

# The clinical effectiveness of BioBran in immunotherapy for patients with hepatitis B

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## Abstract:

Hepatitis B virus (HBV) infection is a serious global health problem with devastating consequences of chronic hepatitis, cirrhosis, and hepatocellular carcinoma. More efficacious treatments, mass immunization programs, and safe injection techniques are essential for eliminating HBV infection and reducing global HBV-related morbidity and mortality. Antiviral therapy has been the primary treatments to date. However, conventional treatment has undesirable side-effects and continuous treatment can lead to the development of resistance. In addition, antiviral medicines are costly, thousands of dollars per year, and are not widely available in many countries, especially in the developing world. BioBran is a food supplement that is combined with conventional treatment to improve the outcome of the disease. There were 3 cases of viral B hepatitis patients who have treated by the combination of conventional antiviral therapy and BioBran were described. In these cases, blood samples were taken to measure liver function and immunopotency, and the results were compared with changes in clinical and image condition. Improvements were noted in most of the cases. Finally, some remarks were provided to enhance the effectiveness of treatment progress.

**Key words:** *Hepatitis B virus infection, antiviral therapy, BioBran*

## Methods

The food supplement BioBran was oral ingestion (at dose of 1 pack/24h) combined with antiviral medicines and **liver support supplement**. The therapeutic effectiveness was assessed by measuring the levels of liver enzymes, immunocompetence and ultrasound images.

## Results

### 1. Case 1 (male, 43 years, viral B hepatitis)

The patient had hepatitis B diagnosed from 2000 with symptoms of fatigue, slight fever, and yellow urine. He had underwent treatment with **liver support supplement**, antiviral therapy (Nucleozid) and BioBran 1 pack/24h, he had obtained good biochemical test result after 18 months of treatment. The test results and treatment progress are shown in table 1. Family history: this patient has a younger brother who also has HBeAg (+), he has been treated by antiviral medicine (Tenofovir) and BioBran 1 pack/24h.

Table 1: Case 1 (male, 43 years, viral B hepatitis)

Time of treatment	Clinical symptoms	Biochemical tests			Ultrasound test	Viral detection tests				Medicines
		AST (U/l)	ALT (U/l)	$\alpha$ FP (ng/ml)		HBsAg	HBeAg	Anti Hbc	HBV DNA quantity (copies/ml)	
11/2007 (before treatment)	Fatigue, yellow urine,	78	84	(-)	Gallbladder polyps; gallbladder	(+)	(-)	(+)	$6.91 \times 10^6$	

	digestion disorder				duct: 1,1mm; unsmooth hepatic echogram					
1 month of treatment		42	60							- Reducing liver enzyme medicine, - Antiviral medicine (Entecavir 0,5mg/24h), - BioBran 1 pack/24h
2 months of treatment		30	36							- Antiviral medicine (Entecavir 0,5mg/24h), - BioBran 1 pack/24h
6 months of treatment		30	28					2.8x10 <sup>4</sup>		- Antiviral medicine (Entecavir 0,5mg/24h), - BioBran 1 pack/24h
12 months of treatment		32	30					1.84x10 <sup>2</sup>		Continuously used 2 medications in 3 months
15 months of treatment		Normal	Normal							
3/4/2010		26.7	24.3	(-)	Small gallbladder polyps		(-)		Unfound	- Stop using antiviral medicine - BioBran plus 1 pack/24h
5/7/2010		26	18				(-)			Indication for HBV immunization

## 2. Case 2 (male, 17 years old and younger brother, 15 years old)

On February 2004, these patients had hepatitis B diagnosed with symptoms of fatigue, weight lost, and lost of appetite. Family history: their mother also has HBsAg (+)

### - Laboratory tests before treatment:

Older brother	Younger brother
- Biochemical tests: AST: 210 (UI/l); ALT: 180 (UI/l), $\alpha$ FP (-) - HBeAg (+), HBeAg (+), Anti Hbe (-) - HBV DNA qualitative analysis (+++) - Ultrasound test: unsmooth hepatic echogram, enlarged spleen: 2cm below costal margin	- Biochemical tests: AST: 230 (UI/l); ALT: 210 (UI/l), $\alpha$ FP (-) - HBeAg (+), HBeAg (+), Anti Hbe (-) - HBV DNA qualitative analysis (+++) - Ultrasound test: unsmooth hepatic echogram, enlarged spleen: 1cm below costal margin

+ Treatment: liver support supplement, viral inhibitor ( Lamivudine 1 tablet/24h), and BioBran 1 pack/24h.

**- Laboratory tests after 6 months of treatment:**

<b>Older brother</b>	<b>Younger brother</b>
<ul style="list-style-type: none"> <li>- Liver enzymes: AST: 80 (UI/l); ALT: 42 (UI/l)</li> <li>- HBeAg (+)</li> <li>- HBV DNA qualitative analysis: (+)</li> <li>- Ultrasound test: unsmooth hepatic echogram, splenomegaly</li> </ul>	<ul style="list-style-type: none"> <li>- Liver enzymes: AST: 78 (UI/l) ; ALT: 46(UI/l)</li> <li>- HBeAg (+)</li> <li>- HBV DNA qualitative analysis: (+)</li> <li>- Ultrasound test: unsmooth hepatic echogram, splenomegaly</li> </ul>

+ Continuous treatment: liver support supplement, viral inhibitor (Lamivudine 1 tablet/24h), and BioBran 1 pack/24.

**- Laboratory tests after 12 months of treatment:**

<b>Older brother</b>	<b>Younger brother</b>
<ul style="list-style-type: none"> <li>- Liver enzymes: AST: 28 (UI/l); ALT: 40 (UI/l)</li> <li>- HBeAg (+)</li> <li>- HBV DNA qualitative analysis: (+)</li> <li>- Ultrasound test: unsmooth hepatic echogram, splenomegaly</li> </ul>	<ul style="list-style-type: none"> <li>- Liver enzymes: AST: 30 (UI/l); ALT: 42 (UI/l)</li> <li>- HBeAg (+)</li> <li>- HBV DNA qualitative analysis: (+)</li> <li>- Ultrasound test: unsmooth hepatic echogram, splenomegaly</li> </ul>

+ Continuous treatment: liver support supplement, viral inhibitor (Lamivudine 1 tablet/24h), and BioBran 1 pack/24h.

**- Laboratory tests after 24 months of treatment:**

<b>Older brother</b>	<b>Younger brother</b>
<ul style="list-style-type: none"> <li>- Liver enzymes: AST: 30 (UI/l); ALT: 26 (UI/l)</li> <li>- HBeAg (+)</li> <li>- HBV DNA qualitative analysis (+)</li> <li>- Ultrasound test: enlarged spleen: 1cm below costal margin</li> </ul>	<ul style="list-style-type: none"> <li>- Liver enzymes: AST: 28 (UI/l); ALT: 24(UI/l)</li> <li>- HBeAg (-)</li> <li>- HBV DNA qualitative analysis (±)</li> <li>- Ultrasound test: normal spleen</li> </ul>

+ Stop using medicines, they only took herbal medicine (Chanca Piedra)

**- February, 2010:**

<b>Older brother</b>	<b>Younger brother</b>
<ul style="list-style-type: none"> <li>- Lost weight, lost of appetite</li> <li>- Liver enzymes: AST: 40 (UI/l); ALT: 86 (UI/l)</li> <li>- HBeAg (+), HBeAg quantity: 152.800 UI/l</li> <li>- HBV DNA quantity: 10<sup>6</sup> copies/ml</li> <li>- Ultrasound test: unsmooth hepatic echogram, enlarged spleen below costal margin</li> </ul>	<ul style="list-style-type: none"> <li>- Liver enzymes: AST: 28 (UI/l); ALT: 20(UI/l)</li> </ul>
Treatment: Reducing liver enzyme medicine, viral inhibitor (Entecavir 0,5g/24h), BioBran 1 pack/24h	Stop using medicines

**- 8/7/2010:**

<b>Older brother</b>	<b>Younger brother</b>
<ul style="list-style-type: none"> <li>- Liver enzymes: AST: 32 (UI/l); ALT: 30 (UI/l)</li> </ul>	<ul style="list-style-type: none"> <li>- Liver enzymes: AST: 26 (UI/l); ALT: 18 (UI/l)</li> </ul>

- HBeAg (-) - HBV DNA quantity: 10 <sup>4</sup> copies/ml - Ultrasound test: enlarged spleen below costal margin	- HBeAg (-) - HBV DNA quantity: unfound - HBeAg qualitative analysis: (-) - Test HBeAg (-) - Ultrasound test: normal
	- Indication for HBV immunization

- These patients kept using herbal medicine (Chanca Piedra) as a drinking during 6 years of treatment.

### 3. Case 3 (female, 23 years old, viral B hepatitis)

The patient had viral B hepatitis diagnosed 1 month after having baby with symptoms of fatigue and lost of appetite. She also has a brother with HBsAg (+). She had underwent treatment with liver support supplement, BioBran 1000 x 1 pack/24h and kept breast feeding. The test results and treatment progress are shown in table 2.

Table 2: Case 3 (female, 23 years, viral B hepatitis)

Time of treatment	Clinical symptoms	Biochemical tests			Ultrasound test	Viral detection tests				Medicines
		AST (U/l)	ALT (U/l)	αFP (ng/ml)		HBsAg	HBeAg	Anti Hbc	HBV DNA quantity (copies/ml)	
3/2006 (Before treatment)	Fatigue, lost of appetite	100	120	(-)	Unsmooth hepatic echogram	(+)	(+)	(-)	10 <sup>5</sup>	- Reducing liver enzyme medicine, - BioBran x 1 pack/24h - Keep breast feeding
2 months of treatment		60	38							- BioBran x 1 pack/24h - Keep breast feeding - Appropriate regime and resting
12/2006 9 months of treatment		32	28				(-)	(+)		- Antiviral medicine (Entecavir 0,5mg/24h), - BioBran x 1 pack/24h
5/2007 14 months of treatment		Normal	Normal				(-)		10 <sup>3</sup>	- BioBran x 1 pack/24h
9/2009		Normal	Normal				(-)	(+)	Unfound	- Having 2 <sup>nd</sup> baby - BioBran x 1 pack/24h during pregnancy

#### **4. Conclusion and recommendation**

The safety of BioBran can be easily imagined because it is extracted from rice bran. The present clinical studies confirmed the safety of BioBran. BioBran for immunotherapy prevented decrease in physical strength and appetite. The patient also reported “When I take it, I feed better”.

The combination of BioBran with antiviral medicines will have effectiveness on viral B hepatitis patients, if the following criteria are compliant:

- + Accurate indication for patients who have high level of liver enzyme and HBV DNA quantity.
- + Taking medicines constantly and regularly.

The treatment is more effectiveness on viral B hepatitis patients who have HBeAg (+). Conversely, it is more difficult to treat viral B hepatitis patients who have HBeAg (-); therefore taking 2 packs/24h is recommended for these patients.

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