Summary & Conclusions

SUMMARY AND CONCLUSIONS

Non communicable diseases (NCDs) are the major public health issues in almost all countries and areas in the developing region. They are no longer "diseases of affluence" limited to developed countries. Developing countries suffer the major impact of NCDs.

Urbanization, industrialization and globalization are bringing about enormous changes in social systems and environments and increasing exposure to unhealthy lifestyles and behavior. It has been predicted that by the year 2020, upto 3 quarters of deaths in developing countries would result from NCDs including CVD, diabetes and cancer. (Kalache A 1999).

The term diabetes mellitus is used to describe a metabolic disorder of multiple etiology characterized by chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, action or both.

WHO (King et al 1998) has projected that the global prevalence of T2DM would more than double from 135 million in 1995 to 300 million by the year 2025. India leads the world in the number of people with diabetes (50.8 million) and this number is expected to rise to 87 million by 2025 (IDF 2009).

Diabetes causes profound alterations in both the micro and macro vascular system affecting nearly every organ in the body. It magnifies the risk of vascular diseases several fold and is thus one of the major cause of morbidity and mortality worldwide (Huxley et al 2006). While macrovascular complications are associated with significant morbidity and mortality in diabetic subjects, microvascular complications also contribute significantly. About 30–45% of diabetic subjects suffer from microvascular complications, and type 2 diabetes has become the principal cause for blindness and end-stage renal disease in western countries (Rainor 2001). Poor glycemic control, disease duration, hypertension and dyslipidemia are considered to be

important risk factors for microvascular complications (DCCT 1993, UKPDS 33 1998, Stratton et al 2001).

Diabetes is an increasingly prevalent and burdensome disease in working populations. The workplace also appears to be a promising focal point for conducting disease screening and prevention programmes based on the proximity of medical services to the employee and the requirements for conducting routine occupational health examinations (Oberlinner et al 2008).

Risk factors are "determinants, characteristics or exposures that are associated with a greater risk of ill health". Risk of diseases increases progressively as the number of risk factors increases (WHO 2002). Diabetes and heart diseases rarely develop from a single risk factor. A cluster of risk factors usually occurs, and a small increase in one risk factor, such as the blood pressure, becomes more critical when combined with other risk factors. Conversely moderate changes in one risk factor can decrease several others at the same time. Various risk factors that have been implicated in the development of T2DM include increased age, a family history of diabetes, overweight/ obesity, prior history of gestational diabetes, impaired glucose tolerance, physical inactivity and race/ethnicity.

Hyperglycemia is the hallmark of diabetes and is the result of several metabolic abnormalities. Thus, the primary goal in the management of diabetes is to maintain euglycemia. Different approaches have been used to manage diabetes mellitus, the most common being drug therapy. However pharmacological therapy is costly and can have side effects. Focus is being drawn towards alternative approaches other than drug therapy to treat diabetes. It is well recognised that foods are the main sources of nutrients used to meet our nutritional needs. However foods, particularly of plant origin, contain a wide range of non nutrient phytochemicals that are elaborated by plants for their own defence and other biological functions. When man ingests these plant foods to meet his nutritional needs, he also ingests a wide variety of these phytochemicals (Rao 2003).

Botanicals are plants valued for their medicinal or therapeutic properties and have been used since ancient times to treat several diseases. Many plants with antihyperglycemic properties have been used to treat diabetes. In this regard, barley grass which is considered to be a treasure house of nutrients and has several purported health benefits is under researched. Therefore there is a need to explore the utility of barley grass in food product development and its use as a functional food in diabetic subjects as it contains a wide spectrum of nutrients and non nutrients.

With this background, the present study was planned with the following objectives

- 1. To study the metabolic alterations in T2DM subjects and to map the prevalence of microalbuminuria.
- To study the risk factors for diabetes in an industrial population of Vadodara and to track glycemic and lipemic control over a period of four years.
- 3. To develop functional food products incorporating Barley Grass Powder.
- 4. To determine the acceptable level of Barley Grass Powder incorporation in the developed food products by sensory evaluation.
- 5. To analyze the nutrient composition of Barley Grass Powder.
- To study the impact of Barley Grass Powder supplementation in the form of capsules for a period of 60 days on the carbohydrate and lipid metabolism of T2DM subjects.
- 7. To determine the feasibility of scaling up Barley Grass Powder Khakhra as a functional food.

The study was carried out in 4 phases as given below:

PHASE I: Metabolic alterations in T2DM subjects and the prevalence of microalbuminuria

- PHASE II: Evaluation of diabetes risk profile in an industrial productive population of Vadodara
- PHASE III (a): Nutritional analysis of BGP
 - (b): Product development using BGP
 - (c): Sensory evaluation of the developed products
- **PHASE IV (a):** Impact of BGP supplementation on the FBG, HbA1C and lipid profile of stable T2DM subjects
 - (b): Scaling up of BGP khakhra for consumers at large

PHASE I: METABOLIC ALTERATIONS IN T2DM SUBJECTS AND THE PREVALENCE OF MICROALBUMINURIA.

In the study, 102 stable diabetic subjects, who gave verbal consent, were enrolled from two pathology laboratories of Vadodara city. Information regarding socio economic status, educational status, anthropometric measurements, family history, lifestyle factors, medical history and 24-hour dietary recall were recorded using a structured pre-tested questionnaire. Biochemical indicators including fasting blood glucose, HbA1C, lipid parameters and renal function tests were also studied.

OBSERVATIONS:

Socio-Economic Status

- The mean age was 58y for the male diabetics and 56y for the female diabetics.
- Around 98% of the subjects in the present study were Hindus and belonged to the middle income group.
- ✤ Majority (60%) of the subjects had received elementary schooling.

Dietary Analysis

The diet of diabetic subjects was high in fat with poor iron and βcarotene content.

Medical and Family History

- The prevalence of hypertension was around 50%.
- A history of diabetes, hypertension and CHD in the family was found in about 61.8%, 28.4% and 6.9% of the subjects respectively.

Obesity Measures and Diabetes Mellitus

- The prevalence of overweight and obesity was 13.7% and 65.6% among the diabetics using the Asia Pacific criteria.
- Around 64.2% of the male diabetics and 91.8% of the female diabetics had abdominal obesity as indicated by high waist circumference values.
- Obesity prevalence calculated from WHR, WSR, WWR and % Body fat was 85.3%, 100%, 54.9% and 83.3% respectively.

Biochemical Indicators

- A high proportion (94.1%) of the subjects had poor glycemic control as indicated by HbA1C levels.
- It was observed that 35% had hypercholesterolemia, 44% had hypertriglyceridemia, 62.7% had elevated levels of atherogenic lipoprotein LDL-C and 60.8% had low levels of HDL-C.
- Majority (93.1%) of the subjects fell into the AIP high risk category.
- Overall prevalence of microalbuminuria was 28.4% (Males: 22.6% and Females: 34.7%).

Risk Factor Profile

The diabetic subjects had 5 risk factors on an average with 86.2% of the subjects having > 3 risk factors.

Lipemic Status and Kidney Function Indicators in Relation to HbA1C Levels

Male diabetic subjects with poor glycemic control had significantly higher levels of TC, TG, VLDL-C, Non HDL-C and the atherogenic lipoproteins.

- ◆ Percent subjects having TG/H ≥ 3 was 73.3% in poorly controlled diabetic subjects as compared to 45.2% in better controlled diabetic subjects.
- Dyslipidemia was present in female diabetic subjects irrespective of glycemic metabolic control.
- Diabetic subjects who had poor glycemic control had significantly higher urine albumin levels in both the genders.

Glycemic Status, Lipemic Status and Kidney Function Indicators in Relation to the Metabolic Syndrome

- Higher FBG and HbA1C values were found in the diabetic subjects in the presence of the metabolic syndrome.
- Male and female diabetic subjects with the metabolic syndrome had significantly higher TG, VLDL-C and atherogenic lipoprotein levels and significantly lower HDL-C levels.
- Lipid aberrations were more profound among the female diabetic subjects.
- The prevalence of microalbuminuria was higher in diabetic subjects with the metabolic syndrome (32.3%) as compared to those without the metabolic syndrome (21.6%).

Glycemic Status, Lipemic Status and Kidney Function Indicators in Relation to the Urine Microalbumin Levels

- Diabetic subjects with microalbuminuria had significantly higher FBG and HbA1C values as compared to the normoalbuminurics.
- In relation to urine microalbumin levels the lipid profile values did not differ significantly.
- Creatinine values, both in serum and urine were found to be significantly lower in the microalbuminuric group.
- Hypertensive diabetic subjects were found to have significantly higher urine microalbumin levels as compared to the normotensives.
- Cross tabulation of albumin excretion with glycemic status and hypertension revealed glycemic control to be an important factor influencing the levels of albumin in the urine.

Atherogenic Index of Plasma

Significantly higher levels of TG, VLDL, Non HDL and the atherogenic lipoproteins and significantly lower HDL levels were observed in the AIP high risk group.

Predictor Variables for Microalbuminuria

Based on correlation analysis, odds ratio and multiple logistic regression analysis the predictor variables influencing urine microalbumin levels were found to be FBG, HbA1C, hypertension and family history for diabetes.

CONCLUSIONS

- Prevalence of overweight/obesity and abdominal obesity was high among the diabetic subjects thus prioritizing the need to address this problem.
- Poor glycemic control among the diabetic subjects is a significant cause for concern and efforts to maintain normoglycemia need to be made through drug, diet and exercise in order to avoid or delay the micro and macrovascular complications of diabetes.
- Hypertension which places an individual at a high risk for coronary events was a common complication among the diabetic subjects. Therefore hypertension management needs to be emphasized.
- Dyslipidemia was a common feature among the diabetic subjects indicating the risk for cardiovascular disease.
- The presence of microalbuminuria in a significant proportion of the diabetic subjects puts them at a risk for developing overt nephropathy.
- Presence of a multiple risk factor scenario calls for developing a surveillance system to monitor and reduce the risk.
- Glycemic control and presence of hypertension were significant predictor variables for microalbuminuria. Thus, tight glycemic and blood control and regular monitoring should be the primary goals for the diabetic subjects in order to avert the secondary complications.

PHASE II: RISK FACTOR ANALYSIS AND TRENDS OF DYSLIPIDEMIA IN T2DM SUBJECTS OF AN INDUSTRIAL POPULATION

In the study a total of 54 type 2 diabetic subjects were identified from 3 work units of a petrochemical industry of Vadodara. Information pertaining to various risk factors like heredity, lifestyle factors, fruit and vegetable consumption, medical history and information on routine tests was obtained using a pre-tested structured questionnaire. Anthropometric data (height, weight), fasting blood glucose, lipid profile values and blood pressure measurements were obtained from medical records. Data on fasting blood glucose, lipid profile and blood pressure for the past four years (2005-2008) was obtained for 43 of the 54 diabetic subjects. This data was used to arrive at the trends of dyslipidemia and blood pressure over a period of four years.

OBSERVATIONS:

Background Information and Medical History of the Subjects

- The subjects were in their productive years with an age range of 39-57 years.
- Around 57.4%, 38.9% and 16.7 % of the subjects had a family history for diabetes, hypertension and heart disease respectively.
- Based on medical history hypertension was a common complication with around 35.2 % of the subjects confirming the presence of hypertension in addition to diabetes.

Risk Factor Analysis

- ☆ Around 37% and 53.7% of the subjects were found to be prehypertensive (≥120/80 mmHg) and hypertensive (≥140/90 mmHg) respectively.
- Based on the Asia Pacific classification, the prevalence of overweight in the study population was 14.8% and that of obesity was 57.4%.
- The habit of smoking, tobacco usage and alcohol consumption was present in 14.8%, 22.2% and 13% of the study population respectively.

- Majority of the subjects (70.4%) reported to be exercising > 3 hours a week.
- About 57.4 % and 77.8% of the subjects reported that their consumption of fruits and green leafy vegetables was more than thrice a week respectively.

Glycemic and Lipemic Status of the T2DM Subjects

- Mean FBG and lipid profile values were high for the subjects indicating poor glycemic and lipemic control.
- It was observed that 25.9% had hypercholesterolemia, 39.6% had hypertriglyceridemia, 62.96% had elevated levels of atherogenic lipoprotein LDL-C and 53.7% had low levels of HDL-C.
- Majority (94.3%) of the subjects fell into the AIP high risk category.

Medical Tests Undergone by the Subjects

- Majority of the diabetic subjects (85.2%) used to get their serum lipids tested followed by eye examination for glasses (72.2%) and kidney function tests (68.5%) excluding microalbuminuria.
- Less than 50% got their HbA1C monitored. Only 20% underwent a foot examination.

Risk Factor Scenario

- All the diabetic subjects had risk factors, peaking between 5-8 risk factors, thus indicating the presence of a multiple risk factor scenario.
- ♦ About 87.2% of the subjects had \geq 5 risk factors.

Tracking the Diabetic Subjects over a Period of Four Years

- Consistently elevated levels of FBG, TG, LDL, Non HDL, TG/H, SBP, DBP and BMI were found in the diabetic subjects over a period of four years.
- High prevalence of dyslipidemia was observed among the diabetic subjects over the four year duration. Consistently low levels of HDL and high TG levels were observed in more than 40% of the subjects. High LDL values were present in about 44-74% of the subjects over

this four year duration. Around 90-100% of the subjects had high risk AIP values.

New cases of hypercholesterolemia, hypertriglyceridemia and hypertension were identified over a period of four years.

CONCLUSIONS

- The prevalence of risk factors was high among the industrial diabetic subjects. Therefore early detection and regular monitoring need to be prioritized for managing the risk factor profile.
- Both dyslipidemia and hypertension which are major risk factors for cardiovascular disease display a persistent pattern in the industrial diabetic population and need to be addressed in a cohesive manner.

PHASE III (a): NUTRITIONAL ANALYSIS OF BGP

PREPARATION OF BARLEY GRASS POWDER

Barley grain was procured from the local market and was authenticated by a botanist from The M.S.University of Baroda. Barley grass was cultivated on a large scale in a farm. The grass was cut when it was around 10-12 inches in height. The entire lot was transported to a food industry where it was cut, washed and subjected to cold dehydration (5°-10° C) for 24-30 hours. The dried product was then ground into a powder form and nitrogen packed (Figure 5.1).

NUTRITIONAL ANALYSIS

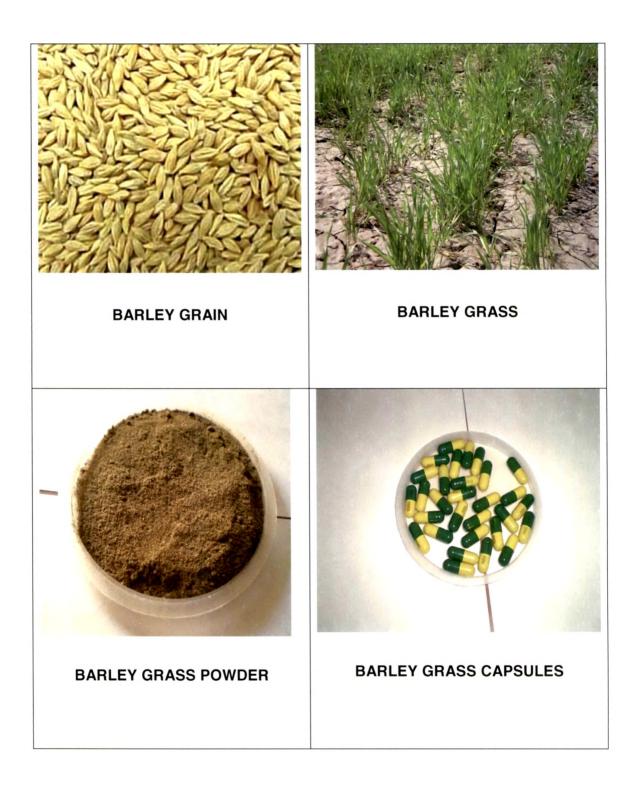
A sample of barley grass powder was sent to an analysis centre (Analytical & Environmental Sciences, Baroda) for nutritional analysis. The sample was mixed properly and homogenized and a representative sample was subjected to analysis for nutritional value.

OBSERVATIONS:

Barley grass powder was found to have high levels of protein, potassium and vitamin C and was low in sodium content.

FIGURE 5.1

STAGES IN THE PREPARATION OF BARLEY GRASS POWDER AND CAPSULES



The sample sent for analysis was reported to be free from insect infestation and fungal growth.

CONCLUSIONS

 Barley grass powder has a rich nutrient profile which may have health benefits.

PHASE III (b) & (c): PRODUCT DEVELOPMENT AND SENSORY EVALUATION OF BARLEY GRASS POWDER (BGP) INCORPORATED FOOD PRODUCTS.

This phase was divided into 2 parts. First was the development of food products incorporating BGP. In this part four traditionally consumed products namely Cutlet, Khakhra, Thepla and Muthiya were developed using standardized recipes and procedures and incorporating BGP at varying levels (0.5g, 1g and 1.5g) into each of these. In the second part, 12 semi trained judges who gave their oral consent for evaluation were selected as panel members. Sensory evaluation of the developed products was then carried out using a composite rating scale and the ranking for finding out the acceptable level of BGP incorporation and for observing changes in other sensory attributes, if any when BGP was added to the products.

OBSERVATIONS:

- BGP can be effectively incorporated in different traditional Indian recipes with high acceptability.
- Of the four products developed, Cutlets were accepted the most based on scores of the composite rating test.
- On the basis of the ranking tests, Cutlets were ranked 1st followed by Thepla, Khakhra and Muthiya.
- Of the various recipes developed using BGP, Khakhra has the potential for commercialization due to its longer shelf life and acceptance as a snack item.

CONCLUSIONS

BGP incorporation in different recipes was found to be highly acceptable. Thus BGP has the potential to be used as a functional food for health benefits.

PHASE IV (a): IMPACT OF BGP SUPPLEMENTATION ON THE FBG, HbA1C AND LIPID PROFILE OF STABLE T2DM SUBJECTS

ENROLLMENT OF SUBJECTS

In this phase, 59 stable T2DM subjects who gave verbal consent were enrolled from pathology laboratories in Vadodara city. The subjects were divided into two groups – Control (N=23) and Experimental (N=36) based on their willingness to consume BGP capsules.

FORMULATION OF BARLEY GRASS POWDER CAPSULES

The barley grass powder prepared and packed under nitrogen gas was given to a local pharmaceutical industry (AIMCO Pharmaceutical Manufacturing Company) for preparation of barley grass powder capsules (300 mg of barley grass powder per capsule) (Figure 5.1).

DATA COLLECTION

Pre data was collected for both the groups regarding socio economic status, anthropometric measurements, family history, lifestyle factors, medical history and 24-hour dietary recall were recorded using a structured pre-tested questionnaire. Biochemical indicators included fasting blood glucose, HbA1C and lipid profile. All the parameters were monitored at the end of the supplementation period for subjects in both the groups.

SUPPLEMENTATION

The experimental group was given 1.2 g/day of BGP i.e. 4 capsules per day for a period of sixty days. During the course of supplementation no modification in the diet or medication was made. The control group received no supplementation.

OBSERVATIONS:

Baseline Profile of the Diabetic Subjects

- The subjects were in the age range of 55 to 62 years.
- Majority of them were overweight or obese as indicated by their BMI.
- Waist circumference for both the male and female diabetic subjects was higher than the normal cut off values.
- The anthropometric profile of the control and the experimental groups revealed that the baseline characteristics were similar in both the groups.
- Habitual consumption of tobacco and smoking were seen in relatively few subjects.

Medical History

- Hypertension was a predominant complication and was present in 43.5% and 52.8% of the diabetic subjects in the control and experimental group respectively.
- About 69.56% and 83.33% of the subjects were overweight or obese in the control and experimental group respectively.

Nutrient Intake

Overall it was observed that the diet was high in fat, low in fibre and iron and was comparable between control and experimental groups

Impact of BGP Supplementation on the Carbohydrate Metabolism of T2DM Subjects

- Supplementation of BGP led to a significant fall in the FBG (10.8%) and HbA1C (5.2%) values in the experimental group. Such a change was not observed in the control group.
- In relation to gender, the fall in HbA1C was significant in the male diabetic subjects.
- Supplementation with BGP led to a significant reduction in the blood glucose and HbA1C values of subjects who had initial fasting blood glucose greater than 140 mg/dl.

Impact of BGP Supplementation on the Lipid Profile of T2DM Subjects

- Supplementation with BGP for a period of two months brought about a desired significant change in the lipid profile of the diabetic subjects.
- There was 5.1% decrease in the total cholesterol values (195 mg/dl vs 185 mg/dl). The atherogenic lipoprotein LDL-C decreased by about 8.2%. The HDL-C increased by about 5.0%. Further there was a 7.7% decrease in the Non HDL-C values which represents a mixture of atherogenic lipoproteins. There was a slight non significant reduction in the triglyceride values. Favourable changes were more profound among the female subjects than in male subjects.
- ✤ Favourable responses were seen in diabetic subjects who had initial TC ≥ 200 mg/dI as compared to those having TC< 200 mg/dI. There was a 8.3% fall in TC, 10.9% in LDL-C and 10.1% in Non HDL-C in subjects having TC ≥ 200 mg/dI. A significant rise in HDL-C was found among subjects in the experimental group who had initial TC <200 mg/dI.
- ★ The fall in TG, TC, VLDL-C and Non HDL-C values was 16.7%, 8.8%, 16.3% and 11.7% respectively in subjects having initial TG ≥ 150 mg/dl.

Impact of BGP Supplementation on the Atherogenic Indices of T2DM Subjects

- Atherogenic indices significantly decreased post BGP supplementation, thus lowering the risk of CHD in the diabetic subjects.
- Significant positive impact on the atherogenic indices were also reflected in subjects who were hypercholesterolemic or hypertriglyceridemic before supplementation.

Impact of BGP Supplementation on the FBG, HbA1C, Lipid Profile and Atherogenic Indices of T2DM Subjects in Relation to their Initial BMI and in T2DM Subjects with Hypertension as a Complication

HbA1C values were significantly lowered in overweight and obese subjects in the experimental group as compared to the normals. Such a trend was not observed in the control group.

- Lipid profile of the diabetic subjects in the experimental and control groups was not influenced by BMI. Atherogenic indices in the experimental group showed favourable changes irrespective of initial BMI.
- HbA1C values were significantly reduced in the experimental group with hypertension.
- In relation to lipid profile values no significant changes were observed other than a significant increase in HDL-C values in normotensive experimental group subjects. A significant lowering of atherogenic indices was observed in both normotensives and hypertensives after the BGP supplementation.
- HbA1C values of diabetic subjects who were overweight or obese and hypertensive were significantly reduced after BGP supplementation. The lipid profile of the subjects did not vary significantly.

Attainment of Normoglycemia and Normolipidemia after BGP Supplementation

- With BGP supplementation 25%, 21.4% and 21.4% of the subjects attained normal FBG, TC and TG levels respectively.
- Improvements in glycemic and lipemic status in response to BGP supplementation were shown by around 30-40% of the subjects.

CONCLUSIONS

The impact of barley grass powder supplementation on the FBG, HbA1C and lipid profile merits attention. It is encouraging to note that BGP with its rich nutrient profile and bioactive components can act as a hypoglycemic and hypolipemic agent and may be a novel approach to lower cardiovascular risk factors among T2DM subjects. Thus BGP may be used as a supportive therapy for diabetics.

PHASE IV (b): SCALING UP OF BGP KHAKHRA FOR CONSUMERS AT LARGE

BGP khakhras were prepared in bulk and kept in one of the health clubs in Vadodara (VLCC). The khakhras were distributed to 45 members of the club

for sensory evaluation and acceptability in terms of taste, colour, willingness to buy the product (if available in the market) and maximum number that can be eaten at one time.

OBSERVATIONS:

- Majority of the respondents liked the taste of the BGP khakhras and found its green colour acceptable.
- The respondents were willing to buy the BGP khakhras if they were to be made available in the market.

CONCLUSIONS

Sensory evaluation data on BGP khakhra makes it an excellent functional food. BGP khakhras can be scaled up at a commercial level for health benefits among the general population.

RECOMMENDATIONS

Looking at the results obtained from the present study and the available literature the following recommendations can be made:

- There is a need to propagate the importance of monitoring biochemical and biophysical parameters on a routine basis amongst diabetics not only in clinics but also in pathology laboratories.
- Once diabetes is detected tight glycemic control and blood pressure control need to be enforced in order to avert the secondary complications of diabetes mellitus especially, to reduce MAU.
- Advocacy measures need to be developed and adopted to sensitize and build capacities of diabetic subjects at pathology laboratories.
- Regular surveillance needs to be addressed for identification of employees at risk and taking subsequent preventive measures.
- To reduce the future prevalence of chronic diseases and their complications nutrition health awareness programs need to be implemented in work settings.
- Anthropometric measurements like the waist circumference, HbA1C, checking for presence of microalbuminuria, foot examination and

funduscopy need to be carried out in addition to the routine parameters monitored at the medical centre.

Barley grass powder (1.2 g/day) can be used as a supportive therapy for diabetics for maintaining their glycemic and lipemic levels.

FUTURE STUDIES

- Long-term follow-up studies in the industrial settings are required in order to understand the influence of risk factors on diabetes outcomes.
- Supplementation of BGP for a longer duration should be carried out to assess the glycemic, lipemic and antioxidant status so as to arrive at meaningful recommendations for T2DM subjects.
- Other BGP incorporated functional foods need to be developed and advocated to the general public as BGP has a great potential for use in traditional Indian recipes.
- To study the impact of various BGP incorporated household recipes on carbohydrate and lipid metabolism.
- In depth analysis of the bioactive components of barley grass needs to be carried out in order to expand the clinical utility of barley grass in other conditions.
- Attempts should be made to commercialize BGP as a neutarceutical product for optimizing health.
- There is a need to promote barley grass cultivation at the household level and to incorporate fresh barley grass in various recipes.

PEARLS FOR PRACTICE

- Pathology laboratories can become an excellent venue for adoption of health promoting strategies for diabetics.
- All pathological labs should develop a nutrition health index card (consisting of risk factors) so that each diabetic subject can be monitored and evaluated efficiently.
- The industrial medical units should include measurement of waist circumference along with BMI for each of its employee. In addition it

should be made mandatory for diabetic subjects to undergo series of medical examinations (annual basis) to avoid micro and macro vascular complications.

Barley grass powder (1.2 g/day) can be used to reduce the cardiovascular risk among diabetics.