

Impact of Balya Protex Powder on Fatigue Levels in Patients with Diabetes Mellitus Adhering to the Ayurveda-Based Comprehensive Diabetic Care Program

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Abstract: Chronic fatigue in diabetic patients can be the outcome of protein deficiency. Plant based protein is closer to nature and bodily acceptable, hence we chose to assess plant-based protein “Balya Protex Powder” over whey protein. A prospective, multicentre, post-market study was conducted in India. Patients with a diagnosis of diabetes mellitus aged 18 years and above were included in this study. All patients adhered to the Comprehensive Diabetic Care (CDC) Program. Comparative data of change in fatigue score was collected retrospectively from type 2 diabetes mellitus patients assigned a low carbohydrate low calorie diet for 90 days. A total of 101 patients were included in this study, 50 patients consumed the Balya Protex Powder whilst 51 did not consume the Balya Protex powder whilst adhering to the CDC program. Weight of the patients decreased by 7.92% and 5.52% in the Balya Protex Powder consumption and Balya Protex Powder non-consumption group, respectively. Body mass index decreased by 5.93% and 5.18% in the Balya Protex Powder consumption and Balya Protex Powder non-consumption group, respectively. Abdomen girth decreased by 8.39% and 4.67% in the Balya Protex Powder consumption and Balya Protex Powder non-consumption group, respectively. Weakness grade decreased by 83.69% and 47.61% in the Balya Protex Powder consumption and Balya Protex Powder non-consumption group, respectively. All patients showed significant reduction in glycated hemoglobin (HbA1c) levels, however patients in the subgroup who were taking 30 gm of Balya Protex Powder daily showed 50% greater reduction in chronic fatigue score. It can be concluded that Balya Protex Powder consumption leads to good glycemic control with reduced fatigue in diabetic patients whilst adhering to the CDC program.

Keywords: Ayurveda, Body Mass Index, Diabetes Mellitus, Fatigue, Protein

1. Introduction

Diabetes mellitus is a complex, chronic disease. The International Diabetes Federation estimated 537 million adults living with diabetes mellitus in 2021. This estimation is projected to increase to 643 million by 2030 and 783 million by 2045 [1]. The American Diabetes Association recommends glycated hemoglobin (HbA1c) level of 6.5% as the diagnostic cut-off [2]. Whilst contemporary treatment strategies focus on attaining numerical targets, these

strategies at times neglect the symptomatic well-being of the patient [2].

Fatigue is a common and distressing complaint of patients with diabetes mellitus. It may be the presenting symptom or one among the broad spectrum of symptoms. Moreover, diabetes related fatigue causes physical and mental functional disabilities. This deters the ability to perform routine activities and deteriorates the overall quality of life [3]. The severity of fatigue is influenced by physiological, psychological, and lifestyle aspects which determine the

extent of physical and functional limitation [4].

Ayurveda is an ancient Indian medicinal practice. It treats diabetes through more than one way by incorporating diet planning, exercise and yoga because the combination of a healthy lifestyle, nutritional diet, and regular exercise will always be key in the management of diabetes mellitus [5]. The Comprehensive Diabetic Care (CDC) Program combines *Panchakarma* and diet management to reverse diabetes. Balya Protex powder is a health supplement that improves diabetes related fatigue. Moreover, this health supplement is an easily digestible source of protein. The aim of the current study was bi-fold (i) to assess the effect the CDC program in patients with diabetes mellitus and additionally the effect of Balya of Protex powder on fatigue levels of patients with diabetes mellitus adhering to the CDC program.

2. Materials & Methods

2.1. Study Design and Study Population

This was a prospective, multicentre, post-market study conducted in India. Patients aged 18 years and above diagnosed with diabetes mellitus according to the American Diabetes Association [2] were included in this study. The exclusion criteria were patients without a diagnosis of diabetes mellitus and patients unwilling to participate in the study.

2.2. Comprehensive Diabetes Control Program

The CDC program consists of 3 sessions and each session lasted for an estimated 65–75 mins. The sessions were initiated after the patients had a light breakfast in the morning. *Snehana* was the first session and this was external oleation with Neem oil that was massaged on hands, legs, shoulders, thorax, abdomen, and the back in a centripetal manner. This session lasted 15–25 minutes considering the application of 15–30 minutes on each of the aforementioned body parts. *Swedana* was the second session. This included passive heat therapy with Dashmoola decoction whilst the patient was in supine position in a wooden box. The patient's neck was allowed to protrude outside the box. This session lasted for 10–15 minutes followed by 3–4 minutes of relaxation following the therapy. *Basti*, was the third session, a medicated enema of 100 ml *Gymnema sylvestre*, *Berberis aristata*, and *Glycyrrhiza glabra*. This drug was administered through the rectum and was to remain inside the body for at least 15 minutes to maximize the absorption. The CDC program included a total of 6 sessions (4 within the first month, 1 in the second month, and 1 in the third month) over a 90-day duration. Patients adhered to a strict diet of 800–1000 calories intake daily.

2.3. Balya Protex Powder

Balya Protex Powder is a classical preparation of sattu that contains, baked chana daal flour with emmer wheat and barley. Other key ingredients are ginger and cardamom. Balya Protex Powder is an indispensable health supplement in the daily diet of a diabetic patient. It is an easily digestible source of protein. It provides essential amino acids used for protein synthesis in the growth and repair of the tissue. It also contains antioxidants that help maintain cardiac health and reduce oxidative stress. It contains 1.60% fat, 10.51% protein, 70.31% carbohydrate, 3337.68 kcal energy, 7.09% crude fibre, 14.61 mg calcium, and 2.04 mg iron per 100g.

2.4. Data Collection

Data for patient demographic, anthropometric, and laboratory findings were collected and studied. A questionnaire was used to collect data with regards to the weakness grades of the patient. All patients and controls answered a structured questionnaire developed by the researchers. On a scale of 0–10, 0 meant the patient did not feel fatigue at all and 10 meant the most severe fatigue one could imagine. Data of day 1 was compared with data of day 90.

2.5. Statistical Analysis

Categorical data are expressed as number (percentage) and continuous data are expressed as mean \pm standard deviation. Differences in the values at baseline and the 90-day follow-up visit was analyzed by the ANOVA test.

3. Results

3.1. Overall Study Population

The mean age of patients in the Balya Protex Powder consumption and Balya Protex Powder non-consumption group was 50.76 years and 50.47 years, respectively. The weight of the patients decreased by 7.92% and 5.52% in the Balya Protex Powder consumption and Balya Protex Powder non-consumption group, respectively. Body mass index decreased by 5.93% and 5.18% in the Balya Protex Powder consumption and Balya Protex Powder non-consumption group, respectively. Abdomen girth (ABG) decreased by 8.39% and 4.67% in the Balya Protex Powder consumption and Balya Protex Powder non-consumption group, respectively. Anthropometric, laboratory, and fatigue measurables for Balya Protex Powder consumption and Balya Protex Powder non-consumption groups of the overall study population are shown in Table 1.

Table 1. Anthropometric, laboratory, and fatigue measurables for Balya Protex Powder consumption and Balya Protex Powder non-consumption groups of the overall study population.

Variable	With Balya Protex Powder			Without Balya Protex Powder		
	Day 1	Day 90	Change%	Day 1	Day 90	Change%
Age, years	50.76			50.47		
Male, n (%)	35			30		
Weight, kg	66.67	61.39	-7.92	74.64	70.51	-5.53

Variable	With Balya Protex Powder			Without Balya Protex Powder		
	Day 1	Day 90	Change%	Day 1	Day 90	Change%
HbA1c,%	8.52	6.98	-18.08	8.66	7.08	-18.24
Body mass index, kg/m ²	24.95	23.47	-5.93	27.79	26.35	-5.18
Abdomen girth, cm	93.16	85.34	-8.39	96.98	92.45	-4.67
Weakness grade	8.34	1.36	-83.69	7.37	3.86	-47.61

3.2. Low Body Mass Index Subgroup Analysis

A subgroup of patients with low body mass index was also studied. The weight of the patients decreased by 4.88% and 3.61% in the Balya Protex Powder consumption and Balya Protex Powder non-consumption group, respectively. Body mass index decreased by 4.58% compared to 3.11% in the Balya Protex Powder

consumption and Balya Protex Powder non-consumption group, respectively. ABG decreased by 5.34% and 3.05% in the Balya Protex Powder consumption and Balya Protex Powder non-consumption group, respectively. Anthropometric, laboratory, and fatigue measurables for Balya Protex Powder consumption and Balya Protex Powder non-consumption groups of the low body mass index subgroup are detailed in Table 2.

Table 2. Anthropometric, laboratory, and fatigue measurables for Balya Protex Powder consumption and Balya Protex Powder non-consumption groups of the low body mass index subgroup.

Variable	With Balya Protex Powder			Without Balya Protex Powder		
	Day 1	Day 90	Change%	Day 1	Day 90	Change%
Male	14			4		
Weight	57.22	54.43	-4.88	60.7	58.51	-3.61
HbA1c,%	8.84	7.64	-13.57	8.18	6.48	-20.78
Body mass index, kg/m ²	20.75	19.8	-4.58	21.87	21.19	-3.11
Abdomen girth, cm	85.94	81.35	-5.34	80.06	82.5	3.05
Weakness grade	8.88	1.76	-80.18	7.66	3	-60.84

3.3. Weakness Grade

The weakness grade decreased by 83.69% in the Balya Protex Powder consumption group (day 1: 8.34 at day 90: 1.36) and by 47.61% in the Balya Protex Powder non-

consumption group (day 1: 7.37 and day 90: 3.86). The results were similar in the low body mass index subgroup. The weakness grades for the overall study patients and the low body mass index subgroup are illustrated in Figure 1.

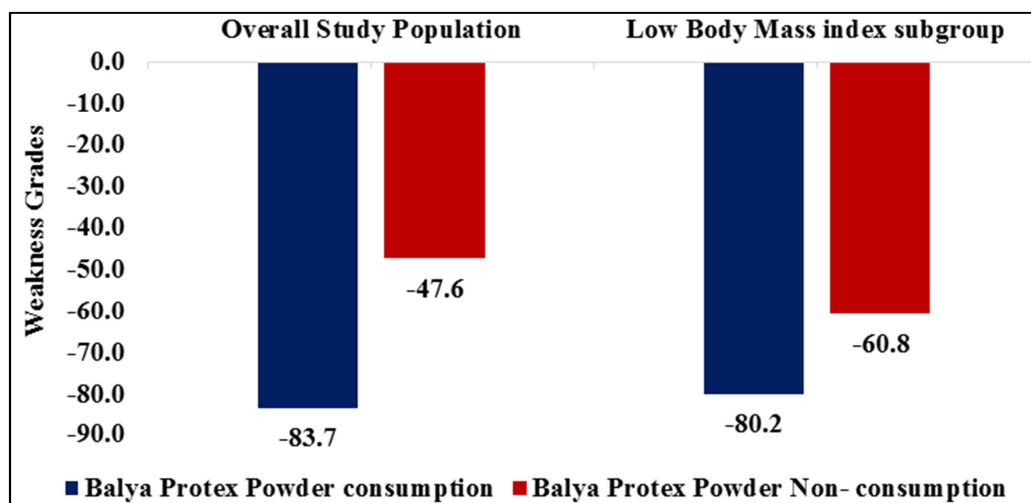


Figure 1. Weakness grades for Balya Protex Powder consumption and Balya Protex Powder non-consumption group for the overall study population and low body mass index subgroup.

4. Discussion

Ayurveda is an ancient traditional medicinal practice that has originated and been practiced for thousands of years in India. It is a multifaceted patient specific tailored approach used to manage diabetes mellitus through diet modification,

Ayurvedic detoxifying and purifying therapies i.e., *Panchakarma*, and Ayurvedic medication (plant-, animal-, or mineral-based, alone or in combination) [6]. The CDC Program combines *Panchakarma* and diet management to reverse diabetes mellitus. Earlier studies assessed the effect of CDC on and anthropometric and HbA1c measurements and revealed satisfactory findings. The current study additionally

assessed the effect of Balya Protex powder on the aforementioned variables. In these earlier studies, weight reduced to 77.11 ± 12.27 kg [7], 69.46 ± 10.39 [8], and 65.15 ± 9.93 kg [9] compared to 61.39 kg in the current study. Body mass index reduced to 31.13 ± 3.91 [7], 25.91 ± 3.29 [8], and 24.91 ± 3.75 [9] compared to 23.7 in the current study. HbA1c level reduced to 6.98 ± 1.73 [7], 7.1 ± 1.30 [8], and 5.79 ± 0.51 [9], compared to 6.98 in the current study. The current study findings in comparison with earlier studies reveal the additional benefits of consumption of the Balya Protex Powder. The current study parallelly assessed the effect of Balya Protex powder on fatigue levels of patients with diabetes mellitus adhering to the CDC program. Findings revealed decrease of 83.69% fatigue levels in the Balya Protex Powder consumption group compared to decrease of 47.61% fatigue levels in Balya Protex Powder non-consumption group. This study is the first to assess the effect of the CDC program in patients with diabetes mellitus and the effect of Balya Protex powder consumption on fatigue levels of patients with diabetes mellitus adhering to the CDC program.

Balya Protex Powder is an indispensable health supplement in the daily diet of a diabetic patient. The ingredients of the Balya Protex Powder include emmer wheat, barley, roasted chickpea, ginger and cardamom. Chickpea, known as *Cicer arietinum*, contains several bioactive components beneficial to patients with diabetes mellitus [10]. A study that investigated chickpea proteins revealed that the protein fraction, lectin, led to inhibition of angiotensin-converting enzymes, α -amylase, and α -glucosidase activities. Moreover, when the IC_{50} values were compared to antidiabetic drug, acarbose, lectin yielded comparable values. These findings substantiate lectin as an anti-hyperglycemic therapeutic molecule [11]. Balya Protex Powder is an easily digestible source of protein. The enhanced digestibility of this supplement can be explained by various mechanisms. The first is heat and mechanical forces that inactivate antinutritional factors such as hemagglutinins, lectins, and trypsin inhibitors. The second mechanism is denaturation of proteins causing unfolding of structures thereby increasing the surface area and exposing enzyme-accessible sites enabling interaction with other components [12].

Ginger, known as *Zingiber officinale* also has proven benefits for patients with diabetes mellitus. A study revealed Ginger supplementation significantly reduced levels of fasting blood sugar and HbA1c [13]. A few mechanisms have been put forth. The first is action of gingerols attributable to facilitation of insulin-dependent glucose uptake by increased translocation of glucose transporter GLUT4 to the muscle plasma membrane surface along with small increases in total GLUT4 protein expression [14]. A second mechanism of reduced blood glucose is inhibition of hepatic phosphorylase enzyme that prevents breakdown of hepatic glycogen storage and increase activity of enzymes thereby improving glycogen synthesis. A third mechanism is suppression of hepatic enzymes that degrade glucose 6-phosphate to glucose and cause an increase in blood glucose level [15]. In line with these proposed mechanisms, *in vitro* studies suggest ethyl

acetate extract of ginger inhibits two key enzymes in the glucose metabolism.

5. Study Limitations

There are a few study limitations that deserve mention. The first is the small sample size. The second is the short follow-up eluding the long-term outcomes of this treatment.

6. Conclusion

Balya Protex (Baked horse gram and emmer wheat premixed) can complement the low carb portioned controlled diet to reduce fatigue in diabetic patients to achieve good glycemic control with reduction in dependency of OHAs.

Conflict of Interest

The authors declare that they have no competing interests.

Authorship Contribution

R. S. conceptualized and designed the study. All authors acquired the data. R. M., G. A., P. G., and H. G. analyzed the data. R. M. performed the statistical analysis, prepared, and edited the manuscript. All authors reviewed the manuscript.

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