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Effect of trikatu compound in hypercholesteremia- a clinical study

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Abstract

A clinical trial was under taken to evaluate the efficacy of the drug Trikatu Compound in treatment of hypercholesteremia patients. The dose of the trial drug was fixed at 3 gram twice a day after meal with lukewarm water for group A. Group-B was on only Atorvastatin 20mg (hypolipidemic drug) and group-C was placebo. After 3 months of drug trial there was highly significant ($p<0.001$) result observed in group A. symptomatic relief was also reported by the patients. Also no adverse effects were reported by group A patients during the study. This study reveals that Trikatu Compound is useful in treatment of hypercholesteremia.

Keywords: trikatu, hypercholesteremia hypertension, SGP

Introduction

Hypercholesteremia is the excessive presence of cholesterol in blood in over a period of decades, chronically elevated serum cholesterol contributes to formation of atheromatous plaques in arteries leads to stenosis or occlusion of involved arteries and then tissue ischaemia. Further this tissue ischemia leads to heart disease, stroke like life threatening disease, which is the major cause of death in present time. The disease is described as a medaroga in Ayurvedic literature. In this study the drug Trikatu Compound described in Ayurveda text Bhavprakash was applied to see the effect of the drug in hypercholesteremia and was found to be effective (Susruta 1995, Agniveasa 1992, Vagbhatta 1989, Bhavmisra 1999, Sharma 1994).

Material and Methods

Selection of patients

90 patients of hypercholesteremia,(30 in each group) were selected from the OPD/IPD of RRI (Ayurveda) Itanagar Arunachal Pradesh. All the cases were registered and recorded with the help of a special proforma prepared for this purpose. Patients were subjected to detailed case history taking, physical examination and laboratory investigations like lipid profile, fasting blood sugar ,SGPT, blood urea and serum creatinine. To exclude other physical abnormalities, normal blood picture i.e TLC, DLC, Hb%, ESR etc. were done. In some cases ECG was done to see the status of cardiac abnormality.

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Inclusion criteria :

Patients were selected on the basis of laboratory investigation having cholesterol >240mg/dl,
Patients of age group between 15-65 yrs
Patients of obesity , hypertension and IHD were included.

Exclusion criteria:

Patients of age group below 15 yrs and above 65yrs
Diabetes mellitus patient (NIDDM or IDDM)
Critically ill cardiac patient.
Drug induced hypercholestermia like steroid or diuretics drug
Hypothyroidism patient

Method of preparation of drug

First, raw drugs of individual ingredient were purchased from the authentic seller of Itanagar Arunachal Pradesh and were identified and powered RRI (Ayurved) Itanagar Arunachal Pradesh. The prepared drug Trikatu Compound contain Pippali (*Piper longum*) Maricha (Piper nigrum) and sunthi (*Zingiber officinale*) in equal ratio.

Method of drug trial

3 groups were planned for the drug trial. 30 patient were in each group. Patients of group A were given 3gms of Trikatu Compound twice a day after meal with leuk warm water. Patients of group B were on hypolipidemic drug only Atorvastin 20mg once after dinner. Group C was placebo group given capsule contains glucose.

Duration of study

The total duration of study was done for 3 months. Patients were advised to come for the follow up every month interval for the assessment of improvement and persistence of any adverse effect.

Criteria for assessment

Assessment was done under the two heading subjective assessment and objective assessment.

Subjective assessment - In each group ,all the patients were assessed for the subjective improvement In which are described in Ay. text in context of Medo rog (Lipid disorder) i.e excessive hunger & thrust, sleep, body smell, fat movement in breast and abdomen, libido, fatigue,
feeling of heaviness, weakness, excessive sweating, moisture of body etc. by means of scale of grading. All these symptoms were divided in five grades (0-4) on the basis of severity and duration.

Table-I Grading of subjective symptoms

Symptoms	Score	Grade	Grading criteria for symptoms
Excessive hunger	0	Absent	-Intake of proper amount of food
	1	Mild	-Craving for food more than twice
	2	Moderate	-3-4 times eating habit
	3	Severe	-Frequent craving for food
	4	Very severe	-Craving for food in night also
Excessive thurst	0	Absent	-normal thurst
	1	Mild	-upto 1lt more intake of water after desirable amount
	2	Moderate	- upto 2lt more intake of water after desirable amount
	3	Severe	-upto 3lt more intake of water after desirable amount
	4	Very severe	-upto 4lt more intake of water after desirable amount
Boby smell	0	Absent	-no smell
	1	Mild	-mild smell but can be avoided after bath
	2	Moderate	-smell can be avoided by application of perfuming agent
	3	Severe	
	4	Very severe	-smell from distance and cant be avoide by perfume -Excessive smell creats discomfort to patient itself
Excessive sleep	0	Absent	-7 to 8 hrs sleep and freshness
	1	Mild	->8 hrs sleep and feeling drowsy
	2	Moderate	->8 hrs sleep, feeling drowsy and frequent yawning
	3	Severe	->10 hrs sleep and feels drowsy in day time
	4	Very severe	->10 hrs sleep and feels depressive
Fat movement in breast and abdomen	0	Absent	-no movement
	1	Mild	-movement seen on exercise
	2	Moderate	-movement seen on walking
	3	Severe	-movement seen on mild body movement
	4	Very severe	-movement seen on very mild body movement
Libido	0	Absent	-proper sexual performance
	1	Mild	-mild dyspnoea after intercourse
	2	Moderate	-moderate dyspnoea after intercourse and weakness
	3	Severe	-Unable to complete sexual intercourse and dyspnoea
	4	Very severe	- unable to perform sexual intercourse
fatigue	0	Absent	-normal work performance
	1	Mild	-tiredness after heavy work
	2	Moderate	- tiredness after moderate work
	3	Severe	- tiredness after mild work
	4	Very severe	-tiredness after very mild work

Feeling of heaviness	0	Absent	-no heaviness
	1	Mild	-feels heaviness but can perform normal work
	2	Moderate	-difficult to perform normal work due to heaviness
	3	Severe	- difficult in normal routine work due to heaviness
	4	Very severe	-depression due to feeling heaviness
Weakness	0	Absent	-well exercise power without tiredness
	1	Mild	-weakness on moderate exercise
	2	Moderate	-weakness on mild exercise
	3	Severe	-feels tired on very mild exercise
	4	Very severe	-unable to do routine activity
Moistureness of body	0	Absent	-normal moisture
	1	Mild	-excess moisture in humidity
	2	Moderate	- excess moisture in dry climate
	3	Severe	-excess moisture in dry climate and make discomfort
	4	Very severe	-excessive continuous moisture all over the body
Excessive sweating	0	Absent	-sweating after heavy work
	1	Mild	- sweating after moderate work
	2	Moderate	- sweating after mild work
	3	Severe	- excessive sweating after mild work
	4	Very severe	- sweating on rest and winter also

Objective assessment

Under the objective parameters laboratory findings were assessed as follows : lipid profile, fasting blood sugar, blood urea, serum creatinine, SGPT, Hb%, TLC, DLC, ESR of every patient was done before and after treatment.

Statistical analyses for changes in all objective criteria were assessed by p-paired test.

Results and Discussion

Under the study of demographic profile of 90 patients it was noted that maximum number of patient (40%) had 36-45 years age. This shows that there is maximum prevalence of disease in middle age group. Gender distribution of the disease showed that male (54.44) were more prone to the disease as compared to female sex. 73.33% of cases registered belong to Hindu community. This may be due to Hindu dominant attendance of patients in Ayurvedic hospitals. Regarding socio-economic status, higher middle status group was 26-66% and minimum 6.66% cases registered belongs to lower income group indicating higher rate of prevalence of hypercholesteromia is in middle to higher socio-economic group. Basal metabolic rate (BMI) of patients were measured and it was found that 92% were above normal limit (>26 kg/m2). Although 100 patients were registered for the study but 10 cases dropped out of the trial at various time points during 3 month treatment period without any specific complaint made by these patients. The progress of the remaining 90 patients is described in detail. In group A improvement of serum cholesterol is 9.67%, triglyceride is 7.72%, serum VLDL is 12.92%, LDL is 22.61% and HDL-20.11%. It indicates highly significant P value i.e <0.001.In group B where Atorvastin 20mg 10 mg was given in OD dose, improvement of serum cholesterol is 12.73%, triglyceride-11.79%, HDL-1.97%, LDL-17.90% and VLDL-16.25%. In case of placebo group C improvement found as cholesterol is 2.12%, triglyceride-1.54%, HDL-2.46%, LDL-2.22% and VLDL-1.54%.Analytical observation found for fasting blood sugar in group A-5.19% ($p<0.01$), group B-0.79% and group C-1.24% improvement. Changes found in SGPT are – in group A it is 27.21%, in group B-6.20% and in group C-1.35%. improvement found in BMI are group A-8.16%, group B-0.44%.Similarly, improvement was seen in subjective assessment factor like in group A 50% in moistureness of body, 45.65% in feeling of heaviness, 35.29%in fatigueness , 34.48% in excessive sweating, 34.88% in excessive hunger, 33.99% in fat movement in breast & abdomen. In case of group B 18.75% improvement in fatigue, 16%in moistureness, 13.51% in excessive thirst, 12.77% in weakness, 11.54% in excessive sweating, 10% in fat movement, 4.76% in feeling of heaviness. In case of group C 13.21% in excessive sweating, 10.53% in fatigue, 9.62% in moistureness, 8.06% in

fatmovement, 3.03% in excessive hunger. Changes in body weight for group A is 2.07% ($p<0.001$) which is highly significant. Group B is 0.84% ($p<0.1$) and group C is 0.10% ($p<0.1$). both group B & C are not significant.

Table 2: Showing percent improvement in lipid profile after treatment

Group-A

Lipid Profile	Mean		Diff.	% improvement	SD	SE	T	P
	B.T.	A.T						
Cholesterol	291.93	263.70	28.23	9.67	15.65	2.86	9.88	<0.001
Triglyceride	237.47	219.13	18.33	7.72	24.22	4.42	4.12	<0.001
H.D.L	42.38	43.78	1.40	3.31	2.71	0.50	2.83	<0.001
L.D.L	171.98	137.39	34.58	20.11	21.96	4.01	8.63	<0.001
V.L.D.L	43.09	37.52	5.57	12.92	5.13	0.94	5.94	<0.001
HDL/ VLDL	4.15	3.21	0.94	22.61	0.62	0.11	8.26	<0.001

Group-B

Lipid Profile	Mean		Diff.	% improvement	SD	SE	T	P
	B.T.	A.T						
Cholesterol	272.57	237.87	34.70	12.73	34.87	6.37	5.45	<0.001
Triglyceride	236.90	208.97	27.93	11.79	29.47	5.38	5.19	<0.001
H.D.L	43.74	42.88	0.86	1.97	2.34	0.43	2.11	<0.1
L.D.L	158.82	130.40	28.42	17.90	21.69	3.96	7.18	<0.001
V.L.D.L	45.73	42.08	3.65	7.98	6.84	1.25	2.92	<0.010
HDL/ VLDL	3.68	3.08	0.60	16.25	0.53	0.10	6.19	<0.001

Group-C

Lipid Profile	Mean		Diff.	% improvement	SD	SE	T	P
	B.T.	A.T						
Cholesterol	288.77	282.63	6.13	2.12	16.77	3.06	2.00	<0.1
Triglyceride	280.10	275.80	4.30	1.54	12.25	2.24	1.92	<0.1
H.D.L	42.83	41.77	1.05	2.46	2.93	0.54	1.96	<0.1
L.D.L	189.92	185.70	4.22	2.22	18.09	3.30	1.28	<0.1
V.L.D.L	56.02	55.16	0.86	1.54	2.45	0.45	1.92	<0.1
HDL/ VLDL	4.47	4.47	0.00	-0.05	0.64	0.12	-0.02	<0.001

Table 3: Comparative study on lipid profile (in %) in different groups

Lipid Profile	Group A	Group B	Group C
Cholesterol	9.67	12.13	2.12
Triglyceride	7.72	11.79	1.54
H.D.L	3.31	1.97	2.46
L.D.L	20.11	17.90	2.22
V.L.D.L	12.92	7.98	1.54
HDL/ VLDL	22.61	16.25	-0.05

Different clinical trials have been established as anti hypercholesteremic agent. The aim of the present study was to evaluate the effect of Trikatu Compound in patients of hypercholesteremia.

Symptomatic relief was found in group A as $p<0.001$ which is highly significant than group B & C as $p<0.1$ and $p>0.1$. The improvement in lipid profile is found to be highly significant in group A and group B i.e $p<0.001$ but the result was not significant in group C ($p<0.1$)Trikatu Compound have highly significant effect on BMI as in group A ($p<0.001$) ,where as in group B & C have shown no such effect.

Conclusion

Looking at the result it may be concluded that Trikatu Compound is a potent hypocholesteremic drug. Although Its effect on cholesterol is slower than atorvastatin but it is found more helpful in improving H D L.However, further more comprising larger group and experimental study on animal is needed to reach the more definite conclusion.

References

Agniveasa 1992. *Charaka samhita, Revised by Charaka and Di habala with the Ayurveda dipika commentary of cakrapa, idatta.* Edited by Vaidya Yadavji Trikamji Acharya. New Delhi: Manoharlal publishers Pvt. Ltd. IV Edition.

Bhavamisra 1999. *Bhavaprakash with Vidyotini Commentary by Sri Bhrama Shankar Shastry.* Varanasi: Chaukhambha Sanskrit. IXth Edition.

P.V. Sharma 1994. *Dravyaguna Vigyana*. *Varanasi* : Chaukhambha Bharti Academy. Vol II XVI Edition.

Susruta 1995. *Susruta Samhita with Ayurveda Tatva Sandipika*. Hindi commentary by Kaviraj Ambikadutta shastri Varanasi:; Chaukambha Sanskrit. IX Edition.

Vagbhata 1989. *Astanga Sangraha with Hindi commentary by Sri Pandit Lal Chandra Shastri Vaidya Nagpur*: Sri Baidyanth Ayurveda Bhavan. 1st Edition.