



International Journal of Pharmaceutical Research and Development (IJPRD)

Platform for Pharmaceutical Researches & Ideas
www.ijprd.com

A STUDY ON THE EFFECT OF ISOFLAVONE ON SERUM TRIGLYCERIDE LEVELS IN HYPERLIPIDAEMIC PATIENTS RECEIVING ANTILIPIDAEMIC DRUG TREATMENT

JOSEPH STALIN D*

*1300/334, rajakkamangalam road, kottar, nagercoil - 629002.

ABSTRACT

The trial was conducted to study the effect of isoflavone on serum triglyceride levels in hyperlipidaemic patients receiving antilipidaemic therapy. It was an open randomized controlled trial. Patients receiving atorvastatin therapy were enrolled for the study. Totally 108 patients were enrolled. All the patients enrolled for the study were divided into two groups at random and categorized as Group 1 and Group 2. The baseline serum triglyceride levels, along with other lipoprotein levels, were measured for all the 108 patients and documented on the patient data sheet. Then Group 1 was given Atorvastatin 40 mg/day as they were already taking that along with drugs for diabetes and/or hypertension. Group 2 patients additionally received Isoflavone 40 mg/day orally. Both the groups of patients were monitored for compliance, and for ADRs and side effects. At the end of 6 months the lipid profile of the patients were measured again as the end point. Then the lipid profiles of Group 1 were compared with those of Group 2. The results showed that the percentage reduction in Triglycerides was much higher in Group 2 compared to Group 1. The percentage reduction in serum total cholesterol, and LDL were much higher in Group 2 compared to Group 1. The percentage increase in serum HDL level was much higher in Group 2 compared to Group 1. The study gives a strong evidence for the lipid lowering action of Isoflavone.

Key words: Isoflavone, Triglycerides, Cholesterol, HDL, Lipid profile

INTRODUCTION

Isoflavone is a phytoestrogen. It is believed to be effective against breast cancer, prostate cancer, menopausal symptoms, heart disease and osteoporosis [1]. Isoflavone is found in small amounts in a number of legumes, grains, and

vegetables, but soy beans are the ones which are the most concentrated source of isoflavones in the human diet [2].

In 2007, Yaki et al did a meta-analysis of 11 randomized controlled trials, which were focused on the effect of Soy isoflavones on serum total and

Correspondence to Author



JOSEPH STALIN D

1300/334, rajakkamangalam road,
kottar, nagercoil - 629002.

Email: joseph25may@aol.com

LDL cholesterol in humans [3]. In 2004, Ira et al, studied the effect of soy protein containing isoflavones on blood lipids in moderately hypercholesterolemic adults [4]. In 1999, Julie et al, performed a randomized trial comparing the effect of casein with that of soy protein containing varying amounts of isoflavones on plasma concentrations of lipids and lipoproteins [5]. In 2001, Gardner et al, studied the effect of soy protein with or without isoflavones relative to milk protein on plasma lipids in hypercholesterolemic postmenopausal women [6]. In 2004, Baghdadi et al studied the Antioxidant activities and lipid lowering effects of isoflavone in male rabbits [7]. Since there is a requirement of a lot of adjuncts in cardio therapy, this study seemed to be more necessary at this juncture. Hence it was performed.

Objectives of the study:

The objectives of this study were

1. To find whether Isoflavone lowers serum triglyceride levels in hyperlipidaemic patients.
2. To compare the level of changes in the serum lipid levels between a group treated without Isoflavone (Group 1) and a group treated with Isoflavone (Group 2).

MATERIALS AND METHODS:

Approval from the Ethics Committee and consent from the enrolled patients were obtained before the start of the study.

Design of Study : Open Randomized Controlled Study.

Sample Size: 108 patients

Study Duration: 6 months (180 days)

No. of Groups : 2

Drugs Used: Group 1 (54 patients): Atorvastatin 40 mg/day (Atocor 40 mg tablets)

Group 2 (54 patients): Atorvastatin 40 mg/day + Isoflavone (Menoflav 40mg Capsules)

Parameter Measured: Serum Lipid Profile

All the 108 patients enrolled, taking into account the inclusion and exclusion criteria, for the study were divided into two groups randomly. Group1 and Group2, 54 patients each. The patients were tested for all parameters of blood; also they were subjected to Ultrasound Scanning to ensure that the patients were not having any infectious diseases and other disorders like hypothyroidism, e.t.c.

Then the baseline lipid profile was taken for all the 108 patients and documented. Then Group 1 was given Atorvastatin 40 mg/day as they were already taking that along with drugs for diabetes and/or hypertension. Group 2 patients additionally received Isoflavone 40 mg/day orally.

Both the groups of patients were monitored for compliance, and for ADRs and side effects. At the end of 6 months the lipid profile of the patients were taken again as the end point. Then the lipid profiles of Group 1 were compared with those of Group 2.

Statistical Tool

All the data were recorded in the Master Chart. The Data Analysis was done using GraphPad InStat 3. Mean, Standard Deviation, Student unpaired t-test and 'p' values were calculated for quantitative variables. The 'p' values were two-tailed and obtained by using the student's unpaired t-test, with the standard deviations of each value to be different. The 'p' value less than 0.05 was considered to imply a significant relationship. The comparative charts were drawn using the mean of the values of different parameters.

RESULTS

The changes observed in the serum lipid profile of the patients enrolled in the study are depicted in Table 1.

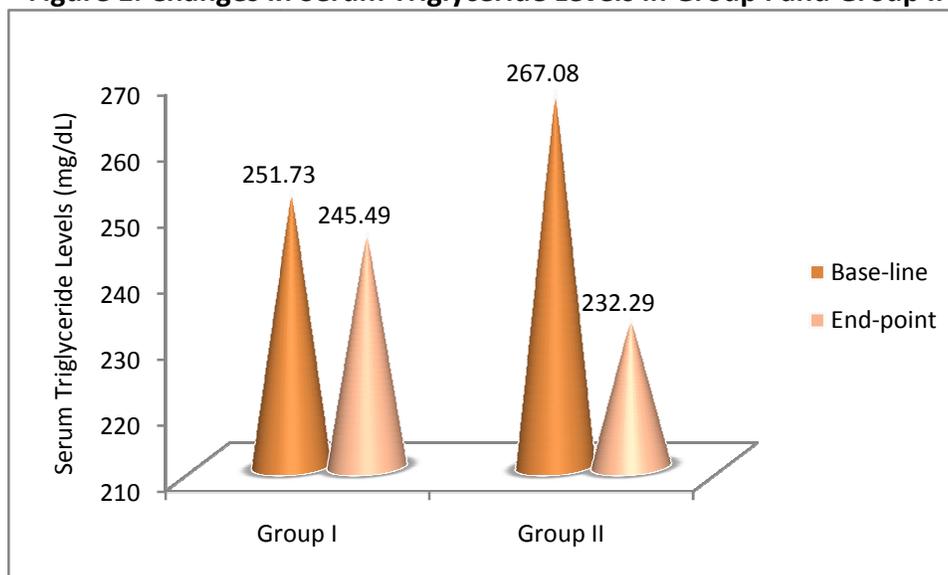
Table 1. Changes in Serum Lipid Levels measured in the study

Lipid Profile	Lipid Levels mg/dL	Group I	Group I 'p' value	Group II	Group II 'p' value
Serum Triglycerides	Base-line	251.73 ± 17.57	0.4416	267.08 ± 22.33	0.0471
	End point	245.49 ± 17.81		232.29 ± 23.38	
Serum Total Cholesterol	Base-line	245.47 ± 16.55	0.6363	275.82 ± 15.80	0.1713
	End point	241.9 ± 16.69		260.54 ± 15.92	
Serum LDL	Base-line	189.36 ± 14.95	0.3505	197.61 ± 9.8	0.0055
	End point	182.93 ± 14.99		173.14 ± 9.74	
Serum HDL	Base-line	29.85 ± 2.54	0.0582	31.29 ± 0.92	0.0346
	End point	32.19 ± 2.6		33.61 ± 1.67	
Serum VLDL	Base-line	76.06 ± 14.67	0.4624	84.57 ± 8.28	0.0901
	End point	71.11 ± 14.80		74.14 ± 8.50	

Note: 'p' < 0.05 implies 'significant'; 'p' value > 0.05 implies 'not significant'

At the end of the study it was found that the reduction of serum triglycerides in Group I was not significant statistically. But the same was statistically significant in Group II (Isoflavone treated group). Also the reduction of LDL was statistically significant in Group II. The increase in

serum HDL was also statistically significant in Group II. But the levels of total cholesterol suffered no significant changes statistically in Group II. Hence it can be concluded that Isoflavone reduces serum triglyceride levels when it is given as an adjunct with antihyperlipidaemic therapy. Figure 1 gives a graphical representation of the reduction of serum triglyceride levels in Group I and Group II.

Figure 1. Changes in Serum Triglyceride Levels in Group I and Group II

DISCUSSION

A number of antilipidaemic drugs are being employed nowadays in hyperlipidaemic patients. But these drugs have the ability to cause a wide range of adverse reactions. To overcome this it is better to use nutrients and biochemicals along with drug therapy. In this aspect, this study provides the

Available online on www.ijprd.com

evidences that support the use of Isoflavone as an agent that reduces serum triglyceride levels. Also, it is necessary to study whether Isoflavone is capable of producing any adverse drug reaction, to promote it to prescribe to patients.

ACKNOWLEDGEMENT

I wish to thank our HOD, my department-mates, and well-wishers for cooperating me throughout the course of the study.

Above all I should remember the part the members of my family had in making all the situations peaceful and allowing me to spend my whole mind and time to my study.

REFERENCES

1. Han et al. Benefits of soy isoflavone therapeutic regimen on menopausal symptoms. *Obstetrics and Gynecology*. March 2002. 99(3):389-94.
2. Alison M. Duncan, Linus Pauling Institute Micronutrient Research for Optimum Health. <http://lpi.oregonstate.edu/>
3. In 2007, Yaki et al did a meta-analysis of 11 randomized controlled trials, which were focused on the effect of Soy isoflavones on serum total and LDL cholesterol in humans. *American Journal of Clinical Nutrition*. April 2007. vol. 85. No. : 4 1148-1156
4. In 2004, Ira et al, Effect of soy protein containing isoflavones on blood lipids in moderately hypercholesterolemic adults: a randomized controlled trial. *Journal of the American College of Nutrition* (2005). 24 (4)
5. Julie et al. A Randomized Trial Comparing the Effect of Casein With That of Soy Protein Containing Varying Amounts of Isoflavones on Plasma Concentrations of Lipids and Lipoproteins. *Archives of Internal Medicine*. 1999, 159(17):2070-2076.
6. Gardner et al. The effect of soy protein with or without isoflavones relative to milk protein on plasma lipids in hypercholesterolemic postmenopausal women. *American Journal of Clinical Nutrition*. 2001, 73:728-35.
7. Baghdadi et al. Antioxidant activities and lipid lowering effects of isoflavone in male rabbits. *Food and Chemical Toxicology*. September 2004, 42(9):1497-503.
