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Effect of flaxseed gum on reduction of blood glucose & cholesterol in Type 2 diabetic patients

GOUTAM THAKUR[1], ANALAVA MITRA[1], KUNAL PAL[2], DÉRICK ROUSSEAU[3]

[1] School of Medical Science and Technology, Indian Institute of Technology, Kharagpur, India-721302 , [2] Department of Biotechnology & Medical Engineering, National Institute of Technology- Rourkela, Orissa, India- 769008, [3] Department of Chemistry and Biology, Ryerson University, ON, Canada M5B 2K3

Correspondence: Dr. Analava Mitra
School of Medical Science and Technology
Indian Institute of Technology, Kharagpur- 721302, India
Telephone: 913222282656/57 -Fax: 913222282221
Email: analavamitra@gmail.com

Abstract

The effects of ingestion of flaxseed gum on blood glucose and cholesterol particularly low density lipoprotein cholesterol (LDL) in Type 2 diabetes were evaluated. Flaxseed gum was incorporated in wheat flour chapattis. Sixty patients of Type 2 diabetes were fed for 3 months a daily diet, along with 6 wheat flour chapattis containing flaxseed gum (5g), as per the recommendations of American Diabetic Association (ADA). The control group (60) consumed identical diet but chapattis were without gum. The blood biochemistry profiles (BBP) on being monitored before starting the study and at monthly intervals showed fasting blood sugar (FBS) in the experimental group decreased from 154±8 mg/dl to 136±7 mg/dl ($p=0.03$) while the total cholesterol (TC) reduced from 182±11 mg/dl to 163±9 mg/dl ($p=0.03$). Result showed decrease in LDL from 110±8 mg/dl to 92±9 mg/dl ($p=0.02$). The study demonstrated the efficacy of flax gum in the BBP of Type 2 diabetes.

Key words: Type 2 diabetes, flaxseed gum, fasting blood sugar, total cholesterol, LDL

Introduction

Diabetes mellitus (DM) is a metabolic disease, which is clinically characterized by hyperglycemia. DM can manifest either due to an abnormal reduced secretion of insulin; resistance of peripheral receptors stimulated by insulin or increased endogenous glucose production by the liver (ADA. 2006). Researchers emphasize that ~366 million people will be suffering from DM by 2030, and that it will be of greater global health concern (Wild et al. 2004; Wu et al. 1998; Hirsch et al. 2000; Gerich 2003). International Diabetes Federation (IDF) has identified DM as the fourth leading cause of human morbidity at 6% (IDF 2007) while its prevalence is much higher in developed countries though its greatest impact will be felt in developing countries (Hossain et al. 2007).

The number of patients with Type 2 DM is increasing at an alarming rate in India (Mohan et al. 2001). Given the high cost of medication, practitioners in India are now looking to control DM with alternatives (McIntosh et al. 2001). Moreover, various studies have reported that low-glycaemic index (GI) diets result in the reduction of urinary C-peptide and serum fructosamine when compared with a high-GI diet (Jenkins et al. 1987and 1988). Low-GI diets can also improve glucose tolerance and insulin sensitivity (Frost et al. 1996 and 1998) and can improve insulin-stimulated glucose uptake in isolated fat cells.

Majority of the Indian population is in the low-income group with their primary diet consisting of carbohydrates being consumed as chapattis and negligible amounts of other nutrients (Mitra et al. 2007). The uses of dietary compositions that are digested slowly reduce carbohydrate digestion and subsequent absorption from the gut. Fibres in the diet are digested slowly and help in decreasing the blood glucose level after a meal, in addition to adding of bulk to the stool and retention of water in the intestine (Leeds 1985). The reduction in the postprandial glucose level in DM after plant gums being consumed have been reported by several authors (Groop et al. 1993; Brenelli et al. 1997, Brown et al. 1988; Glore 1994).

Flax plant (*Linum usitatissimum*) has long been used as industrial oil and fibre crop in India. The plant is widely distributed throughout India, easily available and is very cheap. The main constituents of flax seed include its mucilage (6%), insoluble fibres

(18%), proteins (25%), and oils (30-40%) with α-linolenic acid (50-60% of oils) being the primary fatty acid (Trease and Evans. 1980). Its mucilage can be easily extracted from the seed and has been used as a stabilizer and thickener in the food industry (Mazza and Biliaderis 1989). Animals and human subjects on flaxseed meal have shown a reduction in blood cholesterol levels (Bhathena et al. 2003; Mitra et al. 2005).

The purpose of this study is to investigate the effects of consuming flax mucilage on blood sugar and cholesterol levels in patients with Type 2 DM.

Materials and Methods

Selection of Subject (Volunteers)

A group of 720 volunteers suffering from Type 2 DM were being selected from a pool of 1200 volunteers from local hospitals, clinics, health centre and rural areas. Of these, 120 volunteers (living in close proximity with IIT Kharagpur) were being selected as subjects for the study (Figure. 1). The subjects were randomly divided into two groups of 60 in each. The first group served as control and was fed with chapattis without flax gum, while the other group (experimental) received the flax gum-enriched equivalent. The volunteers were carefully explained the goal of the study as per Indian Council of Medical Research (ICMR) protocols and written consents were obtained. Ethics approval was obtained from the ethical committee at the Indian Institute of Technology, Kharagpur, India. Subjects on lipid-lowering, anti-hypertensive, anti-obesity and anti-hyperglycemic drugs were excluded from the study.

Flax being traditionally used in *ayurveda* comes under ICMR guidelines in the category of clinical evaluation of traditional *ayurveda, siddha, unani* (asu) remedies and medicinal plants and relevant guidelines of ICMR were being followed during experimentation (ICMR 2000). The volunteers underwent clinical, biochemical and anthropometrical evaluations under medical supervision before the start of the study (Figure 1, Table 1). Serum biochemistry was performed at the School of Medical Science and Technology (SMST) and B. C. Roy Technology Hospital, Indian Institute of Technology (IIT), Kharagpur, India.

Flax mucilage extraction

Flax gum was extracted from whole seeds using distilled water where the solids (flax seed) and the solvent (distilled water) was put in a vessel maintaining seed water ratio of 1:8 and was being continuously stirred with an agitator as degumming was time consuming and led to stickiness. Temperature of water was 80^{o}C when the extraction process started and at the end was 31^{o}C. The mixture was checked at every 30 minutes interval to see whether the stickiness was due to the gum on the surface of the flax seed or not. If the stickiness was not there, agitation was stopped and the time was noted (16 hours). The process of filtration separated out the extract (Mitra 2002) and the gum was stored at a lower temperature (4^{o}C) in sealed hygienic condition. The gum thus obtained was weighed using gravimetric methods and lebelled.

Preparation and consumption of chapattis containing flax gum

The gum was incorporated into chapattis made up of wheat flour (wheat flour bags were purchased from a local market and marked safe by Indian standardization organization for food qualities). Addition of flax gum to wheat flour made kneading of the dough easier during preparation of the *chapatti* and there were no perceptible changes in the taste or flavour of the final product as compared to control chapattis (as per results from earlier questionnaire response). Both groups (experimental and control) were monitored daily and instructed to follow identical food intakes and life-style patterns. The daily diet was as per the recommendation of ADA. Local representatives prepared the chapattis (6) for the experimental group by incorporating 5g of flax gum with 25g of wheat flour and 250ml of water while in control group flax gum was excluded. Consumption of 6 *chapattis* met the daily requirements (Mitra 2002). The BBP of the subjects in both groups were monitored at monthly intervals during the study.

Selection and role of local representatives

Ten (10) Local representatives (LR) resided in 5 villages (2 in each village) in close proximity to the institute. The LRs obtained the daily quota of wheat flour and flax gum from the researchers. Preparation of the chapattis was done in Indian-style kitchens under hygienic conditions and these were served to the subjects on a daily basis. For the control group, the chapattis were made in a similar manner without the incorporation of the flax

gum. LRs were also responsible for the daily monitoring of the subjects' health and compliance. During the study there was no drop out.

Collection of blood samples

The subjects were paid as per ICMR guidelines (2000) and were requested to report to the School of Medical Science and Technology (SMST) for monthly clinical testing. Trained laboratory technicians were employed for collection of blood samples. The laboratory technicians involved were not informed of the study in advance.

Venous blood samples from the subjects were collected after 12 hours of fasting and were subsequently labeled. Blood samples were collected on the 25th day of each calendar month for three consecutive months as the study started in 25th January, 2007. The colleted samples were analyzed for the blood biochemistry profiles (BBPs), viz. fasting blood sugar (FBS) and lipid profile commonly marked in total cholesterol (TC), high density lipoprotein cholesterol (VLDL), low density lipoprotein cholesterol (LDL), very low density lipoprotein cholesterol (VLDL) and triglycerides (TG). Due to the economic constraints, serum insulin values were determined only at the beginning and end of the experiment. Results were expressed as ± Standard Deviation (S.D). The results of the BBPs were statistically analyzed using Windows-based SPSS statistical package (version 10.0; SPSS Inc., Chicago, IL, USA). Statistical significance was considered at $p < 0.05$.

Equipment used

The BBPs were evaluated using a Boehringer photometer 4010 (Boehringer, Germany) (Boehringer Mannheim 1983). Very Low Density Lipoprotein (VLDL) was computed as 1/5th of the triglyceride value and LDL was being computed by the difference TC - (VLDL + HDL) (Catalogue no. 400 971; catalogue no. 543 004) (Boehringer Mannheim 1983). Serum insulin values were measured using standard radioimmunoassay kits (Bhaba Atomic Research Centre, Mumbai) (Poznanski and Poznanski. 2006). Homeostatic model assessment (HOMA) is a method for assessing ß-cell function and insulin resistance (IR) from fasting glucose and insulin or C-peptide concentrations. HOMA can also be employed to estimate steady state β-cell function (%B) and insulin sensitivity (%S), as percentages of a normal reference population. This

can throw some light on the β-cell function and insulin sensitivity where the results often correspond to those of the glucose clamp technique and HOMA can only be reliably used for fasting blood samples to assess insulin sensitivity (Bonora et al. 2000)

Results

The clinical and anthropometrical evaluation of the subjects at the beginning of the study has been tabulated in Table 1. The age of the subjects varied from 45-55 years. Sex bias was reduced by recruiting equal numbers of males and females. The weight of the subjects varied from 64-70 kg while the BMI was in the range of 23.4-26.4. The SBP (Systolic Blood Pressure), DBP (Diastolic Blood Pressure), mean blood pressure, pulse, heart and respiratory sounds, anemia and other clinical manifestations such as decubitus, cyanosis, temperature, built, neck veins, lymph nodes, liver and spleen, heart sounds, breath sounds, higher functions, cranial nerves, motor and sensory systems, jerks etc were examined before and after the study. The subjects were found to have higher BP while all other parameters were normal. After the end of the study, the SBP was reduced by 16±4 mm of Hg while the DBP reduced by 8 ± 2 mm of Hg. The mean BP was found to be lowered by 10±4 mm of Hg.

Table 1 and Figure 2 showed the effects of flax gum therapy on key blood parameters. No statistically significant changes of BBPs were observed in the control group ($p > 0.05$) while the statistically significant ($p < 0.05$) changes of the BBPs were found in the experimental group. The TC was reduced from the initial values of 182±11 mg/dl to 161±9 mg/dl after 3 months ($p=0.03$), LDL was reduced from 110±8 mg/dl to 92±9 mg/dl after 3 months ($p=0.02$), and FBS values were reduced from 154±8 mg/dl to136±7 mg/dl after 3 months ($p=0.03$). The changes in the other parameters were found to be insignificant ($p > 0.05$). The initial and final levels of HDL were 45±7 mg/dl and 45±5 mg/dl, respectively. The initial and final value VLDL were 27±6 mg/dl and 26±7 mg/dl, respectively, while the initial and final TG value were 135±8 mg/dl and133±9 mg/dl, respectively.

Table 2 showed that initially, the fasting serum insulin level in the experimental and control group were 106±14 pmol/l and 103±21 pmol/l, respectively, while the level was found to be 98± 12 pmol/l and 106± 14 pmol/l, respectively, at the end of the study. HOMA showed the change in β-cell function was insignificant in control group while the change in the experimental group was quite significant, which increased from 54.6±0.4 (initial) to 64.4±0.5 (final). Insulin sensitivity (%S) showed an increase from 45.4±0.7 (initial) to 50.3±0.6 (end) in the experimental group, while the control group showed no significant change with the change being from 45.3±0.7 (initial) to 45.8±0.6 (end). The change in the insulin resistance (IR) values in the control group was small 2.2±0.3 (initial) and 2.3±0.2 (end) while in the experimental group it ranged from 2.2±0.2 (initial) to 2.0±0.2 (end) respectively.

Discussion

The control of blood sugar levels is very important for patients suffering from DM and for those who are at a high risk of developing it. United kingdom prospective diabetes study (UKPDS) has clearly demonstrated that tight control of blood sugar and blood pressure has reduced the morbidity and mortality in a diabetic (Genuth 2008) . Hyperinsulinaemia/insulin resistance is an independent risk factor for common carotid artery intimae media thickness (CCA-IMT), or it is the accompanying risk factors which contribute to atherosclerosis (Jhamb et al. 2005). Hyperinsulinaemia can also be ameliorated if adequate protective steps are ensured.

The use of a flax lignin complex in diet prevents the acceleration of atherosclerosis (Prasad 1997). The use of whole ground flaxseed have been reported to reduce the plasma and hepatic cholesterol in suitable mice models. This reduction in the cholesterol level has been attributed to the reduced absorption of cholesterol and/or bile acid reabsorption (Pellizzon et al. 2007; Cintra et al. 2006).

In the current study, the consumption of flaxseed gum for 3 months, when incorporated in chapattis, resulted in a significant reduction in the FBS, TC and LDL levels of the subjects indicating the hypoglycemic and hypocholesteremic effect of the

flaxseed gum. The possible reason for the hypoglycemic effect can be attributed to the reduction in the carbohydrate absorption from the gut. Studies on rat models had indicated that pretreatment with flaxseed oil and mucilage protected the gastric mucosa against ethanol-induced gastric ulcer and reduced the gastric emptying time (Dugani et al. 2008). However, Flaxseed cannot be recommended as a treatment for diabetes at this time due to mixed responses obtained in various studies. Flaxseed and its derivative flaxseed oil/linseed oil are rich sources of the essential fatty acid alpha-linolenic acid, which is a biologic precursor to omega-3 fatty acids. Although omega-3 fatty acids have been associated with improved cardiovascular outcomes, evidence from human trials is mixed regarding the efficacy of flaxseed products for coronary artery disease or hyperlipidemia. As a source of fiber mucilage, oral flaxseed (not flaxseed oil) may possess laxative properties, although few human trials have been conducted for this indication. In large doses, or when taken with inadequate water, flaxseed may precipitate bowel obstruction via a mass effect. The effects of flaxseed on blood glucose levels are not clear and hyperglycemic effects are also reported (Dahl et al. 2005). The hypocholesterolemic effect of flaxseed mucilage is attributed to the fact that the mucilage is changed into short chain fatty acids in the colon, which in turn inhibits liver cholesterol synthesis, thereby, increasing the clearance of LDL from the body. *In vitro* and *in vivo* studies in animal models suggest that the flaxseed and flaxseed oil have the ability to lower blood cholesterol levels (Pascos et al. 2007; Pellizzon et al. 2007) while the studies on human subjects indicate mixed results (Mandasescu et al. 2005; Dodin et al. 2005; Lemay et al. 2002).

There are various studies regarding the consumption of the flaxseed. The available literatures suggest that the flaxseed and its oil supplements are well tolerated with negligible side effects (Cunane et al. 1993 and 1995; Mitra 2002). The U.S. Food and Drug Administration do not strictly regulate herbs and supplements. The main disadvantage of the herbal products and supplement lies in the fact that the strength, purity and effects of the products may vary from person to person. As India is a country with different peoples of diverse socio-cultural and socio-economic backgrounds, the present study should be expanded and designed to include a larger population for a longer period of time before any firm recommendation can be made.

Conclusion

India is a developing country with a large portion of people suffering from DM and its complications. A large portion of the population lives in rural sectors with poor health infrastructures. The high costs for therapeutic treatment has compelled physicians to look for alternative cost-effective methods to minimize complications associated with DM. Flax is widely cultivated in India and has been used for long as edible oil. The mucilage can be easily extracted from the waste of the flaxseed industry, which generally serves as animal feed. This study indicated has shown the use of flax seed mucilage to reduce the clinical symptoms of DM associated with dyslipidaemia. Beyond the beneficial effects shown here, the use of flaxseed mucilage in combination with other mucilage may offer added benefit for controlling Type 2 DM.

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Figure1: Consort Flow Chart of Type 2 Diabetes Volunteers in the Study

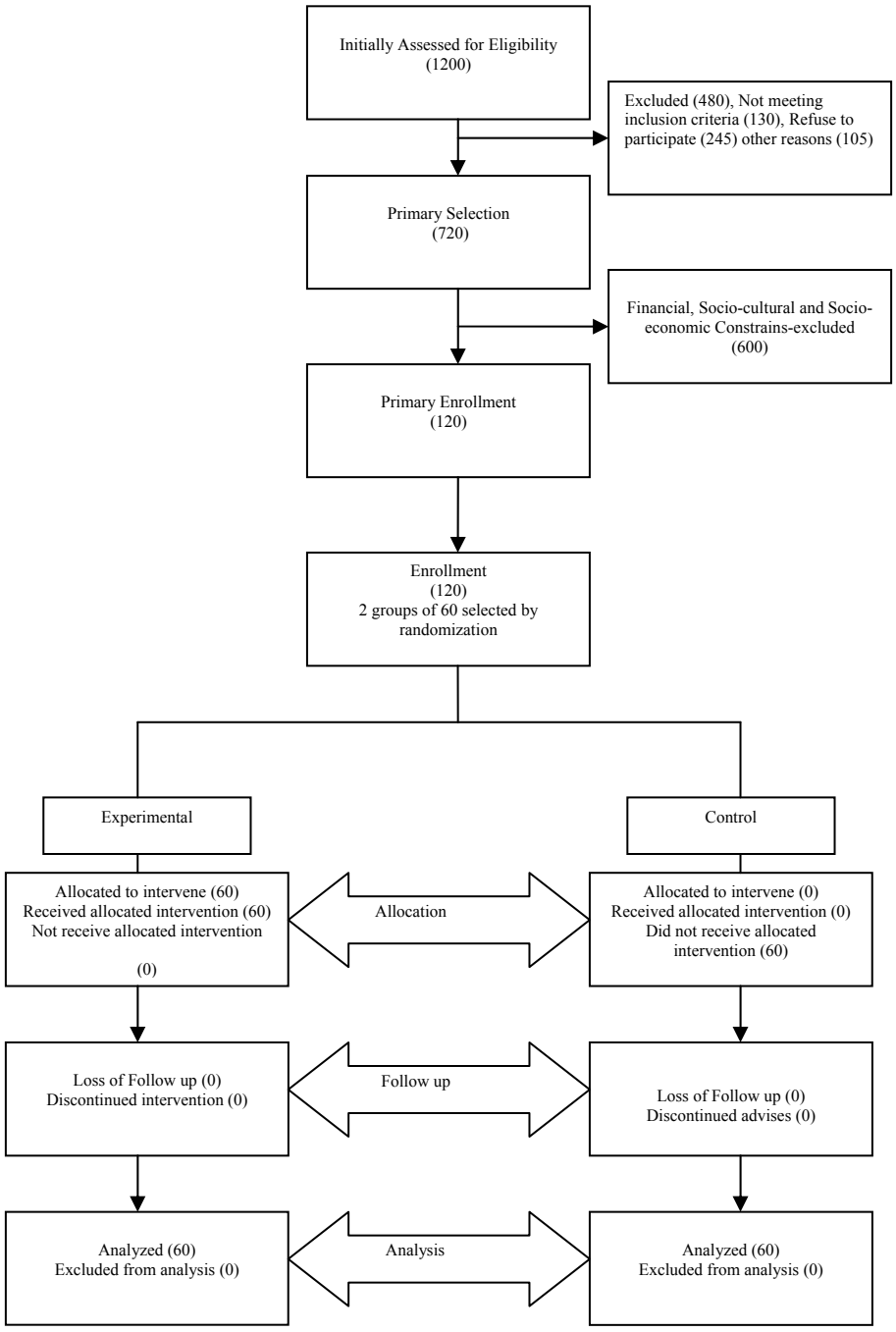

Figure 2: BBP of 60 Type 2 diabetic volunteers who were on normal diet and before receiving flax gum and effect of flax gum on Type 2 diabetic volunteers compared. C0, C1, C2, C3 are the controls of the beginning of experiment and after 1, 2 and 3 months respectively while E0, E1, E2 and E3 are the experimental of the beginning of experiment and after 1, 2 and 3 months respectively.

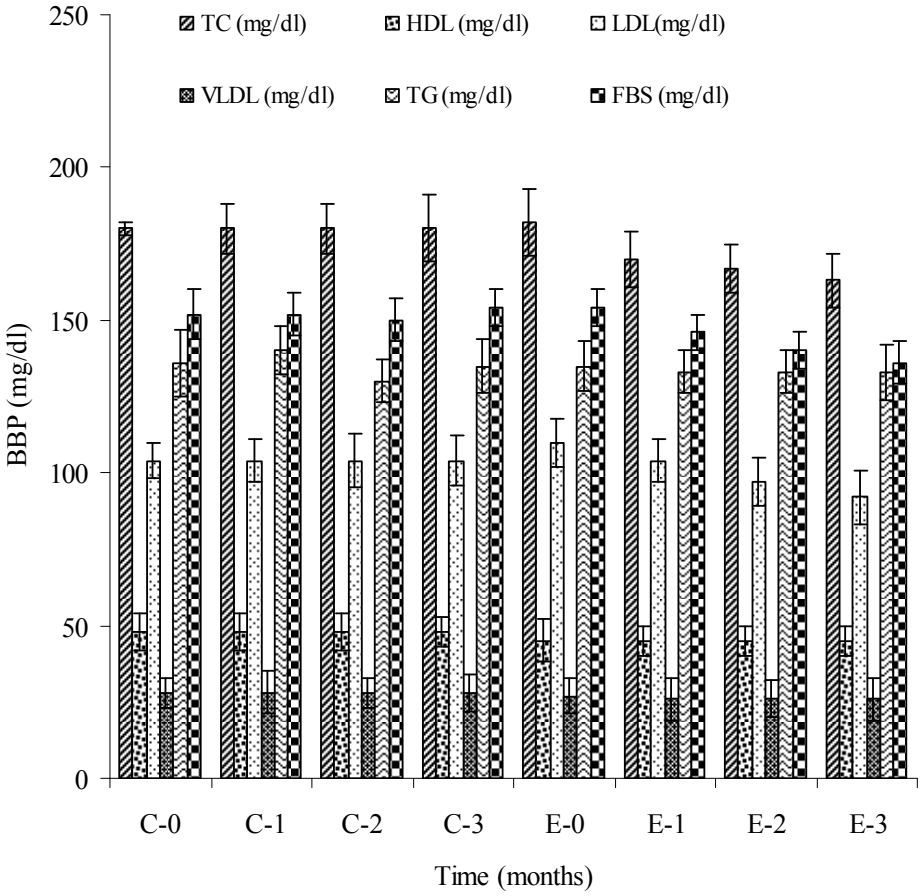

Table 1: Average anthropometrical, clinical and biochemical characteristics of volunteers (n=60)

	Experimental group	Control group
Age	48.62 ± 4.76 years	47.38 ± 3.78 years
Males	31	31
Females	29	29
Weight	72±3kg (start)	66±3kg (start)
	72±2 kg (end)	66±2 kg (end)
Body Mass Index (BMI)	24.4±3.4 units (start)	24.5±2.1 units (start)
	24.3±3.3 units (end)	24.3±1.9 units (end)
Systolic blood pressure	146±12 mm of Hg (start)	140±14 mm of Hg (start)
(SBP)	130±14 mm of Hg (end)	138±14 mm of Hg (end)
Diastolic blood pressure	100±12 mm of Hg (start)	94±8 mm of Hg (start)
(DBP)	92±8 mm of Hg (end)	92±10 mm of Hg (end)
Mean pressure	115±8 mm of Hg (start)	109±10 mm of Hg (start)
	105±5 mm of Hg (end)	107±9 mm of Hg (end)
TC (mg/dl)	182±11 (start)	180±2 (start)
	163±9 (end)	180±11 (end)
HDL (mg/dl)	45±7 (start)	48±6 (start)
	45±5 (end)	48±5 (end)
LDL (mg/dl)	110±8 (start)	104±6 (start)
	92±9 (end)	104+8 (end)
VLDL (mg/dl)	27±6 (start)	28±5 (start)
	26±7 (end)	28±6 (end)
TG (mg/dl)	135±8 (start)	136±11 (start)
	133±9 (end)	135±9 (end)
FBS (mg/dl)	154±8 (start)	152±8 (start)
	136±7 (end)	154±6 (end)

Table 2: Serum insulin and HOMA 2 values of volunteers (n=60)

Time (months)	Experimental group				Control Group			
	Serum insulin (pmol/l)	%B	%S	IR	Serum insulin (pmol/l)	%B	%S	IR
0	106±14	54.6±0.4	45.4±0.7	2.2±0.2	106±14	54.2±0.6	45.3±0.7	2.2±0.3
3	98±12	64.4±0.5	50.3±0.6	2.0±0.2	106±14	54.5±0.4	45.8±0.6	2.3±0.2