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Abstract

The clinical treatments for cancer were (1) surgery, (2) radiotherapy, and (3) chemotherapy with anticancer drugs. For surgery, even if the procedure used is highly sophisticated, cancer cells may be transported to other organs via the vascular or lymph system. For radiotherapy, although it destroys cancer tissues it may also damage the surrounding functioning tissues. Anticancer drugs may destroy cancer cells as well as normally functioning cells of other organs.

Consequently, these drawbacks of the three types of treatments must be recognized when addressing cancer patients. This is where immunotherapy counts. The author has been working with immunotherapy for 25 years, and this time chose combination therapy with BioBran (rice bran arabinoxylan derivative), and BRP (Bio-Reproducing Protein) intravenously.

Case 1. K. M. 67-year-old, M. Liver cancer with intestinal metastasis
Case 2. M. O. 65-year-old, M. Liver cancer
Case 3. F. M. 71-year-old, F . Liver cancer
Case 4. H. H. 76-year-old, F . Lung cancer
Case 5. T. O. 58-year-old, M. Colorectal cancer with liver metastasis

Above five cases, blood samples were taken once a month to measure tumor markers and immunopotency, and the results were compared with the change in clinical conditions. As a result, improvements were noted in all the cases.

Key words: immunotherapy, rice bran arabinoxylan derivative, BRP (Bio-Reproducing Protein)

The Clinical Significance of BioBran (Rice Bran Arabinoxylan Derivative) in the Immunotherapy for Cancer

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Clinical Pharmacology and Therapy

Table 1　Case 1 (K.M. 67 years, male, liver cancer with intestinal metastasis)

Test item / Time of treatment	LDH (IU/I 37°C)	PIVKA-II (mAU/ml)	α-FP (ng/ml)	CEA (ng/ml)	TK activity (U/I)
Before treatment	392	5,467	132.3	4.4	17.8
1 year of treatment	377	10,234	4,360.0	4.6	46.0
2 years of treatment	314	195	12.2	4.4	9.0
3 years of treatment	349	299	81.4	5.6	6.3
4 years of treatment	366	763	188.0	13.6	6.9
5 years of treatment	177	4,688	5,854.0	52.8	8.5
6 years of treatment	194	4,990	3,262.0	29.7	13.0
Normal value	115-245	< 40	≤ 20.0	≤ 5.0	≤ 5

Methods

The immunotherapy used was oral ingestion of BioBran[1)] combined with intravenous infusion of BRP (Bio-Reproducing Protein)[2)]. The therapeutic effect was determined by measuring the levels of tumor markers and immunocompetence.

BioBran was taken orally at 3.0 g/day (1.0 g × 3), and BRP was infused intravenously once every 4 weeks.

Results

Results in 5 cases are reported.

1. Case 1 (K.M., 67 years, male, liver cancer with intestinal metastasis)

The patient had liver cancer diagnosed and underwent treatment for about 1 year at a training-designated hospital with over 500 beds, but did not obtain good results, and the attending physician said to his family, "He has about 1 month of life remaining, and there are no more treatment options. You should take him home." He had no choice other than discharge and visited our hospital.

For 6 years after the first visit on December 4, 1997, he worked hard and maintained a normal daily life. The test results are shown in Table 1. The general condition (LDH), tumor markers (PIVKA-II, α-FP, and CEA), and immunocompetence (TK activity) rapidly improved after 2 years of treatment, he has had no symptoms until now, and the fecal color has changed from white to normal.

PIVKA-II and α-FP have tended to increase after 5 years of treatment, but LDH is kept at a good level, suggesting the effect of the long-term immunotherapy on the cancer.

Now that he has entered his 7th year of treatment, he keeps on working (as a company president) almost normally and makes a business trip once a month while receiving treatment on an outpatient basis.

BioBran was administered for a total of 157 days.

2. Case 2 (M.O., 65 years, male, liver cancer)

The patient received treatment at 2 medical institutions, including a university hospital, but obtained no good result before he visited our hospital first on April 22, 2002. Laboratory tests at the first visit showed impaired liver functions (GOT and GPT), the increased marker for liver cancer (α-FP), and poor immunocompetence (TK activity). At 6 months of treatment, the liver-cancer marker and the immunocompetence improved, but GOT and GPT showed further increases. Both GOT and GPT decreased at 1 year of treatment, and the decreases remained at 1 year and 11 months of treatment (see Table 2). During the period, jaundice disappeared, appetite improved, no pain occurred, and there was no special finding. The increases in GOT and GPT compared with the pretreatment values at 6 months suggested serious liver dysfunction due to the cancer.

BioBran was administered for a total of 72 days.

Table 2 Case 2 (M.O. 65 years, male, liver cancer)

Test item / Time of treatment	GOT (IU/I 37°C)	GPT (IU/I 37°C)	α-FP (ng/ml)	TK activity (U/I)
Before treatment	84	120	57.8	6.5
6 months of treatment	126	185	26.8	5.3
1 year of treatment	48	64	10.1	6.2
1 year and 6 months of treatment	58	75	8.8	5.3
1 year and 11 months of treatment	66	91	15.2	5.4
Normal value	10-40	5-45	≤ 20.0	≤ 5

Table 3　Case 3 (F.M. 71 years, female, liver cancer)

Test item / Time of treatment	CA19-9 (U/ml)	PIVKA-II (mAU/ml)	α-FP (ng/ml)	TK activity (U/I)
Before treatment	72	55	1,865	4.9
3 months of treatment	104	197	1,699	4.4
6 months of treatment	48	34	2,781	3.6
1 year of treatment	29	14	1,839	2.5
Normal value	≤ 37	< 40	≤ 20.0	≤ 5

Table 4　Case 4 (H.H. 76 years, female, lung cancer)

Test item / Time of treatment	TPA (U/I)	TK activity (U/I)
Before treatment	128	11.0
1 month of treatment	93	8.6
2 months of treatment	117	11.0
3 months of treatment	132	9.1
4 months of treatment	126	10.8
5 months of treatment	93	9.1
6 months of treatment	103	8.5
7 months of treatment	96	7.1
Normal value	≤ 70	≤ 5

Table 5　Case 5 (T.O. 58 years, male, colorectal cancer with liver metastasis)

Test item / Time of treatment	GPT (IU/I 37°C)	TK activity (U/I)
Before treatment	135	8.2
1 month of treatment	71	5.1
2 months of treatment	64	4.8
3 months of treatment	91	5.0
4 months of treatment	88	5.2
Normal value	Male ≤ 75	≤ 5

3. Case 3 (F.M., 71 years, female, liver cancer)

The patient received treatment at another hospital, but the result was not good and jaundice appeared. She wanted to receive immunotherapy and visited our hospital on May 31, 2002. For hepatic tumor markers, α-FP slightly decreased at 3 months of treatment, but CA19-9 and PIVKA-II tended to increase. At 6 months of and 1 year of treatment, however, CA19-9 and PIVKA-II decreased, clinical symptoms improved, and jaundice disappeared. The result for immunity (TK activity) was good (Table 3).

BioBran was given for a total of 392 days.

4. Case 4 (H.H., 76 years, female, lung cancer)

The patient had treatment against cancer at another hospital, but obtained no improvement, and visited our hospital on September 26, 2003.

The cancer was adenocarcinoma and had spread throughout both lung fields.

The lung tumor marker (TPA) tended to decrease at 1 month of treatment, but slightly increased at 2 and 3 months and began to decrease again at 4 months. Coughing decreased at the same time. The immunocompetence (TK activity) has gradually increased (see Table 4).

BioBran was ingested for a total of 128 days.

5. Case 5 (T.O., 58 years, male, colorectal cancer with liver metastasis)

The patient underwent an operation for colorectal cancer at another hospital, but liver metastasis occurred. He wanted to receive immunotherapy and visited our hospital on August 16, 2003.

The liver function (GPT) began to improve rapidly at 1 month of treatment. After that, good values were obtained at 2, 3, and 4 months. The immunocompetence (TK activity) stabilized after 1 month of treatment (Table 5).

He has no subjective symptoms now and continues his work.

BioBran was administered for a total of 77 days.

Discussion

The following points were drawn from changes in general conditions, immunocompetence, and tumor markers in the 5 cases.

1) The therapeutic effect of the immunotherapy appears at 1 month of treatment in some cases and at 2 years in other cases. The appearance of the therapeutic effect differs largely between individuals. This means that it is important to continue immunotherapy with patience.

2) This therapy caused no adverse reaction in any of the 5 cases. Many patients suffer from serious adverse reactions of anticancer drugs. Large doses of radiotherapy also cause adverse reactions and a lot of suffering to patients. Removal of organs by surgery may make the patient's life difficult. Therefore, it is preferable that patient-friendly immunotherapy be a main treatment for cancer.

3) For planning of treatment for cancer, it is important to grasp the patient's disease state from the 3 viewpoints of general condition, immunity, and tumor markers.

In case 1, the patient underwent treatment for 1 year or more at the department of surgery in a foundation hospital, but the attending physician recommended discharge because "there was no more treatment option and he had about 1 month of life remaining." He visited our hospital and received my immunotherapy. As a result, he still works now (after he has entered his 7th year of immunotherapy). This suggests the clinical significance of immunotherapy.

The safety of BioBran can be easily imagined, because it is extracted from rice bran. The present clinical studies confirmed the safety of BioBran. Although the overproduction of rice has been a concern in Japan in recent years, it is advisable to produce more rice and use BioBran not only in the treatment, but also in the prevention of cancer. The Ministry of Agriculture, Forestry, and Fisheries should make an administrative effort.

Conclusion

The author used the oral ingestion of BioBran combined with BRP infusion as immunotherapy in the treatment of cancer patients, and good clinical effects and test results (tumor marker and immunity) were obtained.

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