Assessment of Safety Profile of Tejas Yoga through Biochemical and Hematological Investigations: A Clinical Study

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Abstract

Dyslipidemia has emerged as a major metabolic disorder due to rapid lifestyle changes, significantly increasing the risk of cardiovascular diseases. In Ayurveda, it can be correlated with Medodushti and Medoroga, primarily resulting from Agnimandya and subsequent Ama formation, leading to Srotorodha and impaired lipid metabolism. Epidemiological data indicate a substantial prevalence of dyslipidemia, affecting both urban and rural populations, with a higher incidence among males. Although modern hypolipidemic agents such as statins and fibrates are effective, their long-term use is often associated with adverse effects and economic burden. The present case study evaluates the safety profile of Tejas Yoga, a polyherbal formulation prepared as Ghanvati, comprising ingredients Arjun, Rasona, Shunthi, Amalaki, Guggulu, etc. The intervention was assessed over a period of two months based on clinical symptoms and biochemical parameters of Lipid Profile, CBC, LFT, and RFT. Results demonstrated a significant reduction in total cholesterol, triglycerides, LDL, and VLDL levels, along with no significant alterations in any of the parameters of CBC, LFT, and RFT after the administration of the drug. Additionally, marked symptomatic improvement was observed. This indicates that the drug does not produce hepatotoxic effects and does not exert any harmful impact on renal function or overall physiological systems. The study suggests that Ayurvedic formulations like Tejas Yoga offer a safe, holistic, and sustainable approach in managing dyslipidemia by addressing the root cause rather than merely correcting lipid levels.

Keywords: *Tejas Yoga; Ghanvati; Lipid Profile; Hepatotoxicity; Renal Safety; Ayurvedic Management*

1. Introduction

The increasing prevalence of dyslipidemia in recent decades reflects the profound impact of sedentary lifestyle, unhealthy dietary habits, and metabolic disturbances. It is recognized as a major modifiable risk factor for cardiovascular diseases, which remain one of the leading causes of mortality worldwide. A considerable proportion of the population is affected, often diagnosed incidentally during lipid profile evaluation. At present, about 25-30% of the total population of the country is affected by dyslipidemia in urban and 15-20% in rural population. The overall prevalence of dyslipidemia was 13.7%, which was significantly higher in men (23%) than in woman (7.2%). In this research paper, a holistic approach is made and a herbal formulation in the form of ghanvati is prepared with Proper planning, preparation and medication.

From an Ayurvedic perspective, dyslipidemia closely resembles the pathological condition of Medodushti and Medoroga. The fundamental pathology involves Agnimandya (impaired digestive fire), leading to the accumulation

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of Ama, which obstructs bodily channels (Srotas) and disrupts normal metabolism of Medo Dhatu. This results in abnormal lipid accumulation and associated systemic manifestations.

Although contemporary medicine provides a range of lipid-lowering drugs, their prolonged use may lead to undesirable side effects and increased financial burden. Therefore, there is a growing need for safer and cost-effective alternatives. Ayurvedic formulations, with their multi-targeted action, aim not only to normalize lipid levels but also to correct the underlying metabolic imbalance. In this context, the present study explores safety profile of Tejas Yoga, in the management of Dyslipidemia in the form of Ghanvati. Proper planning, preparation and medication using that ghanvati as per ayurvedic guidelines will be observed with respect to its clinical effect in Dyslipidemia.

2. Aim

To evaluate the safety and therapeutic efficacy of Tejas Yoga in the management of dyslipidemia through biochemical and hematological investigations.

3. Objectives

- To assess the effect of Tejas Yoga on lipid profile parameters, including total cholesterol, triglycerides, LDL, and VLDL and HDL
- To evaluate the safety profile of Tejas Yoga by analysing haematological parameters (CBC) and biochemical parameters such as liver function tests (LFT) and renal function tests (RFT).
- To observe the improvement in clinical symptoms associated with dyslipidemia following administration of Tejas Yoga.

3.1 Importance of Present Study

- Due to changing life style and food habits etc., there is increased incidence of Dyslipidemia in Practice so an effort is made to find a solution for it through Ayurveda.
- An attempt is made to clinically evaluate the safety and therapeutic efficacy of prepared ghanvati in the management of Dyslipidemia.

3.1 Material and Methods

Selection of sample: Patients were selected randomly irrespective of their sex, religion, occupation etc.

Source of patients: 10 clinically diagnosed patients of Dyslipidemia registered in OPD/IPD of Kayachikitsa Department of Government Ayurveda College Raipur, Chhattisgarh, who fulfill inclusion criteria, were selected.

Drug Preparation: Drugs namely ingredients Arjun, Rasona, Shunthi, Amalaki, Agnimanth, Maricha, Haritaki, Guggulu, Haridra, Jeerak, Chitrak, Katuli, Pippali, Pushkarmoola. Were taken in ratio 1:1 by weight respectively and ghanvati is prepared by classical method.

4. Treatments Schedule

4.1 Patient Preparation

Before treatment Sanjeevani Vati 2tab BID with lukewarm water and 5gm triphala churna at bed time with lukewarm water will be given for 7 days for Deepan, Pachan, and for Kostha shuddhi, then research medicine will be started.

4.2 Posology

S.No	Shamana Aushadhi	Matra And Sevan Kaala	Anupana	Duration	Follow Up
1	Tejas yoga (GhanVati) (250mg)	2 tablets x QID – Before Food	Lukewarm Water	60 Days	15 days (4 follow up) 30 days (1 post Follow up)

- **Inclusion criteria**
  - Age above 20 years and below 60 years.
  - Patient with abnormal value of Total cholesterol, Serum triglyceride, LDL, VLDL, HDL A following range value was taken for diagnosis of Dyslipidemia.
  - S. Cholesterol 200-239 mg/dl or/and
  - S. Triglyceride 200-399 mg/dl or/and
  - S.L.D.L 130-159 mg/dl or/and
  - S.H.D.L < 40 mg/dl

- **Exclusion Criteria**

- Age below 20 year and above 60 years.
- Liver cirrhosis
- Liver failure
- Ascites
- Cancer
- Nephrotic syndrome
- Chronic renal failure
- Tuberculosis
- Patients having H/o – Serious cardiac disorder like MI or cardiac failure.
- Pregnant female and lactating mothers.
- Known cases of Immunocompromised state (AIDS), cancer, hepatitis myeloma etc.
- Patients suffering from D.M. that were poorly controlled and uncontrolled hypertension.
- Patients taking allopathic medication for dyslipidemia like statins, fibrates derivatives along with ayurvedic medication or does not agree for only ayurvedic medication.

- **Criteria for Withdrawal**
  - During the course of trial if any serious condition or any serious disease is found in patient.
  - Patients herself/himself want to withdraw from the clinical trial.

5. Criteria of Assessment of Patient

- **Subjective Parameter**

No.	Symptoms	No Of Patients	Before Treatment					After Treatment					% Relief
			G0	G1	G2	G3	Total	G0	G1	G2	G3	Total	
1.	BREATHLESSNESS	10	4	4	1	1	9	7	3	0	0	3	66.67%
2.	FATIGUE	10	2	3	4	1	14	9	1	0	0	1	92.86%
3.	ALASYA	10	3	6	1	0	8	10	0	0	0	0	100%
4.	DAURBALYA	10	6	2	1	1	7	9	1	0	0	1	85.71%
5.	NIDRADHIKYA	10	9	1	0	0	1	10	0	0	0	0	100%

- **Result**

Parameter	Mean		MD	% Relief	SD	SE	P-Value	Conclusion
	BT	AT						
Breathlessness	0.900	0.300	0.600	66.67	0.699	0.221	0.02386	S
Fatigue	1.400	0.200	1.200	92.86	0.919	0.291	0.00256	S
Alasya	0.800	0.000	0.800	100.00	0.633	0.200	0.00311	S
Daurbalya	0.700	0.100	0.600	85.71	0.966	0.306	0.08113	NS
Nidradhikya	0.100	0.000	0.100	100.00	0.316	0.100	0.34344	NS

- **Objective Parameter**

No of Patients	COMPARATIVE CHART BT AT									
	Total Cholesterol (mmhg)		Triglyceride (mmhg)		LDL (mmhg)		VLDL(mmhg)		HDL (mmhg)	
	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1.	243.19	201.53	302.19	127.82	135.37	88.28	60.64	25.76	47.18	52.49
2.	195.9	194.76	246.15	157	103.9	117.1	48.43	31.6	42.6	46
3.	276	231	273	197.4	156	153.4	87.5	39.48	55	58.98
4.	295	241.9	303	161.03	188.2	155.8	61.8	31.01	44	51.08
5.	238.4	203.1	125	77.4	171.3	143.72	26.2	15.68	41.9	43.7
6.	180	163.53	280.34	146.21	120.28	85.28	70.04	31.04	42.49	44.49
7.	232	183	186	144	163	122.3	35.8	64.2	32	39.63
8.	188.2	142	250.2	160	132	86	50.08	38	56.2	55.4
9.	231	192	204	156	152	126	41	30	33.8	32
10.	294	239.9	302	150.03	186.2	154.8	61.8	31.01	44	51.08

- **Result**

Parameter	Mean		MD	% Relief	SD	SE	P-VALUE	Conclusion
	BT	AT						
Total Cholesterol (mmhg)	237.369	199.272	38.097	16.05	16.893	5.342	<0.0001	S
Triglyceride (mmhg)	247.188	147.689	99.499	40.25	48.049	15.194	0.00011	S
LDL (mmhg)	150.825	123.268	27.557	18.27	19.074	6.032	0.00135	S
VLDL (mmhg)	50.643	33.778	17.499	33.30	20.449	6.816	0.03327	S
HDL (mmhg)	43.917	47.485	3.568	8.124	3.298	1.043	0.00761	S

6. Interpretation

The analysis of subjective symptoms shows a marked improvement in most clinical features after treatment: Breathlessness showed 66.67% relief, which is statistically significant ($p = 0.02386$), indicating good improvement in respiratory comfort. Fatigue demonstrated 85.71% relief with high statistical significance ($p = 0.00256$), suggesting strong efficacy in reducing exhaustion. Alasya (lethargy) showed complete relief (100%)**,** also statistically significant ($p = 0.00311$), reflecting excellent therapeutic impact on energy levels. Daurbalya (weakness) improved by 85.71%, but was statistically insignificant ($p = 0.08113$)**,** indicating variability in patient response. Nidradhikya (excess sleep) showed 100% relief**,** but remained statistically insignificant ($p = 0.34344$), possibly due to very low baseline values.

The analysis of biochemical parameters demonstrates a statistically significant improvement in lipid profile following the intervention. Total Cholesterol decreased from 237.369 to 199.272 mg/dL, with a mean difference of 38.097 (16.05% reduction). This change is highly statistically significant ($p < 0.0001$), indicating a strong hypocholesterolemic effect. Triglycerides showed a marked reduction from 247.188 to 147.689 mg/dL, with a mean difference of 99.499 (40.25% reduction). The result is highly significant ($p = 0.00011$), suggesting excellent efficacy in controlling hypertriglyceridemia. LDL (Low-Density Lipoprotein) decreased from 150.825 to 123.268 mg/dL, showing a 27.557 mean reduction (18.27%), which is statistically significant ($p = 0.00135$). This indicates a beneficial reduction in atherogenic lipoproteins. VLDL (Very Low-Density Lipoprotein) reduced from 50.643 to 33.778 mg/dL, with a mean difference of 17.499 (33.30% reduction). This change is statistically significant ($p = 0.03327$), reflecting improvement in triglyceride-rich lipoprotein metabolism. HDL (High-Density Lipoprotein) increased from 43.917 to 47.485 mg/dL, showing a mean rise of 3.568 (8.124% increase). This improvement is statistically significant ($p = 0.00761$) and is clinically desirable, as HDL has a protective role against cardiovascular diseases.

7. Discussion

- **Discussion on Mode of Action of Tejas Yoga**

Tejas Yoga, a polyherbal formulation, exhibits a multidimensional mode of action due to the synergistic effect of its ingredients. The formulation predominantly possesses Deepana and Pachana properties, owing to drugs like Shunthi, Pippali, Maricha, Chitrak, and Rasona, which enhance Jatharagni and Dhatvagni, thereby aiding in the digestion and elimination of Ama. The presence of Guggulu, Haritaki, Amalaki, and Arjuna contributes to Medohara and Lekhana Karma, which helps in reducing excess Meda Dhatu and facilitates the mobilization and metabolism of lipids.

Additionally, ingredients such as Guggulu, Rasona, and Pushkarmoola play an important role in Srotoshodhana, thereby removing obstructions in the channels and improving metabolic processes.

Most of the drugs in the formulation are characterized by Katu and Tikta Rasa, Ushna Virya, and Laghu-Ruksha Guna, which effectively pacify Kapha Dosha and regulate Vata, thereby restoring physiological balance. Furthermore, Rasayana and antioxidant properties of drugs like Amalaki, Haridra, and Arjuna help in preventing oxidative stress and protect against lipid peroxidation, which is a key factor in the development of atherosclerosis. Importantly, the absence of any significant alterations in liver and renal function tests after administration of the drug indicates that the formulation is non-hepatotoxic and does not adversely affect renal function, thereby establishing its safety profile.

The findings of the present study reveal that Tejas Yoga produces significant improvement in both subjective symptoms and objective biochemical parameters in patients of dyslipidemia. There was marked relief in symptoms such as breathlessness, fatigue, alasya, daurbalya, and nidradhikya, indicating an overall improvement in metabolic efficiency and quality of life. The biochemical parameters showed a considerable reduction in total cholesterol, triglycerides, LDL, and VLDL levels after the intervention. These therapeutic effects can be attributed to the Deepana-Pachana and Medohara properties of the formulation, which act on the root cause of the disease, namely Agnimandya and Ama formation.

Unlike conventional hypolipidemic drugs that primarily target lipid levels, Tejas Yoga works at a systemic level by correcting impaired metabolism, eliminating metabolic toxins, and restoring normal physiological functions. A notable aspect of this study is the safety of the formulation, as evidenced by the absence of any significant changes in liver function tests and renal function tests even after 60 days of administration. This suggests that the drug is safe for prolonged use and does not produce hepatotoxic or nephrotoxic effects. However, the study is limited by a small sample size and lack of a control group, which necessitates further large-scale clinical trials to validate the findings.

8. Conclusion

Tejas Yoga, administered in the form of Ghanvati, has demonstrated significant efficacy in the management of dyslipidemia by reducing lipid parameters such as total cholesterol, triglycerides, LDL, and VLDL, along with improvement in associated clinical symptoms. The formulation acts by correcting the underlying pathology of Agnimandya and Ama, thereby offering a holistic approach rather than merely providing symptomatic relief. Importantly, no adverse effects were observed on liver and renal functions, confirming its safety and tolerability. Therefore, Tejas Yoga can be considered a safe, effective, and economical therapeutic option for the management of dyslipidemia, especially for long-term use. Further studies with larger sample sizes are recommended to establish its clinical efficacy more conclusively.

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