

Clinical trial of Liv.52 in burns

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INTRODUCTION

Burns are an ever-present problem. A burn may vary from a minor first degree wound to the most severe form of injury. The stress associated with the burn injury is so severe that it can involve virtually every organ system in the body. The magnitude of trauma determines the extent of physiological changes. The deep burn requires time for the removal of the dead eschars before closure. The persistence of this dead tissue delays the healing process and additional systemic derangements occur.

Haemo-concentration, hypotension, systemic anoxia of secondary shock are apt to predispose to degenerative changes in the liver. A severe burn injury impairs the hepatic function, leading to disturbance of carbohydrate and protein metabolism and increased storage of fat. In severe burns, the albumin fraction of protein is lost in greater amount than the globulin fraction which results in initial reversal of albumin globulin ratio. During the sub-acute phase, there is increased nitrogen catabolism and this protein imbalance is not corrected until late in convalescence (Blocker and his associates, 1954, 1955, 1962). Fatty metamorphosis and hepatic necrosis occur in cases of deep burns.

PHARMACOLOGY AND COMPOSITION

Liv.52 (Himalaya) is a herbal preparation found to have anabolic aperient and diuretic effects with protective and regenerative action of the liver. Each tablet of Liv.52 contains:

<i>Capparis spinosa</i>	65 mg
<i>Cichorium intybus</i>	65 mg
<i>Solanum nigrum</i>	32 mg
<i>Cassia occidentalis</i>	16 mg
<i>Terminalia arjuna</i>	32 mg
<i>Achillea millefolium</i>	16 mg
<i>Tamarix gallica</i>	16 mg
Mandur bhasma	35 mg

Processed in *Eclipta alba*, *Phyllanthus niruri*, *Boerhaavia diffusa*, *Tinospora cordifolia*, *Berberis aristata*, *Raphanus sativus*, *Phyllanthus emblica*, *Plumbago zeylanica*, *Embelia ribes*, *Terminalia chebula*, *Fumaria officinalis*.

MATERIAL AND METHODS

For the study of the effect of Liv.52 in burns, 40 cases admitted to the Burns Centre, Victoria Hospital, for the period April 1979 to July 1980, were randomised into two groups of 20 each. They were designated as Liv.52 group and Control Group. They ranged in age between 10 and 60 years, with burns from 15% to 35%.

A pro forma was designed for the purpose of the study. This included a detailed case history, physical examination, routine investigations like haemoglobin percentage, urine analysis, erythrocyte sedimentation rate, bleeding time, clotting time, blood urea, serum bilirubin, total proteins, serum alkaline phosphatase, thymol turbidity, albumin/globulin ratio, serum electrolytes as sodium, potassium and chlorides.

The trial cases were treated with Liv.52, 2 tablets four times a day for 4 months in addition to the usual treatment for burns.

The control cases received only specific therapy.

Blood samples were drawn once a week for the first month, once a fortnight in the second month; once a month for the third and fourth months from the time of admission. These were drawn to study the level of blood urea, liver function tests and serum electrolytes. Urine examination for albumin, sugar, microscopy and blood examination for haemoglobin percentage, E.S.R., bleeding and clotting time were assessed once a week. Weight was also recorded every week.

The age and sex distribution are shown in Table I. In the Liv.52 group there were 8 males and 12 females and in the control group there were 7 males and 13 females. Females preponderated in both the groups.

Age in years	Liv.52 group	Control group
Males	8	7
Females	12	13
10 – 20	8	6
21 – 30	7	13
31 – 40	2	1
41 – 50	1	–
51 – 60	2	–

The type of burns randomised to the Liv.52 and Control groups are detailed in Table II.

Cause	Liv.52 group	Control group
Open fire	4	12
Stove with wick	9	3
Water	2	1
Oil	1	1
Explosion	–	2
Flash	–	1
Acid	2	–
Kerosene lamp	2	–
	20	20

In the Liv.52 group there were six cases of 2nd degree of burns and fourteen of second degree and 3rd degree burns. In the control group there were 5 cases of 2nd degree and 15 of second and third degree burns. Percentage of the surface of burns varied from 15% to 35% (Table III).

Percentage of burns	Liv.52 group	Control group
15 – 19%	6	7
20 – 24%	6	5
25 – 29%	6	5
30 – 35%	2	3

Fourteen out of 20 cases (70%) had a hospital stay of less than 50 days in Liv.52 group as against only 6 out of 20 cases (30%) in the control group. Duration of stay in the hospital is shown in Table IV.

No. of days	Liv.52 group	Control group
20 – 30	5	2
31 – 40	6	3
41 – 50	3	1
51 – 60	3	10
61 – 70	–	2
71 – 80	2	2
81 – 90	–	–
91 – 100	1	–
	20	20

The biochemical and laboratory studies in detail were made as mentioned earlier. It would be difficult to express the changes in each and every parameter in progress such as initial, once a week in the first one month, twice a month in the second month and once a month in the third and fourth month i.e., 8 samples for each test were studied. Table V shows the initial, average value of eight (8) samples for each test and the final value thereof in the Liv.52 and Control groups.

Sl. No.	Parameters Tests	Liv.52 group			Control group		
		Range			Range		
		Initial	Average in 8 samples	Final	Initial	Average in 8 samples	Final
1.	Total serum proteins g%	4.4/7.2	6.3/7.9	6.6/7.6	6.2/7.2	6.6/7.5	6.6/7.2
2.	Albumin/globulin ratio	2.2/2.2 to 3.8/3.6	3.4/2.9 to 4.7/3.2	3.6/3.0 to 4.6/3.0	3.6/2.6 to 3.5/3.4	3.2/3.4 to 3.9/3.6	3.0/3.6 to 3.8/3.4
3.	Serum alkaline phosphatase in units	12/25	11.1/17.4	5/15	10/16	12/15	10/18
4.	Thymol turbidity test in K.A. units	4/15	4.3/11.1	1/10	4/8	5/7	3/8
5.	Serum bilirubin mg%	0.5/2.8	0.3/1	0.1/1	0.2/0.8	0.3/0.8	0.2/0.6
6.	Blood Urea in mg%	20/90	20.4/42	9/26	30/80	27/53	20/55
7.	Blood sodium in Meq/l	110/160	108/146	130/145	130/145	135/142	132/142
8.	Blood potassium in Meq/l	2.2/4.9	3.4/4.2	3.2/5	3.1/4.6	3.1/4.5	3/4.1
9.	Blood chloride in Meq/l	104/130	103/121	95/115	102/108	103/106	101/106
10.	Haemoglobin in g%	6.6/14	7.8/13.2	9/14	9/12.5	9.5/13	10.5/13
11.	Body weight in Kg.	30/65	–	35/68	31/53	–	33/54
12.	% Weight gain			Many up to 20% maximum			Few up to 15.5% maximum

The Table clearly shows that the return to normal was much earlier in the Liv.52 group. This could be easily seen on perusal of details of the progress of each of the findings from week to week and

month to month up to four months. Here only the average of the findings of 8 samples in each biochemical test is presented. The comparison clearly speaks for the significantly good results in the Liv.52 group.

The results were assessed from two points of view: one as saving as life and the other being the evidences of standard biochemical and clinical assessment. All the patients who lived but had some resulting scars, contracture or residual deformities proportional to the various degrees and types of burns, the main causative condition for admission for treatment at the hospital, were deemed as cured. The results in respect of all these were classified as “excellent”, “satisfactory” and “poor” based on the following criteria:

- (a) Improvement in serum electrolytes,
- (b) Total blood proteins,
- (c) Albumin/globulin ratio,
- (d) Improvement in liver function tests,
- (e) Level of blood urea,
- (f) Serum bilirubin,
- (g) Haemoglobin percentage,
- (h) Improvement of appetite, and
- (i) Gain in weight.

Judged by a balanced assessment of these nine criteria along with the results of clinical and general examination, the results were labelled as excellent, satisfactory or poor. Albumin, globulin ratio was reversed in all the cases of Liv.52 and Control groups. There was a remarkable improvement in protein metabolism with normal albumin globulin ratio in cases treated with Liv.52 whereas the control group showed insignificant changes. The total serum proteins improved considerably with positive nitrogen balance in Liv.52 cases compared with the Control group. The other biochemical tests have shown that the liver functions have improved considerably with Liv.52 when compared to the Control group. The results are shown in Table VI.

	Liv.52 group	Control group
Excellent	7	–
Satisfactory	9	5
Poor	4	15

The results were excellent in 7 cases in Liv.52 group and none in the Control group, satisfactory in 9 cases in Liv.52 group and 5 in Control group and poor in 4 cases of Liv.52 group and 15 in Control group.

There were no toxic or untoward effects in any of the patients kept on prolonged Liv.52 therapy.

SUMMARY

- (1) A controlled study of Liv.52 was made in 40 cases of burns varying in age from 10 to 60 years and in percentage from 15 to 35 was made, noting the degree of burns.
- (2) Serial biochemical studies of liver function tests, blood electrolytes, haemoglobin % and gain in weight were made weekly for the first month, fortnightly for the second month and monthly in the third and fourth months – in all, eight times for each chemical or biochemical or other tests. The progress was regularly recorded and the results of initial, average of eight observations and final results were noted and charted.

- (3) The duration of hospital stay was much shorter in 14 out of 20 cases (70%) in Liv.52 group as against 6 out of 20 (30%) in Controls.
- (4) Criteria for the results as excellent, satisfactory or poor or defined in accordance with the grade of improvement in 9 parameters.
- (5) The result was excellent in 7 cases in Liv.52 group, nil in the Control group; satisfactory in 9 cases in Liv.52 group and five in Control group; poor in 4 cases in Liv.52 group and fifteen cases in the Control group.
- (6) There were no toxic or untoward effects on prolonged Liv.52 therapy.

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