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Research Article

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A Dual-Action Therapeutic Composition from Solanum Aethiopicum for Integrated Management of Type 2 Diabetes and Obesity

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ABSTRACT

Background: Type 2 diabetes and obesity are tightly linked pandemics with shared pathophysiology and mounting global burden. Conventional pharmacotherapies frequently target single pathways and may worsen weight gain or fail to address composite metabolic risk. We developed YKD-001, a standardized therapeutic composition derived from Solanum aethiopicum L. (African eggplant) fruits, designed for simultaneous glycemic and weight control through multi-pathway actions.

Methods: Fruits of S. aethiopicum were authenticated and processed via a proprietary hydroethanolic extraction and enrichment protocol that concentrates glycoalkaloids, steroidal alkaloids, and phenolic constituents. Phytochemical profiling used HPLC-DAD and LC–MS/MS against reference markers (e.g., solamargine, solasonine, chlorogenic acid, rutin). Bioactivity was evaluated in digestive enzyme assays (α-glucosidase, α-amylase, pancreatic lipase), cellular models of glucose uptake and insulin signaling (L6 myotubes and 3T3-L1 adipocytes), and diet-induced metabolic dysfunction in rodents. Safety was assessed by in vitro cytotoxicity and acute/subacute oral toxicity. Analyses employed ANOVA with post hoc tests.

Results: The standardized extract yielded reproducible chemical fingerprints with batch-to-batch variation <10% for primary markers. YKD-001 inhibited α-glucosidase by 78%, α-amylase by 65%, and pancreatic lipase by 72% at standardized activity units, indicating concurrent attenuation of carbohydrate and lipid hydrolysis. In vivo, YKD-001 reduced fasting glucose by 35%, decreased HbA1c-equivalent markers by 28%, and produced 12% body weight loss versus baseline in obesediabetic rodent models. Cellular assays showed increased insulin-stimulated glucose uptake and enhanced AKT phosphorylation, with modest inhibition of adipogenesis and reduction in ROS. No acute toxicity was observed at limit doses; subacute administration showed no clinically meaningful changes in hematology, clinical chemistry, or histopathology.

Conclusions: YKD-001 is a dual-action, multi-target composition that integrates enzyme inhibition, insulin sensitization, and antioxidant pathways to improve glycemic control and weight outcomes. These preclinical data support clinical evaluation of YKD-001 as a safe, standardized natural product candidate for metabolic syndrome, type 2 diabetes, and obesity.

Keywords: Solanum Aethiopicum, Glycoalkaloids, α-Glucosidase, Pancreatic Lipase, Insulin Sensitivity, Metabolic Syndrome, Nutraceutical

Introduction

Type 2 diabetes mellitus (T2DM) and obesity continue to surge worldwide, now affecting hundreds of millions of adults and straining health systems and economies. The International Diabetes Federation estimates 537 million adults living with diabetes in 2021, with projections to 643 million by 2030 [1]. In Sub-Saharan Africa, rapid urbanization and nutrition transitions are linked to escalating metabolic risk, with striking urban–rural gradients in the Democratic Republic of Congo (DRC): diabetes prevalence is typically lower in rural settings (around 4%) and substantially higher in urban centers (up to ~8%), with community surveys reporting 3.5–4.8% overall prevalence in selected regions [2-6].

Despite advances (e.g., GLP-1 receptor agonists, SGLT2 inhibitors), many pharmacotherapies remain single-target and can be costly, injection-based, or limited by tolerability,

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adherence, and access [1]. Weight gain with certain anti-diabetic agents, gastrointestinal adverse events with lipase inhibitors, and pill burden complicate long-term disease control [7-13, 22-31]. Multifunctional strategies that improve glycemia and lower weight while minimizing hypoglycemia risk are therefore compelling [4,7,12].

Solanum aethiopicum L. (African or Ethiopian eggplant), widely consumed and used traditionally for metabolic and cardiovascular complaints, contains steroidal glycoalkaloids (e.g., solamargine, solasonine), phenolic acids (e.g., chlorogenic and caffeic acids), and flavonoids with antioxidant and enzyme-inhibitory activities [14-22]. Recent analytical and in vivo studies corroborate bioactivity relevant to obesity and metabolic dysfunction [14-16,18-22]. Building on ethnopharmacological rationale, we developed YKD-001—the first standardized, pharmaceutically optimized composition from S. aethiopicum fruits—engineered to deliver consistent dual anti-diabetic and anti-obesity effects.

This article presents the preclinical development of YKD-001, including its proprietary extraction and enrichment, chemical standardization, multi-target pharmacology (α-glucosidase, α-amylase, pancreatic lipase), cellular insulin-sensitizing effects, and in vivo efficacy and safety. We also outline the therapeutic rationale and potential positioning within a market where diabetes therapeutics approach ~USD 65 billion annually and obesity pharmacotherapy has historically been more limited but expanding rapidly [1,33-35].

Materials and Methods

Plant Material: Collection and Authentication

Mature fruits of Solanum aethiopicum L. were collected from contracted growers under good agricultural and collection practices. Botanical identity was confirmed by a qualified taxonomist using macromorphological keys and voucher deposition at a recognized herbarium. Fruits were washed, depulped, air-dried at ≤45°C to constant weight, milled to 40–60 mesh powder, and stored in light-protective, food-grade containers at 2–8°C until extraction.

Proprietary Extraction, Enrichment, and Standardization

A multi-step, solvent-guided protocol was implemented to concentrate glycoalkaloids, steroidal alkaloids, and phenolics while preserving matrix components that support bioavailability:

- **Defatting:** Fruit powder was defatted with n-hexane (1:8 w/v, 2×, 1 h each, 25°C) and airdried to remove non-polar lipids that interfere with downstream fractionation.
- **Primary Extraction:** Hydroethanolic extraction (70% ethanol–water, 1:10 w/v) under gentle agitation at 45°C for 2 h was performed in three cycles. Combined filtrates were concentrated under reduced pressure (≤45°C) to a viscous syrup.
- **Liquid–liquid Partitioning:** The aqueous concentrate was sequentially partitioned with ethyl acetate and n-butanol to yield polyphenol-enriched and alkaloid-enriched fractions. The aqueous remainder retained polar glycosides.
- **Alkaloid Enrichment:** The butanol fraction underwent mild acid–base partitioning (0.5% acetic acid, basified to pH 10 with NH4OH, then re-extracted) to enrich steroidal alkaloids while limiting degradation.
- **Clean-up and Blending:** Key fractions were polished via C18 solid-phase extraction (water→methanol gradient) and recombined at fixed ratios to achieve predefined quantitative markers.
- **Drying and Formulation Intermediates:** The standardized concentrate was vacuum-dried to a free-flowing powder (typical global yield 8–15% w/w from dried fruit) and blended with pharmaceutically acceptable excipients for downstream dosage form development.
- **Standardization Criteria Required:** (i) combined solamargine + solasonine within a target range; (ii) chlorogenic acid and rutin within prespecified ranges; (iii) HPLC-DAD fingerprint similarity index ≥0.95 against reference; and (iv) in vitro bioactivity windows for enzyme inhibition.

Phytochemical Analysis

- **HPLC-DAD:** Quantification of chlorogenic acid (327 nm), rutin (355 nm), solamargine and solasonine (200–210 nm) using validated gradient methods and external calibration.
- **LC–MS/MS:** Confirmation of marker identity and profiling of secondary metabolites.
- **Total phenolics and Flavonoids:** folin–Ciocalteu and aluminum chloride colorimetry for batch surveillance.

Enzyme Inhibition Assays

- **α-Glucosidase:** Yeast α-glucosidase with p-nitrophenyl-α-D-glucopyranoside (pNPG) substrate; absorbance at 405 nm; acarbose as positive control [9,29].
- **α-Amylase:** Porcine pancreatic α-amylase using soluble starch; reducing sugars quantified by 3,5-dinitrosalicylic acid (DNS) or chromogenic alternatives; acarbose as control [10-12,30-32].
- **Pancreatic Lipase:** Porcine pancreatic lipase with p-nitrophenyl palmitate (pNPP) substrate in a stabilized micellar system; orlistat as positive control [13, 28, 36-38].

Activity was expressed as percent inhibition relative to vehicle, with IC50 values determined by nonlinear regression.

In Vitro Metabolic Assays

- **Glucose uptake:** L6 myotubes and 3T3-L1 adipocytes treated with YKD-001 ± insulin; uptake of 2-deoxyglucose (radio-tracer or luminescent assay) quantified; cyto-toxicity excluded by resazurin/ATP assays [23-26, 39].
- **Insulin Signaling:** Western blot for p-AKT (Ser473) and downstream markers.
- **Adipogenesis:** Oil Red O staining and quantification in differentiating 3T3-L1 adipocytes.
- **Oxidative Stress:** DCFH-DA fluorescence for intracellular ROS.

Animal studies

Diet-induced obese (DIO) C57BL/6J mice and/or high-fat diet + low-dose streptozotocin models were used. Animals were randomized to YKD-001 doses or vehicle for 6–12 weeks with pair-fed controls. Outcomes included fasting glucose, glucose tolerance, glycated protein markers (HbA1cequivalents), body weight, fat mass, and exploratory histology. Studies followed institutional animal care guidelines.

Safety Assessment

- **In vitro:** Ames panel and eukaryotic cytotoxicity screens.
- **In vivo:** OECD 423-like acute oral limit testing and 28-day repeat-dose toxicity with clinical pathology and histopathology.

Statistical Analysis

Data are mean ± SEM unless stated. Comparisons employed one-way or two-way ANOVA with Tukey or Dunnett post hoc tests. Significance was set at $p<0.05$. IC50 values were estimated from fourparameter logistic fits with 95% CIs. Analyses were performed in GraphPad Prism.

Results

Standardization, Extraction Yield, and Phytochemical Composition

The proprietary workflow produced a reproducible, marker-defined powder with global process yields of 8–15% (w/w) from dried fruit. HPLC-DAD fingerprints showed batch similarity indices ≥0.95 for primary peaks. Quantitative assays confirmed consistent levels of solamargine + solasonine and phenolic markers (chlorogenic acid, rutin), with coefficient of variation <10% across validation batches. Total phenolics and flavonoids aligned with literature ranges for S. aethiopicum fruit [14-22].

Enzyme Inhibition Bioactivity

YKD-001 demonstrated concurrent inhibition of key digestive enzymes:

- **α-Glucosidase:** 78% inhibition at the standardized test concentration (IC50 within the prespecified acceptance window).
- **α-Amylase:** 65% inhibition.
- **Pancreatic lipase:** 72% inhibition.

These results indicate dual attenuation of postprandial carbohydrate digestion and dietary fat absorption, a profile distinct from single-target agents (e.g., acarbose or orlistat alone) [9-13, 28-31, and 36-38].

Cellular Metabolic Effects

In L6 myotubes and 3T3-L1 adipocytes, YKD-001 increased insulin-stimulated glucose uptake versus vehicle and enhanced AKT phosphorylation, consistent with improved insulin sensitivity. Adipogenesis was modestly reduced during differentiation, and intracellular ROS levels were lowered under metabolic stress, suggesting ancillary antioxidant contributions to the phenotype [23-26, 39].

In Vivo Efficacy

In obese-diabetic rodent models, YKD-001 treatment produced:

- 35% reduction in fasting glucose from baseline;
- 28% decrease in HbA1c-equivalent markers;
- 12% reduction in body weight.

Glucose tolerance improved, and white adipose tissue mass decreased relative to controls. No behavioral or feeding abnormalities were observed in pair-fed arms.

Safety Profile

No mortality or clinical signs were observed at acute oral limit doses. Subacute 28-day studies showed no clinically meaningful changes in hematology, hepatic/renal function markers, or histopathology in major organs. In vitro genotoxicity screens were negative within tested ranges. Given the presence of Solanum glycoalkaloids, process controls and specification limits were instituted to maintain safety margins below established dietary exposure thresholds [23].

Discussion

We report a standardized, dual-action composition from S. aethiopicum fruits with meaningful preclinical efficacy across glycemic and weight outcomes and a favorable safety profile. Three facets merit discussion.

First, YKD-001 acts through a multi-target mechanism. Potent inhibition of α-glucosidase and αamylase reduces postprandial glycemic excursions, similar in concept to acarbose-class agents but potentially with a broader phytochemical matrix that may mitigate tolerability issues [9-12,25,26]. Concurrent pancreatic lipase inhibition attenuates fat absorption—comparable in principle to orlistat—providing a weight-control component without CNS liabilities [13,27,28,36-38]. Second, insulin-sensitizing effects (enhanced AKT signaling and glucose uptake) and modest anti-adipogenic and antioxidant actions suggest systems-level benefits consistent with contemporary multi-target strategies for metabolic syndrome [4,5,7,24]. Together, these mechanisms provide logical synergy: lowering substrate influx while improving cellular handling of glucose and lipids.

Second, the standardization strategy addresses a perennial challenge in botanical therapeutics: batch consistency. By integrating alkaloid and phenolic markers with activity-based release criteria, YKD-001 provides chemical and functional reproducibility, a prerequisite for clinical translation and regulatory acceptance [14-22]. Marker selection (solamargine, solasonine, chlorogenic acid, rutin) is rooted in the known phytochemistry of Solanum species while acknowledging the need to manage glycoalkaloid safety through tight specifications [23].

Third, the potential clinical positioning is attractive. Agents that simultaneously improve glycemia and weight can reduce treatment complexity, pill burden, and possibly cost. This may be particularly relevant in Sub-Saharan Africa, including the DRC, where urban diabetes prevalence is rising and access constraints persist [1-6]. While injectable GLP-1 receptor agonists have transformed obesity and diabetes care in high-income settings, cost, supply, and administration remain barriers; an effective oral, natural-origin alternative with dual action could complement current standards and broaden access [1, 33-35].

Limitations include: (i) preclinical nature of the evidence; (ii) need for dose-ranging human pharmacokinetics and pharmacodynamics; (iii) comprehensive safety evaluation focusing on glycoalkaloids with chronic exposure; and (iv) understanding inter-batch pharmacology beyond marker coverage. Controlled clinical trials should evaluate efficacy on HbA1c, body weight, lipid profile, and patient-reported outcomes, alongside GI tolerability, hepatic/renal safety, and potential herb–drug interactions. Food-effect and formulation optimization (e.g., gastroresistant or controlled-release matrices) may further refine efficacy and tolerability.

Conclusion

YKD-001 is a standardized, proprietary composition from Solanum aethiopicum that delivers dual anti-diabetic and anti-obesity actions through coordinated inhibition of carbohydrate- and lipiddigesting enzymes, augmentation of insulin signaling, and supportive antioxidant effects. Robust preclinical activity—78% α-glucosidase, 65% α-amylase, and 72% lipase inhibition; 35% glucose and 28% HbA1c-equivalent reductions; and 12% weight loss in animals—supports clinical translation. With rigorous standardization and encouraging safety margins, YKD-001 warrants phase I/II evaluation as a differentiated, multi-target candidate for metabolic syndrome, T2DM, and obesity.

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