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A OPEN LABEL PILOT STUDY TO EVALUATE EFFICACY OF CHITRAKADI VATI IN THE MANAGEMENT OF GRADE 1 NON ALCOHOLIC FATTY LIVER DISEASE

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ABSTRACT

Background: Non-alcoholic fatty liver disease (NAFLD) is a rapidly rising metabolic disorder characterized by excessive hepatic fat accumulation without significant alcohol intake. In Ayurveda, it correlates with Yakṛt dūṣṭi and Meda dhātu vriddhi, conditions involving impaired Agni and Āma formation leading to Srotorodha and hepatic dysfunction. **Aim:** To evaluate the clinical efficacy of Chitrakadi Vati administered with Takra in patients of NAFLD. **Materials and Methods:** An open-label clinical study was conducted on 15 diagnosed cases of NAFLD. Each patient received Chitrakadi Vati (500 mg twice daily) with Takra for 60 days. Follow-up and assessment were done on the 90th day, with biochemical (SGOT, SGPT) and ultrasonographic evaluation before and after treatment. Data were statistically analyzed using the Wilcoxon signed-rank and paired t-tests. **Results:** Significant improvement was observed in clinical symptoms such as Udara śūla, Utkleśa, Aruchi, and Hṛt-kantha-dāha ($p < 0.001$ for all). Mean SGOT decreased from 80.73 ± 11.44 U/L to 31.00 ± 2.80 U/L, and SGPT from 63.73 ± 6.63 U/L to 28.20 ± 3.69 U/L ($p < 0.001$). Overall therapeutic effectiveness was 76%.

KEYWORDS: NAFLD, Chitrakadi Vati, Takra, Meda dūṣṭi, Yakṛt vikāra, Ayurveda, Gut–liver axis.

INTRODUCTION

NAFLD is currently the most common chronic liver disease worldwide, with prevalence exceeding 25% in adults. It encompasses a spectrum from simple steatosis to non-alcoholic steatohepatitis and cirrhosis. From an Ayurvedic viewpoint, excessive Meda dhātu sanchaya, Agnimāndya, and Āma production result in Yakṛt vikāra.

"अग्निमान्द्यादहमादोषात् मेदोवृद्धिः प्रजायते।"

(Chakrapāṇi on Su. Sū. 15/38) Due to weakened Agni and Āma accumulation, derangement of fat metabolism occurs. Chitrakadi Vati is a classical Āma-pācaka and Agnideepaka formulation, indicated for Agnimāndya, Āma-dosha, and metabolic disorders. Takra, described by Āchārya Charaka as "nectar for those suffering from Grahaṇi," enhances digestion and balances Vāta and Kapha.

"तक्रं लघु रुच्यं दीपनं वातकफापहम्।"(C. Su. 27/239)

The present study evaluates the effect of Chitrakadi Vati with Takra on clinical and biochemical parameters of NAFLD.

AIMS AND OBJECTIVES

To assess the clinical efficacy of Chitrakadi Vati with Takra in NAFLD.

To analyze its impact on biochemical liver function (SGOT, SGPT) and USG grading.

To interpret findings through Ayurvedic principles of Meda dushti and Yakṛt vikāra.

MATERIALS AND METHODS

Study Design An open-label, single-arm, clinical trial.

Sample Size 15 patients diagnosed with NAFLD.

Inclusion Criteria

Diagnosed NAFLD (USG Grade I).

Age 30 – 60 years.

Non-alcoholic history.

Exclusion Criteria

1. patients age <30 or >60
2. patients with IHD, heart diasease, uncontrolled hypertension, MI, cerebrovascular event, cardiac arrythmias, pregnancy, active maligannat disease were excluded from the study.
3. patients with altered thyroid harmone levels.
4. patients siffering from HIV, TB, GOITRE, ENCEPHALOPATHY, or other immune disorder
5. lactating and pregnant women.

Intervention

Chitrakadi Vati – 500 mg BID orally after meals with Takra for 60 days.

Takra – 150 ml freshly prepared, twice daily.

Diet advised: light, non-oily, easily digestible, avoiding Guru and Snigdha Ahara.

Assessment Criteria

Subjective parameters

Udara śūla, Utkleśa, Aruchi, Hṛt-kantha-dāha.

Objective parameters

SGOT, SGPT, and USG grading. Follow-up: Day 90.

Table no. 1: Grading system for sujective parameter.

subjective parameter	severity	grade
UDARSHOOLA	SEVERE (continuous, agonizing pain, severe interference with daily life	3
	MODERATE(frequent or persistant pain, mild interference with work/sleep	2
	MILD (occasional dull pain, doesnt interferance with daily activities	1
	ABSENT (no pain, discomfort)	0

UTKLESHA	SEVERE(constant nausea, often lead to vommiting) MODERATE(frequent nausea throughout the day) MILD (occasional nausea, specially after heavy meals or fatty meals) ABSENT (no nausea)	3 2 1 0
ARUCHI	SEVERE (complete aversion to taste) MODERATE can only eat onemeal a day or forcefull eating MILD reduced desire for food, but can eat two full meals a day ABSENT (normal desire for food, normal taste perception	3 2 1 0
HRITKANTHADAHA	SEVERE (continuos burning sensation even on empty stomach MODERATE (frequent burning sensation after normal meals relied by antacid or water) MILD(burning sensation only after very spicy or oily food) ABSENTno burning sensation in chest or stomach	3 2 1 0

Statistical Analysis

Data analyzed using Wilcoxon signed-rank test for subjective symptoms and paired t-test for biochemical parameters. $p < 0.05$ considered significant.

OBSERVATIONS AND RESULTS

Demographic Data Of 15 participants, 9 (60%) were male, 6 (40%) female.

Predominant Prakṛti – Kaphavāta (66.67%).93% followed non-vegetarian diet; most belonged to Ānupa Deśa (66.67%).

Observation and Results

Table 1: Distribution of Study Participants (n = 15).

Variable	Category	Frequency	Percentage
Gender	Male	9	60.00%
	Female	6	40.00%
Prakruti	KV	10	66.67%
	KP	2	13.33%
	PK	2	13.33%
	VK	1	6.67%
Addiction	No	14	93.33%
	Tobacco	1	6.67%
Diet	Non-Vegetarian	14	93.33%
	Vegetarian	1	6.67%
Marital Status	Married	13	86.67%
	Unmarried	2	13.33%
Occupation	Employee	6	40.00%
	Farmer	3	20.00%
	Housewife	2	13.33%
	RMO	2	13.33%
	IT Employee	1	6.67%
	Security Guard	1	6.67%
Desh	Anupa	10	66.67%
	Jangala	4	26.67%
	Sadharan	1	6.67%
USG Grade 1 Fatty Liver (AT)	Yes	3	20.00%
	No	12	80.00%
USG Grade 1 Fatty Liver (BT)	Yes	15	100.00%

Sex-wise distribution demonstrated a male predominance, with males constituting 60.00% (n = 9) and females 40.00% (n = 6) of the study participants. Analysis of *Prakruti* showed that KV type was most common, observed in 66.67% (n = 10) of participants. KP and PK types were equally distributed, each seen in 13.33% (n = 2), while VK type was present in 6.67% (n = 1).

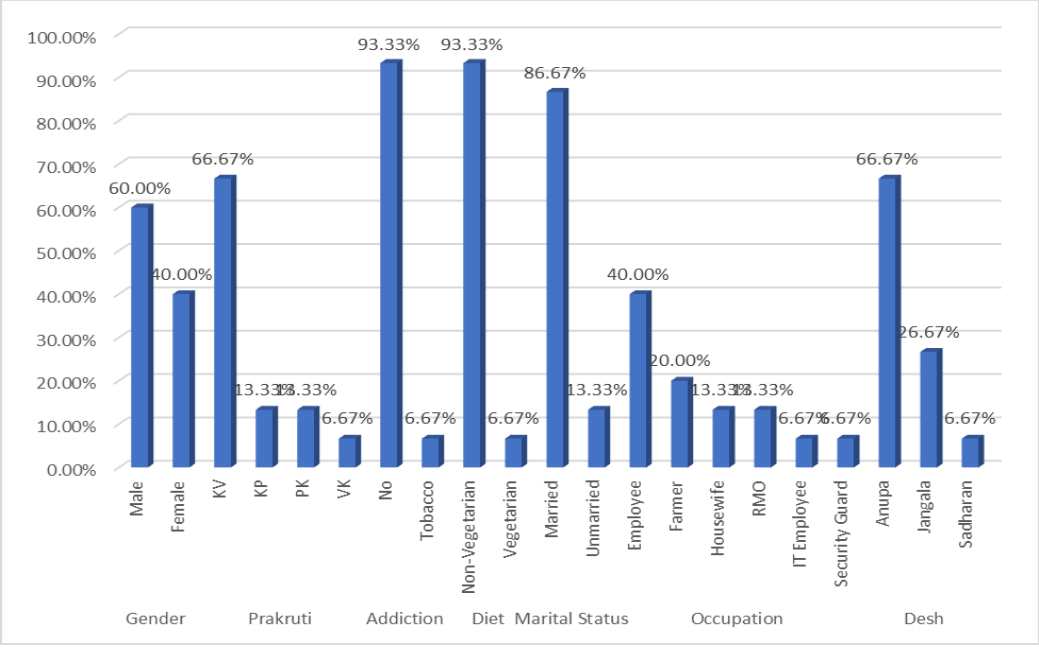
The distribution of addiction status revealed that the majority of participants did not have any form of addiction. Out of 15 participants, 14 (93.33%) reported no addiction, while only 1 participant (6.67%) had a history of tobacco use. Dietary habits showed a predominance of non-vegetarian intake. A total of 14 participants (93.33%) consumed a non-vegetarian diet,

whereas only 1 participant (6.67%) followed a vegetarian diet. In terms of marital status, the majority were married. Thirteen participants (86.67%) were married, while 2 participants (13.33%) were unmarried.

The occupational distribution indicated that employees formed the largest group (40.00%, n = 6), followed by farmers (20.00%, n = 3). Housewives and RMOs each constituted 13.33% (n = 2) of the study population. IT employees and security guards accounted for 6.67% (n = 1) each.

Regarding *Desh*, most participants belonged to the Anupa type, accounting for 66.67% (n = 10), followed by Jangala in 26.67% (n = 4) and Sadharan in 6.67% (n = 1). Ultrasonography findings indicated that Grade 1 fatty liver changes at baseline (AT) were present in 20.00% (n = 3) of participants, while 80.00% (n = 12) did not show such changes. However, at follow-up (BT), all participants (100.00%, n = 15) demonstrated Grade 1 fatty liver changes on USG.

Overall, the study population was predominantly male, married, non-addicted, non-vegetarian, and belonged mainly to the Anupa Desh and KV Prakruti categories, with a notable increase in Grade 1 fatty liver changes observed at follow-up.



Statistical Analysis symptoms (By Wilcoxon Singed Rank Test)

Hypothesis

Null Hypothesis H_0:- There is no significant difference between median ranks of score before treatment and after treatment. That is "***treatment is not effective***".

Alternative Hypothesis H_a:- There is significant difference between median ranks of score before treatment and after treatment. That is "***treatment is effective***".

Symptom	Time	Mean	SD	Median	Wilcoxon W test statistics	p-value
Udarṣhoola	BT	2.2	0.68	2	3.345	0.001
	AT	0.53	0.52	1		
Utklesha	BT	2.2	0.68	2	3.36	0.001
	AT	0.47	0.52	0		
Aruchi	BT	2.33	0.72	2	3.345	0.001
	AT	0.53	0.64	0		
Hritkanthadaha	BT	2.4	0.74	3	3.473	0.001
	AT	0.67	0.62	1		

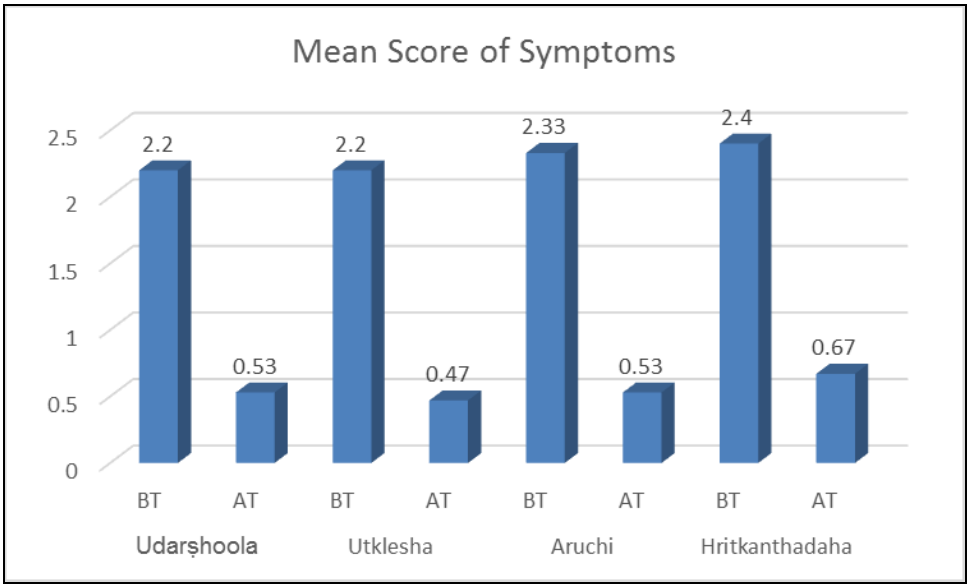
The comparison of symptom severity before treatment (BT) and after treatment (AT) demonstrated a marked reduction in all assessed symptoms. For **Udarṣhoola**, the mean score decreased from 2.20 ± 0.68 (median = 2) at baseline to 0.53 ± 0.52 (median = 1) after treatment. This reduction was statistically significant as evidenced by the Wilcoxon signed-rank test (W = 3.345, p = 0.001).

Similarly, **Utklesha** showed a substantial improvement, with the mean score declining from 2.20 ± 0.68 (median = 2) at BT to 0.47 ± 0.52 (median = 0) at AT. The change was statistically significant (W = 3.360, p = 0.001).

For **Aruchi**, the baseline mean score of 2.33 ± 0.72 (median = 2) was reduced to 0.53 ± 0.64 (median = 0) following treatment, indicating a significant improvement (W = 3.345, p = 0.001).

Similarly, **Hritkanthadaha** demonstrated a notable reduction in severity, with mean scores decreasing from 2.40 ± 0.74 (median = 3) before treatment to 0.67 ± 0.62 (median = 1) after treatment. This change was also statistically significant (W = 3.473, p = 0.001).

Overall, the Wilcoxon signed-rank test confirmed that the treatment resulted in a statistically significant reduction in all symptom scores, indicating a meaningful clinical improvement across the study participants.



Overall effect of therapy

Pt. No.	BT	AT	Relieved	Percentage
1	12	2	10	83%
2	9	2	7	78%
3	10	3	7	70%
4	10	2	8	80%
5	7	1	6	86%
6	9	1	8	89%
7	8	4	4	50%
8	9	2	7	78%
9	9	2	7	78%
10	9	1	8	89%
11	7	1	6	86%
12	8	3	5	63%
13	9	3	6	67%
14	11	4	7	64%
15	10	2	8	80%
Overall effect of therapy				76%

The overall effect of therapy showed a substantial improvement in the study participants. An overall therapeutic effectiveness of 76% was observed, indicating that more than three-quarters of the participants experienced marked relief in their symptoms following the intervention.

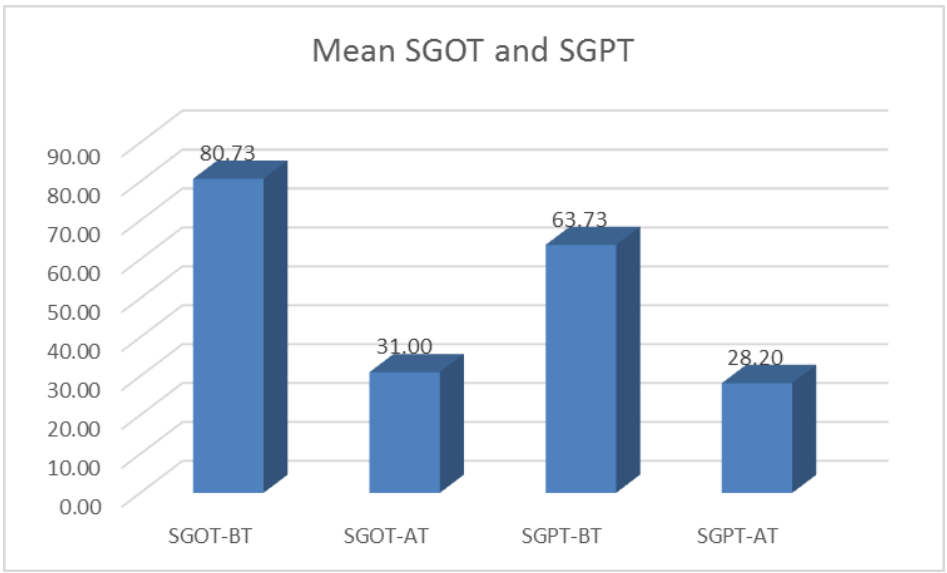
Table: Comparison of Liver Enzyme Levels Before and After Treatment.

Parameter	BT Mean ± SD	AT Mean ± SD	t value	p value
SGOT (U/L)	80.73 ± 11.44	31.00 ± 2.80	16.41	< 0.001
SGPT (U/L)	63.73 ± 6.63	28.20 ± 3.69	19.09	< 0.001

The comparison of liver enzyme levels before and after treatment revealed a statistically significant reduction in both SGOT and SGPT values. The mean SGOT level decreased markedly from 80.73 ± 11.44 U/L before treatment to 31.00 ± 2.80 U/L after treatment. This reduction was highly significant, as indicated by the paired t-test ($t = 16.41$, $p < 0.001$).

Similarly, the mean SGPT level showed a substantial decline from 63.73 ± 6.63 U/L at baseline to 28.20 ± 3.69 U/L following treatment. The observed change was also statistically highly significant ($t = 19.09$, $p < 0.001$).

Overall, these findings demonstrate that the therapy was highly effective in significantly improving liver enzyme profiles, indicating a marked biochemical improvement after treatment.



Overall clinical effectiveness = 76%.

DISCUSSION

Ayurvedic Interpretation

Discussion

The current study evaluated the efficacy of Chitrakadi Vati in the management of Grade 1 Non-Alcoholic Fatty Liver Disease (NAFLD) over a two-month period. The demographic analysis revealed a male predominance (60.00\%). Despite a high percentage of participants

(93.33\%) being non-addicted, the prevalence of a non-vegetarian diet (93.33\%) was notably high. From an Ayurvedic perspective, the majority of participants belonged to KV Prakruti (66.67\%) and Anupa Desh (66.67\%). These factors are traditionally associated with Agni-mandya (weak digestive fire) and Sroto-avarodha (obstruction of channels), which are central to the pathogenesis of fatty liver.

Takra serves as Anupāna, enhancing Agni, correcting Kaphamedo dushti, and promoting Purishdhara Kala function — thereby re-establishing the gut–liver axis.

Modern science supports the gut–liver connection via microbiota-derived endotoxins and inflammatory mediators. Takra, being probiotic, modulates intestinal flora, improving hepatic fat metabolism and reducing inflammation.

Mechanism of Action

Deepana–Pachana → Improved hepatic enzyme activity.

Ama-pachana → Reduced hepatic fat infiltration.

Srotoshodhana → Cleared micro-obstructions in Meda vaha srotas.

Gut–Liver Axis Modulation → Balanced intestinal microbiota.

Purishdhara Kala Support → Restores proper nutrient absorption and excretion.

These mechanisms jointly explain the statistically significant improvements in SGOT/SGPT and symptomatic relief.

Symptomatic Improvement

The administration of Chitrakadi Vati resulted in a statistically significant reduction in all subjective parameters ($p = 0.001$).

Udarṣhoola (Abdominal pain): The mean score decreased from 2.20 \pm 0.68 to 0.53 \pm 0.52.

Utklesha (Nausea): Improved from a baseline mean of 2.20 \pm 0.68 to 0.47 \pm 0.52.

Aruchi (Anorexia): Significant reduction from 2.33 \pm 0.72 to 0.53 \pm 0.64.

Hritkanthadaha (Heartburn): Showed a notable decline from 2.40 \pm 0.74 to 0.67 \pm 0.62.

These results suggest that the Deepana (appetizer) and Pachana (digestive) properties of the ingredients in Chitrakadi Vati helped in the digestion of Ama (metabolic toxins) and improved liver function.

Biochemical and Radiological Outcomes

The most significant finding was the impact on liver enzymes. The mean SGOT levels decreased from 80.73 \pm 11.44 \text{U/L} to 31.00 \pm 2.80 \text{U/L} ($p < 0.001$). Similarly, SGPT levels dropped from 63.73 \pm 6.63 \text{U/L} to 28.20 \pm 3.69 \text{U/L} ($p < 0.001$). While Grade 1 fatty liver changes persisted on ultrasonography for all participants at follow-up, the rapid normalization of enzymes indicates a significant reduction in hepatic inflammation. The overall therapeutic effectiveness was recorded at 76%.

CONCLUSION

The study concludes that Chitrakadi Vati is highly effective in the clinical and biochemical management of Grade 1 NAFLD. The therapy provides significant relief from dyspeptic symptoms and successfully normalizes elevated liver enzymes (SGOT and SGPT) within 60 days of treatment. The alternative hypothesis was accepted, confirming that the treatment is statistically effective ($p < 0.001$).

Future Scope

Extended Duration: Long-term studies (6 months or more) are required to evaluate the potential for complete radiological reversal of Grade 1 fatty liver changes on USG.

Large-scale Trials: Multicentric trials with a larger sample size are recommended to validate these findings across different ethnicities and age groups.

Comparative Research: Randomized controlled trials (RCTs) comparing Chitrakadi Vati with standard modern hepatoprotectives (like Silymarin or Ursodeoxycholic acid) would further establish its clinical standing.

Histopathological Correlation: Future research could include FibroScan or liver biopsy to assess the degree of fat reduction and fibrosis more accurately than conventional USG.

Maintenance Dose: Investigating the role of a lower maintenance dose to prevent the recurrence of fatty infiltration in high-risk Anupa Desh and KV Prakruti populations.

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