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ORIGINAL ARTICLE

Effectiveness of ozone therapy in the healing of infected surgical wounds: case-control study

Efectividad de la ozonoterapia en la cicatrización de la herida quirúrgica infectada: estudio de casos y controles

Eficácia da ozonioterapia na cicatrização de feridas cirúrgicas infectadas: estudo caso-controle

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ABSTRACT

Introduction: ozone therapy improves human health, contributes to tissue repair, has antimicrobial action, and is an alternative that helps promote proper healing of surgical wounds. Despite numerous studies on wound healing and infection in surgical wounds, the results on the use of ozone therapy in these entities are still considered insufficient. **Objective:** to evaluate the effectiveness of ozone use in speeding up the healing of infected surgical wounds. **Method:** a prospective, analytical, observational, case-control study was conducted to evaluate the effectiveness of ozone use in speeding up the healing of infected surgical wounds. The sample consisted of 52 patients (n = 52), treated in the ozone therapy clinics of the Hospital Provincial Universitario "Celia Sánchez Manduley" in Granma from January 1 to June 30, 2023. **Results:** high blood pressure was the most frequent comorbid disease, present in 44.23% of patients, while acute appendicitis was the most frequent operative diagnosis, with 30.77%. The most performed surgical procedures were appendectomy and herniorrhaphy, both with a prevalence of 30.77%. Superficial infection was more prevalent in both groups, accounting for 65.39% of total infections. The healing rate in the case group was higher in both patients with superficial and deep infections. **Conclusions:** ozone therapy is a useful adjuvant for the healing of infected surgical wounds.

Keywords: ozone therapy; antisepsis; asepsis; healing; infected surgical wound; surgical wound infection; surgical site infection; ozone

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RESUMEN

Introducción: la ozonoterapia logra mejorar la salud humana, contribuye a la reparación tisular, posee acción antimicrobiana y es una alternativa que ayuda a la cicatrización adecuada de la herida quirúrgica; a pesar de existir múltiples investigaciones sobre cicatrización e infección de heridas quirúrgicas aún se consideran insuficientes los resultados sobre el uso de la ozonoterapia en estas entidades. **Objetivo:** evaluar la efectividad del uso del ozono en la velocidad de cicatrización de heridas quirúrgicas infectadas. **Método:** se realizó un estudio prospectivo, analítico, observacional, de casos y controles para evaluar la efectividad del uso del ozono en la velocidad de cicatrización de heridas quirúrgicas infectadas. La muestra quedó constituida por 52 pacientes(n = 52), atendidos en las consultas de ozonoterapia del Hospital Provincial Universitario "Celia Sánchez Manduley" de Granma en el período del 1de enero al 30 de junio de 2023. **Resultados:** la hipertensión arterial fue la enfermedad comórbida más frecuente, presente en el 44,23 % de los pacientes, mientras que la apendicitis aguda fue el diagnóstico operatorio más frecuente, con el 30,77 %. Los procederes quirúrgicos más realizados fueron la apendicetomía y la herniorrafia, ambos con una prevalencia del 30,77 %. La infección superficial presentó mayor prevalencia en ambos grupos, en el 65,39 % del total de infecciones. La velocidad de cicatrización en el grupo de casos fue mayor tanto en los pacientes con infección superficial como aquellos con infección profunda. **Conclusiones:** la ozonoterapia es un adyuvante útil para la cicatrización de la herida quirúrgica infectada.

Palabras clave: ozonoterapia; antisepsia; asepsia; cicatrización; herida quirúrgica infectada; infección de la herida quirúrgica; infección del sitio operatorio; ozono

RESUMO

Introdução: a ozonioterapia melhora a saúde humana, contribui para a reparação tecidual, tem ação antimicrobiana e é uma alternativa que auxilia na cicatrização adequada da ferida cirúrgica; Apesar de existirem múltiplas investigações sobre cicatrização e infecção de feridas cirúrgicas, os resultados sobre a utilização da ozonioterapia nestas entidades ainda são considerados insuficientes. **Objetivo:** avaliar a eficácia do uso do ozônio na velocidade de cicatrização de feridas cirúrgicas infectadas. **Método:** foi realizado estudo prospectivo, analítico, observacional, caso-controle, para avaliar a eficácia do uso do ozônio na velocidade de cicatrização de feridas cirúrgicas infectadas. A amostra foi composta por 52 pacientes (n = 52), atendidos nas consultas de ozonioterapia do Hospital Provincial Universitario "Celia Sánchez Manduley"do Granma no período de 1º de janeiro a 30 de junho de 2023. **Resultados:** a hipertensão arterial foi a comorbidade mais frequente, presente em 44,23% dos pacientes, enquanto a apendicite aguda foi o diagnóstico operatório mais frequente, com o 30,77%. Os procedimentos cirúrgicos mais realizados foram apendicectomia e herniorrafia, ambos com prevalência de 30,77%. A infecção superficial teve maior prevalência em ambos os grupos, com 65,39% de todas as infecções. A velocidade de cicatrização no grupo de caso foi maior tanto nos pacientes com infecção superficial quanto naqueles com infecção profunda. **Conclusões:** a ozonioterapia é um adjuvante útil na cicatrização da ferida cirúrgica infectada.

Palavras-chave: ozonioterapia; antissepsia; assepsia; cicatrização; ferida cirúrgica infectada; infecção de ferida cirúrgica; infecção de sítio cirúrgico; ozônio

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INTRODUCTION

Surgical interventions play a very important role among the daily procedures performed in secondary care centers, therefore, it is very important to offer a high quality and safe medical service; but even when this is fulfilled, the professionals working in General Surgery wards still face a complication related to surgical care: surgical wound infection (SWI).[1]

SWI is defined by the National Center for Health Technology Excellence and the U.S. Centers for Disease Control and Prevention as any "infection related to a surgical procedure that occurs near the surgical site within 30 days after surgery."[2]

The introduction to health services of the principles of asepsis (1851) and antisepsis (1867) in line with the development of antibiotics led to a decrease in HAI rates from 80% to 90% of cases to only 10% of cases. It was thought that this created a definitive solution to this problem, however, studies on the subject have shown the opposite, since the incidence of HAIs represents 20 to 25% of the total number of infections registered in hospitals worldwide.[3]

In general surgery services complications related to CAH deserve the attention of the doctors and nurses who work there. Since these complications are the main causes of post-surgical morbimortality which make it essential to know the microorganisms that are part of the microbiota of the surgical site, while this could be the origin of CAH; among these microorganisms, aerobic and anaerobic bacteria stand out.[4] There are various means to treat CAH and achieve its healing.

There are various means to treat the IHQ and achieve healing. Natural substances such as ozone and honey are used, as well as gene therapy.[5] Ozone therapy is a branch of Natural and Traditional Medicine that uses ozone gas to improve human health and it is an alternative that helps the surgical wound to heal properly.[6] This technique is based on the high potential of the ozone gas in the surgical wound.

This technique is based on the high oxidizing potential of ozone, which gives the technique a powerful antimicrobial action, causing an oxidation of the walls and membranes of bacterial cells. Ozone also favors the metabolism of healthy cells and contributes to tissue repair.[7]

Likewise, ozone causes controlled tissue oxidative stress with release of oxidizing agents that induce the generation of antioxidant enzymes such as catalase and superoxide dismutase enzyme, which promotes and enhances cellular antioxidant capacity.[7]

Despite the existence of multiple investigations on surgical wound healing and infection, the results obtained are still considered insufficient, which makes it necessary to carry out new studies that offer viable and effective alternatives to treat surgical site infection, especially in a field for which there is little evidence, such as the use of ozone therapy.

For all of the above, the present research aims to evaluate the effectiveness of the use of ozone in the speed of healing of infected surgical wounds in the Provincial University Hospital" Celia Sánchez Manduley."

METHOD

A prospective, analytical, observational, observational, case-control study was carried out to evaluate the effectiveness of the use of ozone in the speed of healing of infected surgical wounds, during the period from January 1 to June 30, 2023.

The study universe was constituted by 60 patients (N = 60) and the sample was conformed by the 52 patients (n= 52) attended in the ozone therapy consultations of the University Provincial Hospital "Celia Sánchez Manduley" of Manzanillo, Granma, Cuba.

The sample was divided into two groups using the simple random method. Descriptive biostatistics was used as a statistical method to summarize the information contained in the data collected.

Cases: patients with medical diagnosis of surgical wound infection (SWI) treated with ozone as adjuvant treatment.

Controls: patients with a medical diagnosis of surgical wound infection treated with conventional treatment.

Inclusion criteria:

- Patients with a diagnosis of surgical wound infection.
- Patients older than 18 years old
- Patients under 60 years of age
- Patients who agreed to be part of the study and who signed the informed consent

Exclusion criteria:

- Patients with incomplete medical records

Exit criteria:

- Patients who expressed their willingness not to continue their participation in the study
- Patients who died during the study

Limitations of the study: some data collection bias may have occurred, given the nature of the data, since they were obtained by means of procedures subject to interobserver variation reflected in the clinical histories. This bias was minimized by the detailed way in which the data were searched and collected in all patients by the same observer, which nullified the interobserver difference. This did not affect the internal or external validity of the study.

Definition of terms

Comorbidity: defined as the term used to describe two or more disorders or diseases that occur in the same person without accounting for the underlying disorder or disease:

- Arterial hypertension
- Glaucoma
- Hemorrhoids
- Psoriasis
- Varicose veins of the lower limbs
- Ulcerative colitis
- Renoureteral lithiasis

Operative diagnosis: medical diagnosis is the study performed by a health professional to identify and determine whether the affected person has a disease or condition. Operative diagnosis was defined as the diagnosis made at the end of the surgical procedure:

- Acute appendicitis
- Lipoma
- Acute cholecystitis
- Uncomplicated inguinal hernia
- Complicated inguinal hernia
- Umbilical hernia
- Intestinal obstruction by flanges
- Perforated peptic ulcer
- Tubo-ovarian abscess

Surgical procedure: defined as the total of sequential maneuvers and procedures to cure, palliate or minimize a disease that merits surgical intervention:

- Appendectomy
- Lysis of bridles
- Inguinal herniorrhaphy
- Inguinal hernioplasty
- Cholecystectomy
- Excision
- Gastric suture and epipoplasty

Type of surgical infection: it is defined as the colonization, growth and perpetuation of germs with hystastic and systemic lesions. For the purposes of this research, it was considered when it occurred in the surgical wound.

Namely:

- Superficial Incisional IHQ: that in which the following conditions are present:
  Occurs within 30 days after surgery; involves only the skin and soft tissues subcutaneous to the incision.

  Minimum one of the following conditions: a) purulent drainage, with or without microbiological confirmation from the superficial incision; b) isolation of the microorganism in fluid or tissue; c) minimum one of the following signs or symptoms of infection: pain, swelling, erythema, warmth, or the surgeon deliberately opened the surgical wound, except if culture is negative; and d) IHQ diagnosis by the surgeon.

  Not included inflammation or discharge from the site where the stitch enters; infection at episiotomy or newborn circumcision, infection from a burn, nor if the incision involves deeper planes and extends into fascia or muscle.

- *Deep Incisional IHQ:* one in which the following conditions are present:
  Infection occurring within 30 days after surgery, if there is no implant. Up to one year later if there is, an implant related to the surgery. The infection involves deep soft tissues (fascia and muscle).

Healing evolution time: defined as the units that separate the occurrence of events; the time in days from the declaration of the IHQ diagnosis to its closure was considered in the study.

Description of the technique

Case group: comprised of 26 patients. Perilesional injectable ozone was applied at a rate of 20 µg per ml of injectable solution in the entire wound contour, as an adjuvant of the process and the surgical wounds were treated with antibiotic ointment and daily moist dressings.

Control group: 26 patients. Surgical wounds were treated with antibiotic ointment and daily moist dressings.

Data collection

The data obtained were manually recorded in the data collection form, processed in Microsoft Office 2016 Word and Excel programs.

Ethical parameters

Regarding ethical considerations, informed consent was requested from the participants. The research was conducted with the approval of the ethics committee and scientific council of the Provincial University Hospital "Celia Sánchez Manduley." Likewise, the ethical principles were taken into account: autonomy, protection, beneficence, non-maleficence and justice; as well as the application of the principles stated in the Declaration of Helsinki for the development of research on human beings.

RESULTS

Arterial hypertension was the most frequent comorbid disease in both groups, with prevalence in 50 % of patients in the case group and prevalence in 38.46 % of patients in the control group, which had an overall impact on 44.23 % of all patients (Table 1).

Table 1: Patients in both groups according to comorbidity

Comorbidity	Total patients				Total n=52	
	Case group n=26		Control group n=26			
	No.	%	No.	%	No.	%
Arterial hypertension	13	50,00	10	38,46	23	44,23
Renoureteral lithiasis	3	11,54	4	15,39	7	13,46
Hemorrhoids	3	11,54	4	15,39	7	13,46
Varicose veins of lower limbs	2	7,69	3	11,52	5	9,62
Glaucoma	1	3,84	1	3,85	2	3,85
Ulcerative colitis	1	3,84	-	-	1	1,92
Psoriasis	1	3,84	-	-	1	1,92

Acute appendicitis was the most frequent operative diagnosis in both groups, with prevalence in 26.92 % of patients in the case group and prevalence in 34.62 % of patients in the control group, the disease in 30.77 % of all patients (Table 2).

Table 2: Patients in both groups according to their operative diagnosis

Diagnostic surgery	Total patients				Total n=52	
	Case group n=26		Case group n=26			
	No.	%	No.	%	No.	%
Acute appendicitis	7	26,92	9	34,62	16	30,77
Lipoma	-	-	1	3,85	1	1,92
Acute cholecystitis	3	11,54	1	3,85	4	7,69
Uncomplicated inguinal hernia	2	7,69	-	-	2	3,85
Complicated inguinal hernia	6	23,08	8	30,77	14	26,92
Umbilical hernia	2	7,69	-	-	2	3,85
Intestinal bridle obstruction	3	11,54	5	19,23	8	15,39
Perforated peptic ulcer	2	7,69	-	-	2	3,85
Tubo-ovarian abscess	1	3,85	2	7,69	3	5,77

The most frequently performed surgical procedures in both groups were appendectomy and herniorrhaphy, both with a prevalence of 30.77 % of patients (Table 3).

Table 3: Patients in both groups according to the surgical procedure performed.

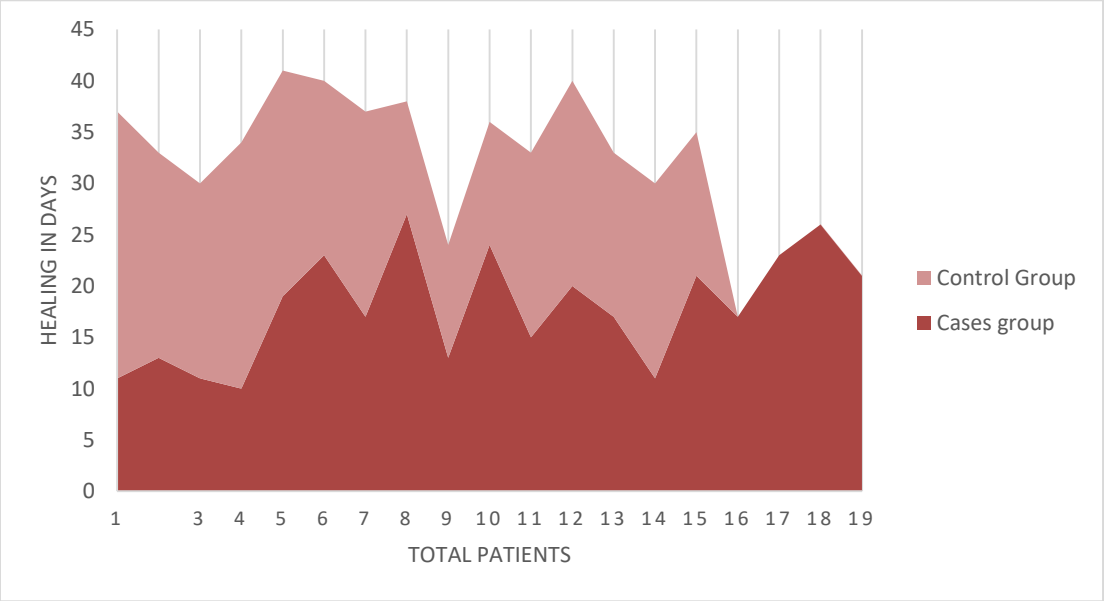
Surgical procedure	Total patients				Total n=52	
	Case group n=26		Case group n=26			
	No.	%	No.	%	No.	%
Appendectomy	7	26,92	9	34,62	16	30,77
Lysis of bridles	-	-	1	3,85	1	1,92
Herniorrhaphy	8	30,77	8	30,77	16	30,77
Hernioplasty	2	7,69	-	-	2	3,85
Cholecystectomy	3	1,54	1	3,85	4	7,69
Excision	-	-	1	3,85	1	1,92
Suture and epipoplasty	2	7,69	-	-	2	3,85
Adnexectomy	1	3,85	2	7,69	3	5,77

Surface infection was more prevalent in both groups, accounting for 65.39% of the total number of infections (Table 4).

Table 4: Patients in both groups according to the type of surgical infection

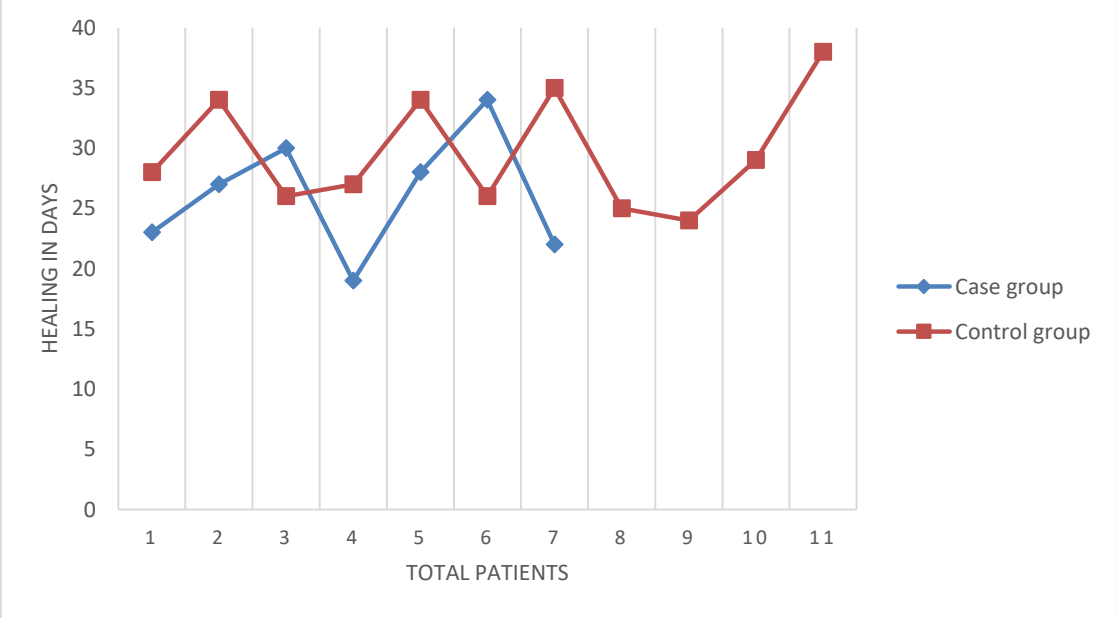
Surgical infection type	Total patients				Total n=52	
	Case group n=26		Case group n=26			
	No.	%	No.	%	No.	%
Superficial surgical wound infection	19	73,08	15	57,69	34	65,39
Deep surgical wound infection	7	26,92	11	42,31	18	34,62

The speed of healing in patients with superficial surgical wound infection was higher in the case group versus the control group (Graph 1).



Graph 1: Patients in both groups with superficial surgical wound infection according to healing time

The speed of healing in patients with deep surgical wound infection was higher in the case group versus the control group (Figure 2).



Graph 2: Patients in both groups with deep surgical wound infection according to healing time

DISCUSSION

Surgical site infection can trigger serious consequences for patients, such as poorly faced edges and separation of the surgical wound. This complication can be aggravated by causing evisceration and fistula formation between the bowel and the skin, which makes its management even more difficult and challenging. Research has proven that these complications are related to increased morbidity and may increase the risk of mortality; it can reach up to 45 %.[8]

A study by Vázquez-Rodríguez et al.[9] shows that the most predominant comorbidity in cases of surgical wound infection is arterial hypertension in 28 % of the cases, which coincides with the results obtained in the present study. These results could be explained by the fact that cardiovascular diseases are the most frequent in Cuba and the first world countries and, within these, arterial hypertension is the disease that shows the highest prevalence rate.

Several countries have implemented regulations for the control and prevention of surgical wound infection through the assessment of the incidence rate and the operative site in relation to hospital discharges and their diagnoses. It is reported that 3.2 per 100 hospital discharges present intrahospital and surgical site infections, and a communiqué from the Ministry of Health of Peru in 2021, indicates that the incidence of acute appendicitis predominates in individuals under 60 years of age, which represents 17%.[10]

Gómez Santiago and Silva Díaz[11] in their research report that 27.5% of patients with surgical site infection underwent appendectomy, which is consistent with the data obtained in the present research. These data may be due to the fact that appendicitis is the most common cause of acute abdomen and appendectomy is one of the surgical procedures most frequently performed by surgeons.

The incidence of surgical site infection is related to numerous factors, such as age over 60 years, malnutrition by excess or defect, immunological deficit, concomitant diseases, prolonged surgical time and the type of surgery. It is referred in the literature that the care provided in General Surgery wards is not related to the occurrence of surgical site infections, and that those responsible for the infection rate of aseptic wounds are the surgeons, so the factors for success in the prevention of surgical wound infection reside in the operating room.[12]

An investigation carried out by Andrade-Méndez et al.[13] shows that patients with deep surgical wound infection predominate, both in the case group and in the control group, with an incidence of 48.27% and 47.93%, respectively. These results differ from those obtained in the present study, where superficial surgical wound infection predominated, which may be due to variations in the performance of the surgical interventions and differences in the follow up of the asepsis and antisepsis protocols.

On the other hand, the effects of ozone on the biochemical cascade, through reactive oxygen species, inhibit the action of proinflammatory prostaglandins, serotonin, bradykinin or substance P, which justifies its analgesic and anti-inflammatory effect. The anti-inflammatory action of ozone would also be enhanced by the inhibition of proinflammatory cytokines and phospholipase A2, and by the stimulating action of immunosuppressive cytokines with anti-inflammatory and tissue repairing effects.[14]

No articles were found in the scientific literature evaluating the effect of ozone therapy on the speed of healing of infected surgical wounds in humans. But Alvarez Correa[15] concludes, that the results of his study support the efficacy of ozone therapy, especially in an integral use in the healing of diabetic foot ulcers and the reduction of infections and amputations.

CONCLUSIONS

Ozone therapy is a useful adjuvant for the healing of the infected surgical wound. In patients with surgical site infection there is a predominance of arterial hypertension as comorbid disease, appendicitis as operative diagnosis and appendectomy and herniorrhaphy as operative techniques. The speed of healing of the infected surgical wound was higher in the case group both in patients with superficial infection and in patients with deep infection.

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Conflicts of interest:
The authors declare that there are no conflicts of interest.

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Robin Fajardo Alcalá: conceptualization, research, methodology, validation, visualization, original draft writing, writing-revision and editing
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