The Effect of Balance of Nature upon Patients with Cirrhosis

(Clinical Trial)

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The trial started in September 2004 and was terminated in March 2006. It included 26 patients (14 males and 12 females) aged 27 to 62 (mean age 46,6±3,7) with chronic hepatitis, cirrhotic stage, who periodically developed hepatic failure (with encephalopathy, jaundice and ascitis) and had to be hospitalized. Some of them were hospitalized once, others 2 – 3 times. The treatment consisted of Forced Diuresis, Infusion of Glucose with Insulin, Potassium and Magnesium, Vitamin K, anti-ascitic measures: Veroshperon (Aldosteron Antagonist); and anti-encephalopathetic: Lactulose. Also while in the hospital they were compelled to stop alcohol abuse which mostly was the cause of hepatic failure.

All the patients while at the hospital were regularly examined by the doctor clinically and laboratory tests have been done on them at least once a week including Total protein (g/l), Total Bilirubin (mcmol/l), ALAT (U/l), Prothrombin (%), Base Phosphotase (U/l).

All the clinical features in combination with laboratory findings were used for integrative assessment of the patients' state: they were ranked according to a scale as follows:

Parameter / Points		0	1	2	3
E	Encephalopathy (clinically)	Absent	Obnubilation or Euphoria	Sopor or Delirium	Coma
P	Protein Synthesis (Prothrombin Level)	> 80%	45 – 79%	35 – 44%	< 35%
B	Metabolic Activity (Non-bound Bilirubin Level)	< 10 mcmol/l	11 – 40 mcmol/l	41 – 80 mcmol/l	> 80 mcmol/l
A	Ascitis	Absent	Revealed by Ultrasound	Visible	Tense

All the points were then summed up to yield an integrative parameter – Hepatic failure class (X):

E + P + B + A = X (Hepatic failure Class):

Class A – ≥ 6 points: Severe hepatic failure
Class B – 4 – 5 points: Intermediate hepatic failure
Class C – 1 – 3 points: Light hepatic failure

One of the groups ("experimental") – 13 patients (mean age 45,1±4,2) took Balance of Nature (BoN) in triple doses while the other group ("control") (mean age 48,7±4,6) did not receive BoN. The patients of the experimental group took BoN for periods of different duration. Some took it only during hospitalizations, others continued after they were discharged from the hospital although it is difficult to check whether they took it regularly while outside of the hospital.

Most of the patients were hospitalized at B-class - Intermediate hepatic failure, a few at A-class - Severe hepatic failure. Ordinary treatment (without BoN) usually improved condition of the patients in 1 – 4 weeks (mean 2,3±0,4) of hospitalization down to Class C (light Hepatic failure) from B-class. In case of A-class initial state it took 3 – 6 weeks (mean 4,1±0,3) to improve it down to C-class.

Several weeks of BoN speeded up this process: B → C transition took 1,8±0,3 weeks; A → C transition took 3,5±0,3 weeks.

Analyzing the dynamical changes of the leading symptoms separately one should indicate that in patients who did not receive BoN it took 1 – 6 weeks to cope with Encephalopathy of varying severity: E1 with Obnubilation or Euphoria or E2 with Sopor or Delirium – (E1→E0 transition took 2,2±0,2 weeks; E2→E0 transition took 4,4±0,5 weeks). BoN speeded up this process (E1→E0 transition took 1,9±0,4 weeks; E2→E0 transition took 3,4±0,6 weeks).

Protein synthesis disturbance proved to be more resistant to treatment: although in some of the cases it was possible to increase Prothrombin index by 10 – 12% during 4-5 weeks of hospitalization still it never reached minimum margin of normal values. We did not discover any statistically valid difference between the Clinincal and the Control groups regarding the effects of BoN upon Prothrombin index. The mean value of Prothrombin index at the time of discharge from the hospital in the patients who did not take BoN was 59±7% while in the patents who took BoN it was 61±9%.

However we have revealed a slight increment of the increase of total protein concentration caused by BoN. The total protein concentration by the end of the treatment course at the time of discharge from the hospital in the patients who did not take BoN was 47,1±3,0 g/l while in the patents who took BoN it was 52,2±1,7 g/l.

The levels of Aminotrasferases as well as Base Phosphotase were considerably increased in all patients prior to hospitalization. The regular treatment resulted in a nominal decrease of the level of ALAT and almost a double fold decrease of the latter, however the levels of both were twice as high as each hepatic enzyme's maximum normal concentration. BoN did not appear to seriously affect these

changes. No statistically valid difference has been demonstrated between the Clincal and the Control groups.

Another parameter that describes hepatic metabolic activity i.e. Total Bilirubin level prior to hospitalization was very high (298±44 mcmol/l). It took 2-4 weeks to decrease it below 100 mcmol/l. However further decrease of bilirubin levels required much more time and effort. BoN facilitated this stage of treatment: total Bilirubin level by the time of discharge from the hospital in patients who took BoN was 58,2±4,1 mcmol/l while in the Control group it was 71,3±8,2 mcmol/l; besides it took less time to achieve total bilirubin level below 70 – 80 mcmol/l in the Clinical group (3,1±0,6 weeks) vs 4,2±0,5 weeks in the Controls.

Ascitis (visible or only revealed by ultrasound examination) was present in all the patients prior to hospitalization. By the end of hospitalization at the time of discharge from the hospital it disappeared in 13 patients out of 13 who received BoN (100%) while in the Control group only 4 out of 13 patients did not have ascitis at the time when they were discharged from the hospital (31%).

CONCLUSION:

BoN proved to play a positive role in compensating the state of cirrhotic patients: it shortens the period of treatment necessary for conversion of severe or intermediate hepatic failure into light clinical forms, namely it helps to cope with encephalopathetic symptoms, improves protein synthesis facilitating a more substantial increase of total protein plasma level and metabolic activity – a faster and more substantial decrease of total Bilirubin blood level. It also makes anti-ascitic treatment much more effective.

There are also indications that BoN extends the periods between hospitalizations slowing down decompensatory changes without treatment and BoN may be helping cirrhotic patients to lead a sober life.