

Impact of Gplife advanced diabetic support tablet in diabetes mellitus treatment in a single-arm, prospective clinical trial

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ABSTRACT

Aim: This study aims to study the effectiveness of Gplife advanced diabetic support tablet as adjuvant therapy in patients with diabetes mellitus. **Materials and Methods:** The study was conducted as a single-arm, a prospective clinical trial at two sites, fasting plasma glucose (FPG), post-meal glucose (PMG), and glycated hemoglobin (HbA1c) were evaluated till 60 days in 30 diabetic subjects. **Results:** Initially, the levels of mean FPG were 344.70 ± 80.12 mg/dL, for day 60, it was reduced to 155.80 ± 31.44 mg/dL. At the baseline visit, the mean PMG level was 436.22 ± 102.73 mg/dL, for day 60, it was reduced to 204.87 ± 27.74 mg/dL and HbA1C % was 10.35 ± 1.95 , for day 60, it was reduced to 7.34 ± 0.97 mg/dL. There was a reduction in clinical symptoms of diabetes. Treatment caused a reduction in doses of insulin and oral hypoglycemic agents in the test population at 60 days. **Conclusion:** It can be concluded that adjuvant therapy of Gplife advanced diabetic support tablet is significantly effective in reducing levels of FPG and PMG from baseline to 60 days. The change was not significant in any of the safety parameters suggesting safety. It showed a reduction in existing doses of conventional treatment hence can be used as an adjuvant in diabetes.

Keywords: Clinical trial, C-peptide, diabetes, glycated hemoglobin, Gplife advanced diabetic support tablet, Homeostasis model assessment

Introduction

Diabetes mellitus (DM) is a fast gaining prominence as a probable epidemic with more than 62 million patients in India. The 31.7 million capped the world with the uppermost number of patients with DM in India, followed by 20.8 million in the case of China while the 17.7 million for the U.S. in the 2nd and 3rd place correspondingly. Commonly stated that the occurrence of DM in India is forecast to twice internationally from 171 in 2000 to 366 million in 2030 with an extreme rise. Indeed, in India by 2030, DM might trouble up to 79.4 million

people, while other countries will also get considerable upsurges in those affected. The etiology of DM is multifactorial and encompasses genetic factors combined with ecological impacts including fitness associated with changing lifestyle standards. DM, a long-lasting ailment that raises once the pancreas stops producing adequate insulin or the body cannot proficiently utilize the insulin available. The significance of uncontrolled DM consequences in hyperglycemia or raised blood sugar which after a certain time leads to serious harm to many body organs, predominantly the nerves and blood vessels.^[1,2]

The widespread study described for DM exposed that DM is classified into two different types grounded on its etiology and clinical management. Type 1 DM: Severe autoimmune DM characterized by insulin deficiency and the presence of autoantibodies. Type 2 DM: Severe insulin-deficient DM is categorized by younger age, insulin insufficiency, and deprived metabolic regulation.^[3-5]

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Prolonged overabundance is the main pathogenic incident that initiates the progression of type 2 DM in heritably and epigenetically vulnerable person.^[6-8] The development of DM is barely perceived in most determinedly enormous and overweight people or it may develop late over a time in life. Indeed, obese individuals remain resistant to type II DM and steadily partition added calories to subcutaneous adipose tissue instead of to the skeletal muscle, islet β -cells, heart, and liver. The mechanisms behind such reactions are due to active islet β -cell compensation; management of proximate normal blood nutrient levels; nominal insulin resistance development; augmented expansion of subcutaneous adipose tissue comparable to visceral adipose tissue; as well as partial proliferation in liver fat. Thus, the vital organs of the body evade damage induced through nutrients.^[9-20] On the other hand, failure to regulate the desired level of glycated hemoglobin (HbA1c) has been considered as a major contributor to the worsening character of DM.^[18,19] As a result, for better glycemic control, progressive insulin administration has been advised.^[20,21]

It has been shown that initiating insulin treatment in individuals using metformin alone aids in achieving glycemic control and a decrease in HbA1c.^[18] Nevertheless, supplementary risks including hypoglycemia and weight gained require to be measured while maintenance of DM by consuming insulin.^[19] In addition, the unapproachability, expense of insulin by the oral administration, insulin resistance, and medicine compliance are the foremost hindrances in insulin treatment for treating DM. Adjuvant treatment with oral hypoglycemic agent (OHA) may result in long-term glycemic control and a decrease in the recurrence in which OHA is used.^[21,22] Consequently, awareness of adjuvant therapies to OHA is growing amongst patients suffering from DM. Herbal medicine may be considered an effective and safe treatment replacement for meeting an unmet therapeutic requirement as an “adjuvant therapy” to OHA in the long-term management of diabetes. Henceforth, Gplife health care has developed Gplife advanced diabetic support tablet, a nutraceuticals product; almost all ingredients of the product were reported to help to normalize elevated fasting plasma glucose (FPG), post-meal glucose (PMG), and HbA1c parameters.^[23-42] Therefore, a single-arm, open-label, prospective clinical trial for assessing the safety as well as the efficacy of “Gplife advanced diabetic support tablet” as adjuvant treatment in DM patients was designed to explore this hypothesis.

Materials and Methods

Study design and protocol

The study was a prospective, open-label clinical trial. The research was authorized by the ethics committee of Dr. D. Y. Patil College of Ayurveda and Research Center, Pune, and Lokmanya Medical Research Centre, Pune. The study’s registration number is CTRI/2019/05/019355 with the Clinical Trials Registry of India. Informed consent was obtained as patient privacy rights must always be observed. A study was designed as a single-arm, open-label, prospective clinical trial for identifying the effectiveness and safety dose of tablet as adjuvant treatment in DM patients. The dosage of the product was two tablets twice a day at least 30–45 min before a meal with water for 60 days. The objectives were to evaluate variations from

baseline in FPG to 60 days, to evaluate variations from baseline in 2 h, PMG to 60 days, to evaluate variations from baseline in HbA1c at 60 days, HbA1c is measured as a percent, to evaluate variations from baseline in fasting insulin to 60 days, and to evaluate variations from baseline in 2 h post-meal insulin 60 days. The study had a screening and enrollment phase, which was as follows: Screening visit (–14 days), baseline visit (0 day), 1st visit (30th day), and 2nd visit (60th day) during which patients continued background medication consisting of OHA and insulin, and a phase of treatment in which patients were given the experimental medication twice daily as adjuvant therapy of DM.

Toxicity study

On the premises of the animal house of Dr. D. Y. Patil Institute of Pharmaceutical Science and Research, Pimpri, Pune-based researchers conducted a 90-day oral toxicity study on Wistar rats with repeated dosage. Eighteen compliances with the test guidelines positioned in OECD-408 adapted on September 21, 1998. The technical protocol’s goals were met, and no unfavorable events took place that compromised the study’s integrity or quality.

Product details

Product details are mentioned in Table 1.

Inclusion and exclusion criteria

Inclusion criteria were as follows: (1) Patients between the ages of 18 and 60 (inclusive), both sexes, (2) patients administrating OHA and/or insulin as on-going medication for DM, (3) HbA1c >6.5% and <14.5% (both inclusive), (4) subjects having a body mass index of 20–35 kg/m², and (5) FPG >130 mg/dL and <450 mg/dL (both inclusive). Exclusion criteria were as follows: (1) Patients with simultaneous severe hepatic dysfunction (described as AST or ALT >3 times of the higher normal limit) or renal dysfunction (described as serum creatinine >1.4 mg/dL), uncontrolled pulmonary dysfunction (patients with COPD and asthmatic), or other concurrent acute illness, (2) women who are pregnant or lactating, (3) drug abusers/alcoholics/smokers, (4) patients who have been diagnosed with cancer, (5) patients with serious systemic illnesses that need long-term medication therapy (psycho-neuro-endocrinal diseases and rheumatoid arthritis), (6) involvement in any other study requiring drug therapy, (7) renal dysfunction as evidenced by raised serum creatinine from renal function test, (8) uncontrolled hypertension (diastolic blood pressure >110 mmHg or systolic blood pressure >180 mmHg), (9) unwillingness to undergo therapy, (10) known hypersensitivity to any of the ingredients of study tablets, and (11) other problems that, in the investigators’ judgment, render the patient

Table 1: Product contains a proprietary blend of extracts

<i>Gymnema Sylvestre</i>	<i>Boerhavia diffusa</i>	<i>Momordica charantia</i>
<i>Withania coagulans</i>	<i>Bacopa monnieri</i>	<i>Sennoside-A</i>
<i>Cinnamomum verum</i>	<i>Panax Ginseng</i>	<i>Cynara scolymus</i>
<i>Enicostemma littorale</i>	<i>Banaba ext</i>	<i>Phyllanthus emblica</i>
<i>Trigonella Foenum-Graecum</i>	<i>Curcuma longa</i>	<i>Salacia reticulata,</i>
<i>Tinospora cordifolia</i>	<i>Andrographis paniculata</i>	<i>Withania somnifera</i>
		<i>Eugenia jambolana</i>

unfit for participation or potentially obstruct the patient's involvement in the completion of the trial.

Withdrawal criteria

For the following reasons, subjects are removed from the trial (and hence from any future clinical trial or research process) such as (1) on their demand, that is, withdrawal of consent at any time for personal reasons. (2) If the examiner believes that continuing the trial would be injurious to the health of the subject. (3) Protocol deviations that could invalidate interpretation of the results (i.e., intake of not permitted concomitant treatments, etc.)

Compliance with ethics

All of the patients gave their signed, informed permission. The research procedure (protocol no. MHC/CT/19-20/004) was authorized by institutional ethics committees of all centers. The research was carried out following the Declaration of Helsinki and the international conference on harmonization's good clinical practice guidelines.

Compliance with treatment

Subjects were instructed not to skip or lower their medicine doses on their own. On the relevant page of the case report form, lapses identified during visits are reported. The researchers measured the amount of unused medicine in the patient's pillbox to assess treatment compliance. The patient was deemed non-compliant and was removed from the experiment if he or she did not ingest more than 20% of the entire prescription drug every 2 weeks.

Statistics

The data were analyzed by a consultant biostatistician with the statistical software SPSS 10.0. The mean or median \pm SD or SE, or the mean with range, was used to describe quantitative quantities. Counts and percentages were used to illustrate qualitative characteristics. One-way ANOVA was used to examine the data followed by the Bonferroni test.

Results

A total of 37 people were tested for this investigation. Out of 37 individuals, five did not fulfill inclusion criteria as identified to be out of criteria for HbA1C with other complications and hence were not recruited in the study. There were two dropouts in this trial. On the completion of the trial, 30 participants were declared evaluable cases. Seventeen of the 30 confirmed participants were men, with a mean age of 49.53 ± 10.31 years. Thirteen of the 30 confirmed individuals were women, with a mean age of 48.20 ± 10.47 years. The difference between male and female groups was statistically negligible when sex and age were compared. The mean body mass index in males was found to be 24.61 ± 1.95 and 26.5 ± 2.75 kg/m² which were according to the inclusion criteria and were found non-significant between males and females. Table 2 summarizes the information.

Toxicity study

The test product had no negative effects on the general health, growth, neurological, behavioral, clinical chemistry, hematological, and urinalysis parameters, organ weights, or gross of the organs/tissues of mice treated at a dosage level of 2000 mg/kg body weight, according to the results of the study.

Changes in vital parameters

There was no substantial variation in any of the physiological parameters (body temperature, pulse rate, and respiration rate, body weight, and diastolic and systolic blood pressure) from baseline to completion of treatment in either group.

Efficacy assessments

FPG

The mean FPG level was 344.70 ± 80.12 mg/dL at the baseline visit, 199.51 ± 30.89 mg/dL on the 30th day, and 155.80 ± 31.44 mg/dL on the completion of the trial, that is, on the 60th day. On the 30th day, the mean FPG was seen to be significant with $P = 0.001$ whereas considerable with $P = 0.001$ on the 60th day, that is, on the completion of the trial. Table 3 presents the values.

PMG (post-meal plasma glucose)

The mean PMG level is 436.22 ± 102.73 mg/dL at the baseline visit, on the 30th day, it is decreased to the value of 259.35 ± 45.48 mg/dL and was reduced up to 204.87 ± 27.74 mg/dL on the completion of the trial, that is, on the 60th day. The mean PMG is shown to be significant on day 30 with $P = 0.0001$ and significant on day 60 with $P = 0.0001$ on the completion of the trial. Table 4 summarizes the results.

Table 2: Demographic data

Parameters	Males	Females
Cases number	17	13
Mean age (yrs.)	49.53 ± 10.31	48.20 ± 10.47
Mean BMI kg/m ²	24.61 ± 1.95	26.5 ± 2.75

Table 3: Mean FPG values

Duration	Mean FPG (mg/dl)
Baseline	344.70 ± 80.12
30 th day	$199.51 \pm 30.89^{***}$
60 th day	$155.80 \pm 31.44^{***}$

The value represents mean \pm SD analyzed by ANOVA followed by multiple comparisons, Bonferroni test is done to compare the values between baseline, 30th day, and completion of the trial. $P < 0.001$ significant

Table 4: Mean values of PMG

Duration	Mean PMG (mg/dl)
Baseline	436.22 ± 102.73
Day 30	$259.35 \pm 45.48^{****}$
Day 60	$204.87 \pm 27.74^{****}$

The value represents mean \pm SD analyzed by ANOVA followed by multiple comparisons, Bonferroni test is done to compare the values between baseline, 30th day, and on completion of trial $P < 0.0001$ significant

Percent HbA1C

The mean HbA1C percent level was 10.35 ± 1.95 at the baseline visit, however, it was decreased to 7.34 ± 0.97 mg/dL on the 60th day. On the 60th day, that is, on completion of the trial, the mean HbA1C percent was shown to be statistically important with $P = 0.001$. Table 5 presents the results.

C-Peptide (n = 30)

At the baseline visit, the mean C-peptide ng/mL level was 2.28 ± 0.67 , on the 60th day, the value was 2.47 ± 0.48 mg/dl. The mean C-peptide ng/mL is found to considerably decrease with $P > 0.05$ on the 60th day, that is, on trial completion day. Table 6 presents the values.

Fasting and post-meal insulin

The treatment with the product after 60 days of therapy showed significant changes in serum insulin. Fasting basal insulin, which was 7.88 ± 6.05 μ U/mL, significantly increased with test drug treatment to 13.29 ± 7.13 . Post-meal insulin, which was 32.64 ± 14.42 μ g, significantly increased with test drug treatment to 63.10 ± 15.36 . The statistical analysis using the analysis of variance, the serum insulin levels increased considerably, according to the Bonferroni test ($***P < 0.001$). Table 7 summarizes the information.

Subjective assessment of clinical symptoms

Polyuria assessment: Number of respondents with a grade-based assessment category* (Represented as several subjects and percent population) symptom evaluation (*Grades: 0=None, 1=Mild, 2=Moderate, and 3=Severe). Table 8 summarizes the results.

Homeostasis model assessment (HOMA) B and HOMA insulin resistance (HOMA-IR) score evaluation

The HOMA-cell function (HOMA-B) score increased after administration of “Gplife advanced diabetic support tablet” ($0.0121 \pm 0.01-0.05 \pm 0.024$) baseline to day 60 and there was a drop in HOMA-IR (“Homeostasis model assessment insulin resistance”) score ($6.71 \pm 6.01-5.46 \pm 2.45$) baseline to day 60 in DM patients.

Table 5: Mean percent of HbA1C

Duration	Mean HbA1C %
Baseline	10.35 ± 1.95
60 th Day	$7.34 \pm 0.97***$

The value represents mean \pm SD analyzed by ANOVA followed by multiple comparisons, Bonferroni test is done to measure the values between baseline, 30th day, and on completion of trial $P < 0.001$ significant

Table 6: Mean C-peptide

Duration	Mean C-peptide (ng/ml)
Baseline	2.28 ± 0.67
Day 60	2.47 ± 0.48

The value represents mean \pm SD analyzed by ANOVA followed by multiple comparisons, Bonferroni test is done to measure the values between baseline, 30th day, and on completion of trial $P > 0.05$ non-significant

Safety analysis

All the parameters of hemogram, liver profile, lipid profile, and renal profile were within normal limits at baseline visit. There were no large differences in any of the hemogram, liver profile, or renal profile measures when the therapy was completed. This suggests the safety of test drugs on biochemical parameters. There was a slight reduction in elevated levels of cholesterol in some patients suggestive of hypolipidemic activity of test drug. The details are presented in Table 6.

The investigator assesses the global assessment for overall progress

According to investigator evaluation, 26 (86.7%) participants in test group $n = 30$ exhibited extreme overall progress and 4 (13.3%) patients indicated very much overall progress after the trial.

Global assessment for overall improvement by subject

According to subject evaluation, 21 (70.00%) of test group $n = 30$ respondents revealed very much overall progress and 8 (26.66%) of test group $n = 30$ respondents exhibited considerable overall progress on completion of the trial. According to subject evaluation, 1 (3.33%) respondents indicated modest overall progress after the trial. Table 9 summarizes the results.

Tolerability of study drug by physician

Physicians indicated good tolerability of study medications for 25 (83.33%) of the test group $n = 30$, and physician indicated

Table 7: Fasting and post-meal serum insulin

Parameter	Baseline	Day 60
Fasting insulin (μ U/ml)	7.88 ± 6.05	$13.29 \pm 4.53***$
Post-meal insulin (μ U/ml)	32.64 ± 14.42	$63.10 \pm 15.36***$

The value represents mean \pm SD analyzed by ANOVA followed by multiple comparisons, Bonferroni test is done to measure the values between baseline, 30th day, and completion of trial $P < 0.001$ significant

Table 8: Assessment of clinical symptoms

Clinical symptoms	Score	Baseline (%)	Day 30 (%)	Day 60 (%)
Polyuria	0	0	0	8 (26.67)
	1	0	12 (40)	18 (60)
	2	23 (76.67)	15 (50)	4 (13.33)
	3	7 (23.33)	3 (10)	0
Polydipsia	0	0	0	9 (30)
	1	0	12 (40.00)	19 (63.33)
	2	19 (63.33)	10 (33.33)	2 (6.66)
	3	11 (36.66)	8 (26.66)	0
Polyphagia	0	0	0	6 (20)
	1	0	0	22 (73.33)
	2	9 (30)	21 (70)	2 (6.66)
	3	21 (70)	9 (30)	0

The value represents subject frequency and percentile for each symptom at every time point

Table 9: Assessment of laboratory investigation

Laboratory investigation	Baseline	Day 60
Total leukocyte count	6.39±02.03	6.55±01.52
Neutrophils	57.40±09.21	55.56±09.16
Lymphocytes	35.00±08.07	35.62±06.42
Monocytes	3.41±01.38	3.89±01.48
Eosinophils	3.25±03.41	4.38±02.32
Total RBC count	4.90±00.69	5.04±00.35
Basophils	0.18±00.20	0.35±00.21
Hemoglobin	14.02±02.53	14.59±01.57
Hematocrit	43.12±06.29	45.04±04.73
Platelets	226.57±75.63	254.62±52.08
Erythrocyte sedimentation rate	12.81±07.79	10.54±01.51
Total cholesterol	180.88±36.25	155.26±28.74
Cholesterol HDL direct	43.98±10.08	47.92±08.75
Triglycerides	127.66±61.65	123.0±47.56
LDL cholesterol	115.21±29.09	105.08±23.89
VLDL cholesterol	26.67±12.09	25.99±07.57
TC/HDL ratio	04.38±01.90	3.94±00.84
LDL/HDL ratio	2.95±01.15	2.74±00.61
Blood urea nitrogen	13.19±04.40	12.89±03.91
Serum uric acid	5.16±01.14	5.31±01.34
Serum calcium	9.12±00.94	9.08±00.55
Serum creatinine	0.86±00.21	0.81±00.11
Bilirubin total	0.64±0.28	0.68±0.28
Bilirubin direct	0.24±0.19	0.19±0.08
Bilirubin indirect	1.23±4.30	0.50±0.23
SGOT	28.44±8.03	26.75±8.11
SGPT	30.14±22.09	23.18±11.01
Alkaline phosphatase	101.92±32.98	109.71±38.45
GGTP	26.53±17.90	21.81±11.85
Total proteins	7.38±0.45	7.56±0.42
Serum albumin	4.23±0.31	4.39±0.54

Each value signifies mean±SD. The values between baseline and on completion of the trial are compared with paired "t-test." P>0.05 non-significant

tolerability of study drugs for 5 (16.66%) on completion of the trial, according to physician evaluation.

Tolerability of study drug by respondents

Respondents in the test group n = 30 confirmed great tolerability of study medicines 20 (66.66%) and 10 (33.33%) indicated tolerability of study drugs on completion of the trial, according to physician evaluation. Table 10 summarizes the information.

Profile of adverse events

According to the findings, 30% of the patients (nine individuals) had negative incidents including vomiting, headache, fever, hyperacidity, as well as body pain, with 35 negative incidents reported out of a total of nine patients. These side effects were most likely unrelated to the

Table 10: Tolerability of study drugs evaluated by respondents

Assessment	Test group (n=30)	
	No.	%
Excellent	20	66.66
Good	10	33.33
Fair	-	-
Poor	-	-

study drug. The test medication did not need to be discontinued. These negative occurrences were of mild-to-moderate severity. Following the administration of rescue medicine, these adverse effects were entirely resolved.

Discussion

DM is a metabolic condition that disrupts a variety of human systems, necessitating the use of medicinal herbs and nutraceuticals with multifunctional and synergistic qualities for DM therapy. All ingredients used in the Gplife advanced diabetic support tablet are utilized; the conventional medical practitioners have been practicing for centuries past and are scientifically proven to be effective in the management of DM. Since it is a multiherb nutraceuticals product, it has a manifold and comprehensive action on several facets of DM. It was observed that adjuvant therapy with "Gplife advanced diabetic support tablet" is significantly helpful in mitigating FPG levels from baseline till day 30 as well as 60 days. Fasting hyperglycemia is a spectacle that has been perceived in fundamentally all persons with DM and may be due to deregulation of the regular circadian hormonal configurations resulting in increased hepatic glucose production. Fasting hyperglycemia commonly can be accredited to insufficient or incorrect hepatic insulinization, the potential of Gplife advanced diabetic support tablet in reducing FPG is evidence of better utilization of glucose to get transformed to energy and improvement in insulin resistance so the insulinization of hepatic tissue happens to reduce the hyperglycemia in fasting. This effect was clinically evident by patient-reported less fatigue than baseline to day 60.

It was also noted that adjuvant therapy with "Gplife advanced diabetic support tablet" was significantly helpful in reducing levels of PMG from baseline till day 30 as well as day 60, that is, ends of study. There can be a strong connection of probable alpha-glycosidase inhibitory action of Gplife advanced diabetic support tablet in Type 2 DM which slows down the digestion of carbohydrates in the small intestine and consequently can help to decrease afterward meal blood sugar levels.

As an adjuvant with this tablet was provocatively beneficial in lowering % HbA1c levels from baseline to 60 days, the study's conclusion. HbA1c is a long-term glycemic index that is determined by the lifespan of red blood cells, which differs from person to person. However, for HbA1c alterations to attain their 50% highest capacity, a 1-month period is generally sufficient, and after 2 months, 80% of HbA1c changes are apparent. As a result, a trial lasting at least 2 months would encompass the trial respondents' different RBC life spans. As phytochemicals present in the product work great as an antioxidant,^[43]

the length of time that patients have been afflicted is an important element in determining the success of these drugs.

HbA1c levels that are lower have been linked to less and later macrovascular and microvascular problems. The objective of DM treatment must be to keep HbA1c as low as feasible while avoiding hyperglycemia or hypoglycemia that is chronic or severe. With the treatment of Gplife advanced diabetic support tablet, a significant reduction in HbA1C is attained. Gplife advanced diabetic support tablet can protect arresting progression of the pathophysiology of diabetic complications by making good glycemic support over a long period. The probable mechanism could be improving insulin resistance in Type 2 DM.

As an adjuvant medication, Gplife advanced diabetic support tablet was shown to be considerably helpful in boosting C-peptide levels from baseline to day 60, the study's conclusion. C-peptide is cosecreted by the pancreas with insulin and might be utilized to diagnose diabetes. After therapy with this tablet, C-peptide levels in patients with DM improved when compared to C-peptide levels in the overall respondents. This action suggests selective indication of product in improving endogenous insulin secretion.^[44]

In DM patients, there was an increase in the HOMA-B score and a substantial drop in the HOMA-IR score after therapy with "Gplife advanced diabetic support tablet." There is a considerable reduction in HOMA-IR score in DM suggestive of increasing insulin sensitivity and reducing insulin resistance through improved insulin receptor signaling cascade.^[45-49]

The HOMA model is the best widely used surrogate model for assessing insulin resistance as well as beta-cell activity in DM persons. Insulin resistance is categorized by the decrease in insulin-mediated glucose disposal in insulin-sensitive tissue and increased hepatic glucose production whereas beta-cell dysfunction occurs when beta-cells were incapable to recompense for the insulin resistance. In the case of DM patients, there is an increase in the HOMA-B suggestive of possible regeneration of pancreatic cells in the pancreas. The quality of life of the patient is greatly improved with patients feeling better at their energy levels as well as toward reduced stress and fatigue is also reported.

Conclusion

The present clinical study concluded that "Gplife advanced diabetic support tablet" can act as an adjuvant to OHA and insulin, lowering the levels of fasting and post-meal blood glucose, as well as HbA1c. The use of such tablets as an adjuvant treatment could be explained as it caused a reduction in existing doses of insulin and OHA. The above-explained potential actions and probable mechanism were the outcomes of rational selection of herbal blends with their specifications used as an extract and toward the purity and quality maintained from a selection of ingredients up to manufacturing and packing of the finished product. Thus "Gplife advanced diabetic support tablet" was a safe and effective alternative as an adjuvant in DM.

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