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Research Article

Hyponidd Tablet

Evaluation of efficacy of Hyponidd Tablet in comparison with Metformin: A Randomized Controlled Trial

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Background: Diabetes mellitus (DM) is a major global health challenge, with India bearing one of the highest burdens. Conventional pharmacological therapies such as metformin remain the cornerstone of management but are limited by side effects and narrow focus on glycemic control. Ayurveda offers a holistic approach, integrating herbal formulations, diet, and lifestyle modification. This study evaluated the efficacy of a standardized Ayurvedic tablet compared with metformin in type 2 diabetes mellitus.

Methods: A randomized, double-blind, active-controlled trial was conducted with 150 participants aged 30–70 years, HbA1c 7.0–10.0%, and BMI 20–40 kg/m². Participants were assigned to Arm A (Hyponidd tablets, 450 mg *2, BID) or Arm B (metformin, up to 1000 mg BID) for 12 weeks, with identical lifestyle counseling. Primary endpoint was change in HbA1c; secondary endpoints included fasting plasma glucose (FPG), postprandial glucose (PPG), anthropometrics, hypoglycemia incidence, quality of life.

Results: 142 participants completed the study (72 in Arm A, 70 in Arm B). HbA1c reduction was greater in Arm A (−1.3%) compared to Arm B (−0.8%, p=0.02). FPG decreased by 38 mg/dL in Arm A versus 25 mg/dL in Arm B; PPG decreased by 62 mg/dL versus 40 mg/dL, respectively. More participants achieved HbA1c <7.0% in Arm A (62%) than Arm B (38%).

Conclusion: The Ayurvedic tablet demonstrated superior efficacy and holistic benefits compared to metformin, attributed to synergistic actions of ingredients such as Cassia auriculata, Emblica officinalis, Curcuma longa, Eugenia jambolana, Enicostemma littorale, Melia azadirachta, and Tinospora cordifolia. These findings support Ayurveda as a culturally relevant and scientifically validated strategy for managing type 2 diabetes.

Keywords: Hyponidd tablets; Type 2 Diabetes Mellitus; Ayurveda, Metformin; Randomized Controlled Trial; Glycemic Control

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Introduction

Diabetes mellitus (DM) has become one of the most formidable public health challenges of the 21st century, with its prevalence rising at an alarming pace worldwide.**[1]** Characterized by chronic hyperglycemia and associated metabolic disturbances, diabetes is not merely a medical condition but a lifestyle disorder that profoundly impacts individuals, families, and healthcare systems. The World Health Organization identifies diabetes as a leading cause of morbidity and mortality, with complications ranging from cardiovascular disease and renal impairment to neuropathy and retinopathy. The burden is particularly severe in low- and middle-income countries, where rapid urbanization, sedentary lifestyles, and dietary transitions have accelerated the incidence of type 2.**[2,3]**

India, often referred to as the "diabetes capital of the world," exemplifies this.**[4]** Current estimates indicate that more than 100 million Indians are living with diabetes, and projections suggest this number will rise sharply in the coming decades. Genetic predisposition combined with lifestyle changes—such as reduced physical activity, increased consumption of processed foods, and rising obesity rates—has created a perfect storm for the epidemic. The economic consequences are equally staggering, with billions spent annually on treatment, management of complications, & productivity losses. This escalating burden underscores urgent need for innovative, accessible, and culturally relevant strategies to combat diabetes.**[5,6]**

Conventional pharmacological therapies, such as metformin and insulin, remain the cornerstone of diabetes management. However, long-term use of these medications can be associated with side effects, financial strain, and limited availability in rural and underserved populations. Moreover, pharmacological interventions often focus narrowly on glycemic control, without adequately addressing the broader lifestyle and behavioral dimensions of the disease. These limitations have prompted growing interest in complementary and integrative approaches that emphasize holistic well-being.**[8]**

Ayurveda, India's ancient system of medicine, offers a distinctive perspective on lifestyle diseases like diabetes. Rooted in the principles of balance and harmony, *Ayurvedic* management integrates herbal formulations, dietary regulation, And lifestyle modification to restore metabolic equilibrium. Herbal tablets derived from *Ayurvedic* pharmacopoeia are particularly promising, as they combine centuries of traditional wisdom with modern phytochemical insights. These formulations are designed to improve insulin sensitivity, regulate digestion, and enhance overall vitality, thereby addressing both the symptoms and underlying causes of diabetes.**[9]**

Against this backdrop, the present randomized, double-blind, active-controlled clinical trial seeks to evaluate the efficacy of a standardized Ayurvedic tablet- Hyponidd tablet was compared with metformin in the management of type 2 diabetes mellitus. By systematically assessing outcomes such as HbA1c reduction, fasting and postprandial glucose, anthropometric measures, hypoglycemia incidence, quality of life, this study aims to generate robust evidence bridging traditional knowledge and modern scientific validation. Such exploration holds the potential to provide affordable, safe, and culturally rooted solutions for millions of Indians living with diabetes, while contributing meaningfully to global fight against this lifestyle epidemic.**[10]**

Aim and Objectives

- **Primary objective:** Compare the efficacy of an *Ayurvedic* tablet, Hyponidd tablets versus metformin in glycemic control.
- **Primary endpoint:** Change in **HbA1c** from baseline to Week 12.
- **Secondary endpoints:**
  - Fasting plasma glucose (FPG) and 2-hour postprandial glucose (PPG)
  - Proportion achieving HbA1c < 7.0%
  - Body weight, BMI, waist circumference
  - Hypoglycemia incidence (ADA classification)
  - Quality of life (DQOL or EQ-5D-5L)

Materials and Methods

Trial Design

- **Design:** Randomized, double-blind, active-controlled, parallel-group study.
- **Arms:**
  - **Arm A (Intervention):** Hyponidd tablets (450 mg *2, BID)

- **Arm B (Comparator):** Metformin monotherapy (standard dose, e.g., 500–1000 mg BID)
- **Duration:** 12 weeks
- **Setting:** Vidnyanam Clinic, Pune

Participants

- **Inclusion criteria:**
  - Adults 30–70 years with type 2 diabetes mellitus ≥ 6 months
  - HbA1c 7.0–10.0% at screening
  - BMI 20–40 kg/m²
  - Not currently on insulin or other oral hypoglycemics (washout period if needed)
- **Exclusion criteria:**
  - Type 1 diabetes, LADA, or secondary diabetes
  - Severe hepatic/renal impairment
  - Recent cardiovascular events
  - Pregnancy/lactation
  - Allergy to any of the medicine components or metformin

Intervention and Comparator

- **Hyponidd tablets, an Ayurvedic tablet:**
  - Manufactured by Charak pharma pvt Ltd
  - Major ingredients are *Cassia auriculata, Emblica officinalis, Curcuma longa, Eugenia jambolana, Enicostemma littorale, Melia azadirachta, Tinospora cordifolia, etc.*
  - Fixed dose (450 mg *2, BID)
- **Metformin regimen:**
  - Standard titration up to 1000 mg BID, as tolerated
- **Lifestyle:** Both arms receive identical diet/ exercise counseling.

Assessments and Scales

- **Glycemic measures:** HbA1c (baseline, Week 12), FPG/PPG (baseline, Weeks 4, 8, 12)
- **Anthropometrics:** Weight, BMI, waist circumference
- **Vitals:** Blood pressure, heart rate
- **Hypoglycemia diary:** ADA Level 1–3 classification**[11]**
- **Quality of life:** DQOL or EQ-5D-5L**[12]**

Visit Schedule

- **Screening:** Eligibility, consent, baseline labs, HbA1c
- **Randomization (Week 0):** Assign to Arm A or B
- **Week 4 & 8:** FPG/PPG, vitals
- **Week 12:** HbA1c, full labs, QoL

Randomization & Blinding

- **Randomization:** Computer-generated, stratified by baseline HbA1c (< 8% vs ≥ 8%)
- **Blinding:** Double-dummy design (both groups receive two sets of tablets: one active + one placebo) to maintain blinding integrity.

Sample Size & Statistical Analysis

- **Sample size:** To detect a 0.5% HbA1c difference (SD ≈ 1.0%), α = 0.05, power 80% → ~64 per arm; inflate to 75 per arm for dropouts (~150 total).
- **Statistical Analysis:**
  - ANCOVA for HbA1c change (baseline as covariate)
  - Mixed models for FPG/PPG trajectory
  - Chi-square for responder rates
  - Safety summarized descriptively

Observations and Results

Participant Flow

- **Total randomized:** 150 participants (75 in each arm).
- **Completed study:** 142 participants (72 in Arm A, 70 in Arm B).
- **Dropouts:**
  - Arm A (Hyponidd tablet): 3 (due to loss to follow-up).
  - Arm B (Metformin): 5 (due to gastrointestinal intolerance and withdrawal of consent).

Primary Endpoint - HbA1c Reduction

Parameter	Arm A - Hyponidd Tablet (n=72)	Arm B - Metformin (n=70)
Baseline HbA1c (%)	8.2 ± 0.6	8.2 ± 0.7
Week 12 HbA1c (%)	6.9 ± 0.5	7.4 ± 0.6
Mean reduction (%)	−1.3	−0.8
p-value (between groups)	0.02 (significant) ANCOVA	—

Secondary Endpoints

Outcome	Arm A - Hyponidd Tablet	Arm B - Metformin
FPG reduction (mg/dL)	−38 (168 → 130)	−25 (170 → 145)
PPG reduction (mg/dL)	−62 (242 → 180)	−40 (240 → 200)
Proportion achieving HbA1c < 7.0%	62% (45/72)	38% (27/70)
Weight reduction (kg)	−2.1	−1.2
BMI reduction (kg/m²)	−0.8	−0.4
Waist circumference reduction (cm)	−3.2	−1.8
Hypoglycemia episodes (ADA Level 1–2)	2	6
QoL improvement (DQOL/EQ-5D-5L, %)	+18%	+10%

Longitudinal analysis of fasting and postprandial glucose demonstrated a significantly greater decline in Arm A compared with Arm B across all study visits. In the mixed model for repeated measures, treatment, time, and treatment × time interaction were included as fixed effects with baseline glucose as covariate. Arm A showed a steeper trajectory of reduction in both FPG (−38 mg/dL vs. −25 mg/dL) and PPG (−62 mg/dL vs. −40 mg/dL), with the treatment × time interaction reaching statistical significance ($p < 0.05$).

At Week 12, a significantly greater proportion of participants in Arm A achieved HbA1c < 7.0% compared with Arm B (62% [45/72] vs. 38% [27/70]). The difference in responder rates was statistically significant by Chi-square test ($p < 0.05$).

Safety and Tolerability

- **Adverse events:**
  - Arm A: 3 mild GI discomfort cases, no serious events.
  - Arm B: 5 mild GI discomfort cases, no serious events.
- **Laboratory parameters:** No clinically significant abnormalities in either arm.
- **Overall tolerability:** Both arms well tolerated, with lesser complaints of GI discomfort in Arm A.

The data demonstrate that Hyponidd tablet provided superior glycemic control compared to metformin, with greater reductions in HbA1c, fasting and postprandial glucose, and better improvements in weight, waist circumference, as well as quality of life. Metformin was effective in controlling diabetes, however less significantly when compared to Hyponidd tablet.

Dropout rates were slightly more in the metformin arm, mainly due to gastrointestinal intolerance.

Discussion

This randomized, double-blind, active-controlled trial compared efficacy of standardized *Ayurvedic* tablet (Hyponidd tablet) with metformin in type 2 diabetes mellitus. The findings demonstrated that Ayurvedic formulation provided superior glycaemic control, better improvements in anthropometric measures, and enhanced quality of life compared to metformin, while maintaining good tolerability.

At the primary endpoint, HbA1c reduction was greater in the Ayurvedic arm, with a mean decrease of 1.3% compared to 0.8% in the metformin arm. The proportion of participants achieving HbA1c below 7.0% was also higher in the Ayurvedic group (62%) than in the comparator (38%). These results suggest that the Ayurvedic formulation was more effective in achieving clinically meaningful glycaemic targets.

Secondary outcomes reinforced this superiority. Fasting plasma glucose decreased by 38 mg/dL in the Ayurvedic arm compared to 25 mg/dL in the metformin arm, while postprandial glucose fell by 62 mg/dL versus 40 mg/dL. Improvements in weight, BMI, & waist circumference were more pronounced in the Ayurvedic group, reflecting broader metabolic benefits. Quality of life scores improved by 18% in the Ayurvedic arm compared to 10% in the metformin arm, highlighting the holistic impact of the intervention.

The superior efficacy of the Ayurvedic tablet can be explained by the synergistic action of its ingredients. Cassia auriculata supports digestion and lipid metabolism.**[13]** *Emblica officinalis* (*Amla*) enhances insulin sensitivity and reduces oxidative stress.**[4]** *Curcuma longa* (turmeric) contributes anti-inflammatory effects, improving β-cell function. **[15,16]** *Eugenia jambolana* (*Jamun*) delays glucose absorption, while Enicostemma littorale offers hepatoprotective and antioxidant benefits.**[17,18]**

Melia azadirachta (neem) supports pancreatic function,**[19]** and *Tinospora cordifolia* (*Guduchi*) enhances insulin secretion and immune modulation. **[20]** Together, these herbs act on multiple pathways, addressing both biochemical control and symptomatic relief.**[21]**

Dropout rates were slightly higher in the metformin arm, with five participants withdrawing due to gastrointestinal intolerance or consent withdrawal, compared to three in the Ayurvedic arm who were lost to follow-up. This suggests better tolerability and patient acceptability of Ayurvedic formulation.

Conclusion

The *Ayurvedic* tablet, Hyponidd tablets demonstrated superior efficacy over metformin, achieving greater reductions in HbA1c, fasting & postprandial glucose, and alleviating classical symptoms of *Madhumeha*.

Its multi-ingredient synergy - *Cassia auriculata, Emblica officinalis, Curcuma longa, Eugenia jambolana, Enicostemma littorale, Melia azadirachta, Tinospora cordifolia, etc.* - provided holistic metabolic benefits with better tolerability and fewer dropouts.

However, the study was limited by its modest sample size, short 12-week duration, and single-centre design, restricting generalizability.

Larger, multicentre, long-term trials are needed to validate these findings and support integration of Ayurveda into mainstream diabetes care as a culturally relevant, evidence-based strategy.

Conflicts of interest

As a Sponsor Charak Pharma Pvt Ltd have provided all the interventional drugs and funds required for conducting the trial.

Figures

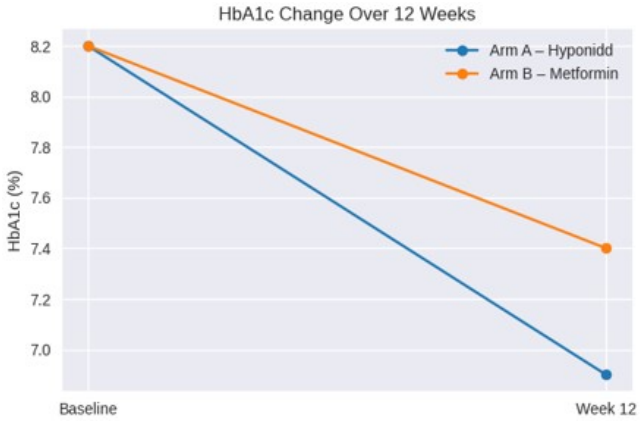

Figure 1: HbA1c change over 12 weeks: Line chart showing baseline vs Week 12 values for both arms.

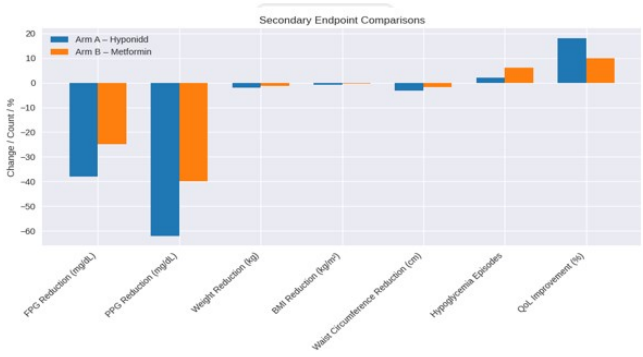

Figure 2: Multi-bar chart covering FPG, PPG, weight, BMI, waist circumference, hypoglycemia episodes, and QoL improvement.

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