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Research Article

CLINICAL EVALUATION OF STEM BARK POWDER OF *SHIGRU* (*MORINGA OLEIFERA* LAM.) IN DYSLIPIDEMIA

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KEYWORDS: Dyslipidemia, *Shigru twak, Medoghna Moringa oleifera* Lam.

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ABSTRACT

In recent times drastic changes have taken place in dietary habits and mode of life style which has resulted in precipitation of various metabolic diseases. One such alarming condition, which is on a high rise in the society, is Dyslipidemia. Since the pathology has a clear link with a person's life style, the body demands a more holistic approach in treatment, hence indigenous system of medicine especially herbal preparations can play major role in finding a safe, simple and cost effective solution for the management of Dyslipidemia. *Shigru* botanically identified as *Moringa oleifera* Lam. is one of such commonly available plant which is greatly praised for its *Medoghna* property in various *Nighantus*.

A clinical study of *Shigru twak* (stem bark) was conducted on 30 patients at OPD level of Government Ayurveda College Hospital, Tripunithura, Kerala. *Shigru* stem bark powder (*Choornam*) was given in the form of capsule, in a dose of 3gm per day along with lukewarm water before food for a period of 45 days. Assessment based on blood lipid levels and clinical features was done before and after treatment. The results were statistically analyzed. After the intervention Total Cholesterol, Serum LDL, Serum VLDL, Serum Triglyceride and Body weight were significantly reduced. On symptomatic evaluation the drug was significantly effective in reducing heaviness of body, chest pain, excessive sleep, excessive sweating, and breathlessness on exertion, palpitation and lethargy. The study revealed that *Shigru twak* is safe and effective in Dyslipidemia.

INTRODUCTION

Ayurveda is an eternal science playing a key role in the treatment of many incurable, chronic diseases and even minor ailments which are hampering the excellence of life. The present era is immensely occupied by disarray, stress and strain due to lifestyle modification, changes in dietary habits and urbanization. This has led to the upsurge of various metabolic diseases such as Diabetes, Hypertension, Hyperlipidemia, Cardio vascular diseases etc. One such alarming condition, which is on a high rise in the society, is Dyslipidemia. According to World Health Organisation (WHO) almost one fifth (18%) of global stroke events and about 56% of Global Heart diseases are attributed to Hyperlipidemia. This is responsible for about 4.4 million deaths (7.9% of total) and 2.8% of global disease burden[1]. Dyslipidemia has been found to be one of the most important contributing factors for Cardio vascular disease (CAD) which is the most prevalent cause of death and disability in both developed and developing countries[2].

The etiology and pathogenesis of Dyslipidemia, to a great extent is alike the *Nidana* and *Samprapti* of *Medoroga.* The causes of Dyslipidemia like junk and fatty food, sedentary life style etc. are much similar to *Ati snigdha, Guru, Picchila ahara sevana* and *Cheshta dvesha* which leads to *Medoroga* and *Medo Vridhi*. In addition being a metabolic syndrome, there is a definite relation between pathophysiology of Dyslipidemia with the *Agnivaigunya* at different levels, starting from *Jatharagni* up to *Dhatvagni*. *Ayurveda* as well considers *Agni vikriti* as the root cause of *Medoroga*. Accordingly we can say that the most similar condition which can be put side by side to Dyslipidemia is *Medoroga.*

Shigru is a commonly available plant cultivated all over India. Its leaves and fruits (pods) are used in preparation of food. In *Ayurveda* it has been mentioned as a common ingredient in various formulations for *Sthula chikitsa* by *Acharya Charaka*[3] and *Acharya Vagbhata*[4]. According to Ayurveda Pharmacopoeia of India, *Moringa oleifera* Lam. belonging to Moringaceae

family is the botanical source of *Shigru.* Experimental studies have proved its Anti Hypertensive, Hypocholesteromic, Anti ulcer and Wound healing properties[5-8]. It is also established that the aqueous extract of *Moringa oleifera* Lam. stem bark is significant to reduce the levels of cholesterol, triglycerides, VLDL and LDL and to increase the level of HDL[9].

Based on the above references *Shigru* (*Moringa oleifera* Lam.) can be considered as a beneficial drug in Dyslipidemia. Hence this study has been undertaken to evaluate the effect of stem bark powder of *Shigru* (*Moringa oleifera* Lam.) in Dyslipidemia.

Considering its greater prevalence and need for the search of a cost effective alternative medicine that can prevail over Dyslipidemia with no side effects, this study has been taken.

Objectives of the study

- To evaluate the efficacy of stem bark powder of *Shigru* (*Moringa oleifera* Lam.) in Dyslipidemia.

MATERIALS AND METHODS

Sample: The patients (samples), coming under the inclusion criteria, were randomly selected for the study from the OP units of the Dept. of Dravyaguna and other Departments of Govt. Ayurveda College Hospital, Tripunithura.

Sample frame

a. **Study design:** Single arm, Randomized, Interventional, Quasi-experimental
b. **Sample size:** 30
c. **Study duration:** 18 months
d. **Selection of patients:** As per inclusion and exclusion criteria
e. **Study setting:** Govt. Ayurveda College Hospital, Tripunithura, Kerala

Inclusion criteria

a. Patient of both sexes having any one or all of the following altered lipid levels will be selected. (ATP III Guidelines, NCEP)
   - Total cholesterol above 200mg/ dl
   - LDL cholesterol above 130mg/dl
   - HDL cholesterol below 40 mg/dl
   - Triglycerides above 150mg/dl
b. Age group- 20 – 70 years
c. Patient willing to give written informed consent.

Exclusion criteria

a. Patient below 20 years and above 70 years.
b. Patient having serious Cardiac disorders like MI, Cardiac failure etc.
c. Severe Hepatic disorders, Renal insufficiency
d. Pregnant and lactating females
e. Patient having history of untreated Thyroid disorders
f. Uncontrolled Diabetes mellitus
g. Patients taking any other form of medication for Dyslipidemia.
h. Any other condition that may jeopardize the study.

Drug preparation

1. Study drug: The drug used in the study was *Shigru twak churna* (stem bark powder of *Moringa oleifera* Lam.).

2. Collection of raw materials: The study drug, stem bark of *Shigru* (*Moringa oleifera* Lam.) was collected from the open market and was pharmacognostically identified.

3. Preparation of medicine: Stem bark of *Shigru* (*Moringa oleifera* Lam.) was checked for earthly and foreign matter, allowed to dry in shade. After attaining proper dryness the drug was made into fine powder of mesh size-120. Then this powdered drug was filled into 500mg capsules.

Dose and mode of administration

The dose was fixed as per Ayurveda Pharmacopoeia of India. The patients were advised to take 3 gm of *Shigru twak churna* (2 capsules thrice a day, i.e. 1gm drug thrice a day) along with lukewarm water before food for a continuous period of 45 days.

Table 1: Treatment Schedule

Particulars	Details
Sample size	30
Drug	*Shigru twak churna*
Form of medication	Capsule
Dose	3gm (2 capsules thrice a day, i.e. 1gm drug thrice a day)
Anupana	Luke warm water
Duration	45 days

Assessment Criteria

The patients were assessed mainly on the investigation of fasting lipid levels like

- Serum total cholesterol.
- Serum low density lipoprotein.
- Serum very low density lipoprotein.
- Serum high density lipoprotein.
- Serum triglycerides.

These were assessed before taking drug, on 15th & 30th day and after the completion of intervention (i.e. on 45th day). Changes in subjective symptoms like palpitation, chest pain, and heaviness of body, breathlessness on exertion, excessive sleep, excessive sweating and lethargy were evaluated before and after treatment. The change in the body weight was also assessed on 1st day and after completion of intervention.

Follow up

A follow up was done for three months, all patients were advised to come to OPD at regular interval of 1 month after study period, but in case of any feeling of discomfort they were advised to come to OPD at any time. Both subjective and objective data were collected from patients at regular intervals and were documented.

Ethical considerations

An informed consent was obtained from all patients before trial. The conditions of informed consent were fully carried out and autonomy of the patients was given

utmost respect. Approval from Institutional Ethical Committee was also obtained and the details of the study were also informed to the committee periodically.

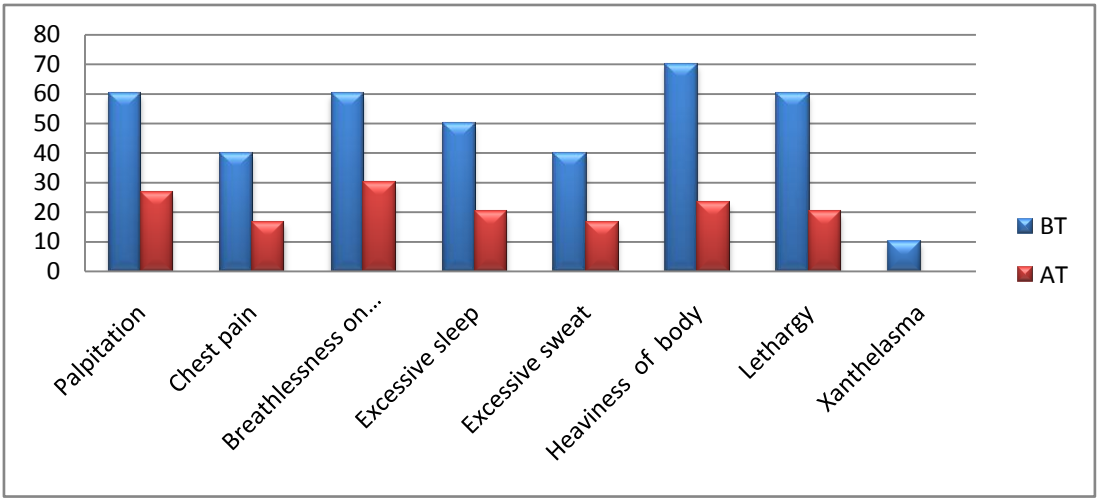
Results and Discussion

The information gathered on the basis of above observations was subjected to statistical analysis using suitable statistical tools. Arithmetic mean (AM), standard deviation (SD), mean difference (MD), frequencies and percentages were used for summarizing the collected data. Paired 't' test was applied for the objective parameters which are measured on an interval scale to analyze the before –after effect of therapy of respective parameters. Chi square test was carried out for subjective criteria to analyze the before –after effect of therapy of respective parameters.

1. Effectiveness of treatment on clinical symptoms

Table 2: Effectiveness of treatment on clinical symptoms

Symptom	BT		AT		Chi square	P value
	N	%	N	%		
Palpitation	18	60	8	26.67	6.780	<0.05
Chest pain	12	40	5	16.67	4.020	<0.05
Breathlessness on exertion	18	60	9	30	5.450	<0.01
Excessive sleep	15	50	6	20	5.930	<0.01
Excessive sweat	12	40	5	16.67	4.020	<0.05
Heaviness of body	21	70	7	23.33	13.12	<0.001
Lethargy	18	60	6	20	10.00	<0.001



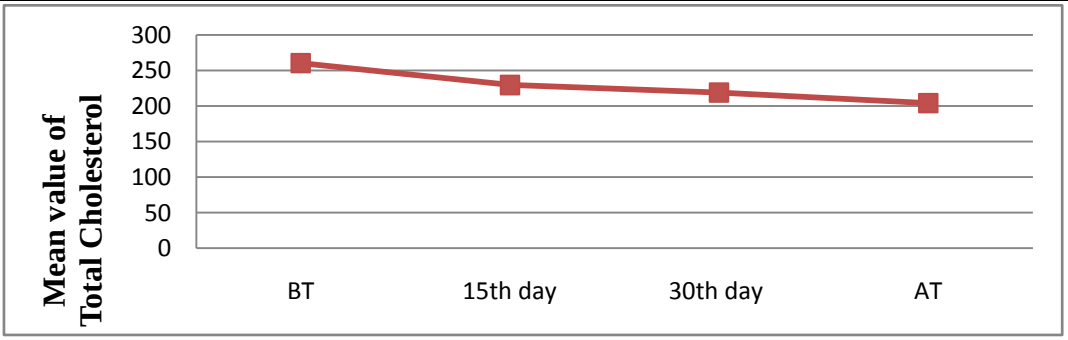
Graph 1: Effectiveness of treatment on Clinical symptoms

Chi square analysis showed that reduction in symptoms like palpitation, chest pain and excessive sweating was statistically significant ($p<0.05$). Effectiveness of the drug on breathlessness on exertion and excessive sleep was also found to be statistically highly significant ($p<0.01$). Also there was a marked reduction in symptoms like heaviness of body and lethargy and it was found to be highly significant ($p<0.001$).

2. Evaluation of the effectiveness of interventions on Blood parameters

Table 3: Effectiveness of treatment on total cholesterol

Stage	Mean	SD	N	Group	Mean difference	Paired 't'	P
BT	260.26	39.708	30	BT Vs 15th	30.766	1.198	>0.05
15th day	229.50	38.884	30	BT Vs 30th	10.6	3.779	<0.001
30th day	218.90	31.772	30	BT Vs AT	14.8	4.319	<0.001
AT	204.10	30.465	30				



Graph 2: Analysis of effect of treatment on Total Cholesterol

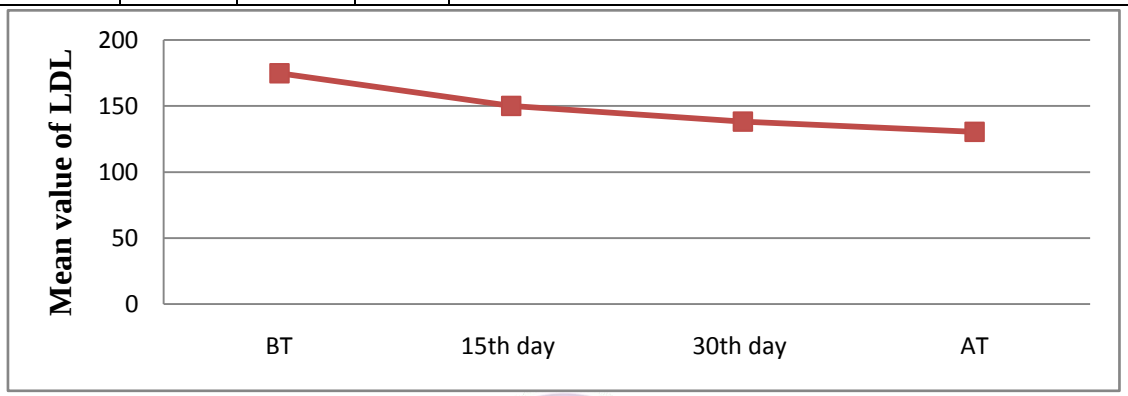
Total cholesterol was analyzed before intervention, on 15th day, 30th day and after intervention. Considering the changes in total cholesterol values before treatment and on the 15th day reduction of 30.766 was observed in mean which was statistically not significant (p>0.05).

On evaluating the total cholesterol values before treatment and on 30th day of intervention reduction in mean was 10.6 which was highly significant (p<0.001). Analyzing total cholesterol values before and after intervention mean difference observed was 14.8 and the reduction was found to be highly significant (p<0.001).

3. Effectiveness of treatment on LDL cholesterol

Table 4: Effectiveness of treatment on LDL cholesterol

Stage	Mean	SD	N	Group	Mean difference	Paired 't'	P value
BT	174.73	40.994	30	BT Vs 15th	23.80	0.0001	>0.05
15th day	150.93	43.811	30	BT Vs 30th	12.83	2.7248	<0.05
30th day	138.10	34.042	30	BT Vs AT	9.769	3.9120	<0.001
AT	130.33	40.025	30				



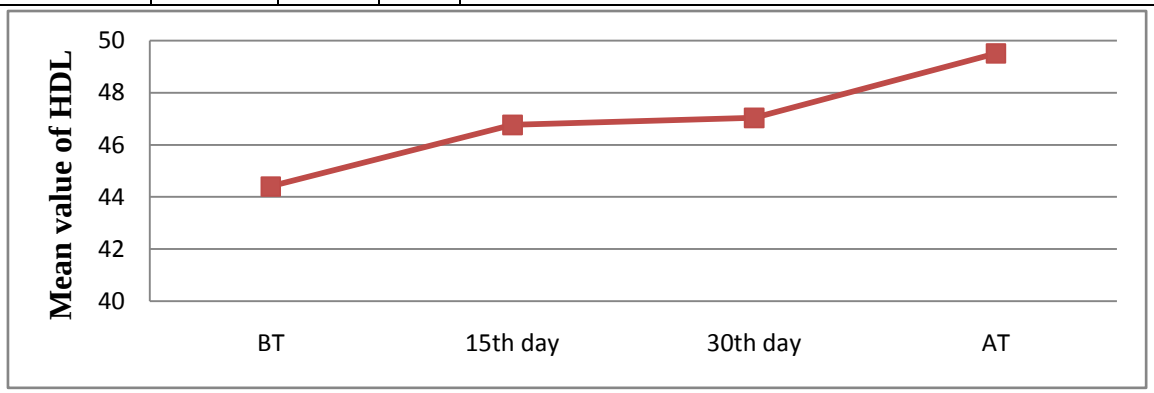
Graph 3: Analysis of effect of treatment on LDL

On analyzing the changes in LDL values before treatment and on the 15th day, reduction observed in mean was 23.80 which was statistically not significant (p>0.05). On evaluating LDL values before treatment and on 30th day of intervention, mean difference of 12.83 was observed which was statistically significant (p<0.05). Analyzing LDL values before and after intervention, the mean difference of 9.769 was observed and the reduction was found to be highly significant (p<0.001).

4. Effectiveness of treatment on HDL cholesterol

Table 5: Effectiveness of treatment on HDL cholesterol

Stage	Mean	SD	N	Group	Mean difference	Paired 't'	P
BT	44.40	9.015	30	BT Vs 15th	2.360	0.0264	>0.05
15th day	46.76	8.045	30	BT Vs 30th	0.270	0.0303	>0.05
30th day	47.03	8.256	30	BT Vs AT	2.470	0.0010	>0.05
AT	49.50	9.694	30				



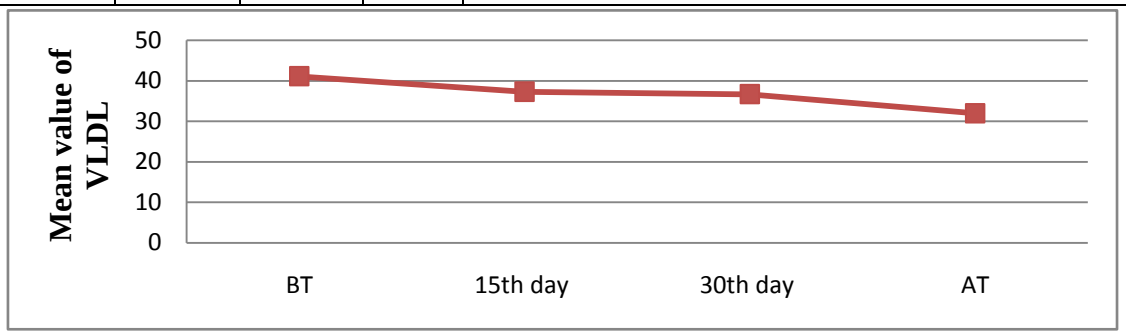
Graph 4: Analysis of effect of treatment on HDL

On analyzing the changes in HDL values before treatment and on the 15th day, an increase of 2.36 was observed in mean which was statistically not significant (p>0.05). On evaluating HDL values before treatment and on 30th day of intervention, an increase of 0.27 was observed in mean, but it was statistically not significant (p>0.05). Analyzing HDL values before and after intervention, an increase of 2.47 was observed in mean, which was also statistically not significant (p>0.05).

5. Effectiveness of treatment on VLDL cholesterol

Table 6: Effectiveness of treatment on VLDL cholesterol

Stage	Mean	SD	N	Group	Mean difference	Paired 't'	P
BT	41.066	19.592	30	BT Vs 15th	3.80	0.0177	>0.05
15th day	37.266	18.192	30	BT Vs 30th	0.60	0.0152	>0.05
30th day	36.666	20.672	30	BT Vs AT	4.70	2.9844	<0.01
AT	31.966	13.296	30				



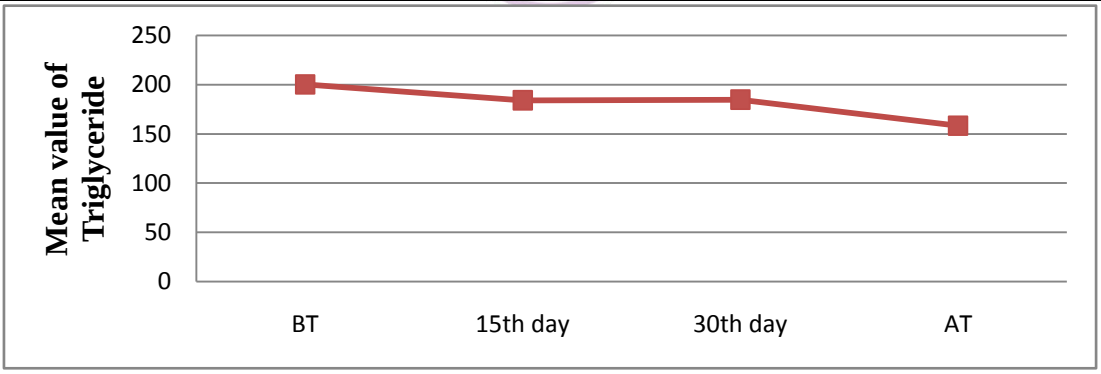
Graph 5: Analysis of effect of treatment on VLDL

Considering the changes in VLDL values before treatment and on the 15th day, reduction observed in mean was 3.80, which was statistically not significant (p>0.05). On evaluating VLDL values before treatment and on 30th day of intervention, reduction observed in mean was 0.60, but it was statistically not significant (p>0.05). Analyzing VLDL values before and after intervention mean difference observed was 4.70 and the reduction was found to be statistically highly significant (p<0.01).

6. Effectiveness of treatment on Triglyceride

Table 7: Effectiveness of treatment on Triglyceride

Stage	Mean	SD	N	Group	Mean difference	Paired 't'	P value
BT	200.16	98.293	30	BT Vs 15th	16.10	0.0248	>0.05
15th day	184.06	87.348	30	BT Vs 30th	0.67	0.0196	>0.05
30th day	184.73	102.08	30	BT Vs AT	26.47	6.6776	<0.001
AT	158.26	79.023	30				



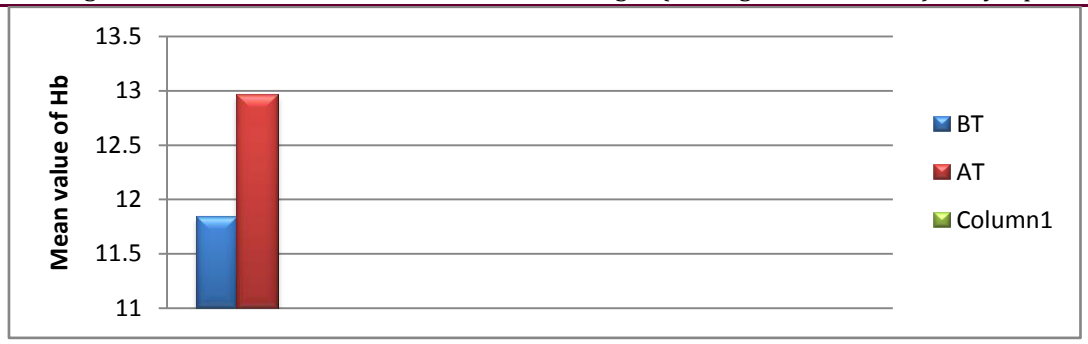
Graph 6: Analysis of effect of treatment on Triglyceride

Considering the changes in triglyceride values, before treatment and on the 15th day, reduction observed in mean was 16.10, which was statistically not significant (p>0.05). On evaluating triglyceride values before treatment and on 30th day of intervention, reduction observed in mean was 0.67, but it was statistically not significant (p>0.05). Analyzing triglyceride values before and after intervention, mean difference observed was 26.47 and the reduction was found to be highly significant (p<0.001).

7. Effectiveness of treatment on Haemoglobin

Table 8: Effectiveness of treatment on Haemoglobin

Stage	Mean	SD	N	Mean Difference	Paired 't'	P
BT	11.84	2.029	30	1.12	1.0285	0.6663
AT	12.96	1.824	30			



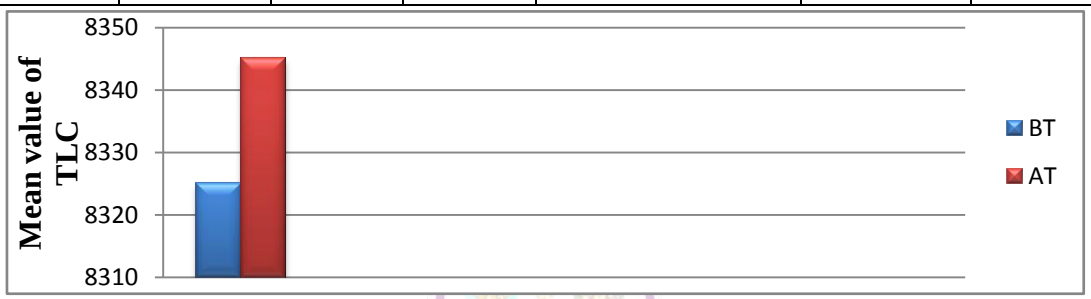
Graph 7: Analysis of effect of treatment on Haemoglobin

On analysis the effectiveness on haemoglobin the difference in mean was 1.12 and it was statistically not significant in increasing the Haemoglobin (p>0.05).

8. Effectiveness of treatment on Total Leucocyte Count

Table 9: Effectiveness of treatment on Total Leucocyte Count

Stage	Mean	SD	N	Mean Difference	Paired 't'	P value
BT	8325	1130.4	30	20	0.5247	0.6058
AT	8345	1051.6	30			



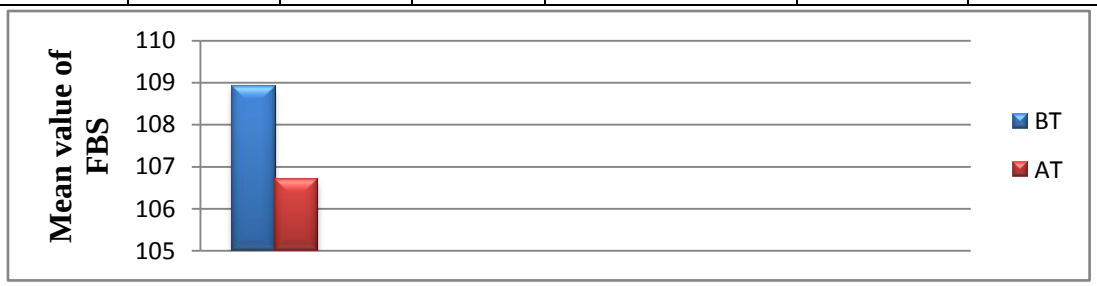
Graph No.8 Analysis of effect of treatment on TLC

On analyzing the changes in Total Leucocyte Count value, an increase of 20 was observed in mean which was statistically not significant for increasing Total Leucocyte Count (p>0.05).

9. Effectiveness of treatment on FBS

Table 9: Effectiveness of treatment on FBS

Stage	Mean	SD	N	Mean Difference	Paired 't'	P
BT	108.9	11.756	30	2.2	2.152	0.0445
AT	106.7	8.189	30			



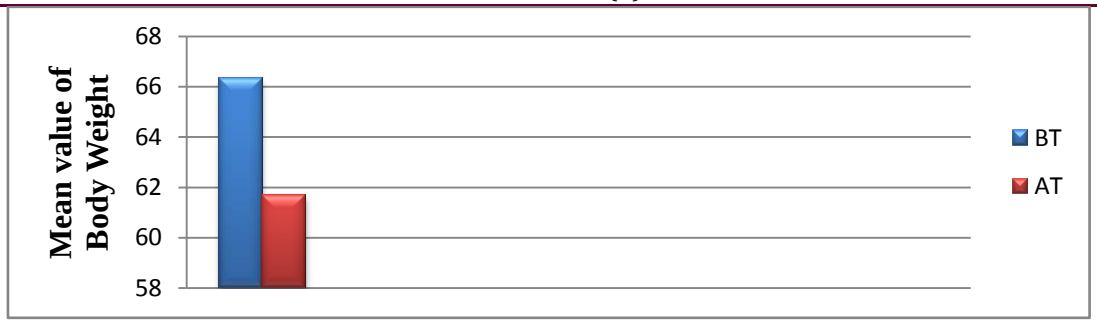
Graph 8: Analysis of effect of treatment on FBS

On analyzing the changes in FBS reduction of 2.2 observed in mean which was statistically significant (p<0.05) for reduction in FBS level.

10. Evaluation of the efficacy and comparison of intervention on body weight

Table 10: Effectiveness of treatment on body weight

Stage	Mean	SD	N	Mean Difference	Paired 't'	P value
BT	66.33	10.94	30	4.63	9.976	<0.05
AT	61.70	9.97	30			



Graph 9: Analysis of effect of treatment on Body weight

On comparing body weight before and after treatment reduction of 4.63 was observed in mean which was statistically significant ($p<0.05$)

DISCUSSION

Shigru as the name implies that which is *Tikshna* in nature; is endowed with the properties like *Tikta, Katu rasas, Laghu, Ruksha, Tikshna gunas, Ushna veerya* and *Katu vipaka*.

Tikta rasa is having the properties *Agni deepana, Ama pachana, Lekhana* and *Kleda-meda-vasa-majja-sweda upshoshana. Katu rasa* possess properties like *Agni deepana, Ama pachana, Sroto vivarana* (dilating *Srotas*), *Shodhana, Lekhana, Srotobandha bhedana* (removing obstruction in the *Srotas*) and *Kleda-meda vishoshana. Sroto vivarana* and *Lekhana* property of *Katu rasa* has direct action on *Srotas;* thereby clearing the *Srotosanga* and dilating the body channels; thus providing proper nourishment to the *Dhatus*, which was previously hampered by the blocked *Srotas*. Also *Katu rasa* is having the property of *Kleda meda vishoshana* and *Kapha samana.* In *Medoroga*, *Meda Dhatu* is increased; here *Katu rasa* owing to its *Kleda-meda vishoshana* property causes *Vishoshana* of *Medo dhatu* and thus alleviates the excess *Meda.* Thus, both the *Rasas* in *Shigru* plays vital role in *Samprapti vighatana* of *Medoroga* through *Agni deepana, Ama pachana, Kapha shamana* and *Meda vishoshana* properties. *Laghu* and *Ruksha guna* exhibits their action through *Samanya- Vishesha sidhanta* to reduce *guru* and *Snigdha guna* of *Ama* and *Medo dhatu.* Constriction in *Srotas* is relieved through *Laghu, ruksha* and *Tikshna guna.* Furthermore *Tikshna guna* is responsible for cleaning action of body channels and fast action of the drug. Main *Dosha* vitiated in *Medoroga* is *Kapha* and *Vata. Ushna virya* of *Shigru* pacifies the vitiated *Vata* and also alleviates *Kapha dosha.* Moreover it is *Agni Vardhaka* and *Pachaka* therefore corrects the vitiated *Agni* and alleviates the *Ama*.

At *Dhatu* level due to *Medoshoshana* property of *Katu, Tikta rasa* and *Laghu, Ruksha guna*, the drug brings down the increased *Medodhatu* to normalcy. On considering the drug action on *Srotas* due to *srotoshodhaka* and *Lekhana* property of *Katu* and *tikta rasa,* and *Gunas* like- *Laghu, Ruksha* and *Teekshna;* it removes *Srotorodha*. As well as owing to its *Laghu guna* it goes through the minute *Srotas*. Also due to its *Teekshna guna* the drug action is prompt.

Considering the action of *Shigru* on *Agni;* its *Agni deepana* property, *Laghu* and *Teekshna guna* will alleviate the vitiated *Jatharagni* and *Dhathavagni*. As a result of this *Dhatu nirmana* process gets normal up and this ultimately leads to their proper formation. The *Ama Pachana* property of its *rasa* (*Katu, Tikta rasa*) and *Guna* (*Laghu* and *Ruksha*) will alleviate *Ama,* which is also the root cause of *Medoroga.*

Thus *Shigru* is vital in *Samprapti vighatana* of *Medoroga* owing to its *Tikta, Katu rasas, Laghu, Ruksha, Tikshna gunas, Ushna veerya* and *Katu vipaka*.

Experimental researches have also proved that *Shigru (Moringa oleifera* Lam.) decreases Total cholesterol and Triglyceride level by increasing activity of extra hepatic lipoprotein lipase[10] which is responsible for circulating lipoprotein in a non atherogenic direction by efficient lipogenesis of triglyceride rich lipoprotein in heart, skeletal muscle and adipose tissue[11]. β-sitosterol was isolated from the stem of *Moringa oleifera* Lam[12-13]. It is a plant sterol and is believed to lower cholesterol by lowering plasma concentrations of LDL[14]. Also it inhibits the reabsorption of cholesterol and thus increases its excretion into faeces (in the form of neutral steroids) that results in decrease of body lipids[15].

Accordingly from the above symposium on the *Rasapanchaka;* it can be concluded that the drug *Shigru* substantially shows *Medohara* property (antihyper-lipidemic activity) and is competent in treatment of Dyslipidemia. Experimental researches also prop up its antihyperlipidemic and antioxidant activities; which confirms that it can be utilized as an efficient drug for Dyslipidemia. Hence *Shigru* is having all the pharmacological properties for the treatment of *Medoroga*.

Thus the present study reveals that, there is a significant difference in clinical and biochemical parameters of Dyslipidemia patient before and after receiving *Shigru twak choorna*. So it can be said that *Shigru twak* has shown noteworthy efficacy in reducing serum lipid levels and clinical symptoms. At the same time through the observation it is exceedingly apparent that the drug showed even far better results in reducing the objective and subjective parameters when taken for longer duration.

CONCLUSION

On the basis of this study it can be concluded that, Dyslipidemia to some exposure can be considered as a sharing out of *Medoroga,* specifically as *Medo dhatu vriddhi. Vata-kapha prakriti* individuals are seen to be more affected by Dyslipidemia. Patients treated with *Shigru twak* showed that there was a significant decrease

in S. Cholesterol, S. LDL, S. VLDL, S. Triglycerides, FBS and body weight. Though the test drug *Shigru twak* was significantly not effective in increasing the HDL cholesterol level but there was a considerable increase in it; may be a prolong use of the drug can be helpful in escalating the S. HDL level up to a significant level. Also no adverse effect was observed during the clinical study.

The results shown by drug *Shigru* (*Moringa oleifera* Lam.) can be attributed to its *Katu, Tikta Rasa, Laghu-Ruksha, Teekshna Guna, Ushna veerya, Katu Vipaka* and *Kapha-vata shamana* properties.

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