CLINICAL

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TREATMENT WITH CITOMIX™ OF PATIENTS WITH HVBC, HVCC AND HVBC+HVCC

RIASSUNTO

20 patients have been included in the study (15 men and 5 women, aged between 18 and 51): 9 were diagnosed with chronic viral hepatitis B (HVBC), 10 diagnosed with chronic viral hepatitis C (HVCC), and 1 with mixed chronic viral hepatitis B+C (HVBC+HVCC).
The diagnosis has been confirmed by laboratory tests [in HVBC patients, anti-HBs (AgHBs, AgHBe, anti-HBe, anti-HBc) and in HVCC (anti-HVC IgM and anti-HVC)].
The treatment with Citomix™ lasted three months:
- Citomix™: 10 granules, twice a day (morning and evening) for the first 5 days; afterwards 3 granules, twice a day (morning and evening), 15 minutes before meals for 6 days a week.
Patients have been clinically monitored at the beginning of the treatment, after one, two months and at the end of the treatment through biochemical methods (ALAT, ASAT, thymol test and prothrombin index), serologic tests (in HVBC patients: AgHBe, anti-HBe and anti-HBs; in HVCC patients: anti-HCV IgM) and the haemogram at the beginning and the end of the treatment.
- The treatment with Citomix™ had positive results: clinical improvement in patients with HVBC and HVCC; decrease or normalization of liver and spleen sizes; normalization of ALAT, thymol test and prothrombinic index values; formation of Anti-HBs in 4 patients diagnosed with HVBC; improvement of the immune status more marked in patients with HVBC and HVBC+HVCC.

KEY WORDS **HVBC, HVCC, HVBC+HVCC, HEPATITIS, CITOMIX™, IMMUNOLOGICAL STATUS**

INTRODUCTION

Viral chronic hepatitis B and C represent a worldwide public health problem. Their modern treatment is an antiviral one using Interferons.
This therapy is difficult to manage because of multiple side effects; it is contraindicated, and only 30-40% of the patients can benefit from this treatment.
What about the rest of them?
- The aim of our study is to show the efficiency of treatment with **Citomix™** in chronic viral hepatitis B,C and mixed B+C.

PATIENTS AND METHODS

20 patients were included in the study –15 men and 5 women aged between 18 and 51 years, with 9 among them diagnosed with having HVBC for between 1 and 18 years, and 10 patients diagnosed with having HVCC for between 2 and 22 years. One patient with mixed chronic viral hepatitis B+C was diagnosed with having HVBC for 12 years, and HVCC for 11 years.
Patients with HVCC, HVBC and mixed HVCC+HVBC were clinically examined: anamnesis, liver and spleen palpation and percussion, chest auscultation and percussion and heart auscultation.

The dynamics of paraclinical and clinical investigations

Laboratory tests: serological investigations: the detection of AgHBe, anti-HBe, anti-HBs, IgM anti-HVC; biochemistry investigations: the determination of values of ALAT, ASAT, bilirubin, tymol test, prothrombin; and clinical exam: hemogram, were made at the start and end of treatment.

Patients were administered only Citomix™

- The first month of treatment: Citomix™ 10 pellets twice a day sublingually, in the morning and evening for the first 5 days, and for the next 21 days 3 pellets twice a day sublingually in the morning and evening.
On Sundays the medicine was not administered.
- The second and third month of treatment: Citomix™ 3 pellets twice a day sublingually in the morning and evening one hour before meals or one hour after meals.

RESULTS AND DISCUSSION

TAB. 1 shows the improvement in clinical symptomatology in patients treated

with Citomix™ in all of the three groups. The liver and spleen dimensions had normalized in 50% of the patients in the study, and had decreased by 2 cm in the other 50% of patients.

TAB. 2 shows the normalization of ALAT, thymol test and prothrombin index values and the improvement of ASAT values after the treatment with Citomix™.

TAB. 3 shows that chronic viral hepatitis B was AgHBe-negative in patients from the study. Anti-HBs had formed in patients after treatment in significant titres 91.6UI/l. So this may be an index of possible antiviral capacity of Citomix™.
IgM Anti-HBVC was revealed with the same frequency at the start and at the end of treatment.
Therefore, possible antiviral capacities had not been shown.

TAB. 4 shows **T** cell immunosuppression in patients diagnosed with HVBC at the start of treatment – 2nd degree in 75% and 1st degree in 25%, and **B** lymphocytosis of 3rd degree in 50% and 1st degree in 25% of patients.

An improvement with return of immune status to normal values had been established at the end of treatment in 75% and a persistence of **B** lymphocytosis of 1st degree in 25% of patients.

A T cell immunosupression was noted in patients diagnosed with HVCC at the start of treatment:3rd degree in 40%, which persisted after treatment in 20%, a B lymphocytosis of the 2nd degree in 20% initially, but after treatment lymphocytosis of 2nd degree in 40% patients.
▶ Citomix™ has probably an immunomodulator effect on humoral immunity.

A T cell immunosupression of the 2nd degree and lymphocytosis of the 1st degree in patients with the HVBC+HVCC were observed.
These indices returned to normal values after the treatment.

SYMPTOMS	AT THE TREATMENT'S START			AT THE TREATMENT'S END		
	HVBC n=9	HVCC n=10	HVBC+HVCC n=1	HVBC n=9	HVCC n=10	HVBC+HVCC n=1
Asthenia	4	4	1	2	-	-
Pain in the right hypochondrium	6	6	1	-	2	-
Vertigo	-	6	-	-	-	-
Myalgia	4	2	+	2	2	-
Joints pain	6	6	+	-	2	-
Nausea	-	8	-	-	-	-
General weakness	-	2	-	-	-	-
Pruritus	-	-	-	-	-	-
Hepatomegaly	9	10	1	4	4	-
Splenomegaly	9	4	-	4	4	-

TAB. 1

The dynamics of clinical symptomatology in patients treated with Citomix™ at the start and the end of treatment.

BIOCHEMICAL INDICES	AT THE TREATMENT'S START			AT THE TREATMENT'S END		
	HVBC n=9	HVCC n=10	HVBC+HVCC n=1	HVBC n=9	HVCC n=10	HVBC+HVCC n=1
ALAT (increased)	4	8	-	0	0	0
ASAT (increased)	2	8	-	0	3	0
Bilirubin (increased)	4	6	-	1	2	0
Thymol test (increased)	4	4	-	0	0	0
Prothrombin Index (decreased)	4	6	-	0	0	0

TAB. 2

The dynamics of biochemical indices in patients treated with Citomix™.

MARKERS	AT THE TREATMENT'S START			AT THE TREATMENT'S END		
	HVBC n=9	HVCC n=10	HVBC+HVCC n=1	HVBC n=9	HVCC n=10	HVBC+ HVCC n=1
AgHBe	-	-	-	-	-	-
Anti-HBe	9	-	1	9	-	1
Anti-HBs	-	-	-	1	-	-
Anti-HVC IgM	-	10	1	-	9	1

TAB. 3

The dynamics of viral markers in patients treated with Citomix™.

INDEX	NORMAL VALUES	AT THE TREATMENT'S START			AT THE TREATMENT'S END		
		HVBC n=9	HVCC n=10	HVBC+HVCC n=1	HVBC n=9	HVCC n=10	HVBC+HVCC n=1
Leukocytes (10^9/l)	4,5-8,0	6,325±0,342	5,5±0,63	4,6	6,95±0,464	5,08±0,649	4,4
Lymphocytes (%)	22-38	37±6,096	34±3,209	41	34,75±6,725	29,8±3,104	45
Lymphocytes (10^9/l)	1,2-2,4	2,425±0,249	1,916±0,345	1,9	2,325±0,271	1,56±0,302	2,0
Lymphocytes Ta (%)	20-34	20±3,240	13,8±2,905	16	15,5±1,5	18,6±1,363	16
Lymphocytes Ta (10^9/l)	0,3-0,7	0,525±0,131	0,286±0,081	0,3	0,377±0,078	0,206±0,068	0,32
Lymphocytes Ttot (%)	55-75	33,75±2,286	40,6±3,108	38	45±5,416	42,4±2,712	41
Lymphocytes Ttot (10^9/l)	0,9-1,5	0,85±0,125	0,822±0,183	0,7	1,092±0,269	0,66±0,143	0,8
Lymphocytes Tterm (%)	0-5	2,5±1,892	1±0,632	4	0	1,8±1,8	0
Lymphocytes Tterm (10^9/l)	0-0,09	0,057±0,042	0,02±0,013	0,07	0	0,032±0,032	0
Lymphocytes TFR-E-RFC (%)	38-58	22,75±2,428	28±1,760	25	29,5±3,685	26,2±1,827	30
Lymphocytes TFR-E-RFC (10^9/l)	0,7-1,1	0,57±0,113	0,558±0,121	0,5	0,725±0,16	0,442±0,104	0,6
Lymphocytes TFS (%)	12-28	11±0,912	12,6±1,503	13	15,5±2,872	17,2±2,537	11
Lymphocytes TFS (10^9/l)	0,23-0,43	0,267±0,032	0,258±0,064	0,25	0,38±0,114	0,33±0,106	0,22
Lymphocytes EAC-RFC (%)	9-18	27±6,916	22±4,062	22	20±4,242	26,4±2,158	17
Lymphocytes EAC-RFC (10^9/l)	0,18-0,32	0,64±0,162	0,43±0,114	0,42	0,397±0,058	0,412±0,093	0,34
CIC (U.E.)	≤ 60	45,25±11,360	59,2±15,477	90	66±16,643	45,6±18,004	34
LTL	4-7	7,945±1,181	7,67±1,083	6,5	7,35±1,504	8,22±1,075	5,5
T/B	2,0-5,0	1,715±0,418	2,05±0,430	1,7	2,75±0,850	1,55±0,197	2,4
TFR/TFS	2,0-4,0	2,037±0,380	2,28±0,152	1,9	2,075±0,375	1,668±0,303	2,7

TAB. 4

The dynamics of immunological indices in patients treated with Citomix™ at the treatment's start and end.

CONCLUSIONS

The treatment with Citomix™ contributed to:

1) a clinical amelioration in patients with HVBC and HVCC.

2) the liver and spleen dimensions were normalised in 50% of patients in the study, and in 50% the dimensions had reduced by 2 cm.

3) the normalization of ALAT, thymol test and prothrombin index values.

4) anti-HBs in significant titres was revealed in one patient out of 9 diagnosed with HVBC, and this suggests the presence of Citomix™ antiviral capacities.

5) the amelioration of immune status with an immunomodulatory action, which was more conclusive in patients with HVBC and HVBC+ HVCC.

An analysis of dynamics of control group had not established any clinical, biochemical or immunological amelioration.

This confirms the necessity of a pathogenic and immunomodulatory treatment.

The study needs to be continued taking into account some contradictory biochemical and immunological results for the determination of patient groups and treatment duration. ■

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