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Research Article

Efficacy Evaluation of Dabur Dia Control Juice, an Ayurvedic Formulation as an Adjuvant in NIDDM

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Abstract

Global burden of Type 2 Diabetes Mellitus (T2DM) has reached alarming proportions, with prevalence surging from 200 million to over 830 million over three decades. India bears a disproportionate share of this crisis, with approximately 77 million individuals living with T2DM and an additional 25 million in the prediabetic range (HbA1c: 5.7–6.4%), collectively imposing significant threats to workforce productivity and national healthcare expenditure. While anti-hyperglycemic (AHG) agents combined with lifestyle modifications remain the cornerstone of T2DM management, long-term dependence on escalating pharmacological doses and the risk of chronic complications have intensified interest in adjunctive therapeutic strategies. In this context, the present study evaluated the adjunctive efficacy and safety of a proprietary ayurvedic formulation (sugar-free juice), DRDC/2025/010, in individuals with T2DM already on standard AHG therapy. This ethically approved, CTRI-registered clinical study enrolled 30 T2DM participants screened against predefined inclusion and exclusion criteria. Participants received 30 mL of DRDC/2025/010 diluted in 250 mL of drinking water, consumed twice daily for 90 days, alongside their existing AHG regimen, dietary guidance, and exercise routine. Efficacy endpoints included fasting blood sugar (FBS), random blood sugar (RBS), glycated hemoglobin (HbA1c), body mass index (BMI), and quality of life (QoL). Safety was monitored through biochemical parameters, vital signs, and adverse event (AE) surveillance throughout the study period. DRDC/2025/010 demonstrated statistically significant reductions in FBS at Day 60 ($p < 0.05$) and Day 90 ($p < 0.0001$), and in RBS at Day 60 ($p < 0.05$) and Day 90 ($p < 0.0001$), relative to baseline. A significant ($P<0.0001$) decrease in BMI levels of the diabetic participants was observed at 90th day (20.7±8.56 kg/m^2) compared to baseline (25.1±3.00 kg/m^2). Mean HbA1c levels also declined significantly at Day 90 ($p = 0.024$), accompanied by meaningful improvements in QoL. Notably, no adverse events were recorded, and biochemical parameters and vital signs remained stable throughout the intervention, affirming a favorable safety profile. These findings suggest that DRDC/2025/010 holds promising potential as a safe and effective adjunct to standard T2DM pharmacotherapy, contributing to improved glycemic control and patient well-being.

Keywords

Type 2 Diabetes, Adjunctive Therapy, HbA1C, Anti-hyperglycemic (AHGs) Agents

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1. Introduction

Glucose serves as fuel for metabolism and is the primary source for energy production, due to it's ability of rapid conversion to ATP. Blood glucose levels are tightly regulated in healthy individuals through the coordinated action of insulin, secreted by pancreas, glucose deposited in the liver as glycogen, which in turn will be released into blood to meet the required concentrations. When insulin production is insufficient &/or ineffective use of produced insulin, results in raised blood glucose termed as 'diabetes' [1]. Glucose is not only a necessary biochemical fuel but also play a central part of safe and effective diabetes control [2].

According to the Centers for Disease Control and Prevention's National Diabetes Statistics Report [3], an estimated 40 million people in the United States, or 11.6% of the population, have diabetes. About 1 in 5 adults with diabetes don't know that they are diabetic. A survey carried out among Indian adults aged 45 years have reported diabetes prevalence of 19·8% (95% CI 19·4-20·2), with men and women are equally affected [4]. In addition, the same study unveiled that diabetes prevalence (30·0% [95% CI 29·1-30·8]) among adults from urban area was approximately twice as high as rural prevalence (15·0% [14·6-15·5]).

Hyperglycaemia, the raised blood glucose or raised blood sugar, is a chronic non-communicable disease, over time leads to serious damage to many of the body's systems, especially the nerves and blood vessels. Microvascular complications include neuropathy, retinopathy, and nephropathy, while macrovascular disease affects the coronary arteries, cerebral circulation, and peripheral arteries [5, 6].

NIDDM (Non-Insulin-Dependent Diabetes Mellitus), a term historically used to describe what is now universally known as Type 2 Diabetes (T2D), is a major condition reported worldwide and a leading cause of lifestyle diseases. Diabetes affects the Quality-of-Life (QoL) by affecting both physiological and psychological functions. For instance, persistent fatigue and tiredness can occur due to elevated blood glucose levels [7]. In addition, polyuria, polyphagia, polydipsia, visual disturbances, etc. are associated with chronic diabetes, which ultimately lead to compromised QoL among diabetes persons. Systematic analysis of the data collated from diabetes person's life-expectancy suggested that an estimated shorter life span of 6 years for chronic diabetes individuals compared to people without diabetes, due to the chronic diabetes complications [8, 9].

Treatment options vary depending upon the diabetes categories viz. type 1 diabetes must rely on insulin, whereas type 2 diabetes can use either oral medications or injectable-insulin to manage their diabetes effectively. Medicaments of type 2 diabetes include, Metformin, Dipeptidyl peptidase 4 (DPP-4) inhibitors, Glucagon-like peptide 1 (GLP-1) and dual glucose-dependent insulinotropic polypeptide (GIP) and GLP-1 receptor agonists, Sodium-glucose cotransporter 2 (SGLT2) inhibitors, Sulfonylureas, Thiazolidinediones (TZDs) [10]. The mode of action all these drugs varies in the maintenance of blood glucose levels and have their own side effects eg. Metformin causes diarrhoea, if not taken with food. It has been evident that apart from 'Anti-hyper glycaemic' (AHGs) agents constant use to maintain the target blood glucose levels, the lifestyle changes like dietary habits, physical activity/exercise etc. are advised by healthcare professionals. In addition, certain botanical/herbal ingredients, food / health supplements were known for their adjunctive action in controlling the blood sugar levels along with AHGs [11]. Traditional system of medicine has also reported the anti-glycaemic potential of medicinal plants.

In view of the above Dabur India Ltd., has formulated the 'Ayurvedic Sugar Free Juice' (Code: DRDC/2025/010) to address the maintenance of blood sugar levels and improvement in QoL among diabetes individuals.

2. Methodology

2.1. Study Site and Participants

The study was carried out in Type II Diabetics patients at Govt. Ayurveda College & Hospital (GAC&H), Balangir, Odisha in India, after obtaining the Ethical committee approvals and registration of the study with 'Clinical Trial Registry of India' (CTRI). A total of 30 participants, were screened as per inclusion and exclusion criteria mentioned in the Table 1. The schematic flow of the study with activities and scheduled visits was given in Figure 1.

Table 1. *Inclusion & Exclusion Criteria.*

Inclusion Criteria	Exclusion Criteria
1. Subjects aged > 18 years of age who agreed to participate in the study and able to answer the questionnaire and give their written informed consent. 2. Participants were recruited with following criteria: For Diabetics: 1) Participant with initial HbA1c value 6.5% and above.	1) Women with regular menstruation history having missed periods. 2) Confirmed cases of pregnancy and lactation. 3) Patients who are on insulin therapy. 4) Patients with a history of chronic illness type

Inclusion Criteria	Exclusion Criteria
2) Patients who are under the treatment of oral antidiabetic drugs. 3) Patients who have not changed their medication in the last three months prior to signing up for the study. (However, dosage modifications were allowed and documented on CRF). For prediabetics: 1) Participant with initial HbA1c value 5.7 to 6.4%. 2) Known cases of pre-diabetes with fasting blood sugar not exceeding 130mg/dl with obesity and having family history of diabetes. 3. Subjects with Body Mass Index (BMI) >23 kg/m^2 and <45 kg/m^2 4. Women of childbearing potential must be willing to use double-barrier contraception for the entire study.	1 diabetes and /or history of ketoacidosis. 5) Patients with Insulin use and/or hyperosmolar hyperglycaemic state. 6) Patients with secondary diabetes (including disease of the exocrine pancreas, endocrinopathies. 7) 7. Any condition of the patient which may have an impact on the objective and outcome of the trial example: patients currently undergoing major/minor surgical procedures.

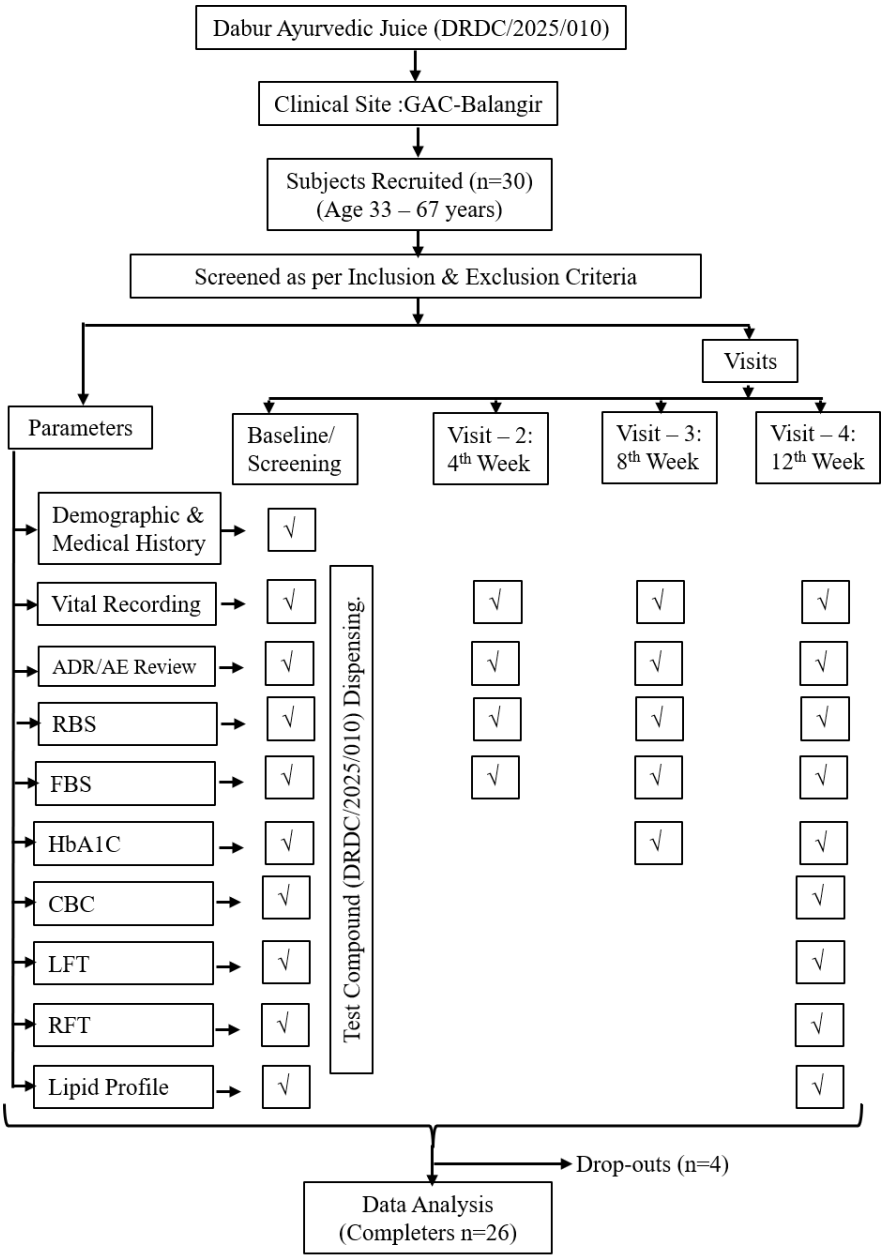

Figure 1. *Schematic Flow of Study with Events & Visits. The information of the clinical sites, number of participants, screening through inclusion & exclusion criteria were shown. The events with timelines for follow-up visits and assessment activities was provided.*

2.2. Follow-up Visits & Parameters Assessed

At baseline/screening visit, the information about demographic, anthropometric, medical history was recorded from all the participants. Vitals such a pulse, respiration rate, blood pressure and body temperature were recorded. Blood was collected analyzed for complete blood count (CBC), lipid profile, liver & renal function tests.

The test compound was disbursed and instructed the dosage and frequency as '30mL of DRDC/2025/010' diluted with 250 mL of drinking water and consumed twice a day preferably at least one hour, before breakfast and before dinner for a period of 90 days. The diabetic participants who were following specific dietary, exercise activities and AHGs, were advised to continue those practices as such through-out the study period. The participants were informed about the follow-up visits on every 30th day during the study period without overnight fasting. Efficacy of the test compound was assessed by change in diabetic parameters viz. Fasting Blood Sugar (FBS), Random Blood Sugar (RBS) and HbA1C levels on 3 follow-up visits from baseline. In addition, the change in Body Mass Index (BMI) and improvement in Quality of Life (QoL) through questionnaire pertaining to the symptoms of diabetes were assessed at baseline and 90th day. The Adverse Events (AEs), if any related to the test compound consumption were documented. Biochemical parameters such as CBC, lipid profile, LFT and RFT were analyzed at 90th day (last follow-up visit).

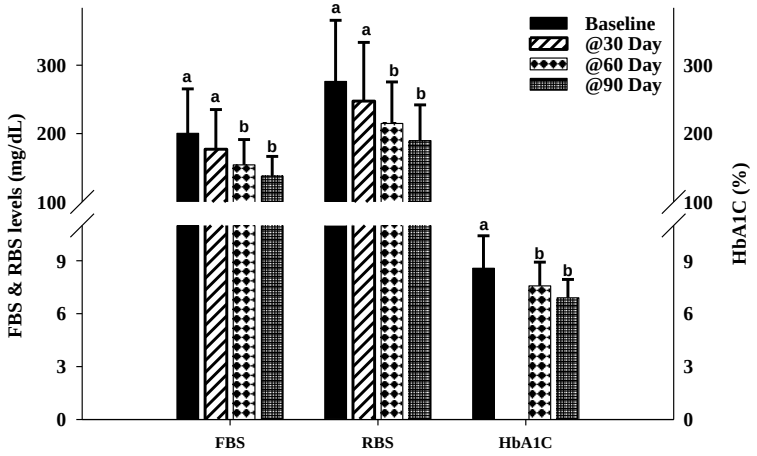

Figure 2. Diabetic Parameters - FBS, RBS & HbA1C levels. Bars represent mean±SD of FBS, RBS & HbA1C levels of the participants at different time points. Differ-ent superscripts indicated significantly difference from baseline to end of treatment. HbA1C levels were as-sessed at baseline, 30 days, 60 days and 90 days.

2.3. Statistical Analysis

Both quantitative and qualitative data were compiled and analyzed. Quantitative variables were expressed as mean ± standard deviation (SD), while qualitative variables were summarized as counts and percentages. For categorical data, McNemar's test was applied to evaluate before-and-after treatment effects. The treatment effects were assessed using the paired sample t-test, and the Wilcoxon signed-rank test respectively. All analyses were performed using RStudio 2026.01.1 with p-values reported from two-sided tests. Statistical significance was interpreted at the 5% level ($\alpha = 0.05$).

3. Results

3.1. Demographic and Anthropometric Profile

A total of 30 participants were recruited into the study and among them 26 nos. of participants completed the study (male-18 and female - 8). During course of study 4 participants dropped out. The participants the study site were residing in the urban, sub-urban and rural regions of the Balangir town.

Occupation of the diabetic participants of clinical sites includes home-makers (majority of female participants), Govt. employees, business, private and daily-wage employees. Mean age of participants was 49±9.60 years, with a range from 33 - 67 years. The height of participants ranged between 162.1±8.19 cm; and weight was 66.6±11.37 kg.

3.2. Diabetic Parameters

The diabetic parameters such as FBS, RBS & HbA1C of participants have been shown in Figure 2. The mean FBS levels at baseline, 1st month, 2nd month and 3rd month visits were 200.2±65.11; 177.0±57.98; 154.2±36.86 and 137.6±28.92 mg/dL, respectively.

Though mean FBS levels were reduced at 1st month visit compared to baseline, but statistically insignificant. Whereas

subsequent visits i.e. 2nd ($p<0.0063$) and 3rd month ($p<0.0001$) follow-up visits the FBS levels were significantly reduced compared to baseline (Figure 2). In between visit FBS levels viz. 1st month vs 2nd month and 2nd month vs 3rd month were statistically insignificant, however 3rd month FBS mean levels were significantly ($p<0.026$) reduced compared to 1st month (Figure 2).

Similarly, mean RBS levels at baseline, 1st month, 2nd month and 3rd month visits were 276.1±89.50; 247.4±85.89; 214.7±60.82 and 189.6±52.28 mg/dL, respectively. The mean RBS levels were significantly decreased at 02nd ($p<0.016$) and 03rd ($p<0.0003$) month visits when compared to baseline. However, no difference was noted baseline vs 1st month and 1st month vs 2nd month visit RBS levels. Nonetheless, mean RBS levels were significantly reduced at 3rd month visit compared to 2nd month visit ($p<0.026$) (Figure 2).

The mean HbA1C levels of pooled data at baseline, 2nd & 3rd month visits were 8.57±1.84; 7.57±1.35 and 6.90±1.04%, respectively. The mean HbA1C levels were significantly decreased at 2nd ($p<0.043$) and 3rd ($p<0.0003$) month visit compared with baseline. (Figure 2).

3.3. BMI and QoL

The BMI of the diabetic participants at baseline was 25.1±3.00 kg/m^2 and at end of the study period the BMI was 20.7±8.56 kg/m^2. A significant ($p<0.0001$) decrease in mean BMI levels of the diabetic participants was observed at 90th day compared to baseline. The QoL assessed by symptoms viz. Polyuria, Polyphagia, Exhaustion /Tiredness and Body ache were reduced among the diabetic participants by the end of treatment compared to baseline. Although there was change in multiple parameters at Day 0 and Day 90, but statistically insignificant (Table 2).

Table 2. *QoL - Symptoms of Diabetes.*

Time Points			
S. No.	**QoL Parameter**	**0th Day**	**90th Day**
1	Polyuria	46	42
2	Polyphagia	35	35
3	Polydipsia	19	12
4	Exhaustion / Tiredness	77	65
5	BW loss	27	27
6	Body ache	77	65
7	Giddiness	65	62
8	Polyneuritis	73	58
9	Visual Disturbances	12	12

Values are% of individuals with symptoms.

3.4. Biochemical Parameters

CBC parameters of the participants viz., MCV, MCH, MCHC, monocytes and platelet levels were significantly different from baseline to end of the treatment period, whereas other CBC parameters were comparable (Table 3). The LFT and RFT parameters have not shown significant difference between end of treatment period and baseline, except that BUN levels were significantly different between two time points (Table 3). The mean cholesterol levels were notably decreased at day 90 (163.0 ± 37.25), compared to baseline – day 0 (189.1 ± 53.61).

Similarly, triglyceride and VLDL levels were noted to decrease at day 90 compared to baseline (Figure 3). Furthermore, the mean HDL levels increased significantly (*$p<0.001$*) at day 90 compared to baseline, while there was a significant decrease in LDL levels (*$p<0.001$*) at end of day 90 compared to baseline (Figure 3).

Table 3. *Hematological Parameters of Participants.*

S. No.	Parameter	0th Day	90th Day
Haematological Parameters			
1	Hb (gm/dl)	14.3±2.02	14.5±1.15
2	RBC (×10^6/µL)	5.6±0.64	5.3±0.54
3	MCV	84.9±9.05	93.2±7.29**
4	MCH	25.5±3.13	27.6±3.18*
5	MCHC	30.0±1.73	28.6±1.11**
6	WBC (×10^3/µL)	8.6±1.92	8.1±1.45
7	Neutrophil (%)	61.3±6.32	61.9±6.64
8	Lymphocyte (%)	31.1±6.10	30.1±6.70
9	Monocyte (%)	3.2±3.33	3.2±0.78
10	Eosinophil (%)	4.2±3.11	4.2±1.69
11	Basophil (%)	0.59±0.298	0.47±0.201
12	Platelet (×10^3/µL)	285.1±73.41	247.7±72.05*

*P<0.05 & **p<0.001 are Level of significance at two different time points.

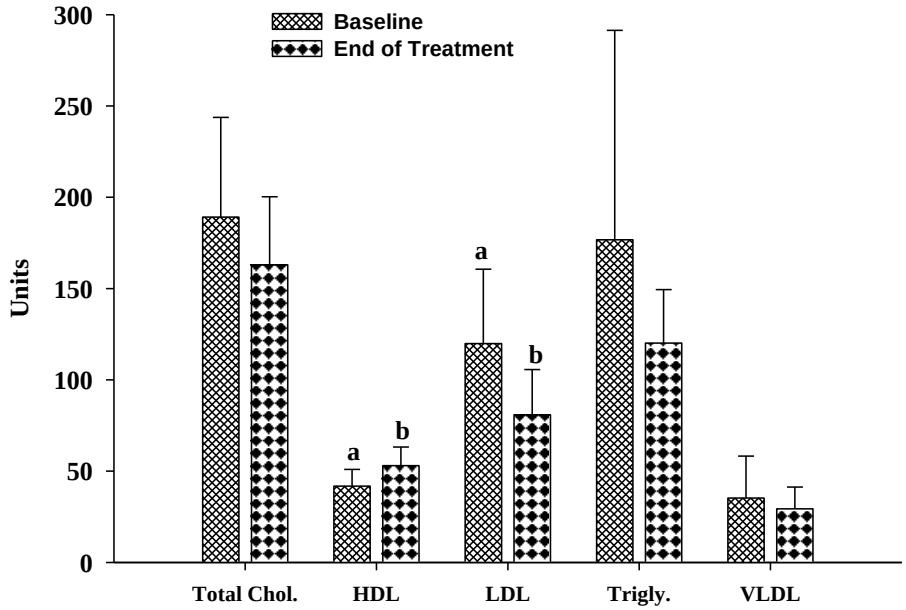

Figure 3. *Lipid Profile of Participants – Total Cholesterol, HDL, LDL, Triglycerides, VLDL. Bars represent mean±SD of Total Cholesterol, HDL, LDL, Triglycerides, VLDL levels of the participants. Different superscripts indicated significantly difference from baseline to end of treatment. The lipid profile was assessed at baseline and at end of treatment (90 days).*

3.5. Vitals

The pulse of the diabetic patients were noted at 74.4±4.96/min at day 0 and 75.9±3.82/min day 90. Similarly, respiration rate/min at day 0 was noted at 18.1±1.04 and at day 90 was noted at 18.7±0.84; body temperature (in ^{o}F) at day 0 was 98.4±0.24 and at day 90 was 98.2±0.27; the Blood pressure (mm of Hg) systolic was noted to be 126.9±10.87 at day 0 and 126.4±10.65 at day 90 while the diastolic readings were 80.8±8.12 at day 0 and 80.6± 8.12 at day 90. The vitals above, were comparable before and after intake of the test compound.

3.6. Safety of Test Compound

None of the participants from the clinical study site have shown any adverse event (AE) / adverse drug reaction (ADR) related to the test compound i.e. Ayurvedic Sugar Free Juice. In addition, no significant difference in the vitals recorded during the course of study period suggests that the test compound have no visible side effects. Further to this, the biochemical analysis such as CBC, LFT and RFT parameters were also comparable, though few parameters varied in the participants at initial to end of the treatment period (90 days) suggests the test compound's safety.

4. Discussion

Adjunctive therapeutic process / agents are gaining the momentum in counter-acting the chronic effects of diabetes along with 'Anti-hyper glycaemic' (AHGs) agents. The QoL of diabetes patient with chronic and severe hyperglycaemia is adversely affected, and resulting in tiredness and lethargy thereby a decrease in work performance was noted in adults [12]. To meet the requirements and avoid further increase the dosage of AHGs healthcare professional suggests for life-style changes for diabetes individuals especially dietary modifications and regular exercise. A study carried out among diabetes personal with stress management showed small but significant decrease in glycohemoglobin after 1 year [13].

In addition, to the life-style changes use of alternate medicines such as botanical/herbal ingredients, food / health supplements were known for their adjunctive action in controlling the blood sugar levels along with AHGs (Pandey, et al., 2011). In the current study, the test compound is comprised of botanicals such as *Aloe barbadensis*, *Emblica officinalis*, *Syzgium cumini*, *Momordica charantia*, *Azadirachta indica*, *Tinospora cordifolia*, *Terminalia chebula*, *Terminalia billerica*, *Gymnema sylvestre*, *Trigonella foenumgraecum*, *Withania somnifera*, *Pterocarpus marsupium*.

Different species of Aloe vera have reported the hypoglycemic and antidiabetic potential through *in vitro* and *in vivo* studies [14]. Similarly a study conducted on rats with Jamun and metformin, alone and combination have revealed that combination of metformin and Jamun have significantly reduced the HbA1C levels in diabetic condition, whereas in prediabetics alone of Jamun could show it's potential effect [15]. Current study results corroborated with reduction in HbA1C levels at 90 days regular consumption along with AHGs. In addition, the RBS and FBS levels were also significantly decreased among the diabetic participants at end of treatment duration (12th week) compared to baseline / screening stage along with AHGs, their regular dietary and exercise pattern.

Overall, in the study it was observed that upon systematic usage of the test compound DRDC/2025/010 for 90 days, there was 31.27% reduction in fasting blood sugar (FBS), 31.33% reduction in random blood sugar (RBS) and 19.49% reduction in glycated hemoglobin (HbA1c) among the study participants. Further, the QoL assessed by set of questionnaires have also revealed notable decrease in the symptoms associated with diabetes. The test compound have shown no adverse events (AEs) / ADRs during the course of efficacy evaluation. Added to this, the vitals and biochemical parameters were in the normal range suggesting the safety of the test compound.

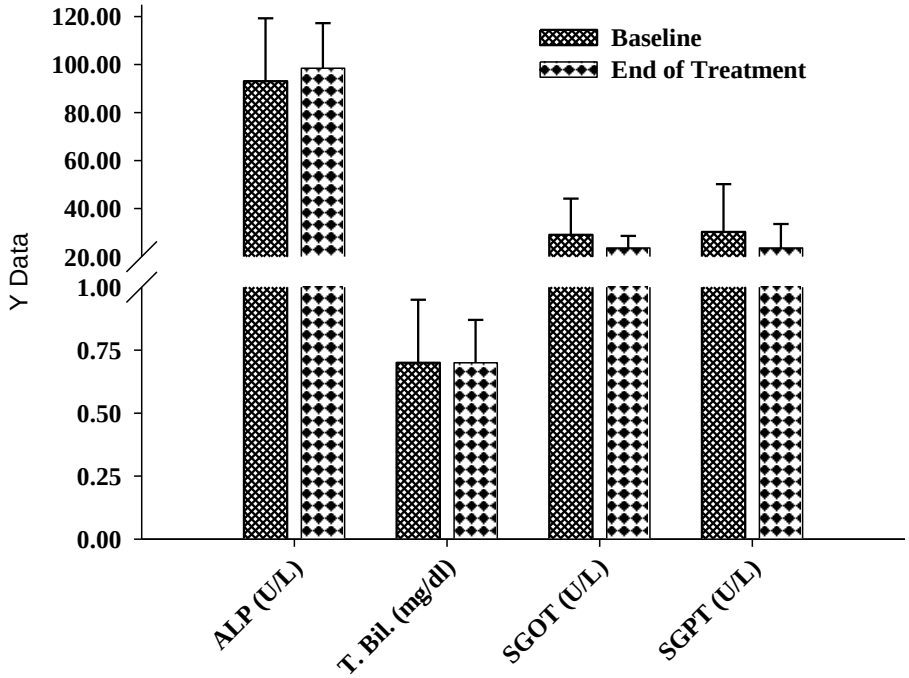

Figure 4. *Liver Function Assessment of Participants – ALP, Total Bilirubin, SGPT, SGOT. Bars represent mean±SD of ALP, Total Bilirubin, SGPT, SGOT levels of the participants. Different superscripts indicated significantly difference from baseline to end of treatment. The lipid profile was assessed at baseline and at end of treatment (90 days).*

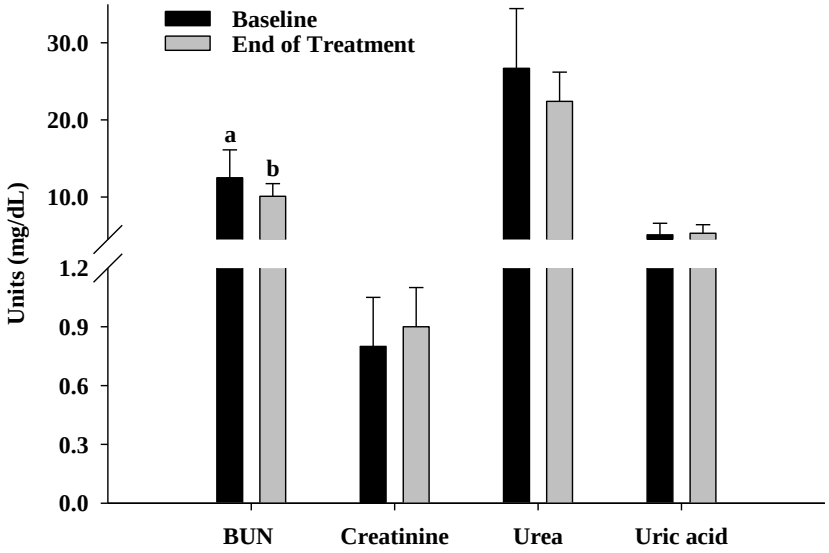

Figure 5. *Renal Function Assessment of Participants – BUN, Creatinine, Urea, Uric Aci Bars represent mean±SD of BUN, Creatinine, Urea, Uric Acid levels of the participants. Different super-scripts indicated significantly difference from baseline to end of treatment. The lipid profile was assessed at baseline and at end of treatment (90 days).*

5. Conclusion

Current study has unveiled the safety of the test compound as there were no adverse events, vitals and biochemical parameters within the normal range during the course of the experimental period. The test compound DRDC/2025/010 have shown significant ($p<0.05$) reduction in FBS, RBS, HbA1c and BMI levels among the participants of study at the 'end of treatment (90 days)', compared to baseline. The above observations indicate the test compound's potential as an 'adjunctive agent' for diabetic patients, who are on AHGs, following the dietary and exercise guidelines, could improve from hyper-glycemia, upon constant usage.

Abbreviations

ALP	Alkaline Phosphatase
ATP	Adenosine Triphosphate
BUN	Blood Urea Nitrogen
DL	Decilitre
FBS	Fasting Blood Sugar
GM	Gram
HB	Hemoglobin
HbA1c	Hemoglobin A1c (Glycated Hemoglobin)
HDL	High-density Lipoprotein
LDL	Low-density Lipoprotein
LFT	Liver Function Test
MCHC	Mean Corpuscular Hemoglobin Concentration
MCV	Mean Corpuscular Volume
MG	Milligram
QoL	Quality of Life
RBC	Red Blood Cells
RBS	Random Blood Sugar
RFT	Renal Functional Test
SGOT	Serum Glutamate Pyruvate Transaminase
SGPT	Serum Glutamic-Oxaloacetic Transaminase
T. Bil	Total Billirubin
Trigly.	Triglyceride
Ul	Micro-liter
VLDL	Very-low-density Lipoprotein
WBC	White Blood Cells

Author Contributions

Baidyanath Mishra: Conceptualization, Resources, Funding acquisition, Project administration, Supervision, Validation

Srinivasa Reddy Yathapu: Supervision, Methodology, Formal Analysis, Validation, Writing – original draft, Writing – review & editing

Simadri Bhusan Nayak: Investigation, Data curation, Formal Analysis

Sushanta Sahu: Investigation, Data curation, Formal Analysis

Garima Gupta: Project administration, Supervision, Methodology, Investigation, Formal Analysis

Apratim Sai Rajesh: Project administration, Data Analysis, Writing – original draft, Writing – review & editing

Conflicts of Interest

The authors declare no conflict of interest.

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