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ORIGINAL

Ozone therapy in periodontal disease in type 2 diabetic patients

Ozonoterapia en la enfermedad periodontal de pacientes con diabetes mellitus tipo 2

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ABSTRACT

Introduction: periodontopathies are frequent in the world population and Cuba does not escape from this situation. In the search for more effective treatments, ozone therapy is a therapeutic alternative.
Objective: to determine the efficacy of oleozon in the treatment of periodontal disease in diabetic patients.
Methods: quasi-experimental study of therapeutic intervention in patients with diabetes mellitus type 2 and periodontal disease who attended Periodontics consultation at the "Hermanos Saiz" Stomatological Clinic of San Juan y Martínez, Pinar del Río in the period November 2023-April 2024. Universe: 125 patients. By means of intentional sampling by expert criteria, the sample was 96 patients, divided into 2 homogeneous groups: group I (oleozon) and group II (aqueous chlorhexidine 0,2 %). The Russell Periodontal Index, a revised WHO form to determine prevalence and severity of periodontal disease, was applied. The results were expressed in absolute and percentage frequencies and the non-parametric Chi-square test.
Results: male patients and the 50-60 years age group predominated with higher numbers of advanced periodontitis in both groups before and after treatment. Bleeding on probing was eliminated 21 days after treatment in both groups. Most of the patients were cured after 21 days and the treatment applied was successful in both treatment groups.
Conclusions: oleozon is an effective drug in the treatment of chronic inflammatory periodontal diseases in diabetic patients.

Keywords: Periodontal Disease; Periodontitis; Diabetes Mellitus; Ozone Therapy.

RESUMEN

Introducción: las periodontopatías son frecuentes en la población mundial y Cuba no escapa de esta situación. En la búsqueda de tratamientos más efectivos, la ozonoterapia es una alternativa terapéutica.
Objetivo: determinar la eficacia del oleozon en el tratamiento de la enfermedad periodontal de pacientes diabéticos.
Métodos: estudio cuasi experimental de intervención terapéutica en pacientes con diabetes mellitus tipo 2 y enfermedad periodontal que acudieron a consulta de Periodoncia en la Clínica Estomatológica "Hermanos Saiz" de San Juan y Martínez, Pinar del Río en el período noviembre 2023-abril 2024. Universo: 125 pacientes. Mediante muestreo intencional a criterio de expertos, la muestra fue de 96 pacientes, divididos en 2 grupos homogéneos: grupo I (oleozon) y grupo II (clorhexidina acuosa 0,2 %). Se aplicó Índice periodontal de Russell, forma OMS revisado para determinar prevalencia y gravedad de la enfermedad periodontal. Los resultados se expresaron en frecuencias absolutas y porcentuales y la prueba no paramétrica de Chi cuadrado.
Resultados: predominaron pacientes masculinos y grupo de 50-60 años con mayores cifras de periodontitis avanzada en ambos grupos antes y después del tratamiento. El sangramiento al sondeo se eliminó a los 21 días de tratamiento en ambos grupos. La mayoría de los pacientes se curaron a los 21 días y el tratamiento aplicado fue exitoso en ambos grupos de tratamiento.
Conclusiones: el oleozon es un medicamento eficaz en el tratamiento de las enfermedades periodontales inflamatorias crónicas de pacientes diabéticos.

Palabras Clave: Enfermedad Periodontal; Periodontitis; Diabetes Mellitus; Ozonoterapia.

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INTRODUCTION

Ozone therapy has been used as a therapeutic alternative for different conditions in several parts of the world. Examples are Germany, Russia, Italy, Austria, Spain, France, England, Sweden, Switzerland, Mexico, Japan, Argentina, Chile, Uruguay, Peru, and Venezuela. It was introduced in 1986 in Cuba, and more than 100 000 applications have already been performed without adverse reactions. [1]

Medical ozone is composed of ozone and pure oxygen. It is considered one of the best disinfectants due to its strong oxidizing character. In biology, its mechanism of action is based on the generation of secondary products from the organic compounds found in plasma and cell membranes. [2]

It can be used in gaseous (topical or systemic), aqueous (topical), and oily (topical) forms. In dentistry, the most common form of application is topical. Ozonized oil is frequently used in this branch of medicine since it has been shown to have great germicidal power. It is useful in treating oral cavity diseases with great bacterial, viral, and fungal involvement. [2, 3]

Chlorhexidine is another of the products used to treat these diseases since, depending on its concentration, it has bacteriostatic or bactericidal activity on numerous gram-positive and gram-negative aerobic and facultative anaerobic microorganisms; it also inhibits the deleterious effects of the excessive production of oxygen free radicals in gingival inflammation and is a very effective antiseptic, since it favors the reduction of plaque by up to 60 %. [4]

Periodontopathies are among the most frequent diseases in humans, with a prevalence of more than 95 % worldwide. They are defined as a group of inflammatory diseases that affect the supporting tissues of the teeth, gums, bone, and periodontal ligament. They appear due to the imbalance between the immunological interaction of the host and the flora of the marginal dental plaque that colonizes the gingival sulcus. They include gingivitis and periodontitis. [5]

Type 2 diabetes mellitus is a condition in which patients require continuous medical care to prevent acute complications, reduce the risk of chronic complications, and increase the quality of life. In diabetic patients, the lesions produced in the periodontal tissues are irreparable. It is said that in young adults and the elderly, a large part of the natural dentition is destroyed, depriving many of their teeth during old age. [6]

A poorly controlled diabetic is more at risk of infection than a healthy patient. Therefore, they easily contract infections, and oral tissues are not exempt from this [6] many studies have been conducted on the use of oleozon in oral conditions. In Ecuador, the effectiveness of ozone therapy and other drugs in the reduction of oral bacteria was compared, demonstrating that 5 % ozonized water presented a similar bactericidal effect to 5,25 % sodium hypochlorite and chlorhexidine, which are considered effective treatments against Actinomyces Israeli. [7]

In Manzanillo, Granma, a study was carried out that showed favorable results in the cure of fibro edematous gingivitis in 76,5 % of those affected 15 days after treatment, supported by the total disappearance of lesions. [8]

In Villa Clara, the effectiveness of oleozon therapy was also demonstrated in an investigation carried out in the Faculty of Stomatology, where they were able to eliminate the totality of periodontal pockets and also showed improvement in clinical parameters such as gingival bleeding and clinical insertion gain. [9]

Periodontal disease in diabetic patients is a condition that is frequently observed in the population that attends the service of the Hermanos Saiz Stomatological Clinic in the municipality of San Juan y Martinez, Pinar del Rio, so it has become necessary to expand the range of treatments that can be used in these patients. The need to find a safe and effective alternative in the treatment of periodontal disease in diabetic patients constitutes a problem to be solved.

Due to the interest in using this procedure in daily practice, taking into account its easy handling, low cost, and accessibility, this research was carried out to determine the effectiveness of ozonized oil in periodontal disease in diabetic patients belonging to the "Hermanos Saiz" Stomatological Clinic of San Juan y Martínez, Pinar del Río in the period November 2023-April 2024.

METHOD

A quasi-experimental study of therapeutic intervention was carried out to determine the efficacy of oleozon in periodontal disease in type 2 diabetic patients who attended Periodontics consultation at the "Hermanos Saiz" Stomatology Clinic in San Juan y Martínez, Pinar del Río during the period November 2023-April 2024.

Universe: 125 type 2 diabetic patients attended Periodontics consultation with clinical diagnosis of periodontal disease during the mentioned study period.

Sample: 96 patients with type 2 diabetes mellitus and periodontal disease were selected by purposive sampling using expert judgment. The sample was divided into two groups (I and II) of 48 members each. Group I received oleozon, and Group II received conventional treatment with chlorhexidine.

For the selection of the sample, patients with type 2 diabetes mellitus of both sexes, ages between 19 and 60 years, presence of periodontal disease, not allergic to oleozon, chlorhexidine, or both, and willingness to participate in the study were taken into account.

Patients with general diseases and habits that modify the host response, compromise the prognosis of the disease, and act as influencing factors were excluded, such as hematologic conditions (leukemia, anemia, and thrombocytopenic purpura) of the immune system (agranulocytosis, cyclic neutropenia, agammaglobulinemia, AIDS); debilitating diseases (syphilis, chronic nephritis, tuberculosis); avitaminosis; hypervitaminosis; coronary heart disease; sustained stress and habits (mouth breathing, unilateral chewing, atypical swallowing, bruxism). Patients consuming contraceptive hormones or those affecting the evolution of periodontal tissues and patients with special needs were also excluded.

Data collection techniques

Once oral and written consent was obtained from the patients to participate in the research, a clinical-buccal examination was performed in the periodontics office using a dental unit, a flat oral mirror, forceps, an explorer, a natural and artificial light source and a periodontal probe to determine the severity of the disease and periodontal bleeding.

The evaluation of bleeding of the gingival sulcus at probing is an integral part of the periodontal clinical examination; its presence or absence is recorded 15 to 30 seconds after the soft probing of the sulcus.

The Periodontal Clinical History and the data collection form for this purpose were prepared, where the variables of interest for the study were collected.

The dialectical-materialistic method was used as a base method that allowed the integration of the results obtained from applying the theoretical and empirical methods and the methods of descriptive and inferential statistics.

Statistical Processing

The information necessary for the study of each patient was recorded in a database structured by variables in Microsoft Excel spreadsheets. The information was summarized using absolute and percentage frequencies and Chi-square values (X2), with a significance level of p=0,05 %.

Work Dynamics

The revised WHO Russell Periodontal Index was used to determine the severity of periodontal disease. This index has been historically used in Cuba and deals with the most obvious signs of the disease (inflammation, pocket formation, tooth mobility). With this index, only the value assigned to the most severely affected tooth was recorded. [4]

Once the sample had been selected, two groups of homogeneous patients were made up, with an equal number of cases, called Group I and Group II.

Both groups of patients were guaranteed an initial preparation consisting of health education and motivation, control of antibacterial plaque, gastrectomy, essential extractions, correction of harmful habits, and assessment of the patient's general condition.

Subsequently, basic restorative treatments were performed (when necessary), which included:

- Treatment of dental caries.
- Correction of treatments that irritate or injure the periodontium.
- Placement of provisional prosthesis.

Finally, the evolutionary control corresponding to the first phase of treatment or initial treatment was carried out.

As part of the corrective treatment, drug therapy was performed, taking into account two therapeutic variants:

Group I patients had the affected area cleaned with distilled water and baptized with Chirurgie; the operative field was isolated and dried with cotton rolls, and oleozon was applied for one minute. In cases of gingivitis, the application was performed at the bottom of the sulcus, and in periodontitis, it was done inside the periodontal pocket.

It was also advised not to ingest liquids or rinse the mouth until 30 minutes had elapsed. The frequency of the applications was twice a week in consultation (Monday and Thursday), and the treatment results were evaluated after 15 and 30 days, respectively.

The patients in Group II underwent the same procedure, using chlorhexidine and indicating gingival massages.

The IP-Russell WHO revised form (IP-R) was applied to each patient before and after the conclusion of the therapy selected according to the group to which they belonged in the investigation.[4]

Ethical aspects

The Scientific Research Ethics Committee and the Scientific Council of the institution approved the research.

The principles and recommendations for biomedical research on human beings adopted in the Declaration of Helsinki were followed, such as beneficence and non-maleficence, the principle of justice and autonomy of each person, adopting as a working principle, respect for the anonymity of participants and confidentiality of data obtained, to be used for strictly scientific purposes.

RESULTS

Male patients were predominantly located in Groupgroups I (56,3 %) and Group II (52,1 %), for 54,2 %. The most represented age group in both groups was 50,60 (31,3 %) (table 1).

Table 1. Distribution of diabetic patients with periodontal disease according to sociodemographic variables and treatment groups. Saiz Brothers Stomatology Clinic. 2023-2024

Age groups	Group I		Group II		Total	
	No	%	No	%	No	%
19-29	8	16,7	7	14,6	15	15,6
30-39	11	22,9	12	25,0	23	24,0
40-49	14	29,2	14	29,2	28	29,2
50-60	15	31,3	15	31,3	30	31,3

Sex							
Male		27	56,3	25	52,1	52	54,2
Female		21	43,8	23	47,9	44	45,8
Total		48	50,0	48	50,0	96	100
$X^2 = 0,17$	GL= 2	Prob=0,6820					

As shown in table 2, the severity of periodontal disease before and after treatment in both study groups is presented. Advanced periodontitis predominated in both groups at the beginning of treatment, with 50 % (group I) and 47,9 % (group II). After treatment, the disease decreased similarly in both groups to 41,7 % and 43,8 % respectively.

After the Chi-square statistical analysis, it is evident that there is correspondence between the observed and expected values (Group I: p=0,4860 and Group II: p=0,3698).

Table 2. Severity of periodontal disease before and after treatment

Severity of periodontal disease		**Group I**				**Group II**			
		Before treatment		**After treatment**		**Before treatment**		**After treatment**	
		No.	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**
Gingivitis	Mild	3	6,3	0	0,0	3	6,3	0	0,0
	Advanced	5	10,4	0	0,0	6	12,5	1	2,1
Periodontitis	Mild	16	33,3	10	20,8	16	33,3	13	27,1
	Advanced	24	50,0	20	41,7	23	47,9	21	43,8
Total		48	100	30	62,5	48	100	35	72,9
Group I:				$X^2 = 1,44$	GL= 2	Prob= 0,4860			
Group II:				$X^2 = 1,99$	GL= 2	Prob= 0,3698			

The effectiveness of oleozon as an agent in reducing the level of bleeding. When bleeding at probing was evaluated, it was almost completely controlled at 21 days, both in the control group (89,6 %) and the study group (77,1 %). (Table 3).

Table 3. Bleeding at probing according to time of application of the treatment

Bleeding to the borehole		**Treatment application time**					
		7 days		**14 days**		**21 days**	
		No.	**%**	**No.**	**%**	**No.**	**%**
Group I	Yes	30	62,5	19	39,6	5	10,4
	No	18	37,5	29	60,4	43	89,6
	Total	48	100	48	100	48	100
Group II	Yes	32	66,7	23	47,9	11	22,9
	No	16	33,3	25	52,1	37	77,1
	Total	48	100	48	100	48	100

Regarding the response to treatment according to the time of application described in Table 4, a predominance of patients were cured after 21 days of treatment in group I (43,8 %) and in group II (39,6 %).

Table 4. Response to treatment according to time of application

Response to treatment		**Treatment application time**					
		7 days		**14 days**		**21 days**	
		No.	**%**	**No.**	**%**	**No.**	**%**
Group I	Curing	1	2,1	3	6,3	21	43,8
	Enhanced	3	6,3	16	33,3	10	20,8
	Same	44	91,7	29	60,4	17	35,4
Group II	Curing	0	0,0	0	0,0	19	39,6
	Enhanced	7	14,6	11	22,9	11	22,9
	Same	41	85,4	37	77,1	18	37,5

The treatment applied in both groups was successful, with 64,6 % of patients in group I treated with oleozon and 62,5 % in group II receiving treatment with chlorhexidine (table 5).

When analyzing the Chi-square test, no significant statistical association was observed between the variables in this table (p=0,8931).

Table 5. Effectiveness of treatment received with both therapeutic modalities

Effectiveness of treatment	Group I		Group II	
	No.	%	No.	%
Success	31	64,6	30	62,5
Failure	17	35,4	18	37,5
Total	48	100	48	100
$X^2 = 0,02$ GL= 1 Prob=0,8931				

DISCUSSION

The results show a predominance of advanced periodontitis in male patients and the 50-60 years age group. In line with these results, Ramos Perfecto and collaborators in Mexico [10] and Tergas Díaz et al. [11] in Las Tunas obtained a predominance of the male sex with more than 50 % of affected patients. An increase of the disease as age increases in a study where a population of diabetic patients with chronic periodontal disease was characterized.

In the study of Hernandez Rodriguez et al.[12], a discrete predominance of the male sex was obtained with 50,9 %, but they do not coincide with the predominant age group, which was 32-39 years old with 27,3 %.

Different results were obtained by Rodriguez et al.[13], in whose study the morbidity of diabetes mellitus increased with age and the female sex predominated. Soler Otero and collaborators [8] found greater affectation in the population aged 20-29 years with periodontal disease for 38,2 %.

The increase in the number of patients as age advances has been observed in studies such as that of Martínez Pita and collaborators [14], which agrees with this study. As the years go by, morphological changes occur in all tissues of the organism that are typical of aging, and the oral cavity is not exempt from them.

The literature consulted suggests that the incidence of periodontal disease is 10 % higher in men than in women, which may be because risk factors such as inadequate oral hygiene habits, smoking, and infrequent brushing are more common in men, which increase the severity of the pathology with advancing age. [11, 13]

The results of this research reflect the current situation of the disease since diabetes mellitus has a late diagnosis, taking into account that the gradual increase of hyperglycemia is evident without the patients realizing that they are sick; on the other hand, the aging of the population that Cuba is going through is manifested in these data.

The predominance of advanced stages of periodontal disease in the present study coincides with that obtained by Martínez Pita et al. [14] in Pinar del Río, who reported 57,4 % of patients affected by this disease.

Valerino Guzmán et al. [15] obtained a predominance of the mild intensity of inflammation with ozone therapy and the persistence of inflammatory signs in those treated with chlorhexidine. These results coincide in part with this study.

Different were the results of Rodriguez and collaborators [13] in Bayamo, Granma, where 48,8 % of patients with gingivitis and only 39,3 % with periodontitis were reported.

Gingivitis decreased in almost all affected patients in both groups. On the other hand, Trujillo Gálvez et al. [16] suggest a decrease in the inflammatory process due to microbial control thanks to treatment with oleozon, which can be attributed to this drug's antimicrobial and regenerative properties.

The author considers that diabetes with poor metabolic control is a determining risk factor in the increase in periodontal disease's prevalence, extension, and severity. This demonstrates that, although diabetes alone does not cause periodontal disease, it does modify the host response to the presence of certain local irritants capable of triggering periodontal disease.

Bleeding on periodontal probing has generated controversy; although it has been considered a predictive factor of periodontal disease, its presence is not always synonymous with periodontal disease; however, the absence of bleeding on probing is indicative that the periodontium is healthy.

By measuring this variable, it is possible to determine the efficacy of the treatment in the reconstruction of the connective tissue of the soft wall of the pocket, thus gradually reducing its inflammatory response. Ozone therapy reduces free radicals and naturally supports cell protection by increasing the activity of antidegenerative tissue enzymes such as glutathione peroxidase, glutathione reductase, and superoxide dismutase. [16]

Hernandez Rodriguez et al.[12] show coincident results. Gingival bleeding decreased gradually as the evaluation was carried out at different times, for 0,6 % of the study group were treated with oleozon. In contrast, this sign was maintained at 1,3 % in the control group. As the results of the treatment were evaluated, an improvement in this clinical sign was observed.

The results obtained by Ramos Perfecto et al.[10] were also equivalent, where the bleeding was almost totally controlled, eliminated in the control group (95 %) and in the study group (90 %).

Falcón Pasapera et al. [2] found a reduction in the bleeding rate (26 %) in patients with chronic generalized periodontitis by

irrigating the periodontal pockets with ozonized water, which resulted in a notable reduction of the disease, in agreement with this research.

Bleeding on probing indicates disease activity, even when the preliminary observation of the tissues impresses that they are healthy. It is an indicator of great predictive value that is considered in the diagnostic evaluations and the evolutionary controls of the periodontal patient.[17]

Many times when treating destructive disease, a new insertion of the tissues is not achieved; the gingiva remains with a pathological deepening, adapted to the surface of the tooth, but without bleeding on probing; for the clinician, this is an important finding, and although he cannot abandon the surveillance of the case, he considers that the therapy was effective. [17]

The results in Table 4 coincide with the study carried out by Diaz Couso [9], who obtained a decrease in gingival inflammation when treated with ozone therapy and chlorhexidine in both treatment groups.

Another similar research was carried out in Mexico by Ramos Perfecto and collaborators [10], in which they reported that all periodontal and microbiological indicators in type 2 diabetic patients with periodontitis improved.

Hernandez Castillo[18] reported decreased pocket depth, similar in patients with both therapies. Ozone in the periodontal pocket effectively eliminates the pathogens present, adequately restores oxygen metabolism, induces a favorable ecological environment, increases circulation, activates the immune response, and stimulates the humoral antioxidant system. All of these are favorable mechanisms for tissue repair of the bursa.

Chlorhexidine has its maximum effect within 20 seconds, as the growth of microorganisms is prevented for approximately 29 hours by its subsequent residual effect.[4, 7, 9]

In this study, conventional irrigation with chlorhexidine and ozone therapy were compared in the non-surgical periodontal treatment of periodontitis, and it was determined that ozone therapy has certain advantages over chlorhexidine in the healing process with additional analgesic effect, so both methods were considered effective in the elimination of microorganisms.

Bacteria considered periodontopathogenic come from the oral or commensal flora; under certain conditions, they proliferate or associate with exogenous bacteria, giving rise to an organized, proliferating structure with enzymatic activity and potentially pathogenic, which is none other than the biofilm or antibacterial plaque (PDB).[8,12,16]

Initially, this PDB on smooth surfaces is formed by an acellular matrix and microorganisms that vary from its appearance to the conformation of its internal structure through microbial succession. In the first stage, it is characterized by being aerobic and anaerobic, but as the days go by, the maturation of this occurs, and the aerobic microorganisms decrease, predominating from the fifth day onwards the anaerobic bacteria. [8,12,16]

The microorganisms of the plaque of smooth surfaces by contiguity reach the gingival sulcus, initiating their colonization and organizing this type of plaque, whose composition changes over time due to the anatomical structure of the sulcus, the pH of the sulcus, oxidation-reduction potential, and the presence of gingival fluid. All these factors favor the predominance of anaerobic microorganisms.[8,12,16]

On the other hand, medical ozone is composed of oxygen and ozone. *Ozone* is a very unstable particle that transforms into an oxygen atom a few minutes after being applied, released into the environment, or combined with free radicals. That is why dentistry is used to prevent infection or superinfection of lesions and help tissue healing. It also has antibacterial, bactericidal, fungicidal, virucidal, healing, antiseptic, disinfectant, anti-inflammatory, immunomodulatory and regenerative properties.[8,12,16]

Similar results were shown by Soler Otero et al.[8], with 76,5 % of patients cured at the end of the evaluation of clinical parameters in patients with fibro edematous gingivitis in 15 days.

In the study by Hernandez Rodriguez et al.[12], the response to oleozon therapy was evaluated twelve months after receiving this treatment in the study group. In patients suffering from gingivitis, 100 % of the patients were cured, while in the control group, only 93,5 % were cured. In the case of periodontitis, the treatment was moderately effective (improved) in the study group by 60 %, while those in the control group sustained a 51,5 % improvement.

With what has been demonstrated in previous investigations and considering the results obtained in the present one, it can be affirmed that the best method of non-surgical periodontal treatment is the one that fulfills the expectations of the specialist who applies it, according to the advantages and disadvantages that conventional irrigation with chlorhexidine or ozone therapy can offer. In this way, risk-benefit should be evaluated, based mainly on the spectrum of action and tissue regeneration, as well as cost and accessibility to obtain the desired results.

The results of table 5 correspond to the study of Hernández Rodríguez et al.[12], who consider that the application of oleozon is effective in the treatment of non-surgical periodontal therapy due to the antimicrobial and regenerative properties of this product; given that when the medicine was applied, all the pockets were eliminated and no bleeding was found. The treatment was 100% effective in the study group and 93,5% in the control group.

The application of oleozon was effective in the treatment of chronic edematous and fibro edematous gingivitis, studied by Trujillo Gálvez et al.[16], where better results were observed in fibro edematous gingivitis segments with pockets, dental calculus, and bleeding improved notably. At the end of the treatment, most of the patients went from more severe to milder forms of the disease, so they considered oleozon as a viable and effective drug in periodontal diseases.

Pantoja Trávez[7] did not find significant differences regarding the efficacy of topical oleozon and chlorhexidine in his work on treating chronic fibroedematous gingivitis; both options were effective in most cases.

Pérez Hernández et al.[19] affirmed that ozonized water is effective in treating chronic periodontitis because the patients went from moderate to mild or no inflammation in seven days of treatment and in 15 days. Most of them were without inflammation. All these results coincide with those reported in this research.

The results showed that oleozon is an effective drug in treating chronic inflammatory periodontal diseases in diabetic patients, achieving good results in a short period. It is an inexpensive, accessible product, easy to apply, and well-tolerated by patients.

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No funding was received for this study.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

AUTHORSHIP CONTRIBUTION

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