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Review Article

Polyherbal formulations for sustainable glycemic control in diabetes mellitus: phytochemical profiling, mechanistic insights, standardization and integration with conventional therapeutic approaches

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ABSTRACT

Diabetes mellitus is a chronic metabolic disease characterized by insulin resistance and pancreatic β-cell dysfunction persistent hyperglycemia, contributing to severe complications including cardiovascular, renal, hepatic, and neurological disorders. Worldwide incidence of diabetes has risen significantly, with over 537 million individuals affected in 2021, and projections indicate 783 million by 2045, imposing a significant public health and economic burden. Polyherbalism leverages synergistic interactions between multiple medicinal plants, enhancing therapeutic efficacy while minimizing toxicity. Commonly studied antidiabetic plants include *Momordica charantia*, *Gymnema sylvestre*, *Trigonella foenum-graecum*, *Syzygium cumini*, and *Ocimum sanctum*, which demonstrate hypoglycemic, antioxidant, and antihyperlipidemic activities by pathway like β-cell regeneration, decreased of glucose assimilation, and modulation of oxidative stress. This review highlights the potential of polyherbal formulations as safe, economically viable, and multi-targeted interventions for sustainable glycemic control, emphasizing the need for rigorous pharmacological, clinical, and formulation research to integrate traditional remedies into modern diabetes management.

Keywords: Type 2 diabetes mellitus, Polyherbal formulations, Phytochemical analysis, Glycemic control, Preclinical studies, Drug delivery systems

INTRODUCTION

The global rise in diabetes-related disease and transience has increased the demand for safe and effective treatment strategies. Traditional medicine, particularly polyherbal formulations, is gaining attention due to their perceived efficacy and safety in managing Type 2 Diabetes Mellitus (T2DM). Meta-analysis using RevMan 5.2 demonstrated that polyherbal formulations significantly reduced Glycated hemoglobin (HbA1c), postprandial blood sugar, and fasting blood sugar compared to control groups. The reductions were statistically significant, with notable improvements in postprandial glucose and HbA1c in contrast to metformin.[1-3] Conventional treatments like metformin, sulfonylureas, and insulin remain standard treatments, they commonly exhibit certain weaknesses including adverse therapeutic responses that wane with prolonged use, and suboptimal regulation of blood sugar levels. This has led to increased interest in novel therapeutic strategies. Recent innovations include dual incretin receptor agonists like tirzepatide, which target modulating GLP-1 and GIP receptors to increase glucose-dependent insulin release, suppress glucagon, and contribute to body weight reduction. Similar to this, dual SGLT1/2 inhibitors, such as sotagliflozin, improve glycemic control and help with weight management by

controlling glucose absorption in the kidneys and intestines.[4-7] Additional experimental approaches involve therapeutics acting as glucagon receptor inhibitors, GPR119 activators, and synthetic FGF21 analogs aimed at improving insulin sensitivity and glucose metabolism. Furthermore, cutting-edge technologies such as CRISPR-Cas9 gene editing and drugs that enhance AMPK activity are being explored to correct the root causes of T2DM. Even though these emerging remedies offer promising avenues for more effective diabetes management, their long-duration safety profile and efficacy are still under evaluation.[8-13]

BURDEN AND CHALLENGES OF LONG-TERM GLYCEMIC CONTROL

Diabetes is causing the chronic kidney disease (SKD) but maintain the optimal glycaemic control can slow the progression of SKD. Younger patients and those with type 1 diabetes experienced higher levels of distress across all domains.[14] Less than half of the participants demonstrated satisfactory treatment adherence. Both DRD and poor SRAT were significantly associated with higher HbA1c levels. Importantly, treatment adherence partially mediated the relationship between DRD and glycemic control, indicating that psychological distress adversely affects diabetes outcomes both directly and indirectly through reduced adherence (Figure 1). As mortality from cardiovascular diseases declines, conditions such as cancer and dementia are emerging as leading causes of death among individuals with diabetes in certain regions (Figure 2).

Identification and metabolism of sugar in the body (Pathophysiology of Type 2 diabetes)

High blood sugar and insulin resistance can hurt the reproductive health of both men and women. In women, metabolic imbalance can disrupt hormonal regulation, hinder ovulation, and contribute to conditions such as polycystic ovary syndrome (PCOS). Chronic hyperglycemia in men may compromise sperm quality, diminish motility, and influence testosterone levels. High sugar intake can also cause systemic inflammation and oxidative stress, which can make reproductive function even worse. (Figure 3).[17]

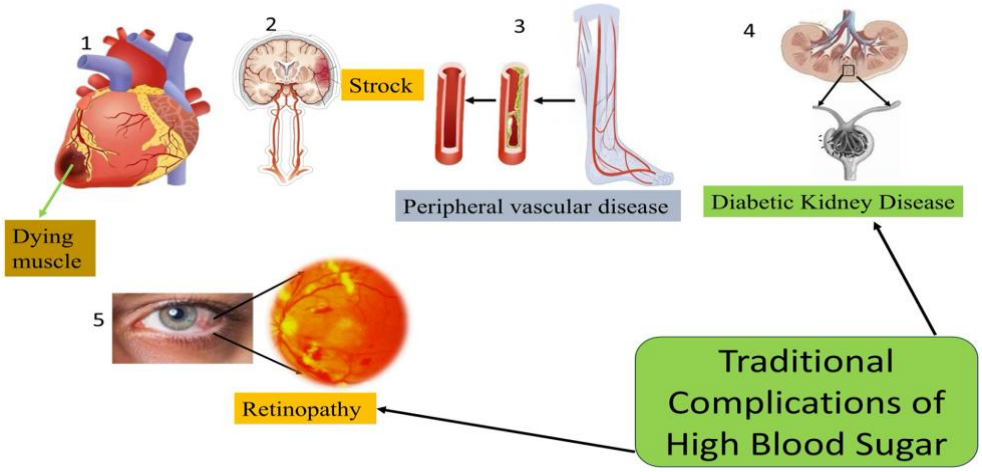

Figure 1: Traditional complications of diabetes: - The picture shows the traditional problems that come with chronic hyperglyemia (diabetes mellitus) and shows how long-term high blood sugar slowly harms many organ systems by damaging blood vessels.[15]

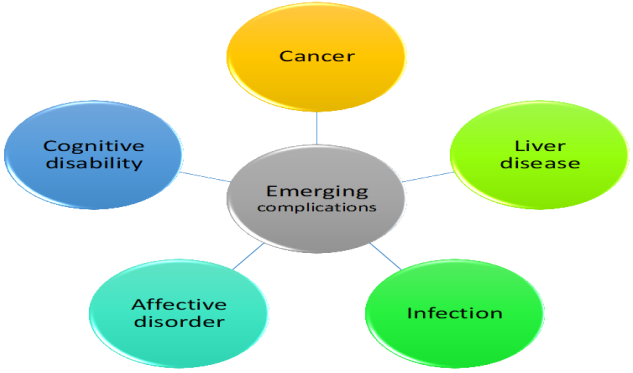

Figure 2: The image depicts the evolving complications of chronic hyperglycemia (diabetes mellitus) that surpass conventional vascular complications, including heart disease, nephropathy, and retinopathy.[16]

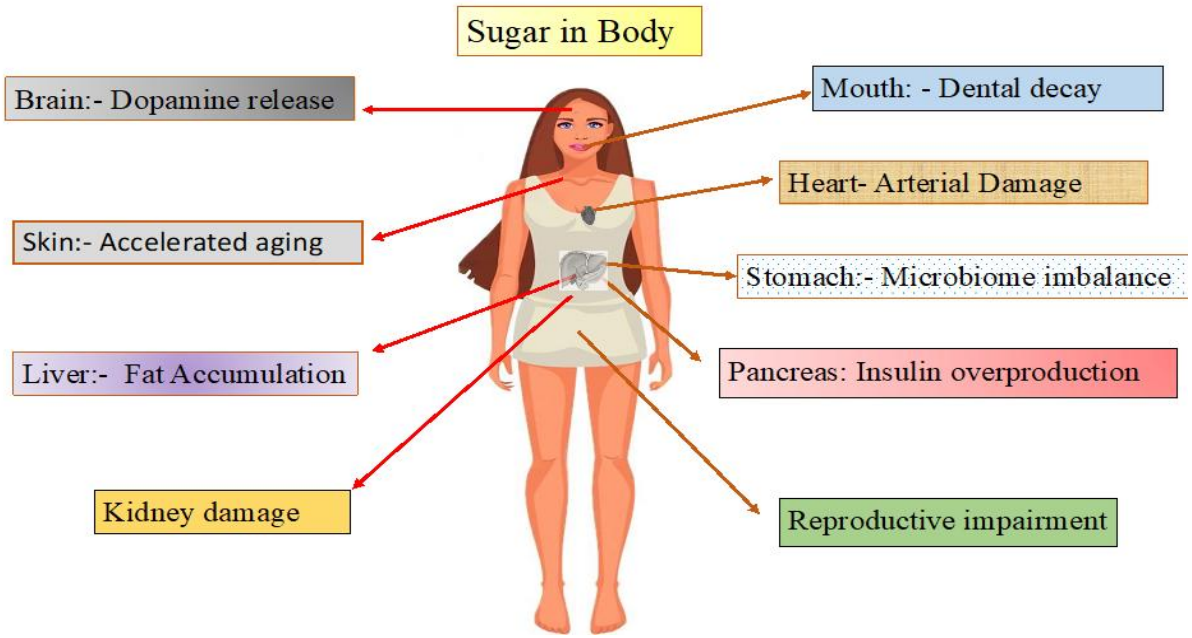

Figure 3: Excessive sugar consumption harmful for many parts of the body, like the brain, mouth, heart, stomach, pancreas, liver, kidneys, skin, and reproductive system.[18]

LIMITATIONS OF CONVENTIONAL ANTI-DIABETIC THERAPIES

Diabetes, a multifactorial metabolic disorder, is associated with complications such as hyperlipidaemia, hepatic toxicity, and immune dysfunction, necessitating multi-target therapeutic approaches rather than mono-drug therapy. A hydro-alcoholic polyherbal extract (HA), comprising *Momordica charantia*, *Trigonella foenum-graecum* and *Withania somnifera* (2:2:1), was optimized using an oral glucose tolerance test in normal Wistar rats.[19]

Extract demonstrated significant glucose-lowering effects in oral glucose tolerance tests and sustained antihyperglycemic activity over a 28-day treatment period, particularly at PH I doses of 400 mg/kg followed by 200 mg/kg. Additionally, the formulation improved lipid profiles, enhanced antioxidant defences, and normalized hepatic and renal function markers. Histopathological findings supported these biochemical outcomes, and the developed polyherbal tablets met acceptable pre- and post-compression quality parameters.[20]

Rationale for Herbal and Polyherbal Approaches:

Barleria prattensis Santapau is a regularly employed medicinal plant with reported antimicrobial and antioxidant properties. *C. caudatus* is a promising candidate for developing functional foods targeting obesity.[21] Targeted phytochemical analysis, metabolomics adopts an untargeted, data-driven approach to comprehensively assess measurable metabolites, offering predictive power (Figure-4).

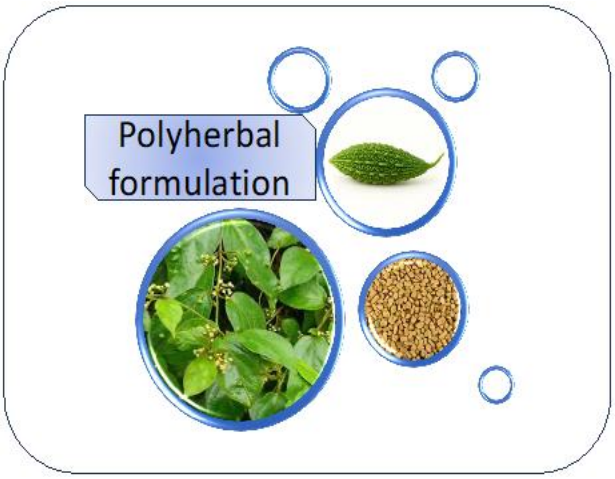

Figure 4: For Polyherbal formation used various ingredients such as *Gymnema sylvestre* leaves, *Momordica charantia* (fruit), and *Trigonella foenum-graecum* (seeds).[22]

POLYHERBAL AND NOVEL THERAPIES FOR TYPE 2 DIABETES

An ethnobotanical study explored traditional polyherbal formulations used for treating skin infections in the Ibadan metropolis (Figure-5). It is also known as the "Insulin plant." It helps the liver make more glycogen and lowers markers of oxidative stress. It may also keep pancreatic cells from getting hurt (Figure-6).

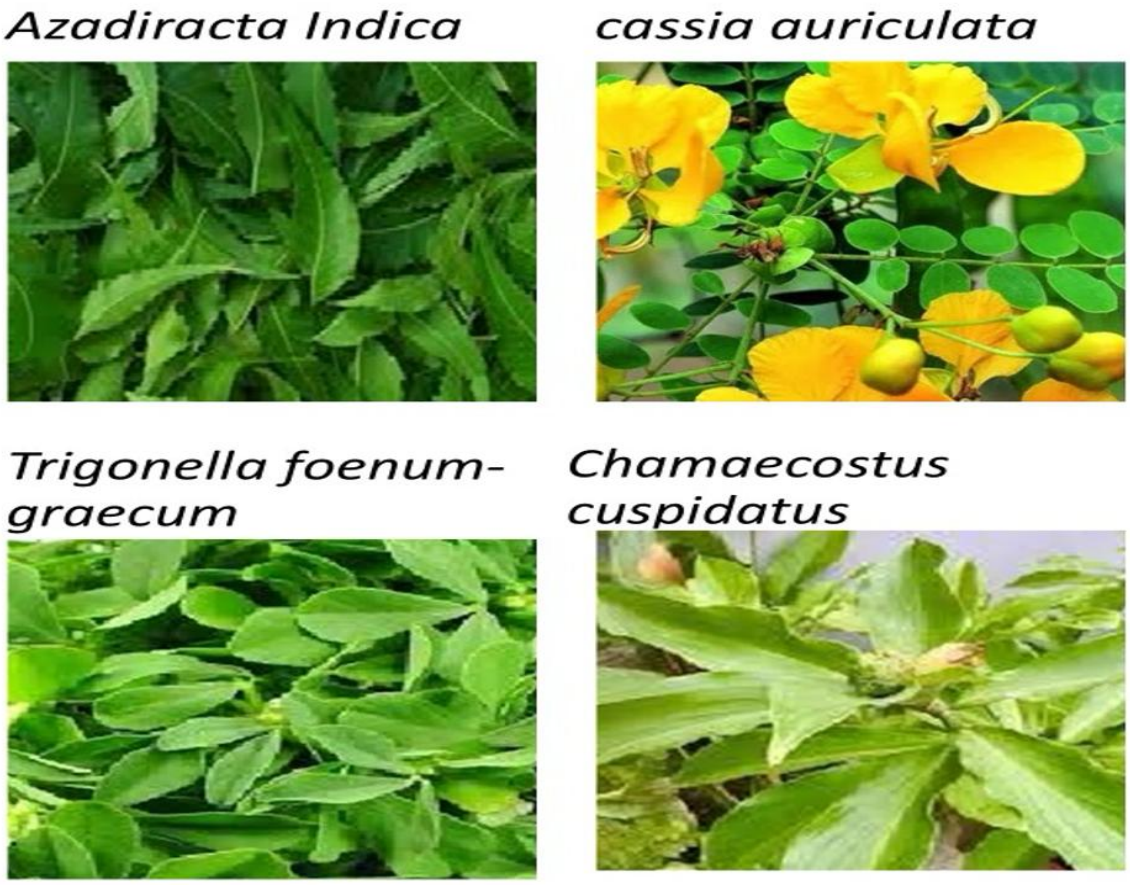

Figure 5: A polyherbal formulation comprising *Azadirachta indica, Cassia auriculata, Trigonella foenum-graecum* and *Chamaecostus cuspidatus* offers a scientifically validated, multi-faceted strategy for the treatment of diabetes mellitus.[23]

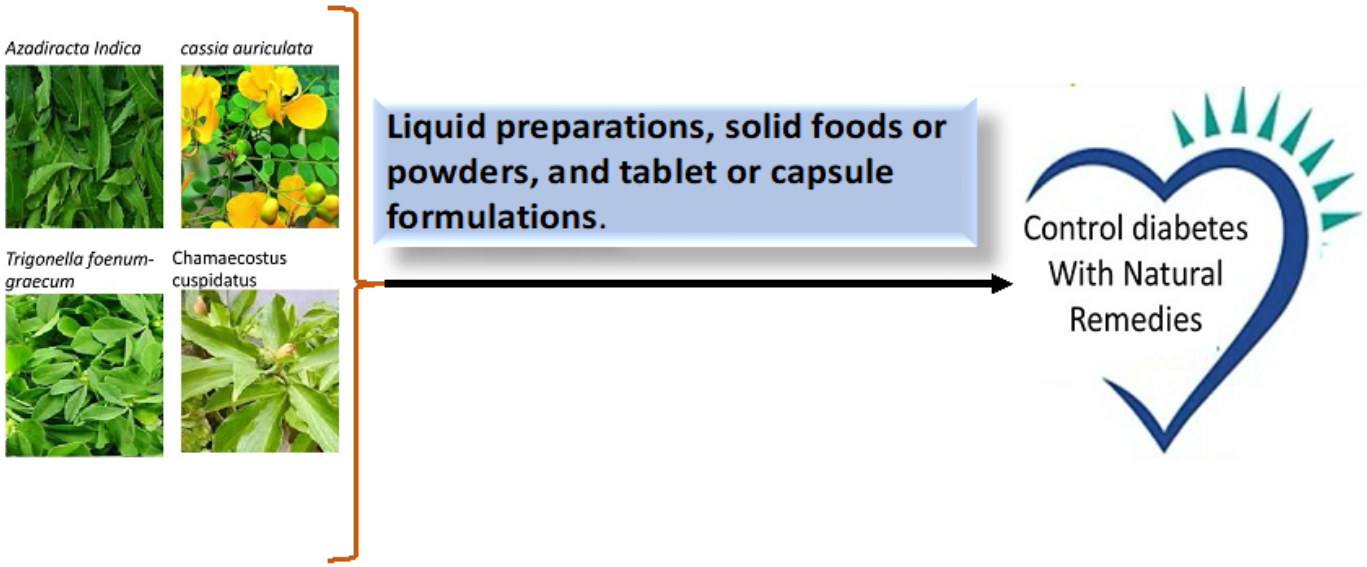

Figure 6: Herbal remedies can intake in body in a number of ways, such as liquids (like decoctions, extracts, and syrups), solid foods or powders, or tablets or capsules.[24]

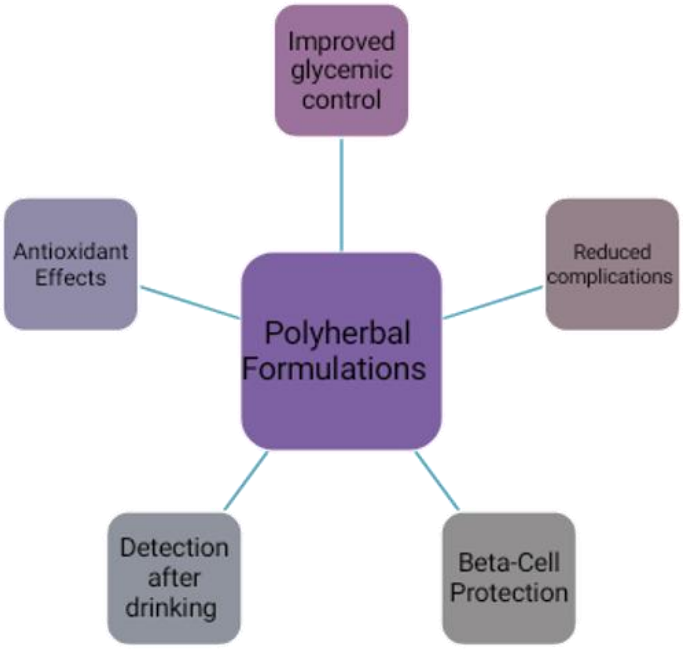

Figure 7: The diagram shows how polyherbal formulations can help treat metabolic disorders. These formulations help control blood sugar levels, have antioxidant effects, and protect pancreatic β-cells, which are necessary for insulin secretion.[26]

Different extracts of Cassia fistula Linn. (Leguminosae) flowers, like petroleum ether (60–80 °C), chloroform, acetone, ethanol, aqueous, and crude aqueous extracts (Figure 6). The water-soluble percentage of the ethanol extract had the strongest effect of all the samples tested. Its activity was similar to that of the standard drug glibenclamide (5 mg/kg) (Figure-7).[25]

POLYHERBAL ANTI-DIABETIC STRATEGIES

Five plants that have been shown to have antihyperglycemic properties: *Syzygium cumini* (jamun), *Ocimum sanctum* (holy basil), *Gymnema sylvestre* (gurmar), *Trigonella foenum-graecum* (fenugreek), and *Momordica charantia* (bitter melon). The incorporation of these herbal methods within the larger framework of managing diabetes. The traditional therapies, such as metformin, insulin, and α-glucosidase inhibitors.[27]

Oxidative stress, poor insulin synthesis and secretion, and pancreatic islet inflammation are all given special attention. Furthermore, diabetes-associated complications affecting the liver, kidneys, immune system, retina, and peripheral nerves are examined.28 It systematically discusses commonly used antidiabetic plants, types of extracts, plant parts employed, and dosing regimens reported in experimental studies.

PRECLINICAL EVALUATION OF HERBAL AND SYNTHETIC ANTIDIABETIC THERAPIES

Acute toxicity studies conducted according to OECD guideline 425 confirmed the safety of both formulationsAfter identifying the self-emulsifying region using a ternary phase diagram made with Capmul MCM C8 NF, Cremophor RH 40, and Transcutol HP, liquid SNEDDS were optimized using D-optimal experimental design (Table 1).

PREFORMULATION, CHARACTERIZATION, AND PERFORMANCE EVALUATION OF CONVENTIONAL AND NOVEL DRUG DELIVERY SYSTEMS

The optimized formulation exhibited small globule size, low polydispersity, and enhanced drug solubility, with in vitro dissolution showing rapid drug release in comparison to the basic medication (97.84% within 30 minutes). In order to create self-nanoemulsifying powder and pellets, the optimized liquid SNEDDS was further transformed into solid SNEDDS which were successfully characterized by FTIR, XRD, DSC, and SEM. Solid SNEDDS formulations also demonstrated significantly improved dissolution profiles. When compared to the plain medication suspension, in vivo trials demonstrated a significant decrease in blood glucose levels and a twofold improvement in bioavailability indicating that SNEDDS represents an effective lipid-based delivery approach for improving gliclazide therapy in diabetes management.[45]

RATIONAL DESIGN OF LIPID-BASED AND COMBINATION DRUG DELIVERY SYSTEMS

One of the best methods for increasing the oral bioavailability of poorly water-soluble medications is the use of lipid-based drug delivery systems (LBDDS), which

are used in many U.S. Products approved by the Food and Drug Administration (FDA. Multiparticulate solids can partially replace liquids, while dispersible forms enhance safe and efficient use. Innovations in administration devices and drug-device combinations, potentially. Poor solubility and low oral bioavailability of new drug candidates remain significant challenges in pharmaceutical development.[46]

Table-1 Paraclinical evolution of herbal and synthetic antidiabetic therapies

S.No	Herbal Therapy	Preclinical Model	Key Findings / Mechanism	Reference
1	*Momordica charantia*	STZ-induced diabetic rats	Decrease Fasting blood glucose, increase insulin secretion, β-cell regeneration	30
2	*Gymnema sylvestre*	Alloxan & STZ diabetic rats	Regenerates pancreatic β-cells, improves insulin levels	31
3	*Berberine* (from Berberis spp.)	High-fat diet + STZ rats	Activates AMPK pathway, improves insulin sensitivity	32
4	*Trigonella foenum-graecum*	STZ diabetic rats	Delays carbohydrate absorption, increase peripheral glucose utilization	33
5	*Azadirachta indica*	STZ diabetic rats	Hypoglycemic effect via enhanced insulin signaling	34
6	Metformin	HFD + STZ rat models	Decrease Hepatic gluconeogenesis via AMPK activation	35
7	Glibenclamide	STZ diabetic rats	Stimulates pancreatic β-cell insulin secretion	36
8	Sitagliptin (DPP-4 inhibitor)	Diabetic rodent models	Increase GLP-1 levels, enhances insulin secretion	37
9	Dapagliflozin (SGLT2 inhibitor)	Zucker diabetic fatty rats	Increase Urinary glucose excretion, decrease hyperglycemia	38
10	Acarbose	Oral glucose tolerance test in rats	Inhibits α-glucosidase → decrease postprandial glucose	39
11	*Withania somnifera*	STZ-induced diabetic Wistar rats	Root extract significantly reduced serum glucose, improved lipid profile and antioxidant enzymes	40
12	*Berberis asiatica*	STZ-nicotinamide induced type-2 diabetic Wistar rats	Plant extract improved glycemic control and metabolic parameters in T2DM rats	41
13	*Withania somnifera* + *Berberis asiatica* (polyherbal)	STZ-nicotinamide induced T2DM rat model	Combination therapy improved body weight and metabolic disturbances in diabetic rats	42
14	*Withania somnifera* (root extract)	High-fat diet + low dose STZ induced T2DM rat model	Extract improved cognitive deficits and metabolic dysfunction associated with diabetes	43
15	*Withania somnifera* (root & leaf extracts)	Alloxan-induced diabetic rats	Hypoglycemic and hypolipidemic effects through improved insulin function and antioxidant activity	44

NANOTECHNOLOGY-ENABLED HERBAL THERAPEUTICS AND COMPLEMENTARY APPROACHES IN DIABETES MANAGEMENT

Nanocrystals have emerged as a versatile formulation strategy to overcome these issues, offering improved solubility, rate of dissolution, and bioavailability for medications with low solubility. The second-generation nanocrystals (<100 nm), known as smart Crystals, and surveys products currently on the market or in clinical development. Nanocrystals are utilized in various dosage forms such as tablets, capsules, and aqueous nanosuspensions, primarily for oral and intravenous delivery.

The article also explores potential applications in dermal, mucosal, ocular, pulmonary, and targeted drug delivery, including brain targeting via protein adsorption.[47]

PHOSPHOLIPID-ENCAPSULATED POLYHERBAL THERAPY AND CLINICAL EVIDENCE OF NIGELLA SATIVA IN TYPE 2 DIABETES MANAGEMENT

The effects of Nigella sativa (NS) oil on the lipid profile and glycemic management of individuals with type 2 diabetes mellitus (T2DM) were assessed in this double-blind randomized controlled experiment. For 12 weeks, 72 patients between the ages of 30 and 60 were randomized to receive either 3 g of NS oil per day or a placebo. After controlling for confounding variables, intention-to-treat analysis revealed that NS oil supplementation significantly lowered fasting blood sugar, glycated hemoglobin (HbA1c), triglycerides, and low-density lipoprotein cholesterol when compared to placebo ($p < 0.05$).[48]

CONCLUSION

The accumulated evidence highlights the growing therapeutic potential of herbal interventions in the management of type 2 diabetes mellitus (T2DM). Nigella sativa's position as a safe and effective addition to conventional therapy is confirmed by clinical studies that show significant reductions in fasting blood glucose, HbA1c, lipid profile, oxidative stress indicators, and β-cell activity.

Overall, integrating clinical validation, rational polyherbal combinations, and advanced lipid-based delivery systems represents a promising strategy for optimizing herbal antidiabetic therapy. To make sure constant efficacy, safety, and quality in the treatment of diabetes, future research should concentrate on large-scale clinical trials, formulation standardization, and translational development.

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Conflict of interest: None declared
Ethical approval: Not required

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