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Research Article

IS THERE ANY ROLE OF FLAXSEED THERAPY IN GLYCAEMIC CONTROL IN METABOLIC SYNDROME PATIENTS?

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ABSTRACT

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. This metabolic alteration consists of a simultaneous presence of a set of cardiovascular risk factors characterized by hypertension, abdominal obesity, increased triglycerides, decreased high density lipoproteins (HDL-c), and increased glycemia/type 2 diabetes. Flax plant is the most abundant source of omega-3 (α-linolenic acid, ALA). Many studies have shown its positive effects when used as a supplemental feeding. 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. In present study two groups each having 50 patients dividing into two groups. Group I patients were given conventional treatment only and will serve as the control group. Group II patients besides conventional treatment were given Alsi/ Flaxseeds and were serve as the study group. Patients included in the study group were asked to take whole flaxseed 3 to 4 table spoons daily. Patients of metabolic syndrome were randomly selected for this study attending the Diabetes Care and Research Center of P.B.M. Hospital, Bikaner within 15 days baseline investigation was completed. This study was conducted in the department of physiology Sardar Patel Medical College, Bikaner. Patients were evaluated weekly for Fasting Blood Sugar level and at baseline and after 3 month for Glycosylated Haemoglobin (Hb_1Ac). The results were statistically analysed by applying paired "t" test. The difference was statistically highly significant ($p<0.001$) for both the parameters. Reduction was more profound in study group than in control group.

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 (Kanbak G *et al* 2011 and Chillarón JJ *et al* 2008). This metabolic alteration consists of a simultaneous presence of a set of cardiovascular risk factors Blondeau B *et al* (2011) characterized by hypertension, abdominal obesity, increased triglycerides, decreased high density lipoproteins (HDL-c), and increased glycemia/type 2 diabetes Chen CC *et al* (2012).

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 Hypertension.

National Cholesterol Education Program, Adult Treatment Panel III (NCEP: ATP III 2001) criteria for the metabolic syndrome: three or more of the following[5]

1. **Central obesity**: Waist Circumference, Male>102cm, Female> 88cm.
2. **Hypertriglyceridemia**: Triglyceride ≥150mg/dl or specific medication.
3. **Low HDL Cholesterol** : <40mg/dl and <50mg/dl for men and women, respectively or specific medication.
4. **Hypertension**: Blood Pressure ≥130mmHg systolic or ≥85mmHg diastolic or specific medication.
5. **Fasting plasma glucose**: ≥ 100mg/dl or specific medication or previously diagnosed type II diabetes.

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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 acid Robinson LE *et al* (2007). 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, antithrombotic, and antiarrhythmic properties Faintuch J *et al* (2007).

Flax seeds comprise of the following nutrients

Omega-3 fatty acid alpha- Linolenic acid (ALA)
Lignans (Fibres like compounds) Mucilage (gum), Vit. B1, Copper, Magnese, Magnesium, Phosphorus, Selenium.

MATERIAL AND METHOD

This study has taken birth and conducted in physiology department Sardar Patel Medical College, Bikaner. Patients were selected from the diabetic clinic that is situated in the Diabetes Care and Research Center as well as OPD of General Medicine of P.B.M. Hospital, Bikaner.

Type of Study: Randomized Control Trial

Selection of Patients

One hundred patients of metabolic syndrome were randomly selected for this study attending the Diabetes Care and Research Center of P.B.M. Hospital, Bikaner within 15 days baseline investigation was completed. A detailed history of each patient was obtained as per the attached proforma.

Exclusion Criteria

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 with metabolic syndrome were excluded from the study.

METHOD

The selected patients were divided randomly into two groups comprising of 50 patients each.

Group I

These patients were given conventional treatment only and will serve as the control group.

Group II

These patients besides conventional treatment were given Alsi/ Flaxseeds and were serve as the study group.

Flaxseed/Linseed

Availability – At Ayurvedic medical & Some General shops.
Preparation – Airtight pack of 250gm. whole flaxseed.
Preservative – No preservative use.

Procedure

Patients included in the study group were asked to take whole flaxseed 3 to 4 table spoon daily[26] to benefit from the fibre & Omega-3 fatty acid. Chew the seed thoroughly to aid in their digestion & access the nutritional benefits for three months regularly.

Flaxseed can be eaten whole or ground & put into food and drink.

Before starting flaxseeds baseline parameters were taken for every patient i.e. body mass index, fasting blood sugar. Patients were evaluated weekly for Body Mass Index, Fasting Blood Sugar. Those under control group were also evaluated weekly and after three months for these above mentioned parameters.

Fasting Blood Sugar (FBS) Dochev D et al (1983)

FBS measured by glucose oxidase method, using enzymatic kits (GOD-POD) method).

For statistical comparison of data, appropriate statistical model were applied using SPSS version 10 software of statistical analysis.

RESULTS

Table 1 Comparison between two groups according to their age and sex

Age Group (years)	Sex											
	Control Group						Study Group					
	Female		Male		Total		Female		Male		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
≤40	4	30.8	8	21.6	12	24.0	4	12.9	0	-	4	8.0
41-50	1	7.7	8	21.6	9	18.0	8	25.8	7	36.8	15	30.0
51-60	0	-	13	35.1	13	26.0	12	38.7	5	26.3	17	34.0
>60	8	61.5	8	21.6	16	32.0	7	22.6	7	36.8	14	28.0
Total	13	26	37	74	50	100	31	62	19	38	50	100

Table 2 Mean age of subjects under study

	Female		Male		Total	
	Control Group	Study Group	Control Group	Study Group	Control Group	Study Group
Mean	53.92	52.74	51.95	55.74	52.46	53.88
SD	12.63	9.52	12.89	7.19	12.73	8.76
SE	3.51	1.71	2.12	1.65	1.80	1.24
P	0.735		0.241		0.517	

Table 1 and 2 show the demographic profile of both groups. 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. There was statistically insignificant difference between the groups. The mean age of males in control group was 51.95±12.89 years whereas the mean age of males in study group 55.74±7.19 years. Difference between them was statistically insignificant. Similarly the difference between the mean age of females of both the groups was also insignificant in which the mean age of females in control group was 53.92±12.63 years and in study group 52.74±9.52 years.

Table 3 Anthropometric and Glycemic Control parameters in Control Group

Parameters		Base Line		Post Treatment		p
		Mean	SD	Mean	SD	
BMI		31.14	2.88	31.14	2.88	1.000
Glycemic Control	FBS	192.08	40.64	182.12	38.20	<0.001
	HbA_1C	8.07	1.74	7.98	1.72	<0.001

The mean BMI at initial month was 31.14±2.88kg/m^2 and after 3 months 31.14±2.88kg/m^2. This difference was statistically insignificant (p=1.000). The means fasting blood sugar at initial and after 3 months were 192.08±40.64mg/dl and 182.12±38.20mg/dl respectively. The difference was statistically highly significant (p<0.001).The means HbA_1C at initial and after 3 months were 8.07±1.74% and 7.98±1.72%. The difference was statistically highly significant (p<0.001).

Table 4 Effect of Flaxseed on anthropometric and Glycemic Control parameters parameters in Study Group

Parameters		Base Line		Post Treatment		P
		Mean	SD	Mean	SD	
BMI		32.71	5.35	32.70	5.35	0.182
Glycemic Control	FBS	169.04	46.01	149.58	44.97	<0.001
	HbA_1C	7.27	1.53	7.02	1.48	<0.001

The mean BMI at initial month was 32.71±5.35kg/m^2 and after 3 months 32.70±5.35kg/m^2. This difference was statistically insignificant (p=0.182).The mean fasting blood sugar at initial and after 3 months was 169.04±46.01mg/dl and 149.58±44.97mg/dl respectively. The difference was statistically highly significant (p<0.001) The mean HbA_1C at initial and after 3 months were 7.27±1.53% and 7.02±1.48%. The difference was statistically highly significant (p<0.001).

Table 5 Comparison of different parameters between the groups at post-treatment

Parameters		Control Group		Study Group		p
		Mean	SD	Mean	SD	
BMI		31.14	2.88	32.71	5.35	0.071
Glycemic Control	FBS	182.12	38.20	149.58	44.97	<0.001
	HbA_1C	7.98	1.72	7.02	1.48	0.003

The mean BMI in control group was 31.14±2.88kg/m^2 and in study group was 32.71±5.35kg/m^2. The difference of BMI in two groups was statistically insignificant (p=0.071).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).The mean HbA_1C in control and study groups were 7.98±1.72% and 7.02±1.48%. The difference was statistically significant (p=0.003).

Table 6 Comparison of BMI for the two groups according to their age group

Age Group (years)	Control Group				p	Study Group				p
	Initial		Final			Initial		Final		
	Mean	SD	Mean	SD		Mean	SD	Mean	SD	
≤40	30.49	2.47	30.49	2.47	-	38.62	6.14	38.62	6.14	-
41-50	30.92	4.64	30.91	4.64	-	32.64	4.82	32.64	4.82	-
51-60	30.50	2.95	30.50	2.95	-	33.28	5.19	33.28	5.19	-
>60	32.27	1.44	32.27	1.44	-	30.41	4.93	30.41	4.93	-

Table 6 shows difference in BMI of the patients in the both control and study groups at 0 and 3 months in different age groups.

Table 7 Comparison of Fasting Blood Sugar for the two groups according to their age group

Age Group (years)	Control Group				p	Study Group				p
	Initial		Final			Initial		Final		
	Mean	SD	Mean	SD		Mean	SD	Mean	SD	
≤40	196.33	40.30	192.17	43.85	0.055	166.25	54.06	148.50	54.37	0.001
41-50	209.78	55.42	188.89	51.34	<0.001	163.87	51.17	146.27	51.20	<0.001
51-60	198.31	31.52	190.00	26.17	0.005	160.82	46.66	143.41	47.67	<0.001
>60	173.88	34.39	163.75	31.47	<0.001	185.36	37.37	160.93	33.46	<0.001

No statistically significant difference was found in all the age groups in control and study groups.

Table 7 shows difference in Fasting Blood Sugar of the patients in the both control and study groups at 0 and 3 months in different age groups. Statistically highly significant differences were found in age groups 41-50 and >60 years in control group and in study group highly significant differences were found in age groups 41-50, 51-60 and >60 years (p<0.001), while significant differences were found in age group ≤40 years in study group (p<0.01) and in age group 51-60 in control group (p<0.01) and no statistically significant difference was found in the ≤40 years age group in control group (p=0.055).

Table 8 Comparison of Glycosylated Haemoglobin (HbA_1C) for the two groups according to their age group

Age Group (years)	Control Group				p	Study Group				p
	Initial		Final			Initial		Final		
	Mean	SD	Mean	SD		Mean	SD	Mean	SD	
≤40	7.62	1.46	7.56	1.47	0.001	7.33	0.91	7.08	0.88	0.001
41-50	9.21	2.41	9.09	2.38	<0.001	7.18	1.13	6.92	1.08	<0.001
51-60	8.35	1.83	8.25	1.80	<0.001	6.85	1.34	6.62	1.30	<0.001
>60	7.54	1.11	7.45	1.10	<0.001	7.88	2.11	7.60	2.05	<0.001

Table 8 shows difference in Glycosylated Hemoglobin of the patients in the both control and study groups at 0 and 3 months in different age groups.

Statistically highly significant differences were found in age groups 41-50, 51-60 and >60 years (p<0.001) in both study and control groups except ≤40 years in control and study groups where the difference was found statistically significant (p<0.05).

DISCUSSION

Greater understanding about the pathogenesis of metabolic syndrome and potential causes suggests that plant FLAX SEED (Linum usitatissimum) polyphenols might be useful as a treatment. Dietary excess energy can be stored in adipocytes, leading to the release of pro-inflammatory cytokines and adipose-related hormones that cause vascular injury. High omega 3 fatty acids, lignans, mucilage (gum) content are being actively studied as potential treatments for components of the metabolic syndrome. Flax seed lowers weight, blood pressure, glucose, and insulin resistance in rodents. Omega 3 fatty acid decreases lipid and glucose levels in obese rats, and in a human investigation of subjects with the metabolic syndrome has lowered blood pressure. Flax seed is number one natural occurring source of lignans. Lignans are fiber like compounds; they provide antioxidant protection due to their structure polyphenols

Mechanism of Hypoglycemic Effect of Linum Usitatissimum

Diabetes mellitus is the most common endocrine disorder that affects more than 194 million people worldwide. If nothing is done to control this disease, the number will exceed 333 million by 2025 (6.3% of population). In 2003, Kuwait was among the five countries of the world with the highest diabetes prevalence in the adult population (12.8%)[9].

In addition to the primary effects of diabetes, diabetes is accompanied by increased risk factors such as hyperglycaemia, dyslipidemia, hypertension, decreased fibrinolytic activity, increased platelet aggregation, and severe atherosclerosis[10,11]. Many synthetic drugs have been developed for the treatment of

diabetes. However, these drugs have limits in terms of efficacy and side effects.

Therefore, there is much interest in discovering natural treatments without negative side effects that can reduce these risk factors in diabetic patients.

Flaxseed has been reported to possess a variety of medicinal properties including hypoglycaemic, hypcholesterolaemic and hypolipidaemic activities.

Djousse *et al*[12] studied 3993 nondiabetic subjects and found that a higher consumption of ALA was associated with higher plasma insulin, but not glucose levels. The authors suggested that plant-based ω-3 fatty acids might influence insulin secretion in vivo, and improve glucose use and efficiency.

In the year 2000, Prasad[13] studied that secoisolariciresinol diglucoside (SDG) isolated from flaxseed has antioxidant activity and found that incidence of diabetes was 72.7% in untreated and 21.4% in SDG-treated group of rats as determined by glycosuria and hyperglycemia. SDG prevented the development of diabetes by approximately 71%. Development of diabetes was associated with an increase in serum and pancreatic malondialdehyde (MDA) and a decrease in antioxidant reserve. Prevention in development of diabetes by SDG was associated with a decrease in serum and pancreatic-MDA and an increase in antioxidant reserve. These results suggest that IDDM is mediated through oxidative stress and that SDG prevents the development of diabetes.

Dietary fibers, lignans, and ω-3 fatty acids, present in flaxseed have a protective effect against diabetes risk[14,15]. Flaxseed lignan SDG has been shown to inhibit expression of the phosphoenolpyruvate carboxykinase gene, which codes for a key enzyme responsible for glucose synthesis in the liver[16]. Supplementation of diet of type 2 diabetics with 10 g of flaxseed powder for a period of 1 month reduced fasting blood glucose by 19.7 % and glycated haemoglobin by 15.6%[17]. It could be due to lower content of glycemic carbohydrates and higher content of dietary fibers of flaxseed.

In our study we found that flaxseed therapy had good glycemic control both fasting blood sugar and HbA_1C improved significantly in study group after flaxseed therapy.

CONCLUSIONS

1. Flaxseed therapy can be used as an adjuvant with diet and medicines in management of metabolic syndrome.
2. Such studies should be further encouraged as medicinal herbs constitute the corner stones of traditional medicinal practice worldwide.

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