

Prospective randomised study to check the results of treatment using endogenous electromagnetic fields, in the case of slight liver cell damage

Key words:

Summary:

Introduction

The fundamental question of how a living organism such as a human being, which is composed of an astronomical number of cells, is able to coordinate optimal function and above all the entire life cycle (cell proliferation, differentiation, apoptosis, etc.) of each individual cell in such a way that the integrity of the overall system is retained, is as old as science itself.

The currently generally accepted model assumes that appropriate effector/receptor interactions and the microbiological processes triggered by these, at all organisational levels, can adequately explain the phenomenon known as life.

As a result, allopathic drug-based treatments are also based on the assumption that a therapeutic substance can only act via the active substance/receptor interaction described above.

The, at least theoretically possible, contribution of energetic reaction systems to the coordination of biological processes, e.g. in the sense of cell communication based on biophotons, remains largely ignored in biochemical models.

Although important diagnostic methods are based on the electromagnetic and thus energetic properties of living organisms, such as e.g. EEC, ECG, EMG, electromagnetic fields have been used hitherto only for the fixing of pseudoarthrosis affected bone fractures (refs. 1, 2), for treating certain forms of epilepsy (refs. 3, 4, 5) and in some approaches to the treatment of Parkinson's disease (ref. 6).

This situation is very remarkable since there are now very extensive experimental results available which, on the one hand, prove the physiological basis of an approach to the phenomenon of illness which is based on natural philosophy and, on the other hand, the connection between the energetic regulatory systems postulated in this approach and the electromagnetic properties of a very wide variety of organisms, using the methods of Western natural science (refs. 7, 8, 9).

In addition to the classical energetic methods of treatment, such as acupuncture and homeopathy, treatment using endogenous (the patient's own) electromagnetic fields has become established in the past 20 years, in particular in the area of complementary medicine. The basis for an understanding of bioresonance therapy (BRT) is the assumption that the alternating electromagnetic fields (EMFs) which are detectably emitted by living organisms (refs. 10, 11, 12, 13, 14) and are characterised by intensity (amplitude) and frequency contain biologically significant information which is used for communication between cells, tissues and organs.

Furthermore, if it is assumed that the start of any disease is evident in a change in energetic reaction systems long before the occurrence of pathophysiological changes, then the back-coupling of endogenous EMFs and the interference phenomena resulting therefrom should, at least temporarily, eliminate the effect of defective cell communication systems. A diseased organism thus becomes able to re-adjust its own energetic regulatory system within the context of self-healing.

However, currently there is no comprehensive, convincing, and numerically reproducible, theoretical model of bioresonance. In addition, there are fundamental considerations which make it questionable whether this will ever be possible using the principles of classical physics. Highly promising quantum physical descriptive models are still at the discussion stage (refs. 15, 16, 17).

The aim of the present trial was therefore to check, using a defined clinical picture, whether measurable changes in biochemical parameters could be induced by bioresonance treatment. A group of patients with chronic liver disease was selected for this purpose and the target criterion was a reduction in the activity of enzymatic indicators of liver damage (GOT, GPT, gamma-GT) in the blood of treated patients as compared with a non-treated control group.

Functional disorders of the liver, as the most important metabolic, blood storing and detoxifying organ, can greatly impair the general condition of health of a patient.

1. Patients and methods

This was intended to be a prospective, randomised, controlled, two-pronged therapy study. 28 patients were involved in the study. All were recruited, nursed and treated in a medical practice. All the patients had chronic liver damage which had been recognised for at least a year and had not been treated with drugs.

Criteria for inclusion

At least two elevated liver enzymes (GOT, GPT, gamma-GT). The elevated liver values were measured at least twice at an interval of 4 weeks.

No previous treatment for liver cell damage.

Exclusion criteria

Cirrhosis of the liver, acute hepatitis, autoimmune diseases, existing alcohol abuse, chemotherapy.

Randomisation and creation of the code lists were performed by the Out-patient's department for naturopathy at the Carstens Foundation in Heidelberg. 14 patients were allocated to the therapy group, 14 patients to the control group. The following tests were performed on all the patients: erythrocyte sedimentation rate, coarse blood count, determination of GOT, GPT and gamma-GT; hepatitis serology A, B, C;

antinuclear factors; palpation of the abdomen and liver; ultrasound scanning of the upper abdomen.

The main criterion used to detect the efficacy of BRT treatment was the lowering of GPT activity by at least one third after two weeks of treatment. GOT and gamma-GT activities were used as secondary criteria, as well as an improvement in subjective state of health.

After accepting the patients as part of the study, the examining doctor led a detailed discussion about health, stress factors and dietary habits. All the participants were recommended to eat less animal protein and less sugar. After 4, 8 and 12 weeks, the patients were summoned back for blood tests and for more discussions with the doctor. The initial discussion lasted about 45 minutes, the follow-up discussions about 30 minutes and there was no difference in subject matter between the two groups. Following the blood tests, the patients in the therapy group were subjected to bioresonance therapy performed by the doctor's assistant.

1.1. Bioresonance therapy

The BICOM instrument manufactured by Regumed GmbH, Gräfeling was used for the treatment. In essence, this consists of an electronic amplifier which electronically modifies the changes in potential picked up via the main electrodes and returns them to the patient via the same output electrodes. The instrument generally operates in the frequency range from 10 Hz to 150 kHz. The manufacturer provides 300 fixed settings, programmed into the machine and called up by programme numbers, which can be individually adapted and combined to suit the patient's situation, after energetic testing and diagnosis by a doctor. As can be seen from the circuit diagram in the figure below, five different types of therapy can be set.

Figure BICOM circuit diagram

The bandpass can be varied in the following ways:

- a) A fixed, narrow bandpass, which is centred round a middle frequency with an upper and lower tolerance of $\pm 3.5\%$.
- b) A wobbling bandpass:
The narrow bandpass wobbles about the freely adjustable middle frequency.
- c) A sweeping bandpass:
The narrow bandpass sweeps the entire frequency band, in steps, from 10 Hz to 150 kHz at a rate which may vary from 3 to 180 seconds per sweep.
- d) All frequencies:
The narrow bandpass is switched off and the entire frequency band is transferred.

The amplitudes of the adjustable bandpasses may be increased by up to 64 times, or reduced to a minimum of 0.025.

In the first stage, basic programme number 102 was used (type of therapy Ai / amplification 18 / frequency sweep for bandpass, 18 seconds rate of sweep / therapy

time 5 minutes). This treatment is intended to improve the basic energetic condition of a patient.

Then the patient was treated with programme number 201 “lymphs, chronic degenerative” (type of therapy H+Di / middle frequency 680 Hz / amplification of H fraction 4, and if Di fraction 0.5, wobbling / therapy time 4 minutes). This treatment is intended to improve the detoxification capacity due to stimulation of the lymphatic flow.

Then an attempt to have a positive effect on the intestinal flora was made using programme number 561 “intestinal treatment” (type of therapy, H+Di / middle frequency 10 Hz, wobbling / amplification of H fraction 4, of Di fraction 0.05 / therapy time 3 minutes).

For support during this treatment, a magnetic articulated probe was laid on the solar plexus of the patient and an additional output electrode was placed in the region of the lower lumbar spinal column.

Finally, the liver reflex area of the patient was stroked using an electrode in the form of a metal double roller. During this treatment, the patient’s feet were placed on metal plate electrodes which were connected to the output of the instrument.

The total duration of treatment was 22 minutes.

1.2. Enzyme diagnosis for assessing the integrity of liver cells

The following enzymes were used as indicators of liver cell damage:

glutamate-pyruvate-transaminase	(GPT), in cytoplasm
glutamate-oxalacetate-transaminase	(GOT), in cytoplasm and mitochondria
gamma-glutamyl-transferase	(γ -GT), membrane-bonded

The enzymes GPT and gamma-GT are regarded as being liver-specific. The simultaneous determination of GOT activity enables an estimate of the extent of liver cell damage by calculating the **De Ritis quotient** GOT / GPT.

For slight liver damage, GOT / GPT < 1.

Blood samples from patients were tested in the Dr Schottdorf Laboratory, Augsburg during the entire period of the study. GOT and GPT activities were determined using the optimised standard methods of the German Society for Clinical Chemistry. Gamma-GT activity was determined using Szasz's method (ref.). The test results were sent simultaneously to the practice and to the Institute for Biometry and Study Evaluation idv, Gauting, Munich, from the Dr Schottdorf Laboratory.

1.3. Statistical methods

Since this was an exploratory study, the results obtained have to be checked in further tests. Therefore the questions are not focused. Several hypotheses were tested statistically, without adjustment to a multiple alpha for the study. Nevertheless, as usual, data can be said to be significant when $p < 0.05$. The data, however, can be interpreted only in a descriptive manner. A simple comparison of the statistical characteristics was undertaken in order to check the comparability of the two groups, using the demographic data and baseline data for the efficacy criteria.

Wei-Lachin's method for criteria pooling (ref. 18) was used as the main test for the criteria relating to activity values of the enzymatic indicators for liver damage (GOT, GPT, gamma-GT), this enabling differences between the two groups in weeks 4, 8 and 12 for the individual criteria and also for all the criteria and times to be represented in summary form. The criteria-pooling method is a directional test (all criteria with the same direction being pooled), or a test on stochastically ordered alternatives within the context of the generalised Wilcoxon-Mann-Whitney method in accordance with Wei-Lachin. The Wilcoxon-Mann-Whitney test was used for the criteria relating to success of the therapy. A symmetry test was used to detect normalisation of the transaminase values. The Mann-Whitney value (MW) was used to detect the relevance of the effect of therapy and the size of the effect. These values indicate the probability that a randomly selected patient from one group produces a better therapy result than a randomly selected patient from the other group (ref. 19).

The following were used for evaluation purposes:

MW $P(X < Y) + 0.5 P(X = Y)$:	0.50 = identical
	0.56 = small effect

0.64 = moderate effect

0.71 = large effect

In the symmetry test, the identity coefficient omega was used as the measure of relevance.

The following applied when evaluating relevance here: ω^2 = 0.01 = small
= 0.10 = moderate
= 0.25 = large

2. Results

There were no statistical differences between the therapy and the control group with regard to distribution of the sexes, age structure, height and weight (table 1). In each group there was only one patient who had a risk occupation and had therefore had contact with substances which might be toxic to the liver. In the therapy group, one patient smoked, in the control group three patients smoked. A total of three patients said they drank alcohol, but very rarely. Positive hepatitis serology was noted in five patients in the therapy group and seven patients in the control group. In two other patients in the therapy group, liver problems had already started, after suffering a severe, non-specific infection. Two patients in each group exhibited a condition following cholelithiasis or pancreatitis. In three patients in the therapy group and four patients in the control group, the source of liver cell damage was still unclear. No antinuclear factors could be detected in any of the patients.

Ultrasound scanning and palpation revealed nothing untoward with the liver in the majority of cases. Changes (enlargement, breaking up, hardening) were diagnosed in four patients in the therapy group and five patients in the control group. The subjective clinical pictures are given in table 2. The most frequently cited problems in both groups were sleep disorders, tiredness, feeling weak and exhaustion. The next most frequently cited problems in the therapy group were soft tissue rheumatic disorders and abdominal symptoms; in the control group, problems with concentrating and disorders of the circulation. Slightly more problems were mentioned by patients in the therapy group than patients in the control group (36 to 29).

At the start of the course of therapy, no statistically significant difference in the activity values of the enzymatic indicators of liver cell damage tested could be detected between the two groups (tables, 3, 4 and 5, baseline columns)

Change in GOT value

Table 3 gives the GOT values determined experimentally after 4, 8 and 12 weeks of treatment, as compared with those for the untreated controls. Experimental values which exceed the upper normal value are marked with a > symbol. A graphical representation of the GOT values (median with confidence interval) is shown in figures 1A (BICOM group) and 1B (controls). It can be seen that the median and the upper confidence interval for the BICOM group after completion of treatment (12

weeks) lies within the normal range for GOT activities. The control group does not exhibit any normalisation of GOT values at all. The average percentage decrease in GOT activity in the BICOM group was 42% after 12 weeks as compared with a 4% decrease after 12 weeks in the control group.

Change in GPT value

Table 4 gives the experimental GPT values after 4, 8 and 12 weeks. A graphical representation of the GPT values is shown in figures 2A (BICOM group) and 2B (controls). The median for the BICOM group after 12 weeks' treatment lies within the normal range. The control group did not exhibit any normalisation of GOT values. The average percentage decrease in GOT activity in the BICOM group was 50% after 12 weeks' treatment as compared with a 5% decrease in the control group.

Change in the gamma-GT value

Table 5 gives the gamma-GT values determined experimentally after 4, 8 and 12 weeks of treatment. A graphical representation of the gamma-GT values (median and confidence interval) is shown in figures 3A (BICOM group) and 3B (controls). The gamma-GT values also reached the normal range after 12 weeks' treatment (BICOM group). On the other hand, the values for the controls remained virtually unchanged. The average percentage decrease in gamma-GT activity in the BICOM group was 38% after 12 weeks'. In the control group, a decrease in gamma-GT activity of only 7% was observed.

3. Discussion

The low degree of acceptance of holistic methods of therapy from the point of view of medicine based on natural science is based essentially on two points:

1. Intellectual models and sometimes extremely philosophically expressed concepts of the phenomena of living and illness are apparently incompatible with the findings of natural science and above all of physics.
2. Placebo-controlled clinical studies aimed at proving the efficacy of holistic methods of therapy have been initiated only very recently and are not yet complete, apart from one study proving the efficacy of homeopathic treatments (metaanalysis) (ref.).

As for the first point, it has to be noted that the experimental proof of the existence of a data transfer system between cells and tissues based on electromagnetic waves has been demonstrated in a large number of studies (ref.). According to these, many different, probably all, living biological systems are capable of emitting, receiving and storing electromagnetic signals up to the region of visible light (refs. 20, 21, 22, 23).

Currently, a number of explanatory models for bioresonance phenomena are being discussed in the scientific literature. All the serious models are based on the findings

of quantum physics and so-called chaos theory. A presentation of these topics would be far beyond the scope of this paper, so any interested readers should refer to the relevant specialist literature (refs. 24, 25).

The test presented here is therefore intended to contribute to an empirical proof of the efficacy of BRT. In the group of patients with slight liver cell damage (de Ritis quotient for all participants was less than 1), the effects of therapy using BICOM resonance has been demonstrated by determining three enzymatic indicators for liver cell damage. Even considering only the raw data on activity determinations for GOT, GPT and gamma-GT, a drastic decrease in the activity values due to BRT treatment is quite obvious. The average percentage decreases in GOT, GPT and gamma-GT values were 42%, 50% and 38%, with respect to the activity values before treatment. In the control group, these values were 4%, 5% and 7% respectively.

The geometric averages for the degree of improvement for the test parameter GOT activity was 45% (controls 5%) and for GPT activity was 55% (controls showed slight deterioration) while for gamma-GT activity the degree of improvement was 45% (controls, slight deterioration).

The symmetry test showed that, with regard to GOT activity, normalisation as compared with the baseline had occurred after 12 weeks in 64% of patients in the treatment group. No improvement could be detected in 29% of patients in this group. The symmetry test produced no change in the control group.

For GPT activity, normalisation as compared with the baseline was produced in 71% of patients in the treatment group (29% no improvement) in the symmetry test. In the control group, no decrease in elevated GPT values occurred in 91% of the patients, in fact 7% exhibited deterioration.

For gamma-GT values, the symmetry test showed normalisation in 29% of patients in the treatment group as compared with the baseline (initial values). In 50% of patients, no improvement in elevated gamma-GT activities was observed. In the control group, no change was observed.

With regard to the three parameters tested, both the P values and also the relevance measure, ω^2 , indicated high effectiveness for the BICOM treatment (tables 1-5).

The experimental findings demonstrate quite clearly that treatment of slight liver cell damage with endogenous fields in the frequency range 10 Hz to 150 kHz can bring about the reconstitution of damaged liver cells.

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Table 1: Clinical variables of 28 patients, of which 14 were treated with BICOM and 14 made up the control group

Clinical variables	Therapy group	Control group	Significance p
Sex male female	6 (43%) 8	5 (36%) 9	1.000
Age (years: med./QD/range)	45/35/16-70	45/13/34-64	0.919
Height (cm: “ “ “)	171/7/159-193	171/15/158-185	0.708
Weight (kg: “ “ “)	72/22/52-124	77/17/64-105	0.883
Occupation: housewife/pupil salaried employee at risk	5 8 1 (c)	7 6 1 (d)	?
Smoker		1	30.596
Alcohol now (rarely)	1	2	0.482
Alcohol/drugs (previously)	3	3	1.000
Aetiology (a) Hepatitis serology (pos.) Infect. non-sp. bacteria Cond. after cholelit./pancreat. Non-specific	5 2 2 3 (b)	7 0 2 4	
Ultrasound scan + palpation of liver: both normal discrete, enlarged, broken up hardened round focus (haemangioma?)	10 3 1 0	9 2 2 1	

a) = multiple allocation possible

b) = Pat. 1970 breast cancer + remote cobalt irradiation of ovaries
Pat. chronically persistent hepatitis since 1985
Pat. lipometabolic problems type II

c) = HGV mechanic + hepatitis

d) = printing block manufacturer + drugs + alcohol + hepatitis

Table 2: Number and type of problems commented on by patients before therapy

Multiple comments possible

Problems	Therapy group	Control group
Sleep problems, tiredness, weakness	13	10
Stomach pains, tympanites	6	2
Susceptible to infection	1	3
Circulation problems, dizziness, headaches	5	5
Soft tissue rheumatism, pains	8	4
Problem with concentrating	2	5
Hair loss	1	-
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Number of items	1	1
	2	6
	3	5
	4	2
	total	2
		-
		29

Table 3: Liver study Bicom v. no treatment SGOT (≤ 18 U/l)

Bicom				
Pat. No.	Baseline	Week 4	Week 8	Week 12
15	37>	21>	19>	19>
16	30>	24>	22>	22>
17	25>	25>	11	12
18	16	9	9	9
19	24>	16	18	18
20	37>	25>	21>	7
21	21>	12	11	9
22	20>	21>	12	12
23	20>	19>	13	14
24	26>	26>	24>	20>
25	21>	17	16	9
26	20>	20>	22>	12
27	24>	16	18	17
28	28>	25>	21>	19>
Validtn.	14	14	14	14
Mean	24.9	19.7	16.9	14.2
Std. dev.	6.28	5.22	4.92	4.89
LB 95.0	21.3	16.7	14.1	11.4
UB 95.0	28.6	22.7	19.8	17.0
Median	24.0	20.5	18.0	13.0
Min	16.0	9.0	9.0	7.0
Max	37.0	26.0	24.0	22.0
No treatment				
Pat. No.	Baseline	Week 4	Week 8	Week 12
1	15	14	33>	16
2	18	16	18	18
3	14	15	14	13
4	35>	30>	44>	35>
5	31>	45>	44>	30>
6	41>	43>	28>	28>
7	11	10	10	12
8	30>	23>	20>	37>
9	33>	26>	22>	22>
10	14	15	12	13
11	24>	19>	21>	23>
12	32>	21>	27>	28>
13	50>	57>	29>	49>
14	34>	16	32>	37>
Validtn.	14	14	14	14
Mean	27.3	25.0	25.3	25.8
Std. dev.	11.61	13.97	10.66	11.09
LB 95.0	20.6	16.9	19.1	19.4
UB 95.0	34.0	33.1	31.5	32.2
Median	30.5	20.0	24.5	25.5
Min	11.0	10.0	10.0	12.0
Max	50.0	57.0	44.0	49.0

Table 4: Liver study Bicom v. no treatment SGPT (≤ 24 U/l)

Bicom				
Pat. No.	Baseline	Week 4	Week 8	Week 12
15	44>	30>	28>	24
16	42>	22	20	19
17	53>	52>	24	23
18	35>	26>	24	16
19	52>	33>	30>	31>
20	76>	61>	45>	9
21	43>	17	17	6
22	32>	24	15	15
23	46>	37>	31>	28>
24	59>	49>	42>	36>
25	29>	26>	24	13
26	28>	26>	24	24
27	52>	33>	30>	33>
28	37>	26>	25>	24
Validtn.	14	14	14	14
Mean	44.9	33.0	27.1	21.5
Std. dev.	13.04	12.65	8.40	8.96
LB 95.0	37.3	25.7	22.2	16.3
UB 95.0	52.4	40.3	31.9	26.7
Median	43.5	28.0	24.5	23.5
Min	28.0	17.0	15.0	6.0
Max	76.0	61.0	45.0	36.0
No treatment				
Pat. No.	Baseline	Week 4	Week 8	Week 12
1	29>	40>	90>	48>
2	47>	46>	55>	52>
3	23	24	25>	26>
4	68>	83>	92>	63>
5	58>	101>	89>	59>
6	82>	91>	58>	62>
7	26>	24	25>	27>
8	50>	50>	45>	87>
9	76>	59>	41>	43>
10	33>	31>	26>	34>
11	29>	28>	32>	36>
12	49>	39>	42>	47>
13	120>	133>	77>	126>
14	92>	41>	67>	48>
Validtn.	14	14	14	14
Mean	55.9	56.4	54.6	54.1
Std. dev.	28.77	33.14	24.84	26.20
LB 95.0	39.2	37.2	40.2	38.9
UB 95.0	72.5	75.6	69.0	69.3
Median	49.5	43.5	50.0	48.0
Min	23.0	24.0	25.0	26.0
Max	120.0	133.0	92.0	126.0

Table 5: Liver study Bicom v. no treatment Gamma-GT (≤ 28 U/l)

Bicom				
Pat. No.	Baseline	Week 4	Week 8	Week 12
15	43>	42>	34>	30>
16	259>	195>	205>	194>
17	44>	30>	29>	26
18	218>	77>	60>	63>
19	93>	41>	41>	40>
20	19	19	19	11
21	57>	13	12	13
22	79>	68>	57>	57>
23	9	9	11	11
24	30>	34>	30>	27
25	27	17	25	15
26	192>	141>	140>	144>
27	93>	41>	40>	14
28	60>	60>	54>	49>
Validtn.	14	14	14	14
Mean	87.4	56.2	54.1	49.6
Std. dev.	78.87	52.55	53.98	54.30
LB 95.0	41.6	25.7	22.8	18.1
UB 95.0	133.1	86.7	85.4	81.1
Median	58.5	41.0	37.0	28.5
Min	9.0	9.0	11.0	11.0
Max	259.0	195.0	205.0	194.0
No treatment				
Pat. No.	Baseline	Week 4	Week 8	Week 12
1	71>	66>	79>	73>
2	28	36>	31>	34>
3	56>	64>	52>	55>
4	12	14	11	9
5	11	11	12	9
6	14	13	16	20
7	86>	68>	73>	72>
8	120>	138>	111>	190>
9	9	9	7	10
10	31>	22	24	21
11	50>	56>	51>	59>
12	153>	234>	212>	231>
13	35>	33>	30>	35>
14	330>	220>	310>	304>
Validtn.	14	14	14	14
Mean	71.9	70.3	72.8	80.1
Std. dev.	85.94	74.77	87.30	93.01
LB 95.0	22.0	26.9	22.2	26.2
UB 95.0	121.7	113.7	123.4	134.1
Median	42.5	46.0	41.0	45.0
Min	9.0	9.0	7.0	9.0
Max	330.0	234.0	310.0	304.0

