

Clinical Evaluation of “Immunoaugmentative Therapy (IAT)”: An Unconventional Cancer Treatment

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Immunoaugmentative therapy (IAT) is an unconventional therapy used by thousands of cancer patients that has not been systematically evaluated for safety and efficacy. The authors evaluated the toxicity and effects of this therapy in a series of consecutively treated cancer patients. *Methods.* A sample of 46 consecutive patients treated at the Immune Therapy Clinic in Playas, Mexico, from April to December 1989 were evaluated for adverse reactions, tumor response, quality of life and immune status over 12 weeks of IAT treatment. Patients' blood was tested for HIV and hepatitis B antibody before and after treatment. Histological confirmation of cancer and staging was obtained in all patients, and the results of follow-up radiological examinations were judged in a blinded fashion by independent diagnostic radiologists. *Results.* There were no signs of toxicity (SWOG criteria) and no HIV or hepatitis B conversion attributable to IAT. None of the 46 patients showed tumor regression. Forty patients (87%) had disease progression, and 25 (55%) died within 6 months from disease progression. Thirty-five patients (76%) noticed a decline in their quality of life during IAT. Thirty-eight patients (83%) opted to continue with the IAT treatment, despite its lack of effectiveness. *Conclusions.* No indication of toxicity or effectiveness was found in an uncontrolled, consecutively selected series of 46 cancer patients undergoing IAT treatment. In addition, the therapy did not appear to contribute to improved quality of life in most patients. This study does not justify its continued use.

Patients with cancer are among the highest users of unconventional medical treatments. Nearly half of all cancer patients use some unconventional treatment during the course of their illness.^{1,2} Unconventional cancer therapies can generate controversy and heated debate at least partly because there is so little research in an area where patients may be desperate for any kind of treatment that gives hope of survival. A MEDLINE search of “alternative therapies” and “cancer,” for example, results in fewer than 100 randomized controlled trials in alternative cancer treatments compared with more than 25,000 in conventional medicine. In addition, nonprotocol complementary and alternative medicine (CAM) cancer therapies can be difficult therapies to evaluate. They may have been developed by an

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individual clinician or researcher who then guards against any attempt to discredit his or her therapy.

We used an evaluation system called the Prospective Outcomes Documentation System (PODS). PODS involves complete data collection on a sample of consecutive patients with advanced disease and with documented diagnoses and treatments. Regular clinical and laboratory outcomes are measured using standard procedures. The alternative treatment procedures are delivered by the practitioners without interference but are thoroughly documented. Since all patients are expected to progress or remain stable, improvement is suggestive of the therapies' effectiveness. This study is the first independent evaluation of the outcomes of consecutive patients treated with one of the most popular and controversial CAM therapies for cancer—immunoaugmentative therapy (IAT). IAT was developed by the late Lawrence Burton, PhD, after he published a series of laboratory experiments claiming to have isolated several factors in mice that regulated tumor growth.^{3,4} He subsequently developed the hypothesis that 4 specific immune serum protein fractions are involved in the immune response against cancer.^{5,6} According to Burton, these fractions are tumor antibody (TA), tumor complement (TC), blocking protein (BP), and deblocking protein (DP). Burton believed that a single antibody existed against various histological types of cancer. This antibody would be activated by the TC fraction to attack cancer cells. BP would shield cancer cells and prevent the activated TA from attacking too many cancer cells at any one time. The DP is thought to neutralize the action of BP and, therefore, enable TA again to attack cancer cells. An effective immune response against cancer would only exist in the presence of a balanced proportion of these 4 serum protein fractions. Burton further stated that IAT treatment is based on his testing of the

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“Immunocompetence” of a patient. This involves measurement of the relative concentrations of the 4 serum protein fractions in the patients’ blood and comparison of these values with data from past patients with the same diagnosis and similar status.^{5,6}

Thousands of patients have been treated with this approach in clinics in the Bahamas, Germany, and Mexico.⁷ Assertion that IAT is unproven,⁸ or warnings about IAT treatment serum being manufactured without quality control,⁹⁻¹² are not sufficient information for desperately ill patients and their physicians. Today, almost 20 years after the news show *60 Minutes* sensationalized Burton’s treatment, skeptics and proponents continue to claim that IAT is worthless or effective, respectively.^{7,10,13,14}

During the past decade, interest in the role of the immune system in host defense against cancer and the therapeutic utilization of this concept has been renewed. One reason for the resurgence of tumor immunology is the technological progress in immunology and molecular biology leading to the isolation, identification, and production of substances that can enhance and target the immune response to cancer. The concept of augmenting immune system function of an organism to fight cancer is not new. As early as 1909, Paul Ehrlich¹⁵ recognized the importance of an intact immune system for the host to defend cancer growth. The concept was restated by Thomas¹⁶ in 1959 and further refined as immunological surveillance by Burnet¹⁷ in 1970. Presently, there are numerous immunological therapies for advanced malignancies under investigation in “conventional” medical areas.

In 1990, the United States Office of Technology Assessment (OTA) published a report on the status of unconventional cancer treatments.⁷ IAT was the only single therapy to have an entire chapter devoted to it in this report. The OTA report also described how difficult it is to evaluate CAM therapies when the proponents and skeptics do not trust each other or work cooperatively together. The OTA made extensive, but unsuccessful, efforts to set up a clinical trial acceptable to both Burton and the National Cancer Institute (NCI) (H. Gelband, Project Director—OTA, personal communication, 1990).⁷ Now, more than 20 years after Burton’s original claims and almost 10 years after OTA’s attempts to develop a test of these claims, no systematic data have been collected on the effects of this therapy in humans. One case series reported by Burton on 11 patients with mesothelioma claimed a mean survival of 30 months (range of 7 to 80 months) relative to the literature reporting a survival range of 1 to 60 months for this diagnosis.¹⁸ A second assessment was attempted by independent investigators¹⁹ using a telephone survey of 79 patients with metastatic disease from a variety of cancer tumor types treated with IAT.

Fifty patients were reported to be alive an average of 65 months after the diagnosis, but confirmation of diagnosis, stage, other treatments, and outcomes was inadequate to make any conclusions about the therapy.

The Office of Alternative Medicine (OAM) (now the National Center for Complementary and Alternative Medicine) was started at the NIH in 1992; it is charged with facilitating the investigation of unconventional therapies, including those on cancer. The OAM recognized early that more and better communication bridges are needed between conventional researchers and practitioners of alternative cancer treatments before viable research opportunities in these areas can be developed. Systematic steps for evaluating CAM cancer therapies have been outlined and include methods such as best case series and field investigations, prospective practice outcomes evaluation and controlled clinical trials (www.cancer.gov/occam/bestcase.html).

We were able to evaluate the effects of IAT on cancer patients by following a sample of patients treated with IAT. We did this by working closely with an IAT clinic under Burton’s supervision in Playas, Mexico, and arranging for complete follow-up of a consecutive sample of these patients by their oncologists in the United States. Our goal was to obtain data to help answer the following questions: (1) Does IAT have toxic side effects? (2) Does IAT show any objective benefit in the treatment of cancer patients?

Methods

From April until December 1989, a sample of 50 patients selected from consecutive patients treated with IAT at the Immune Therapy Clinic in Playas, Mexico, were invited to be followed and evaluated. This clinic was an exact replica of Burton’s clinic in the Bahamas and was under his direct supervision during the evaluation of these patients. Every other patient who came to the Playas clinic between April and December 1989 was asked if he or she would sign informed consent to follow-up for 12 weeks (with phone call follow-up at 24 and 48 weeks) to evaluate tumor response, quality of life, and immune status during and after their treatment. Patients were informed that no interference in their choice of therapy would occur by participating in follow-up.

American board certified oncologists performed all diagnostic procedures, including staging. Staging had to be accomplished within 3 weeks prior to initiation of IAT treatment, and the estimated survival prognosis needed to be at least 3 months from the start of the IAT program. Verification of diagnosis was required by histological examination of tumor tissue. Two independent medical teams, including physicians

at the Immune Therapy Clinic in Playas, Mexico, and oncologists in the United States, followed these patients during the clinical trial. During the first month of the study, the patients reported to the Immune Therapy Clinic daily (Monday through Friday) to have blood withdrawn for the IAT Immuno-competence Test and to receive treatment serum for self-injection (see below). During the second and third months of the study, the patients were seen every 2 weeks for follow-up. Blood samples were withdrawn at each of these clinic visits, and treatment serum was provided to the patients for the 2-week interval between visits. All therapy was directed by Dr. Burton. The patients were asked by Dr. Burton's staff not to use any other cancer therapy during the 12-week study period. Pain medication was allowed and no specific diet was recommended. Patients were offered to continue on study medication after completion of the study period. Telephone contact was attempted for all surviving patients at 24 and 48 weeks to assess general status and survival.

IAT Procedure

Technical details of Burton's laboratory procedure to measure the concentration of the 4 serum protein fractions are reported elsewhere,⁷ and the exact procedure used at the Playas clinic (which was identical to that used in the Bahamas clinic) is available upon request. In short, differential centrifugation and various heat denaturation steps (55° to 60° Celsius for 10 minutes) are used to isolate the serum protein fractions. The isolated materials are then analyzed using a Beckman Acta V spectrophotometer. The spectrophotometer readings were transmitted to Burton's clinic in the Bahamas and entered into a database. By comparison with the data of former patients, Burton then prescribed the daily dosage of TA, TC, and DP for each patient to be administered by subcutaneous injections to correct existing imbalances in the blood concentration of the 4 protein fractions. BP is not administered as part of the IAT regimen. Treatment serum for this study was provided by Burton, shipped by overnight mail from the Bahamas to the Playas clinic. TA and DP are derived from pooled sera of healthy donors; TC is derived from blood clots of patients with different types of cancer.

Assessment of IAT Toxicity

The toxicity of IAT was assessed by the physicians at the Immune Therapy Clinic in Playas according to a modified 5-grade system proposed by Miller et al.²⁰ In addition to this, the skin reaction at the injection site was examined in each patient. Furthermore, each patient's blood was tested twice for HIV and hepatitis B antibody, once before and once after the 12-week IAT

treatment protocol was completed, as were all injected materials.

Assessment of IAT Effectiveness

The effects of IAT on cancer were determined by 2 independent teams of physicians, using standard methods for objective response. Complete (CR) or partial (PR) response was monitored according to the rules outlined in the report by Miller et al.,²⁰ and each is similar to that described using the NCI/OCCAM "best case series" method. The clinical status, the Karnofsky performance index,²¹ results of x-ray, computer-tomography (CT), bone scintigraphy (BS), and magnetic resonance imaging (MRI), as well as blood chemistry and tumor marker determinations, were compared for each patient before, during, and after the IAT treatment. The results of x-ray, CT, BS, and MRI examinations were judged in a blinded fashion by independent diagnostic radiologists.

The immune system status of 12 randomly selected patients was examined before and after IAT treatment. Total leukocyte count, total lymphocyte count, B and T cells, and helper/inducer (T4) and suppressor/cytotoxic (T8) subgroups, as well as the concentrations of the immune globulin fractions IgG, IgA, and IgM, were determined in 4 patients with colon cancer, 4 with breast cancer, and 4 with prostate cancer. All patients answered a questionnaire to assess their quality of life before, and at 4, 8, and 12 weeks of IAT treatment. Patients were asked at this time to judge their daily life activity, mood, physical strength, ability to concentrate, pain, and other discomfort, using a linear scale from 0 to 10, with 0 = very bad and 10 = very good. Pain scores were assessed separately using a visual analog scale from 0 to 10 with 0 = no pain and 10 = excruciating pain.

Results

Details about the patients evaluated are summarized in Table 1. Of the 50 patients eligible and approached for the study, 92% (46) accepted and were entered into the series to be followed. The study group represented a number of different tumor types and stages but included at least 8 patients each with the diagnoses of colon, breast, and prostate cancer. Thirty-nine patients (85%) were in advanced stages (liver, bone, or distant metastases). Thirty-six patients (78%) had received prior conventional treatment, such as surgery, chemotherapy, and radiation, whereas 10 patients (22%) started IAT as their primary treatment. Nine patients had colon cancer (8 in stage Duke D) and 32 had either colon, breast, prostate, or lung cancer. All but 7 had distant metastases or advanced disease and a poor prognosis.

Table 1. Characteristics of Patients Referred for Immunoaugmentative Therapy

Diagnosis	Staging	Number of Patients	Gender		Age (Mean/Range)	Prior Therapy
			Female	Male		
Colon-CA	Duke D	8	2	6	53 (37-80)	S, CH
	Duke B	1	1		80	R
Breast-CA	II	4	4		42 (40-46)	S
	III	2	2		39, 54	S, CH, R
	IV	3	3		39, 58, 70	S, CH, R
Prostate-CA	C	2		2	65, 70	N
	D1	2		2	61, 64	N, S, H
	D2	4		4	66 (63-70)	S, R, H
Lung-CA	II	2	2		60, 70	S, R
	III	4	2	2	55 (39-71)	N, S, CH, R
Glioma-Multif.	III	3	1	2	28, 47, 62	S, R
Pancreas-CA	III	4	1	3	71 (62-90)	N, S
Hodgkin	III	1	1		41	N
Adrenal-CA	Lung-Metast.	1	1		68	S, CH
Liver-CA	Lung-Metast.	1	1		31	S, CH
Pancoast-Tm	Spine-Metast.	1	1		62	R
Thyroid-CA	III	1		1	54	S, R
Renal-CA	IV	1		1	65	S, R
Mesotheliom	Pleural	1		1	63	N

N = no prior therapy; S = surgery; CH = chemotherapy; R = radiation; H = hormonal therapy.

IAT Toxicity

There were no signs of major toxicity observed from IAT during the 12-week treatment period. Redness over the injection site and fever up to about 38° Celsius were noticed in about half of the patients. The HIV and hepatitis B testing before and after the treatment was negative in 44 patients. One patient tested positive for HIV antibody before and after IAT treatment; another patient became positive for hepatitis B after the treatment, but apparently from an exposure unrelated to IAT treatment.

IAT Effectiveness

None of the 46 patients showed tumor regression (Table 2). Forty patients (87%) had disease progression under the IAT treatment. Twenty-five patients (55%) died owing to the progression of their malignant disease within 6 months after initiation of IAT treatment. Among those, 4 patients suffering from lung cancer and 2 patients with pancreatic cancer died within 6 weeks on the IAT protocol. Stable disease was observed in 6 patients (13%); 2 of those had prostate cancer (stage C) and 4 had breast cancer (stage II). There was no improvement of the Karnofsky index during the 12 weeks of IAT treatment. The index remained unchanged in 12 patients (26%) and worsened in 34 patients (74%). The assessment of quality of life revealed in 12 patients (26%) an intermediate improvement during the first month of IAT treatment; it did not last through the remaining 2 months of the study. Thirty-five patients (76%) noticed a decline in their quality of life during the IAT treatment; 11 patients (24%) noticed no change at all. After completing the

3-month study period, 38 patients (83%) opted to continue with the IAT treatment, despite its lack of effectiveness. After completion of the study, 17 of those patients (37%) were combining IAT with other alternative treatment methods, such as high-dose vitamin C in 5 cases, laetrile in 4 cases, Gerson therapy in 3 cases, anti-neoplastons in 2 cases, and herbal medicines and meditation in 1 case each.

Comparison of the immune status before and after IAT treatment did not reveal any significant changes with regard to cell counts or immune globulin concentrations in the patients with prostate cancer (n = 8) and breast cancer (n = 9) who were tested. There was a 25% increase in suppressor (T8) cells at the end of the IAT treatment in 4 patients with colon cancer. We examined results from the diagnostic groups of colon cancer, breast cancer, and prostate cancer in more detail since these groups contained 8 or more patients each.

Colon Cancer

All 9 patients in this group showed evidence of disease progression during the IAT treatment. Follow-up CT examination showed an increase in the number and volume of liver metastases in 8 patients. In 1 patient without liver metastasis, an increase of the primary tumor volume was observed. Six patients died within 6 months of the IAT treatment owing to liver involvement, 1 patient died within 9 months after IAT owing to kidney failure after the primary tumor had blocked both the ureters. The follow-up results of liver enzymes (SGOT [serum glutamic oxaloacetic transaminase] and SGPT [serum glutamate pyruvate transaminase]), bilirubin, and the tumor marker CEA

Table 2. Follow-up Data of Patients With Immunoaugmentative Therapy (IAT) Treatment

Patient Number	Diagnosis	Before IAT			After IAT			Disease Status After 12 Weeks of IAT Clin. Exam, Tumor Marker, CT, MRI, Bone Scan	Follow-up 24 Weeks	Follow-up 48 Weeks
		KI	QOL	Pain	KI	QOL	Pain			
1	Colon D	70	6	3	50	4	6	Progression, more liver metastases	Died	
2	Colon D	80	7	1	80	3	6	Progression, primary increased	Liver metastases	More metastases
3	Colon D	70	5	4	50	2	5	Progression, more liver metastases, lung metastasis	Died	
4	Colon D	60	7	3	40	6	4	Progression, more liver metastases	Died	
5	Colon D	60	6	2	50	5	2	Progression, more liver metastases, brain metastasis	Died	
6	Colon D	70	6	2	30	4	4	Progression, more liver metastases, carcinomatosis	Died	
7	Colon D	70	5	3	20	2	7	Progression, more liver metastases, kidney metastases	ICU, kidney failure	Died
8	Colon D	70	4	5	20	0	8	Progression, more liver metastases	Died	
9	Colon B	80	9	0	50	7	5	Progression, more liver metastases	Died	
10	Breast II	100	9	0	100	10	0	Stable	Stable	Unavailable
11	Breast II	100	10	0	100	10	0	Stable	Stable	Stable
12	Breast II	100	10	0	90	10	0	Stable	Stable	Stable
13	Breast II	90	10	0	90	9	0	Developed lymph node metastasis	Bone metastases	More bone metastases
14	Breast III	100	10	0	100	10	0	Stable	Stable	Bone metastases
15	Breast III	80	7	2	80	5	2	Progression, bone + liver metastases	More metastases	Unavailable
16	Breast IV	80	6	3	50	2	5	Progression, more bone + liver metastases	Died on ICU, liver failure	
17	Breast IV	70	5	4	60	3	7	Progression, more bone metastases	More metastases	Died
18	Breast IV	70	5	5	40	2	7	Progression, more bone metastases	Died	
19	Prostate C	100	9	0	100	8	1	Stable, PSA 13.4	Stable, PSA 12.9	Stable, PSA 13.2
20	Prostate C	90	9	0	90	9	0	Stable, PSA 23.0	Stable, PSA 22.7	Stable, PSA 23.2
21	Prostate D1	90	9	1	70	8	2	Progression, local + bone metastases	More metastases	Stable
22	Prostate D1	80	9	2	80	8	2	Progression, local + bone metastases	More metastases	Unavailable
23	Prostate D2	70	5	3	70	4	5	Progression, lung + bone metastases	Hip fracture	Died
24	Prostate D2	70	6	2	50	5	6	Progression, local, lung + bone metastases	Died	
25	Prostate D2	70	8	3	50	7	2	Progression, local + bone metastases	More metastases	Unavailable
26	Prostate D2	80	7	5	60	5	5	Progression, local, lung + bone metastases	Died	
27	Lung II	60	5	0	60	4	0	Progression to Stage IV, brain metastases	Increase of brain metastases	Died
28	Lung II	80	6	1	50	2	3	Progression to Stage III b, cervical nodes	Increase of primary	Died
29	Lung III a	70	5	0	NA	NA	NA	Progression, pneumonia, bleeding	Died after 5 weeks	
30	Lung III b	60	4	1	NA	NA	NA	Progression, pneumonia	Died after 6 weeks	
31	Lung III b	70	4	2	NA	NA	NA	Progression, pulmonary emboli	Died after 6 weeks	
32	Lung III b	60	2	3	NA	NA	NA	Progression, pneumonia, aspiration	Died after 3 weeks	
33	Glioblastoma	60	5	1	20	2	1	Progression by CT criteria	Died	
34	Glioblastoma	60	4	1	30	2	2	Progression by CT criteria	Died	

(continued)

Table 2 (continued)

Patient Number	Diagnosis	Before IAT			After IAT			Disease Status After 12 Weeks of IAT Clin. Exam, Tumor Marker, CT, MRI, Bone Scan	Follow-up 24 Weeks	Follow-up 48 Weeks
		KI	QOL	Pain	KI	QOL	Pain			
35	Glioblastoma	80	7	2	60	4	3	Progression by CT criteria	Died	
36	Pancreas III	60	5	5	20	2	7	Progression, parenteral nutrition	Died	
37	Pancreas III	50	3	7	NA	NA	NA	Progression, liver coma	Died after 3 weeks	
38	Pancreas III	70	5	5	20	1	8	Progression, parenteral nutrition	Died	
39	Pancreas III	60	4	6	NA	NA	NA	Progression, bile obstruction, septicemia	Died after 4 weeks	
40	Hodgkin III	80	9	1	70	8	2	Progression by CT criteria	Bone marrow involved	Unavailable
41	Adrenal CA	70	5	2	60	3	2	Progression, pneumonia, septicemia	Died, lung metastases on autopsy	
42	Liver CA	100	8	2	80	7	4	Progression, new nodule in left lobe	Jaundice, ascites	Died, hepatic coma
43	Pancoast	80	8	4	80	7	4	Slow progression, by CT criteria	Plexus invasion	Unavailable
44	Thyroid III	80	7	0	70	5	3	Progression, metastases to bone	New lung lesion	Unavailable
45	Renal CA IV	70	5	2	60	2	2	Progression, more lung metastases, new liver met	Died	
46	Pleural Meso	70	6	3	60	3	4	Progression, pleural effusions	Died, small bowel obstruction	

KI = Karnofsky Index; QOL = Quality of Life Index; Pain = Pain Score.

(carcinoembryonic antigen) showed steady elevation from month to month (Figure 1).

Breast Cancer

Five of the 9 patients in this group started IAT treatment without measurable disease, for example, the primary tumor had been surgically removed and no metastases were found. One of these patients developed lymph node metastasis during the IAT treatment. The remaining 4 patients had metastases on entering the IAT protocol and showed disease progression. Liver involvement increased in 2 patients, and bone metastases increased in the other 2.

Prostate Cancer

Two of the 8 patients in this group showed a stable course of their disease when entering the study protocol. Both patients had stage C prostate cancer, their Gleason values were 3 and 4, respectively, and they started IAT without any other prior therapy. The low Gleason scores as seen in these 2 patients usually indicate a good prognosis. One of these 2 patients discontinued IAT after 4 months and remained stable during the following 8 months of follow-up without any further therapy. The remaining 6 patients (4 in stage D2, 2 in stage D1) showed progressive disease with increasing prostate-specific antigen and increasing number and volume of bone and/or lung metastases.

Discussion

We found that 12 weeks of IAT treatment in a consecutive series of 46 patients with cancer was not associated with any partial or complete responses. This contrasts sharply to the information in the patient brochure that reports a response rate greater than 50% for colon, breast, prostate, and lung cancer. In our series, disease progressed in 87% of the patients and malignancy-related deaths occurred in 55% of the patients within 6 months after starting IAT. Although a noncontrolled study such as this one cannot provide definitive proof for or against any therapy, our data speak against the likelihood that this treatment can markedly influence the disease course positively. Prior chemotherapy and/or radiation could have influenced the clinical outcome in 78% of the study patients receiving such treatment before entering the IAT study. However, there was neither a partial nor a complete response found among the remaining 10 patients who did not receive any pretreatment.

The immune system status of the 12 patients examined did not change during the study. Immune cell counts and concentrations of immune globulins only give a limited picture about immune system function. It remains unclear what aspect of immune function IAT augments. On the other hand, it also remains unclear how to interpret the 25% increase in suppressor (T8) cells in the 4 colon cancer patients.

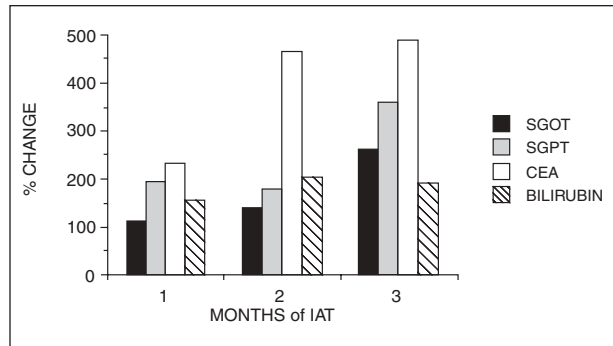


Figure 1 Percentage changes in SGOT (serum glutamic oxaloacetic transaminase) and SGPT (serum glutamate pyruvate transaminase), and bilirubin and CEA (carcinoembryonic antigen) during immunoaugmentative therapy (IAT) treatment in patients with colon cancer.

The stability of the Karnofsky index in 10 patients probably cannot be attributed to IAT treatment since 5 of these patients did not have any measurable disease entering the study and 2 other patients showed disease progression with an unchanged Karnofsky index. We suspect that short-term improvement in quality of life in 12 patients was related to diminishing toxic side effects from prior chemotherapy and/or radiation in 9 patients because their disease progressed during IAT treatment. Still, some unidentified factors in IAT or a placebo effect may have played a role in the remaining 3 patients, since their assessment of life quality did not correlate with their Karnofsky index and further clinical course.

The cause for the positive hepatitis B test in 1 patient at the end of the treatment could not be traced to the IAT serum fractions. Follow-up examination after 9 months in 3 patients who had continued with IAT revealed septicemia. Whether this was a consequence of injecting possibly contaminated IAT serum, as reported earlier,^{9,12} or was due to immune deficiency in conjunction with the malignant disease, cannot be determined.

Current therapies with medically approved protocols directed at augmenting immune system function in cancer patients are potentially limited because of the already compromised immune system found in late-stage cancer. Moreover, because of the uncertainty associated with such protocols and the initial use of conventional therapies for many cancers, the eligibility criteria of most immunotherapy protocols include only patients who have failed the standard methods already. The latter is also true for many patients who seek out alternative cancer therapies. This situation makes it difficult to know the true effects of new immunotherapy or alternative treatment approaches on these conditions. In general, there is little to no scientific data regarding efficacy

and toxicity for alternative methods for treating cancer, including IAT. Nevertheless, thousands of patients opt for these methods and more than 80% of surviving patients in this series chose to continue IAT treatment, even in the face of disease progression.

When questioned for their motives for undergoing IAT treatment in Mexico, 38 patients (82%) in this study cited fear of side effects from new or additional chemotherapy cycles or radiation; 4 patients (9%) rejected conventional treatment altogether; and the remaining 4 patients had exhausted all conventional methods, including immunotherapy, in the United States. For many of our study patients, the motivation to seek out alternative therapy becomes understandable, since IAT does not produce the classical symptoms of toxicity, as is often observed with chemotherapy and radiation. Furthermore, although there have been no peer-reviewed data on efficacy, the information available in the IAT Patient Brochure⁶ and from other alternative cancer therapy information sources¹⁴ claims high response rates with long-term regression of tumors and/or remission of symptoms.

Conclusion

In summary, no indication of toxicity or effectiveness was found in an uncontrolled, consecutively selected series of 46 cancer patients undergoing IAT treatment. In addition, the therapy did not appear to contribute to improved quality of life in most patients studied. Since it is difficult to know if the patients in this series would have fared better or worse had they not received IAT, a definitive answer to the question of IAT efficacy remains unanswered. This study, however, does not justify its continued use. Prospective Outcomes Documentation of diverse cancers and treatments is a feasible, low-cost method for voluntary care practices.

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