LABIOFAM
Grupo Empresarial

FINAL REPORT

Assessment of the efficacy of VIDATOX® 30 CH among Colombian cancer patients

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ABSTRACT

Cancer has been the third commonest cause of death in Colombia; breast and cervico-uterine cancer are among the most significant in terms of their impact on public health, society and the economy. Against this background, a descriptive, retrospective study has been performed involving 80 patients of both sexes to assess the efficacy of VIDATOX® 30 CH among patients with breast, cervico-uterine and brain cancer. These were split into two groups, Group I receiving oncospecific treatment plus VIDATOX® 30 CH, while Group II received the test substance alone. In both cases, monitoring consultations were held 3, 7, 12, 18 and 24 months after the start of the treatment, to determine pain intensity and frequency, survival and clinical symptoms. It was concluded that VIDATOX® 30 CH has an analgesic effect, increases survival in the main by over 25 months and reduces the clinical symptoms of the disease.

INTRODUCTION

Cancer is a significant public-health problem worldwide; it is predicted that in 2030, reflecting demographic changes and greater exposure to risk factors, it will kill over 1.6 million people.[1] Colombia is no exception: cancer is the number three cause of death in the country for both sexes, preceded only by diseases of the circulatory system and those attributable to external causes.[2-5]

The magnitude of the problem is illustrated by the statistic that this group of diseases is one of the main causes of lost years of life among Colombians. Breast and cervico-uterine cancer stand out in terms of morbidity and mortality. The former causes 5,526 new cases and 2,253 deaths annually, while the latter is the primary cause of death related to sexual/reproductive health, involving 7,000 new cases and 3,300 fatalities per year. [6, 7]

Despite a prevention and screening programme at local and national level, Colombia (like other countries) has failed to achieve the expected results. The public-health, social and economic impact of this situation prompts a search for new treatment options that are effective in arresting oncological diseases and improve the quality of life of their sufferers. Against this background, homeopathy offers a therapeutic method in cancer treatment[8] whose advantage lies in its ability to evoke a reaction by the sick organism and stimulate the mechanisms of self-healing.

In particular, the use of scorpion venom in cancer treatment originated with research conducted by Debin & col. in 1991,which demonstrated for the first time that the venom of the *Leiurus quinquestriatus* scorpion possessed anti-tumour activity and inhibited glioma migration. The same activity was subsequently demonstrated for the *Buthus martensii* Karsch (BmK) species, although in murine models. Similarly, the venom of the *Euscorpius italicus* (Herbst, 1800) scorpion has been referenced in the Willmar Schwabe homeopathic pharmacopoeia. Clinical trials with BmK venom demonstrated the potential of these substances in the treatment of pain. [9,10] The venom of this species has been used in traditional Chinese medicine for treating conditions such as epilepsy, the pain caused by meningitis and rheumatism.

The venom of the *Rhopalurus junceus* scorpion, a species endemic to Cuba, has been used in Cuban traditional medicine to treat various diseases, including cancer. [11] Preclinical studies have demonstrated the substance's low toxic potential from oral administration, and significant analgesic, anti-inflammatory, anti-tumour and anti-metastatic effects among experimental animals (unpublished work). This led to the development of a simple homeopathic biotherapeutic from a mother tincture of the venom of this species, named VIDATOX® 30CH. The aim of the present study was to assess the efficacy of this preparation among Colombian patients diagnosed with cancer of the breast, cervix/uterus and brain.

MATERIALS & METHOD

Experiment design

A descriptive, retrospective study was performed involving 80 patients of both sexes to assess the efficacy of VIDATOX® 30 CH among sufferers from breast, cervico-uterine and brain tumours.

These were split into two groups:

- Group I (48 patients) received surgery, chemotherapy or radiotherapy or a combination of these, plus VIDATOX® 30 CH, while
- Group II (32 patients) received the test substance alone.

Universe

Colombian nationals, adult, of both sexes, suffering from the above-mentioned diseases as confirmed by at least two diagnostic techniques, who attended the Grupo Empresarial LABIOFAM medical service between May 2008 and December 2010.

Inclusion criteria

1. Colombian nationality
2. Expressly volunteering for the study, in writing
3. Over 55 years of age and 65 or less years of age
4. Type of cancer confirmed by histological or imaging techniques

5. Having the upper digestive tract open.

Exclusion criteria

1. Diagnosed with more than one type of cancer
2. Too physically or mentally impaired to reply to the survey
3. Presenting the following diseases: chronic pulmonary disease, cirrhosis of the liver, uncompensated diabetes mellitus, myocardial infarction, genito-urinary disorders, cerebral vascular accident (CVA), hypogonadism, asthma, any autoimmune disease.

Exit criteria

1. Voluntary withdrawal
2. Failure to complete the treatment profiles.

A chart was prepared for each patient, directly by the attending physician, recording the following information: sex, age, histological classification location of the tumour.

Dosage and method of use

The subjects of both groups received 5 sublingual drops of the test substance every 12 hours.

Bioethical considerations

Bioethical principles were followed throughout the research, including those of independence, goodwill, absence of malice, dignity and safety of the volunteers. The identities of the volunteers were protected, after obtaining their informed consent to the purely scientific use of the results.[12]

Variables monitored

Clinical assessment was performed by monitoring consultations held every three months. These assessed pain intensity and frequency, and decline in the clinical symptoms described at the first consultation. Relative survival at the 3, 7, 12, 18, 24 and over 25 months points was estimated according to the Hakulinen method at a confidence level of 95%.[13, 14]

RESULTS

Of the 80 patients in the study, 76.25% were women and 23.75% men. This female predominance reflects the fact that most of the malignant conditions included in the study mainly or exclusively attack females. The commonest histological type of tumour was the carcinoma (65.75%); the remaining 34.25% were adenocarcinomas.

Table 1. Distribution of patients by sex and tumour location

Group	*Sex*	*Tumour site*			*Total*
		Breast	*Cervico-uterine*	*Brain*	
I	Male	--	--	11	11
	Female	13	15	9	37
	Total	**13**	**15**	**20**	**48**
II	Male	--	--	8	8
	Female	10	8	6	24
	Total	**10**	**8**	**12**	**32**
				Grand total	**80**

Table 2 reflects the analgesic effect of the test substance in terms of relief from pain after 3 months' administration, combined or alone, by tumour site and sex. As the table shows, in general the patients in both groups reported reduced pain intensity and frequency, and a consequently reduced dependence on conventional analgesics.

Significantly however, performance differed as between the two groups: more Group II patients reported reduced pain, notably those with breast cancer. This may be attributable not only to taking the preparation but also to the absence of oncospecific treatments, which are usually highly aggressive. Despite these inter-Group differences, the clinical results are consistent with those of the preclinical pharmacological studies, which demonstrated pain inhibition by the venom both under the hot plate method and with acetic-acid induced contortions.

Table 2. Analgesic effect of VIDATOX® 30 CH among volunteer oncological patients

Group I				
		Inhibition of pain (%)		
Site	*Sex*	*Time 0*	*Month 3*	*n/t*
Breast	M	--	--	--
	F	100	61.53	8/13
Cervico-uterine	M	--	--	--
	F	100	40.00	6/15
Brain	M	100	72.72	8/11
	F	100	77.77	7/9
Group II				
Breast	M	--	--	--
	F	100	100	10/10
Cervico-uterine	M	--	--	--
	F	100	87.5	7/8
Brain	M	100	87.5	7/8
	F	100	66.66	4/6

n: number of patients reporting improvement, by tumour site.
t: total number of patients by tumour site.

As regards survival, the results included survival rates among breast-cancer patients of 13-18 months post-treatment in 92.30% of cases in Group I and 90.00% in Group II. The corresponding rates for the cervico-uterine cancer cases were 93.33% and 100%; those treated with the test substance alone presented average survival rates 7 percentage points higher than those under the combined treatment regime. Importantly, 18.75% of the volunteers survived beyond 25 months, without reporting any adverse effects from taking the test substance.

Table 3. Relative survival in the two study groups

Group	*Tumour site*	*Relative survival (months)*					
		<7	*7-12*	*13-18*	*19-24*	*>25*	*n*
I	Breast	--	1	4	3	5	13
	Cervico-uterine	1	1	5	4	4	15
	Brain	3	7	10	--	--	20
II	Breast	--	1	2	3	4	10
	Cervico-uterine	--	1	3	2	2	8
	Brain	2	6	4	--	--	12

n: number of patients, by tumour site

Table 4 summarizes the remission of the clinical symptoms present on first consultation. This was apparent across the tumour types after three months' treatment: breast cancer (pain on palpation, secretions, invagination of the nipple and reduction in tumescent areas), cervico-uterine cancer (pain, bleeding), and brain cancer (headache, convulsions, slurred speech, vomiting). None reported feeling run-down, loss of appetite or significant weight loss since the first consultation.

Table 4. Improvement in clinical symptoms associated with taking VIDATOX® 30 CH

Group I				
Tumour site	*Sex*	*Presence of clinical symptoms (%)*		
		Time 0	*Month 3*	*n/t*
Breast	M	--	--	--
	F	100	100.00	13/13
Cervico-uterine	M	--	--	--
	F	100	86.66	13/15
Brain	M	100	90.90	10/11
	F	100	88.88	8/9
Group II				
Breast	M	--	--	--
	F	100	100.00	10/10
Cervico-uterine	M	--	--	--
	F	100	87.5	7/8
Brain	M	100	100.00	8/8
	F	100	83.33	5/6

n: number of patients reporting improvement, by tumour site
t: total number of patients by tumour site.

CONCLUSION

Based on an analysis of the study data, the administration of VIDATOX® 30 CH to cancer patients produces: a reduction in pain, survival beyond 25 months and improvement in clinical symptoms.

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Signature sheet

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