Randomized control trial to evaluate the efficacy of *Chavyadi Churna* in the management of *Medoroga* w. s. r. to *hyperlipidemia*

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ABSTRACT

Medoroga is a disorder of Medovaha strotas as per Ayurvedic concept characterised by deposition of Meda at the site of Sphika (buttocks), Udara (abdomen), Stana (breast) and all over body. The associated symptoms like kshudraswasa (dyspnoea), Trishna (thirst), Nidra (sleep), Angasada (malaise), Kshudha (hunger), Sweda (sweating), Daurgandhya (foul smelling), Alpa prana (decreased immunity) and Alpa maithuna (decreased libido) etc. are also found in this condition. As per modern concept, it can be correlated with Hyperlipidemia. It is a disorder of lipoprotein metabolism, including lipoprotein overproduction.It is manifested by elevation of the total cholesterol, low-density lipoprotein (LDL) cholesterol and the triglyceride concentrations, in the blood. It is the key risk factor for most of the life threatening non communicable diseases like cardio vascular disease, diabetes, hypertension etc.

Since synthetic drugs have been shown to have side effect, clinical importance of ayurvedic drugs in the treatment of Hyperlipidemia has received considerable attention in recent years. Chavyadi Churna is described as Medohara i.e. Anti-hyperlipidemic drugs in Ayurvedic classics due its content of drugs having property of katu and kashaya rasa, ushna virya, katu vipaka.

Keywords:
Hyperlipidemia, BMI, medoroga, chavyadi churna, tb. atorvastatin.

INTRODUCTION

In Ayurveda, Medoroga has been dealt by different Acharyas in reference to its causes, signs and symptoms, complications, prognosis and management. Acharya Charaka has described it as one among the Ashtanindita purusha (eight despicable persons) and mentioned different principles of management. While Acharya Sushruta considers Sthoola as sadatura because Sthaulya needs regular and continuous care and prevention is the best way of management.

Recent studies have reported that high cholesterol is present in 25–30% of urban and 15–20% rural subjects. This prevalence is lower than high-income countries. The most common dyslipidemia in India are borderline high LDL cholesterol, low HDL cholesterol and high triglycerides.

Studies have reported that over a 20-year period total cholesterol, LDL cholesterol and triglyceride levels have increased among urban populations.

Hyperlipidemia (Medoroga) is the condition of abnormally elevated level of any or all lipids and/or lipoproteins in the blood. It is the most common form of dyslipidemia (which also includes any decreased lipid levels). Lipids and lipoprotein abnormalities are regarded as a modifiable risk factor for CHD/CVD due to their influence on atherosclerosis. In addition some form may predispose to acute pancreatitis. The lipids in contemporary science can be correlated with Medas and hence Medohara treatment can be employed in the treatment of hyperlipidemia (Medoroga). Now a days hyperlipidemia (Medoroga) became a burning problem. A number of herbal, mineral and herbo-mineral medicines are described in various ancient texts of Ayurveda for treating hyperlipidemia (Medoroga).

Hence the proposed study was undertaken to evaluate and establish the Medohara effect of Chavyadi Churna.

Research Question

Is Chavyadi Churna 5gm BD (Intervention) with Anupana of Honey for 12 weeks is more effective than Atorvastatin 10mg HS (Control) in the management of Medoroga, with primary outcome i.e. to decrease the symptoms and level of LDL (Bad cholesterol), VLDL, S. triglycerides and Total cholesterol?

Objectives:

- To study the effect of Chavyadi Churna on Medoroga on the basis of symptoms & bad cholesterol (LDL), VLDL, T. Cholesterol, S.Triglycerides levels.
- To compare the efficacy of chavyadi churna and Tb.atorvastatin on the basis of Symptoms and lipid profile.
- To study the changes in anthropometric parameter BMI at 0 and at the end of 12 weeks.

MATERIAL AND METHODS

Step 1: Preparation of Chavyadi Churna

Materials

- Chavya, Jiraka, shunthi, maricha, pippali, hingu, chitraka, sauvarchala lavana : yava – 1:16 ratios

Methods

All the above ingredients were dried and powdered finely, measured in equal quantity and mixed with 16 parts of fine powdered yava, all the ingredients then mixed well and the final Chavyadi churna was formed and collected in dry container.

Step 2: Clinical Study

30 patients were selected each for Group A and Group B from O.P.D. & I.P.D. of DMM. Ayurvedic College Hospital on the basis of inclusion and exclusion criteria. The selected patients were subjected to take the prescribed drugs, for a period of 3 months. All the patients were subjected to investigations as

mentioned in material and methods. The progress and follow-up study was conducted in every 30 days.

IEC clearance number- IEC ref. 1465-77 was gained from the institution for the study

Inclusion Criteria:
Subjects of either sex (both male & female), any caste, religion in the age group of 30 to 60 yrs, Direct LDL-C ≥ 130 mg/dl.

Exclusion Criteria
Patients aged below 30 yrs and above 60 yrs, Patients with systemic, metabolic and endocrine disorders like Diabetes, Hypothyroidism etc. except hypertension.

Assessment Criteria
Efficacy of treatment was assessed by the marked changes observed in the signs and symptoms which were recorded before, during and after the course of clinical trial. The assessment was done with the help of objective parameters and self-graded assessment scale for subjective parameters.

Subjective parameters
Ayasa swasa (Dyspnoea on exertion), Adhika kshudha (Excessive Hunger), Adhika Pipasa (excessive thirst), Sweda adhikyata (Excess sweating), Daurbalya (debility), Daurgandhya (Bad body odours) and Kruchravayava (loss of libido).

Objective parameters:
Lipid profile and BMI

Study design
Groups
The Subjects with Medoroga (Hyperlipidemia) willing to undergo study and fulfilling the inclusive criteria were randomly divided into two groups :

Group A: A group of 30 Subjects were given with Chavyadi Churna in a dosage of 5gm twice daily with honey and water 3 months.

Group B: A group of 30 Subjects were administered with Tb. Atorvastatin 10mg with water at night.

Grading for subjective parameters
Assessment of Ayasa shwasa (Dyspnoea on exertion):
Absent - grade 0
Dyspnoea on moderate work - grade 1
Dyspnoea on slight work - grade 2
Dyspnoea even at rest - grade 3

Assessment of Adhika kshudha (excessive hunger) :
Feels hunger at next meal only - grade 0
Feels hunger for once in between meals - grade 1
Feels hunger for more than twice – grade 2
Feels hunger always - grade 3

Assessment of Adhika Pipasa (excessive thirst):
Normal thirst - grade 0
Up to one litre excess intake of water / fluids - grade 1
Up to two-three litre excess intake of fluids - grade 2
More than three litre excess intake of fluids - grade 3

Assessment of Sweda Adhika (Excess sweating) :
No sweating - grade 0
Profuse sweating after moderate work - grade 1
Profuse sweating after slight work - grade 2
Sweating even in resting condition - grade 3

Assessment of Daurbalya (Debility) :

Weakness after 2km walk - grade 0

After 1km walk - grade 1

After ½ km walk- grade 2

During routine work - grade 3

Assessment of Daurgandhya (Bad body odours) :

Absent - grade 0

Feeling after moderate work - grade 1

Feeling after slight work - grade 2

Feeling even in resting condition - grade 3

Assessment of Kruchravyava (Loss of libido) :

Never - grade 0

Occasionally - grade 1

Intermittent - grade 2

Always - grade 3

Data Analysis

The findings before and after treatment were recorded and evaluated statistically by using Paired, Unpaired t test, wilcoxon test and mann whitney's test.

RESULTS

Effect of therapy

Table no.1- Effect of therapy according to % Relief in Patients

Pt. No.	Group A				Pt. No	Group B			
	D0	D90	Relief	%Relief		D0	D90	Relief	%Relief
1	14	2	12	85.7	1	10	6	4	40
2	11	4	7	63.6	2	6	2	4	66.7
3	5	0	5	100	3	8	4	4	50
4	11	3	8	72.7	4	5	2	3	60
5	7	1	6	85.7	5	8	3	5	62.5
6	6	1	5	83.3	6	6	2	4	66.7
7	8	2	6	75	7	5	2	3	60
8	8	3	5	62.5	8	6	1	5	83.3
9	9	1	8	88.9	9	5	3	2	40
10	7	1	6	85.7	10	4	3	1	25
11	7	1	6	85.7	11	4	1	3	75
12	9	3	6	66.7	12	5	3	2	40
13	9	1	8	88.9	13	5	2	3	60
14	6	1	5	83.3	14	11	4	7	63.6
15	5	1	4	80	15	9	3	6	66.7
16	9	1	8	88.9	16	5	4	1	20
17	6	1	5	83.3	17	4	2	2	50
18	6	0	6	100	18	6	0	6	100
19	9	1	8	88.9	19	7	4	3	42.9
20	8	2	6	75	20	5	2	3	60
21	6	0	6	100	21	4	1	3	75
22	10	2	8	80	22	4	2	2	50
23	10	3	7	70	23	8	4	4	50
24	8	0	8	100	24	6	1	5	83.3
25	8	2	6	75	25	6	2	4	66.7

26	5	0	5	100	26	4	1	3	75
27	5	1	4	80	27	5	0	5	100
28	5	0	5	100	28	5	1	4	80
29	6	2	4	66.7	29	14	8	6	42.86
30	6	0	6	100	30	11	8	3	27.27

According to % Relief in Symptoms

Table no.2: % Relief in Symptoms of Group A & Group B

Sr. No.	Symptoms	%Relief	
		Group A	Group B
1	Kruchravyavaya	57.14	33.33
2	Daurbalya	85.00	51.61
3	Daurgandhya	95.00	52.94
4	Sweda adhikya	91.67	58.06
5	Adhika kshudha	74.19	58.33
6	Adhika pipasa	85.00	66.67
7	Kshudra shwasa	79.17	76.47
8	Avg. % Relief	**81.02**	**56.77**

According to % Change in parameters

Table no.3: % Change in parameters of Group A & Group B

Sr. No.	Parameters	% Change	
		Group A	Group B
1	LDL	33.07	40.45
2	HDL	9.98	5.80
3	VLDL	10.78	4.87
4	Cholesterol	22.26	28.94
5	Triglyceride	7.37	14.24
6	BMI	3.09	1.11

Overall Effect of Therapy
According % Relief

Table no.4: Overall Effect of Therapy according % Relief

Sr. No.	Relief Criteria	Relief Grade	No. of patients		No. of symptoms	
			Gr. A	Gr. B	Gr. A	Gr. B
1	76% to 100%	Marked	24	08	05	01
2	51% to 75%	Moderate	06	14	01	05
3	25% to 50%	Mild	00	07	01	01
4	00% to 24%	No relief	00	01	00	00

DISCUSSION

Medoroga is a disorder dominated by meda dhatu due to its abnormal accumulation. It is caused by vitiated Kapha dosha initially and later pitta and vata doshas too play a significant role in it's pathogenesis producing symptoms of its own. Further in later stages due to abnormal accumulations of apachita medas in other strotas exhibits various symptoms like Javoparodha, Ayushohrasa, sweda abadha etc. The mode of onset is usually gradual depending upon nidanas followed by patient like, Avyayama, Adhyashana, Divasvapna, Ati madhura, Guru, Snigdha Ahara sevana, various Manasika Bhavas and Beejadosha. The involvement of other doshas like Pitta and Vata are appreciated by the presence of symptoms like Swedadhikya, adhika kshuda, Atipipasa, Daurgandhya, Daurbalya, ayasa shwasa etc.

In modern parlance, Hyperlipidemia is the condition that similes with Medoroga where there is increase of lipids in the body which are fatty substances.

Comparison between Hyperlipidemia with Medoroga - From the physical properties of lipids as they are fat substances can be understood in terms of Meda in the body.These lipids always circulate in the body along with blood and this indicates the Abaddha Meda explained in the classics and involvement of Rasa and Rakta dhatu as well as strotas of same in Medoroga. Even by nature, lipids and Meda are fatty substances in the body.

Role of Agni - Agni plays an important role in both physiology and pathology. As we are talking about Hyperlipidemia which is a resultant of abnormal lipid metabolism which again explains role of agni in causing this condition. This influence occurs at both Jatharagni and Dhatvagni level. The Ahara rasa is transformed to Rasadi dhatus and this process is controlled by Dhatvagni which converts it into Poshya dhatu. So abnormality at dhatvagni certainly causes derangement in this course leading abnormal accumulation of Meda dhatu.

Considering the lipid transport, Triglycerides, Cholesterol and other fatty acids are transported with the help of lipoproteins like HDL,LDL and VLDL.

LDL - carry cholesterol from liver to tissues,

HDL - carry excess cholesterol from body cells to liver to remove it.

VLDL-carry triglycerides from liver to adipose tissue and depositing triglycerides in the adipose cells, VLDL is converted to IDL.

Most of the body cells contain LDL receptors. Once LDL attached to its receptors, it is transported into the cells by receptor mediated endocytosis. Thus the supply of medoposhakamsha is controlled by LDL specific receptor system. If this metabolism is deranged, LDL cannot enter the cells and thereby causes accumulation of cholesterol in and around the smooth muscles and in thin vessel walls.

Discussion on statistical analysis

Statistical Analysis: In Trial Group (chavyadi churna) and In Control Group (tb. atorvastatin)

A) Subjective Parameters (By Wilcoxon Signed Ranks Test) Wilcoxon Signed Ranks test was applied to both groups separately to observe whether the difference between D0 and D90 score is significant or not.

Group A - In the case of symptoms Kruchravyavaya, Daurbalya, Daurgandhya, Sweda adhikya, Adhika kshudha, Adhika pipasa and Ayasa shwasa the test has shown significant difference between D0 and D90 symptom scores. It is hence concluded that Chavyadi churna (5gm BD) is significantly effective to reduce Kruchravyava, Daurbalya, Daurgandhya, Sweda adhikya, Adhika kshudha, Adhika pipasa and Ayasa shwasa symptoms in Medoroga (Hyperlipidemia).

Group B - In the case of symptoms Daurbalya, Daurgandhya, Sweda adhikya, Adhika kshudha, Adhika pipasa and Ayasa shwasa the test has shown significant difference between D0 and D90 symptom scores. It is hence concluded that Atorvastatin (10mg HS) is significantly effective to reduce Daurbalya, Daurgandhya, Sweda adhikya, Adhika kshudha, Adhika pipasa and Ayasa shwasa symptoms in Medoroga (Hyperlipidemia).

In the case of symptoms Kruchravyavaya the test has shown insignificant difference between D0 and D90 symptom scores. It is hence concluded that Atorvastatin (10mg HS) is not significantly effective to reduce Kruchravyava symptom in Medoroga (Hyperlipidemia).

B) Objective Parameters (By Student's t Test for Paired data)

Paired t test was applied to both groups separately to observe whether the difference between D0 and D90 score is significant or not.

Group A

In the case of parameters LDL, HDL, VLDL, Sr. Cholesterol, Sr, Triglyceride and BMI the test has shown significant difference between D0 and D90 scores. It is hence concluded that Chavyadi churna (5gm BD) is significantly effective to reduce LDL, VLDL, Sr. Cholesterol, Sr. Triglyceride, BMI and to increase HDL in Medoroga (Hyperlipidemia).

Group B - In the case of parameters LDL, HDL, VLDL, Sr. Cholesterol, Sr. Triglyceride and BMI the test has shown significant difference between D0 and D90 scores. It is hence concluded that Atorvastatin (10mg HS) is significantly effective to reduce LDL, VLDL, Sr. Cholesterol, Sr. Triglyceride, BMI and to increase HDL in Medoroga (Hyperlipidemia).

A) Subjective parameters (By Mann Whitney's U Test)

Both groups were compared and analyzed statistically by Mann-Whitney's U test.

In the case of symptoms Daurbalya, Daurgandhya, Sweda adhikya, Adhika pipasa and Ayasa shwasa the test has shown **significant difference** between mean differences of Group A and Group B. It is hence concluded that, Chavyadi Churna is significantly effective than Atorvastatin in Medoroga (Hyperlipidemia) to reduce Daurbalya, Daurgandhya, Sweda adhikya, Adhika pipasa and Ayasa shwasa.

In the case of symptoms kruchravyava and Adhika kshudha the test has shown **insignificant difference** between mean differences of Group A and Group B. It is hence concluded that, Chavyadi Churna is not significantly effective than Atorvastatin in Medoroga (Hyperlipidemia) to reduce kruchravyava and Adhika kshudha.

B) Objective parameters (By Student's t Test for Unpaired data)

Both groups were compared and analyzed statistically by Student's t test for Unpaired data. In the case of objectives parameters HDL, VLDL, and BMI the test has shown **significant difference** between mean differences of Group A and Group B. It is hence concluded that, Chavyadi Churna is significantly effective than Atorvastatin in Medoroga (Hyperlipidemia) to reduce BMI, VLDL, and increase in HDL.

In the case of LDL, S.Triglyceride and T.Cholesterol the test has shown **insignificant difference** between mean differences of Group A and Group B. It is hence concluded that, Chavyadi Churna is not significantly effective than Atorvastatin in Medoroga (Hyperlipidemia) to reduce LDL, S.Triglyceride and T.Cholesterol.

Mode of action (Chavyadi Churna)

Chavyadi Churna is a aushadha yoga explained under medoroga chikitsa adhyay of Yogratnakara. It contains chavya, chitraka, jiraka, shunthi, maricha, pippali, hingu, sauvarchala lavana, in equal quantity with 16 parts of yava, anupana honey and water. Thus the largest ingredient being yava which possess kashaya madhura rasa, sheet virya, katu vipaka, rukshaguna which is excellent kapha pitta shamaka.

Hyperlipidemia if seen through the lens of Ayurveda, may be taken as medo dosha, as bahu abaddha medas which circulates all over the body. Ruksha guna, katu vipaka, kashaya rasa causes medovilayana. The drugs such as chavya, jiraka, chitraka are rooksha, sookshma and ushna in nature thus penetrating into the deeper channels and removing sanga/obstruction

In case of hyperlipidemia, obstruction may be seen as atherosclerosis seen due to deposition of fat in arteries. Hence by the virtue of above properties, it helps in liquefaction of these fatty blockages.

Drugs such as madhu and yava by virtue of their sheeta virya, pacifies tikshnagni. Kashaya-Madhura rasa, sheeta virya, madhura vipaka of madhu alleviates pitta dosha. Snighdha, ushna virya of shunthi, maricha, pippali, hingu, sauvarchala lavana alleviates vata.

Hence by virtue of above properties, the samprapti vighatana is done. Therefore the drug Chavyadi Churna which possesses medohara and anti hyperlipidemic property is opted for this study.

CONCLUSION

1. Chavyadi Churna is significantly effective than Atorvastatin in Medoroga (Hyperlipidemia) to reduce Daurbalya, Daurgandhya, sweda adhikya, Adhika pipasa and Ayasa shwasa.

2. Chavyadi Churna is significantly effective than Atorvastatin in Medoroga (Hyperlipidemia) to increase HDL and to reduce VLDL.

3. Chavyadi churna is significantly effective than Atorvastatin in medoroga to reduce BMI.

4. Chavyadi Churna is not significantly effective than Atorvastatin in Medoroga (Hyperlipidemia) to reduce kruchravyavaya and Adhika kshudha.

5. Atorvastatin is significantly effective than Chavyadi Churna in Medoroga (Hyperlipidemia) to reduce LDL, Sr. Cholesterol and Sr. Triglyceride.

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