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"A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF SHODHANANGA SNEHAPANA AND BASTI AS PRAVICHARANA WITH MURCHITHA TILA TAILA IN THE MANAGEMENT OF HYPERLIPIDEMIA"

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ABSTRACT

- Hyperlipidemia has become burning medical problem of today's era, which is the prime cause for vascular diseases like cardiovascular disease, cerebrovascular disease and metabolic syndrome. Hyperlipidemia is a rise in plasma cholesterol, triglyceride or both. Elevated cholesterol primarily refers to high-low density lipoprotein cholesterol (LDL-C). Since approximately 70% of cholesterol is carried in the LDL particle. These lipoproteins are circulatory lipid molecules seen in generally blood vessel. Hyperlipidemia is an asymptomatic and undetected. In hyperlipidemia it is obvious to have aggregation of cholesterol in blood vessel, which make an atherosclerotic plaque responsible for major vascular disorders. Recent studies have reported that high cholesterol is present in 25-30% of urban and 15-20% in rural subject. Considering all these the present study was undertaken to compare the efficacy Murchitha Tila Taila is given as Shodhananga Snehapana

and Basti is used as a Pravicharana Sneha. Thus the study was intended to evaluate the efficacy of Murchitha Tilataila as Pana and Basti in hyperlipidemia

KEY WORDS- Hyperlipidemia, Murchitha Tila Taila, Basti

INTRODUCTION

Vikaranam akushalo na jihniyath kadachana

Na hi sarvavikaranam namato asti druva stiti [1]

As rightly quoted by charaka "A physician should not be embarrassed if he is unable to name a disease as each and every disease cannot be named. This quotation is best fit for today's generation; as today newer disease came into foreground. Hyperlipidemia is such a disease, it has not special reference in ayurvedic literarure. In Ayurveda, hyperlipidemia resembles to many pathologies such as **abadha medas[2], shonitha abhishynda[3], dhamani pratichaya [4], medo dosha, medoroga[5].** The industrialization, stress during the work, dietary habits, lack of exercise, and various unhealthy diet example fast food, soft drink result into disturbance in metabolism. In hyperlipidemia it is obvious to have aggregation of cholesterol in blood vessel, which make an atherosclerotic plaque responsible for major vascular disorders. Recent studies have reported that high cholesterol is present in 25-30% of urban and 15-20% in rural subject[6].

Hyperlipidemia is a such a disorder which is identified as potential risk factor for multitude of diseases like cardiovascular, metabolic syndrome and even hypertension. Hyperlipidemia is a burning problem, lipid and lipoprotein abnormalities are extremely common in general population. Cardiovascular disease, which encompasses condition such as coronary artery disease, stroke, peripheral artery disease is leading cause of mortality worldwide.

Hyperlipidemia does not bear direct reference in the Brihathtaryee. The progression from a physiology to pathology is so prompt that it cannot be pointed out distinctly**.** In Ayurveda, hyperlipidemia resembles to many pathologies such as **Abadha Medas, Shonitha Abhishynda, Dhamani pratichaya, Medo dosha, Medoroga, Sarakta Medas.**

Acharya Charaka stated that main vitiated Dosha responsible for the pathogenesis of Prameha is Bahu Drava Sleshma and **Bahu Abdha Medas[7].** The Abadha Medas or Asthayi Medodhatu can be compared to lipoproteins which are seen to increase in diabetes mellitus.Chakarapani mentioned abdhata as asmhata or aghana, In this fat mobilization from adipose tissue starts which rises free fatty acid in the blood.Riased cholesterol ,raised LDL,atherosclerotic changes ,raised ketone bodies in the blood are due to defect in fat metabolism, Therefore, the abnormal fat metabolism can also be considered as abadha medas, also abadha medas can be considered as circulating lipids.

As hyperlipidemia comes under the category of santarpana janya vikara[8], Shodhana is the prime treatment modality in Santarpanajanyavikaras [9]. In the present study, Murchitha tila taila was taken in arohana krama, but people in the era are afraid of this snehana therapy which is taken in large quantities, may leads to increase in plasma lipids, especially cholesterol, triglyceride which are the important risk factor for atherosclerosis and CHD further life threatening condition. But murchitha Tila Taila is having special properties, Ushna Veerya and Teekshna Guna which is Kaphamedohara action[10].

As accha sneha is given in unmixed form internally it is considered as the best oleation therapy. but practically accha snehapana is not palatable for each and every patient. Many people show dislike towards oil due to its taste, aroma. Due to unpalatability they always feel some sort of discomfort during snehapana leading to noncompliance for the therapy. So in this clinical study, basti as pravicharana administered in arohana krama. In this clinical study murchitha tila taila was given as shodhananga snehapana and basti as pravicharana in arohana krama.

MATERIALS AND METHODS

SOURCE OF DATA:

Subjects was selected from the OPD and IPD of Government Ayurveda Medical College and Hospital, Mysore, Government Hi-tech Panchakarma Hospital, Mysore, Special camps will be conducted and other referral.

METHOD OF COLLECTION OF DATA:

A. SCREENING:

- Screening is done based on inclusive and exclusive criteria

B. DIAGNOSTIC CRITERIA

Combination of the below abnormal biochemical values or in any one of the below in subjects will be considered as diagnostic criteria.

1)Total serum cholesterol- more than 200mg/dl

2)LDL-more than 130mg/dl

3) Triglyceride- more than 150mg/dl

4)HDL- less than 40mg/dl

INCLUSION CRITERIA:

- Subjects who are fit for *Shodhananga Snehapana* and *Basti as Pravicharana,* age between 20-60 years irrespective of all the gender and socioeconomic status.
- Subject who fulfilling the diagnostic criteria
- freshly or previously detected hyperlipidaemia subjects were taken
- subjects who are ready to give written consent for the study

EXCLUSION CRITERIA:

- Subjects if they are suffering from any other systemic illness.
- If the subject on other treatment which shall interrupt the present study was excluded
- Pregnant and lactating woman was excluded

LABORATORY INVESTIGATIONS:

- Haematological investigations (complete blood count)
- Biochemical test (lipid profile)
- Necessary investigation done to rule out the major illness

PLAN OF STUDY:

A. GROUPING:

subjects will be made into two groups, using randomized sampling technique

B. SAMPLE SIZE: Total sample size consists of 40 subjects

Each group will be consisting of 20 subjects

SOURCE OF DRUG:

Required drugs will be procured from GMP certified *Ayurveda* pharmacy

INTERVENTION:

This is a comparative clinical trial consisting of two groups, the intervention are as follows:

- The subjects of Group A were administered with *Murchitha Tila Taila* as *Shodhananga Snehapana* till *Samyak snigdha lakshana or* maximum upto 7 days

- The subjects of Group B were administered with *Murchitha Tila Taila* as *Basti* as *pravicharana Sneha* till *Samyak Snigdha lakshana or* maximum upto 7 days
- In both the groups, the *Matra* of *Sneha* will be calculated by giving *Hrasiyasi Matra,* Acc to the agnibala and kosta of the subjects. Duration will be calculated as per kosta.

GROUP A

Poorva karma- *Deepana pachana* with *Chitakadi Vati* 500mg bid before food *Anupana- ushna jala***,** This was continued till the appearance of *Nirama lakshana*
Pradhana karma- *Shodhananga Snehapana* with *Murchitha Tila Taila* was administered in *Arohana krama* till attainment of *Samyak Snigdha Lakshana* *Anupana- Ushna jala*
Paschath karma- Pathya ahara vihara to be followed

After attainment of *Samyak Snigdha Lakshana* they are subjected for *virechana karma, samsarjana krama* was given, depending on the shuddi lakshanas for 3-7 days

GROUP B

Poorva karma- *Deepana Pachana* with Chitrakadi *Vati* 500mg bid before food Anupana- Ushna jala, This was continued till the appearance of Nirama lakshana.
Pradhana karma- *Basti* as pravicharana with *Murchitha Tila Taila* was administered in *Arohana Krama* till attainment of *Samyak Snigdha Lakshana* observed **a) *Tathkaleena Poorva Karma***-*Sthanika Abhynga* with *Tilataila, Nadisvedha followed* by *Laghu Bhojana* **b) *Pradhana karma-***Basti pranidhana c)***Paschath karma-****Spik Padatala Tadana ,Uttana Shayana,Ushna Upachara,*
Paschath karma- pathya ahara vihara to be followed

After attainment of *Samyak Snigdha Lakshana* they are subjected for *virechana karm*

ASSESSMENT CRITERIA:

- Objective Parameter-Serum lipid profile

ASSESSMENT SCHEDULE:

Group A

- Pretest-0^{th} day
- Post-test-next day after the attainment of *Samyak Snigdha Lakshana*

Group –B

- Pretest- 0^{th} day
- Posttest- next day after the attainment of *Samyak Snigdha Lakshana*

OBSERVATION AND RESULT

a) **Effect on Total cholesterol in group A**

Statistical analysis revealed that mean score of total cholesterol before treatment was 193mg/dl and after treatment was 186.33 mg/dl, with the p value = 0.016 which is highly significant

Mean score		Mean difference	Paired t test			
BT	AT		S.E	t value	df	Significance
193.10	186.65	6.45	8.34200	2.645	19	0.016

b) Effect on Total cholesterol in group B

Statistical analysis revealed that mean score of total cholesterol before treatment was 191mg/dl and after treatment was 195.55 mg/dl, with the p value = 0.174 which is not significant

Mean score		Mean difference	Paired t test			
BT	AT		S.E	t value	df	Significance
191.00	195.55	+4.55	7.206	-1.412	19	0.174

a) showing Effect on Triglyceride in group A

Statistical analysis revealed that mean score of triglyceride before treatment was 178.55mg/dl and after treatment was 142.85 mg/dl, with the p value = 0.000 which is highly significant

Mean score		Mean difference	Paired t test			
BT	AT		S.E	t value	df	Significance
178.55	142.85	35.7	12.95	4.536	19	0.000

b) Effect on Triglyceride in group B

Statistical analysis revealed that mean score of triglyceride before treatment was 175.60 and after treatment was 175.80 mg/dl, with the p value = 0.952 which is not significant

Mean score		Mean difference	Paired t test			
BT	AT		S.E	t value	df	Significance
175.60	175.80	+0.20	9.89	-0.061	19	0.952

a) showing Effect on HDL in group A

Statistical analysis revealed that mean score of HDL before treatment was 39.65mg/dl and after treatment was 42.45 mg/dl, with the p value = 0.000 which is highly significant

Mean score		Mean difference	Paired t test			
BT	AT		S.E	t value	df	Significance
39.65	42.45	2.8	7.09689	-4.958	19	0.000

b) showing Effect on HDL in group B

Statistical analysis revealed that mean score of HDL before treatment was 39.45mg/dl and after treatment was 38.95, with the p value = 0.315 which is not significant

Mean score		Mean difference	Paired t test			
BT	AT		S.E	t value	df	Significance
39.45	38.95	-0.5	1.204	1.033	19	0.315

a) showing Effect on LDL in group A

Statistical analysis revealed that mean score of LDL before treatment was 117.75mg/dl and after treatment was 115.30 mg/dl, with the p value = 0.016 which is not significant

Mean score		Mean difference	Paired t test			
BT	AT		S.E	t value	df	Significance
117.75	115.30	2.45	6.3747	0.824	19	0.420

b) showing Effect on LDL in group B

Statistical analysis revealed that mean score of LDL before treatment was 118.20mg/dl and after treatment was 124.25 mg/dl, with the p value = 0.079 which is not significant

Mean score		Mean difference	Paired t test			
BT	AT		S.E	t value	df	Significance
118.20	124.25	6.05	6.483	-1.856	19	0.079

In Comparision group A got significant result, it shows reduction in serum cholesterol, triglyceride, LDL and raise in HDL. In group B there was no significant reduction in serum cholesterol, triglyceride, LDL here basti as pravicharana was given alternate to snehapana. In pravicharana basti sneha didn't come in contact with agni as compared to shodhananga snehapana.

DISCUSSION

Discussion on procedural effect

Discussion on drug actions

Probable mode of action of sneha pana-

During snehapana, subject will be on complete lipid diet which causes accelerated fat metabolism leading to ketogenesis which promotes mobilization of fatty acid from body.

During snehapana, subjects were given with sneha which is composed entirely of fat

↓

Restriction on carbohydrate diet

↓

Essentially no carbohydrate metabolized

↓

Almost all energy of the body come from metabolism of fat

↓

As a result, more quantity of fatty acid become available to peripheral tissue cells, it is to be used for energy and to liver cells

Majority of fatty acid is converted into ketone bodies

This process increase ketone bodies, acetoacetic acid, acetone

Ketosis, thus it reduces fatty acid in the body

Through increased bile excretion-

Bile is one of the route through which cholesterol is excreted and hence the effect of sneha in the diet on bile flow and its constituents is major asset

For digestion and absorption of fat the role of bile salt is very important on giving murchitha tila taila, secretion of bile occurs according to the proportion of sneha intake and there is enhance in the excretion of cholesterol, phospholipids, bile solids, uronic acid, hence secretion of more bile accounts for the decreasing cholesterol levels

Probable mode of action of basti

Generally oral administration is the route of choice in the daily practice of pharmacotherapy. But it is difficult in some circumstances if patient feels **nausea, vomiting.** In these cases, rectal route may represent a practical alternative route, drugs that administered will in general have higher bioavailability and faster onset. Rectal absorption results in majority of drug reaching systemic circulation with less alteration in route. Rectal administration also reduces side effects such as gastric irritation, nausea, vomiting. And also researches suggest that rectal absorption can prove the good alternative route of drug administration as it provide **partial avoidance of first pass metabolism.** It has been demonstrated that rectal route is more efficient than even intravenous route.

Administration of basti as pravicharana

Drug can cross rectal mucosa like other lipid membrane, the unionized and lipid soluble substances are readily absorbed

Small quantities of short chain fatty acid are absorbed directly into portal blood rather than being converted into triglyceride

Short chain fatty acid water soluble and allows direct diffusion from epithelial cells to capillary blood of villi

In intestine, sneha absorbed by passive diffusion, sneha basti contain hypo osmotic solution facilitates absorption into blood

Later they enter into portal circulation, portal vein to liver, from there inferior venacava, later it reaches systemic circulation

Action of murchitha tila taila-

Murchitha tila taila contains oleic acid, linoleic acid

⇓

Up regulation of AMP activated protein kinase

⇓

Inactivation of acetyl coa and 3 hydroxy-3-methyl-glutryl Coa reductase

⇓

Increased fatty acid efflux (removal) from adipocyte

⇓

Reduced lipid storage and reduced lipogenesis

⇓

Clearance of triglyceride, cholesterol from circulation

Taila is best among the taila varga, taila alleviates vata, but at the same time it does not aggrevate kapha. The importance of tilataila as krishanam brihmanayalam sthoolananm karshanayacha cha" In stoola persons by its sookshma, teekshna, ushna guna it enters sookshma srotas does kshapana karya of meda.

Atisampoorana, Madhura, guru, snigdha ahara sevana, divaswapna

⇓

Medodhatu upachaya

⇓

Medo vraddi

⇓

It leads to sroto poornatva(sroto upalepa)

⇓

Administration of murchitha tila taila

⇓ ⇓

Sookshma srotogami **ushna, teekshna, sara guna**

guna, and vyavayi

By tila taila its properties which are antagonistic to medas, stops the abnormal production of meda dhatu

taila does srotovishodana action thereby it removes dhatupoornatva

Medokshpana in the srotas, by this it does dhatu samyata

The hypolipidemic activity of tilataila when given as shodhananga snehapana-

1) **Sesame lignanas (sesamin and episesamin**) –

lower serum cholesterol concentration by inhibiting absorption and synthesis of cholesterol. In the liver episesamin significantly decrease the activity of microsomal acyl-coa, cholesterol acyl transferase also improves serum lipoprotein metabolism with an increase in apoA-1 and decrease in Apo- b, In the liver both **sesamin** and **episesamin** significantly supress **cholesterol**

accumulation

Study suggest that it can help in **blocking absorption of cholesterol** from the small intestine and lower the activity of enzyme **HMGCOA RECUCTASE** which is involved in making cholesterol in the body.

2) **Sesamolin** – a lignin present in sesame oil, reduce **lipid peroxidation**
3) **Sesamin and sesamolin** may potentiate the effect of vitamin E and they themselves act as ant oxidation which in turn may reduce lipid peroxidation
4) **Sesame oil** contain 40 mg of vitamin E per 100 gm of tila taila –vitamin e has several **Cardio protective activity**.

5) **Alpha linoleic acid-** Also known as ALA and omega 3 fats have been show to **lower triglyceride level**. In research studies it shows result in reducing **triglyceride, LDL and total cholesterol level and slightly increasing HDL level**

6) **Soluble fibre-** Foods high in soluble fibre can help modestly lower LDL cholesterol levels in the blood by preventing **the absorption of cholesterol into blood stream.**

Effect of moorchana drugs-

Amalaki	**Amalaki-** Potent antioxidant drug contain vitamin, glutamic acid, proline, aspartic acid, alanine, lysine Its alcoholic extract **showed hypolipidemic, antiartherogenic** effect
Musta	It is one of the lekhaniya dravya. The ethanol extract of cyperus rotundas rhizome possess **hypolipidemic activity.**
Haridra	contain curcuminoids, curcumin, demethoxy curcumin which are natural antioxidant. Curcumin helps **in reduction of LDL cholesterol level and triglyceride**, it also possesses **cardio protective** action
Manjista	• It has property such as **rakta shodhaka** and **rakta prasadaka** action. In the combined effect they perform **antioxidant activity** which will inhibit oxidation of LDL cholesterol and thus control **formation of cholesterol deposits** • It detoxifies the blood, remove stagnant blood, dissolve obstruction the blood flow

	• Scientific studies have shown that it regulates blood pressure, blood vessel constriction and helps to **protect from blood clot formation** • It is known to **inhibit platelet activity factor**-induced platelet aggregation and may play beneficial in **coronary artery disease**

- In the process of moorchana, taila is heated along with water and other moorchana drugs. In a study conducted at CFTRI, it is found that the heated taila will liberate the cholesterol oxide products oxysterol, Oxysterol and PUFA are also known to inhibit HMGCOA REDUCTASE enzyme activity which is the **rate limiting enzyme for biosynthesis of cholesterol.**

CONCLUSION

hyperlipidemia is one of the major modifiable risk factors for atherosclerosis and its consequences hyperlipidemia does not bear direct references, but can be understood in terms of bahu abadha medas, shonitha abhishynda, medoroga, dhamani pratichaya) shodhananga snehapana and basti as pravicharana with moorchitha tila taila was carried out safely in both the groups in arohana krama

In group A, shodhananga snehapana was done with moorchitha tila taila, there was significant reduction in the serum cholesterol, triglyceride, LDL and HDL.

In group B, basti as pravicharana was done murchitha tila taila, there was no significant reduction in the serum cholesterol, triglyceride, LDL and HDL

even though basti administered as pravicharana sneha samyak snigdha lakshanas were observed without any complications. Murchitha tila taila showed its effect in reducing weight and BMI through its properties.

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