



USE OF VIDATOX® 30CH IN ONCOLOGICAL, AUTOIMMUNES AND DEGENERATIVE DISEASES

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RESUMEN

Introducción: El VIDATOX® 30CH es una dilución homeopática 30 centesimal que utiliza como tintura madre el veneno del alacrán *Rhopalurus Junceus*. En la actualidad considerado como el producto líder de LABIOFAM y registrado como analgésico y antiinflamatorio. **Objetivo:** Describir la evolución clínica de los pacientes tratados con VIDATOX® 30CH. **Materiales y métodos:** Se realizó un estudio observacional descriptivo de pacientes que acudieron a las consultas médicas de LABIOFAM durante el periodo 2011-2012 y fueron tratados con VIDATOX® 30CH. Se incluyeron 2541 pacientes. El tipo de enfermedad, sintomatología motivo de consulta, frecuencia de administración del VIDATOX® 30CH y momento en que comienza a experimentar mejoría de los síntomas fueron las principales variables. Para comparar la evolución clínica de los pacientes por enfermedad, se determinó Chi-cuadrado de Pearson y para comparar el tiempo en que los pacientes experimentaron mejoría de los síntomas, se realizó Análisis de las Varianzas (ANOVA). **Resultados:** Predominaron los pacientes con enfermedades oncoproliferativas (2261; 88,98%) y las degenerativas en segundo (132, 5,19%). El dolor fue el síntoma más referido (1431; 56,32). A la mayoría de los pacientes se les recetó el VIDATOX® 30CH tres veces al día (1389; 54,7%). El 96,92% de los pacientes a los que se le prescribió el VIDATOX® 30CH tres veces al día mejoraron el dolor. **Conclusiones:** Se concluyó que el medicamento homeopático VIDATOX® 30CH es una viable opción terapéutica en el tratamiento sintomático de pacientes portadores de enfermedades oncoproliferativas inflamatorias, autoinmunes y degenerativas.

Palabras clave: VIDATOX® 30CH, homeopático, analgésico, antiinflamatorio. *Rhopalurus Junceus*.

ABSTRACT

Introduction: VIDATOX® 30CH is an homeopathic product from the venom of the *Rhopalurus Junceus* scorpion. **Objective:** To describe the clinical evolution of the patients treated with VIDATOX® 30CH. **Materials and methods:** It was performed an observational and descriptive study of patients attended on the medical services of LABIOFAM treated with VIDATOX® 30CH during the period of 2011-2012. 2541 patients were included. Symptoms consultation reason, frequency of administration of VIDATOX® 30CH and the moment in which they began to improve symptoms were the main variables. The Chi-square of Pearson test was used to compare the clinical evolution and the improvement of the symptoms was tested by Analysis of the Variances (ANOVA). **Results:** The patients with oncoproliferative diseases prevailed (2261; 88,98%) and the degenerative ones were in second place (132, 5,19%). The pain was the most referred symptom (1431; 56,32). The majority of the patients were prescribed VIDATOX® 30CH three times daily (1389; 54,7%). 96,92% of the patients that were prescribed VIDATOX® 30CH three times daily improved the pain. **Conclusions:** The homeopathic product VIDATOX® 30CH is a therapeutic reliable option in the symptomatic treatment of patients with oncological, inflammatory, autoimmune and degenerative disorders.

Key Words: VIDATOX® 30CH, homeopathic, pain reliever, anti-inflammatory, *Rhopalurus Junceus*.

Homeopathy is a medical discipline that has more than 200 years of experience and which has advanced for the way of science, using scientific methods of investigation supported in the advances of immunology, genetics, physics, byocibernetic, etc.; it has a doctrinal statement, laws or very established principles: the law of Similia, constant to be a biological law, the unique remedy and the minimum dose, it can also be mentioned: the patogenesis, activated polar solvents, pathological individualization, medicamentous individualization, healing byocibernetic, etc., and a pharmacopeia totally different to the allopathic one, because the medicine doesn't work by means of chemical or biochemical laws but by means of the vital physic energy^{1,2}

Homeopathy was introduced in Cuba in the first half of the XIX century; in the XX century it had a great advance in the island, some specialists highlighted, such as: the doctors Juan José Hevia, Adolfo de Varona and José Juaquin, Navarro among others, this last one contributed to this therapy, two extracted medicines one of the Cuban flora, guao or *Commocladia dentata* and the other of the Cuban fauna, the hairy spider or *Tarantula Cubensis*. Nevertheless, the lack of schools, of official institutions and the influence of the Doctor-pharmacist North American Industry made possible the decrease of this therapy in the country. It was not up to the year 1992 that, due to the collaboration of two Mexican colleagues, the doors to this discipline were open in Cuba, again.^{1, 3-6}

Nowadays the homeopathic medicine is considered a therapeutic option in the symptomatic cure of patients with diverse diseases.⁴⁻²⁰

The Entrepreneurial Group LABIOFAM is in a moment of maturity and crystallization of a great part of its studies and with great advance in the clinical assays where many of their products are involved, among these VIDATOX® 30CH, an homeopathic product of natural origin.

This product represents one of the most recent achievements of the entity, it allows to improve the life's quality of people that suffer of cancer or that carry any other disease where the inflammatory process prevails.²¹⁻²³

VIDATOX® 30CH is a product, that was registered in March of the year 2011 by the CECMED as an analgesic and antiinflammatory, from now on, it is distributed in Cuba and abroad. In correspondence with its inscription VIDATOX® 30CH; is considered at present as a leader product of LABIOFAM; it is an homeopathic 30 centesimal dilution that uses as mother tincture the venom of the *Rhopalurus Junceus* scorpion.²¹⁻²³

Despite on the lack of knowledge of many people about the potentialities of Homeopathy, there is more certainty every day, that it has visible pharmacological action. In the year 2011 there was a boom in the affluence of patients to the consultations of the Medical Services of the Entrepreneurial Group LABIOFAM, because they were consulted daily more than 150 foreign patients during six months and up to now, they have consulted more than 200 Cuban patients that trust in VIDATOX® 30 CH as a therapeutic option to alleviate their ailments.

The present study is directed to give answer to the following scientific problem: Which is the clinical evolution of the patients treated with VIDATOX® 30CH?

OBJECTIVES

General

To describe the clinical evolution of the patients with diseases of inflammatory origin of the oncoproliferative, autoimmune and degenerative type treated with VIDATOX® 30CH.

Specific

1. To characterize the patients assisted in the consultations of the Medical Services of the Entrepreneurial Group LABIOFAM according to demographic and clinical variables.
2. To describe the behavior of the main signs and symptoms of inflammatory origin with the consumption of VIDATOX® 30CH.

MATERIALS AND METHODS

Context and classification of the study: It was performed a descriptive observational study of patients that went to the consultations of the Medical Services of the Entrepreneurial Group LABIOFAM during the period 2011-2012 and that were treated with VIDATOX® 30CH.

Universe and sample: The universe was constituted by all the patients that went to the medical consultations of LABIOFAM during 2011 -2012 and they were indicated VIDATOX® 30CH. The sample was constituted by 2541 of adult patients with inflammatory, oncoproliferative, autoimmune and degenerative diseases, consuming the homeopathic product for at least one month.

Variable: The main variables were age, sex, disease group, symptoms consultation reason, VIDATOX® 30CH administration frequency and the moment in which the patient begins to have an improvement of the symptoms.

Procedures: The data from the variables of concern in the study, were collected from the database and of the data collecting pattern.

Processing : To characterize the patients according to the demographic and clinical variables, summary measures were determined for qualitative and quantitative variables. To compare the clinical evolution of the patients according to the disease type, it determines the correlation rate with the Chi-square of Pearson test and to compare the period in which the patients experienced improvement of the symptoms according to the disease, the statistician Z, of the statistical analysis test from the variances (ANOVA) was determined. Taken into account an alpha 0,05. The results were presented in tables and in statistical graphics.

ANALYSIS AND DISCUSSION OF THE RESULTS

The inflammation can be due to different exogenous causes; among them, the physics (it includes the traumatisms, wounded, thermal changes), chemical (acids, alcohols, phenols.), radiations and microorganisms. The endogenous causes include the altered immunological reactions (hipersensibility and autoimmunity), privation of the sanguine contribution (ischaemia, heart attack tissue), organic liquids escaped from their original place (bile, urine, blood, synovial liquid) and neoplasias.^{24, 25}

Of 2541 patients included in the study, 1312 (51,63%) are of the feminine sex. The

patients with ages between 50 and 69 years prevailed (1212, 47,7%). Generally the patients affluence to the consultations increased in correspondence with the age. (table 1)

Table 1: Distribution of patients according to sex and age.

Age (years)	SEX				Total	
	Masculine		Femenine			
	No	%	No	%	No	%
Less than 30 years	38	1,50	51	2,01	89	3,50
30 to 49 years	140	5,51	353	13,89	493	19,40
50 to 69 years	670	26,37	542	21,33	1212	47,70
70 years and more	381	14,99	366	14,90	747	29,40
Total	1229	48.37	1312	51.63	2541	100.00

Source :Clinical Histories of the Medical Services Entrepreneurial Group LABIOFAM. 2011- 2012
Chi-Square of Pearson=105,1457 p=0,000

In the table 2, a prevalence of patients with oncoproliferative diseases represented by 2261 patients (88,98%) was observed. The degenerative diseases, had the second place with 132 patients (5,19%), followed in third place, by the patients with inflammatory chronic of the SOMA diseases , 115 (4,53%). The patients with autoimmune diseases were those of less incidence (33, 1,3%) . In all the groups women prevailed.

Among the patients carrier of malignant tumors, a prevalence of the patients with lung malignant tumor was presented (516 cases for 22,8%), followed by the patients with breast malignant tumor , represented by 337 cases (14,9%). 97% of these patients are carrier of epithelial tumors .

Table 2 : Distribution of patients according to the type of disease and sex.

Kind of disease.	Masculine		Femenine		Total	
	No	%	No	%	No	%
Oncoproliferative disease.	1153	45,38	1108	43,60	2261	88,98
Degenerative disease.	35	1,38	97	3,82	132	5,19
Inflammatory chronic of the SOMA disease.	36	1,42	79	3,11	115	4,53
Autoimmune disease.	5	0,20	28	1,10	33	1,30
Total	1229	48,37	1312	51,63	2541	100

When distributing the patients according to the clinical manifestations of the treatment with the homeopathic medication VIDATOX® 30CH, a prevalence of the pain was observed in 1431 patients (56,32%). Followed by the patients with functional impotence (207; 8,15%). The loss of weight (199; 7,83%), the astenia (193; 7,60%), the dyspnoea (175; 6,89%) and the migraine (117; 4,60%), were others of the symptoms mostly referred by the patients that went to the consultations of the Entrepreneurial Group LABIOFAM during the period of 2011-2012.

In the specific case of the patients with cancer, the main reported clinical manifestations were the pain, in 1 051 patients (46,5%), followed by the dyspnoea in 158 (7%) and the astenia in 120 (5,3%). In the rest of the patients the pain and the functional impotence prevailed

The analogy relation that should exist between the sick person symptoms and the action

of the medication was established by Hipocates, centuries later, in 1796, the German doctor Samuel Federico C. Hahnemann (1755-1843) rediscovered, by his own observation, "how the fellow men are treated with the fellow men", enunciating the law of "Similia similibus curentur" for the homeopathic medicines.^{4-6,11, 18, 19}

Not all the symptoms have the same value. The mental ones (state of mood, manias, deliriums, etc) are particularly the ones that occupy the first place, when they mark in the person an important change in his/her character, way of being, or his/her state of health. In second place, almost with the same importance of the mental ones, the general symptoms: these are referred to how the whole organism reacts to the disease, to the temperature, to the feeding, to certain position or posture, wishes (whims) or aversions. The local or particular symptoms that are also most common to several affected people with the same disease, are those of less importance for the indication and prescription of the medication: pain, cough, fever, inflammation, etc.^{4, 5}

To all the patients included in the study were indicated VIDATOX® 30CH. In the table 4 the prescription is described, for which they were taken into account each patient's individual characteristics. It was prescribed five drops of the homeopathic medication, by sublingual via once a day up to four times daily. To most of the patients, it was prescribed VIDATOX® 30CH three times a day (1389; 54,7%), followed by the patients with a prescription of twice daily (1092, 43,0%).

Table 4: Distribution of the patients according to the prescription of VIDATOX® 30CH.

Prescription	Frecuency	Percentage
Five drops once a day.	20	0,79
Five drops twice a day.	1092	42,98
Five drops three times a day.	1232	48,48
Five drops four times a day.	197	7,75
Total	2541	100,0

In the table 5 the patients are distributed according to the pain's evolution before and after the treatment. It was observed that of the 1431 (56,31%) patients that referred pain in the first consultation, only 127 (5%) of them referred pain after the treatment with VIDATOX® 30CH.

Of the 1 051 (46,5%) patients with oncoproliferative diseases that referred pain before the beginning of the treatment with VIDATOX® 30CH, only 79 (3,5%) manifested pain in the last consultation; it means that the evolution of the pain symptom during the study was satisfactory, since 972, presented pain when concluding the period of investigation.

The results of the Mc Nemar statistical test ($p=0,000$), evidence statistically significant

changes in the evolution of this symptom before and after the product's administration. Similar behaviors, are reported in the clinical assays consulted in the literature that presents the patients's answer while facing homeopathic treatments and they experience decrease of the pain .^{2, 3,7, 10, 24}

Table 5: Evolution of the pain before and after of VIDATOX® 30CH administration.

PAIN	BEFORE		AFTER	
	Nº	%	Nº	%
Without pain	1110	43,684	2414	95,002
With pain	1431	56,316	127	4,998
Total	2541	100	2541	100

Source: Clinical Histories of the Medical Services of the Entrepreneurial Group LABIOFAM. 2011- 2012

Proportion differences (%)=51,259 IC (95,0%) =[49,313 – 53,205]

McNemar test Chi-Square =1299,0069 p=0,000

In the table 5 was observed that the 96,92% of the patients that consumed VIDATOX® 30CH three times a day improved the pain. The patients that consumed the product twice a day had a percent of improvement of 95,88%. When determining the test of proportions's comparison it was obtained statistically significant differences with a reliability of 95%.

When analyzing the results that were obtained with the patient carrier of oncoproliferative diseases it can be appreciated that the patients treated with the disease schedules(program) of two (1071) or three (993) times a day, didn't manifest pain in the 98,1% and in the 98,0%, respectively ,when performing the final evaluation of the study, it was obtained statistically significant differences (p=0,012) among the group of patients that consumed the product two or three times a day in relation to the group of patients that consumed VIDATOX® 30CH four times daily.

This decrease of the pain so far as the patients consumed the medication, coincides with the aspects collected in the final results's Report on the use of VIDATOX® 30CH for the supposedly healthy patients (patogenesis), where some of the persons included in the study referred pain with the medicine administration, what presupposes that the consumption of the product by a sick person manifests the contrary effect.

Revisions performed on clinical assays of patients with chronic pain due to the cancer presence, assert that the therapeutic success of the treatments used in these studies is intimately related to the capacity that the products in investigation posses of influencing in the pain's disappearance , which in turn, influences directly in the functional capacity and in the improvement of the life's quality of these patients.^{3, 8, 13, 20, 24-26}

Table 5: Patients according to the daily administration program of VIDATOX® 30CH and presence of pain .

Prescription (Five drops)	SIN DOLOR		CON DOLOR		TOTAL	
	Nº	%	Nº	%	Nº	%
Once a day	7	35,00	13	65,00	20	0,79
Twice a day.	1047	95,88	45	4,12	1092	42,98
Three times daily.	1194	96,92	38	3,08	1232	48,48
Four times daily.	166	84,26	31	15,74*	197	7,75
Total	2414	95,00	127	5, 0	2541	100

Source : Clinical Histories Medical Services of the Entrepreneurial Group LABIOFAM. 2011- 2012
Chi-Square of Pearson= 210,7553 gl=3 p=0,012 *Corrected and classified residuals $\geq 1,96$

More than 70% of the patients reported improvement of their symptoms during the first thirty days of the month of treatment and the patients with joint pain , around the 3er day. Patients with oncoproliferative diseases experienced remarkable improvement of their general state between 45 and 90 days. The time rate in which the patients with oncoproliferative diseases tried with VIDATOX® 30CH showed favorable changes of the symptoms and signs associated to the disease, presented that as an average the patients that consumed the medication three times a day began to modify the symptoms 70 days after initiating the treatment. The smallest time in which the patients with cancer experienced changes in their symptoms, was reached to the 15 days of having consumed the product. The same happens to all the daily administration schedules. The maximum time in which the favorable changes began to appear was of 210 days.

Until now , it is not specified in the consulted literature when the patients begin to experience changes with relation to the initial symptoms , after the consumption of the products in study, that's why, these effects could imply a contribution to the field of the medicine prescription . This result supplements the approach of considering the treatment schedules three times daily as the most suitable for the appropriate prescription of the product.^{2, 3,7, 10, 24}

Table 6: Average of days in which the patient begins to feel an improvement of symptoms and the consultation reason(motive).

Kind of disease	Average (days)	Typical deviation.	Confidence interval for the media IC [95]		Min.	Max.
Oncoproliferative disease.	98,03	33,767	91,30	104,77	15	210
Inflammatory disease.	8,41	3,985	6,36	10,46	3	15
Degenerative and/or autoimmune disease.	9,67	4,550	7,40	11,93	3	21
Total	74,79	48,825	66,45	83,13	3	210

Statistical test Analysis Of Variance of one via (ANOVA) F 119.351 p 0.000

LI: Inferior limit *LS: Superior limit

The adverse events associated to the use of the homeopathic medicine VIDATOX® 30CH, were reported in few patients. The results showed that only 0,95% referred adverse events after the consumption of the medication. The described adverse events, were classified as slight and transitory. The patients recovered without the necessity of changing the attitude concerning the consumption of the medication.

The irritation of the oral mucous, the insomnia, the nausea(sickness), the gingival bleeding, gastritis and vomit were the manifestations referred by the patients who had adverse events(effects). Most of the patients that reported adverse events consumed the medication four times a day and those that fewer reported adverse events consumed VIDATOX® 30CH three times daily.

The use of homeopathics also causes adverse events associated to their consumption. Consulted studies, where this therapy type is used, don't refer numerous adverse reactions to these medications, which should not be interpreted as they don't exist.^{14-16,}

A previous study reports the occurrence of adverse reactions in the 9,4% of the included patients and these occurred events were classified as slight and transitory.¹⁷

The present investigation showed similar results with relation to the intensity and the duration of the adverse events related to the use of the homeopathic medicine VIDATOX® 30CH.

CONCLUSION

It was concluded that the homeopathic medication VIDATOX® 30CH is a viable therapeutic option in the symptomatic treatment of patients carrier of oncoproliferative, inflammatory, autoimmune and degenerative diseases.

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