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A clinical study to evaluate the efficacy of *Vacha* (*Acorus calamus*) in the management of *Sthaulya* with special reference to Hyperlipidemia

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ABSTRACT

Human ardor for herbal medicine dates lower back to *Vedic* life. One such herbal drug is *Vacha* (*Acorus calamus* Linn.). It is indicated in *'Santarpana Janya Vyadhi'* for having *Lekhaniya, Srotoshodhan, Pramathi* actions. As per Ayurvedic concept *Sthaulya* is a disorder of *Medovahasrotas* with symptoms of deposition of *Meda* (fat) at the site of abdomen, buttock, chest, neck and all over the body. It can be correlated with Obesity in present era. Hyperlipidemia is closely related to it which is a disorder of lipoprotein metabolism, which can include overproduction of lipoproteins. The disorder can manifest as an elevation of plasma cholesterol, TGs, or both, together that contributes to the development of atherosclerosis, a precursor for Coronary Artery Disease. Due to increased sedentary lifestyle such metabolic conditions have shown its hike in the present era. A clinical study was designed as a randomised single group open interventional trial. In this study total 41 consenting patients of either sex were registered after screening for the trial from *Kayachikitsa* O.P.D. of Government Ayurvedic Hospital, Patiala, Punjab but 30 patients completed the course of the trial. Test drug *Vacha Churna* capsules of 500mg were given twice daily with water before meal for 30 days. The results shown were highly significant.

Key words: *Vacha, Sthaulya, Medodhatu, Obesity, Hyperlipidemia.*

INTRODUCTION

We live in 21st century, which is the era of modernization and fast life as a result people hate to spend energy or invest physical effort in getting their work done and opt for minimal physical activity and fast food. This has led people to fall in the trap of sedentary lifestyle, which has resulted in the emergence of various disorders like metabolic syndrome, which is characterized by the presence of diabetes, obesity, high blood pressure, hyperlipidemia and cardiovascular diseases such as stroke and heart disease are more likely the result of these problems.

Hyperlipidemia is one of the major problems in today's era. Hyperlipidemia is not an isolated condition, but a range of disorders with a variety of genetic and environmental determinants. It is a condition in which the level of lipoproteins i.e., cholesterol, triglycerides or both are raised in plasma. Out of which cholesterol may get deposit in the coronary or cerebral arteries causing their narrowing and blockage leading to Coronary Artery Disease or Cerebrovascular accidents. Modern anti-hyperlipidemic drugs like statins are found to have many adverse reactions therefore it is

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the need of the hour to find an alternative drug in other systems of medicine. For Hyperlipidemia direct references are not found in any of the classical Ayurvedic texts, yet its rich literature throws light on every problem and its solution. Attempts are being made by various scholars of Ayurveda to clinically co-relate Hyperlipidemia to *Raktgatasnehavridhi* due to similarity in their aetiological factors, symptoms and line of treatment. Hyperlipidemia is contributed by high fat diet, sedentary lifestyle, genetics etc. In Ayurveda similar *Nidanas* like use of *Kaphakar Ahara (Madhura, Snigdha, Guru, Picchila Guna* diet), *Avyayama* (lack of physical activity) and *Beejdosha Swabhava* are said to cause *Sthaulya*.[1] Hence Hyperlipidemia and *Sthaulya* (Obesity) can be better understood under the broad umbrella of *Santarpanjanyavyadhis*.[2]

The *Santarpanjanaya* condition of '*Sthaulya*' has been described by *Acharya Charaka* under the eight impediments of *Ashta-Nindita*.[1] *Acharya Sushruta* has considered *Sthaulya* as a result of vitiated *Meda Dhatu,*[3] as a symptom of disrupted *Medovahastrotas*[4] and as a *Rasa Nimitaja* disorders.[5] *Acharya Vagbhata* has emulated footsteps of *Sushruta Samhita* to describe *Sthaulya* as *Meda Vikriti*[6] and elaborated the etiopathogenesis of *Sthaulya* on the basis of formation of *Ama.* This *Ama* getting mixed with *Kapha* residing in the *Dhatus* causes *Sthaulya*.[7]

It is given that in *Medoroga* (obesity) the *Strotas* are obstructed by *Meda* and other *Dhatus* do not get nourished except *Meda Dhatu* which continues to get accumulated due to lack of *Agni* (*Dhatwagnimandhya*). Also, *Medavritavata* enters *Koshtha* and aggravates *Agni* (appetite) of the *Medasvi*. This is how the vicious cycle of accumulation of *Meda* continues. This abnormal, unequal distribution and collection of *Medo Dhatu* in the body is known as *Medoroga*.[8] *Vacha* (*Acorus calamus* Linn.) has been selected to manage this ailment. Many single and compound drugs are mentioned in Ayurveda to address similar problems like *Sthaulya / Medoroga* but there are ample reasons for selection of *Vacha*, like *Vacha* has *Strotoshodhan*, *Pramathi* action due to its *Katu Rasa, Ushana, Tikshana* properties. Therefore, it is proposed to remove excess of *Meda Dhatu* from the body and blood. It will arrest the root cause by improving *Dhatwagni* and may provide good results in the signs and symptoms of *Sthaulya* (Hyperlipidemia). The plant is easily available and cost effective too. Low dose is required for its therapeutic action. Thus, considering the above facts this study is intended in the management of *Sthaulya* (Hyperlipidemia) with *Vacha Churna* capsules.

AIM OF THE STUDY

To clinically evaluate Antihyperlipidemic activity of *Vacha* (*Acorus calamus* Linn.) rhizome powder in the management of *Sthaulya* w.s.r. to Hyperlipidemia.

MATERIALS AND METHODS

Study design: A randomized open interventional study

Level of study: OPD level

Sample Size: 30

End point: Efficacy based on Subjective & Objective criteria.

Patients: Single group of 30 patients was selected from *Kayachikitsa* O.P.D. of Government Ayurvedic College & Hospital, Patiala (Punjab) with their written consent. The protocol was approved by Institutional Ethics Committee. The study was registered with the CTRI number: 2021/09/036212. The study was conducted in accordance with International Conference on Harmonization - Good clinical Practice (ICH-GCP) guidelines, the Declaration of Helinski, and local regulatory requirements. Total 41 patients were registered. 30 patients completed the course of trial and remaining 11 patients dropped out from the study at different stages due to personal reasons.

Drug Schedule and Duration

Preparation: Powder of rhizome of *Vacha* (*Acorus calamus* Linn.)

Presentation: Capsule form

Route: Oral

Dose: One capsule of 500 mg twice daily on empty stomach

Anupan: Water

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Duration: 1 month (30 days)

Follow up: At D0, D15, D30 and D60 (one month after stopping the medicine)

Patients were enrolled in the study based on the following criteria:

Inclusion criteria:

- Patients who gave written consent for the study
- Patients falling between the age group of 16 to 60 years were selected irrespective of sex, religion and economic status.
- Hyperlipidemia in laboratory investigation.
- Patients having raised BMI between 25-39.9 Kg/m^2

Exclusion criteria:

- Patients who did not gave written consent for the study.
- Patients below the age of 16 and above the age of 60 years.
- Pregnancy and lactating mothers.
- Patients having history of serious cardiac diseases.
- Patients having history of thyroid dysfunction, severe hypertension, kidney and liver diseases, peptic ulcers.
- The *Pittaja Prakriti* (physical constitution) person, as *Vacha* is *Ushna, Tikshana* in *Guna* and may be intolerable to *Pittaja Prakriti* patients.
- Any Systemic illness.
- Severe complicated cases.
- Patients with co morbidities were excluded.
- Patients having BMI>40 Kg/m^2 were also excluded.

Protocol for Clinical work

The patients fulfilling the inclusion criteria were selected for the present study and were assessed before and after treatment. Observations were made according to standard Ayurveda parameters and findings were recorded in well-designed proforma with complete history of present illness, family history, past history, socioeconomic status and personal history of diet, sleep, exercise schedule etc. relevant to Hyperlipidemia and Obesity

The selected patients were evaluated as per following subjective & objective criteria.

Assessment criteria

[A] Subjective criteria:

1. *Snigdhangata* (Glistening of the body)
2. *Angagaurav* (Heaviness in the body)
3. *Swasa Kashtata* (Dyspnoea)
4. *Daurbalya* (*Alpavyayam*)
5. *Krichvyavaya* (Difficulty in sexual act)
6. *Daurgandhata* (Foul smell)
7. *Atipipasa* (Excessive thirst)
8. *Atikshudha* (Excessive hunger)
9. *Swedadhikya* (Excessive sweating)
10. *Utsaha hani* (Lack of interest in work)

All the above sign and symptoms were graded on 0,1,2,3 score i.e., nil, mild, moderate and severe on the basis of its intensity and severity.

1. *Snigdhangata* (Glistening of the body)

Score	Feature
0	Normal *Snigdhata*
1	Oily luster of body in summer season
2	Oily luster of body in dry season
3	Excessive oily luster of body in dry season removed with difficulty

2. *Anga Gaurav* (Heaviness in the body)

Score	Feature
0	No heaviness in the body
1	Feels heaviness in the body but it does not hamper daily routine work

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2	Feels heaviness in the body which hamper daily routine work
3	Feels heaviness with flabbiness in all over the body which cause distress to the person

3. *Swasa Kashtata* (Dyspnoea)

Score	Feature
0	Dyspnoea absent
1	Mild dyspnoea after moderate work
2	Dyspnoea after little work
3	Dyspnoea in resting condition

4. *Daurbalya* (*Alpavyayam)*

Score	Feature
0	Can do routine exercise
1	Can do moderate exercise
2	Can do only mild exercise
3	Cannot do even mild exercise.

5. *Krichvyavaya* (Difficulty in sexual act)

Score	Feature
0	Unimpaired libido & sexual performance
1	Decrease in libido but can perform sexual act
2	Decrease in libido but can perform sexual act with difficulty
3	Loss of libido and cannot perform sexual act

6. *Daurgandhata* (Foul smell)

Score	Feature
0	Absence of bad smell
1	Occasionally bad smell limited to close areas difficult to suppress with deodorants
2	Persistent bad smell felt from long distance is not suppressed by deodorant
3	Persistent bad smell felt from long distance even intolerable to the patient himself

7. *Atipipasa* (Excessive thirst)

Score	Feature
0	Normal thirst
1	Upto 2 liter excess intake of water
2	2 -3 liter excess intake of water
3	More than 3 liter excess intake of water

8. *Atikshudha* (Excessive hunger)

Score	Feature
0	Unwilling for food after meal
1	Unwilling for food but could take the meal
2	Willing towards some specific *Ahara/ Rasa Vishesha*
3	Equal willing towards all *Bhojjaya Padarth*

9. *Swedadhikya* (Excessive sweating)

Score	Feature
0	Sweating after heavy work
1	Profuse sweating after heavy work
2	Profuse sweating after little work
3	Sweating even in resting condition

10. *Utsahahani* (Lack of interest in work)

Score	Feature
0	Doing work satisfactory
1	Doing work satisfactory with initiation late in time
2	Doing work unsatisfactory with lot of mental pressure & late in time

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3	Does not have any initiation & not wants to work even after pressure

Score Evaluation was done before and after treatment:

1-10 Mild symptoms

11-20 Moderate symptoms

21-30 Severe symptoms

[B] Objective Criteria: Following lab investigations were done

- Total lipid profile before and after 30 days.
- Participants were diagnosed on the basis of lipid profile. (NCEP ATP III Guidelines for lipid profile)
- Serum Cholesterol : 201mg/dL or more
- Serum Triglyceride : 150 mg/dL or more
- LDL Cholesterol : 130mg/dL or more
- HDL : <40 mg/dL
- Patients having raised BMI between 25-39.9 Kg/m^2

Result assessment:

For comparing categorical data Wilcoxon signed rank test was performed and for quantitative data paired Student 't'- test was applied. Statistical analysis was done using IBM SPSS software version 22.0 Chicago, Illinois, USA.

Level of significance - w.r.t. 'p' value:

p- values	Significance level
> 0.05	Insignificant (ns)
< 0.05 / 0.05 to 0.001	Significant (*)
< 0.001	Highly significant (**)

Criteria for Result Assessment

Results were assessed as per following percentage relief criteria:

1. Complete relie – 76-100% relief
2. Marked improvement – 51-75% relief
3. Moderate relief – 26-50% relief
4. Mild relief – 10-25% relief
5. No relief – less than 10% relief

OBSERVATIONS

Observations based on socio demographic data:

Total 30 patients were studied in the present study. Maximum patients (43.3%) were belonging to the age group of 51-60 years. Maximum patients were female (56.7%) from Sikh community (80.0%), having Primary education (26.7%), House wives (40.0%), married (90.0%), living in Urban area (93.3%), belonging to Kapha-Pitta Prakriti (46.7%) along with *Madhayama Satva* (50.0%).

Observation based on *Nidanatmaka* data:

Nidanatmaka biostatics revealed that maximum patients were having Dietetic Habit of *Adhyashana* (60.0%), not doing any kind of exercise (66.7%) maximum (46.7%) patients were not sleeping in day time but maximum patients were sleeping for 8 hrs in night (36.7%), maximum patients have negative family history of Hyperlipidemia (56.7%). Analysis of *Agni* shows that maximum patients were having *Teekshana Agni* (63.3%).

RESULTS

Effect of drug on Subjective criteria:

1. *Snigdhangta*: Before treatment maximum of 66.7% patients had *Snigdhangta* in the range of 2, after treatment maximum 60.0% patients had *Snigdhangta* in the range of 1. The Z value came out to be 4.123 and corresponding p- value for this is 0.001 which came out to be statistically highly significant. This implies that treatment decreased *Snigdhangta* value.
2. *Angagaurav:* Before treatment maximum of 66.7% patients had *Angagaurav* in the range of 2, after treatment maximum 50.0% patients had *Angagaurav* in the range of 1. The Z value came out to be 5.070 and corresponding p- value for this is 0.001 which came out to be statistically highly significant. This implies that treatment decreased *Angagaurav* value.
3. *Swasakashta:* Before treatment maximum of 43.3% patients had *Swasakashta* in the range of 1,

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after treatment maximum 50.0% patients had *Swasakashta* in the range of 1. The Z value came out to be 4.243 and corresponding p- value for this is 0.001 which came out to be statistically highly significant. This implies that treatment decreased *Swasakashta* value.

4. *Daurbalaya:* Before treatment maximum of 56.7% patients had *Daurbalaya* in the range of 2, after treatment maximum 53.3% patients had *Daurbalaya* in the range of 1. The Z value came out to be 4.772 and corresponding p- value for this is 0.001 which came out to be statistically highly significant. This implies that treatment decreased *Daurbalaya* value.
5. *Krichavyavaya:* Value of *Krichavyavaya* was same before & after treatment. The Z value came out to be 0.00 and corresponding p- value for this is 1.000 which came out to be statistically insignificant. This implies that treatment neither decreased nor increased *Krichavyavaya* value.
6. *Daurgandhta:* Before treatment maximum of 50.0% patients had *Daurgandhta* in the range of 2, after treatment maximum 63.3% patients had *Daurgandhta* in the range of 1. The Z value came out to be 4.243 and corresponding p- value for this is 0.001 which came out to be statistically highly significant. This implies that treatment decreased *Daurgandhta* value.
7. *Atipipasa:* Before treatment maximum 50.0% patients had *Atipipasa* in the range of 1, after treatment maximum 60.0% patients had *Atipipasa* in the range of 1. The Z value came out to be 2.646 and corresponding p- value for this is 0.008 which came out to be statistically significant. This implies that treatment decreased *Atipipasa* value.
8. *Atikshudha:* Before treatment maximum 36.7% patients had *Atikshudha* in the range of 3, after treatment maximum 56.7% patients had *Atikshudha* in the range of 3. The Z value came out to be 3.638 and corresponding p- value for this is 0.001 which came out to be statistically highly significant increase in *Atikshudha* value.
9. *Swedadikya:* Before treatment maximum of 63.3% patients had *Swedadikya* in the range of 2, after treatment maximum of 60.0% patients had *Swedadikya* in the range of 1. The Z value came out to be 4.243 and corresponding p- value for this is 0.001 which came out to be highly significant. This implies that treatment decreased *Swedadikya* value.
10. *Utsahahani:* Before treatment maximum of 56.7% patients had *Utsahahani* in the range of 1, after treatment maximum of 60.0% patients had *Utsahahani* in the range of 0. The Z value came out to be 4.291 and corresponding p- value for this is 0.001 which came out to be highly significant. This implies that treatment decreased *Utsahahani* value.

Overall effect of drug on symptomatology:

Table 1 shows that before treatment maximum of 73.3% of patients had moderate symptoms in the range of 11-20 after treatment maximum of 60.0% of patients had mild symptoms in the range of 1-10. The t- value came out to be 12.155 and corresponding p- value for this is 0.001 which came out to be highly significant. This implies that treatment decreased symtomatological value.

Table 1: Overall effect of drug on symptomatology.

Symptoms	Score	BT		AT		t-value	p-value
		N	%	N	%		
Mild symptoms	1-10	7	23.3 %	18	60.0 %	12.155	0.001**
Moderate symptoms	11-20	22	73.3 %	12	40.0 %		
Severe symptoms	21-30	1	3.3%	0	0.0%		
Total		30	100 %	30	100 %		

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Effect of drug on Objective criteria

The results are summarized in Table 2.

BMI: The mean BMI of patients was 30.54 before treatment which was reduced to 30.20 after the treatment. The t- value came out to be 5.794 and corresponding p- value for this is 0.001 which came out to be statistically highly significant. This means treatment resulted in decrease mean BMI value.

S. Cholesterol: The mean S. Cholesterol of patients was 235.40 before treatment which was reduced to 203.83 after treatment. The t- value came out to be 6.207 and corresponding p- value for this is 0.001 which came out to be statistically highly significant. This means treatment resulted in decrease mean S. Cholesterol value.

S. Triglyceride: The mean S. Triglyceride of patients was 202.36 before treatment which was reduced to 171.53 after treatment. The t- value came out to be 2.448 and corresponding p- value for this is 0.021 which came out to be statistically significant. This means treatment resulted in decrease mean S. Triglyceride value.

HDL: The mean HDL of patients was 49.01 before treatment which was reduced to 45.99 after treatment. The t- value came out to be 3.030 and corresponding p- value for this is 0.005 which came out to be statistically significant. This means treatment resulted in decrease mean HDL value which was not desirable.

LDL: The mean LDL of patients was 142.63 before treatment which was reduced to 120.54 after treatment. The t- value came out to be 5.510 and corresponding p- value for this is 0.001 which came out to be statistically highly significant. This means treatment resulted in decrease in mean LDL value.

VLDL: The mean VLDL of patients was 39.71 before treatment which was reduced to 34.26 after treatment. The t- value came out to be 2.283 and corresponding p- value for this is 0.030 which came out to be significant. This means treatment resulted in decrease in mean VLDL value.

Table 2: Overall effect of drug on Mean Score of all the Objective Parameters (n=30)

Objective Parameters		Mean	Std. Deviation	Mean ± Sd. Difference	% Relief	95% Confidence Interval of the Difference		t	p
						Lower	Upper		
BMI	BT	30.54	3.80	.35±.33	1.11%	.22	.47	5.794	.001**
	AT	30.20	3.83						
S. Cholesterol	BT	235.40	25.96	31.57±27.85	13.41%	21.17	41.97	6.207	.001**
	AT	203.83	36.13						
S. Triglycerides	BT	202.36	90.10	30.83±68.97	15.23%	5.07	56.58	2.448	.021*
	AT	171.53	72.36						
HDL	BT	49.01	8.30	3.02±5.45	6.16%	.98	5.05	3.030	.005*
	AT	45.99	6.84						
LDL	BT	142.63	29.58	22.09±21.96	15.48%	13.89	30.29	5.510	.001**
	AT	120.54	35.32						
VLDL	BT	39.71	17.20	5.46±13.09		.57			.030*

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	AT	34.26	14.48		13.72%		10.35	2.283	

Overall effect of therapy

It is observed from the Fig. 1, that out of 30 patients 22 patients gained moderate relief (73.3%), 4 patients gained mild relief (13.3%), 3 patients got no relief (10.0%) and remaining 1 patient showed marked improvement (3.3%).

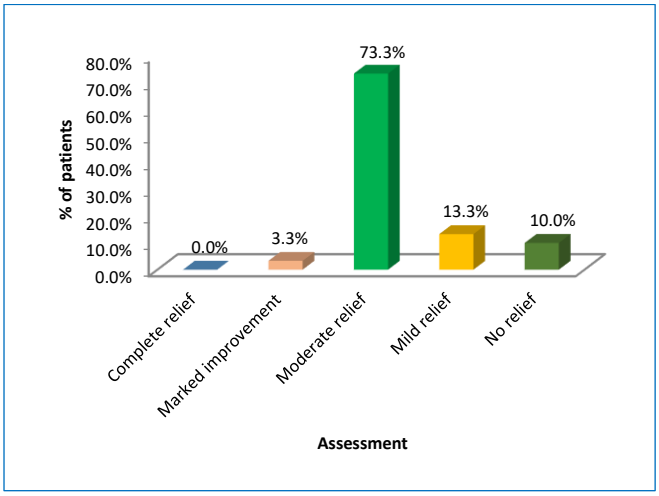

Fig. 1: Overall effect of therapy

DISCUSSION

Present clinical study on *Vacha* has shown overall statistically significant and better improvement was seen in S. Cholesterol, LDL, BMI than in S. Triglycerides, VLDL & HDL. It has also shown statistically highly significant results in all the subjective parameters like *Snigdhangta, Angagaurav, Swasakashta, Daurbalaya, Daurgandhta, Atikshudha, Swedadikya* and *Utsahahani* except *Krichavyavaya* has shown statistically insignificant & *Atipipasa* has shown statistically significant effect.

Probable mode of action of *Vacha*

Vacha has predominantly *Katu, Tikta Rasa, Laghu, Ruksha, Tikshana Guna, Ushana Virya, Katu Vipaka* and *Vata Kapha Shamaka* property. It is mainly *Agni* & *Vayu Mahabhuta* dominant whereas *Sthaulya* & Hyperlipidemia involve *Prithvi* & *Jala Mahabhuta*. Thus, as per *Samanya - Vishesha* principle *Vacha* was proposed to combat *Sthaulya (Baddha Meda)* and Hyperlipidemia (*Abaddha Meda*).

Probable mode of action on *Dosha*

All the *Rasa, Guna, Veerya, Vipaka* of *Vacha* are *Kapha Dosha Shamaka* which is primarily involved in the *Samprapti* of *Sthaulya* causing *Samprapti Vighatana* at grass root level. *Tikshana, Ushana* properties are *Vata Shamak* which balances the *Samana Vata* and *Vyana Vata* involved.

Probable mode of action on *Dushya*

Meda / Kleda are chief culprits in *Sthaulya*. Its *Katu Tikta Rasa* is having *Lekhana* (depletive), *Meda-Vasa-Sleshma Upashoshana* (desiccant of fat) properties. *Katu Rasa* performs various actions like *Mamsa Vilekhyati* (curates fat from muscle tissue), *Shonitasanghatabhinnati* (breaks blood clots and other obstructions) and *Shleshmashamyati* indicate its *Medohara* effect. Also, *Tikshana Guna, Ushana Virya* is *Kleda, Medo Vilayana* (liquifies the impacted fat). Hence the drug is effective in reducing the excess *Abaddha* & *Baddha Meda.*

Probable mode of action on *Agni*

As per *Acharya Sushruta* and *Vagbhata* one main cause in *Sthaulya* is *Amarasa* due to *Agnimandya* (especially *Dhatvagni Mandya*) which leads to accumulation of *Medodhatu*. By virtue of *Ushana Virya, Laghu, Teekshana Guna Vacha* has *Aampachana* property. Thus alleviates *Aparipakwa* & *Ama Dhatu*. It is proposed that *Vacha* increases hepatic conversion of cholesterol to bile acids. It increases the secretion of bile and thus excessive cholesterol can be removed with bile from liver.

Probable mode of action on *Srotasa*

In *Sthaulya,* there is *Sanga* type *Srotodushti* produced by vitiated *Kapha* and *Meda*. The drug *Vacha* opens the channels and clears this *Sanga* (obstruction) in *Srotas* by the virtue of its *Katu Rasa* (*Marganvivrinoti*), *Ushna Virya*, *Pramathi* and *Srotoshodhan* action. Thus, ultimately regulates the functions of *Medovaha Srotasa*. *Vacha* also unblocks all macro and micro channels of the body and mind also owing to its specific

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properties. Therefore, it is proposed to act on LDL receptor system at cellular level of capillaries and may increase the activity of lipoprotein lipase found on the surface of endothelial cells lining the capillaries in the muscle and adipose tissue thus helpful in removing the fatty acids of triglycerides.

The combined effect of all the *Rasapanchaka* of *Vacha* is thus proposed to combat *Sthaulya* (Hyperlipidemia) and gave relief in the symptoms.

Conclusion

From the results of present clinical study, it can be concluded that *Vacha* has good potential for the treatment of Hyperlipidemia especially S. Cholesterol and LDL levels. It even gave symptomatic relief in patients of *Sthaulya*. It can be a promising adjuvant drug to deal with this problem.

Limitations of present study and suggestions for further research works:

- The present research work has been done in limited time on limited patients. For better results, there is a need for study to be done on a large number of patients, for longer duration.
- *Sthaulya* is a *Yapya* type of disease. *Vacha* alone was insufficient to combat obesity. Thus, it is proposed that it can be given as adjuvant to some other drugs or *Shodhana* therapy especially for class II Obesity and the therapy need to be administered for a longer duration to get consistent results.
- *Vacha* capsule were administered empty stomach as advised textually for *Lekhana Aushadh.* Though capsules were palatable but due to its *Teekshana Guna* and *Ushna Virya* it was difficult for the patient to take the medicine on an empty stomach.

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