

Individuals at Risk of Coronary Heart Disease (CHD), its Prevention and Management by an Indigenous Compound.

Dr. G.P. DUBEY, DR. ARUNA AGRAWAL, DR.S.P. DIXIT, DR.S.R.PATHAK

Instt. Of Medical sciences
Banaras Hindu University

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ABSTRACT: A variety of risk factors have been suspected for causing the coronary heart disease. 406 cases of both sex groups with age range of 35 to 55 years were selected from three distinct localities of varanasi city. Individuals who reported single or more risk factors of CHD were isolated from the population of the particular areas. After a detailed preliminary screening of the subjects various physical, physiological, psychological and biochemical measurements were carried out. On the basis of initial findings, the cases who showed abnormal lipid profile with dominant psychological involvement were given the organic extract of *Inula racemosa* (Pushkarmool), *Commiphora mukul* (Guggulu), *Centella asiatica* (Mandukaparni) and *Hypericum perforatum* (Basant) in prescribed doses continuously for 6 months. Correction in the lipid profile including triglycerides, blood pressure and the psychological factors like anxiety and depression to a significant level following least drug treatment indicated the cardioprotective and therapeutic effects of the present formulation.

Hence, by modifying the coronary risk factors, the incidence of CHD can be minimized to a great extent as well as the test formulation may also be advocated in the prevention and management of CHD.

INTRODUCTION

The risk factor concept implies that a person with at least one risk factor for coronary heart disease is more likely to appear so earlier in comparison to a person with only one risk factor. The presence of multiple risk factors further accelerates the high occurrence of atherosclerosis associated with multiple pathology.

Hypercholesterolemia, hyperglycemia (diabetes), high caloric intake with least physical exercise, hypertension and cigarette smoking etc., are the most potent causative factors of CHD. The age, Sex and genetic factors are considered as the irreversible risk factors for CHD. Genetic factors have been observed to have direct effects on arterial wall cell structure and

metabolism or indirectly act to manifest hypertension, hyperlipidemia, diabetes and obesity (YLA Herttuala, 1991).

Hypercholesterolemia and hypertriglyceridemia are the most important abnormalities causing the event of atherosclerosis. A strong correlation between the cholesterol concentration and incidence of ischaemic heart diseases has been established which suggests that the increasing risk of CHD can be detected when the cholesterol level is higher than 200 mg/dl for the age group of 40 to 49 years (Bierman, 1993).

According to castelli et al (1986), Cholesterol levels in men below age of 40 years are closely related to the future occurrence of CHD. The multiple risk factor intervention trial has reported that the men with cholesterol levels of 240 mg/dl have a higher increase in risk of CHD death in comparison to men with a cholesterol level below 200 mg/dl.

As regards prevention and management of coronary risk factors are concerned. Following three basic steps appear to be taken into consideration:-

1. Prevention of occurrence of adverse risk factors of CHD,
2. management of established adverse risk factors before the clinical manifestation of CHD
3. Management of coronary risk factors after the clinical manifestation.

Keeping the above facts in view an early detection of coronary risk factors was carried out and the individuals found at risk were administered herbal formulation for its prevention and management to reduce the incidence of any severity of coronary heart disease.

MATERIAL AND METHOD:

406 individuals of both sexes found at risk of CHD were selected from their distinct locality of varanasi city in order to evaluate the clinical efficacy of an indigenous compound formulation containing pushkarmool Guggulu, Mandukparni and Basant. Out of the selected 406 cases, 297 were males and remaining 109 were females. To assess the beneficial role of the test formulation, 57 males and 28 females showing single or multiple coronary risk factor were kept on placebo treatment.

Following a detailed preliminary screening, the comprehensive clinical examinations of all the individuals under study were assessed on certain biochemical and psychological parameters. Total lipid profile including triglycerides, anxiety and depression scores were recorded before introducing the drug treatment. Different fractions of lipoproteins were measured following the method developed by Reinhold (1965). Anxiety and depression scores were determined as per the standard scales.

The present test formulation containing the organic extract of medicinally important part of certain plants in the following doses was selected to be used in suitable capsule form of 500mg.

1. Root extract of pushkarmool (*Inula racemosa*) = 3.0 mg/kg
2. Gum-Resin (*Niryas*) extract of Guggulu (*Commiphora mukul*) = 7.0mg/kg.
3. Whole plant extract of mandukaparni (*Centella asiatica*) = 8.0mg/kg
4. Leaf extract of basant (*Hypericum perforatum*) = 0mg/kg.

Total = 20.00 mg/kg

The above capsules were prepared by filling the mixture of the extracted part of the plant drugs as indicated and were orally administered in the divided doses continuously for six months. Placebo capsules were also prepared similar to the test drug by using the dextrin powder and were introduced to the placebo group.

Successive follow-up studies upto six months were carried out with the recordings of different parameters at the interval of each month. At the end of six months, the results were statistically analysed and

compared with each other following students paired t-test.

RESULTS AND OBSERVATIONS:

The test compound drug brought about significant improvement in specific clinical features like nervousness, insomnia, palpitation tremors, irritability and earl fatigue. However placebo series did not exert any significant change and rather certain conditions were found more deteriorated in majority of the cases (Table - 1 systolic and diastolic blood pressure shoed a considerable declining trend in the treated group at the end of therapy while in placebo group no such change could be noticed (Table -2)

At the basal level, total cholesterol was found towards higher side while the HDL -c showed comparatively low level indicating higher risk of CHD than the normal individuals. After six months of drug treatment the TC and HDL-c ratio was corrected significantly (Table -3)

When the different fractions of lipoprotein cholesterol were measured a high value of LDL-c and VLDL-c was recorded. Triglycerides also exhibited higher level indicating the risk of CHD of the individuals. The test drug sowed beneficial effect in reducing the above levels (Table - 4).

A high anxiety and depression score was noticed in majority of the cases. Following six months of test drug treatment that individuals showed a significant improvement in the psychic involvement indicating the relaxed state of mind and reduced anxiety and stress caused due to varying reasons (Table -5)

The continuous use of the present herbal formulation did not sow any adverse effect.

DISCUSSION:

The prevention and treatment of risk factors are the fundamental approach in the management of coronary heart diseases. Hypercholesterolemia and hypertriglycerdemia are the two important factors that have been very clearly indicated to be responsible for the development of atherosclerotic lesion of coronary artery leading to myocardial infraction. Apart from the hyperlipidemia and hypertriglycerdemia that are also associated with obesity and hypertension, hypertriglycerdemia also plays significant role in the precipitation of coronary heart disease (Glomset et al. 1980). The presence of other risk factors has been reported by several workers to progress the atherosclerotic changes of coronary vessels and precipitates the severity of myocardial ischaemia in CD patients (Castelli et al 1986).

Various studies have suggested that essential hypertension is one of the major risk factor for the incidence of coronary heart disease. Heredity, age, anxiety, stress and strain, smoking, obesity, alcohol intake etc. are most often found to be the factors responsible for the onset of essential hypertension (Healton et al 1984, Grundy et al 1979). Thus it seems to be essential that earl onset of hypertension should be manages effectively.

It is observed that stress of modern society leads to serious health hazards and ultimately precipitates the incidence of coronary heart disease. Anxiety and depression directly reflecting the emotional conflicts in day today life further progress the severity of disease prognosis.

Hence, the individuals at relatively high risk of developing coronary heart disease (CHD) require a careful medical interventions for its management/modification. Several evidences indicate that reducing the cigarette smoking helps fairly a rapid decline in the incidence of heart attack to the persons who never smoked (Day research group 1990, Dayton et al 1969, Collins et al 1992). There is strong evidence that effective treatment of moderate and high degrees of hypertension result in lower mortality particularly from strokes and congestive heart failure (Muldoon et al 1990). A major multicentric trial has shown that reduction of hypercholesterolemia reduces that reduction of hypercholesterolemia reduces that risk of CHD. Similarly, reduction of obesity also minimizes the mortality rate CHD.

Thus, unless the risk factors associated with CHD are managed, it is not possible to prevent the incidence of coronary heart disease. Many drug and non drug methods have been advocated for the prevention and management of CHD. Dietary regulation, adequate, management of diabetes mellitus, reduction in body weight, reducing alcohol and tobacco intake etc. can definitely minimize the rate of CHD occurrence.

Many drug therapy used as anti-hypertensive vasodilatory, anti-arrhythmic agents are although being practiced greatly, but the application of such synthetic chemical agents are limited as their prolonged use are claimed to produce untoward effects in biological system. In the recent past, various available drugs used for the management of hypercholesterolemia and hypertriglyceridemia have been abused due to tremendous adverse effect they produce on their long term administration. Hence there is an urgent need of some safer

remedial measures for the management of lipid disorders which are the most common causative factors of CHD.

In the present series of study, the herbal test formulation has shown beneficial effect among the selected individuals at risk of CHD by modifying the blood pressure levels, different fractions of cholesterol and by correcting the deteriorated psychic status. Increase in the levels of HDL -c and decrease in TC following test drug treatment without an adverse effect indicates the applicability in the proper and safe management of abnormal lipid metabolism among the individuals at risk of CHD.

The most important and noticeable finding of this study is the correction of TC, DL -c ratio anxiety and depression scores in the patients following test drug treatment. Thus, the test formulation besides having beneficial role in the regulation of abnormal lipid metabolism, which is the most important risk factor in the occurrence of CHD. Directly or indirectly it has capacity to reduce the anxiety and stress with the result it causes reduction in blood pressure, anxiety level and depression score. Such effects indicate that the test formulation viz. *I. racemosa* (Pushkarmool) as anti-anginal, cardiostimulant, hypolipidaemic and hypoglycaemic, and *C. mukul* (Guggulu) as potent anti-atherogenic, hypolipidaemic, hepatostimulant, diuretic and general strengthening agents useful in prevention and treatment of ischaemic heart disease (Satyavati et al 1976, 1997 Sharma 1994.) Similarly, reports are also available for *C. asiatica* (Mandukaparni) an anxiolytic, brain tonic, general vitaliser and cardiostimulant (Sharma 1994), and *H. Perforatum* (Basant) as mood elevation anti-depressant (Agrawal et al 1994), anti-oxidant (Tripathi et al 1999) diuretic, hypotensive and cardiostimulant agents (Sharma 1994, Satyavati et al 1997).

With the combination of above properties, the test formulation, containing the above ingredients and showing beneficial effect in the psychosomatic of CHD patients without

an adverse effect in the administered dosages, may be a drug of choice for minimising the risk of coronary heart disease.

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Table -1 Changes in various clinical symptomatology under influence of test formulation among the individuals at coronary risk.

Group	No. of cases	Clinical symptomatology															
		Nervousness		Insomnia		Palpitation		Tremors		Irritability		Early		obesity		Fatiguability	
		B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A
Placebo Treated	M	57	71%	80%	79%	76%	57%	49%	62%	60%	77%	79%	66%	65%	39%	39%	
	F	28	93%	94%	52%	48%	64%	67%	68%	67%	61%	64%	50%	48%	48%	48%	49%
Test drug Treated	M	297	70%	25%	82%	48%	68%	30%	67%	24%	79%	34%	72%	28%	36%	25%	
	F	109	78% 37%		89%	42%	77%	36%	80%	35%	84%	29%	81%	34%	47%	33%	

A= After therapy, B= Before Therapy M= Male, F= Female

Table 2: Effect of Test formulation on blood pressure levels among the individuals at coronary risk

Groups	No. of cases		Systolic B.P. (mm Hg)			Diastolic B.P. (mm Hg)		
			Before therapy Therapy	After six months therapy	Camp Before Vs Six month therapy	Before therapy Therapy	After six months therapy	Camp Before Vs Six month therapy
Placebo Treated	M	57	158.48 ± 12.02	162.75 ± 13.39	P>0.05	94.36 ± 6.04	95.39 ± 6.85	P<0.05
	F	28	152.65 ± 14.38	158.80 ± 13.78	P>0.05	92.88 ± 4.75	93.2 ± 5.14	P<0.05
Test drug Treated	M	297	160.44 ± 12.90	134.35 ± 920	P>0.001	94.38 ± 5.34	86.40 ± 5.82	P<0.001
	F	109	157.95 ± 10.36	13604 ± 7.85	P>0.001	92.75 ± 5.16	85.34 ± 4.72	P<0.001

M= Male, F= Female

Table 3: Effect of Test formulation on TC and HDL-c among the individuals at coronary risk

Groups	No. of cases		Before treatment			After 6 months treatment		
			TC (mg/dl)	HDL-c(mg/dl)	TC & HDL-c risk factor	TC (mg/dl)	HDL-c(mg/dl)	TC & HDL-c risk factor
Placebo Treated	M	57	240.70 ± 22.35	62.68 ± 6.78	3.84	254.65 ± 20.05	66.14 ± 6.12	3.85
	F	28	244.60 ± 21.45	63.20 ± 5.25	3.87	258.05 ± 21.35	66.34 ± 5.14	3.89
Test drug Treated	M	297	248.25 ± 21.43	63.98 ± 4.98	3.88	198.84 ± 18.96	67.18 ± 5.14	2.96
	F	109	253.65 ± 19.37	65.04 ± .37	3.90	19..35 ± 19.38	68.23 ± 6.12	2.79

M= Male, F= Female

Table 4: Effect of Test formulation on LDL-c, VLDL-c and triglycerides among the individuals at coronary risk

Groups	No. of cases		LDL-c (mg/dl)		VLDL-c (mg/dl)		Triglycerides (mg/dl)	
			Before treatment	After 6 months treatment	Before treatment	After 6 months treatment	Before treatment	After 6 months treatment
Placebo Treated	M	57	128.72 ± 20.75	137.87 ± 23.71	56.32 ± 8.30	60.72 ± 6.12	180.14 ± 25.31	181.95 ± 27.30
	F	28	126.35 ± 16.44	130.20 ± 15.84	54.65 ± 7.32	60.92± 5.02	175.30 ± 2.72	177.32 ± 28.31
Test drug Treated	M	297	130.67 ± 14.02	103.79 ± 13.92	60.72 ± 7.94	40.38 ± 5.41	182.94 ± 23.85	161.72 ± 22.945
	F	109	128.42 ± 15.11	95.87 ± 10.88	64.85 ± 6.48	36.75 ± 4.86	180.36 ± 22.92	158.22 ± 21.42
Comparison (Before Vs 6 months treatment)			P>0.05 P>0.05 P<0.001 P<0.001		P>0.05 P>0.05 P<0.001 P<0.001		P>0.05 P>0.05 P<0.001 P<0.001	

M= Male, F= Female

Table 5: Effect of Test formulation on anxiety and depression score among the individuals at coronary risk

Groups	No. of cases		Anxiety Level (Score)			Depression score		
			Before treatment	After 6 months treatment	Comp before Vs 6 months treatment	Before treatment	After 6 months treatment	Comp before Vs 6 months treatment
Placebo Treated	M	57	65.38 ± 6.39	4.80 ± 7.78	P>0.05	33.88 ± 4.38	34.77± 4.92	P>0.05
	F	28	63.92 ± 5.99	64.72 ± 7.12	P>0.05	35.34 ± 3.22	36.70 ± 5.04	P>0.05
Test drug Treated	M	297	64.94 ± 5.88	52.44 ± 4.20	P<0.001	34.05 ± 3.12	27.92 ± 3.04	P<0.001
	F	109	61.74 ± 6.07	51.85 ± 4.22	P<0.001	35.38 ± 4.10	26.95 ± 3.11	P<0.001

M= Male, F= Female