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Clinical Trial with Liv.52 in cases of Malignant Diseases Treated at the Barnard Institute of Radiology

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The aim of this study was to assess the potentiality or therapeutic utility of Liv.52 as an anabolic agent, particularly in a disease in which catabolism was at a high level leading on to cachexia, emaciation and asthenia.

MATERIAL AND METHODS

The patients selected were histologically proved cases with different kinds of malignant disease. They were of both sexes and of varying age groups. All the patients were hospitalised and given the same diet; they received specific treatment for malignant disease either radiotherapy or chemotherapy. Radiotherapy was administered either with Orthovoltage or $Cobalt^{60}$, depending on the needs of the case. The curative dosage schedule was 5000r in 4 weeks, while patients treated for palliation received 3000r in 2 weeks. The chemotherapeutic drugs used were mainly cyclophosphamide and Mitomycin-C; the dose of the former was 200 mg on alternative days up to a total of 6000 mg and Mitomycin-C i.v. 4 mg twice a week-up to a total dosage of 60 mg.

Sixty eight patients formed the subjects of this study, 27 of whom served as controls. The 41 patients were given Liv.52 for four to five weeks during the course of the specific therapy. Those patients who could not swallow tablets were given Liv.52 drops. Three dosage schedules were adopted: *namely*, 2 tablets, t.d.s., 3 tablets t.d.s., and 4 tablets t.d.s., or ½ teaspoonful twice a day, ½ teaspoonful thrice a day and one teaspoonful twice a day.

Before starting treatment, patients were individually assessed with particular emphasis on, weight, appetite, sense of well-being and liver function (total serum-protein, thymol-turbidity, zinc sulphate turbidity, blood uric acid) and haemogram values (total WBC, RBC, Hb%, platelet count); also bio-chemical investigations were done before commencement of therapy and at the end of therapy (vide Table 1).

RESULTS

Patients who were given Liv.52 in addition to specific therapy, showed increase in weight, (2 to 4 kg) and in appetite as also a feeling of well-being.

Periodic blood examinations showed improvement in the RBC, WBC, Hb% and platelet values demonstrating the good effect of Liv.52 on haematopoiesis. Liver function tests showed an increase of 1 to 2% in serum proteins. Three different dosage schedules were used without any side effects in any, even at the higher dosage (4 t.d.s.).

Though the patients who served as control showed local regression of the tumour and satisfactory response, there was no gain in body weight or elevation in serum protein or improvement in the haemogram value. Some actually showed a decrease in the body weight. Although they were given identical diet, the anabolic effect was not appreciable as compared with patients given Lvi.52 (vide statistical data attached in Table 1).

Table 1 – Statistical Data

Sl. No.	Difference between		Weight in kg		WBC in c.mm. in thousand		RBC in c.mm. in million		Hb%		Platelet in c.mm. in lakhs		Serum protein gms%		Thymol turbidity in units		Zinc sulph. turb. units		Blood uric acid in mg%	
	AT	BT	L	C	L	C	L	C	L	C	L	C	L	C	L	C	L	C	L	C
1	20	16.0	–	–	–	–	–	–	1	–	–	–	–	–	–	–	2	1	–	–
2	16.5	13.1	–	–	–	–	–	–	1	6	–	–	–	–	–	–	1	–	–	–
3	13	9.6	–	–	2	–	–	–	5	7	–	–	–	–	–	–	2	1	–	–
4	9.5	6.1	–	–	2	–	–	–	–	1	–	–	–	–	–	1	2	2	1	–
5	6.0	2.6	–	5	7	7	–	–	3	7	–	–	–	–	5	2	10	6	12	20
6	2.5	0.0	9	20	19	17	17	25	7	3	17	24	15	23	17	16	9	9	10	5
7	0.1	0.9	–	–	2	1	16	1	–	–	20	1	16	2	7	4	4	3	13	2
8	1.0	4.4	32	2	4	2	4	–	4	–	–	2	6	1	4	4	7	4	–	–
9	4.5	7.9	–	–	1	–	–	–	6	–	–	–	–	1	4	–	–	1	1	–
10	8.0	11.4	–	–	–	–	–	–	4	–	–	–	–	–	–	–	–	–	–	–
11	11.5	14.5	–	–	–	–	–	–	2	–	–	–	–	–	–	–	–	–	–	–
12	15.0	18.4	–	–	–	–	–	–	3	–	–	–	–	–	–	–	–	–	–	–
13	18.5	28.9	–	–	–	–	–	–	1	–	–	–	–	–	–	–	–	–	–	–
14	29.0	32.4	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Total No. of cases			41	27	37	27	37	27	37	27	37	27	37	27	37	27	37	27	37	27
Note: Four cases were not available for final evaluation since the patients either discontinued treatment or got discharged due to other reasons.																				
AT - After treatment; BT - Before treatment; L - Liv.52; C - Control.																				

Results	Appetite		Well-being	
	Liv.52	Control	Liv.52	Control
Improved	31	1	32	1
Same	10	24	8	1
Deteriorated	–	2	1	3

CONCLUSION

Liv.52 is thus a suitable anabolic agent in a most debilitating disease like malignancy. Limitations and untoward side effects associated with steroids and hormones are not present with Liv.52 therapy. Incidentally the hepatotoxicity associated with the chemotherapy (Oncolytic drug) is also sufficiently controlled.

STATISTICAL EVALUATION

The statements furnished with this report present the difference before and after treatment among various factors such as weight, appetite, haemogram values serum protein etc. The readings before treatment have been uniformaly subtracted from the after treatment readings so that we have whole range of values between 20 and 32. For each factor the two different categories, *namely*, Liv.52 and Control are given separately for comparison. The rows headed from 1 to 6 give negative values marking the deterioration and rows headed from 7 to 14 signify an improvement.

The weight gain is very marked in the Liv.52 group, whereas in the control group the weight shows a fall. The appetite and well-being of the patients show considerable improvement in Liv.52 groups while it is either the same or deteriorate in the control group. Even in the various blood examinations Liv.52 groups seem to have a positive concentration rather than the negative concentration which seems to be the case with the control group.

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