

ORIGINAL ARTICLE

Clinical Study of Patients with Heart Failure under treatment with Ozone Therapy

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ABSTRACT

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Heart failure (HF) is framed in one of the types of cardiovascular diseases; it consists of an acute and chronic form. The disease can evolve slowly from asymptomatic left ventricular dysfunction, to a state of severe disability, presenting a wide prevalence in the population around 10% in people over 70 years old. More than three-quarters of the deaths from this pathology normally occur in low or middle-income countries. Angola is not exempt from this health problem be observed in a relatively young people, bringing disability and death at an early stage of life. Scientific advances and innovative treatments for the control and prevention of the disease continue to be insufficient.

The ozone for its antioxidant, hemoreological properties, oxygenation enhancers and blood circulation is an alternative treatment for these patients.

We have performed a study where 45 patients who were diagnosed with a chronic stage of II-III HF due to the functional classification of the New York Heart Association (NYHA) and American Cardiology College / American Heart Association (ACC / AHA), previous echocardiogram with a Fracture of Left Ventricular Ejection (LVEF) less than 45%. We administered a Major Autohemotherapy with a protocol of 15 sessions, maintenance every 15 days and cycles every 6 months at 50 µg of concentration, an initial dose of 4,000 µg / mL up to 12,000 µg / mL during the 3 years of treatment.

Patients after the first treatment cycle improve their functional physical capacity and LVEF increased to normal levels (55%). It was proved that Autohemotherapy is an adjuvant, viable and beneficial treatment in chronic HF.

Keywords: Heart failure, major autohemotherapy, ozone therapy, left ventricular ejection fraction

Introduction

Heart failure (HF) is a worldwide public health problem in developed countries, approximately 2% of the adult population has HF, a prevalence that increases exponentially with age, as it is less than 1% before the 50 years and then doubles with each decade to exceed 8% among those over 75 years [1,2].

HF is the inability of the heart to pump blood properly according to the needs of the hepatic metabolism; if it succeeds, it does so at the expense of an abnormal elevation of the filling pressure of the cardiac ventricles either by myocardial disease or excessive overload. This brings with it a neurohormonal response with effort intolerance, fluid retention and reduced longevity.

In 2003, the American Heart Association (AHA) reported that 48 million hospital discharges occurred in the United States with this diagnosis [3]. In the Framingham study, HF in men aged 50-59 years was 8 per 1,000 inhabitants and increasing to 70 per 1,000 in patients over 80 years (very similar numbers in women) [4].

However, in Africa it has a rather different etiology to that described in Europe and America, it is related to the degree of development of the continent and affects predominantly a young population. Damasceno, in his study on heart failure in Africa, throughout a meta-analysis including studies published up to 2007 by Bongani Mayosi et al. [5] found that arterial hypertension was the main cause of heart failure followed by cardiomyopathies.

The current therapeutic approach of patients with HF is aimed at improving signs and symptoms, correcting volume overload, increasing end-organ perfusion, improving cardiac contractility and hemodynamic status [6].

During the last 24 years, the mechanisms of action of ozone in human blood have been clarified [7]. It is stated that its therapeutic properties are: improving the metabolism of oxygen, modulate biological oxidative stress, modulate the immune system, intervene in the synthesis and / or release of autacoids (endogenous substances with diverse actions physiological and pharmacological), regulate metabolism, in addition to exert a great effect as germicide [8].

For all of the above, our team decided to analyze the clinical and echocardiographic (LVEF) effects induced by major autohemotherapy applied in patients with CHF.

Materials and methods

A retrospective cross-sectional study was performed at the Cardiozono Medical Center located in Luanda, Angola. The final sample consisted of 45 patients of both sexes, who presented a diagnosis of CHF, referred from our Cardiology Department and other Hospital offices, who started treatment of ozone therapy indistinctly in the period from June 2014 to June 2017. We emphasize that in our work we performed an analysis of the patients treated in this time period of their evolution corresponding to one year performing the therapy.

Inclusion criteria were:

Patients with a diagnosis of HFC class II-III of the New York Heart Association (NYHA) [9] and American Cardiology College / American Heart Association (ACC / AHA), previous echocardiography with a (LVEF) between 35% and 50% and patients with a time greater than 6 months of treatment with furosemide 40 mg at 8 hours and 40 mg at 16 hours, spironolactone 50 mg every 12 hours, hydrochlorothiazide 25 mg daily, carvedilol 12.5 mg every 12 hours, mononitrate of isosorbide 20 mg daily and aspirin 100 mg daily. During the period of time analyzed. 45 patients were included in the

treatment, 20 were women and 25 men, the age of the patients was from 40 to 65 years, (60 to 65 years, 20 patients, 11 women and 9 men, from 50 to 59 years, 20 patients, 13 men and 7 women and from 40 to 49 years old, 5 patients, 3 men and 2 women).

Exclusion criteria were:

Patients with HF of a diagnosis (less than 6 months) with medical treatment and patients with secondary HF produced by autoimmune diseases.

Treatment Protocol:

The patients received 15 sessions of major autohemotherapy (one daily session). In each session we used a German-made Promedic Humazon equipment (Humares GmbH, Bruchsal, Germany), 3-way stopcock, epicranial needle 19 G, Sangiset (Humares GmbH, Bruchsal, Germany) with capacity of 350 mL where we put 10 mL of 3.13 % sodium citrate to avoid blood clot during the procedure and other disposable material.

The major autohemotherapy (Table 1) was performed at a concentration of 50 µg / mL in 100 mL of blood; the initial dose of the therapy was 4000 µg (80 mL of ozone gas at 50 µg / mL concentration); we increased the dose by 2000 µg every 2 days until reaching a dose of 12000 µg (240 mL of ozone gas at 50 µg / mL concentration), maintaining this dose as a maintenance dose every 15 days throughout the year.

Table 1: Ozone Treatment protocol

Days of treatment	Amount of O ₃ (µg)
Days 1-2	(4000) µg per 100 mL, 50 µg/mL
Days 3-4	(6000) µg per 100 mL, 50 µg/mL
Days 5-6	(8000) µg per 100 mL, 50 µg/mL
Days 7-8	(10000) µg per 100 mL, 50 µg/mL
Days 9-15	(12000) µg per 100 mL, 50 µg/mL
Maintenance every 15 days	(12000) µg per 100 mL, 50 µg/mL

The parameters evaluated were:

- Heart failure Functional Classification according NYHA [9] (New York Heart Association) (Table 2)
- Ejection Fraction Classification according NYHA [9]:
 - Ejection fraction NORMAL ≈ 50-70% is expelled during each contraction (there is usually a sense of comfort during physical activities)
 - Ejection fraction LIMIT ≈ 41-49% is expelled during each contraction (symptoms may be more noticeable during physical activity)
 - Reduced ejection fraction ≤ 40% is expelled during each contraction (symptoms may be more noticeable at rest)

Tabla 2. Functional Classification of NYHA (New York Heart Association) HF.

CLASS	CHARACTERÍSTICS	DEFINITION
I	Without limitation: normal physical exercise does not cause fatigue, dyspnoea or undue palpitation	Asymptomatic Left Ventricular Dysfunction
II	Slight limitation of physical activity: without symptoms at rest, normal physical activity causes fatigue, palpitations or dyspnoea.	Mild Heart Failure
III	Charged physical limitation: no symptoms at rest, any physical activity causes the appearance of symptoms	Moderate Heart Failure
IV	Inability to perform physical activity: the symptoms of heart failure are present even at rest and increase with any physical activity	Severe Heart Failure

Statistical analysis:

We used SPSS 19.0 statistic software and we categorized the values using contingency tables utility and chi-square analysis for the significance on the changes before and after the treatment. Values of chi-square under 0,05 were considered significant.

Results and Discussion

The NYHA functional classification assesses the physical activity of the patient with CHF, based on the subjective assessment made by the physician during the examination of the presence and severity of dyspnoea. This has an important prognostic value since it allows following the evolution and response to the treatment [9].

During ozone therapy, we observed that most of the patients were in class III for 66.7% of the patients before starting the treatment. At 45 days after the 15 sessions, a significant change was observed, with 86.7% cases in class II, results that remained in progress throughout the year under treatment until reaching 53.3% of them to class I. (Table 3).

This process suggests that the response of the organism to autohemotherapy with the doses used was favorable, although it is not able to eradicate the disease; it tends to significantly improve the functional limitations of HF, which agrees with similar studies [10].

The ejection fraction was assessed during different stages of our study (Table 4). Before starting treatment, most patients had an LVEF of 35-40 for 22.2%, and 44.4% had a Fraction of Ereccion of 45-50 per year, attributing the effects of ozone on the contractile function of the myocardium, which

improves the metabolism of the cardiac muscle, increases the circulating serotonin and causes a cardioprotective effect already mentioned in previous studies [11,12].

Tabla 3. Behavior of the Functional Classification of HF in 45 patients treated with ozone therapy.

CLASS	Before starting treatment	45 days after completion of treatment	6 months	1 year
I	0	6(13.3%)*	19(42.22%)*	24(53.3%)*
II	15(33.3%)	39(86.7%)*	26(57.8%)*	21(46.7%)*
III	30(66.7%)	0	0	0
IV	0	0	0	0

*chi-square significant value

Tabla 4. Eject Fraction Behavior in 45 patients treated with ozone therapy.

FEVI	Before starting treatment	45 days after completion of treatment	6 months	1 year
30-35	11(24.5%)	6(13.3%)*	0	0
35-40	19(42.2%)	13(28.9%)*	13(28.9%)*	2(4.4%)*
40-45	10(22.2%)	15(33.3%)*	14(31.1%)*	17(37.9%)*
45-50	5(11.1%)	7(15.6%)*	12(26.7%)*	20(44.4%)*
> 50		4(8.9%)*	6(13.3%)*	6(13.3%)*

*chi-square significant value

Conclusions

This study strongly suggests that the application of major autohemotherapy produced a clinical and functional improvement in patients with CHF, evidencing its effectiveness as adjuvant therapy.

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