First Journal of Homeopathic Pharmacology
Published under the auspices of the Romanian Academy of Medical Sciences
Volume II, Nº 1, 2014

Anti-cytolytic homeopathic remedy, beneficial in chronic viral hepatitis

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Abstract

Based on the cellular and molecular level similitude law, discovered by one of the authors, an original homeopathic anti-cytolytic was developed. Administered to patients with chronic B and C hepatitis, the product has determined a significant decrease in serum ALT levels or its normalization. The action was due to increased resistance of the liver cell to viral aggression. Following the interruption of the hepatitis disease process in its first phase of cytolysis, it is expected that the other phases (inflammation and fibrosis) to be decelerated or stopped. The results demonstrate the correctness of the working hypothesis and represent an argument for the existence of the law of similarity at cellular and molecular level, evidence of the effectiveness of homeopathic remedies in underweight doses and the accuracy of the *Nanofarmacologie* term, given to *Homeopathic Pharmacology*.

Keywords: Pharmacology, homeopathic remedy, anti-cytolytic

Rezumat

Pe baza legii similitudinii la nivel celular si molecular, descoperita de unul din autori, a fost elaborat un produs homeopat original, cu actiune anticitolitica. Administrat la bolnavi cu hepatita cronica cu virus B si C, produsul a determinat scaderea semnificativa a nivelului ALT seric sau normalizarea acestuia. Actiunea s-ar datora cresterii rezistentei celulei hepatice la agresiunea virala. Urmare intreruperii procesului patologic hapatitic din prima lui faza, de citoliza, este de asteptat ca celelalte faze (inflamatie, apoi fibroza) sa fie incetinite sau oprite. Rezultatele obtinute demonstreaza justetea ipotezei de lucru, reprezinta o pledoarie pentru existenta legii similitudinii la nivel celular si molecular, o dovada a eficacitatii remediilor homeopate in doze subponderale si a corectitudinii denumirii de Nanopharmacology, data Farmacologiei homeopate.

Cuvinte cheie: farmacologie, remediu homeopat, anticitolitic

ISSN: 2344-1569
ISSN–L: 2344-1569

INTRODUCTION

With regrards to the classification of drugs in terms of allopathic pharmacotherapy, there are four categories:

1. Etiotropic action, on the cause of a disease (antibiotics, anthelmintics, etc.)
2. Antipathogenical action, modifying the pathophysiological mechanisms that cause disease (digitalics, vasoconstrictor, etc.)
3. Symptomatic action, of reducing or removing symptoms (analgesics, antipyretics, etc.).
4. Replacement of physiological factors action, in their absence or in hyposecretion (hormones, enzymes, etc.).

In homeopathy, the possibility of drugs to have etiotropic action is excluded, this type of action being reserved by nature only for allopathic medicines (2). Regarding replacement medication, homeopathy uses diluted and dinamized organotherapeutic drugs, but with much broader capabilities than allopathy. Homeopathic organotherapeutic preparations can determine stimulation, inhibition or normalization of the espected organs' or tissues' functions, depending on dilution.

In therapeutic practice, the usefulness and impact of efficiency have the highest value for the etiotropic medication followed by, in decreasing order, antipathogenic and symptomatic medication.

The disease is a health disorder due to the confrontation of two factors, the pathogen and the body. The result of the confrontation, the intensity and severity of the disease, depend on the ratio between the degree of aggressiveness of the pathogen and the resistance and defense capacity of the body. In medical practice allopathy "*has focused almost exclusively on the study of the case*" therefore on the pathogen, while homeopathy focused on "*a thorough study of the territory*" - the body condition (3).

In the therapy of viral hepatitis, drugs that address the two factors (the *pathogen* and the *territory*) can be used in theory. Still, many particular concerns remain.

Pathogens are viruses, microorganisms with biological features, due to which there can be no drugs with in vivo virus-killing action. In vivo viruses can not be killed, except by the body's immune system. Therefore, if a body is infected with a hepatitis virus and the immune capacity of the body cannot kill the virus from the first contact, the virus remains in the body until the end of its life, with rare exceptions. Currently there are many allopathic antiviral medication active against hepatitis, but all are virustatic. In patients treated with these substances, viruses no longer replicate, they become latent. Even if they determine the disappearance of

ISSN: 2344-1569
ISSN–L: 2344-1569

viremia, after a while without antiviral treatment the viremia reappears. Results can be improved by combination of 2-3 antivirals, but such treatment is very expensive. At least at this current stage, the eradication of viral hepatitis by systematic administration of antiviral associations to millions of patients infected with hepatitis is a chimera. One of the newest and most active antiviral - Sofosbuvir - recently approved by the FDA in the U.S., recommended in double combination with ribavirin against virus genotype 1 and 2, and in triple combination with ribavirin and peginterferon against virus genotype 3, has a cost of $84.000 for 12 weeks in the case of the double combination and $168.000 for 24 weeks, for the triple combination (4).

Taking into account the limitations and constraints raised, regarding the treatment of pathogens, an interesting and useful contribution could be the treatment of the *territory*, not so interesting for allopathy. In contrast, in the case of chronic hepatitis, classical homeopathy can play a role by treating the symptoms of viral infection. It is a symptomatic medication, but having secondary importance, as it is without influence on the evolution of the disease.

The discovery of the analogy between allopathy and homeopathy allowed one of the authors to develop the concept of homeopathic pharmacology and the analogy of allopathic pharmacology and homeopathic pharmacology. In this context the "law of similarity to the cellular and molecular level" was developed (5).

To demonstrate the validity of this law, a homeopathic anti-cytolytic preparation was developed. This preparation falls into the category of antipathogenic medications of the pharmacotherapeutic classification. In the treatment of chronic viral hepatitis, it would represent a second type of antipathogenical medication, along with interferon, another antipathogenic and etiotropic allopathic medication and the symptomatic allopathic and homeopathic one.

Materials and Methods

48 patients were treated, 36 with chronic hepatitis C and 12 with chronic hepatitis B. A few facts concerning the treated patients are shown in the following table.

	Hepatitis C	**Hepatitis B**
Age (years)	15-74	34-59
Illness duration (years)	1-20	2-29
Previously on Interferon (1-3 series)	12	-
Diabetes	12	-

ISSN: 2344-1569
ISSN–L: 2344-1569

The anti-cytolytic remedy was administered orally as capsules in the morning on an empty stomach. One capsule contained 200 mg lactose impregnated with anti-cytolytic homeopathic remedy, in final dilution 5 CH. One capsule per week was administered in cases with ALT serum levels above 120 U and 2 capsules per week in cases with ALT serum levels below 120 U. The duration of treatment and observation was 6 months for patients with virus C and 3 months for patients with virus B.
It was determined that the serum ALT (SGPT) before and at 3 and 6 months in patients with virus C and at 3 months in patients with virus B.

Experimental results and statistical evaluation

Statistical calculation was performed using GraphPad Prism version 5.0 for Windows (GraphPad Software - San Diego , California , SUA; www.graphpad.com).

The normality of the experimental results was established using the D'Agostino & Pearson test.

In order to compare the groups, the following tests were used:

- Parametric ANOVA test (compares n-groups) followed by Dunnett's post test (for baseline response);

- Student *t* test (compares two groups) - evaluation of ALT levels 3 months and 6 months compared to baseline

Table 1 – Serum ALT(SGPT) (IU) before and after treatment [C virus infection]

Nr	ALT IU - before treatment	ALT UI - 3 months through treatment	ALT UI - 6 months after treatment
1.	158	111	82
2.	141	103	101
3.	114	84	-
4.	214	126	91
5.	89	38	-
6.	109	94	23
7.	197	47	42
8.	199	151	-
9.	52	41	18
10.	143	37	39
11.	176	69	-
12.	176	92	-
13.	248	157	-
14.	240	30	-
15.	62	-	29
16.	141	129	61
17.	93	34	-
18.	128	61	-
19.	156	119	80
20.	143	105	103
21.	113	83	-
22.	215	127	92
23.	88	37	-
24.	110	95	24
25.	195	45	40
26.	201	153	-
27.	51	40	19
28.	144	38	40
29.	174	67	-
30.	178	94	-
31.	246	155	-
32.	242	32	-
33.	61	-	28
34.	140	128	60
35.	95	35	-
36.	128	61	-
M±SEM	**148.9 ± 9.425**	**82.88 ± 7.172**	**54.00 ± 7.097**

ISSN: 2344-1569

Table 2 - Change in serum ALT (IU) after treatment [C virus infection], through 3 months and 6 months. Statistical significance of the results (*t* Student: Compared to the original; ANOVA; Dunett post test)

Parameter	ALT IU - before treatment	ALT UI - 3 months through treatment	ALT UI - 6 months after treatment
M±SEM	148.9 ± 9.425	82.88 ± 7.172	54.00 ± 7.097
Effect/initial		-43.86%	-63.73%
t Student p/initial		< 0.0001***	< 0.0001***
ANOVA	0.0142*		
Dunett Post test		< 0.0001***	< 0.0001***

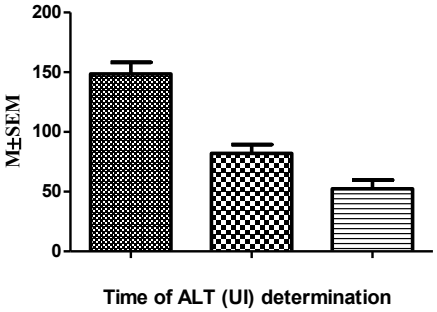

Figure 1- Average values of ALT (IU) before treatment and after 3 months and 6 months [C virus infection].

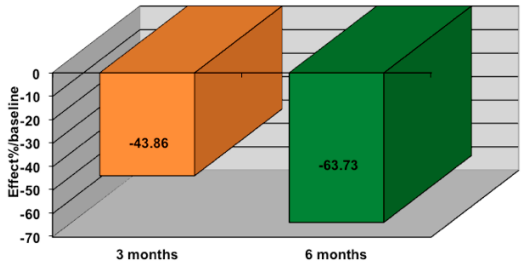

Figure 2 – Change in serum ALT (IU) after 3 months and 6 months of treatment, compared to the initial values [C virus infection].

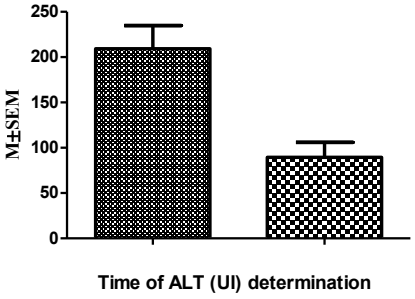

Figure 3 - Average values of ALT (IU) before and 3 months after treatment [B virus infection].

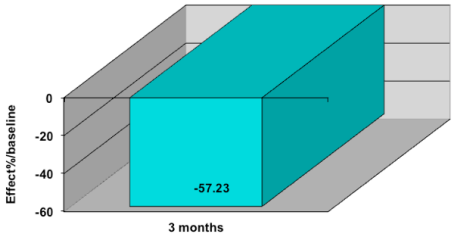

Figure 4 – Change in serum ALT (IU) after 3 months and 6 months of treatment, compared to the initial values [C virus infection].

Table 3 – ALT (SGPT) values (IU) before and after treatment [B virus infection]

Nr	ALT IU - before treatment	ALT UI - 3 months after treatment
1.	194	55
2.	167	116
3.	128	22
4.	346	103
5.	300	188
6.	121	53
7.	192	53
8.	169	118
9.	126	20
10.	348	105
11.	298	186
12.	123	55
M±SD	209.3 ± 25.64	89.50 ± 16.37
Effect/initial		-57.23%
t Student p/initial		0.0007***

Normal serum ALT values were obtained for:
- patients with C virus:
  -After 3 months in 12 patients = 33.33%
  -After 6 months in 8 patients = 44.44%
- patients with B virus:
  -After 3 months, 6 patients = 50%

During treatment with the anti-cytolytic, no other drugs were administered. All patients have undergone anti-cytolytic treatment with no adverse effect, a characteristic feature of homeopathic remedies.

Results and Discussion

The anti-cytolytic remedy produced a decrease in serum ALT levels in some patients and normalization in other patients. After three months, the decrease was 43.86% in patients with C virus and 57.23% in patients with B virus. After 6 months, in patients with C virus, ALT decreased by 63.73%. The level reached normal values of ALT, in 33.33% of patients after three months and 44.44% after 6 months, for C virus patients. Normal ALT values were obtained in 50% of B virus patients after 3 months. All results are statistically significant.

The results express the existence of an obvious anti-cytolytice action of the preparation, while maintaining viremia. It can be considered that the product increases the resistance of the liver cell against hepatitis virus aggression, which determines the lysis of a smaller number of liver cells. Moreover, in some patients that we could determine the serum gamma-globulins, a marker of the inflammatory process triggered by cytolysis, we found a decrease in the values of gamma-globulin, proof of the hepatitis process regression. It is notable that resistance to viral aggression, determined by the anti-cytolytic product, sustains over time. Some patients, which have repeated control tests after 1-2 years, serum ALT levels were kept at low levels, although the viral infection was persistent. These data allow the statement that, during that period, the cytolytic process, therefore hepatitis did not progressed.

Conclusions

Based on the law of cellular and molecular similitude, discovered by one of the authors of this article, an original anti-cytolytic homeopathic remedy was developed, useful in chronic viral hepatitis B and C. Liver cell cytolysis decrease represents the expression of these cells' increased resistance against hepatitis viruses aggression and places the remedy in the antipathogenic medication category. The effect is likely to be due to of immunomodulatory action, knowing that the destruction of liver cells in B and C virus infection occurs mainly through the actions of the immune system on the liver cell. Arguments in favor of such actions could be the favorable effects observed by one of the authors following administration of the anti-cytolytic drug in two patients with autoimmune hepatitis and a patient with Hashimoto's disease.
Our results appear to be comparable to those obtained by administration of interferon, another antipathogenical medication, but with the difference that the homeopathic product does not cause any side effects and is incomparably cheaper.

ISSN: 2344-1569

Reaching the anti-cytolytic effect, the reducing and even discontinuing the first stage of evolution of viral hepatitis, allow the statement that it is expected to produce deceleration and even stopping the patologic process triggered by this virus. In this way, the next stages of cytolysis, inflammation and fibrosis may diminish.

The results obtained by administering the homeopathic anti-cytolytic remedy in chronic viral hepatitis confirm the accuracy of the employed hypothesis and is an objective argument for the existence of the cellular and molecular similitude law, formulated by one of the authors. At the same time it demonstrates the efficacy of a homeopathic remedy in underweight dose. One capsule contains $0.2x10^{-10}$g active ingredient. This value is close to the concentration of the order of ng/g, concentration seen in many biologically active substances in the body and thus justifies the nanopharmacology term that was given to homeopathic pharmacology.

Further research on this product in chronic hepatitis, could confirm the real usefulness, possibly in larger scale. Of particular interest might be homeopathic anti-cytolytic product testing in double or triple combination with antivirals, replacing interferon from the current combinations. It would be a great step forward, knowing that interferon is not supported by 50% of patients. And with a cost of treatment thousands times smaller, it would prove substantial savings for the health system. Joint anti-cytolytic remedy and antivirals may be reserved for patients who do not support interferon. The association of the anti-cytolytic remedy with hepatitis B vaccine is also possible, both in its current form and as a homeopathic preparation, diluted and dinamized. Another interesting aspect could be product testing in acute viral hepatitis.

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