PJN
ISSN 1680-5194

PAKISTAN JOURNAL OF NUTRITION

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Pakistan Journal of Nutrition 1 (3): 119-120, 2002

Adjuvant Nutritional Therapy in the Management of Malnourished Cancer Patients

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Abstract: A new Nutritional Adjunct was tested as an adjuvant with radiotherapy for cervical cancer in Dhaka Medical College Hospital, Bangladesh. In addition to the cancer induced malnutrition, most Bangladeshi people are basically malnourished. The main objective of this study was, therefore, to examine if this newly patented Nutritional Adjunct could at least be useful in preventing further deterioration of the nutritional status of cancer patients receiving chemo- and/or radiotherapy. Twenty female subjects with stage III cervical cancer participated in this preliminary case-control clinical trial. Ten subjects receiving the Nutritional Adjunct showed a significant improvement in their nutritional status, at least in terms body weight changes and a general feeling of wellness, compared to the patients in the control group. Furthermore, the bone marrow status, as measured by the platelet counts (PC), was found to be enhanced significantly ($p < 0.001$), i.e. PC was increased from $2.6 \pm 0.10 \times 10^4$ Cu mm to $3.9 \pm 0.3 \times 10^4$ Cu mm, in the supplemented group. These preliminary results, therefore, strongly suggest prospective full clinical trial to ascertain any therapeutic efficacy of this new Nutritional Adjunct.

Key Words: Nutrition, cervical cancer, radiotherapy

Introduction

Malnutrition plays a major role in the morbidity of cancer patients receiving chemo-and/or radiotherapies. Such health condition may be attributed to the nutritional status of the patients prior to the development of cancer, to the carcinogenesis and/or to the therapeutic regimens. Aggressive therapeutic modalities along with progressive malnutrition may result in the death of a patient. Cachexia and anorexia are the common features observed clinically in cancer patients. Even well-nourished patients undergoing radiation therapy for the cervical, prostate and bladder cancers develop diarrhoea and nausea resulting in anorexia and cachexia(Bosch and Frias, 1977; Weisbrot *et al*., 1975; Harding *et al*., 1990). Parenteral and enteral nutritional supports are usually given as adjunct to the cancer therapies (Robuck and Fleetwood, 1992; Sax and Souba, 1993), although with little or no significant success in alleviating these conditions. Nutritional pharmacology, however, is an emerging field where one should manipulate nutritional requirement of cancer patients to achieve desired physiological results. Most Bangladeshi patients are basically malnourished. We always, therefore, search for any nutritional adjuvant for the managements of our cancer patients receiving either chemo- and/or radiotherapies. In this respect, a new Nutritional Adjunct has recently been patented (Khaled, 1999) and claimed to combat antineoplastic therapy-induced toxicities. This product is a composite of several nutrients chelated together in order to enhance their bio-availability. We procured this product and conducted a preliminary a case-control clinical trial on cervical cancer patients receiving radiotherapy.

Materials and Methods

Female patients, between the age of 25 to 50 years, with cervical cancer, stage III, were recruited for this study under the approval of the Dhaka Medical College Hospital, Dhaka, Bangladesh. Stage III cervical cancer indicates an advance state of carcinoma that involves the lower third of the vagina extending up to the lateral pelvic wall. Patients normally at this stage report to the hospital with poor health conditions, particularly with progressive weight loss and anemia. Twenty such patients participated in this preliminary study, half belonging to control groups (10 patients) who received placebo (similar capsules filled with cooked and dried rice powder) and other half (10 patients) received the Nutritional Adjunct (2 caps, three times/day with meals) four days prior to the initiation of radiation therapy and continued until the end of the therapy. The Nutritional Adjunct was supplied by the Life Sciences' Technologies, Inc. (LSTI), Birmingham, Alabama (USA). A cobalt-60 teletherapy machine was used in this study. Irradiation dose was 45 to 50 Gray given over a period of 4.5 to 5.0 weeks.

Blood samples were collected before giving either placebo or the Nutritional Adjunct and after completing the radiation therapy. These samples were analyzed particularly for hemoglobin (Hb), white blood cell (WBC) and platelet count (PC). Clinically patients conditions were monitored for weight loss, vomiting, nausea, diarrhea, loss of appetite (leading to anorexia), lethargy (loss of physical energy) and most of all, their feeling of wellness. The blood biochemical parameters, as obtained in this study, are listed in Table 1. Table 2 gives the subjective clinical observations that were made during the period of radiation therapy. Energy and/or a feeling of wellness in each patient were assessed from their day to day's activity. For example, the control patient who received placebo could walk only a few steps compared to the patients receiving this Nutritional Adjunct. The control patients always felt tired and some of them even had to be carried with a stretcher from their bed to the radiation clinic, whereas the supplemented patients walked the same distance (about 250 ft) easily and comfortably.

Results and Discussion

Loss of body weight (cachexia) and appetite (anorexia) is a serious problem usually encountered during the treatment of cancer patients with chemo- and/or radiotherapies. Such condition was obviously observed in the control patients in this study whose mean body weight decreased to 36.7 ± 5.5 kg from a pretreatment body weight of 41.1 ± 4.4 kg. Statistically this is a significant ($p = 0.06$) weight loss over a period of 4 to 5 weeks. Nutritionally supplemented patients, on the other hand, did not show any reduction in their body weight (Table 1), rather, some of them gained some weight, albeit not significantly. Stability of body weight, particularly during the therapy, is highly desirable.

Bone marrow toxicity (myelosuppression) due to chemo-and/or radiotherapies many times poses life threatening problem to the cancer patients by making them more prone to many opportunistic diseases (Fyles *et al*., 1995; Makino *et al*., 1995). In fact, antineoplastic therapy-associated toxicities may be the secondary factors of patients mortality (Rudolph *et al*., 1994; Hahn *et al*., 1994). Moreover, success of any anticancer therapy could be dependent on immuno-compatibility, which may be

Table 1: Objective observations on the biochemical parameters of cervical patients before and after the treatment

Parameters		Control (n = 10)	p^a	Supplemented (n = 10)	p^a	p^b
Age (year)		39.6 ± 11.8	---	40.1 ± 11.2	-----	0.92
Height (cm)		151.1 ± 5.9	---	152.8 ± 6.4	-----	0.54
Weight (kg)						
	Pre[c]	41.1 ± 4.4	0.06	38.1 ± 4.1	0.96	0.13
	Post[c]	36.7 ± 5.5		38.2 ± 3.8		0.49
Hemoglobin (%)						
	Pre	61.7 ± 3.3	< 0.001	61.3 ± 3.6	< 0.01	0.80
	Post	48.7 ± 3.3		53.2 ± 4.3		0.02
WBC (Cu mm x 10^3)						
	Pre	10.3 ± 0.9	< 0.001	9.4 ± 1.0	0.59	0.049
	Post	8.2 ± 0.5		9.6 ± 0.6		< 0.001
Platelet (Cu mm x 10^4)						
	Pre	2.5 ± 0.2	0.017	2.6 ± 0.10	< 0.001	0.17
	Post	2.2 ± 0.3		3.9 ± 0.30		< 0.001

p^a = Statistical significance within the group, p^b = Statistical significance between the groups, i.e. control and supplemented
c = Before (pre) and after (post) supplementation

Table 2: Subjective observations on the health status of cervical patients at the end of the treatment

Parameters	Control	Supplemented
Cachexia	Yes	No
Anorexia	Yes	No
Nausea	Yes	No
Anemia	Yes	No
Feeling of wellness	No	Yes
Feeling of energy	No	Yes
Consent to further participation	No	Yes
Attitude towards life	Negative	Positive

severely compromised in malnourished patients and/or may be altered due to the therapeutic modalities. The measured mean value of platelet count (PC), i.e. the bone marrow status, in the nutritionally supplemented patients in this study was found to be enhanced from 2.6 ± 0.10 x 10^4 Cu mm to 3.9 ± 0.3 x 10^4 Cu mm which is significantly higher within the group and between the groups, i.e. control versus supplemented. This therefore indicated that the Nutritional Adjunct not only prevented the bone marrow depletion, rather increased it significantly (Table 1).

From the subjective clinical examinations, as listed in Table 2, it could be noted that the most important observation was the feeling of wellness and energy by the patients receiving Nutritional Adjunct. This is extremely helpful to cancer patients undergoing any aggressive therapeutic modalities. It was surprising to see that the nutritionally supplemented patients left hospital after completion of radiation therapy with a feeling of wellness and energy while the control patients appeared more malnourished with some kind of discomfort prevailing in them. While a follow-up examination of these patients will determine any therapeutic efficacy, these preliminary results, however, warrant prospective full clinical trial of this new Nutritional Adjunct on a larger cohort of cancer patients populations using perhaps more cytotoxic therapeutic modalities.

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