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FUNCTIONAL INGREDIENT MIX AT PAR WITH NUTRITION TREND AND ITS IMPACT ON BLOOD LIPIDS IN TYPE 2 DIABETICS

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ABSTRACT

Objective:

The past decades have witnessed the increased consumption of instant and processed foods that have contributed to the dramatic rise in prevalence of obesity and diabetes. A change in the diet structure is needed to keep up with the ongoing nutrition transition and also to combat the ever rising incidences of coronary heart disease, diabetes and obesity. Inclusion of super cereals and other locally available nutritional foods, which were way back consumed by people in the Indian food system are gaining much importance now. The objective of the present study is to develop a functional ingredient mix at par with the nutrition transition trend and to determine whether the developed product aids in the reduction of lipid values in type 2 diabetics.

Methods:

Functional Ingredient Mix was prepared using cereals like quinoa, pulses and spices in requisite proportions and tested with panel members on a hedonic rating scale for its acceptance and supplemented to 75 diabetic dyslipidemic samples who were not on lipid lowering agents. Blood samples were analyzed for lipid profile, pre and post supplementation.

Results and Discussion:

Regular consumption of FIM was found to show reduction in serum total cholesterol, triglycerides and low density lipoprotein levels which were statistically significant at 1 per cent level ($p \leq 0.01$).

Conclusion:

The study highlights the fact that inclusion of foods with functional properties would aid in the reduction of associated heart complications in type 2 diabetics. A need to change the existing diet pattern with inclusion of organic, novel and functional foods is the need of the hour. Education and awareness in this direction of nutrition transition would help in combating the rising prevalence of lifestyle disorders to a greater extent.

Key words: Functional Ingredient Mix, Cereals, Type 2 diabetes, Lipids

Introduction

Diabetes mellitus (DM) is one of the leading health problems contributing significantly to morbidity and mortality and adversely affecting both the quality and length of life (Gordon etal, 2010)[1]. The rising prevalence of diabetes and its vascular complications is a global public health issue (Sun etal, 2011)[2]. Non-communicable diseases predominate, with the highest mortality caused by atherosclerotic CVD, most frequently ischemic heart disease and atherothrombotic stroke, especially at ages below 50 years. This phase is found in urban India (Yusuf etal, 2001)[3].

Lipid abnormalities are common in diabetics and frequently seen in type 2 diabetics. Dyslipidemias make diabetics prone to develop CHD and other complications of atherosclerosis (Uttra etal, 2011)[4]. Characteristics abnormalities in lipids in type 2 DM include elevated triglyceride (TG) levels, decreased athero-protective high density lipoprotein–cholesterol (HDL-C) levels, and increased levels of small dense low density lipoprotein cholesterol (LDL-C) (Gordon etal, 2010)[1].

Because type 2 diabetes can be considered a cardiovascular disease in its own right, current American Diabetes Association and National Cholesterol Education Program guidelines recommend aggressive treatment of dyslipidemia in people with diabetes, particularly for elevated LDL cholesterol levels. Use of appropriate treatment as determined by the pattern of lipid abnormalities can substantially reduce the risk of macrovascular disease (Henry, 2001)[5].

Over the past 15 years, there has been increasing evidence that the structure of dietary intakes around the developing world have been changing at an increasingly rapid pace. In many ways, these shifts are a continuation of large-scale changes that have occurred repeatedly over time. (Popkin and Larson, 2004)[6]

Each ethnic group has its own culturally based foods and food habits. Conversely, the foods of mainstream culture have been influenced by the presence of these ethnic cultures. Fast-food restaurants and other take-away restaurants now offer such wide-ranging selections as pizza, tacos, falafel, tandoori, egg rolls, hamburgers and other similar products. Thus, the diet of Asian Indians has changed from one featuring low-fat, high-fiber foods to one characterized by higher-fat animal protein, low fiber, and high levels of saturated fat. (Kulkarni, 2004)[7].

A healthy dietary pattern is the cornerstone for the prevention and treatment of cardiovascular disease and type 2 diabetes (T2DM). Compelling scientific evidence has shown many health effects of individual foods (including herbs and spices) beverages and their constituent nutrients and bioactive components on the risk of chronic disease and their associated risk factors. The unique benefits of these functional foods have been the basis for recommending their inclusion in healthy dietary pattern (Sikand etal, 2015)[8].

Functional foods for prevention of type 2 diabetes, several unmodified foods with functional properties have already been identified (low saturated fat products, vegetables, fruit, wholegrain foods, low glycemic index starchy foods) (Riccardi etal, 2005)[9].

Cereals are staple diet in India and the percentage of carbohydrate intake in Indian diets has remained relatively constant (55-65% of total calories). But Indians are experiencing heart attacks a decade earlier than the western population and the incidence of non communicable diseases has increased (Indira, 2013)[10].

Healthy eating may be best achieved with a plant-based diet, that encourages whole, plant-based foods and discourages meats, dairy products, and eggs as well as all refined and processed foods (Tuso etal, 2013)[11].

Drug treatments are not always been satisfactory and dietary supplements through effective supplementation are known to effective in bringing down the blood sugars and the lipid levels. Considering the tremendous economic and the human costs associated with diabetes and dyslipidemia, public health intervention programs aiming at preventing the diabetic related cardiovascular events need to be addressed.. Position statements from the American Heart Association, American Diabetes Association, and American Cancer Society emphasize the importance of healthful dietary patterns in prolonging life quality and slowing disease rates (Nettleton etal, 2009)[12].

The most important lifestyle factors which affect the serum lipid profile are diet composition, body weight and physical activity. The modification of blood lipid levels will be beneficial especially to those who are at higher risk of coronary heart disease. Screening for these abnormalities is essential and must be followed by active and effective interventions. Interventions may be more effective if they are targeted at specific socio-demographic sub-groups. Dietary advice to younger people should address undesirable aspects of food patterns. Combining campaigns to improve diet with efforts to increase physical activity may be needed to effectively reduce CVD risk (Chitra etal, 2012)[13].

People throughout the world are becoming increasingly convinced that the foods they consume can not only modulate performance but also influence their risk of acquiring a variety of diseases. It is logical to assume that consumer demand for these health promoting foods and the physiologically active compounds they contain will continue to grow in the foreseeable future, as will the availability of novel foods (Milner A J, 2000)[14].

A change in the diet structure is needed to keep up with the ongoing nutrition transition and also to combat the ever rising incidences of coronary heart disease, diabetes and obesity. Inclusion of super cereals and other locally available nutritional foods, which were way back consumed by people in the Indian food system are gaining much more importance now. With this background the objective of the present study is

1. To develop a functional ingredient mix at par with the nutrition transition trend.
2. To determine whether the developed product aids in the reduction of lipid values in type 2 diabetics before and after supplementation.

Methodology

Formulation of Functional Ingredient Mix

Functional Ingredient Mix which is a low cost, highly nutritious with easily available ingredients

and readily consumable nature was formulated. The functional ingredient mix contains oats, broken wheat, quinoa, ragi, green gram, split chick peas, defatted soy flour, fenugreek seeds, cinnamon and cardamom. Table 1 provides the details of nutritive value of FIM.

These particular ingredients were chosen as they contain carbohydrates, protein and fat besides a few anti hyperglycemic agents in proportions making it an ideal meal supplement that is low in cost, low glycemic index and a highly nutritious recipe which is not available with the commercial complimentary drinks meant for diabetics.

Since all the commodities are easily available, they were procured from local stores (except for quinoa). Quinoa seeds contain saponin - a bitter substance and hence it requires special cleaning to remove the saponin layer. Since it is time consuming to remove the saponin content through manual methods, processed quinoa

TABLE - I : Nutritive Value of Functional Ingredient Mix (25 gms)

Nutrients	Quantity	RDI	Admissible
Total energy	100 Kcal	1500-1800 kcal/day	Admissible
Total carbohydrate	18.16 gms (72.65%)	40-50% of total energy/day	Admissible
Total Protein	3.84 gms (15.39%)	53 gm/day	Admissible
Total Crude Fibre	434 mgs (1.74%)	25 gms/day	Admissible
Total Fat	1.39 gms (5.59%)	30% of total energy/day	Admissible
Total calcium	1947.6 ppm (1.9 mg)	1000-1300 mg/day	Admissible
Total Ash content	0.70 gms	-	Admissible
Total Selenium	1.9 ppm (0.0019 mg)	70 µg	Admissible
Total Iron	324.6 ppm(0.3246mg)	10-15 mg/day	Admissible
Total Zinc	37.07 ppm (0.037mg)	15 mg/day	Admissible
Moisture content	3.59%	-	Admissible
Sodium	71.432 ppm (0.071mg)	<2400 mg/day	Admissible
Potassium	564.85 ppm (0.56 mg)	4700 mg/day	Admissible
Vitamin C	5.36 mg	90 mg/day	Admissible
Yeast and Mould	Not detected	-	Admissible
Vitamin E & D	Not detected	-	Admissible

which is available in select super stores was used. The processed quinoa is free of saponin content and can be used for consumption directly. Wet heat removes the trypsin inhibitor in the soy flour. The functional ingredient mix being a predetermined proportion of commonly available food items may taste bland. Hence a small proportion of cardamom is added to enhance the flavor of the mix. and make it palatable for consumption.

The individual raw materials were first procured and all the grains were cleaned, made free of any dust or other foreign materials. They were then sun dried to remove moisture content if any, winnowed and measured using a digital weighing scale in the required quantity. Since all the ingredients are naturally occurring food items, the FIM was can be processed at room temperature.

Sample Selection

The study comprised of a total of 75 type 2 diabetic subjects who were selected on random basis from both the genders, aged between 31 to 85 years and who visited the outpatient clinic in South Bangalore. Detailed protocol containing information on socio-economic background, dietary details including food frequency and food pattern was formulated. The details were elicited from the selected subjects through personal interview.

The following Anthropometric measurement of height, weight, waist-to-hip ratio (WHR) were calculated. Height, waist and hip circumferences were measured in centimeters and weight in kilograms using a Stadiometer, flexible tape and Omron weighing scale.

The baseline biochemical parameters like fasting blood sugars, post prandial blood sugars were obtained from the secondary sources. Fasting lipid profile was also assessed in fasting condition by immunoturbidometric method.

Method of Supplementation The 75 diabetic dyslipidemic subjects selected for the study were not on any lipid lowering agents. An informed consent form was individually signed and collected from the study population. The Institutional ethics committee approved the supplementation protocols.

An orientation programme on the health and nutrition benefits of the prepared Functional Ingredient Mix (FIM) on the lipid profiles was given along with basic information about diet and diabetes co-relating the potential effects of diabetic dyslipidemia. The functional ingredient mix was prepared using cereals, pulses and spices in requisite proportions and tested for its acceptance palatability and flavor, with a panel of members on a hedonic rating scale for its acceptance, and then used for the intervention programme. The nutritional analysis of the Functional Ingredient Mix was done from FRAC laboratory at New Delhi.

About 25 grams of the powdered FIM was provided to the subjects which is to be mixed with water and boiled in order to be consumed as a mid-morning or mid-evening snack daily. Blood lipid profile readings were recorded before the start of the supplementation.

Impact of Supplementation

After the supplementation of FIM for the period of 3 months, blood sample were analysed for lipid profile. The collected data was analysed statistically using "t" test.

Results and Discussion

Age and Sex of the selected samples

According to the recent update by the International Diabetes Federation (IDF) more than 382 million adults aged 20–79 years had diabetes in 2013 (Ramachandran etal, 2013)[15] which corroborates in this study population (table II) in which females constituted 53 .3 per cent of the total samples who outnumbered the males of 46 .7 per cent.

Among 31- 40 years of age range, males constituted 8.0 per cent and females, 4.0 per cent. 9.3 per cent of females and 4.3 per cent of males were between 41-49 years category.

Under 50-59 year age, 13.1 per cent were males and 25.3 per cent were females. Similarly 13.1 per cent of males and 8.0 per cent of the females were between 60-69 years of age. 6.6 per cent males and 5.3 per cent of females were found to be within 70-79 years category. Only 1.3 per cent of female was in the age range of 80-85 years. Similar results were observed in the study done by Javid Ahmed etal, 2011[16] and Jamal Zafar etal, 2011[17] .

Socio-economic status, whether assessed by income, education, or occupation, is linked to a wide range of health problems, including low birth weight, cardiovascular disease, hypertension, arthritis, diabetes, and cancer (Nancy etal, 2002)[18].

Table II : Age and sex distribution

Age (years)	Male	Female	Total
31-40	6(8%)	3(4%)	9(12.0%)
41-49	4(5.33%)	7(9.3%)	11(14.6%)
50-59	10(13.13%)	19(25.3%)	29(38.7%)
60-69	10(13.14%))	6(8%)	16(21.4%)
70-79	5(6.67%)	4(5.3%))	9(12.0%)
80-85	0	1(1.3%)	1(1.30%)

Table III : Occupational Activity Details

Occupational Activity Details	n	%
Sedentary	52	69.4
Moderately active	19	25.3
Very active	4	5.3
Total	75	100.00

The occupational details of the study population revealed that majority (69.4 per cent) were having sedentary type of occupation and 25.3 per cent moderately active and 5.3 per cent were very active in their occupation. Sedentary activity is associated with an increased risk of diabetes, cardiovascular disease and all-cause mortality; the strength of the association is most consistent for diabetes (Wilmot, 2012)[19].

Anthropometric measurements

The mean height, mean weight and BMI of the subjects are presented in the Table IV.

The mean height of the all the selected samples were 1.64 meters ± 0.01 and 1.52 ± 0.01 for males and females respectively. Similarly the mean weight showed males had 73.13± 0.17 kgs and females 68.68 ± 3.58 kgs. The mean

Table IV

Anthropometric indices	Male	Female
Mean Height (meters)	1.64 ± 0.01	1.52 ± 0.01
Mean Weight (kilograms)	73.13 ± 0.17	68.68 ± 3.58
Mean BMI	26.51 ± 1.51	29.03 ±1.02

Body Mass Index (BMI) was found to be on the higher side for both genders with males having 26.51 ± 1.51 and 29.03 ± 1.02 for females depicting the prevalence of obesity in the study population. Jayner Palmer (2009)[20] states that the degree of being overweight or obese was associated with an elevated risk of adverse cardiovascular events and mortality.

Food Pattern

Dietary factors are important in the development of obesity and cardiovascular disease (CVD). However, many issues remain unsettled, and we need more knowledge about optimal intake of nutrients and foods and how the intake varies between individuals. Food pattern may be a stronger predictor of disease risk when many dietary associations exist for the disease, as for CVD, and can provide complementary information to analyses of associations with single food components (Berg etal, 2008)[21].

Food pattern of the population is of five types. Vegetarian type of food pattern means a diet completely devoid of all animal products and by products like meat, milk, eggs, cheese, poultry, fish, yogurt etc, while lacto and ovo-vegetarian refers to the inclusion of milk and egg in the diet respectively. On the other hand ovo-lacto vegetarian implies the inclusion of both eggs and milk and its products while non-vegetarian includes all the above types of food in the diet. Accordingly, it was felt essential to find the food pattern of the study group.

It can be inferred from the above table that 61 per cent of the samples belonged to lacto vegetarian, 36 per cent were non- vegetarian and 2.3 per cent who were found to be lacto-ovo vegetarians. The study found that only 0.3

Table V : Food Pattern

Food Pattern	n	%
Lacto-vegetarian	49	65.33
Non-vegetarian	24	32.00
Lacto-ovo-vegetarian	2	2.67
Total	75	100

per cent and 0.2 per cent were vegetarians and ovo-vegetarians respectively. Research has found that vegetarians have lower rates of a number of health problems, including overweight and obesity, cardiovascular disease (CVD), hypertension, type 2 diabetes, some cancers, gallstones, kidney stones, constipation, and diverticular disease (Marsh etal, 2012)[22]. Similarly other studies have also supported vegetarian food pattern providing protection against chronic diseases (Winston J Craig, 2009)[23].

Changes in Lipid Profile Pre and Post Supplementation

The changes in the lipid profile of the 75 subjects selected for the supplementation program is provided in the Table VI. Out of the 75 samples selected, 35 samples were male and 40 samples were females.

It is evident from table VI, the serum total cholesterol decreased by 11.54 mg /dl and was

found to be statistically significant ($p \leq 0.01$). Similar reductions were observed in triglycerides and low density lipoprotein levels also at one per cent level ($p \leq 0.01$). Consumption of whole-grain diets lowers LDL cholesterol and TC, but not HDL cholesterol or triglycerides. Whole-grain oat appears to be the most effective whole grain for lowering cholesterol (Hollaender etal, 2015)[24]. Long-term cohort studies have indicated that whole-grain consumption reduces the risk of both type 2 diabetes and cardiovascular disease. In addition, nuts (eg, almonds), viscous fibers (eg, fibers from oats and barley), soy proteins, and plant sterols, which may be part of the vegetarian diet, reduce serum lipids. In combination, these plant food components may have a very significant impact on cardiovascular disease, one of the major complications of diabetes (Jenkins, 2003)[25]. Brans derived from rice, wheat, oat, barley, sorghum, millet, rye and maize have been characterized to possess a wealth of health-promoting ingredients. They have been validated to impart antilipaemic, antiatherogenic, antihypertensive and hypoglycaemic properties. They have been verified to combat oxidative stress, attenuate insulin resistance, avert obesity risk by inducing satiety and alleviate cardiovascular complications (Patel, 2015)[26].

Table VI : Changes in lipid profile pre and post supplementation

Biochemical parameters	Pre-supplementation	Post-supplementation	P value
Total cholesterol (mg/dl)	173.51	161.97	0.001*
Triglycerides (mg/dl)	133.56	120.96	0.026*
HDL (mg/dl)	41.48	42.23	NS
LDL (mg/dl)	104.98	97.63	0.036*
VLDL (mg/dl)	26.05	25.98	NS
Ratio	4.27	4.50	NS

*Significant at one percent level
NS – Not Significant

Though there was decrease in the very low density lipoprotein levels, it was not statistically significant. High Density lipoproteins and the ratio between total cholesterol and HDL also did not counter reduction and were not found to be statistically significant..

Summary and Conclusion

The present study summarises that formulation and supplementation of Functional Ingredient Mix supports the fact that active components in each ingredient selected contributes to the reduction of total cholesterol ($p \leq 0.01$) triglycerides ($p \leq 0.01$) and low density lipoprotein ($p \leq 0.01$) levels in type 2 diabetics. Similar findings were also observed in various other observational and interventional studies.

Inclusion of traditionally cultivated crops and food grains which were way back consumed by people are slowly gaining importance now owing to their nutritional benefits and also to

the ability to fight and prevent the non-communicable diseases and their associated risk factors.

Taking this trend of nutrition transition towards the functional foods concepts requires huge momentum and dissemination of the same in relation to their health benefits. Functional foods have the potential to be an increasingly important component of healthy lifestyle and to be beneficial for public health as well as provide an insight for a wider product range for the food industry.

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