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SEVEN-YEAR SURVIVAL IN PATIENT WITH RECTAL ADENOCARCINOMA DUE TO A NOVEL BACTERIAL-BASED THERAPEUTIC APPROACH. A CASE REPORT

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To the Editor :

At present, it is clear that conventional anti-cancer methods are of little efficiency in people with metastases while the upcoming approach such as gene therapy¹ is far from introduction into a broad clinical practice in the near future. Moreover, application even the latest therapeutic strategies^{2, 3} and radiation techniques^{4, 5} may result in severe weakness, depression of bone marrow, loss of hair, damage of internal organs and dermatoses⁶. Therefore, development of news anti-cancer approaches is one of the most important challenges in modern medicine.

Recently, we have reported briefly⁷ about application of new bacterial-based therapeutic methodology that is able to inhibit metastatic growth and significantly improve the patient's quality of life. The essence of our method is peroral administration of *Bacillus oligonitrophilus* KU-1 that has been shown in several observational studies to improve the quality of life of patients with solid cancers. Here we present some additional data on patient with rectal adenocarcinoma who has experienced an exceptional beneficial response to our bacterial-based treatment.

Bacillus oligonitrophilus KU-1 (*Bacteria*; *Firmicutes*; *Bacilli*; *Bacillales*; *Bacillaceae*: according to⁸ strain was isolated from soil of Kazan city. Scheme of administration is presented below.

Patient under study, female, was born in 1937. In November 25, 1998, mild differentiated rectal adenocarcinoma with non-operative metastases into greater omentum was determined (T₃N₁M₁) at Tatarstan Republican Hospital (Kazan, Russia). In November 30, 1998, colonoscopic polypectomy of larger polypus was made. In December 2, 1998, abdominal resection of rectum was made at the same hospital. In December 15, 1998, formation of sigmoid-anal anastomosis was made. Between the operation days, health status was satisfactory and the patient resided in hospital. The overall post-surgical outcome was uneventful. In December 25, 1998, the patient left the hospital.

Since February 1999, peroral administration of *B. oligonitrophilus* KU-1 stationary phase culture (0.5-1.0x10⁹ cells per mL) was started by the patient according to the following scheme: 1st day: 2.5 mL, 2nd day: 5 mL, 3rd day: 10 mL, 4th day: 20 mL, 5th day: 40 mL, 6th day: 60 mL, 7th day: 80 mL, 8th day: 100 mL, 9th day: 120 mL, 10th day: 140 mL, 11th day: 160 mL, 12th day: 180 mL, 13th day: 200 mL and then 200-250 mL per day. In August 1999, regular administration was stopped. Since August 1999 until November 2003, there was only preventive administration during each spring (200-250 mL per day). Since November 2003, regular administration (100 mL per day) of *B. oligonitrophilus* KU-1 culture was renewed. In March 2004, ultrasonography of liver, kidneys, pancreas and spleen was made (results were without pathology). Gastroduodenoscopy studies revealed polypus (0.6x0.8 cm) in stomach without need to operate. In June 2004, regular administration was stopped. During Spring 2005, she received *B. oligonitrophilus* KU-1 (100 mL per day, one week of administration followed one week of interruption). In February 2006, ultrasonography of liver, pancreas and spleen was made (results were without pathology). A few cystic lesions were found on the right and left kidney (up to 16 and 12 mm in diameter, respectively). The size of the stomach polypus is without changes since March 2004. Since March 2006, she receives *B. oligonitrophilus* KU-1 with prophylactic aim. All laboratory findings are shown in Table 1.

This case suggests that peroral administration of *B. oligonitrophilus* KU-1 could be used for therapeutic and preventive use. Of course, our study has a significant limitation because computed tomography and magnetic resonance tomography data were absent. In this connection, we cannot rule out formation of peritoneal metastasis: this probably took place, in parvo, during increment of CA19-9. In the same time, it is reasonable, however, to suggest that there was no enormous metastatic growth because of good health sense and increased survival (more than 7 years). The patient had a favorable tolerance profile: this probably explains the observed therapeutic success and she had no, for example, gastritis, nausea or retching as it took place in our other patients⁷. However, patient demonstrated an increased arterial tension (both systolic and diastolic) in 1999 that was elevated approximately on 20 mm of mercury. We presuppose that elevation of arterial tension might be a consequence of the tumor clone inhibition.

Table 1. Laboratory findings in cancer patient

Date	Parameter						
	HGB	WBC	RBC	HTC	PLT	CEA	CA19-9
30/10/1998	52	4600	NA	19.3	395	NA	NA
26/01/1999	102	5000	4.83	NA	347	NA	NA
23/03/1999	120	7700	4.91	NA	294	NA	NA
22/06/1999	130	5900	5.14	40.0	211	1.0	9.02
26/10/1999	123	5400	5.1	41.0	213	0.6	7.88
22/02/2000	121	5300	5.27	42.5	213	0.8	10.74
20/09/2000	136	5800	4.96	41.8	236	NA	4.38
25/01/2001	139	6500	5.64	44.6	228	NA	NA
2/03/2001	135	5500	4.86	39.8	189	NA	7.06
4/03/2002	120	4500	4.0	NA	186	NA	NA
25/03/2003	126	4900	4.77	38.0	197	NA	5.56
31/10/2003	124	5200	4.96	38.2	219	NA	29.3
6/02/2004	107	3800	4.09	32.9	167	NA	40.1
1/03/2004	114	4800	NA	NA	NA	NA	31.2
1/06/2004	NA	NA	NA	NA	NA	NA	31.1
10/11/2004	130	NA	NA	NA	NA	NA	23.9
18/03/2005	116	3800	4.5	NA	270	NA	19.2
22/02/2006	131	4100	4.42	41.4	201	NA	28.0

Abbreviations: HGB=haemoglobin (g/L), WBC=white blood cell (/ μ L), RBC=red blood cell ($\times 10^9/\mu$ L), PLT=platelet ($\times 10^9/L$), HCT=haematocrit (%), CEA and CA19-9 – oncomarkers (μ g/L and U/mL, respectively), NA – data are not available.

According to theoretical prognosis, over 50 000 people will die (only in USA) in 2006 due to colorectal cancer⁹. This points out an importance of the medical problem. We have to thank conventional chemotherapeutists for their constant efforts to increase tolerance and efficiency of chemotherapeutic drugs by means of various remedy combinations¹⁰⁻¹² but, unfortunately, the frequency of relapse and subsequent death remains significant¹³. Because some lifestyle factors (diet, ataraxy, etc.) were shown to be important in the cancer disease management¹⁴⁻¹⁵, we recommend keeping some recommendations: vegetarian diet, administration of probiotics (their preclusive effect was shown in many studies, see for example 16), and prevention of supercooling, superheating and psychic anxieties.

Although some suppositions on the *B. oligonitrophilus* KU-1 mechanism of action has been made^{7, 17}, it is necessary to perform further research to clarify all possible modes of the observed anti-cancer effect. Moreover, randomized double blind trials are needed to evaluate efficiency of the suggested therapeutic approach in various cancers.

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