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EXPLORING HOMOEOPATHIC INTERVENTIONS FOR PRIMARY PREVENTION OF CARDIOVASCULAR DISEASE IN MIDDLE-AGED MEN WITH DYSLIPIDEMIA: A PILOT STUDY

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ABSTRACT

Dyslipidaemia is a key risk factor for cardiovascular disease (CVD), a leading cause of death worldwide. Traditional CVD risk factors like smoking, high blood pressure, cholesterol, diabetes, and obesity increase atherosclerosis risk. This pilot trial examines homoeopathic therapy as a key CVD preventive strategy for middle-aged dyslipidaemia men. The study examined how individualised homoeopathic treatments and lifestyle changes reduced cholesterol levels, improved cardiovascular health, and prevented CVD. The study included 15 men aged 36–55 who underwent socio-demographic screening, medical history, and lifestyle assessments. Lipid profiles, FBS, and HBA1c were tested. All individuals got customised homoeopathic treatments and lifestyle changes and were assessed after three months for the Framingham Risk Score (FRS). Results demonstrated considerable blood pressure, sugar, and cholesterol reductions. Total cholesterol, LDL cholesterol, and triglycerides fell while HDL rose. Weight and BMI decreased significantly, lowering cardiovascular risk scores. In dyslipidemic patients, homoeopathic treatment may improve lipid profiles and CVD risk factors. These results need to be confirmed with larger samples and longer follow-up.

KEYWORDS: Homoeopathy, Primary prevention, Dyslipidemia, CVD Risk

INTRODUCTION:

A global increase of pandemic proportions in vascular difficulties is expected to occur in the near future, according to the current epidemiological estimates. The proportion of the population that is at an increased risk of developing cardiovascular disease is growing. Over the course of the past three decades, there has been a discernible increase in the prevalence of dyslipidaemias around the world. To be more specific, atherogenic dyslipidaemia is a condition that is common in people who have metabolic syndrome or diabetes. This condition is characterised by the presence of small, dense LDL particles in addition to raised triglyceride levels and low HDL cholesterol levels. It is important to note that this combination considerably increases the risk of cardiovascular disease in persons who are affected. ⁽¹⁾ The adoption of a Westernised way of life has a variety of effects on metabolic and vascular problems, and these effects vary from particular population to population. For example, in comparison to Europeans, South Asians had a higher prevalence of coronary heart disease (CHD) and mortality from cardiovascular disease.

The perspective of the World Health Organisation, India is accountable for twenty percent of all deaths that occur worldwide, mainly among the younger population. India has a death rate from cardiovascular disease (CVD) that is much higher than the global average of 235 deaths per 100,000 people, according to the findings of the Global Burden of Disease research. The death rate in India is 272 deaths per 100,000 people. Interestingly, cardiovascular diseases strike Indians ten years earlier than they do in Western countries. ⁽²⁾⁽³⁾ The higher prevalence of coronary artery disease (CAD) in the Indian population is assumed to be considerably contributed to by traditional risk factors such as hypertension, diabetes mellitus, dyslipidaemia, smoking, and obesity than in other populations. An insufficient amount of physical exercise, a lack of consumption of fruits and vegetables, and psychological and social stress were among the nine prevalent risk factors that were discovered by the INTERHEART study. Surprisingly, the combination of these factors was responsible for more than ninety percent of all acute myocardial infarctions (AMIs) that occurred in South Asians. ⁽⁴⁾ The risk factors for cardiovascular disease can be broken down into two categories: those that cannot be changed, such as age, gender, and family history, and those that can be changed, those that include hypertension, dyslipidaemia, overweight/obesity, diabetes/insulin resistance, and renal sickness. ⁽⁵⁾ The malfunctioning of endothelial cells is a common underlying

component that contributes to the development of atherosclerosis. This is because both hypertension and dyslipidaemia are associated with higher blood pressure. This dysfunction, in conjunction with other cardiometabolic variables such as diabetes mellitus and obesity, contributes to an even greater increase in the risk of atherosclerosis. ⁽⁶⁾ In addition to this, There is a correlation between the probability of developing cardiovascular disease (CVD) and the degree to which LDL-C (low-density lipoprotein cholesterol) levels are raised as well as the length of time that these elevated levels have been present. ⁽⁷⁾ In the year 2020, approximately 4.51 million deaths were attributed to elevated levels of LDL-C, amounting to a 19% increase in the number of deaths when compared to the year 2010. ⁽⁸⁾⁽⁹⁾ Recent studies have shown that adult-onset cardiovascular disease (ASCVD) is becoming more prevalent among younger people, despite the fact that advanced age continues to be one of the most major risk factors for the condition. Changing one's lifestyle, which includes making adjustments to one's nutrition, is the primary method for managing the risk factors associated with cardiometabolic disease. ⁽¹⁰⁾ The structure of this approach to the prevention of cardiovascular disease.

The use of homoeopathic medicines involves screening, risk assessment, the selection of individualised homoeopathic medicines, and customised lifestyle interventions, such as dietary changes, that are also tailored to the preferences of the individual patient in order to achieve meaningful improvements in lipid and lipoprotein profiles. The purpose of risk stratification is to modify the level of therapeutic or preventative treatments for a patient in accordance with the degree of the risk that the patient is exposed to. Through the process of risk classification, Framingham risk scores (CRS) make it possible to organise lifestyle interventions. These interventions can include interventions pertaining to food, physical activity, and smoking prevention. An Individualised preventative method that makes use of a Framingham risk assessment is going to be evaluated in this pilot project to see whether or not it is feasible and whether or not it is successful. Personalised medicines, lifestyle follow-ups, and dietary changes are all components of a comprehensive approach to the administration of evidence-based screening and preventive care in homoeopathy. In addition to addressing medical risk factors including blood pressure, cholesterol levels, and glucose sensitivity, this strategy takes into account environmental factors such as personal choices, the dynamics of the community, and lifestyle choices. The goal is to include individualised

health and lifestyle management measures into homoeopathic practice in order to achieve holistic wellness. The purpose of this pilot project is to develop a preventative and multidisciplinary program that will last for three months and focus on lifestyle behaviours and cardiovascular risk assessment using the FRS in conjunction with homoeopathic medicine.

Population and Study Design

A pilot pre-post clinical experiment involving many disciplines was conducted at Sarada Krishna Homoeopathic Medical College Hospital for three months. Inclusion and exclusion criteria were used to screen patients for cardiovascular disease (CVD) risk but not clinical CVD. Fifteen men aged 36–55 with dyslipidaemia were studied. Patients with persistent cardiovascular disease and other systemic illnesses were excluded. Baseline examinations included demographics, medical history, lifestyle factors, and cardiovascular disease risk factors such as blood pressure, cholesterol, blood sugar, and BMI. Three months of risk assessment using the Framingham Risk Score (FRS), extensive homoeopathic case taking, selection of constitutional medications, patient education, counselling, and diet and exercise programs comprised the primary prevention program. The trial subjects were monitored and supported throughout the intervention period. A three-month post-intervention blood pressure, blood sugar, lipid profile, and weight evaluation was done. After collection, data were statistically evaluated.

Assessment

Quantification of the Framingham Risk Score (FRS) and other factors was accomplished through the utilisation of standardised procedures. Blood samples were collected in a laboratory that was specifically designated for the study in order to guarantee consistency.

Lipid Profile

To determine total cholesterol, high-density lipoprotein (HDL), low-density lipoprotein (LDL) cholesterol, and triglycerides, venous blood withdrawal was carried out after at least 12 hours of fasting.

Blood Pressure

Systolic blood pressure (SBP) was measured according to AHA guidelines. It was determined twice within a few minutes.

Diabetes Mellitus

Fasting blood glucose was measured after at least 12 hours of fasting. Patients were diagnosed with diabetes if their fasting blood sugar level was equal to or greater than 126 mg/dL.

Smoking Habit

A smoker is defined as a person who smokes tobacco regularly every day (even only one cigarette) or has quit for less than 12 months.

Alcohol Consumption

Patients' alcohol consumption history was gathered during assessments.

Framingham Risk Score Assessment

The 10-year risk assessment for CVD was determined using the conventional Framingham Risk Score Calculator via a mobile application.

Data Sources and Management

Initial measurements, including an evaluation of each individual's risk of cardiovascular disease, were carried out, as well as at the three-month point. It was determined by laboratory tests that the amounts of total blood glucose and cholesterol were present. The patient's age, gender, education level, occupation, marital status, nationality, smoking habits, nutrition, physical activity level, and blood pressure were among the many personal facts that were collected. It was also necessary to collect information regarding lifestyle and mental symptoms in order to select appropriate constitutional medicines. Monitoring was done on the participants' participation in lifestyle intervention activities. The comprehensive evaluations were carried out in conjunction with a dietician. Statistical analysis was performed on all of the information that was gathered, which was then organised into a dataset created in Excel.

Health prevention and promotion intervention

Control group:

Nutritional Counselling: Participants learnt nutrition basics. ASCVD prevention and management nutritional guidelines are mostly based on Western studies, but Asians may have different nutritional demands. To maintain a healthy weight, the patient should limit energy intake, stress vegetables, fruits, legumes, nuts, whole grains, and seafood, and avoid processed meats, refined carbohydrates, and sugary beverages, according to the American Heart Association. Eat MUFAs and PUFAs instead of SFAs and limit trans fats. Reduce salt, alcohol, and cholesterol. Next, a nutritionist described macronutrient groupings and highlighted items that could affect CVD risk positively or negatively, and all patients received customised dietary advice to reduce CVD risk. ⁽¹³⁾ **Physical Activity Counselling:** American Heart Association guidelines encourage moderate to vigorous aerobic activity, mobility, and muscular building for adults. Psychosocial stress and stress situations affect CVD independently depending on intensity, duration, and response. **Psychological Counselling:** ⁽¹⁴⁾ Assessing and counselling patients' psychosocial status—stress, mental health, social support, and health behaviours. Advised the patient to avoid alcohol and smoking, sleep 9 hours, prevent stress, and maintain good connections.

Experimental group:

After thorough case taking, Homoeopathic evaluation, and analysis a constitutional medicine was selected and was prescribed as a single dose in 200 potency once a week to the intervention group, also a personalized health management plan like nutritional counseling and physical activity counseling, and Psychological Counselling tailored to each individual's needs. Follow-up assessments were conducted at the 3-month mark.

Statistical Analysis:

The data collected were subjected to statistical analysis and the data were described through mean and standard deviation and frequencies. A descriptive analysis has been done. The significance level was set at 0.05 and the SPSS software (version 22) was used for the analysis.

RESULTS

After screening, 15 middle-aged males with dyslipidaemia from Sarada Krishna Homoeopathic Medical College were invited for baseline testing. Two patients left before the final assessment. We added two patients. All patients agreed to follow up. The average age was 46. Among the included patients Five (33.3%) are Grade I hypertension patients, and five (33.3%) are Grade II. 2 (20%) have high normal blood pressure and 2 (13.3%) have normal. The selected patients include 6 (40%) diabetics, 6 (pre-diabetics), and 3 (20%) with normal blood sugar. 13.3% (2 people) were obese, 60% (9 participants) were overweight, and 26.7% (4 participants) were healthy. The mean patient weight dropped from 75.34 kg to 73.73 kg after 3 months of treatment. Homoeopathic treatment also lowered BMI. The baseline cardiovascular risk score was 13.7%, however obesity, ethnicity, and sedentary lifestyle affected practically all subjects, increasing it. and all patients are from Kanyakumari. Clinical changes at 3 months are seen in Table 2. The baseline mean CVD risk score (FRS score) was 13.72 and decreased to 9.68 after 3 months, $P = 0.014$. The number of high-risk people and individualised cardiovascular disease (CVD) risk ratings declined dramatically. Some 15 persons with fairly high individualised risk (>10% over 10 years) had their risk level drop to low. Diabetes kept those initially categorised as high-risk. Diabetics remain high-risk despite regulated blood sugar and lowered CVD risk. Treatment reduced blood pressure in the study. Initially, there were 5 grade II, 5 grade I, 3 high-normal, and 2 normal blood pressure patients. After treatment, there was 1 grade I hypertensive, 3 grade II, 4 high-normal, and 7 normal blood pressure patients. Other risk variables also improved. All patients' mean total cholesterol reduced from 188.08 to 156 after treatment (P value: -0.001). HDL levels increased from 43.7 to 49.5 and LDL from 122 to 98.7 (P value: 0.011), both statistically significant improvements. Triglycerides, VLDL, and BMI improved similarly.

Table 1.CVD Risk variables mean at Baseline and at 3 Months

Variables	Pts N	Overall at Baseline	Overall at 3 months	Change since baseline	P value
Weight (kg)	15	75.34	73.73	-1.6	0.000016
BMI(kg/m ²)	15	27.17	26.66	-0.51	0.1128
Glycemia (mg/dL)	15	124.9	112.86	-12.06	0.020

Total cholesterol (mg/dL)	15	195.5	166.4	-29.0667	0.001
HDLcholesterol (mg/dL)	15	43.73	49.5	5.77	0.1139
LDLcholesterol (mg/dL)	15	122.8	98.7	-24.1	0.011
Triglycerides (mg/dL)	15	202.1	175.9	-26.1	0.41
Systolic blood pressure (mmHg)	15	133.6	123.9	-9.7	0.003
Diastolic blood pressure (mmHg)	15	82.9	82	-0.84	0.81
Cardiovascular risk score	15	13.74	9.68	-4.06	0.014

DISCUSSION

Regular exercise and diet improve cardiovascular health, studies show. ^(16,17). The "2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease," recommends promoting a healthy lifestyle from an early age and maintaining it ^(18,19,20).

To minimise cardiovascular risk, address controllable risk factors such regular physical activity, a healthy weight, a balanced diet, and quitting tobacco and alcohol ^(21,22,23). Limited physical activity is a primary predictor of poor cardiovascular health and is connected to more cardiovascular disease risk factors.⁽²⁴⁾ Lifestyle modifications typically require behavioural adjustments, emphasising the importance of healthcare practitioners using effective techniques to manage patients' lifestyles. Additionally, clinical research have shown that proper drugs can boost effectiveness beyond therapeutic lifestyle changes alone. ^(25,26) Homoeopathic treatments have been shown to treat cardiometabolic diseases such dyslipidaemia, hypertension, diabetes, and obesity ^(27, 28, 29).

Our study examines how constitutional homoeopathic remedies and therapeutic lifestyle changes can reduce cardiovascular disease risk in middle-aged men with dyslipidaemia, hypertension, diabetes, and obesity. Men's baseline total cholesterol levels were strongly associated with myocardial infarction (MI) risk in a prospective cohort analysis in the MASHAD research population ⁽³⁰⁾. All 15 individuals with high total cholesterol in our study who received constitutional homoeopathic drugs achieved normal cholesterol levels. They had lower

cardiovascular disease risk after treatment. Homoeopathic treatment also lowers total cholesterol, according to Navin Prakash Ray et al. ⁽²⁷⁾ and Dr. Neil Praisly ⁽³¹⁾. (Additionally, Murali BA et al. found significant reductions in total cholesterol, HDL, LDL, and triglycerides. ⁽³²⁾ Triglyceride levels decreased after therapy in our study, but not significantly. In a clinical study, Praise N et al. found that constitutional homoeopathic treatment significantly reduced systolic and diastolic blood pressure, fasting blood sugar, total cholesterol, triglycerides, LDL, VLDL, and HDL. ⁽³¹⁾ Our patients' systolic and diastolic blood pressures decreased significantly and mildly after receiving homoeopathic constitutional medicine. Other research show that constitutional homoeopathic drugs lower systolic and diastolic blood pressure. ^(33,34,35). Praise et al. also found a significant decrease in fasting blood sugar and cardiac risk variables. ⁽³¹⁾ Although this fits our fasting blood sugar data, this study also shows significant reduction. Many additional studies examine how personalised homoeopathic treatments affect Diabetes. ^(36, 37). After homoeopathic treatment, CVD risk score decreases. Many studies show that lowering total cholesterol and raising HDL lowers CVD risk. ^(38, 39). Our study indicated an increase in CV risk, but homoeopathic medicine and TLC lowered it. All diabetics are high-risk. Although their FRS risk scores reduce following treatment, diabetics remain high-risk for CVD. ⁽⁴⁰⁾ In the context of constitutional medicine, the most frequently prescribed remedy was Lycopodium, which was given to 5 out of the 15 patients, accounting for 33.3% of the cases. Calcarea carbonica was prescribed to 4 patients, representing 26.7%. Sulphur was prescribed to 3 patients, which corresponds to 20%. Nux vomica was given to 2 patients, amounting to 13.3%. Lastly, Pulsatilla was prescribed to 1 patient, representing 6.7%. Previous studies also support these findings, showing a similar distribution in the frequency of prescribed remedies⁽⁴¹⁾

CONCLUSION:

Our study underscores the significant role that constitutional homeopathic remedies, combined with therapeutic lifestyle changes (TLC), play in reducing cardiovascular disease (CVD) risk in middle-aged men with dyslipidemia, hypertension, diabetes, and obesity. The findings align with existing research, demonstrating that constitutional homeopathic treatments can effectively normalize total cholesterol levels, lower systolic and diastolic blood pressure, and manage other cardiometabolic risk factors. Moreover, the study highlights the importance of integrating lifestyle modifications, such as regular physical activity and a

balanced diet, with homeopathic treatments to achieve optimal cardiovascular health outcomes. Despite the observed reductions in cardiovascular risk scores post-treatment, it is essential to recognize that certain high-risk groups, particularly diabetics, may require ongoing management and intervention to maintain reduced CVD risk.

In summary, constitutional homeopathic remedies, particularly those frequently prescribed such as *Lycopodium Clavatum*, *Calcarea carbonica*, and *Sulphur*, along with TLC, offer a promising approach to managing cardiovascular risk factors and improving overall cardiovascular health. Further research is encouraged to explore the long-term benefits and potential of homeopathic treatments in broader populations.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the Ethical Committee. The patients/participants provided their written informed consent to participate in this study.

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