



ISSN No. : XXXX-XXXX
Volume : 01
Issue : 02
DOI : 10.5281/zenodo.10451114



Publisher
**ROGANIDAN VIKRUTIVIGYAN PG ASSOCIATION
FOR PATHOLOGY AND RADIOIGNOSIS**
Reg. No. : MAHA-703/16(NAG) Year of Establishment – 2016

INTERNATIONAL JOURNAL OF DIAGNOSTICS AND RESEARCH

Evaluation of Herbo - mineral compound 'Sidoliv' in the treatment of Cirrhosis of Liver w.s.r. to Disease 'Kumbhakamala' in Ayurveda

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Article Info: Published on : 02 /01/2024

Cite this article as : - Dr. Subhash Waghe (2024) ;Evaluation of Herbo - mineral compound 'Sidoliv' in the treatment of Cirrhosis of Liver w.s.r. to Disease 'Kumbhakamala' in Ayurveda ; Inter.J.Dignostics and Research 1(2) 1-6, <https://doi.org/10.5281/zenodo.10451114>

Abstract

Cirrhosis is a chronic liver disease in which there is necrosis of liver cells followed by fibrosis and nodule formation causing gross derangement of the liver architecture. It is a leading cause of death due to complications associated with it like variceal bleeding, encephalopathy and ascites. The major causes of cirrhosis of liver includes chronic viral infections with hepatitis B or C virus, Chronic alcoholic liver disease, non-alcoholic fatty liver disease. It was associated with 2.4% of the global deaths in 2019 [1]. In Ayurveda syndrome of Cirrhosis of liver can be correlated to the disease *Kumbhakamala*. As per *Acharya* Charaka, the disease *Kumbhakamala* is a complication of diseases *Kamala* (hepatocellular jaundice) [3]. The disease *Kamala* on chronicity or if left untreated advances to the complicated stage called *Kumbhakamala* characterized by hematemesis, malena, ascites, edema, anorexia, anemia, jaundice, drowsiness and coma. While, preparing the diagnostic criteria, the features mentioned in both Ayurvedic as well as modern science were considered. Drugs like Guduchi, Daruharidra, Bhumyamalki, Ashwagandha Punarnawa, Katuki, and Arjuna have hepatoprotective activities. Katuki act as cholagogue. Guduchi, Daruharidra and Bhumyamalki, acts as antiviral. Ashwagandha and Arjuna acts as hepatoprotective. Punanava acts as diuretic and anti-inflammatory. Considering their pharmacological profile, they were selected for making the unified herbo-mineral compound Sidoliv. Patients having history of prolonged intake of alcohol or chronic infection with HBV or HCV having features of Cirrhosis of liver supported with pathological and sonological findings were selected for the study from OPD and IPD sections of Pakwasa Samnvaya Rugnalaya and all India Ayurveda Research Institute, Hanuman-nagar Nagpur. Two capsules were given with plain water twice a day for 45 days. The capsules were provided by Shree Baidynath Bhavan, Nagpur. Three follow ups were taken at the interval of 15 days. Investigations were done before and after the trial. Non parametric tests like Npar test and Wilcoxon Signed Rank tests were applied to assess the result in clinical features where severity of these features was graded in the score between 0 to 3 and where such severity gradation was not possible, McNemar test was applied for assessment of the response to the drug therapy. It is observed and concluded that the present randomized clinical trial does not show any significant improvement with regard to clinical features or pathological parameters.

Keywords: *Kumbhakamala*, Cirrhosis

Review Of Literature:

Cirrhosis is a chronic condition of liver disease in which there is necrosis of liver tissue followed by fibrosis and nodule formation [2]. In Ayurveda syndrome of Cirrhosis of liver can be correlated to the disease *Kumbhakamala*. As per *Acharya* Charaka, the disease *Kumbhakamala* is a complication of

disease *Kamala* (hepatocellular jaundice) [3]. The disease *Kamala* on chronicity or if left untreated advances to the complicated stage called *Kumbhakamala* characterized by hematemesis, malena, ascites, oedema, anorexia, anemia, jaundice, drowsiness and coma. The development of features like hematemesis, melena, ascites, and splenomegaly indicates portal hypertension. The development of

features like drowsiness and coma indicated encephalopathy. The development of dyspnea may occur due to hepato pulmonary syndrome. Drugs like Guduchi (*tinospora cardifolia*), Daruharidra (*Barberis aristata*), Bhumyamalki (*Phyllanthus amarus*), Ashwagandha (*Withania somnifera*) Punarnawa (*Boerhavia diffusa*), Katuki (*Picrorhiza kuroa*), Arjun (*Termanalia arjuna*) have hepatoprotective activities. Drugs like Katuki act as cholagogue. Guduchi, Daruharidra, Bhumyamalki, acts as antiviral. Ashwagandha and Arjuna acts as hepatoprotective. Punanava acts as diuretic and anti-inflammatory. Considering their pharmacological profile, they were selected for making the unified herbo-mineral compound Sidoliv.

Material & Method:

Selection of Patients & Place of Study

Patients having clinical features of Cirrhosis of liver supported with laboratory findings were selected without any prejudice from OPD and IPD sections of Pakwasa Samnvaya Rugnalaya and all India Ayurveda Research Institute, Hanuman-nagar, Nagpur.

Diagnostic and Selection criteria

Patients having history of prolonged intake of alcohol or chronic infection with HBV or HCV having features of Cirrhosis of liver supported with pathological and sonological findings were selected for the study.

Clinical Trial

A randomized clinical trial of herbo-mineral compound (Sidoliv capsule) comprising of extracts of Guduchi, Daruharidra, Bhumyamalki, Ashwagandha Punarnawa, Katuki, Arjun and powder of Shwetparpati was administered to 10 diagnosed patients of Cirrhosis of liver in the capsule form. Two capsules were given with plain water twice a day for 45 days. The capsules were provided by Shree Baidynath Bhavan, Nagpur. Three follow ups were taken at the interval of 15 days. Investigations were done before and after the trial. Response to therapy was assessed with respect to clinical features and pathological findings.

Statistical Evaluation:

Non parametric tests like Npar test and Wilcoxon Signed Rank tests were applied to assess the result in clinical features where severity of these features was graded in the score between 0 to 3 and where such severity gradation was not possible, McNemar test was applied for assessment of the response to the drug therapy

Observations:

Table No. 1 [n = 10] (Npar Test)

Sr.	Clinical Feature	Mean BT	Mean AT	SD - BT	SD - AT
1	Aruchi	1.6000	0.8000	0.9661	1.0328
2	Avipaka	1.4000	0.9000	0.9661	0.9944
3	Nashtagni	1.5000	0.8000	0.9718	1.0328
4	Anaha	2.1000	1.3000	0.5676	0.6749
5	Udaradhman	2.2000	1.3000	0.4216	0.8233
6	Daurbalya	2.2000	2.1000	0.7888	0.7379
7	Sadanam	2.2000	2.0000	0.7888	0.8165
8	Hatendriyata	1.9000	1.6000	1.1005	1.2649
9	Karshan	2.2000	2.1000	1.0328	1.1972
10	Daha	0.1000	0.0000	0.3162	0.0000
11	Trishna	0.1000	0.1000	0.3162	0.3162
12	Haridra Netrata	0.2000	0.0000	0.4216	0.0000
13	Jwara	0.2000	0.0000	0.4216	0.0000
14	Tamyata	0.5000	0.1000	0.7071	0.3162
15	Yakrit Vriddhi	0.3000	0.2000	0.4830	0.4216
16	Pleeha Vriddhi	0.6000	0.5000	1.0750	0.8498
17	Jalodara	2.4000	0.5000	0.6992	0.8498
18	Shoona	1.8000	1.0000	0.7888	0.8165
19	Sarakta Chhardi	0.0000	0.2000	0.0000	0.6325

Table No. 2 [n = 10] (Wilcoxon Signed Rank Test)

Sr.	Clinical Feature	Z	Two tailed
1	Aruchi	- 2.271a	0.023
2	Avipaka	- 1.890a	0.059
3	Nashtagni	- 2.333a	0.020
4	Anaha	- 2. 530a	0.011
5	Udaradhman	- 2.460a	0.014
6	Daarbalya	- 1.000a	0.317
7	Sadanam	- 1.414a	0.157
8	Hatendriyata	- 1.3421	0.180
9	Karshan	- 1.000a	0.317
10	Daha	- 1.000a	0.317
11	Trishna	- 0.000b	1.000
12	Haridra Netrata	- 1.414a	0.157
13	Jwara	- 1.414a	0.157
14	Tamyata	- 2.000a	0.046
15	Yakrit Vriddhi	- 1.000a	0.317
16	Pleeha Vriddhi	- 0.577a	0.564
17	Jalodara	- 2.714a	0.007
18	Shoona	- 2.530a	0.011
19	Sarakta Chhardi	- 1.000c	0.317

Descriptive Statistics :

Features where gradation of severity was not possible, were arranged by using Npar test and its result after treatment was assessed by applying McNemar test.

Table No. 3 [n = 10]

Sr.	Clinical Feature	Mean BT	Mean AT	SD (BT)	SD (AT)
1	Gynaeco-mastia	0.4000	0.4000	0.5164	0.5164
2	Testicular Atrophy	0.1000	0.9000	0.3162	0.3162
3	Dupytren's contracture	0.2000	0.2000	0.4216	0.4216
4	Loss of libido	0.8000	0.8000	0.4216	0.4216
5	Dilated veins on abdomen	0.6000	0.3000	0.5164	0.4830

Test Statistics (McNemar Test) :**Table No. 4 [n = 10]**

Sr.	Clinical Feature	Exact Sig. (2-tailed)
1	Gynaeco-mastia	0.250a
2	Testicular Atrophy	1.000a
3	Dupytren's contracture	1.000a
4	Loss of libido	1.000a
5	Dilated veins on abdomen	1.000a

Table No. 5 – Clinical Features outcome

Sr.	Clinical Feature	Cured	Improved	Unchanged
1	Aruchi	-	10	-
2	Avipaka	-	-	10
3	Nashtagni	-	10	-
4	Anaha	-	10	-
5	Udaradhman	-	10	-
6	Daarbalya	-	-	10
7	Sadanam	-	-	10
8	Hatendriyata	-	-	10
9	Karshan	-	-	10
10	Daha	-	-	10
11	Trishna	-	-	10
12	Haridra Netrata	-	-	10
13	Jwara	-	-	10
14	Tamyata	-	10	-
15	Yakrit Vriddhi	-	-	10
16	Pleeha Vriddhi	-	-	10
17	Jalodara	-	10	-
18	Shoona	-	10	-
19	Sarakta Chhardi	-	-	10
20	Gynaeco-mastia	-	-	10
21	Testicular Atrophy	-	-	10
22	Dupytren's contracture	-	-	10
23	Loss of libido	-	-	10
24	Dilated veins on abdomen	-	-	10

Paired T test was used to assess the response to the drug therapy with respect to the pathological investigations.

Table no. 6 [n = 10] - pathological investigations (Paired t test)

Sr.	Clinical Feature	Mean (BT)	Mean (AT)	SD (BT)	SD (AT)	SE (BT)	SE (AT)
1	Sr. Bilirubin (T)	1.7400	1.7200	0.5232	0.4392	0.1655	0.1389
2	Sr. Bilirubin (D)	1.0100	0.9800	0.4067	0.1874	0.1286	5.925
3	Sr. Bilirubin (I)	0.7300	0.7400	0.5908	0.5562	0.1868	0.1759
4	Sr. AST	67.4000	56.7000	44.2925	36.9115	14.0065	11.6724
5	Sr. ALT	45.9000	50.3000	26.7226	33.4466	8.4504	10.5768
6	Sr. Albumin	2.7300	2.9200	0.3773	0.3853	0.1193	0.1218
7	Sr. Prothrombin Time Index	73.9150	76.9140	11.7242	6.0614	3.7075	1.9168
8	Sr. Prothrombin Difference (P-C)	4.7400	4.0200	2.4829	1.5583	0.7852	0.4928
9	Sr. Sodium	139.7000	126.8000	8.1928	30.4624	2.5908	9.6330
10	Hemoglobin	10.3200	10.2800	1.3161	0.6052	0.3593	0.1914

Table no. 7 - Paired Sample Test

Pair BT - AT	Mean	SD	SE	95% Confidence Interval of the difference		Probability
				Lower	Upper	
Sr. Bilirubin (T)	2.000E-02	0.3155	9.978E-02	-0.2057	0.2457	0.200
Sr. Bilirubin (D)	3.000E-02	0.3335	0.1055	-0.2086	0.2686	0.284
Sr. Bilirubin (I)	-1.00E-02	0.1197	3.7886E-02	-9.56E-02	7.564E-02	-0.264
Sr. AST	10.7000	32.8906	10.4009	-12.8285	34.2285	1.029
Sr. ALT	-4.4000	22.2671	7.0415	-20.3289	11.5289	-0.625
Sr. Albumin	-0.1900	0.4358	0.1378	-0.5017	20.3289	-0.625
Sr. Prothrombin Time Index	-2.9990	14.5370	4.5970	-13.3982	7.4002	-0.652
Sr. Prothrombin Difference (P-C)	0.7200	3.2964	1.0424	-1.6381	3.0781	0.691
Sr. Sodium	12.9000	28.0533	8.8712	-7.1681	32.9681	1.454
Hemoglobin	4.000E-02	0.6022	0.1904	-0.3908	0.4708	0.210

Table No. 8 - Paired Sample Test Data Analysis

Sr.	Pair (BT -AT)	Df	Sig. (2 tailed)
1	Sr. Bilirubin (T)	9	0.846
2	Sr. Bilirubin (D)	9	0.782
3	Sr. Bilirubin (I)	9	0.798
4	Sr. AST	9	0.330
5	Sr. ALT	9	0.548
6	Sr. Albumin	9	0.201
7	Sr. Prothrombin Time Index	9	0.530
8	Sr. Prothrombin Difference (P-C)	9	0.507
9	Sr. Sodium	9	0.180
10	Hemoglobin	9	0.838

Table No. 9 - Pathological Results of Clinical Trial

Sr.	Clinical Feature	Cured	Improved	Unchanged
1	Sr. Bilirubin (T)	--	--	10
2	Sr. Bilirubin (D)	--	--	10
3	Sr. Bilirubin (I)	--	--	10
4	Sr. AST	--	--	10
5	Sr. ALT	--	--	10
6	Sr. Albumin	--	--	10
7	Sr. Prothrombin Time Index	--	--	10
8	Sr. Prothrombin Difference (P-C)	--	--	10
9	Sr. Sodium	--	--	10
10	Hemoglobin	--	--	10

Since the value of the signed (2 tailed) test is not having the probability < 0.05 , it is concluded that pathologically no significant response was observed after treatment with the trial drug in any of the pathological investigation.

Discussion:

The clinical trial of herbo-mineral compound (Sidoliv) comprising of extracts of Guduchi, Daruharidra, Bhumyamalki, Ashwagandha Punarnawa, Katuki, Arjun and powder of Shwetparpati was conducted in 10 patients of Cirrhosis of liver. Out of 10 patients, 9 were male and 1 patient was female. 90% of the patients were in the age group between 40-60 years and 10% patients were between 60-80 years. Alcohol was directly responsible for development of cirrhosis in 70% cases. HBV infection in 20% and HCV in 10% patients. Non parametric tests like Npar and Wilcoxon Signed Rank tests were applied to assess the results in clinical features. Severity of the features were graded in the score between 0-3. The features like gynaecomastia, testicular atrophy, Dupuytren's contractures, loss of libido, dilated veins where gradation of severity was not possible, other non-parametric test like McNemar test was applied. Features of encephalopathy were absent in this group. The urine, stool was normal. Hematemesis and malena was absent. Paired T test was applied to assess the result of therapy with respect to pathological investigations. Findings showing probability < 0.05 were considered significant. Significant symptomatic relief was observed after treatment in only seven features like malaise, anorexia, constipation syndrome, abdominal distension, ascites, and edema feet out of total 24 features. No significant change was seen in pathological findings before and after treatment.

Conclusion:

Since the value of the signed (2 tailed) test is not having the probability < 0.05 , it is concluded that pathologically no significant response was observed after treatment with the trial drug sidoliv in any of the pathological investigation or clinical features. This is a study on small sample in limited time. Further study can be conducted on larger sample at bigger institute.

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DOI : 10.5281/zenodo.10451114

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