[***Probe*** (1974): (XIII), 3, 136-141]

Clinico-biochemical Trials with an Indigenous Drug — Liv.52 — In Malnutrition

Mathur, P.S., *M.D., D.C.H.*, **Chandra, I.,** *M.B.,B.S., D.C.H.*, and
Khan, M.A., *M.D., D.C.H.,*
Department of Pediatrics, M.G.M. Medical College, Indore, M.P., India.

In developing countries, malnutrition in its various forms is the most common disorder in infants and children. More than half of the world's population suffer from varying degrees of undernutrition and malnutrition. Malnutrition is the result of nutritional inadequacy in which tissues do not receive the necessary amount of essential nutrients. If the inadequacy is unchecked a series of changes occur in the tissue eventually ending in the anatomical lesions of a deficiency disease. If the nutritional inadequacy continues and the nutrient reserves are exhausted, tissue depletion occurs which is followed by biochemical lesions besides functional and anatomical changes. Non-availability of proteins and other essential dietary factors, faulty feeding technique, superimposition of additional stress in the form of infection and infestation, make the problem a very major one.

Malnutrition causes tissue damage and necrosis in various organs, of which the liver is the most important. Liver changes in malnutrition are non-specific and do not point towards any specific factor deficient in the diet.

The present study was undertaken to evaluate the possible role of Liv.52 in various types of malnutrition and to compare the results with those of other workers, who have tried Liv.52 in malnutrition and found good results.

Sheth *et al.* (1963) studied cases of malnutrition treated with Liv.52 and found improvement in their liver function tests and a return of normal appetite and gain in weight. Prasad *et al.* (1969) also observed similar improvements in their cases of malnutrition. Dayal *et al*. (1970) studied 31 cases of malnutrition and found improved in general condition and gain in weight. The total serum proteins and liver function tests showed improvement after 2 to 4 weeks of therapy.

MATERIAL AND METHODS

Ten children of various grades of malnutrition admitted to the Paediatric ward of M.Y. Hospital, Indore, were treated with specific treatment, which included high protein diet and adequate amount of calories, minerals, vitamins and an appropriate antibiotic. These cases served as control.

Seventy cases of various grades of malnutrition were studied. (Table I). Most of the cases were of the 2^{nd} and 3^{rd} grade of malnutrition. They were treated with specific treatment, along with Liv.52 in recommended doses. Both the groups were followed for a period of two months. All the cases were evaluated clinically and biochemically after an interval of one month for two months. Clinically patients were evaluated for gain in weight, improvement in appetite, subsidence of cough, diarrhoea and irritability/apathy. Biochemically they were evaluated by estimating haemoglobin, total proteins, albumin, globulin, transaminase and alkaline phosphatase. These investigations were repeated every month for two consecutive months.

Table I: Shows the Age and Sex Distribution in the Present Study					
Sl. no.	Age in years	Sex		Total no. of cases	Percentage
		Male	Female		
1.	Upto 1 year	11	8	19	27.1%
2.	1 – 2 years	13	7	20	28.6%
3.	2 – 3 years	7	9	16	22.9%
4.	3 – 4 years	5	2	7	10.0%
5.	Above 4 years	3	5	8	11.4%
Total		39	31	70	100.0%

OBSERVATIONS AND DISCUSSION

In the control series there were six males and four females of varying ages ranging from 9 months to 4 years. All the cases complained of loss of appetite, cough and loose motions. Swelling all over the body and fever were present in nine cases, while vomiting and pain the abdomen were present in eight and five cases respectively. There was a past history of diarrhoea, broncho-pneumonia and measles. After two months of specific treatment there was 60% improvement in loss of appetite, 70% in cough, 80% in loose motions, 88.9% in fever, 66.7% in swelling all over the body, 75% in vomiting and 80% in pain in the abdomen (see Table II). Improvement in signs in both control and trial cases is shown in Table III. Table IV shows the biochemical changes in control cases before and after specific treatment.

Table II: Shows improvement in Symptoms										
		Total No. of cases	1st follow-up				2nd follow-up			
			Improved		No change	Did not turn up	Improved		No change	Did not turn up
			No.	%			No.	%		
1.	**Loss of appetite**									
	Controls	10	4	(40.0)	6	—	6	(60.0)	4	—
	Liv.52 treated	60	38	(63.3)	20	2	49	(81.7)	3	8
2.	**Fever**									
	Controls	9	6	(66.7)	3	—	8	(88.9)	1	—
	Liv.52 treated	55	54	(98.2)	—	1	—	—	—	—
3.	**Cough**									
	Controls	10	5	(50.0)	5	—	7	(70.0)	3	—
	Liv.52 treated	43	27	(62.8)	15	1	31	(72.1)	6	6
4.	**Loose motions**									
	Controls	10	7	(70.0)	3	—	8	(80.0)	2	—
	Liv.52 treated	58	50	(86.2)	6	2	50	(86.0)	—	8
5.	**Vomiting**									
	Controls	8	3	(37.5)	5	—	6	(75.0)	2	—
	Liv.52 treated	46	32	(69.6)	12	2	39	(84.8)	—	7
6.	**Swelling all over body**									
	Controls	9	4	(44.4)	5	—	6	(66.7)	3	—
	Liv.52 treated	32	15	(46.9)	15	2	24	(75.0)	—	8
7.	**Pain in abdomen**									
	Controls	5	3	(60.0)	2	—	4	(80.0)	1	—
	Liv.52 treated	17	12	(70.6)	5	—	14	(82.4)	—	3

Table III: Shows improvement in Signs										
		Total No. of cases	1st follow-up				2nd follow-up			
			Improved		No change	Did not turn up	Improved		No change	Did not turn up
			No.	%			No.	%		
1.	**Hepatomegaly**									
	Controls	9	4	(44.4)	5	—	6	(66.7)	3	—
	Liv.52 treated	58	30	(51.7)	26	2	43	(74.1)	7	8
2.	**Lymphadenopathy**									
	Controls	6	2	(33.3)	4	—	3	(50.0)	3	—
	Liv.52 treated	32	15	(46.9)	15	2	21	(65.6)	3	8
3.	**Anaemia**									
	Controls	5	2	(40.0)	3	—	3	(60.0)	2	—
	Liv.52 treated	56	33	(58.9)	21	2	41	(73.2)	7	8
4.	**Hair changes**									
	Controls	7	3	(42.9)	4	—	4	(57.1)	3	—
	Liv.52 treated	38	19	(50.0)	17	2	27	(71.1)	3	8
5.	**Skin changes**									
	Controls	7	2	(28.6)	5	—	4	(57.1)	3	—
	Liv.52 treated	41	16	(39.0)	23	2	24	(58.5)	9	8
6.	**Oedema**									
	Controls	7	4	(57.1)	3	—	5	(71.4)	2	—
	Liv.52 treated	43	31	(72.1)	10	2	35	(81.4)	8	—
7.	**Xerosis**									
	Controls	6	2	(33.3)	4	—	4	(66.7)	2	—
	Liv.52 treated	27	16	(59.3)	11	—	21	(77.8)	1	5
8.	**Rickets**									
	Controls	7	3	(42.9)	4	—	4	(57.1)	3	—
	Liv.52 treated	31	23	(74.2)	7	1	25	(80.6)	2	4
9.	**Stomatitis**									
	Controls	4	2	(50.0)	2	—	4	(100.0)	—	—
	Liv.52 treated	18	16	(88.9)	2	—	18	(100.0)	—	—
10.	**Resp. Infection**									
	Controls	6	5	(83.3)	1	—	6	(100.0)	—	—
	Liv.52 treated	22	22	100.0)	—	—	—	—	—	—
11.	**Splenomegaly**									
	Controls	2	—	—	2	—	1	(50.0)	1	—
	Liv.52 treated	9	4	(44.4)	4	1	5	(55.6)	1	3
12.	**Irritability**									
	Controls	8	4	(50.0)	4	—	5	(62.5)	3	—
	Liv.52 treated	23	13	(56.5)	8	2	16	(69.6)	1	6
13.	**Apathy**									
	Controls	7	3	(42.9)	4	—	4	(57.1)	3	—
	Liv.52 treated	19	14	(73.7)	5	—	19	(100.0)	—	—
14.	**Gain in weight**									
	Controls	10	4	(40.0)	6	—	6	(60.0)	4	—
	Liv.52 treated	70	38	(54.3)	30	2	57	(81.4)	5	8

Table IV: Showing Mean and Range of Haemoglobin, Total Proteins, Albumin and Globulin				
		Before therapy	After one month therapy	After two months therapy
Hb. in gms%				
Controls	Mean	7.55	8.64	9.00
	Range	5.00–9.40	6.80–11.00	7.00–13.60
Liv.52 treated	Mean	8.80	9.01	9.70
	Range	6.00–11.20	4.80–11.60	7.20–16.60
Total proteins gms%				
Controls	Mean	4.44	4.65	5.20
	Range	3.60–5.40	3.90–5.70	4.20–6.20
Liv.52 treated	Mean	4.94	5.66	6.50
	Range	3.40–6.00	4.80–6.80	5.70–7.80
Albumin gms%				
Controls	Mean	2.11	2.86	3.21
	Range	1.50–3.00	2.20–3.00	2.80–4.20
Liv.52 treated	Mean	2.28	3.10	3.59
	Range	1.20–3.60	2.00–3.80	2.30–4.40
Globulin gms%				
Controls	Mean	2.33	2.90	3.01
	Range	1.80–3.00	2.00–3.60	3.40–3.90
Liv.52 treated	Mean	3.02	2.04	2.90
	Range	1.40–4.20	1.80–3.80	2.00-3.80

Seventy cases of various grades of malnutrition treated with specific treatment along with Liv.52 were studied. Out of these seventy cases, two cases did not turn up for follow up after one month of treatment, while in the second follow up two cases died and eight (including two of the 1st follow up) did not turn up for follow up. These ten cases were excluded from the present study. The cases were evaluated clinically and biochemically as shown in Tables II, III and IV. By comparing the control series with the Liv.52 treated case, it is obvious that there is much greater improvement in clinical as well as biochemical data of the cases treated with Liv.52 along with specific treatment. Our findings are comparable with the findings of Dayal *et al.* (1970), Prasad *et al.* (1971), Saxena *et al.* (1971), Indirabai *et al* (1970), Seshachari (1971) who studied the effect of Liv.52 in anorexia associated with various disorders including malnutrition and found good clinical improvement. The present study findings are in conformity with these workers.

The exact mechanism of Liv.52 in malnutrition is not known, but the present study on the effect of Liv.52 in malnourished children, who have a tendency towards a fatty liver, has demonstrated a gain weight reflecting a positive nitrogen balance during the period of treatment. The same effect has been demonstrated by Kulkarni and Joglekar (1970).

It is commonly noted in malnourished children that they do not have a good appetite, which is the main obstacle to better intake of calories and protein. For this reason some sort of medication is required to overcome the initial anorexia. Liv.52 has a definite role in improving the appetite as is evident from our observations. Probably Liv.52 acts by stimulating the complex mechanism of the liver to increase the appetite. The increase in total proteins and serum albumin in our present study can be explained on the basis that probably Liv.52 acts by correcting the hepatic function in malnutrition. No toxic effect of Liv.52 was noted.

From the improvement in clinical and biochemical data observed in our study, it is obvious that Liv.52 has a definite place in the therapy of malnourished children as an adjuvant.

ACKNOWLEDGEMENT
We are thankful to Himalaya Drug company Private Ltd., for supplying the drug Liv.52 for clinical trial.

REFERENCES

1. Dayal, R.S., Kalra, K., Rajvanshi, V.S. and Baheti, P.c., A Clinico, Pathological Study of Hepatomegaly with Special Reference to Liv.52 Therapy. *J.I.M.P.* (1970): 9, 7768.

2. Indirabai, K., Mallikarjuna Rao, V.P.R. and Subba Rao, K.V., Therapy of Anorexia with Liv.52 *Antiseptic* (1970): 8, 615.

3. Kulkarni, S.D. and Joglekar, G.V., Effect of Liv.52 on Growing Rats under the Influence of Corticosteroids. *Indian Practitioner* (1970): 1, 299.

4. Prasad, L.S. and Prasad, K., Some Observations on Liv.52 in Treatment of Infective Hepatitis and Cirrhosis of Liver. *Probe* (1971): 10, 114.

5. Prasad, L.S. and Tripathi, D., Studies with Liv.52. *Probe* (1969): 1, 1.

6. Saxena, Mrs. S., Liv.52 in Anorexia in Pediatric Practice. *Current Medical Practice* (1971): 1, 580.

7. Sesha Chari, K.R., Liv.52 in Anorexia in Children. *Bharat Medical Journal* (1971): 2, 181.

8. Sheth, S.C., Tibrewala, N.S., Warerkar, U.R., and Karande, V.S., Therapy of Anorexia with Liv.52. *Probe* (1963): 4, 137.