

The Life Prolongation and QOL Improvement Effect of Rice Bran Arabinoxylan Derivative (MGN-3, BioBran) for Progressive Cancer

Kihachiro TAKAHARA and Kamataro SANO

Sano Surgery Clinic

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Abstract

The present study was designed to determine whether or not the administration of MGN-3 could have its apothanasia effect and improve the QOL for 205 progressive and partially metastasized cancer patients in late III-IV stages after surgery. MGN-3 is a rice bran arabinoxylan derivative and known to have immunomodulation activity. The participants in this clinical study are hospitalized patients in our clinic treated with complementary alternative medicines (we call it "Non-Conventional Therapy") and anticancer medicines with lesser side effects. The 205 patients hospitalized for 6 months were grouped into two groups, viz, 109 patients (control group) treated with our standard complementary alternative medicines, and 96 patients who were further given MGN-3 (MGN-3 group) for one year and a half.

All the patients were measured for natural killer activity as an indication for the variation of immunoparameters. Simultaneously, the QOL of the patients was also checked. The NK cell activities of the patients after surgery were low on average; however, by the administration of MGN-3, NK activity was observed to increase and the apothanasia ratio also increased; the higher the patient NK activity is, the higher the apothanasia ratio was observed to rise. The above findings indicate that NK activity can be used as a pathological index of progressive cancers. QOL improvement was also observed with the administration of MGN-3.

Key words: complementary alternative medicines, rice bran arabinoxylan derivative, natural killer activity, apothanasia effect

Introduction

We perform a complementary alternative therapy developed in our clinic on progressive cancer patients who have a metastasis or unresectable lesion after surgery to maintain high QOL and prolong their survival time, and have obtained good results. This therapy consists of hospitalization and home treatment. The mean duration of hospitalization is 1 month, during which patients are treated and trained for treatment at home. After discharge, they are based on home care and periodically visit the clinic for examination and treatment. This therapy causes

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no large damage to patients in principle. The main aim of the therapy is to put cancer cells into the dormant state. Normally, this therapy should be tried in postoperative patients without recurrence or metastasis. In the present study, however, the life prolongation effect of MGN-3 (BioBran) was confirmed in 205 cancer patients in late III-IV stages, including those who had a metastasis or unresectable lesion left after surgery. The purpose of this study was to determine whether the addition of MGN-3 to our complementary alternative therapy prolongs the survival time and improves QOL by enhancing the original effect of the therapy.

Methods

1. Patients

Subjects were patients hospitalized in our clinic who were treated with a complementary alternative therapy developed in this clinic (Table 1) and anticancer drugs that induce less adverse reactions. They were 205 progressive-cancer patients in late III-IV stages, who had recurrence, unresectable lesions, or metastasis after surgery. The primary lesion was in the lung (31 patients), liver (18), uterus (7), breast (33), prostate (4), rectum (28), stomach (34), lymph node (11), and others (29).

Table 1 Details of Complementary Alternative Therapy

immuno-enhancement:	CDA-II (enzyme in urine), germanium mushroom polysaccharides, specific substance Maruyama (SSM) oriental medicines, Lymphocytes
diet therapy:	Gerson's special diet therapy, kale vegetable juice, vitamins
intra-intestinal environmental improvement:	probiotics, prebiotics
thermotherapy:	far infrared ray, thermotherapy with loquest leaves
blood catharsis:	SOD, coffee enema
psycho-therapy:	thoroughgoing of positive way of thinking by seminars/lectures

Table 2 Patients participated in the clinical study, MGN-3 Group and Control Group

Cancer site	MGN-3 Group	Control Group
Lung	14	17
Liver	10	8
Uterine	7	0
Breast	18	15
Prostate	3	1
Large intestine	9	19
Stomach	15	19
Lymph nod	7	4
Others	13	26
Total	96	109
Sex	Male 55, Female 41	Male 59, Female 50
Average age	56.0	53.5

Table 3 Scoring of QOL checkpoints and levels

pain, malaise and nausea		appetite	
none:	0	no appetite:	0
scarcely:	1	scarcely:	1
fairly strong:	2	fairly:	2
strong:	3	good appetite:	3
very strong:	4	-	

2. Investigational substance

MGN-3 is a rice bran arabinoxylan derivative obtained by hydrolyzing hemicellulose of rice bran with many carbohydrases, which have an immunomodulatory effect²⁻³⁾, active-oxygen scavenging effect⁴⁾, blood-sugar controlling effect⁵⁾, and effect of reducing adverse reactions to anticancer drugs⁶⁾. The brand name of MGN-3 is Lentin Plus 1000, manufactured by Daiwa Pharmaceutical Co., Ltd. (Tokyo).

3. Methods

A total of 205 patients who visited our clinic within about 6 months were randomly divided into 2 groups (the control and MGN-3 groups). The control group was given a treatment prescribed in our clinic, and the MGN-3 group was given MGN-3 in addition to the same clinic-prescribed therapy. The breakdown of the patients is shown in Table 2. MGN-3 at 1 g was given orally 3 times a day after meals. The observation period was 18

months, and the patients visited once a month during the period to determine the activity of natural killer cells (NK activity) as an immune parameter. Patients who stopped visits without notice were excluded as dropouts from the study. Patients' QOL was checked by observation and inquiry during the study. Pain, malaise, and vomiting were evaluated using 4 grades, and appetite assessed using 3 grades to compare the scores before and after treatment. Table 3 shows the details.

Table 4 Relation among total survival rate, NK activity and survival rates in 2 groups

Group	MGN-3 Group	Control Group
Total survival rate	52/96 (54.2%)	19/56 (35.8%)
NK activity category		
Less than 19.9%	17/40 (42.5%)**	2/16 (12.5%)
20%-40%	18/35 (51.4%)*	7/25 (28.0%)
More than 40%	17/21 (81.0%)	10/15 (66.7%)

※ significant to the control group ** p < 0.01 * p < 0.05

Table 5 QOL amelioration

QOL	Pain			Malaise			Nausea			Appetite		
	BT	AT	%	BT	AT	%	BT	AT	%	BT	AT	%
Control group	2.9	2.5	-14.0	3.5	2.9	-17.1	2.5	2.9	-14.6	1.6	1.9	+15.6
MGN-3 group	2.2	1.9	-15.9	2.9	2.4	-17.3	2.3	2.0	-13.3	1.7	2.1	+24.2

Note; BT: Before treatment AT: After treatment

%: Amelioration degree = (Scores at initiation less scores at termination) divide by scores at initiation

(-): indicates negative factors (decrease), (+): indicates positive factors (increase).

Results

1. Subjects included in analysis

A total of 152 of 205 patients were eligible for analysis, including 96 in the MGN-3 group and 56 in the control group. The main reasons for dropout were that the prescribed treatment became impossible because of increased pain, malaise, and vomiting, and decreased appetite due to cancer progression in some cases, and that other patients were pessimistic and gave up the prescribed treatment. There were no dropouts in the MGN-3 group, and all patients were included in the analysis. In the control group, 53 patients, accounting for 49%, dropped out.

2. The number of survival patients and the survival rates at 18 months

The survival rate at 18 months of treatment was 54.2% for the MGN-3 group (52 patients) and 35.8% for the control group (19). An investigation showed that no dropout survived. This means that the survival rate for the control group was 17.4% of 109 patients at the start of study.

3. Changes in NK activity

After starting the study, patients had decreased, unchanged, or increased NK activity. In the MGN-3 group, the NK activity decreased in 45.9% of patients, was unchanged in 21.9%, and increased in 32.3%. In the control group, the NK activity decreased in 51.8%, was unchanged in 9.0%, and increased in 39.3%. There was no difference in patients with increase or decrease in NK activity between both groups, but the rate of patients with unchanged NK activity was higher in the MGN-3 group.

4. Relation between NK activity and life prolongation

The NK activity before completion of the study was classified into categories of $\leq 20\%$, 20%-40%, and $\geq 40\%$ to compare the survival rates. As a result, the survival rate was higher in patients with higher NK activity in both groups. The results are shown in Table 4.

5. QOL

Table 5 shows mean QOL scores and improvements (%) before and after treatment for 96 patients in the MGN-3 group and 56 in the control group.

Improvement of QOL was observed in both the control and MGN-groups, suggesting that our clinic's complementary alternative therapy is effective in improvement of QOL for patients with progressive cancer. Especially, the MGN-3 group had a marked increase in appetite.

Conclusion

The life prolonging and QOL improving effects of MGN-3 were studied in progressive cancer patients given a clinic-prescribed therapy and those given the same therapy plus MGN-3. As a result, clear life prolongation and QOL improvement were observed. The mean duration of hospitalization was 1 month. Although the maintenance of patients was not perfect during the study, a total of 205 patients participated in the study, and data were obtained from 152 of them. This number is sufficient for statistical analysis. The patients' NK activity had clearly decreased, and the survival rate tended to be low in patients with decreased NK activity. The rate of patients with unchanged or increased NK activity was higher in the MGN-3 group than in the control group, resulting in a 1.5 times higher survival rate obtained in the former group. There are many reports on the NK activity modulating

effect of MGN-3, and the results of the present study supported the effect. With respect to QOL improvement, appetite clearly increased in the MGN-3 group. While 49% dropped out in the control group, there was no dropout in the MGN-3 group. This was at least in part because of the improvement of the nutritional state due to increased appetite.

The relation between the NK activity and immunity against a tumor is controversial, and the role of NK cells is not completely clear. However, it is considered a good indicator for the nutritional state in progressive cancer patients, because patients with NK activity above a fixed level are likely to survive for a longer time. To prevent NK activity from the decline and maintain it at a high level may lead to life prolongation.

MGN-3, which helps the maintenance and enhancement of patient's self-curative ability, can be a useful tool for complementary alternative therapy.

Finally, we would like to thank Daiwa Pharmaceutical for supplying MGN-3 (BioBran) and Mitsubishi Chemical Laboratory (B.C.L.) for cooperation in blood tests.

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This paper is a translation of an article in *Clinical Pharmacology and Therapy*, Vol. 14/No. 3/May 2004.