Loss by age and gender

Age groups	Female		Male		Total	
	No	%	No	%	No	%
25-34	1	2,85	0	0	1	2,85
35-44	2	5,71	3	8,57	5	14,29
45-54	5	14,29	7	20	12	34,29
55-64	3	8,57	7	20	10	28,57
65 and over	4	11,43	3	8,57	7	20
Total	15	42,85	20	57,15	35	100

Table 2. Risk factors in patients with Sensorineural Hearing Loss

Risk factors	No.	%
Hypertension and Diabetes Mellitus	14	40
Hypertension	9	25,71
Diabetes Mellitus	7	20
Exposure to noise	3	8,58
Acoustic Trauma	2	5,71
Total	35	100

Table 3. Distribution of patients based on treatment response

Treatment Response	No.	%
Good	19	54,20
Fair	10	28,57
Poor	6	17,14
Total	35	100

Table 1 illustrates the distribution of 35 patients afflicted with sensorineural hearing loss categorized by age group and gender. The data reveals a notable prevalence within the age group of 45 to 54 years, constituting 34,2 %, with males comprising 57,15 % of this subgroup.

Data from the WHO indicates that approximately 360 million individuals worldwide suffer from various forms of hearing impairment, leading to a disability (in moderate hearing loss), 91 % of these cases are observed among adults, with males constituting 56 % of this population. This equates to 5,3 % of the global population. However, estimations suggest that up to 15 % of the world's adult population may experience any degree of hearing loss, and this figure escalates to one-third of the population over the age of 65. Furthermore, the projected percentage growth in the global population aged 65 or older during the period spanning 2010 to 2020 is anticipated to range from 18 % to 50 % across all regions.[2]

From a Western medical standpoint, advancing age brings about changes in the ear that contribute to the onset of hearing loss, encompassing several factors, such as the stiffening of the basilar membrane within the organ of Corti, arteriosclerosis, degeneration of the organ of Corti, cilia loss, degeneration of the spiral ganglion, and perturbations in the neural regulation of the endolymph.[1]

Within the framework of Traditional Chinese Medicine (TCM), hearing loss within the reported age groups can be attributed to the depletion of the essence or Jing. This, in turn, triggers the degradation of the functions of the Zang-Fu organs, a gradual weakening of Yin, Kidney and Spleen Yang deficiency, the deterioration of Ming Men, and a disturbance in the equilibrium among the fundamental constituents.[10,15]

Studies conducted in Cuba concur with the aforementioned trends. A study led by Del Cerro and colleagues, which involved 24 patients, revealed that a substantial proportion (42 %) of the participants fell within the age range of 46 to 55 years.[13] This observation aligns with international research findings. In a study conducted by Fiorella, encompassing 53 patients with hearing impairment, the reported average age was 53,92 ± 6,46.[12]

These findings are consistent with pertinent references that elucidate a similar pattern. In a group of 151 Cuban individuals afflicted with profound bilateral sensorineural hearing loss who underwent implantation, the distribution comprised 53 % males and 47 % females.[14] In a study conducted by Toledo Valdés and colleagues, which involved 387 hearing-impaired patients aged over 60 years, a higher percentage of males (69,5 %) were affected.[1] This trend is also evident in the research sample investigated by Fiorella, in which 31 patients (58,49 %) were of the male gender.[12]

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Traditionally, this phenomenon may be explained by considering the evolution of an individual's Kidney energy, which attains full maturity by the age of 56. Following a dynamic phase of energetic abundance, a phase of decline initiates, characterized by the decline of Kidney Jing, reduced semen production, loss of muscle tone, hair, and teeth, marking the onset of senescence. Men tend to experience more frequent and pronounced essence loss over the course of their lives. This can be linked to strenuous physical labor, excessive sexual activity, and inappropriate dietary habits, among other factors, all of which contribute to the depletion of Jing.[15]

In the examined sample, the association of hypertension and diabetes mellitus as risk factors for hearing loss was predominant in 14 patients (40 %), followed by hypertension alone in 9 patients (25,71 %), and diabetes mellitus in 14 patients (20 %). Additionally, exposure to noise and acoustic trauma also contributed to the risk factors within the study population, accounting for 8,58 % and 5,71 %, respectively.

Fiorella and colleagues concur with these findings, highlighting an association between hypertension and diabetes mellitus in 14 out of 53 patients (26,42 %).[12] Zivkovic Marinkov et al.[16] conducted a study involving 80 patients aged between 40 and 60 years, affirming that Diabetes Mellitus is linked with inner ear damage, characterized by the loss of outer hair cells and elongation of wave intervals within the auditory nerve pathway. Additionally, Fanzo et al.[17], in their study, delineated the frequency and attributes of hearing loss in diabetic patients, revealing a prevalence of hearing impairment in this population, reaching 49,2 %. In an investigation encompassing 387 hearing-impaired patients aged over 60 years, vascular diseases prevailed, with hypertension (77,7 %) and diabetes mellitus (51,1 %) standing as the most frequently observed conditions.[1]

Table 3 illustrates the treatment response to rectal ozone therapy within the examined patient cohort. It is apparent that 19 patients (54,2 %) demonstrated a good response to the treatment, exhibiting positive changes in both audiometric parameters and clinical symptoms. Of the total sample, 10 patients (28,57 %) manifested a regular response to the investigational treatment, while 6 patients (17,14 %) showed no appreciable alterations in their audiometric measures or clinical symptoms.

The mechanism of action of ozone hinges on its capacity to induce a small, transient, and regulated oxidative stress (oxidative preconditioning), at therapeutic dosages. Such controlled oxidative stress serves to activate a range of depressed biological functions without instigating adverse effects. This ozone preconditioning effect can restore the perturbed redox equilibrium in the body resulting from pathological stimuli. The generated shorter-chain peroxides can permeate erythrocytes and exert a distinctive influence on their metabolism. The functional sequence, therefore, occurs through the orchestrated activation of antioxidant defense systems engendered by this therapeutic intervention.[13]

Within the detoxification pathway involving the glutathione system, there is an initiation of glycolysis, which yields direct impacts on the augmentation of 2,3-diphosphoglycerate (2,3-DPG) concentrations, facilitating ion exchange at the cellular membrane level and culminating in the generation of energy in the form of ATP. 2,3-DPG plays a multifaceted role, influencing the dissociation of oxygen from oxyhemoglobin, thereby promoting heightened oxygen delivery to adjacent tissues. The augmented oxygenation and favorable outcomes of ozone therapy in ischemic diseases may be linked to the micro-release of ATP from erythrocytes and the observed vasodilation. The lipid peroxides generated during ozone therapy can stimulate the production of oxidative stress proteins, such as heme oxygenase-1 (HO-1), which, upon heme group breakdown, liberates valuable compounds like carbon monoxide (CO) and bilirubin. Bilirubin, recognized as a lipophilic antioxidant, and trace quantities of CO synergize with nitric oxide (NO) in the regulation of vasodilation while activating cyclic GMP production.[13,18]

There are studies that demonstrate the capacity of ozone to modulate nitric oxide (NO) levels. It is known that inner ear disruptions, often attributed to the presence of excessive calcium, can diminish the generation of negative potential, and imbalances in chloride and potassium levels can perturb the morphology of hair cells. Both of these phenomena can exert an influence on the membranes of the inner ear, as they are subject to notable processes that may affect the active metabolism of the cochlear vestibular organ. Ozone, with its regulatory impact on calcium homeostasis and cellular oxidative metabolism, exerts a beneficial effect on these perturbations, recognizing that the vascular stria is among the tissues with the most elevated metabolic activity.[13]

Preclinical studies have offered insights into the amelioration of the vascular stria in guinea pigs subjected to ototoxic substances and subsequently treated with ozone. Clinical trials have also been documented, implementing rectal ozone therapy in the context of cochleovestibular syndrome and sensorineural hearing loss, with a specific focus on auditory impairments in deaf and hearing-impaired children, and assessing their psychopedagogical outcomes three to five years after ozone treatment. In all of these instances, discernible improvements are evident in patients who underwent ozone therapy.[13]

In a sample comprising 31 patients diagnosed with benign peripheral vertigo, Del Cerro and colleagues administered ozone therapy to the paravertebral muscles at locations corresponding to the C2-C3 cervical region, situated bilaterally at a distance of 2 cm from the spinous process. This therapy was administered

twice a week, with a total of 20 sessions. Among these patients, 74 % had tinnitus, and 68 % exhibited hearing loss. Upon the completion of the treatment, a remarkable 62 % reduction in hearing loss and a 61 % decrease in tinnitus were attained.[13]

Migliora M et al.[19] reported a case involving an 88-year-old patient experiencing nocturnal tinnitus. After the administration of rectal ozone therapy, this patient achieved a 100 % remission, after concluding 20 therapy sessions.

Studies conducted within our nation align with these outcomes. Machín González V et al. employed ozone therapy and laser puncture in the treatment of 20 patients ranging from 35 to 58 years of age with sudden deafness. Their findings revealed that 88 % achieved full recovery, 9 % experienced partial recovery, and 3 % did not exhibit any improvement.[20]

In an immunotest involving the application of rectal ozone therapy to 19 children of varying ages suffering from hearing impairment, the results of audiometric assessments revealed significant improvements in 15 of the children. Among these, 11 experienced enhancements in their severe hearing loss, achieving an average gain of 21,9 dB.[20]

In a prospective, descriptive study spanning five years, wherein rectal ozone therapy was administered for three weeks alongside conventional treatment to patients afflicted with diverse ear conditions, positive outcomes were documented following the intervention. Among the 65 patients diagnosed with sensorineural hearing loss, 53,8 % achieved complete recovery, while 30,8 % exhibited noticeable improvement. Only 15,4 % of this subgroup did not benefit from the treatment. Of the 76 patients suffering from both tinnitus and hearing loss, complete recovery was reported in 64,5 %, an improvement in 22,4 %, and no discernible benefit in 13,1 %. For cases of tinnitus in isolation, complete improvement was noted in 64,6 %, an improvement in 26,2 %, and no remission in 9,2 %.[21]

CONCLUSIONS

Sensorineural hearing loss exhibited a predominance among males aged 45 to 54 years and was found to be associated with risk factors such as hypertension and type 2 diabetes mellitus. The effectiveness of rectal ozone therapy as a treatment for this condition has been demonstrated through clinical and audiometric improvements observed in patients.

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CONFLICT OF INTEREST

There was no conflict of interest.

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