

CLINICAL ASSESSMENT OF AN INTEGRATIVE THERAPEUTIC APPROACH USING LIV IMMUNE CAPSULES IN PATIENTS WITH FATTY LIVER AND DYSLIPIDEMIA: AN OPEN-LABEL CLINICAL STUDY

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ABSTRACT

Background: non-alcoholic fatty liver disease (grade 1–2) and hypercholesterolemia/dyslipidemia are common metabolic conditions, coexisting with fatigue, and constipation. There is increasing interest in integrative ayurvedic approaches combining herbal formulations with diet and yoga for hepatic and lipid metabolic support. **Aim:** to evaluate the clinical outcomes of liv immune capsules, combined with a personalized diet and structured yoga protocol, on liver status (ultrasonographic grading), lipid profile (total cholesterol, ldl, triglycerides), and associated symptoms (fatigue, constipation) in patients presenting with fatty liver and/or dyslipidemia. **Materials and Methods:** an open-label, clinical study was conducted over a duration of 3 months involving 15 patients (n=15, age range 18–79 years) presenting with grade 1–2 fatty liver and/or hypercholesterolemia/dyslipidemia, associated with or without fatigue or constipation. Patients received liv immune capsules (2–0–2) along with an individualized diet plan and a structured yoga protocol. Assessment was based on pre- versus post-treatment lipid profile and, where available, pre- versus post-treatment liver ultrasonography. **Results:** a total of 15 patients were included in the study. Hypercholesterolemia/dyslipidemia was present in 6 patients, all of whom demonstrated improvement in one or more lipid parameters (total cholesterol, ldl cholesterol, and/or triglycerides) following treatment. Fatty liver on ultrasonography was evaluated in 8 patients; follow-up usg revealed complete resolution in 3 patients, measurable improvement in 4 patients, and no radiological change in 1 patient. Fatigue was reported by 5 patients, of whom 4 showed clinical improvement, while constipation resolved completely in the four affected patient. **Conclusion:** the integrative protocol of liv immune capsules with personalized diet and yoga was associated with consistent improvement in lipid parameters and variable improvement in fatty liver imaging findings, along with symptomatic relief in several patients. As a retrospective case series with a small, heterogeneous sample and non-uniform follow-up duration, the findings are preliminary and support the design of a prospective, standardized clinical study.

KEYWORDS: Fatty Liver, Yakrit Vikara, Hypercholesterolemia, Dyslipidemia, Liv Immune, Integrative Medicine, Ayurveda.

INTRODUCTION

Non-alcoholic fatty liver disease (NAFLD) and dyslipidemia are among the most prevalent metabolic disorders seen in general clinical practice, coexisting with fatigue, and constipation. If Neglected, these conditions carry risk of progression to more advanced hepatic and cardiovascular disease.

Conventional management relies on statins/lipid-lowering agents and lifestyle modification. Many patients, particularly those with mild (Grade 1) disease or those wishing to avoid long-term pharmacological therapy, seek complementary approaches addressing the underlying metabolic dysfunction with a favourable safety profile.

Liv Immune capsules are a proprietary polyherbal formulation traditionally positioned for hepatoprotective (Yakrit-Vikara-hara), lipid-regulating (Medohara), digestive (Deepana-Pachana), and immunomodulatory (Vyadhikshamatva-varadhaka) support. This case series was undertaken to document the clinical outcomes of Liv Immune capsules, combined with personalized dietary correction and a structured yoga protocol, in patients presenting with fatty liver and/or dyslipidemia.

Ayurveda view

Fatty liver, dyslipidemia, fatigue and constipation are commonly observed together in individuals with sedentary lifestyles, irregular dietary habits and impaired digestion. From an Ayurvedic physician's perspective, this cluster of complaints can be understood through the concepts of Agnimandya, Āma, Medo dushti and Kapha aggravation, along with disturbance of Apāna Vāta affecting normal bowel function.

In Ayurveda, proper functioning of Agni is considered fundamental to digestion, nourishment and maintenance of health. When Agni becomes impaired, improper digestion and accumulation of Āma may occur, contributing to heaviness, sluggishness, reduced appetite and bowel irregularity. Persistent imbalance in the formation and utilization of Meda dhātu may manifest as excessive fat accumulation and derangement of lipid metabolism, providing an Ayurvedic perspective to conditions such as fatty liver and dyslipidemia.

The associated fatigue can be correlated with Klama and Daurbalya, reflecting reduced functional capacity and inadequate nourishment of the tissues. Constipation, particularly when associated with dryness, irregular

bowel habits and abdominal discomfort, may be understood through Apāna Vāta dushti and impaired digestive function.

Therefore, an Ayurvedic approach to such presentations aims to identify and address the underlying disturbance in Agni, Meda and Vāta-Kapha balance, rather than treating each complaint in isolation. Appropriate dietary correction, lifestyle modification, digestive and bowel regulation, along with individualized Ayurvedic interventions, form the basis of a comprehensive approach.

MATERIALS AND METHODS

Study Design: An open-label, single-arm clinical study conducted over a period of 3 months by DR.SHREEVARMA's Wellness.

Inclusion criteria: Patients diagnosed with Grade 1 or Grade II fatty liver on ultrasonography and/or hypercholesterolemia/dyslipidemia on lipid profile, with or without associated fatigue, or constipation; age range in this series 18–79 years; willingness to receive Liv Immune capsules with dietary and yoga guidance.

Exclusion criteria: To be specified decompensated liver disease, pregnancy/lactation, malignancy, serious systemic illness, use of concurrent hepatotoxic medication. Not documented in the source case records and should be defined explicitly for a prospective study.

Intervention Protocol

- Liv Immune capsules: 2 capsules morning – 0 – 2 capsules evening (2–0–2), oral
- Dietary Standardization: Individualized diet plan emphasizing whole grains (brown rice, oats, millets), fresh vegetables, green leafy vegetables and seasonal fruits, steamed/boiled/lightly cooked preparations, adequate protein, healthy fats, and probiotics (buttermilk/curd); hydration 2–3 L/day; Avoidance of alcohol, smoking, fried/oily/processed/high-fat foods, refined sugar, carbonated drinks, packaged juices, excess salt, excess tea/coffee, overeating and prolonged gaps between meals.
- Yoga Protocol: Asanas — Tadasana, Trikonasana, Ardha Matsyendrasana, Bhujangasana, Dhanurasana, Pawanmuktasana,; Pranayama — Deep Diaphragmatic Breathing, Nadi Shudhi Pranayama, Anulom Vilom Pranayama, Bhramari Pranayama, Kapalabhati Pranayama; Relaxation/Meditation — Shavasana, Yoga Nidra.

Liv immune capsules

Ingredient composition

Table 1: Ingredient Composition.

Ingredient (Botanical Name)	Quantity(mg)
Swertia chirata	52
Eclipta alba	42
Curcuma longa	31
Acacia leucophloea	73

Leucas cephalotes	21
Picrorhiza kurroa	31
Emblica officinalis	21
Withania somnifera	26
Abutilon indicum	10
Aconitum heterophyllum	21
Woodfordia fruticosa	21
Tinospora cordifolia	31
Terminalia chebula	48
Ocimum sanctum	31
Azadirachta indica	21
Myrica nagi	10
Sida rhombifolia	10

Assessment Parameters

Clinical and biochemical response was assessed on the basis of:

- (1) Change in liver ultrasonographic grading/findings (where pre- and post-treatment imaging were both available),
- (2) Change in lipid profile — total cholesterol (TC), LDL, and/or triglycerides (TG) (where pre- and post-treatment values were both available), and

- (3) Change in associated symptoms — fatigue and constipation — as documented in clinical notes.

Results & statistical classification

1. Demographic and Baseline Clinical Profile

The case series (n=15) had an age range of 18–79 years, mean age 51.1 years. Gender was explicitly recorded for patients (7 female, 8 male)

Table 2: Baseline Clinical Characteristics (n=15)

Clinical parameter	Total no of patients	Patients with complaints
Fatty liver (Grade 1 or Grade II) on USG	15	8
Hypercholesterolemia / dyslipidemia (TC/LDL/TG elevated)	15	6
Fatigue	15	5
Constipation	15	4

Explanation: Each of the 15 patients in this case series has been classified under a single, primary presenting complaint. Of these, 8 patients presented primarily with fatty liver (Grade 1 or Grade II) on ultrasonography, 6 patients presented primarily with

hypercholesterolemia/dyslipidemia, 5 patients presented primarily with fatigue, and 4 patient presented primarily with constipation. Together these four categories account for the full cohort of 15 patients.

**Distribution of Clinical Complaints
(Total Patients = 15)**

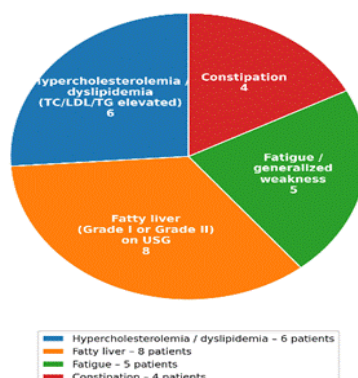


Fig 1

2. Lipid Profile Outcomes

six of fifteen patients had a quantifiable lipid parameter (TC, LDL, and/or TG) recorded at both baseline and follow-up.

Table 3: Patient-wise Lipid Outcomes (n=6)

Patient id	Total cholesterol before treatment	Total cholesterol after treatment	LDL before treatment	LDL after treatment	Triglycerides before treatment	Triglycerides after treatment
Case 1	225	200	145.4	125	200	184
Case 2	236	208	121	112	-	-
Case 3	215	208	104	87	170	155
Case 4	239	210	140	110	210	191.5
Case 5	253.8	235.1	140	124	-	-
Case 6	255	202.7	183	132.4	180	152

Note: All units mg/dl.

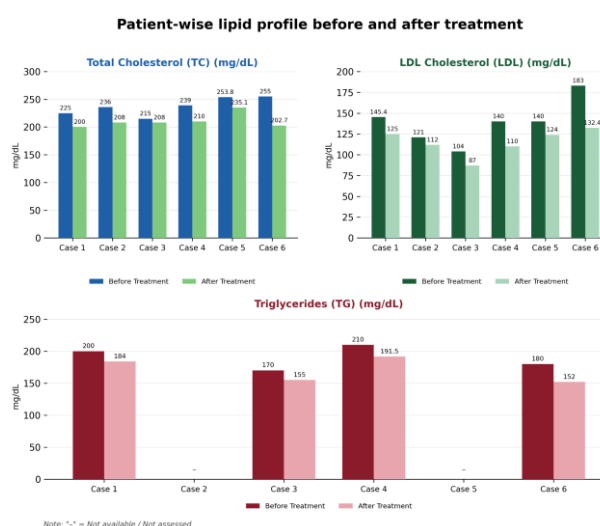


Fig 2

3. Liver Ultrasonographic Outcomes

Of 6 patients presenting with fatty liver, follow-up ultrasonography comparable to baseline

Table 4: Liver USG Outcome (n=8)

USG Outcome	Total no of patients	No of Patients with improvement
Complete resolution (normal liver)	8	3
Measurable improvement (reduced size, grade not restated)	8	4
No radiological change	8	1

Explanation: Of the 8 patients with comparable pre- and post-treatment liver ultrasonography, 3 patient showed complete resolution to normal liver morphology, 4 patients showed measurable improvement (reduction in

size or grade, without full normalization), and 1 patient showed no radiological change. Overall, 7 of 8 evaluated patients showed some degree of improvement on repeat imaging.

**USG Outcome After Treatment
(Total Patients = 8)**

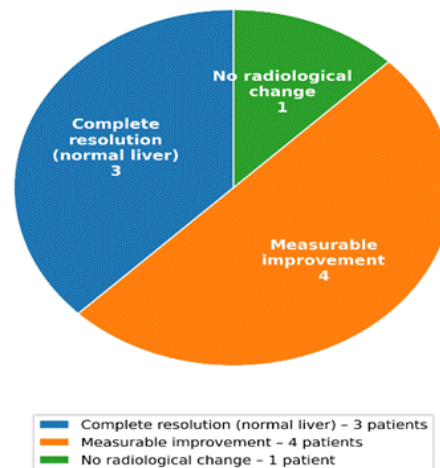


Fig3

4. Associated Symptom Outcomes

Table 5: Symptomatic Outcomes (n=9)

Clinical parameter	No of Patients with symptoms	No of patients with Clinical Improvement
Fatigue	5	4
Constipation	4	4

Explanation: Of the 9 patients presenting with fatigue as a primary complaint, 4 reported symptomatic improvement at follow-up. The 4 patient presenting with

constipation as a primary complaint reported complete relief.

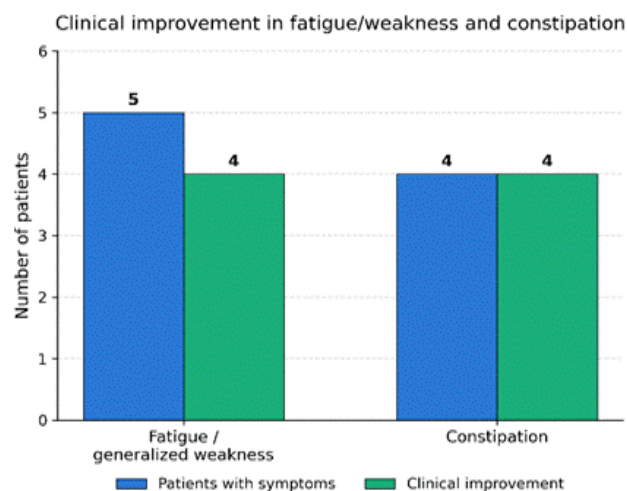


Fig4

5. Overall Clinical Response Classification

Criteria for Overall Clinical Response (proposed, adapted to the parameters available in this series)

- Complete Response: Normalization of liver imaging and normalization/near-normalization of lipid profile
- Marked Response: Significant improvement in lipid profile ($\geq 10\%$ reduction in TC/LDL/TG) with stable or

improved liver imaging (where available), or documented symptomatic improvement

- Moderate Response: Modest lipid improvement ($< 10\%$ reduction) and/or no change in liver imaging, without documented symptomatic improvement

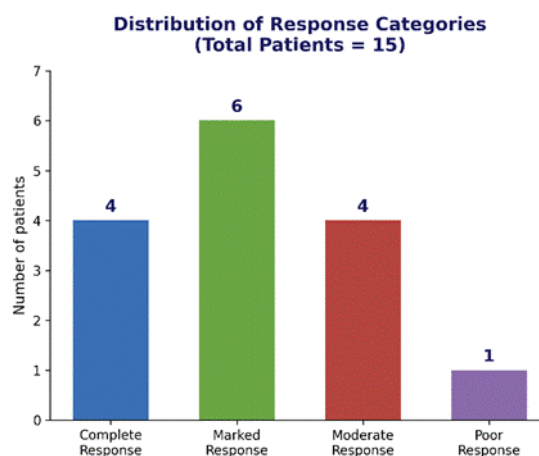
- Poor Response: No improvement in any assessed parameter

Table 6: Overall Clinical Response (n=15)

Response category	Total no of patients	No of patients with Clinical improvement
Complete Response	15	4
Marked Response	15	6
Moderate Response	15	4
Poor Response	15	1

Explanation: Applying the Overall Clinical Response classification across the full cohort, 4 patient achieved a Complete Response, 6 patients achieved a Marked

Response, 4 patients a Moderate Response, and 1 patient a Poor Response. Combined, 14 of 15 patients achieved at least a Moderate or better clinical response.

**Fig 5**

DISCUSSION

The therapeutic efficacy of Liv Immune Capsule in patients with fatty liver and dyslipidemia may be attributed to its synergistic hepatoprotective, lipid-regulating, digestive, and immunomodulatory actions. The formulation demonstrated consistent improvement in lipid profile, symptomatic relief, and favourable changes in liver status following treatment.

The hepatoprotective effect is primarily supported by Kiratatikta (*Swertia chirata*), Bhrngaraja (*Eclipta alba*), Katuka (*Picrorhiza kurroa*), Haridra (*Curcuma longa*), Guduci (*Tinospora cordifolia*), and Amalaki (*Emblica officinalis*), which are traditionally indicated for liver disorders and possess documented antioxidant, hepatoprotective, and anti-inflammatory properties. Haritaki (*Terminalia chebula*), Ativisa (*Aconitum heterophyllum*), and Dronapuspi (*Leucas cephalotes*) enhance digestion and metabolism (Deepana–Pachana), facilitating the reduction of metabolic toxins (Ama) and improving gastrointestinal symptoms.

The lipid-lowering activity of the formulation may be attributed to Arimeda (*Acacia leucophloea*), Dhataki (*Woodfordia fruticosa*), and Katphala (*Myrica nagi*), which possess Kapha-Medohara properties and support healthy lipid metabolism. Guduci, Tulasi (*Ocimum sanctum*), and Ashwagandha (*Withania somnifera*) contribute immunomodulatory, adaptogenic, and rejuvenative (Rasayana) effects, promoting overall well-being and reducing fatigue.

The observed improvements in serum lipid parameters, symptomatic relief, and favourable ultrasonographic changes suggest that Liv Immune Capsule provides a comprehensive therapeutic approach in the management of fatty liver associated with dyslipidemia. Dietary modification and yoga/pranayama practiced during the study may also have contributed to improved insulin sensitivity, lipid metabolism, and liver health, thereby enhancing the overall clinical outcome.

CONCLUSION

This retrospective open-label case series suggests that Liv Immune capsules, combined with a personalized diet and structured yoga protocol, may be associated with consistent improvement in lipid parameters and variable improvement in fatty liver ultrasonographic grading, along with symptomatic relief (fatigue, constipation) in a majority of documented cases. Given the retrospective design, small heterogeneous sample, and non-standardized follow-up interval, these findings should be regarded as preliminary. A prospective, standardized open-label or controlled clinical study — with a fixed follow-up interval (e.g., 3 months), complete pre-/post-imaging for all fatty-liver patients, standardized symptom grading, and inclusion of liver-enzyme and metabolic markers — is recommended to establish efficacy more conclusively.

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