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**COMPARATIVE CLINICAL STUDIES OF *ECLIPTA PROSTRATA*
WITH MARKETED POLYHERBAL FORMULATION LIVER CARE
CHURNA FOR LIVER DISEASE**

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ABSTRACT

Comparative study of indigenous plant *Eclipta prostrata* and marketed Polyherbal formulation Liver care Churna were selected for clinical investigation of hepatoprotective activity. Clinical study of patients were suffering from liver disease jaundice, they were selected. The antihepatotoxic activity of the herb *Eclipta prostrata* and marketed polyherbal formulation studied on human. Marketed Polyherbal formulation was made by preparing mixture of powder of different plants of herb which were known to be rich source of hepatoprotective activity. The ability of whole plant dried drug powder of *Eclipta prostrata* (traditionally used in treatment of jaundice) and marketed formulation were tested for hepatoprotective activity on 191 patients who were suffering from liver disease. Among them 93 patients for Liver care Churna and 98 patients for *Eclipta prostrata* were tested. The powder Liver care Churna and *Eclipta prostrata* was given thrice a day (morning, noon and night, 3gm each time) orally with water for 30-45 days depending on the severity of the disease. The comparative clinical studies was done by selection and screening of patient of different age by administering the drug *Eclipta prostrata* and Liver care Churna. The clinical parameters were evaluated like SGPT, Bilirubin and HB. The whole plant of drug *Eclipta prostrata* and the marketed polyherbal formulation Liver care Churna both produced remarkable reduces in SGPT, Bilirubin while increase in HB.

Key words: Antihepatotoxic activity, *Eclipta prostrata*, Liver care Churna, Clinical study

INTRODUCTION

Liver plays a vital role in the metabolism and elimination of various exogenous and endogenous compounds. As a result of its continuous involvement, it is susceptible to

toxic injuries caused by certain agents and any damage to hepatic cells disturb body metabolism. In recent times lot of interest has been generated to find out a natural remedy for hepatic disorders caused by toxins like alcohol and hepatitis virus^[1]. The agent should protect against such damage, especially of one which facilitates regeneration by proliferation of parenchymal cells after damage and arrest growth of fibrous tissue^[2]. There is not remedy for liver diseases which are so prevalent in the population. The treatment is mainly symptomatic^[2].

The powder of whole plant *Eclipta prostrata* use as hepatoprotective^[3], it improves in hair growth^[4], hepatic tonic^[5], hepatitis^[6], anti diabetes^[7], Antiasthmatic^[8], anti cancer^[9].

Polyherbal formulation name as a Liver care Churna containing *Eclipta prostrata*, *Embelia officinalis*, *Terminalia chebula*, *Phyllanthus amarus*, *Boerhaavia diffusa*, *Andrographis paniculata*, *Terminalia bellerica* and *Picrorrhiza kurroa* were made by preparing mixture of different parts of herb which were known to be rich sources of hepatoprotective activity^[10-11]. Clinical trials of marketed Polyherbal formulation shows Antihepatotoxic activity^[12-13].

MATERIAL AND METHOD:

The plant of *Eclipta prostrata* was collected in the month of August 2006 from fields of a village Dugarwada in Modasa Taluka in Sabarkatha (S.K.) District (Gujarat) where it is growing wild. The herb was authenticated by Dr. H.B. Singh, Scientist F & Head, Raw Materials Herbarium & Museum, Council of Scientific and Industrial Research (CSIR), NISCAIR, New Delhi. (Date: 04-08-08, Ref. 1031/62). Marketed formulation Liver care Churna was collected from Rajsha Pharmaceuticals, Ahmedabad, Gujarat.

The ability of whole dried drug Liver care Churna and *Eclipta prostrata* were tested at Sapan Hospital, Bayad, Dist-S.K., Gujarat, for hepatoprotective activity on 191 patients who were suffering from liver disease, their distribution of patients with age and sex shown in Table no.1 & 2. The powder Liver care Churna and *Eclipta prostrata* were given thrice a day (morning, noon and night, 3 gm each time) orally with glucose to the liver damage patients for one, two, three, four and six weeks and treatment was continued until recovered. Comparative pathological parameter like SGPT, Bilirubin and

Haemoglobin were monitored during the treatment. SGPT levels expressed in U/ml, Bilirubin expressed in mg% and Haemoglobin expressed in gm%.

Material and reagents are used in clinical investigations were collected from Span Diagnostic Ltd, Shivam Surgical Ahmedabad. Estimation of SGPT, Bilirubin and HB, parameter was evaluated.

Table 1: Distribution of patients with Age and Sex for *Eclipta prostrata*.

<i>ECLIPTA PROSTRATA</i>			
Age	Patients(98)	M/F	Patients
0-15	12	M	8
		F	4
16-30	28	M	18
		F	10
31-45	31	M	15
		F	16
46-60	23	M	18
		F	5
61-ABOVE	4	M	4
		F	0

Table 2: Distribution of patients with Age and Sex for Liver care Churna.

LIVER CARE CHURNA			
Age	Patients(93)	M/F	Patients
0-15	2	M	1
		F	1
16-30	23	M	15
		F	8
31-45	37	M	22
		F	15
46-60	30	M	21
		F	9
61-ABOVE	1	M	0
		F	1

ESTIMATION OF SGPT^[14-15]

Reagent 1: Buffered alanine α -KG substrate.

Reagent 2: DNPH color reagent.

Reagent 3: sodium hydroxide, 4N.

Reagent 4: Working pyruvate standard, 2mM.

Solution 1: One ml of Reagent No.3 was diluted to 10 ml with distilled water. Reagent 1, 2 & 4 are ready for use as such.

Reagent 1 (Buffered alanine α -KG substrate) 0.5 ml taken in test tube. It was incubated for 37°C for 5 min. fasted serum 0.1 ml was added to the test tube. It was mixed well and incubated for 37°C for 30 min. Reagent 2: DNPH color reagent 0.5 ml was added to the above test tube. It was allow to stand at room temperature for 20 min. Solution 1, 5 ml was added to the solution of the test tube. It was mixed well and allow to stand for 10 min. the absorbance of the solution was measured 505 nm using water as blank.

Estimation of Bilirubin^[16]

The estimation of total and direct Bilirubin is of importance for diagnosis, differentiation and follows up of jaundice. The serum levels of unconjugated Bilirubin rises in the cases of hemolytic jaundice. Whereas conjugated serum Bilirubin levels rises in the cases of obstructive jaundice. Hepatic jaundice is characterized by simultaneous rise in both, conjugated and unconjugated serum Bilirubin levels.

Reagent A: Total Bilirubin reagent.

Reagent B: Direct Bilirubin reagent.

Reagent C: Sodium nitrite reagent.

Reagent D: Artificial standard C = 10mg% Bilirubin.

All reagents in the kit are ready to use as such.

For total Bilirubin estimation 3 ml of reagent A and 0.1 ml of reagent C were mixed by inversion and waited for 30 seconds. Fasted serum 0.15 ml was added. The content was mixed well and incubated for 37°C for 5 min. absorbance was read at 540 nm using water as blank.

For direct Bilirubin estimation 3 ml of reagent B and 0.1 ml of reagent C were mixed by inversion and waited for 30 seconds. Fasted serum 0.15 ml was added. The content was mixed well and incubated for 37°C for 5 min. absorbance was read at 540 nm using water as blank.

The absorbance of the reagent 4 (artificial standard) was read directly against distilled water. The standard once used was discarded. Serum Bilirubin in mg%

$$\text{Total Billirubin(A)} = \frac{\text{Absorbance of T} - \text{Absorbance of TB}}{\text{Absorbance of Standered}} * 10$$

$$\text{Direct Billirubin (B)} = \frac{\text{Absorbance of D} - \text{Absorbance of DB}}{\text{Absorbance of Standered}} * 10$$

Where T= Total Bilirubin, TB= Total Bilirubin blank, D= Direct Bilirubin, DB= Direct Bilirubin blank.

Determination of Haemoglobin.^[17]

The graduated diluting tube and the micropipette are cleaned thoroughly and dried. The graduated diluting tube is filled with N/10 HCl up to the mark 2 gm or till the micropipette touches the level of acid in the tube. The finger is cleaned with 70% alcohol and it is pricked to obtain a drop of blood. First drop is wiped out. Second drop is sucked in the micropipette up to the mark 20cmm. The blood is immediately deposited at the bottom of the graduated tube. The pipette is rinsed two to three times in HCl. The blood is mixed with the help of stirrer and then solution is allowed to stand for 10-15 minutes so that all Haemoglobin is converted into acid haematin. Then mixture is diluted with distilled water. Distilled water is added drop by drop and every time it is stirred till the exact match with standard glass tubes is obtain and the scale is read on the side of tube.

Statistical analysis

Result of biochemical estimation SGPT, Bilirubin and Haemoglobin were reported by Mean, S.D, SEM and Median. For determination of significant P value inter group difference of each parameter was analyzed separately. One way analysis of variance P value was carried out by Graph Pad statistics software.

RESULTS AND DISCUSSION

The mean values of SGPT for *Eclipta prostrata* initially 987.77, first 654.63, second week 378.69, third week 222.48, fourth week 152.82 and sixth week 62.30 respectively. The P value is < 0.0001, which is considered as highly significant shown in Table 3. The mean values of SGPT for Liver care Churna initially 1092.344, first week 651.0753, second week 446.28, third week 334.8936, fourth week 194.5161 and sixth

week 68 respectively. The P value is < 0.0001 , which is considered as highly significant shown in Table 4. Comparative study of SGPT of *Eclipta prostrata* and Liver care Churna is shown in figure 1.

Table No 3: P value of SGPT for *Eclipta prostrata*

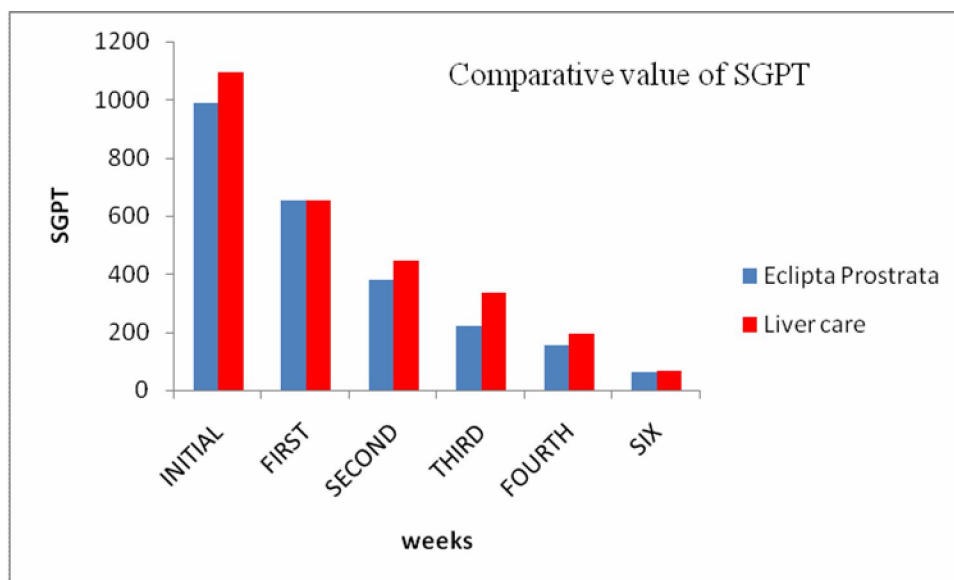
Duration in week	Mean	Standard Deviation	Standard Error of Mean	Median
Initial	947.83	869.90	84.894	621.00
First	635.27	648.86	64.247	390.00
Second	368.88	367.28	38.715	235.00
Third	220.04	227.91	28.489	110.00
Fourth	152.82	145.98	24.675	75.000
Sixth	62.308	16.596	4.436	63.654

The P value is < 0.0001 , considered extremely significant.

Table 4: P value of SGPT for Liver care Churna

Duration in week	Mean	Standard Deviation	Standard Error of Mean	Median
Initial	1092.3	933.22	96.254	750.00
First	651.08	658.63	67.932	420.00
Second	446.28	463.63	53.182	310.00
Third	334.89	309.64	44.692	210.00
Fourth	194.52	192.65	34.056	90.00
Sixth	68.000	22.935	6.915	75.00

The P value is < 0.0001 , considered extremely significant.

**Figure 1**

Comparative study of SGPT v/s week. Column graph showing value of SGPT for different week using *Eclipta prostrata* and Liver care Churna.

The mean value of Bilirubin for *Eclipta prostrata* initially 6.336, first week 4.40, second week 3.009, third week 2.174, fourth week 1.678 and sixth week 1.107 respectively. The P value is < 0.0001 , which is considered as highly significant shown in Table 5. The mean value of Bilirubin for Liver care Churna initially 5.8516, for first week 3.648, second week 2.737, third week 2.1659, fourth week 1.4516 and sixth week 0.94 respectively. The P value is < 0.0001 , which is considered as highly significant shown in Table 6. Comparative study of Bilirubin of *Eclipta prostrata* and Liver care Churna is shown in figure 2.

Table 5: P value of Bilirubin for *Eclipta prostrata*

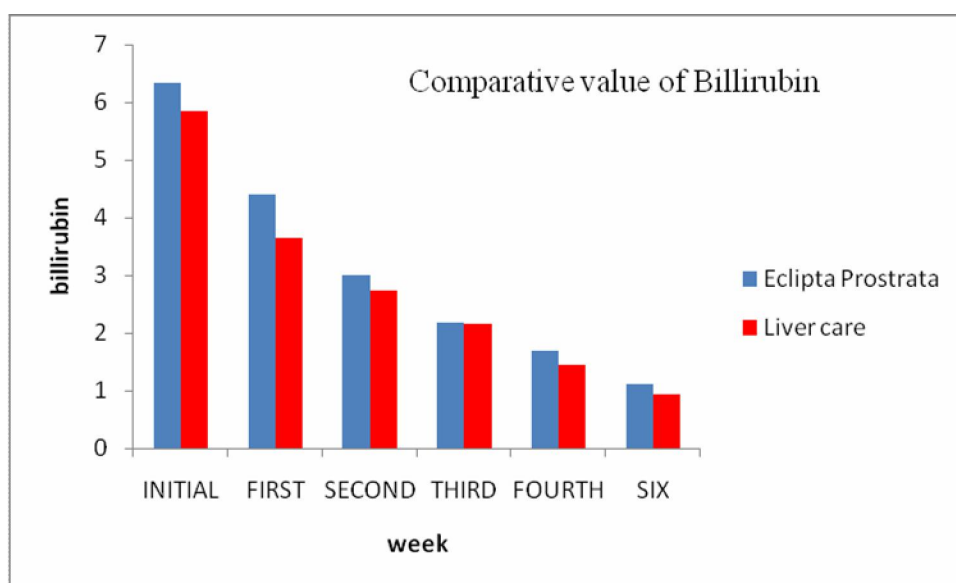
Duration in week	Mean	Standard Deviation	Standard Error of Mean	Median
Initial	5.595	3.782	0.3745	4.9
First	3.538	2.917	0.2917	2.8
Second	2.667	2.112	0.2326	2.05
Third	2.158	1.354	0.1934	2.1
Fourth	1.443	0.8531	0.1485	1.1
Sixth	0.940	0.1020	0.03075	0.9

The P value is < 0.0001 , considered extremely significant.

Table 6: P value of Bilirubin for Liver care Churna

Duration in week	Mean	Standard Deviation	Standard Error of Mean	Median
Initial	5.602	3.758	0.3614	4.85
First	3.698	2.996	0.2938	2.9
Second	2.672	2.105	0.2297	2.0
Third	2.122	1.347	0.1869	2.05
Fourth	1.427	0.8450	0.1449	1.075
Sixth	0.9400	0.1020	0.03075	0.9

The P value is < 0.0001, considered extremely significant.

**Figure 2**

Comparative study of Bilirubin v/s week. Column graph showing value of Bilirubin for different week using *Eclipta prostrata* and Liver care Churna.

The mean Haemoglobin for *Eclipta prostrata* for zero day was considered. As comparison with zero week, Haemoglobin level increase on first, second and third week, on fourth and sixth week haemoglobin level decreases slightly but in comparison with zero week it is increased. The P value is insignificant for haemoglobin shown in Table 7. The mean Haemoglobin for Liver care Churna for zero day was considered. As comparison with zero week, Haemoglobin level increase on first and second, on third week, fourth and sixth week haemoglobin level decreases slightly but in comparison with zero week it is increased. The P value is insignificant for haemoglobin shown in Table 8.

Comparative study of Haemoglobin of *Eclipta prostrata* and Liver care Churna is shown in figure 3.

Table 7: P value of HB for *Eclipta prostrata*

Duration in week	Mean	Standard Deviation	Standard Error of Mean	Median
Initial	10.760	1.755	0.1764	10.900
First	10.901	1.729	0.1737	11.000
Second	11.043	1.763	0.1890	11.100
Third	11.207	1.777	0.2239	11.300
Fourth	10.976	1.620	0.2739	10.976
Sixth	11.131	1.561	0.4173	11.215

The P value is 0.6946, considered not significant.

Table 8: P value of HB for Liver care Churna

Duration in week	Mean	Standard Deviation	Standard Error of Mean	Median
Initial	10.444	1.395	0.1402	10.4
First	10.667	1.368	0.1389	10.709
Second	10.717	1.413	0.1599	10.719
Third	10.510	1.381	0.1972	10.5
Fourth	10.646	1.299	0.2296	10.615
Sixth	10.260	1.107	0.3339	9.9

The P value is 0.7110, considered not significant.

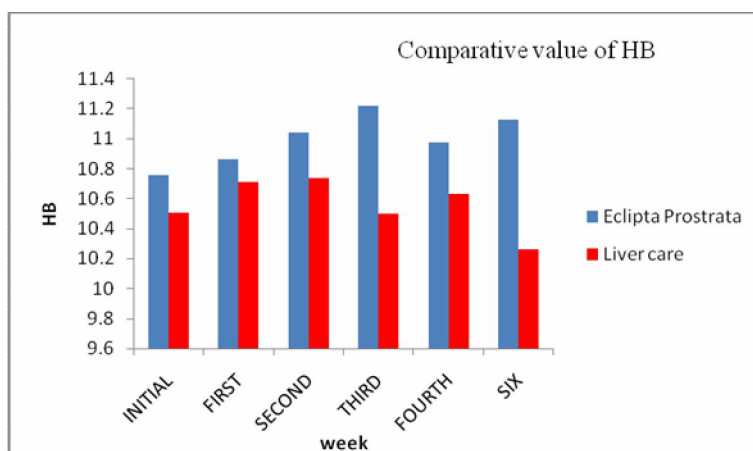


Figure 3

Comparative study of Haemoglobin v/s week. Column graph showing value of haemoglobin for different week using *Eclipta prostrata* and Liver care Churna.

CONCLUSION

Treatment with Polyherbal formulation Liver care Churna and *Eclipta prostrata* both produces improvement in SGPT, Bilirubin, and Hemoglobin profiles in liver damage patients. The powder of *Liver care Churna* showed potent antihepatoprotective activity and recover immediately SGPT as compared to *Eclipta prostrata*. The Liver care Churna could become helpful for liver damage possibly by reducing SGPT, Bilirubin and HB and improvement in life style of such patients.

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