Available online at www.sciencerepository.org

Science Repository

Research Article

Pharmacological Potential of Advance Diabetes Support Product in the Management of Insulin-Dependent Diabetes: Overviews on Case Study

Shridhar Pandya[1], Chetan Savaliya[1], Kamlesh Thummar[1] and Dheeraj Nagore[2*]

[1]*Director, Gplife Healthcare Pvt. Ltd., Surat, India*
[2]*Director, Mprex Healthcare Pvt. Ltd., Pune, India*

ARTICLE INFO

Article history:
Received: 1 August, 2022
Accepted: 16 August, 2022
Published: 16 September, 2022

Keywords:
Type I diabetes
type II diabetes
nutraceutical
pancreatic beta cells

ABSTRACT

Type I or Type II diabetes, once recognized as juvenile diabetes or insulin-dependent diabetes, is a chronic illness in which the pancreas produces slight or no insulin. Insulin-dependent diabetes is a syndrome of glucose homeostasis considered by autoimmune destruction of the insulin-producing pancreatic Beta-cell that gradually leads to insulin deficiency. As there is no perfect treatment for management, Gplife has thought of and developed a product that is found to be effective in the management of insulin-dependent diabetes. After 60 days of evaluation of cases, it is observed that fasting blood glucose was reduced by 62.25%, postprandial glucose levels were reduced by 62.37%, HBA1C levels were reduced by 39.57%, C Peptide levels were increased by 26.67%, also the external insulin injection requirement of the patient's decreased by 88.57%. This case study gives an overview of the current understanding of the disease and the efficacy of advance diabetic support products in insulin-dependent diabetes. It is evident that the said product further helps to reduce insulin and OHA doses for the management of insulin-dependent diabetes. It is suggested that the advance diabetes support product should be further extensively used as a monotherapy or adjunctive therapy for the regulation, or management or control of insulin-dependent diabetes.

Introduction

Diabetes is defined as a group of diseases defined by high glucose levels in the blood. It is caused by inadequate production or function of insulin, which may occur for a variety of reasons, resulting in protein and lipid metabolic disorders. Over time insulin-dependent diabetes is an autoimmune disease characterized by insulin deficiency and resulting in hyperglycemia and hypoglycemia, leading to tissue and organ damage. There has been a rapid increase in knowledge of diabetes over the past 25 years, resulting in a better understanding of many aspects of the disease, including genetics, epidemiology, immune and beta-cell phenotyping, and the burden it places on society [1]. In some cases, diabetic ketoacidosis can cause stupor and coma, while other forms may cause blindness, amputations, strokes, and death. When diabetes becomes severe, it may lead to diabetic ketoacidosis, hyperosmolar ketoacidosis, and diabetic ketoacidosis.

Previously, insulin-dependent diabetes could occur at any age, but it was most prevalent in children and young adults [2]. The incidence of insulin-dependent diabetes in Asia was 15 per 100 000 population, which was statistically significant [3]. The number of people with diabetes today has been rising and causing increasing apprehensions in the medical community and society. Alternatively, natural products, particularly of plant origin, represent the main source for identifying potential drug candidates and will have an enormous impact on the future development of new medicines. There could be great promise in the discovery of the new natural antidiabetic drugs because there are no side effects associated with plant-based preparations, and they are easy to obtain and can be inexpensive. Hundreds of millions of people are currently seeking better management of diabetes through the use of current modern antidiabetic drugs [4]. By assessing the need for strong alternatives in the management of insulin-dependent diabetes, Gplife Healthcare P. Ltd. has developed advance diabetic support products,

Correspondence to: Dr. Dheeraj Nagore, Director, Mprex Healthcare Pvt. Ltd., 501, Crossroads Building, Bhumkar Chowk, Wakad, Pune 411057, India; Tel: 9158791967; E-mail: dheeraj@mprex.in

http://dx.doi.org/10.31487/j.RGM.2022.02.01

which have been comprised of *Gymnema sylvestre*, *Tinospora cordifolia*, *Trigonella foenum-graecum*, *Enicostemma littorale*, *Eugenia jambolana*, *Withania somnifera*, etc. herbal ingredients. We have used all standardized and potential extracts to develop advance diabetic support products. An attempt has been made in this metanalysis of different cases to demonstrate the efficacy of the product in the management of insulin-dependent diabetes.

Case Presentation and Methodology

A total of 26 cases were evaluated who have taken treatment of advance diabetic support product of Gplife Healthcare for 60 days. Only those case are considered who has not missed the doses in the treatment duration. Out of 26 cases, 22 were male and 4 were females. Out of 26 cases, 5 were diagnosed with juvenile diabetes having an age range of 13-22 years. The average age of 26 cases was found to be 50.41±17.62 for males and 49.75±24.39 for females. Improvement in laboratory results of various parameters viz. FBS, PPBS, glycated haemoglobin, and insulin levels, as well as their protective effects on diabetic complications, were evaluated. Doses of oral hypoglycemic agents were also monitored, along with the incidence of adverse events during the evaluation period and compliance with the drug treatment.

Treatment

2 tablets of advance diabetic support product two times a day were given to the subjects involved in the case studies.

Statistical Analysis

Statistical analysis was done according to the intention-to-treat principles. Changes in various parameters from baseline and at the end of the study were pooled and analysed using paired 't-tests. Changes in various parameters from baseline and 30 days and at the end of the study were pooled and analysed using a one-way Anova test. Values are expressed as mean ± SD or as incidences of patients with or without symptoms. P-value < 0.05 was considered significant. Statistical analysis was performed using GraphPad Prism for Windows.

Results

The effect of the advance diabetic support product on various laboratory parameters in patients with insulin-dependent diabetes was evaluated. A total of 26 cases were evaluated who have taken treatment of advance diabetic support product of Gplife Healthcare for 60 days. Only those case are considered who has not missed the doses in the treatment duration. Out of 26 cases, 22 were male and 4 were females. Out of 26 cases, 5 were diagnosed with juvenile diabetes having an age range of 13-22 years. The average age of 26 cases was found to be 50.41±17.62 for males and 49.75±24.39 for females (Table 1).

Table 1: Demographic data.

Parameter	**Treatment**	
Group	**Male (n=22)**	**Female(n=4)**
Age (years)	50.41±17.62	49.75±24.39
Total Age (years)	50.31±18.23	

FBS was evaluated in 26 cases who were treated with advance diabetic support products for a period of 60 days. The initial mean FBS significantly reduced from 372.65±93.75 mg/dl to 204.65±39.60 after 30 days and to 140.69±28.20 after 60 days, where $p < 0.001$ was found to be significant. In inference to the evaluation of the above parameters after 60 days, it has been found that the FBS levels were reduced by 45.08% after 30 days and 62.25% after 60 days (Table 2, Figure 1).

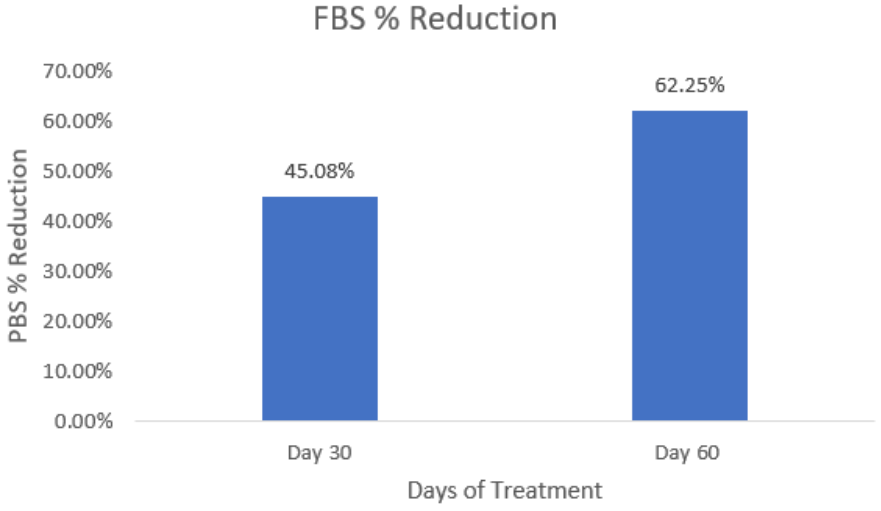

Figure 1: Effect of advance diabetic support product on Fasting Glucose Levels (FBG).

Table 2: Effect of advance diabetic support product on Fasting Glucose Levels (FBG).

Duration	Fasting Glucose Levels - mg/dl (Mean±SD)	% Reduction
	TEST	
Baseline	372.65±93.75	-
Day 30	204.65±39.60	45.08%
Day 60	140.69±28.20	62.25%
P Value	<0.001	

Data analysed by one-way Anova. Significant at p<0.05.

FBS was evaluated in 26 cases who were treated with advance diabetic support products for a period of 60 days. The initial mean FBS significantly reduced from 430.38±103.56 mg/dl to 299.08±34.01 after 30 days and to 161.96±19.04 after 60 days where p < 0.001 was found to be significant. In inference to the evaluation of the above parameters After 60 days, it has been found that the FBS levels were reduced by 30.51% after 30 days and 62.37% after 60 days (Table 3, Figure 2).

Table 3: Effect of advance diabetic support product on Post Prandial Glucose Levels (PPBS).

Duration	Post Prandial Glucose Levels (Mean±SD) - mg/dl	% Reduction
	TEST	
Baseline	430.38±103.56	-
Day 30	299.08±34.01	30.51%
Day 60	161.96±19.04	62.37%
P Value	<0.001	

Data analysed by one-way Anova. Significant at p<0.05.

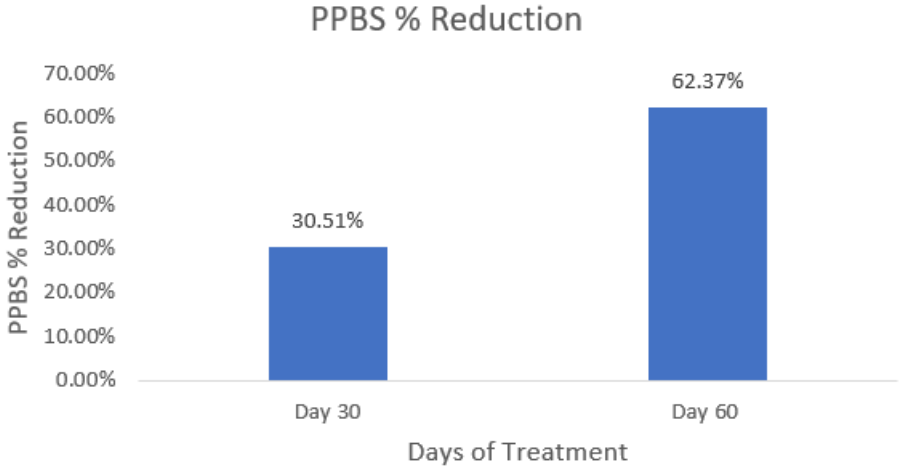

Figure 2: Effect of advance diabetic support product on Post Prandial Glucose Levels (PPBS).

HBA1c was evaluated in 26 cases who were treated with advance diabetic support products for a period of 60 days. The initial mean value for HBA1c significantly reduced from 11.75±2.22 to 7.10±0.74 after 60 days where p < 0.001 was found to be significant. In inference to the evaluation of the above parameters After 60 days, it has been found that the HBA1c levels were reduced by 39.57% after 60 days (Table 4, Figure 3).

Table 4: Effect of advance diabetic support product on HBA1c Levels.

Duration	HBA1c Levels (Mean±SD) - mmol/mol	% Reduction
	TEST	
Baseline	11.75±2.22	-
Day 60	7.10±0.74	39.57%
P Value	<0.001	

Data analysed by student t test. Significant at p<0.05.

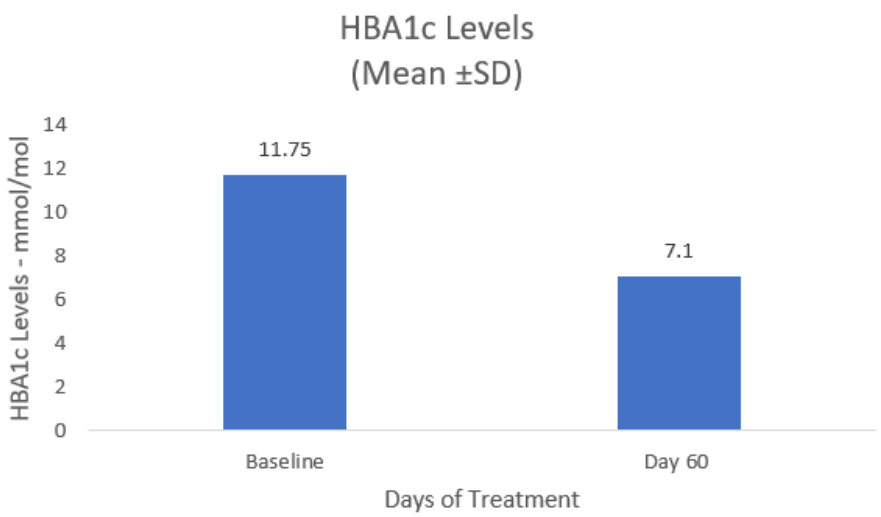

Figure 3: Effect of advance diabetic support product on HBA1c Levels.

C- Peptide Levels was evaluated in 26 cases who were treated with advance diabetic support products for a period of 60 days. The initial mean value for C- Peptide Levels significantly increased from 1.80±1.17 nmol/L to 2.28±1.08 nmol/L after 60 days where $p < 0.003$ was found to be significant. In inference to the evaluation of the above parameters after 60 days, it has been found that the C- Peptide Levels were increased by 26.67% after 60 days (Table 5, Figure 4).

Table 5: Effect of advance diabetic support product on C-Peptide Levels.

Duration	**C- Peptide Levels (Mean±SD) - mmol/mol**	**% Reduction**
	TEST	
Baseline	1.80±1.17	-
Day 60	2.28±1.08	-26.67
P Value	0.003	

Data analysed by student t test. Significant at $p<0.05$.

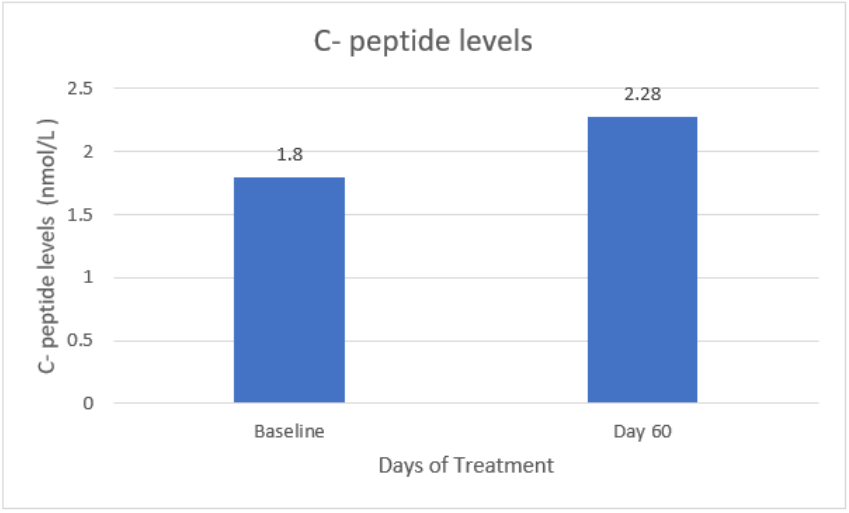

Figure 4: Effect of advance diabetic support product on C- Peptide Levels.

Insulin injection dose were evaluated in 26 cases who were treated with advance diabetic support products for a period of 60 days. The initial mean value for insulin levels significantly reduced from 22.96±13.86 to 2.62±4.73 after 60 days where $p < 0.001$ was found to be significant. In inference to the evaluation of the above parameters After 60 days, it has been found that the insulin dose taken by patient's were reduced by 88.57% after 60 days.(Table 6, Figure 5).

Table 6: Effect of advance diabetic support product on insulin levels.

Duration	**Insulin Levels (Mean±SD) - mIU/L**	**% Reduction**
	TEST	
Baseline	22.96±13.86	-
Day 60	2.62±4.73	88.57%
P Value	<0.001	

Data analysed by student t-test. Significant at p<0.05.

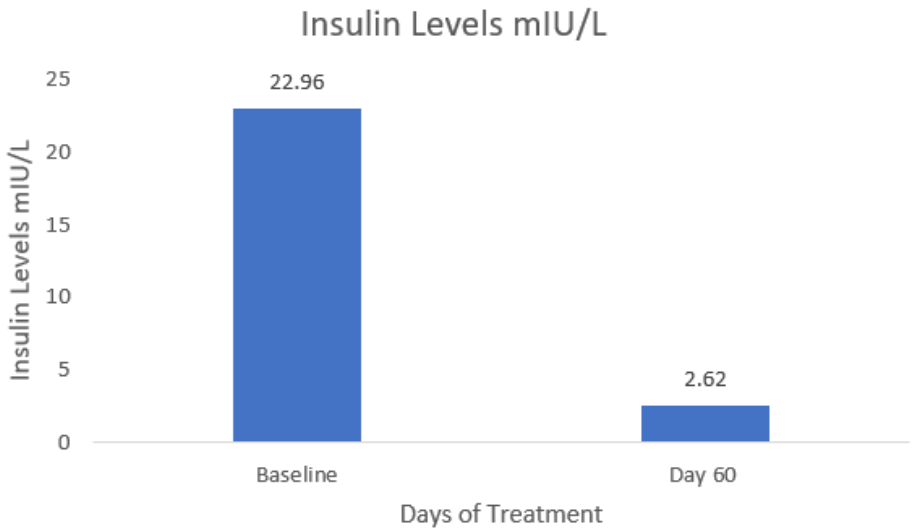

Figure 5: Effect of advance diabetic support product on insulin dose levels.

Discussion

As previously discussed, Diabetes mellitus is a most common endocrine disorder, affecting millions of people worldwide. It is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. Hence Optimal treatment of insulin-dependent diabetes mellitus requires a comprehensive and concerted approach. Most people who have trouble controlling their blood sugar with oral medications will need to start taking insulin or another injectable medication as their levels cannot be appropriately managed with oral medication. In some cases, insulin (or another injectable medication) is recommended first, as initial treatment. Patients with insulin-dependent diabetes often become less responsive to insulin over time, and combination therapy may be needed for adequate control of blood glucose levels before insulin therapy becomes necessary. Near normal and improved glycemic control are associated with a lower risk of microvascular complications in patients with insulin-dependent diabetes. However, the main disadvantage of present insulin therapy is the increased risk of hypoglycemia and loss of efficacy, dizziness, trouble speaking, fatigue, confusion, pale skin, sweating, twitching muscles, seizures, and loss of consciousness. As a result, attention is given to the development of herbal formulations that will enhance sustained glycemic control and reduce insulin resistance and hypoglycemia in individuals with diabetes mellitus [5-7].

The findings in this study demonstrate the potential of the product as an alternative safe medication in the treatment of insulin-dependent diabetes. To summarize the results, the initial mean FBS significantly reduced from 372.65±93.75 mg/dl to 204.65±39.60 after 30 days and to 140.69±28.20 after 60 days where $p < 0.001$ was found to be significant. The initial mean PPBS significantly reduced from 430.38±103.56 mg/dl to 299.08±34.01 after 30 days and to 161.96±19.04 after 60 days where $p < 0.001$ was found to be significant. The initial mean value for HBA1c significantly reduced from 11.75±2.22 to 7.10±0.74 after 60 days where $p < 0.001$ was found to be significant, the initial mean value for C-Peptide levels significantly increased from 1.80 nmol/L to 2.28 nmol/L after 60 days where $p < 0.005$ was found to be significant. The initial mean value for insulin dose levels significantly reduced from 22.96±13.86 to 2.62±4.73 after 60 days where $p < 0.001$ was found to be significant. The above findings showed that the product is acting as an antidiabetic drug in the management of insulin dependent diabetes. It was also evident that this product possesses a similar therapeutic response as compared to insulin since advance diabetic support products also appeared to have a better effect on the improvement in insulin levels.

Indeed, for the development of advance diabetic support products, Gplife Healthcare P Ltd. used both standardized and potential extracts of *Gymnema sylvestre*, *Tinospora cordifolia*, *Trigonella foenum-graecum*, *Enicostemma littorale*, *Eugenia jambolana*, *Withania somnifera*, etc. Beneficial effects of advance diabetic support products in insulin dependent diabetes are due to the synergistic action of its ingredients and technology, which are well-documented and evident that it reduced the doses of insulin and OHAs [5]. Advance diabetes support products alone and in combination with OHA(s) can be effectively used in the management of diabetes mellitus. No adverse events were reported during the course of the study to any of the cases. The said product alone and in combination with OHA(s) helps in the prevention of diabetic

complications. Future studies in a larger regiment may help in the placement of the advance diabetes support products as a substitute to the standard treatment for insulin-dependent diabetes.

Conclusion

Gplife Healthcare advance diabetic support product showed very promising results with respect to glycemic parameters like fasting glucose, PPBS, insulin dose requirement, and C-peptide in patients with insulin-dependent diabetes. It is evident that the advance diabetes support product further helps to reduce the insulin and OHA doses for the management of insulin-dependent diabetes. It is suggested that the advance diabetes support product should be further extensively used as a monotherapy or adjunctive therapy for the regulation or management or control of insulin-dependent diabetes.

Data Availability

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

Conflicts of Interest

Dr. Shridhar Pandya, Dr. Chetan Savaliya, Dr. Kamlesh Thummar are directors in GPlife Healthcare Pvt. Ltd. Other authors declare that they don't have competing interests. Authors received funding from GPlife Healthcare Pvt. Ltd.

Funding

The study medication was provided by Gplife Healthcare Pvt Ltd., Surat along with the expenses for laboratory testing for study participants.

Acknowledgment

The authors would like to acknowledge the research team and the back-office team involved in the research work. We would like to acknowledge the support provided by back office, Gplife Healthcare Pvt. Ltd.

REFERENCES

1. DiMeglio LA, Evans-Molina C, Oram RA (2018) Type 1 diabetes. *Lancet* 391: 2449-2462. [Crossref]
2. Gale EAM (2002) The rise of childhood type 1 diabetes in the 20th century. *Diabetes* 51: 3353-3361. [Crossref]
3. Mobasseri M, Shirmohammadi M, Amiri T, Vahed N, Fard HH et al. (2020) Prevalence and incidence of type 1 diabetes in the world: a systematic review and meta-analysis. *Health Promot Perspect* 10: 98-115. [Crossref]
4. Salehi B, Ata A, Kumar NVA, Sharopov F, Ramírez-Alarcón K et al. (2019) Antidiabetic Potential of Medicinal Plants and Their Active Components. *Biomolecules* 9: 551. [Crossref]
5. Kundu PK, Chatterjee PS (2010) Meta-analysis of Diabecon Tablets: efficacy and safety Outcomes from 15 Clinical Trials in Diabetes Mellitus. *Indian J Clin Pract* 20: 653.
6. Florence JA, Yeager BF (1999) Treatment of type 2 diabetes mellitus. *Am Family Physician* 59: 2835-2850. [Crossref]
7. UK Prospective Diabetes Study (UKPDS) Group (1998) Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet* 352: P837-P853. [Crossref]