

CLINICAL RESEARCH

Clinical evaluation of homoeopathic therapy in the management of hyperlipoproteinemia

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Objectives: This study aimed at evolving a group of useful homoeopathic medicines in the treatment of hyperlipoproteinaemia, to identify their reliable indications, most useful potencies, frequency of administration and relationship with other medicines.

Methods: A prospective observational study was carried out during the period 1992-2003. Three hundred and twenty two patients with hyperlipoproteinaemia and various clinical presentations were studied. Patients of more than 30 years of age, with cholesterol > 200mg/dl, triglycerides > 170mg/dl, LDL > 150mg/dl, VLDL > 50mg/dl and HDL < 35 mg/dl were included in this study. Specific parameters were followed to assess the intensity of complaints and the improvement status. Homoeopathic medicines were prescribed in different potencies (Q to 10M), basing on the presenting complaints, mental and physical attributes of the patients. The patients were advised to have low calorie diet and regular exercise.

Results: Two hundred ninety three (293) patients were followed up regularly and varying degrees of improvement were observed, viz. marked improvement in 77 patients, moderate improvement in 113 patients, mild improvement in 100 patients and no improvement in 03 patients. *Abroma augusta 30*, *Gelsemium 30*, *Lycopodium 1M*, *Bryonia alba 30*, *Pulsatilla 30*, *Nux vomica 30* were found to be useful among the other prescribed medicines.

Conclusion: Results obtained from the study are encouraging with findings that 26% of the patients improved markedly with an evidence of changes in laboratory parameters. However, an experiment in controlled setting with improved protocol and clearer outcome parameters is required.

Key words: homoeopathy; observational study; hyperlipoproteinaemia; abroma augusta; gelsemium; lycopodium; bryonia alba; pulsatilla; nux vomica.

Introduction

In 1970s, Fredrickson and colleagues introduced a classification of the primary hyperlipidaemias, based on lipoprotein ultracentrifugation and electrophoresis.¹ It is estimated that over 60% of the variability in serum lipids is genetically determined, most of this variation being due to polygenic influences. Interaction between the latter and environmental factors is probably the commonest cause of hyperlipidaemia (hyperlipoproteinaemia) in the general population. Familial forms of hyperlipidaemia are usually more clearly

defined, especially those which have a monogenic or dominant pattern of inheritance, but are less common. This type of disorder, exemplified by familial hypercholesterolaemia, is expressed independently of environmental influences. In contrast, in familial type III hyperlipoproteinaemia inheritance of the underlying gene defect is often insufficient to produce hyperlipidaemia unless additional environmental or genetic influences coexist. Rarely, hyperlipidaemia is recessively inherited, as in familial deficiency of lipoprotein lipase and of apolipoprotein CII. Primary hyperlipidaemias characterized by severe hypertriglyceridaemia predispose to acute pancreatitis whereas those disorders characterized by hyper-cholesterolaemia, apart from hyperlipoproteinaemia, are associated with an increased risk of premature vascular disease.²

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Secondary hyperlipidaemia is common and occurs frequently in disorders such as obesity, alcoholism, diabetes mellitus, hypothyroidism, liver and renal diseases and as a side-effect of drug therapy (β blockers, estrogen, furosemide, glucocorticoids, bile acid-binding resins, retinoic acid, HIV protease inhibitors, thiazides, cyclosporine, tegretol). Its management may be important to prevent complications such as coronary heart disease and acute pancreatitis.^{3,4}

Dietary control and exercise are required to overcome this disease since this is the major cause of various cardiovascular diseases occurring and causing death. Studies have clearly established that lipid and lipoprotein levels in human plasma or serum are related to the risk of developing coronary heart disease. Among the more commonly measured lipoproteins the low-density lipoprotein (LDL) and to a lesser extent, the very-low-density lipoprotein (VLDL) are associated in a positive manner with increased risk, while the high-density lipoprotein (HDL) is associated with reduced risk and may be protective.⁵

Various side effects occur from the anti-hyperlipidaemic agents viz. gastrointestinal changes in bowel function, potential to exacerbate pre-existing haemorrhoids, nausea, abdominal discomfort; cutaneous flushing; dryness of the skin, and rarely, blurred vision.⁶

Bauman *et al*⁷ studied the positive role of homoeopathic medicine 'Cholesterinum 3x' in reducing serum cholesterol in rabbit model. In this backdrop, the Central Council for Research in Homoeopathy undertook this study for evaluating the role of homoeopathic therapy in the management of hyperlipoproteinemia.

Aim and objectives

To clinically evaluate the usefulness of homoeopathic medicines in hyperlipoproteinaemia, to identify their reliable indications, most useful potencies, frequency of administration and relationship with other medicines.

Material and Methods

A prospective observational study was carried out during the period 1992-2003 at Regional Research Institute, New Delhi⁸ to explore the usefulness of homoeopathic medicines in management of symptoms related to hyperlipoproteinaemia. There were 135 males and 187 females who belonged to age group between 13 years to 70 years. All patients were diagnosed through laboratory parameters and were included in the study: cholesterol > 200mg/dl, triglycerides > 170mg/dl, LDL > 150 mg/dl, VLDL > 50 mg/dl and HDL < 35 mg/dl. Patients requiring hospitalization/surgical intervention were excluded from the study. The duration of suffering ranged from 2 days to 31 years. Along with the indicated homoeopathic medicines all the patients were advised to adhere to the general measures: low calorie diet, regular exercise and daily walking for 45 minutes and to avoid saturated fats and stress. Predefined parameters were followed to assess the outcome (Table 1).

Observations

In this study it is observed that hyperlipoproteinemia was prevalent in both the sexes of middle age group ranging between 35-60 years (77.3%). Females were more (59.4%) than their male counterparts. Woman patients below 35 years of age (3.1% of 322) were least. Thus it is observed that the trend of hyperlipoproteinemia

Table 1: Parameters adopted for post treatment outcome assessment

Post treatment out come	Criteria for assessment
Cured	When patient was asymptomatic and lipid profile came down to normal level and there was no recurrence for three years.
Improvement	
• Marked	When patient became asymptomatic and lipid profile came down to normal level.
• Moderate	Symptomatic relief with more than 50% reduction in increased lipid profile above normal level.
• Mild	Partial symptomatic relief with less than 50% reduction in increased lipid profile above normal level.
No improvement	No change in lipid profile and symptoms.
Worse	Aggravation of complaints and upward trend in lipid profile.
Dropped out	Poor compliance by the patient as to specific treatment and general management.

proteinemia is more in the middle aged persons (Figure 1). History of pancreatitis was observed in 38 patients.

Sixty two patients received treatment upto 30 days, 115 patients were treated for 1 month to less than 3 months while 145 patients were treated upto 1 year.

TGL was found to be increased in 246 patients; total cholesterol in 249 patients, very low density lipoprotein (VLDL) in 48 patients and 64 patients had increased LDL. Routine urine examination was done in patients at screening level to see any co-related disease conditions (Table 3).

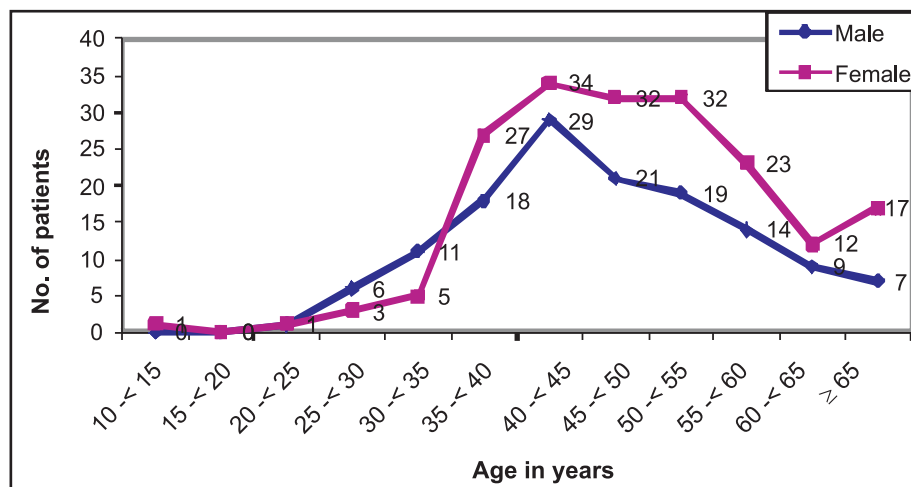
Table 2: Causes of hyperlipoproteinaemia

Causes	No. of patients		
	Male	Female	Total
<i>Primary causes</i>			
• Family history of hyperlipidaemia or xanthomas	04	04	08
<i>Secondary causes</i>			
• Diabetes mellitus	39	39	78
• Hypothyroidism	04	15	19
• Obstructive liver disease	01	04	05
• Antihypertensive drugs	33	53	86
• Alcohol use	59	00	59
• Cigarette smoking	35	03	38
• Increased calorie intake in form of saturated fats and cholesterol	77	89	166

Table 3: Pathological findings

Profile	No. of patients		
	Male	Female	Total
Blood			
Total triglycerides > 170 mg/dl	110	136	246
Total cholesterol > 200 mg/dl	106	143	249
H.D.L. < 35 mg/dl	07	13	20
L.D.L. > 150 mg/dl	26	38	64
V.L.D.L > 50 mg/dl	22	26	48
ESR ↑	23	75	98
Hb% ↓	02	09	11
SGOT ↑	13	07	20
SGPT ↑	12	07	19
Blood sugar ↑	30	31	61
Serum amylase ↑	01	02	03
Uric acid ↑	03	01	04
Serum alkaline phosphate ↑	10	06	16
Bilirubin ↑	01	03	04
Urine			
Protein +	09	20	29
Epithelial cells +	00	16	16
Bacteria +	02	20	22
Sugar +	11	5	16
Cal. oxalate +	05	9	14
Pus cells +	02	14	16
Phosphates +	02	03	05
Urates +	00	01	01
R.B.C. +	00	03	03
Uric acid +	01	03	04

Figure 1: Age profile



Majority of patients (166 patients) had secondary type of hyperlipoproteinaemia (Table 2). This can be co-related with dietary factors like high calorie intake in the form of saturated fats and cholesterol (166 patients), intake of alcohol³ (59 patients), cigarette smoking (38 patients), anti-hypertensive drugs³ (88 patients) and diabetes mellitus³ (78 patients). There was diverse presentation of symptoms and signs in the patients which is shown in Table 5.

Results

Out of 322 patients enrolled, 293 patients (123 males and 170 females) were followed up and 29 patients were dropped out.

Analysis of pathological findings before and after treatment shows that out of 246 patients who had increased triglycerides, 100 patients were found improved; 137 out of 249 patients showed decrease of their increased cholesterol; LDL was reduced in 30 out of 64 patients and VLDL was reduced in 13 out of 48 patients. HDL was found to be in normal range in maximum no. of patients (n=273). Out of 20 patients having HDL < 35 mg/dl, level was improved in 8 patients after the treatment (Table 4). Similarly various symptoms and signs which were

Table 4: Response to treatment (pathological findings)

Findings	No. of patients	
	Prescribed	Improved
Total triglycerides > 170 mg/dl	246	100
Total cholesterol > 200 mg/dl	249	137
H.D.L. < 35 mg/dl	20	8
L.D.L. > 150 mg/dl	64	30
V.L.D.L > 50 mg/dl	48	13
ESR ↑	98	29
Hb.% ↓	11	3
SGOT ↑	20	4
SGPT ↑	19	2
Blood sugar ↑	61	30
Serum amylase ↑	3	0
Uric acid ↑	4	0
Serum alkaline phosphatase ↑	16	7
Bilirubin ↑	4	0

present associated with hyperlipoproteinaemia were also improved after homoeopathic intervention (Table 5).

Out of 293 patients followed up, 290 got improved; among these 26% showed marked improvement, 39% moderate improvement, 34% mild improvement and 01% of the patients showed no improvement (Figure 2).

This study identifies a group of medicines which were found to be useful in hyperlipoproteinaemia, with their indications, and frequency of repetition. The symptomatic indications of these medicines which were studied are mentioned in Table 6.

The useful medicines in the treatment of hyperlipoproteinaemia are as follows: *Abroma augusta* 30 (n=16; 93.5%), *Gelsemium* 30 (n=18; 88.8%), *Lycopodium* 1M (n= 65; 83%), *Pulsatilla* 30 (n=38; 76.3%) and *Nux vomica* 30 (n=16; 75%). The relationships of the medicines (followed well and complementary) are described in Table 7.

Table 5: Response to treatment (symptoms and signs)

Symptoms/signs	No. of patients	
	Prescribed	Improved
Constipation	27	20
Anxiety	37	12
Headache	56	41
Irritability	41	19
Chest pain on exertion	42	30
Palpitation	98	63
Dyspnoea	98	61
Flatulence	107	70
Pain in calf muscles	14	12
Itching of whole body	2	2
Heaviness of abdomen	4	4
Diabetes mellitus	41	20
General weakness	61	39
Cough	17	16
Easy fatigue	9	8
Hypertension	162	103
Pain in joints	37	25
Pain in neck	34	26

Figure 2: Improvement status

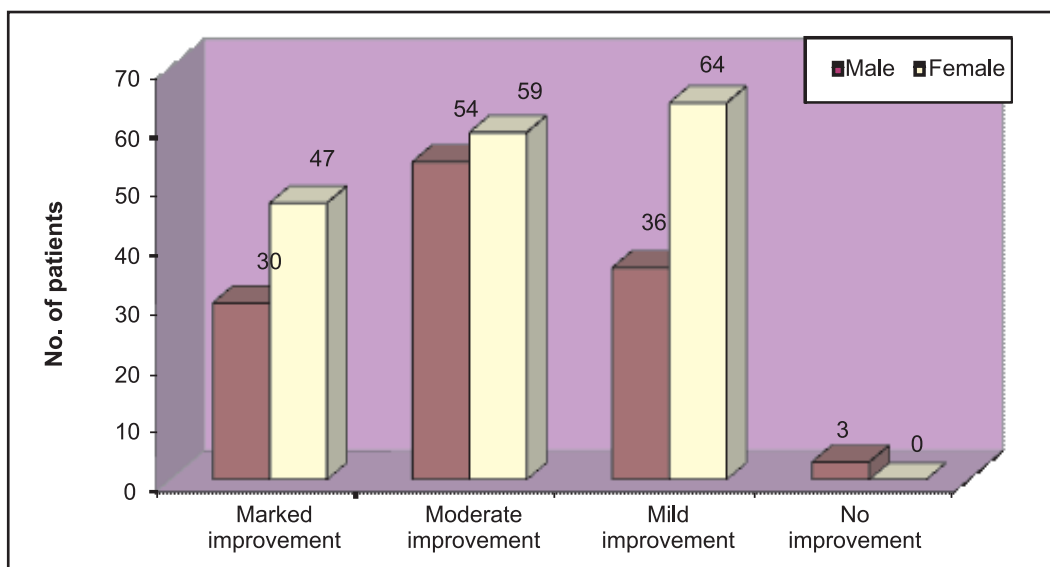


Table 6: Medicines found useful with their frequency of dose and indications

Medicine	Potency	Frequency of dose	No. of patients		Indications
			Prescribed	Improved	
Abroma augusta	30	tds [§] , qid*	16	15	<ul style="list-style-type: none"> Weakness with sleeplessness Urine frequent, profuse; dryness of mouth with great thirst during and after urination Cough with yellow expectoration Diabetes mellitus Constipation: stool hard, lumpy with much straining Leucorrhoea: thin watery and profuse.
Arsenic album	30	tds, qid	7	7	<ul style="list-style-type: none"> Anxiety with restlessness, aversion to be alone, fastidiousness Weakness with sleeplessness Difficulty in breathing, suffocative feeling at night while lying down, going upstairs. Swelling of eyes and feet.
	200	Two doses	1	1	
	1M	Two doses	2	1	
Baryta muriaticum	30	tds, qid	11	4	<ul style="list-style-type: none"> Heaviness of head, vertigo and noises in ear Cough with difficult expectoration with body feeling cold Hypertension.
	200	bds [#]	1	1	
Bryonia alba	30	tds, qid	11	9	<ul style="list-style-type: none"> Fear of suffering Thirst increased, bitter taste Constipation: stool dry and hard Dyspnoea worse from walking, exertion; better from rest
	200	bds	8	6	
	1M	Two doses	5	3	

[§]tds – thrice a day; *qid- four times a day; [#]bds- twice a day

Medicine	Potency	Frequency of dose	No. of patients		Indications
			Prescribed	Improved	
					<ul style="list-style-type: none"> • Dryness of mouth • Pain in joints worse from walking, hot weather; better by pressure.
Cactus grandiflorus	Q	10 drops tds	7	5	<ul style="list-style-type: none"> • Palpitation, dyspnoea, • Constricted feeling in the left side of chest with pain.
	30	tds, qid	4	2	
Calcarea carbonica	1M	Two doses	45	31	<ul style="list-style-type: none"> • Fair, fat, flabby, chilly and obese. • Aversion to work • Palpitation with coldness and oppression of chest.
Gelsemium semperviens	30	tds, qid	18	16	<ul style="list-style-type: none"> • Depression, dullness in general, weakness, drowsiness, dizziness and trembling. • Muscular weakness, worse from motion, better by continued motion. • Palpitation, slow and weak pulse.
Kalmia latifolia	30	tds, qid	10	9	<ul style="list-style-type: none"> • Vertigo; headache worse from sun heat • Palpitation worse from exposure to sun; increased sweating. • Pain in neck worse from pressure, touch, eructation. • Cervical spondylosis
	200	bds	2	2	
Lachesis	200	Two doses	11	5	<ul style="list-style-type: none"> • Jealous, suspicious. • Hot flushes, sleeplessness. • Constipation with anxiety. • Palpitation; pain in left side of body; worse after sleep.
	1M	Two doses	2	2	
Lycopodium	30	tds, qid	64	45	<ul style="list-style-type: none"> • Irritable, sensitive, sad, desires company, memory weak. • Hot patient, general weakness • Desires sweet. • Flatulence worse in the evening; water brash from mouth; distension of abdomen after eating; constipation; heart burn. • Palpitation worse at night and after eating.
	200	Two doses	29	14	
	1M	Two doses	65	54	
	10M	Two doses	1	1	
Natrum muriaticum	30	tds, qid	1	1	<ul style="list-style-type: none"> • Silent, suppressed anger; desires to be alone, depressed, irritable, h/o of grief; consolation aggravates. • Craving for salt. • Severe headache • Palpitation.
	200	Two doses	1	1	
	1M	Two doses	15	11	
	10M	Two doses	1	1	

Medicine	Potency	Frequency of dose	No. of patients		Indications
			Prescribed	Improved	
Nux vomica	30	tds, qid	16	12	<ul style="list-style-type: none"> Irritable, sensitive to noise, oversensitive. Chilly patient. Dyspepsia, flatulence, sour eructation, distension of abdomen worse after eating. Headache with vertigo. Alternate constipation and diarrhea, nausea in the morning; unsatisfactory stool.
	200	Two doses	6	3	
Pulsatilla	30	tds, qid	38	29	<ul style="list-style-type: none"> Mild, gentle, weeps easily, feels better after consolation, melancholic; better in open air. Thirstlessness; acidity, indigestion, flatulence worse taking fried food.
	200	bds, two doses	3	3	
	10M	1 dose	1	1	
Rhus toxi-codendron	30	tds, qid	18	13	<ul style="list-style-type: none"> General weakness, palpitation, restlessness at night, Numbness of left arm, Pain in joints worse cold, wet rainy weather, rising and relieved by continued motion.
	200	bds	5	4	
	1M	Two doses	12	6	
	10M	Two doses	1	1	
	0/1	bds	2	1	
Rauwolfia serpentina	Q	10 drops tds	10	7	<ul style="list-style-type: none"> Irritable, nervous and violent. Hypertension.
Sulphur	200	Two doses	25	13	<ul style="list-style-type: none"> Oppression with burning sensation in chest; chest feels heavy, stitches with palpitation. Flushes of heat, dislikes bathing, itching of whole body with burning.
	1M	Two doses	8	6	

Table 7: Relationship of medicines

Name of the medicine	Name of the related medicine	No. of patients	
		Prescribed	Improved
Followed well			
Calcarea carb.	Lycopodium	8	7
Lycopodium	Nux vomica	3	2
Sulphur	Calc.carb.	4	3
Complementary			
Pulsatilla	Lycopodium	4	4
Bryonia	Rhus tox.	2	2
Rhus tox.	Bryonia	3	2
Calc.carb.	Lycopodium	2	2
Lycopodium	Pulsatilla	6	6

Discussion

This was a prospective observational study showing positive results in the symptoms associated with hyperlipoproteinaemia and changes in laboratory parameters. The age profile reflects high prevalence of hyperlipoproteinaemia in the middle age group, which commensurates with the findings of Jones *et al*.⁵ This increase in prevalence may be due to modern life style.

Abroma augusta 30, *Gelsemium* 30, *Lycopodium* 1M, *Pulsatilla* 30, *Nux vomica* 30 were found be most useful among the medicines prescribed.

Abroma augusta was helpful when prescribed on the basis of common clinical condition like diabetes mellitus associated with constipation, leucorrhoea (thin watery and profuse), weakness with sleeplessness,

frequent profuse urination, dryness of mouth with great thirst during and after urination. Another study⁹ in rat model shows that the extract of *Abroma augusta* along with extract of *Azadirachta indica* could reduce the lipid level and reduce body weight but the study does not indicate the efficacy of *Abroma augusta* alone.

Gelsemium was useful when prescribed for its common symptoms, i.e. depression, dullness, general weakness, drowsiness, dizziness and trembling.

Lycopodium was indicated when the patient presented with symptoms of irritability, sensitivity, sadness, desire for company, weak memory; sensation of heat in body, desire for sweets, flatulence (worse in evening); distension of abdomen after eating; constipation and heart burn.

Pulsatilla was useful when prescribed on the basis of mental and physical generals (mild, gentle, weeps easily, melancholic and feels better after consolation); better in open air, thirstlessness; acidity, indigestion, flatulence worse taking fried food.

The objectives to evaluate the most efficacious medicines, their potencies, reliable indications, frequency of administration and relationship of various remedies were achieved.

Conclusion

The results obtained from the study are encouraging with findings that 26% of the patients improved markedly with an evidence of changes in laboratory parameters. However, an experiment in controlled setting with improved protocol and clearer outcome parameters is required.

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