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ABSTRACT The glucose lowering ability of wheat germ remains unclear. The objective of the study was to assess the effect of wheat germ on diabetic subjects. 30 diabetic subjects were selected and divided into two groups of 15 each. Group A formed the experimental group to which 60 g of wheat germ was supplemented daily for a period of six months. Group B constituted the remaining 15 diabetic subjects who served as control to whom no supplementation was given. Fasting and post prandial glucose and glycosylated haemoglobin was evaluated initially and after the supplementation period. Group A showed significance (P<0.01) difference over group B in all the biochemical tests performed.

INTRODUCTION

Health is a fundamental human right and a worldwide social goal. It encompasses all humans irrespective of age. Geographical conditions, culture, economic status and lifestyle of people have foremost impact on their health. Needless to say that 'Food' is a fundamental need in determining the very existence of living; it also plays a leading role in shaping the health, both physical and mental; of people around the world across time and space. The cultural evolution of human race has been parallel with the style of consumption of food with perfect matching with the geographical conditions and life style of the people. We have now arrived at a time that the food style of the people is not in conformity to the accustomed geographical or cultural conditions. Rapid changes in diets and lifestyles that have occurred with industrialization, urbanization, economic improvement and market globalization have been accelerating since the past decade. This dynamics has a significant impact on the health and nutritional status of populations, particularly in the developing countries and in countries in transition (Food and Agricultural Organization 2007; United Nation 2007).

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Changes in the world food economy are reflected in shifting dietary patterns, for example, increased consumption of energy-dense diets high in fat, particularly saturated fat and low in unrefined carbohydrates (King and Revers 1998). These patterns are pooled with a decline in energy expenditure that is associated with a sedentary lifestyle like motorized transport, labor-saving devices in the home, the phasing out of physically demanding manual tasks in the workplace and leisure occasion that is preponderantly devoted to physically undemanding pastimes. Poor food habits and sedentary hedonistic lifestyles have resulted in the perpetuation of diseases like hyperlipidemia. Heart disease has been one of the leading causes of death globally for the past 80 years and is a major cause of disability. Around 80 per cent of these deaths occurred in Low and Middle Income Countries (LMIC). If appropriate action is not taken, by 2015, an estimated 20 million people will die from cardiovascular disease every year, mainly from heart attacks and strokes (Lori et al. 2006).

Of the 10.7 million deaths from cardiovascular disease every year in India, 4.2 million are due to ischemic heart disease, 2.5 million due to cerebrovascular disease, and an additional 3.9 million due to hypertensive and other heart conditions. As well, at least 20 million people survive heart attacks and strokes every year, a significant proportion of them requiring costly clinical care, which puts a huge burden on longterm care resources. Cardiovascular disease affects people in their mid-life years, undermining the socio-economic development, not only of affected individuals, but also families and nations. Lower socio-economic groups generally have a greater prevalence of risk factors, diseases and mortality in developed countries, and a similar pattern is emerging as the CVD epidemic matures in developing countries and in India, hyperlipidemia has been the chief precipitating factor in CVDs.

Hyperlipidemia is an excess of lipids, largely cholesterol and triglycerides, in the blood. It is also called hyperlipoproteinemia because these fatty substances travel in the blood attached to proteins as lipoproteins. The best-known lipoproteins are Low Density Lipoprotein (LDL) and High Density Lipoprotein (HDL). Excess LDL cholesterol contributes to the blockage of arteries, which eventually leads to 'heart attack'.

In contrast, the lower the level of HDL cholesterol, the greater is the risk of coronary heart disease. As a result, HDL cholesterol is commonly referred to as the "good" cholesterol. Low HDL cholesterol levels are typically accompanied by an increase in blood triglyceride levels. Studies have shown that high triglyceride levels are associated with an increased risk of coronary heart disease (Gupta 2000).

In such a context, there arises an essentiality for addressing the entire gamut of issue through one single medium 'Dietary Modification'. Dietary modification plays an immense task in prevention and treatment strategies for these disease conditions. Several antioxidant and nutrient rich foods have been identified in ameliorating the conditions associated with the scourge and the role of wheat have been highlighted in many supplementation studies conducted world over and for the present study, wheat is chosen as a principal input playing a major role in the proposed dietary supplementation in a zealous attempt to make it as a major factor in the 'dietary modification' discussed afore. But the proposed supplementation of wheat is not per se wheat as conventionally understood but in the forms of 'wheat germ'.

Wheat germ is the most important nutritious part of wheat grain separated by ultra modern milling technology which keeps free radical in check which in turn helps to prevent heart diseases, cancers and diabetes. It is also very important for vitality and healthy heart, further lowering the risk of coronary heart diseases and helps to reduce obesity and delays ageing process. It contains about 27-28 g protein which is rich in all the essential amino-acids particularly lysine. The presence of sugar in germ makes it acceptable and tasty. Over 80 per cent of fat present in wheat germ is made up of Poly Unsaturated Fatty Acids (PUFA). Three table spoons of wheat germ will provide 20 per cent Dietary Reference Intake of folic acid and vitamin E required for pregnant women (Nurhan and Minquan 2003).

The study attains significance under the pretext that the studies in India, despite its massive production have not adequately exploited the viability of wheat in the forms of wheat germ, bran and grass. The present study is intended to fill this gap. The bountiful production of wheat and its high consumption among Indian populace are the encouraging factors for this intended investigation that attains social relevance too. Against such a backdrop, the present study has been undertaken with the following specific objective to supplement wheat germ to selected subjects of diabetes and evaluate the impact.

METHODOLOGY

The locale selected for the study was the District of Villupuram from the State of Tamil Nadu, India. The hyperlipidemic subjects from Villupuram town were selected for the study. The review board of Department of Food Science and Nutrition, Avinashilingam University approved the protocol used in the study and all the subjects gave informed consent for the study. The ethical guidelines were followed and the study was approved by the Committee on Health Research Ethics, Avinashilingam University for Women, Coimbatore (H.E.C.2006.04).

Based on the physicians' opinion on the clinical and biochemical picture obtained from the hospital records and the criteria framed by the investigator, 30 hyperlipidemic subjects were divided randomly into two groups of 15 each respectively (Group A and Group B). Group A received wheat germ and Group B served as the control group and did not receive any supplements other than the usual medications. The selected subjects were in the age group of 45-50 years. All the subjects were examined clinically and information pertaining to age, sex, habits and health status was recorded in the questionnaire. All subjects selected were free from added risk factors like thyroid, kidney disease, smoking and alcoholism.

Determination of Dosage of Wheat Germ

Wheat germ is a good source of phytosterol and one such phytosterol is beta sistosterol which is a plant sterol found in almost all plants. According to Cara et al. (2001), beta sistosterol regulates blood sugar and insulin levels in Type II diabetics by stimulating the release of insulin in the presence of non- stimulatory glucose concentrations and inhibiting glucose -6phosphatase. In the liver, the enzyme glucose -6phosphatase is the primary pathway for conversion of dietary carbohydrates to blood sugar. Glucose -6- phosphatase dephosphorylates glucose -6- phosphate to yield free Dglucose. Free D-glucose passes into the blood, thus elevating blood sugar levels.

Based on this literature and on the estimation of the phytosterol content in wheat germ, it was decided to supplement 60 g of wheat germ which would provide 182.4 mg of beta sistosterol to diabetic subjects.

Supplementation of Wheat Germ

Before starting the feeding trials, all the 15 subjects in the Group A were educated about the beneficial effect of the supplements in alleviating the disease conditions. Sixty grams of wheat germ was supplied in sachets to the Group A subjects every fortnight at the clinic premises.

The following procedure was adopted for feeding the supplements:

30g of wheat germ in 100ml of toned milk was consumed twice a day (at mid-morning and at bed time)

Thus, on a daily basis 60g of wheat was consumed by each subject in the respective experimental groups for a period of six months.

Evaluation of the Impact of Supplementation

Impact of supplementation of wheat germ on selected subjects was evaluated by the following methods

1. Clinical examination and

2. Biochemical assessment

1. Physiological Symptoms: The physiological symptoms of diabetes were evaluated before and after the supplementation period using a check list. The physiological symp-toms screened for diabetes include: Polydypsia, polyphagia, nocturia, constipation, insomnia, shivering, giddiness, excessive sweating, burning sensation in extremities, impaired vision, burning sensation during micturation, hesitancy during micturation and frequency of micturation.

2. Biochemical Analysis: Biochemical changes can be expected to occur prior to clinical manifestation. Therefore biochemical tests which can be conducted on easily accessible body fluids such as blood and urine can help to diagnose disease at the sub clinical stage (Boon and Davidson 1990). All the biochemical parameters were evaluated initially and after six months of supplementation for all the subjects.

The procedure for collection of blood and the method followed in the estimations is elaborated below:

10ml of venous blood was collected after overnight fasting in different containers:

Sodium Fluoride Bulb

1.0ml of blood for glucose estimation.

EDTA Bulb

5.0ml of blood was added. Red blood cells were washed three times with ice cold normal saline and used for the estimation of glycosylated hemoglobin.

(*i*) Fasting and Postprandial Blood Glucose: Fasting and Post prandial glucose were measured using commercial kits from Accurex, India, on automated analyzer.

(*ii*) *Glycosylated Hemoglobin* (*GHb*): Glycosylated hemoglobin was determined by the method of Fulckiger et al. (1977)

Statistical Analysis

Mean, Standard deviation and standard error were calculated. Students 't'test, F test was applied to assess the significance of the result.

RESULTS AND DISCUSSION

a. Changes in Physiological Systems

The physiological symptoms observed in the study are discussed in table 1. Of the various clinical parameters which indicate diabetes, polyuria, polydypsia, polyphagia, nocturia and constipation were found to be the most frequently occurring symptoms in both the groups studied.

Table 1: Changes in physiological symptoms of diabetic subjects

Symptoms*	Group A		Group B	
	Ι	F	Ι	F
Polydypsia	10	1	9	9
Polyphagia	9	-	10	10
Polyuria	8	-	13	12
Nocturia	10	-	10	10
Constipation	12	-	5	5
Insomnia	-	-	-	-
Giddiness	-	-	2	2
Impaired vision	-	-	-	-

* Multiple responses I-Initial ; F-Final

In the initial phase, it was found that ten and nine subjects in the Group A, Group B expressed the occurrence of polydypsia and 9 and 10 subjects of the Group A, Group B expressed polyphagia as a symptom. Around 12 subjects in the Group A were suffering from constipation initially. After six months of supplementation with wheat germ, there was a drastic reduction in the physiological symptoms expect for one or two subjects in whom symptoms like polyuria, polyphagia, nocturia and polydypsia were reduced. Further, it was found that the subjects who expressed constipation as a problem expressed the relief of constipation after the supplementation. This can be owed to the high amount of soluble fiber in the supplements. As observed from the table, there was not much improvement in the physiological symptoms in the control group (Group B).

b. Changes in Biochemical Picture

Mean Serum Fasting and Postprandial Glucose and Glycosylated Hemoglobin Levels

The mean serum fasting, postprandial

glucose and glycosylated hemoglobin levels at the initial and final phase of the study period and results of the statistical analysis is discussed in table 2.

Serum Fasting Glucose Levels

The mean serum fasting glucose levels ranged from 123.20 to 124.80mg/dl in the experimental and control groups as against the normal range of 70 to 99 mg/dl as quoted by Raguram et al.(2007). It is inferred that there was a reduction in fasting glucose levels on supplementation with wheat germ. Group A supplemented with wheat germ had a minimal decrease of 22.07mg/dl. The final values of the serum fasting glucose was significantly lower than the initial values (P<0.01) in Group A. The difference observed between the initial and final values of Group B was not significant.

The one way analysis of variance showed a statistically significant difference in the reduction of serum fasting glucose levels among the two groups at one per cent level. The reduction in the fasting blood glucose levels as observed in group A supplemented with wheat germ could be substantiated with the study done by Cara et al. (2001).

Serum Postprandial Glucose Levels

The mean serum postprandial glucose levels of Group A and Group B ranged from 184.40 to 188.53mg/dl, whereas normal level ranges from 80 to 120 mg/dl as quoted by Raguram et al. (2007). The serum postprandial glucose levels reduced after supplementation of wheat germ. The final mean serum postprandial glucose levels in Group A after the supplementation was 123.93mg/dl.

Table 2: Changes in mean serum fasting and postprandial glucose and glycosylated hemoglobin levels (N=15/group)

Groups	Fasting glucose (mg/dl)	Post prandialglucose (mg/dl)	Glycosylated hemoglobin (%)
Group A			
Initial	123.20 ± 2.62	164.67 ± 3.08	8.42 ±0.17
Final	101.13 ± 0.92	123.93 ± 2.63	6.35 ±0.22
Difference	-22.07 ±2.91	-40.74 ± 4.20	-2.07 ±0.29
't' value	29.32**	37.17**	27.79**
Group B			
Initial	124.80 ± 2.54	163.07 ±2.34	8.39 ± 0.21
Final	124.20 ± 2.65	164.60 ± 2.61	8.36 ±0.13
Difference	-0.60 ± 3.46	1.53 ± 3.74	-0.03 ±0.13
't' value	0.65 ^{NS}	1.53 ^{NS}	0.65 ^{NS}
'F' value between groups 140.29**		409.83**	538.94**

** Significant at one per cent level; NS not significant

Group A supplemented with wheat germ had a decrease of 40.74mg/dl. Decrease in serum postprandial glucose levels in the experimental groups were found to be significant at one per cent level whereas the change observed in Group B was not statistically significant.

One way analysis of variance was performed and the difference between the groups was found to be significant at one per cent level.

Serum Glycosylated Hemoglobin Levels

The glycosylated hemoglobin test (HbA₁C) is an excellent index of long term diabetes control. Unlike blood sugar which tends to fluctuate from day to day and even hour to hour, the HbA₁C test is a true index of the average blood glucose control during previous 2-3 months. HbA₁C test is done in the laboratory rapidly and precisely using the "gold standards" of the HbA₁C testing. The interpretation of the test results are as follows: normal - below 5.6 per cent, good control -5.6 to 7 per cent, fair control -7 to 8 per cent, unsatisfactory control -8 to 10 per cent and poor control -above 10 per cent as quoted by American Diabetic Association (2004) .The mean initial glycosylated hemoglobin levels of the subjects in Group A and Group B were between 8.39 to 8.45 per cent (unsatisfactory control). The impact evaluation showed that the HbA₁C had lowered by the supplementation of wheat germ over a period of six months. Group A supplemented with wheat germ had a reduction of 2.07 per cent with the final values at 6.35 per cent which was considered as 'good control'.

The reduction between the mean initial and final values of HbA₁C in Group A was significant at one per cent level. No such significance was observed in Group B. A study by Yokiko et al. (2002) proved that HbA₁C reduced on supplementation with Antioxidant Biofactor (AOB), a mixture of commercially available fermented grain foods which includes wheat.

From the foregoing discussions, it could be concluded that Group A supplemented with wheat germ is an effective contrivance in fight against diabetes and could be used as an adjunct intervention in ensuring better heath for diabetic subjects; if not completely cure them of the disease. It would be a boon to the diabetic population if all the hidden, health promoting properties of wheat like alleviation of co-morbidities are explored for the fullest use of this nature's gift. It could be concluded from the study that wheat germ is reported to have beneficial effect in alleviating specific health issues like diabetes In this ever changing scenario of emerging varieties of disease, existence of medical assistance without any side effect is much sought after remedy. In this context, the result of the present investigation assumes significance and a small step in such innovative findings on the hitherto – "Wheat – A treasure to treasure".

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