Research Article

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EFFECT OF TIKTA KATU RASA OF SHIGRU (*MORINGA OLEIFERA*) IN THE MANAGEMENT OF HYPERLIPIDEMIA: AN OPEN CLINICAL TRIAL

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ABSTRACT

Hyperlipidemia is one among the leading risk factors of cardiovascular diseases (CVD) accounting for one third of the total death around the world. As per Ayurveda, the abnormal hike of the 4th dhatu meda, results in Hyperlipidemia. The contemporary treatment for Hyperlipidemia using statin drugs have triggered many controversies due to the adverse effects on long term use. The concept of application of rasa in treatment is unique to Ayurveda. Tikta and katu rasa are said to have a scarifying effect on increased kapha and meda. The study was an open clinical trial on 30 patients selected through convenient sampling .15 ml of fresh juice of leaves of Shigru in the morning on empty stomach was administered for 14 days. The participants were assessed for subjective parameters and objective parameters before and after treatment and also after 1-month follow-up. The improvements in the subjective parameters like fatigue and breathlessness was found to be statistically significant ($p < 0.001$). The lipid profile of the participants also showed significant results after treatment and follow-up ($p < 0.001$). The pathophysiology of Hyperlipidemia as per Ayurveda can be explained as an initial phase of medo Dhatu Vriddhi and the latter phase of Ati Sthoulya, based on the pathological fluctuations in the quality of agni. The 14-day intervention was effective in correcting the decreased Dhatwagni, and the drying out excess kapha and meda instigating a depletory effect on medo Dhatu Vriddhi.

Keywords: Medo Dhatu Vriddhi, Hyperlipidemia, Shigrupatra Swarasa, Katu-tikta rasa

INTRODUCTION

Hyperlipidemia is defined as the condition with total cholesterol, low-density lipoprotein (LDL), triglycerides (TG), or very low-density lipoprotein (VLDL) levels greater than the 90th percentile in comparison to the general population, or a high-density lipoprotein (HDL) level less than the 10th percentile when compared to the general population[1]. It is one among the leading risk factors of cardiovascular diseases (CVD) accounting for one third of the total death around the world.[2] However, the prevalence of Hyperlipidemia varies from region to region around the globe.[3]

Ayurveda advocates that health is maintained by the balance between the three dosha (regulatory functional factors of the body), a balanced agni (digestive factors), the balance between seven dhatu (structural components of the body), healthy srotas (structural or functional channels) and proper excretion of mala (waste products).[4] Any disruption in the inherent balance of these elements can result in infirmities.[5] Meda (fat tissue), fourth among the seven dhatu having similar qualities of kapha (Dosha responsible for regulating body fluids and keeping the body constituents cohesive), is constituted predominantly by Prithvi (earth element) and Jala (water element) Mahabhuta (basic elements of physical constitution).[6,7]

The derangement of any one of the seven dhatu can hamper the quality of life of an individual and likewise unduly excess medo dhatu results in complications.[8] Most cases of hyperlipidemia show little or no symptoms at first but its imbalance will be noticed gradually. Medo Dhatu Vriddhi (excess in medo dhatu) in its later stages is marked by fatigue on exertion, breathlessness, sagging of buttocks, breasts and abdomen.[9]

The contemporary treatment for Hyperlipidemia revolve around the use of statin-based drug combinations and the long-term use of these drugs have triggered many controversies regarding its side effects.[10,11] The search for alternative therapies for its management is a long-standing need. Single drug therapies in Ayurveda provide simple, cost effective yet potential remedies for common lifestyle related ailments and associated morbidities. The concept of application of rasa (taste) in treatment is unique to Ayurveda. The tikta (bitter) and katu (pungent) rasa are said to have a scarifying effect on increased kapha and meda.[12] So, tikta-katu rasa predominant drugs can be utilized in Hyperlipidemia. Shigru (*Moringa oleifera*) a member of the Moringaceae family, is a perennial angiosperm native to the Indian subcontinent have predominant tikta-katu rasa.[13] The hypolipidemic effects of Shigru have been reported in several Ayurveda and contemporary literatures. The present paper evaluates the efficacy of tikta-katu rasa of Shigru Patra Swarasa (fresh juice) in Hyperlipidemia (Medo Dhatu Vriddhi).

Objective

To assess the efficacy of tikta-katu rasa of Shigru Patra Swarasa (fresh juice of Moringa oleifera leaves) in the management of Hyperlipidemia (Medo Dhatu Vriddhi)

MATERIAL AND METHODS

Study Design

The study was an open clinical trial on 30 Hyperlipidemia patients. The trial was approved by the Institutional Ethics Committee of SJGAMC & HRI, Koppal. (Reference Number:

SJGAMC & HRI Clinical Ethical Committee 17/261 Dated 18/5/2017)

Source of data

Primary data was collected from patients attending the Out-Patient Department of SJGAMC & HRI, Koppal. Standard Ayurveda textbooks, contemporary modern medicine textbooks, available online database and websites using google as the search engine were reviewed and documented for this study.

Study Setting

Out Patient Department of SJGA Medical College & Hospital, Koppal.

Method of Sampling

Convenient Sampling

Inclusion criteria

- Adults of any gender.
- Between 30 to 60 years of age
- Diagnosed with Hyperlipidemia (with raised Serum Total Cholesterol above 200 mg/dL)

Exclusion criteria

- Subjects on medication for Hyperlipidemia.
- Pregnant and lactating women.
- Subjects with Hepatic and Renal diseases.
- Subjects with Diabetes mellitus.
- Subjects with any substance abuse.
- Subjects with Immuno-deficiencies.
- Subjects with Thyroid diseases.
- Subjects on corticosteroids, diuretics, beta-blockers, oral-contraceptives, cyclosporin, androgens and retinoids.

Method of collection of data

The participants who satisfied the inclusion criteria were selected. Data was collected on the 0^{th} day (before treatment), 15^{th} day (after 14 days treatment) and after 1 month follow-up.

Study tool

- A self-designed case record form was used for the assessment of medo Dhatu Vriddhi and lipid levels in blood.
- The blood samples were drawn for assessing the lipid profile on the 0^{th} day, 15^{th} day and after 1 month follow-up.
- 25 ml of fresh juice of the leaves of Shigru was administered in the morning (empty stomach) for 14 days following Dietary modifications. (Table 1)
- Participants were advised to continue with the dietary modifications for one more month, and data was collected after one month follow-up.

Intervention

Drug: Shigru (*Moringa oleifera*) (Table 2)[13]
Part used: Leaves
Form of administration: Fresh juice
Dosage: 25 ml
Time of administration: Morning, empty stomach
Duration: 15 days
Follow-up: After 1 month

Assessment criteria

Self-prepared rating scale for subjective data and lipid profile of the participants before treatment, after treatment and after follow-up were collected to analyse the changes.

Statistical tests used

The collected data was tabulated and analysed with appropriate statistical tests using SPSS (Statistical package for social sciences-version 20). Demographic data were analysed with statistical means and proportions. Subjective parameters and objective parameters were analysed using Wilcoxon sign rank test and 'paired t' test respectively.

RESULT

42 subjects were screened for the inclusion criteria and 30 were selected and registered for the study. There were no drop outs reported during the study.

Demographic data

Out of 30 subjects, 70% were from the age group of 51-60 years, 20% were from 41–50 years and the rest 10% were from 30-40 years. 53.33% of the participants were female. 96.66% of the participants were from Hindu community. The socio-economic status of 73.3% subjects were middle class and rest 26.67% were from upper class.

Subjective parameters

Out of 30 participants, 100% reported fatigue, 93.33% reported breathlessness, and 70% reported 'sagging of buttocks, breasts and abdomen'. After the intervention, highly significant reduction was noted in Fatigue and breathlessness ($p < 0.001$). The results after follow-up were also found to be highly significant ($p < 0.001$). Changes in 'sagging of buttocks, breast and abdomen' were not statistically significant after treatment as well as after follow-up. (The results are summarized in Table 3)

Objective parameters

Out of 30 participants, 100% reported elevated levels of total cholesterol above 200 mg/dL. 96.66 % of the participants were having elevated TG above 150 mg/dL, 63.33% were having elevated LDL above 130 mg/dL, 100% were having elevated VLDL above 40 mg/dL, and 76.66% were having lowered HDL levels below 40 mg/dL. After the intervention, highly significant reduction was noted in of total cholesterol, TG, LDL and VLDL ($p < 0.001$). The results after follow-up were also found to be highly significant ($p < 0.001$). Improvement in the values of HDL was also noticed at these time points ($p < 0.001$). (The results are summarized in Table 4)

The overall results are summarized in Figure 1-3.

DISCUSSION

Hyperlipidemia is a chronic, progressive metabolic derangement which demands the use of potential lipid-lowering drugs along with dietary and lifestyle modifications. Evidences suggest that elevated levels of lipids in blood increase the risk for the development of atherosclerotic plaques and subsequent vascular diseases.[14] Treatment of Hyperlipidemia is completely based on its underlying pathophysiology. The group of drugs called 'statins' and 'fibrates' are commonly prescribed in this regard.[15] However, these drugs have been associated with complications

like rhabdomyolysis and other muscular diseases.[16,17] The use of traditional medicines and single drug therapies are important aspects of primary and secondary prevention of lifestyle related disorders in a developing country like India. Single drug therapies with minimal side effects are seldom explored, and subjected to scientific evaluation for its efficacy as well as toxicity.

The pathophysiology of Hyperlipidemia can be explained as two phases in Ayurveda, initial phase of medo Dhatu Vriddhi and the latter phase of Ati Sthoulya (obesity). Both phases are based on the pathological fluctuations in the quality of agni.

Agni is responsible for all metabolic activities and for the maintenance of a homeostasis between dosha, dhatu and mala. Jatharagni (metabolic factors located in digestive tract), Bhutagni (metabolic factors located in mahabhuta), and Dhatwagni (metabolic factors located in dhatu) go hand-in-hand in dhatu Poshana (nourishment of dhatu). Impairment of agni may invoke an imbalance in any one of these leading to a state of Ama (toxic by-products of abnormal digestion).

If the jatharagni is diminished, Ama will be restricted to koshtha (digestive tract) hampering the normal production of ahara rasa (first metabolites of digestion) resulting in Dhatu Kshaya (undernourishment of body tissues).

If the Bhutagni is diminished, Ama will be restricted to ahara rasa which becomes incapable of nourishing subsequent dhatu and resulting in Dhatu Kshaya. The Ama thus formed gets accumulated at different sites of the body leading to infirmities. It is important to note that, when a particular Bhutagni diminishes, impairment happens in the nourishment of that particular dhatu which is having the predominance of that particular Mahabhuta.

If the Dhatwagni is diminished, then the particular dhatwagni cannot assimilate nutrients from the circulating ahara rasa or the circulating Poshaka dhatu (source of dhatu). So, such Poshaka dhatu will get accumulated in ahara rasa in abnormal quantities at abnormal sites. This pathological process is termed as leenatwa (deep seated) of Ama in dhatu. Impairment of jatharagni eventually impairs Bhutagni and Dhatwagni which is a fundamental process in the pathogenesis of any chronic metabolic disorders.

When the above-mentioned pathologies influence medo dhatu, there arises an abnormal increase in the Poshaka medo dhatu circulating in the body. This may be referred to the increased lipid values or Hyperlipidemia. This is because the Poshaka medo dhatu cannot be assimilated into stable medo dhatu by medo dhatwagni. Moreover, any causes which can lead to Kapha Vriddhi, Pitta Kshaya or vata prakopa, can result in such a condition. The excess Poshaka medo dhatu may accumulate on the walls of dhamani (arteries) and may cause serious complications related to circulation causing dhamani pratichaya (coating of arteries).

The latter phase of Medo Dhatu Vriddhi is called ati Sthoulya. The intake of high calorie diet and sedentary lifestyle increases medo dhatu. The increased meda causes avarana (occlusion) of vata especially in koshta. The encaged vata (Doṣha responsible for movement and cognition) along with Pachaka agni (metabolic fire) cause an abnormal increase in the agni. This triggers a delayed satiety and increased intake of food and fluids causing further Medo Dhatu Vriddhi. If left untreated, the superfluous accumulation of medo dhatu will cause undernourishment of succeeding three dhatu viz. Asthi (bone tissue), Majja (bone marrow), and Shukra (Reproductive fluids).[8] This abnormality in the metabolism of meda will lead to eight complications enumerated as Ayuhrasa (decrease of life span), Javoparodha (decrease in enthusiasm and activity), krichravyavayata (difficulty in sexual act), dourbalya (decrease of strength), Daurgandhya (bad odour), swedabadha (excess perspiration) and kshut pipasa adhikya (excessive hunger and thirst). Thus, the abnormal state of medo dhatu results in the metabolic syndrome including Hyperlipidemia.[8]

Ayurveda categorise drugs into many gana (groups) based on similarity in their properties, viz. pharmacological actions, therapeutic functions etc. Evidence shows that many of the herbs mentioned in Medohara gana (group of drugs that scale down abnormal meda dhatu) possess hypolipidemic as well as hypoglycaemic action.[18]

Regarding the demographic profile of the participants, majority of the patients belonged to the older age group. This goes hand in hand with the fact that the number of Hyperlipidemia patients and the complications associated with it escalates with increasing age.[19] 10% of the participants were from a younger age group (30-40 years). The degree of Hyperlipidemia was found to be highest among patients with premature coronary artery disease.[1] The higher prevalence of Hyperlipidemia in younger adults clearly indicates the high-risk ratio of CVD in younger age groups.

Gender-wise, Women are more likely to be affected with Hyperlipidemia and associated lipid metabolic errors.[20] Here the study revealed similar observations with 53.33% of the sample being females. Analysing the socio-economic factors, 73.33% of the samples belonged to middle class families and the rest were from upper class families. No subjects were registered from lower class family. Studies show that risk factors of CVD like the tobacco and alcohol use, low intake of fruit and vegetables, and underweight were more common in lower socioeconomic positions; whereas obesity, dyslipidaemia, diabetes and hypertension were more prevalent in higher socio-economic positions. [21]

Hyperlipidemia is a condition that is often associated with the pathogenesis of many diseases and obesity is one among them. The features of medo Dhatu Vriddhi as per Ayurveda are seen to be associated with ati Sthoulya. Analysis of the subjective data in the current study revealed that the participants showed significant improvement in fatigue ($p < 0.001$) and breathlessness ($p < 0.001$) after the intervention and follow-up. Pharmacological evaluation of *Moringa oleifera* leaves extract had affirmed the anti-obesity effects in high-fat fed mice elucidating the effectiveness of the drug in medo dhatu vridhi.[22] Although no significant results were obtained in the 'sagging of buttock, breast and abdomen' ($p > 0.05$) which was quite obvious as minor change in the physical parameters in overweight and obesity demand high intensity diet modifications and exercises.[23]

The major strength of the study was the significant improvements in the lipid profile of the participants. Improvements in Total cholesterol ($p < 0.001$), TG ($p < 0.001$), LDL ($p < 0.001$) and VLDL ($p < 0.001$) was found to be highly significant after the intervention and follow-up. The HDL values of the participants also improved ($p < 0.001$) after the intervention. The hypolipidemic effects of *Moringa oleifera* leaves when evaluated pharmacologically in high-fat fed animals, had presented a significant improvement in deranged lipid profile.[24-26] Thus, the outcome of current study confirms the pharmacological evidence suggesting a positive effect of Shigru leaves on lipid homeostasis.

Table 1: dietary & lifestyle modifications

Do's	Don'ts
Observance of daily routines like sleep-wake cycle, toileting, exercising, bathing and dining.	Irregular eating habits, Picky eating.
Include vegetables like bitter gourd, Green leafy vegetables, whole grains and fruits in diet. Use garlic in food.	Oily foods, fried foods, junk foods, processed/red meat, canned food, aerated drinks and confectioneries
Drink plenty of water	Dairy products especially curd and cheese
Physical activity like jogging/cycling/ walking/swimming etc.	Sedentary lifestyle and work culture.
Yoga (for those who are comfortable)- Under the supervision of a certified trainer practice postures like *Suryanamaskara, dhanurasana, padahasthana, Ardhakati chakrasana*	Avoid exposure to potential stressors.

Table 2: Properties of Shigru *(Moringa Oleifera)*

Rasa	*Katu tikta*
Guna	*Laghu, ruksha, tikshna*
Virya	*Ushna*
Vipaka	*Katu*
Dosha karma	*Kapha vata shamaka*
Gana	*Varunadi gana, katu skanda*

Table 3: Effect of Treatment on subjective parameters (N = 30)

Comparative Pairs	Descriptive Statistics			Wilcoxon Signed Ranks				Test Statistics		
	Mean	±SD	Reduction in %	R	N	Mean Rank	Sum of Ranks	Z	P	Remarks
BT With AT Fatigue				R+ (BT > AT)	16	8.5	136.0	4.00	< 0.001	HS
BT	1.47	0.507	36%	R- (BT < AT)	0	0.0	0			
AT	0.93	0.365		R0 (BT = AT)	14	-	-			
BT With FU Fatigue				R+ (BT > FU)	17	9.0	153.0	4.02	< 0.001	HS
BT	1.47	0.507	41%	R- (BT < FU)	0	0.0	0			
FU	0.87	0.434		R0 (BT = FU)	13	-	-			
BT With AT Breathlessness				R+ (BT > AT)	17	9.0	153.0	4.12	< 0.001	HS
BT	1.43	0.626	40%	R- (BT < AT)	0	0.0	0			
AT	0.87	0.571		R0 (BT = AT)	13	-	-			
BT With FU Breathlessness				R+ (BT > FU)	21	11.0	231.0	4.58	< 0.001	HS
BT	1.43	0.626	49%	R- (BT < FU)	0	0.0	0			
FU	0.73	0.640		R0 (BT = FU)	9	-	-			
BT With AT sagging of Buttock, Breast & Abdomen				R+ (BT > AT)	1	1.0	1.0	1.00	> 0.05	IS
BT	0.30	0.466	11%	R- (BT < AT)	0	0.0	0			
AT	0.27	0.450		R0 (BT = AT)	29	-	-			
BT With FU sagging of Buttock, Breast & Abdomen				R+ (BT > FU)	1	1.0	1.0	1.00	> 0.05	IS
BT	0.30	0.466	11%	R- (BT < FU)	0	0.0	0			
FU	0.27	0.450		R0 (BT = FU)	29	-	-			

IS - Insignificant; MS - Moderately Significant; S - Significant; HS - Highly significant.
BT-before treatment; AT-after treatment; FU-follow-up; SD-standard deviation; Z-z-value; P- p value

Table 4: Effect of Treatment on objective parameters (N = 30)

Effect of Treatment on Total Cholesterol		N = 30							
Paired Samples Statistics		Paired Differences		Paired t-Test findings					
Comparative Pairs	Pairing	Mean	±SD	Decrease in %	Mean Dif.	±SE	T	P	Remarks
BT with AT	BT	236.86	27.94	6.9%	16.44	3.10	5.30	< 0.001	HS
	AT	220.41	22.71						
BT with FU	BT	236.86	27.94	9.4%	22.20	3.54	6.27	< 0.001	HS
	FU	214.66	23.42						
Effect of Treatment on Triglycerides		N = 30							
BT with AT	BT	221.34	53.96	10.4%	22.98	3.26	7.06	< 0.001	HS
	AT	198.36	46.54						
BT with FU	BT	221.34	53.96	14.7%	32.47	3.46	9.39	< 0.001	HS
	FU	188.87	47.48						
Effect of Treatment on LDL		N = 30							
BT with AT	BT	154.86	31.23	14.5%	22.45	4.76	4.72	< 0.001	HS
	AT	132.41	39.18						
BT with FU	BT	154.86	31.23	18.8%	29.07	3.02	9.63	< 0.001	HS
	FU	125.79	30.41						
Effect of Treatment on HDL		N = 30							
BT with AT	BT	48.02	10.47	8.5%	-4.47	0.97	4.62	< 0.001	HS
	AT	52.48	8.52						
BT with FU	BT	48.02	10.47	10.5%	-5.61	0.98	5.72	< 0.001	HS
	FU	53.62	8.72						

Effect of Treatment on VLDL		N = 30							
BT with AT	BT	61.69	22.31	14.7%	9.06	1.65	5.49	< 0.001	HS
	AT	52.63	18.77						
BT with FU	BT	61.69	22.31	21.3%	13.17	1.78	7.39	< 0.001	HS
	FU	48.52	18.41						

IS - Insignificant; MS - Moderately Significant; S - Significant; HS - Highly significant.
BT-before treatment; AT-after treatment; FU-follow-up; SD-standard deviation; Z-z-value; P- p value

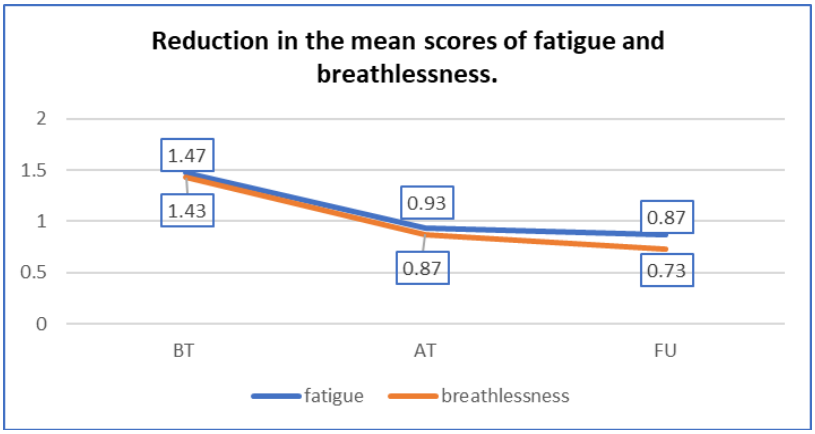

Figure 1: Reduction in the mean scores of fatigue and breathlessness

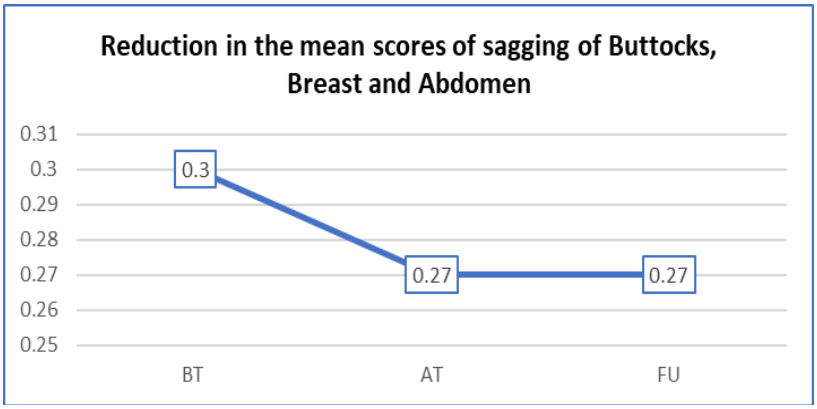

Figure 2: Reduction in the mean scores of fatigue and breathlessness

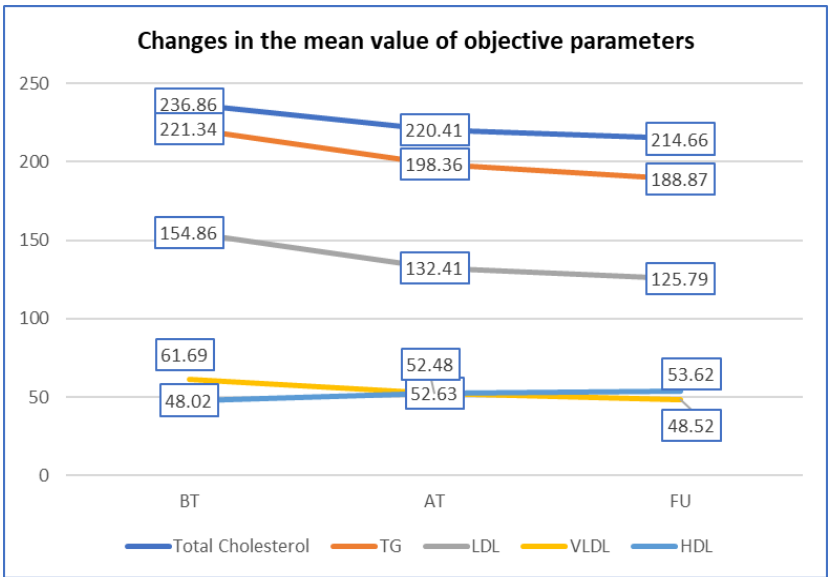

Figure 3: Changes in the mean value of objective parameters

Probable mode of action of katu-tikta rasa of Shigru in Hyperlipidemia

Shigru is katu-tikta in rasa, laghu-ruksha-tikshna in guna (light-rough and quick in quality), ushna in virya (hot in potency), katu in vipaka (bio-transformed to pungent), and kapha-vata-shamaka (subsiding kapha and vata) in karma.[13] Under classical categorization Shigru is one among Varanadi gana according to Acharya Sushruta and Acharya Vagbhata, the group of drugs which pacifies kapha and meda. It is also included in Katuka Skanda (group pf pungent drugs) by Acharya Charaka.[27] Tikta rasa being laghu and ruksha pacifies kapha and medo dushti along with neutralization of Amavisha through its dipaniya, pachaniya (digestion and metabolism enhancing), and vishaghna (anti-toxic) properties.[28] It is carminative and improves agni thereby promoting proper formation of ahara rasa and dhatu. The 14-day intervention was effective in correcting the medo Dhatwagni mandya, promoting the formation of subsequent dhatu, it also dried out of excess of sneha, kapha and meda. All these brought a depletory effect on Medo Dhatu Vriddhi. Katu exerts similar action on ama, kapha and medodushti by its laghu-ushna-ruksha properties. Thus, drugs predominant in katu-tikta rasa, ushna veerya and laghu ruksha guna like Shigru has Medohara and lekhaneeya (therapeutic scrapping) properties.[29]

It has been suggested that, phenolic compounds, in particular flavonoids, play important roles on lipid regulation.[30] Additionally, phenolic compounds of *Moringa oleifera* leaves extract seem to be involved in the inhibition of pancreatic cholesterol esterase activity thus decreasing of plasma cholesterol level.[31]

CONCLUSION

Hyperlipidemia is a lifestyle related metabolic derangement affecting a large section of the population globally. The study design was an open clinical trial involving 30 participants. Analysis of the obtained data yields the conclusion that fresh juice of Shigru Patra pacifies kapha pitta dosha and dries up sneha, meda and kleda, which brings about a depletory effect on Medo Dhatu Vriddhi. Thus, the katu-tikta rasa predominant Shigru Patra can be used in the management of Hyperlipidemia. The evaluation of the subjective and objective parameters yielded results of high statistical significance. The single drug application in a chronic metabolic disorder in a marginal population had shown promising effects. This outcome could be subjected to further evaluation involving better research designs and multiple groups of higher sample size. In addition, the drug should further be evaluated for developing new age drugs with minimal side effects.

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