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ABSTRACT

Aim: To study the effect of Flaxseed therapy on various metabolic derangements of metabolic syndrome and its role as alternative or adjunctive therapy.

Material & Methods: In this randomized control trial, 100 patients of metabolic syndrome attending the Diabetes Care and Research Center of S. P. Medical College &P.B.M. Hospital, Bikaner were randomly selected. The selected patients were divided randomly into two groups comprising of 50 patients each. Control group was given conventional treatment only. Study group, besides conventional treatment was given Alsi/Flaxseeds.

Observations: In our study we found that flaxseed therapy has good glycemic control, both fasting blood sugar and glycosylated haemoglobin highly significant in study group (p<0.001). Systolic and diastolic blood pressure improved, highly significant in study group after flaxseed therapy (p<0.001). Lipid profile improved, highly significant in study group after flaxseed therapy (p<0.001).

Conclusion: Flaxseed therapy can be used as an adjuvant with diet and medicines in management of various metabolic derangements of metabolic syndrome.

Keywords: flaxseed, blood glucose, blood pressure, lipid profile, Body Mass Index.

INTRODUCTION

Metabolic syndrome (MS) is the most common disease today, representing one of the major public health problems of the century and its incidence has gradually increased over time^{1,2}. It is estimated that one quarter of the world population has MS^{3,4}.

The metabolic syndrome (syndrome X, insulin resistance syndrome) consists of constellation of metabolic abnormalities that confer increased risk of cardiovascular disease (CVD) and diabetes mellitus (DM).The major features of the metabolic syndrome includes: Central obesity, Hypertriglyceridemia, Low HDL Cholesterol, Hyperglycemia and Hypertension⁵.

Preventive measures and therapeutic strategies, such as changes in lifestyle including nutrition interventions and physical activity, are the possible ways to avoid the onset of metabolic syndrome⁶. Flax plant is the most abundant source of omega-3 (α -linolenic acid, ALA) and can be easily found, as well as being cheaper than the fish oil, which is also the source of this fatty acid⁷. α -linolenic acid is an essential polyunsaturated fatty acid dependent on foods ingestion that contain it, since it cannot be synthesized by the human body. From 41% of the total fat present in flaxseed oil, 57% come from the omega 3, which has anti-inflammatory, anti-thrombotic, and anti-arrhythmic properties⁸. Based on the results of clinical trials, epidemiological investigations, and

experimental studies, it has been suggested that ALA intake has a high impact on cardiovascular disease (CVD), For this reason, the use of flaxseed has been advocated in the prevention of heart disease and therefore the MS, which is currently the most common metabolic disease among these patients⁹. Flaxseed also contains other components with beneficial effects on health, such as dietary fiber and lignans, from which the Secoisolariciresinol diglucoside (SDG) is the main¹⁰. This oilseed is considered a functional food, producing metabolic and physiological health benefits, in addition to its nutritional properties. Its consumption has been increasing progressively because it is a popular alternative to pharmacological treatment. These effects are manifested as improvement in lipid profile, reducing the development of type 1 and type 2 diabetes mellitus, reducing blood pressure, and controlling weight gain.

MATERIAL AND METHODS

This randomised control trial study was conducted in Sardar Patel Medical College, Bikaner in 2015-16. Patients were selected from the Diabetes Care and Research Center as well as OPD of General Medicine of P.B.M. Hospital, Bikaner. One hundred patients of metabolic syndrome were randomly selected and divided randomly into two groups comprising of 50 patients each. Patients suffering from liver disease, arthritis, pulmonary tuberculosis, malabsorption, alcoholism, asthma, seizure disorder, pregnant and breast feeding women and any other disease in addition to metabolic syndrome and non-cooperative patients were excluded from the study.

Before starting flaxseeds baseline parameters were taken for every patients i.e. body mass index, waist hip ratio, fasting blood sugar, blood pressure and lipid profile. Patients were evaluated weekly for Body Mass Index, Waist Hip Ratio, Fasting Blood Sugar and Blood Pressure. After three months besides above test lipid profile were also estimated. In group 1 patients were given conventional treatment only and will serve as the control group. In group 2 patients besides conventional treatment were given Alsi/ Flaxseeds and serve as the study group. Patients included in the study group were asked to take whole flaxseed 3 to 4 table spoon daily to benefit from the fiber & Omega-3 fatty acid.

Ethical Consideration

Ethical clearance of this study was approved from the regional Ethical Review Committee (ERC). Data regarding the age and sex was recorded in predesigned forms.

RESULT

This randomized control trial study was conducted in Sardar Patel Medical College, Bikaner. Out of the total 100 patients, 50 were in control group (Group 1) and 50 were in study group (Group 2). Within the control group 37 were males and 13 were female patients. In the study group 19 were males and 31 were female patients. The mean age of the subjects in control group was 52.46±12.73 years and in study group was 53.88±8.76 years. All patients evaluated for body mass index, waist hip ratio, fasting blood sugar, blood pressure and lipid profile. Patients were evaluated weekly for Body Mass Index, Waist Hip Ratio, Fasting Blood Sugar and Blood Pressure. After three months besides above test lipid profile were also estimated.

The comparison between means of the difference of the pre and post treatment of control and study groups for different physiological and biochemical parameters was done. Highly significant differences were found in all the parameters (p<0.001) except BMI and WHR where no difference was observed because in study group between 0 to 3 months no mean difference was found. (Table 3)

The pretreatment mean BMI in control group was 31.14 ± 2.88 kg/m² and in study group was 32.71 ± 5.35 kg/m². After treatment mean BMI in control group was 31.14 ± 2.88 kg/m² and in study group was 32.71 ± 5.35 kg/m². The difference of BMI in two groups was statistically insignificant (p=0.071). The pretreatment mean WHR in control group was 0.96 ± 0.02 and in study group 0.94 ± 0.09 . This difference was statistically insignificant difference observed after three month treatment.

The pretreatment mean systolic Blood Pressure in control group was 150.48 ± 11.43 mmHg and in study group, mean systolic BP was 142.60 ± 12.49 mmHg. After treatment the mean systolic Blood Pressure in control group was 147.12 ± 11.66 mmHg and in study group mean systolic BP was 136.76 ± 11.03 mmHg. The difference was statistically highly significant (p<0.001). The mean diastolic BP in control

group was 94.24 ± 6.85 mmHg no significant difference was observed after three month. Whereas In study group before alsi supplement mean diastolic BP was 89.52 ± 7.80 mmHg and after alsi treatment the mean diastolic BP was 89.72 ± 7.41 mmHg. The difference was statistically significant (p=0.002).

The pretreatment mean fasting blood sugar in control and study groups were and 169.04±46.01mg/dl 192.08±40.64mg/dl respectively. After three month the mean fasting blood sugar in control and study groups were 182.12±38.20mg/dl and 149.58±44.97mg/dl respectively. The difference was statistically highly significant (p<0.001). Initially the mean HbA₁C in control and study groups were 8.07±1.74% and 7.28±1.53%. The mean HbA₁C in control and study groups after three month were 7.98±1.72% and 7.02±1.48%. The statistically difference was significant (p=0.003).

Mean total cholesterol in control and study groups were 173.43 ± 39.35 mg/dl and 180.04 ± 43.60 mg/dl respectively. After three month Mean total cholesterol in control and study groups were 171.20 ± 38.80 mg/dl and 165.15 ± 39.98 mg/dl respectively. The difference was statistically insignificant (p=0.445).

Mean Triglyceride in control and study groups were 162.59 ± 78.51 mg/dl and 142.79 ± 47.31 mg/dl. After three month mean Triglyceride in control and study groups were 156.13 ± 56.52 mg/dl and 134.73 ± 41.44 mg/dl respectively and the difference was statistically significant (p=0.033).

Initially mean HDL Cholesterol in control and study groups were 48.99 ± 19.35 mg/dl and 49.47 ± 20.74 mg/dl respectively. After three months mean HDL Cholesterol in control and study groups were 49.17 ± 19.51 mg/dl and 52.63 ± 21.14 mg/dl respectively. The difference was statistically insignificant (p=0.397).

Mean LDL cholesterol in control and study groups were 91.92 ± 40.20 mg/dl and 102.01 ± 37.84 mg/dl initially. After treatment Mean LDL cholesterol in control and study groups were 90.23 ± 39.34 mg/dl and 86.74 ± 35.54 mg/dl respectively. The difference was statistically insignificant (p=0.642). Initial mean VLDL in control and study groups were 32.52 ± 15.70 mg/dl and 28.56 ± 9.46 mg/dl respectively. After treatment mean VLDL in control and study groups were 31.23 ± 11.30 mg/dl and 26.95 ± 8.29 mg/dl respectively. The difference was statistically significant (p=0.033).

DISCUSSION

The pathogenesis of metabolic syndrome and potential causes suggests that plant FLAX SEED (Linum usitatissimum) polyphenols might be useful as a treatment. High omega 3 fatty acids, lignans, mucilage (gum) content are being actively studied as potential treatments for components of the metabolic syndrome.

Flax seed is one of the richest source of the plant based omega 3 fatty acid, alpha linolenic metabolized (ALA).ALA acid is to eicosapentaenoic acid (EPA), which may arachidonic acid in replace membrane phospholipids. Ingestion of flaxseed oil may alter the generation of eicosanoids, procoagulant activity and other membrane-dependent responses and exert anti-allergic, antiatherosclerotic, anti-arrhythmic effects¹¹. Also anti-aggregating have predominant and vasodialating action, with respect to eicosanoids with a predominant thrombotic effect. So dietary ALA has been associated with a lower rate of fatal and nonfatal coronary events¹².

Dyslipidemia is documented as a major risk factor responsible for the development of atherosclerosis and cardiovascular disease¹³. In the year 2009, Bassett et al¹⁴ studied that consuming flaxseed daily can modestly reduce circulating total cholesterol and LDL cholesterol in hypercholesterolemic patients.

In the year 2015, Prasad¹⁵also found that Secoisolariciresinol diglucoside (SDG) isolated from flaxseed inhibit the production of oxygen radicals by polymorphonuclear leukocytes was associated with a decrease in serum cholesterol, LDL, and lipid peroxidation product and an increase in HDL.

In our study we found that lipid profile improved significantly in study group after flax seed therapy. So our results are consistent with the above mentioned studies.

High blood pressure is a silent killer and it influences other body parts and their functions. In the year 2014, Caligiuri et al^{16}

studied that Plasma α -linolenic acid increased with ingestion of flaxseed and was inversely associated with blood pressure. Oxylipins derived from polyunsaturated fatty acids regulate vascular tone. In our study we found that systolic and diastolic blood pressure improved significantly in study group after flaxseed therapy.

Diabetes mellitus is the most common endocrine disorder that affects more than 194 million people worldwide. Flaxseed has been reported to possess a variety of medicinal properties including hypoglycaemic effect. Djousse et al¹⁷ found that flaxseed ingestion was associated with insulin secretion and improve glucose use and efficiency. In the year 2000, Prasad¹⁸ also found that secoisolariciresinol diglucoside (SDG) Flaxseed lignan has been shown to inhibit expression of the phosphoenolpyruvate carboxykinase gene, which codes for a key enzyme responsible for glucose synthesis in the liver. Supplementation of diet of type 2 diabetic with flaxseed reduced fasting blood glucose and glycated haemoglobin. In our study we found

that flaxseed therapy had good glycemic control both fasting blood sugar and HbA₁C improved significantly in study group after flaxseed therapy.

In overweight adolescents, a significant association in terms of derangement among plasma fatty acid composition in metabolic syndrome was identified. Consumption of Flaxseed reduce over-weight ¹⁹. In our study we found that waist Hip ratio and BMI not improved significantly in study group after flaxseed therapy (p>0.05) which may be due to shorter duration of study.

CONCLUSIONS

Flaxseed therapy can be used as an adjuvant with diet and medicines in management of various metabolic derangements of metabolic syndrome. Such studies should be further encouraged as medicinal herbs constitute the corner stone of traditional medicinal practice worldwide. Such studies should be ideally done for a longer duration and large population group to know the changes of BMI and WHR.

 Table1. Comparison of different parameters between the groups at pre-treatment

Parameters		Control Group		Study Group		р
		Mean	SD	Mean	SD	
BMI		31.14	2.88	32.71	5.35	0.071
WHR		0.96	0.02	0.94	0.09	0.098
Blood	Systolic	150.48	11.43	142.60	12.49	< 0.001
Pressure	Diastolic	94.24	6.85	89.52	7.80	0.002
Glycemic	FBS	192.08	40.64	169.04	46.01	0.009
Control	HbA ₁ C	8.07	1.74	7.28	1.53	0.017
Lipid	TC	173.43	39.35	180.04	43.60	0.428
Profile	TG	162.59	78.51	142.79	47.31	0.130
	HDL	48.99	19.35	49.47	20.74	0.906
	LDL	91.92	40.20	102.01	37.84	0.199
	VLDL	32.52	15.70	28.56	9.46	0.130

 Table2. Comparison of different parameters between the groups at post-treatment

Parameters		Control Group		Study Group		р
		Mean	SD	Mean	SD	
BMI		31.14	2.88	32.71	5.35	0.071
WHR		0.96	0.02	0.94	0.09	0.098
Blood	Systolic	147.12	11.66	136.76	11.03	< 0.001
Pressure	Diastolic	94.24	6.85	89.72	7.41	0.002
Glycemic	FBS	182.12	38.20	149.58	44.97	< 0.001
Control	HbA ₁ C	7.98	1.72	7.02	1.48	0.003
Lipid Profile	TC	171.20	38.80	165.15	39.98	0.445
	TG	156.13	56.52	134.73	41.44	0.033
	HDL	49.17	19.51	52.63	21.14	0.397
	LDL	90.23	39.34	86.74	35.54	0.642
	VLDL	31.23	11.30	26.95	8.29	0.033

Table3.Comparison	etween differences	of means	of anthropometric	and biochemical	parameters in both
groups at 0 to 3 months	I				

Parameters BMI		Control Group		Study Group		р
		Mean	SD	Mean	SD	>0.05
		0.00	0.000	0.01	0.006	
WHR		0.00	-	0.00	-	-
Blood	Systolic	3.36	2.57	5.84	3.38	< 0.001
Pressure	Diastolic	3.24	4.59	5.48	4.91	< 0.001
Glycemic	FBS	9.96	9.43	19.46	9.52	< 0.001
Control	HbA ₁ C	0.08	0.03	0.25	0.06	< 0.001
Lipid	TC	2.23	2.97	14.89	3.61	< 0.001
Profile	TG	3.86	6.59	12.06	9.44	< 0.001
	HDL	0.17	0.30	3.16	1.41	< 0.001
	LDL	1.68	0.97	15.27	6.12	< 0.001
	VLDL	0.77	1.32	2.41	1.89	< 0.001

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