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Effects of the intravenous application of sodium ascorbate in patients with the diagnosis of sepsis in the intensive care unit – observational, analytical, retrospective, comparative study

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Abstract

Objectives: To evaluate whether high-dose intravenous sodium ascorbate improves inflammatory markers in patients with sepsis.

Methods: A retrospective, observational, analytical, and comparative study was conducted on patients diagnosed with sepsis and admitted to the ICU at Clínica Estrios (Cartagena, Colombia) between July 1 and 30, 2024. Patients receiving standard treatment were compared with those who also received high-dose intravenous sodium ascorbate (>462 mg/kg/day), supplied by Biological Therapies, Australia. The main outcome was the duration of altered SIRS and SOFA scores.

Results: Patients treated with sodium ascorbate showed a statistically significant reduction in the duration of altered SIRS and SOFA scores (X^2=9.00, p=0.003) compared to those who received standard therapy.

Conclusions: High-dose sodium ascorbate may serve as an effective adjuvant therapy in sepsis.

Keywords: sodium ascorbate; sepsis; vitamin C; ascorbic acid; SOFA; megadose

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Introduction

Sepsis is a potentially life-threatening condition caused when the immune system reacts excessively to an infection, leading to organ dysfunction and damage to the body's own tissues and organs. The severe consequences can range from shock to multiple organ failure and death in some cases, if not treated promptly and appropriately [1].

In 2020, an estimated 48.9 million cases of sepsis were reported worldwide, with 11 million related deaths. Nearly half of the global cases occurred in children under the age of 5. It is estimated that out of every 1,000 hospitalized patients, 15 will develop sepsis as a complication of their care [1].

In Colombia, a study conducted in four cities with 826 patients found that 51 % of patients developed sepsis in the community, 44 % in the ICU, and 5 % during hospitalization. The most common sources of infection were from the abdomen (30 %), urinary tract (22 %), skin and soft tissues (18 %) [2].

In intensive care units (ICUs), sepsis is one of the leading causes of admission and mortality [3]. These patients are particularly vulnerable due to their critical condition, compounded by risk factors such as chronic diseases, invasive procedures, and exposure to antimicrobial-resistant pathogens, among others. Numerous clinical studies have been conducted to determine the most appropriate or effective management strategies for achieving favorable clinical outcomes in sepsis patients. This has led to the development of therapeutic management guidelines aimed at standardizing patient treatment and establishing clear goals, made possible

by advances in the understanding of sepsis specific pathophysiology [4].

The treatment of sepsis in ICUs involves constant monitoring, the prompt administration of broad-spectrum antibiotics, hemodynamic support, and measures to control the source of infection. This approach is based on the clinical practice guidelines available at each institution. However, standardized criteria and assessment tools are necessary to evaluate the severity of sepsis and guide treatment appropriately [5].

To address this, two assessment systems have been used to guide and properly determine treatment. The first is the concept of Systemic Inflammatory Response Syndrome (SIRS), defined by certain abnormalities in vital signs and laboratory values. For a long time, it was used to identify early sepsis, but it was neither very sensitive nor specific. For this reason, a new set of criteria was defined, known as SOFA (Sepsis-related Organ Failure Assessment), as shown in Table 1 [3].

Although both scales serve different purposes – SIRS assesses common symptoms associated with the diagnosis of sepsis, while SOFA evaluates the severity of organ failure in sepsis – it has been observed that SIRS has high sensitivity but low specificity for predicting in-hospital mortality in infected patients. This means that while SIRS can identify patients at risk, it may also include many who will not develop adverse outcomes. In contrast, SOFA has lower sensitivity but higher specificity, making it a more effective tool for identifying patients at greater risk of mortality, although it may overlook some individuals who are also at risk [6].

The antioxidant properties and biological actions of sodium ascorbate are well established, as it functions as an electron donor. In addition to its antioxidant activity, sodium ascorbate exhibits immunostimulatory effects, anti-inflammatory properties, antiviral activity, and potential antimutagenic effects. It enhances neutrophil chemotaxis, phagocytosis, and the proliferation of T cells and Natural Killer cells, thereby modulating immune function [7]. Furthermore, sodium ascorbate has been observed to influence catecholamine synthesis and adrenal steroidogenesis. It also serves as a cofactor for peptidylglycine alpha-amidating monooxygenase, an enzyme essential for the endogenous synthesis of vasopressin [8]. Notably, sodium ascorbate has a longstanding history of contributing to the resolution of various viral diseases, including pneumonia [9].

The action of Sodium ascorbate and its antioxidant effects are well known, as it acts as an electron donor. Sua acción Additionally, it has immunostimulatory effects, anti-inflammatory properties, antiviral effects, and potential antimutagenic effects. It improves neutrophil chemotaxis, phagocytosis, and the proliferation of T cells and Natural Killer cells, modulating their functions. Sodium ascorbate has also been

Table 1: SIRS (systemic inflammatory response syndrome) and SOFA (sepsis-related organ failure assesment).

SIRS (systemic inflammatory response syndrome)					
Criterion	Values				
Temperature	<36 °C or >38 °C				
Respiratory rate	>20 rpm				
Heart rate	>90 bpm				
White blood cells	>12,000/mmHg^3 or <4,000/mmHg^3				
SIRS is defined with the presence of two or more of these criteria					
SOFA (sepsis-related organ failure assesment)					
Criterion	0	1	2	3	4
Breathing PaO_2/FIO_2, mmHg	>400	<400	<300	<200	<100
Platelet coagulation 10/mm3	>150	<150	<100	<50	<20
Liver bilirubin, mg/dL	<1.2	1.2–1.9	2.0–5.9	6.0–11.9	>12.0
Cardiovascular blood pressure	MAP≥70 mmHg	MAP<70 mmHg	Dopamine<5 o Dobutamine (any dose)	Dopamine 5.1–15 or epinephrine≤0.1 or norepinephrine≤0.1	Dopamine>15 or epinephrine>0.1 or norepinephrine>0.1
Central nervous system glasgow scale	15	13–14	10–12	6–9	<6
Renal creatinine (mg/dL) or fujo urinary (mL/d)	<1.2	1.2–1.9	2.0–3.4	3.5–4.9<500	>5.0<200

PaO_2, oxygen blood pressure; FIO_2, Fraction of inspired oxygen; MAP, Mean Arterial Pressure. The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3).

observed to influence the synthesis of catecholamines and adrenal steroidogenesis. It is also a cofactor for the production of peptidyl-glycine alpha-amidating monooxygenase, which is required for the endogenous synthesis of vasopressin.

As a result, there has been increased interest in the use of intravenous ascorbate as an adjunct treatment for sepsis management, supported by various studies, such as the Marik et al. study. In this study, the administration of 1.5 g of Vitamin C every 6 h, for a total of 6 g per day, combined with Hydrocortisone and Thiamine, led to an absolute mortality reduction of over 30 % in 47 patients, despite comorbidities and high mortality risk. Currently, several clinical trials are ongoing to further evaluate these results [10].

For this reason, the present study was conducted in an ICU of a coastal city in Colombia to evaluate the effect of Sodium ascorbate megadoses in patients with sepsis, combined with standard conventional treatment according to clinical guidelines.

Materials and methods

Patients admitted to an ICU in Colombia during July 2023 with a diagnosis of sepsis, regardless of its etiology, were evaluated according to the clinical criteria defined by SIRS and the SOFA scale. The goal was to assess the impact of Sodium ascorbate megadose treatment combined with standard treatment for this condition, based on the physicians clinical decision.

It was submitted to the Research and Ethics Committee of the Colombian Society of Preventive and Orthomolecular Medicine, which reviewed and approved it in accordance with official document COL OBS ASC001-024-003, dated May 29, 2023, following all national and international ethical principles for conducting research involving human subjects.

These two scales were used due to their specific characteristics: the high sensitivity of the SIRS scale, despite its low specificity, in contrast to the SOFA scale's ability to accurately identify patients at higher risk of mortality. However, SOFA may overlook some at-risk patients. For this reason, both scales were chosen for use [6].

Vitamin C for injection was supplied by Biological Therapies "A Division of Orthomolecular Medisearch Laboratories Pty Ltd, (Australia)", in the form of Sodium Ascorbate Solution Injection for intravenous Infusion 30 g in 100 mL Aust R 47757.

Study type

Observational, analytical, retrospective, comparative study of patients with a diagnosis of sepsis who were admitted to the Cliníca Estrios in Cartagena Colombia to the Intensive Care Unit ICU between July 1 and 30, 2024.

Study population selection

The medical records of patients admitted with a diagnosis of sepsis during the specified period were reviewed. The following inclusion criteria were applied:

- Patients over 18 years of age.
- Diagnosis of sepsis of any etiology.
- Patients receiving sepsis treatment according to the institution's clinical practice guidelines, supported by the medical record.
- Patients who completed their treatment within the institution.
- Patients with complete medical records.

The following exclusion criteria were defined:

- Patients under 18 years of age.
- Patients not receiving sepsis treatment according to the institution's clinical practice guidelines, supported by the medical record.
- Patients diagnosed with conditions other than sepsis of any etiology.
- Patients who were transferred without completing treatment within the institution.
- Patients without complete medical records.

Methodology

Using a research form, information was obtained from the patients' medical records, including demographic factors, clinical-epidemiological data, treatment details, and the evaluation of clinical symptoms. Laboratory test results were also collected, all associated with the final outcome of clinical improvement based on the SIRS criteria and the SOFA scale.

The demographic factors considered were age, gender, occupation, education level, socioeconomic status, and work activity. Ensuring that all patients received sepsis treatment according to clinical practice guidelines, the Sodium

ascorbate megadose was determined based on the physicians clinical judgment. Other variables were also assessed, including the length of stay in the ICU, the number of days with alterations in the SIRS and SOFA scores – indicating inflammatory changes and clinical improvement – the duration of clinical improvement, sepsis-related complications, mortality, discharge, and the administered dose of sodium ascorbate. According to the clinic protocol, sodium ascorbate was administered in vials of 30 g in 100 mL (equivalent to 30 g of sodium ascorbate), from Biological Therapies Australia, to be applied at a frequency of 30 g per day for 6 days, for a total of 180 g per week, diluted in 400 mL of SSN09 % to pass in 1 h.

Statistical analysis

For the analysis of this study, an Excel (Microsoft) database was initially used, which was parametrized according to the variables to be studied. The data was recoded for subsequent statistical analysis. A descriptive and analytical analysis was performed using this tool, considering the limitations due to the sample size. Certain variables were dichotomized to apply the Chi-squared (X^2) tests and logistic regression, along with a linear regression test, using IBM SPSS Statistics 27, for the frequencies in the values of each of the scales, the Student's *t*-test for independent samples was used.

Results

The study population consists of nine patients hospitalized in the ICU during the specified time period, with the demographic characteristics outlined in Table 2.

Table 2: Demographic characteristics.

	Female	%	Male	%	Total	%
Total patients	2	22.22	7		9	100.00
Age group						
Under 45 years old		0.00	3	33.33	3	33.33
45–65 years	1	11.11	1	11.11	2	22.22
Over 65 years old	1	11.11	3	33.33	4	44.44
Marital status						
Married		0.00	2	22.22	2	22.22
Free union	2	22.22	4	44.44	6	66.67
Widower		0.00	1	11.11	1	11.11
Schooling						
Primary	1	11.11	4	44.44	5	55.56
Secondary	1	11.11	2	22.22	3	33.33
Technical		0.00	1	11.11	1	11.11
Occupation						
Independent		0.00	1	11.11	1	11.11
Various trades	1	11.11	3	33.33	4	44.44
Pensioner	1	11.11	3	33.33	4	44.44
Work activity						
Current	1	11.11	3	33.33	4	44.44
Unemployed		0.00	1	11.11	1	11.11
Pensioner	1	11.11	3	33.33	4	44.44
Socieconomic stratum						
2	1	11.11	7	77.78	8	88.89
3	1	11.11		0.00	1	11.11

Clinical characterization in hospitalization

As previously mentioned, hospitalized patients received comprehensive sepsis management in accordance with the institution's clinical practice guidelines, which are based on the Surviving Sepsis Campaign: International Guidelines for the Management of Sepsis and Septic Shock (2021) [11]. They presented with various etiologies of sepsis, resulting in a total of nine patients who met all inclusion criteria. However, only four of them were administered Sodium ascorbate according to the protocol. Based on this, several variables were measured, as detailed in Table 3.

Distributing the variables described in Table 3, the doses of Sodium ascorbate administered to patients ranged from 462 mg/kg/day to 600 mg/kg/day. The length of stay, the number of days with altered SIRS and SOFA scores, and the time required for SIRS and SOFA improvement were measured. This data was compared between patients who received Sodium ascorbate and those who did not, as well as the number of days required to reduce C-reactive protein levels, the number of patients discharged, and those who passed away.

Initially, a measurement was conducted to assess the impact of ascorbate in relation to the length of hospitalization. Statistical analysis tests were performed for these variables. For the analytical component, the Chi-square test was applied to outcome variables such as hospital stay duration, days with altered SIRS and SOFA scores, time required to reduce C-reactive protein levels, and the number of discharged and deceased patients. Numerical variables were categorized, and the results are presented in Table 4.

Regarding the values presented for the SOFA and SIRS scales, an analysis of these scores was conducted, as described in Table 5. The analysis considers the moments when the

Table 3: Hospitalization characteristics.

	Female	%	Male	%	Total	%
Type of sepsis						
Bacterial pneumonia	1	11.11	2	22.22	3	33.33
Sepsis secondary to device	0	0.00	2	22.22	2	22.22
Septic shock due to urinary infection	0	0.00	1	11.11	1	11.11
Pneumoconiosis	0	0.00	1	11.11	1	11.11
Sepsis due to respiratory tract infection	1	11.11	0	0.00	1	11.11
Sepsis from foot ulcer	0	0.00	1	11.11	1	11.11
Patients with sodium ascorbate treatment						
Patients with sodium ascorbate	1	11.11	3	33.33	4	44.44
Patients without sodium ascorbate	1	11.11	4	44.44	5	55.56
Daily dose of sodium ascorbate						
462 mg/kg/day	0	0.00	1	11.11	1	11.11
500 mg/kg/day	0	0.00	1	11.11	1	11.11
600 mg/kg/day	1	11.11	1	11.11	2	22.22
Without sodium ascorbate	1	11.11	4	44.44	5	55.56
Days of stay						
Less than 10 days	1	11.11	2	22.22	3	33.33
10–20 days	1	11.11	3	33.33	4	44.44
21–30 days	0	0.00	1	11.11	1	11.11
More than 30 days	0	0.00	1	11.11	1	11.11
Days SIRS and SOFA altered in patients with sodium ascorbate treatment						
Less than 5 days	0	0.00	3	33.33	3	33.33
5–10 days	1	11.11	0	0.00	1	11.11
Days altered SIRS and SOFA in patients without treatment with sodium ascorbate						
Less than 5 days	0	0.00	0	0.00	0	0.00
5–10 days	1	11.11	0	0.00	1	11.11
More than 10 days	0	0.00	4	44.44	4	44.44
Days that sodium ascorbate improved SIRS and SOFA in patients						
Less than 5 days	1	11.11	3	33.33	4	44.44
Days that conventional treatment improved SIRS and SOFA in patients						
5–10 days	1	11.11	0	0.00	1	11.11
More than 10 days	0	0.00	4	44.44	4	44.44
Patients with sodium ascorbate treatment						
Deceased	0	0.00	0	0.00	0	0.00
Hospital discharge	1	11.11	3	33.33	4	44.44
Improves C-reactive protein in less than 5 days	1	11.11	3	33.33	4	44.44
Patients without sodium ascorbate treatment						
Deceased	1	11.11	1	11.11	2	22.22
Hospital discharge	0	0.00	3	33.33	3	33.33
Improves C-reactive protein in less than 5 days	0	0.00	0	0.00	0	0.00

Table 4: Association between patients treated with sodium ascorbate and those who were not (X^2 and logistic regression).

	X^2 Test	p-Value
Days of stay	2.70	0.099
Days with SIRS and SOFA altered	9.00	0.003
Deceased	2.05	0.151
Hospital discharge	2.05	0.151
Logistic regression	**Days with SIRS and SOFA altered**	
Variable	**Wald**	**p-Value**
Age	0.04	0.837
Gender	0.03	0.858
Treatment with ascorbate/without treatment with ascorbate	9.00	0.003
Days of stay	2.11	0.157
Deceased	2.06	0.150
Hospital discharge	2.06	0.151

patient is admitted to the Intensive Care Unit, when treatment with ascorbate is initiated, and upon discharge from the Intensive Care Unit (Table 6).

Discussion

There has been extensive discussion about the potential impact of Vitamin C, its various antioxidant effects, and its possible role as an adjuvant in the treatment of different diseases, enhancing therapeutic outcomes and improving patients' quality of life [12].

However, there are different forms of Vitamin C, such as ascorbic acid and sodium ascorbate, among others. The latter is less acidic and more stable in solution, making it the preferred form for intravenous administration. This allows for the safe administration of high doses, which has been tested in various conditions, including sepsis in the ICUs [13, 14].

Several articles have been published on the use of Vitamin C as an adjuvant in various conditions, clearly

Table 5: Values of the SOFA and SIRS scale, for patients hospitalized in the ICU, according to the application of ascorbate.

Patients	SOFA Scale value				SIRS Scale value				Output status
	Income	Beginning ascorbate treatment	Ascorbate final	Exit	Income	Beginning ascorbate treatment	Ascorbate final	Exit	
Patients 1	1	1	0	0	4	4	1	0	Medical discharge
Patients 2	1	1	0	0	4	4	0	0	Medical discharge
Patients 3	2	N/A	N/A	8	4	N/A	N/A	4	Death
Patients 4	0	0	0	0	4	4	0	0	Medical discharge
Patients 5	0	N/A	N/A	0	4	N/A	N/A	0	Medical discharge
Patients 6	1	N/A	N/A	4	4	N/A	N/A	4	Death
Patients 7	2	2	0	0	4	4	2	0	Medical discharge
Patients 8	3	N/A	N/A	0	4	N/A	N/A	0	Medical discharge
Patients 9	3	N/A	N/A	0	4	N/A	N/A	0	Medical discharge

showing that the clinical outcome of its application largely depends on the daily dose administered [15, 16]. As demonstrated in different studies, this raises an important question about how Vitamin C should be applied according to therapeutic objectives.

Regarding sepsis, multiple studies have been published. One notable example is the study by Fowler et al., which included a sample of 167 patients. Vitamin C, in the form of ascorbic acid, was administered over 96 h at a dose of 200 mg/kg/day, with the SOFA score being the primary outcome measured. The results were not statistically significant for the SOFA score. However, among the 46 secondary outcomes assessed, statistical significance was observed in mortality, the number of ventilator days, and survival [17].

Additionally, a meta-analysis published in 2022 by Chen et al. reviewed all of the existing literature on the application of Vitamin C in sepsis. The meta-analysis included 24 studies with a total of 3,759 patients and concluded that intravenous vitamin C could reduce mortality and SOFA scores, though these results were not statistically significant. Furthermore, the analyzed studies were heterogeneous. Notably, while the analysis considered intravenous administration, it did not include the dose of Vitamin C in the evaluation of results an important variable in determining statistical significance for sepsis outcome measures [18].

Based on previous research, there is potential evidence of a beneficial impact of intravenous Vitamin C administration in sepsis. However, the results, while promising, often lack statistical significance. For this reason, we decided to conduct this pilot study to evaluate whether high doses of 462–600 mg/kg/day, combined with standard treatment defined by clinical practice guidelines, could impact SIRS and SOFA scores in ICU patients with sepsis. The findings were promising, particularly regarding the number of days with altered SIRS and SOFA scores in patients treated with Vitamin C compared to those who were not. Similarly, the number of discharged patients and deaths was evaluated, although these latter two variables were not statistically significant (X^2: 2.05, p=0.151). However, the variable “days with SIRS and SOFA” was statistically significant (X^2: 9.00, p=0.003).

These findings suggest the need for more robust and methodologically sound studies. Future research should focus not on ascorbic acid but on Sodium ascorbate administered at doses exceeding 462 mg/kg/day to establish the therapeutic dose of Sodium ascorbate for complex conditions such as sepsis in the ICU.

Regarding the values, we observe that although the patients who received ascorbate treatment exhibit better numerical outcomes compared to those who did not, there are still two deceased individuals within this group.

Table 6: Frequencies of the values presented in the SOFA and SIRS scale concerning the application of ascorbate.

	Average	Median	SD	Minimum	Maximum	*F*	p-Value	IC/95 %
Patients with ascorbate								
SOFA Scale (ICU admission)	1.00	1.00	0.18	0.00	2.00			
SOFA Scale (home ascorbate treatment)	1.00	1.00	0.18	0.00	2.00			
SOFA Scale (final treatment with ascorbate)	0.00	0.00	0.00	0.00	0.00			
SOFA Scale (ICU output)	0.00	0.00	0.00	0.00	0.00	13.20	0.008	(−6.69–1.89)
SIRS Scale (ICU admission)	4.00	4.00	0.00	4.00	4.00			
SIRS Scale (start ascorbate treatment)	4.00	4.00	0.00	4.00	4.00			
SIRS Scale (final treatment with ascorbate)	0.75	0.50	0.96	0.00	2.00			
SIRS Scale (ICU output)	0.00	0.00	0.00	0.00	0.00	74.66	0.001	(−1.05–0.25)
Patients with ascorbate								
SOFA Scale (ICU admission)	1.80	2.00	1.30	0.00	3.00			
SOFA Scale (ICU output)	2.40	0.00	3.58	0.00	8.00	13.20	0.008	(−6.69–1.89)
SIRS Scale (ICU admission)	4.00	4.00	0.00	4.00	4.00			
SIRS Scale (ICU output)	1.60	0.00	2.19	0.00	4.00	13.20	0.008	(−6.69–1.89)
Output status	**Patients with ascorbate**	**%**	**Patients with ascorbate**	**%**				
Medical discharge	4	100.00	3	60.00				
Death	0	0.00	2	40.00				
Total	4	100.00	5	100.00				

However, these differences are not statistically significant. This may be due to the limited sample size and the short follow-up period, highlighting the need for a larger study with greater methodological robustness that incorporates these variables.

Conclusions

Considering the limitations of this study in terms of follow-up duration and sample size, we can conclude that Vitamin C, specifically in the form of Sodium ascorbate, has a direct impact on improving organ function and potentially inflammation (SIRS and SOFA scores) in patients admitted to an Intensive Care Unit. For future clinical trials involving septic patients, it is essential to use doses exceeding 462 mg/kg/day and ensure the inclusion of Sodium ascorbate as a coadjuvant in the treatment of this patient population.

Limitations

The limitations of this study lie primarily in the methodological aspects of its design, given its short duration and the restricted sample size, as well as its retrospective nature. However, its findings provide valuable guidance on how a future randomized, prospective, double-blind clinical trial should be structured. Furthermore, if vitamin C is to be used as an adjuvant in the treatment of sepsis in intensive care settings, it must be administered at a dose exceeding 462 mg/kg/day, and the specific form of vitamin C to be included should be Sodium ascorbate.

Research ethics: The Research Ethics Committee of the Colombian Society of Preventive and Orthomolecular Medicine is an independent Ethics Committee based in the city of Bogotá, which is governed by the national regulations of Colombia, as well as by international guidelines applicable

to research with human beings. The approval of this study by this Ethics Committee is based on ethical and legal standards; including the Declaration of Helsinki, to which the authors of this study adhere and follow its guidelines, information management is part of purely descriptive processes and does not represent a risk to the integrity or confidentiality of the research subject.

Informed consent: Informed consent was obtained from the person included in this study.

Author contributions: The authors of this study confirmed the contribution to the article as follows: conception and design of the study: Martinez Ramos Adlay – Clinical Follow-up of patients; Galindo Salom Hugo Mario – Clinical assessment of patients and medical consultant on the application of ascorbate, writing of the article; Prieto Lozano Helber Armando – Design of the medical consulting study on the application of ascorbate; Lozada Posada Paulo Andres – Information Collection, Article Writing; Martinez Juan Manuel – Interpretation of results, review of the article; Guerrero Maritza – Interpretation of the results, writing and review of the methodology and writing; Carrillo Bravo Carlos Alberto – Study design, data analysis, writing of the article, submission to the journal. All authors reviewed the results and approved the final version of the manuscript.

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