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Efficacy of Neem (Azadirachta Indica) in Regulating Blood Glucose Levels: A Study on Food-Induced Diabetes in Patna

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ABSTRACT

Diabetes mellitus, a chronic metabolic disorder characterized by elevated blood glucose levels, is a growing public health concern worldwide. This study investigates the hypoglycemic potential of Neem (Azadirachta indica) leaf extract in individuals with food-induced Type 2 Diabetes Mellitus (T2DM) through a randomized controlled trial (RCT) conducted in Patna, India. A total of 20 participants were randomly assigned to two groups: the control group (n = 10), which received standard diabetic medication and lifestyle modifications, and the experimental group (n = 10), which received 500 mg/day of Neem leaf extract in addition to standard treatment. Blood glucose levels were assessed at baseline, week 4, and week 8, measuring fasting blood glucose (FBG), postprandial blood glucose (PPBG), glycated hemoglobin (HbA1c), and insulin resistance (HOMA-IR index). Results demonstrated a statistically significant reduction in both FBG and PPBG levels in the experimental group compared to the control group ($p < 0.05$). The study attributes Neem's hypoglycemic effects to its bioactive compounds, which enhance insulin sensitivity, reduce oxidative stress, and improve pancreatic β-cell function. These findings indicate that Neem may serve as an effective adjunct therapy for managing diabetes. However, further large-scale, long-term clinical trials are needed to validate its efficacy, safety, and optimal dosage. If proven effective, Neem could emerge as a natural, cost-effective intervention in diabetes management, particularly in resource-limited settings.

Keywords: *Neem; Azadirachta indica; Blood Glucose; Diabetes; Insulin Sensitivity; Herbal Medicine*

INTRODUCTION

Diabetes mellitus is a chronic metabolic disorder that affects millions of people worldwide. It is characterized by persistently elevated blood glucose levels due to impaired insulin secretion, insulin resistance, or both. The disorder is classified into several types, with Type 2 diabetes mellitus (T2DM) being the most common form. This type of diabetes is closely linked to lifestyle factors, including poor dietary habits, sedentary lifestyles, and obesity. One of the emerging concerns in urban areas like Patna is the increasing prevalence of food-induced diabetes, which results from excessive consumption of high-calorie diets rich in refined carbohydrates, fats, and sugars.

The Growing Burden of Diabetes in India

India has often been referred to as the "Diabetes Capital of the World" due to the rapid increase in diabetes cases. According to the International Diabetes Federation (IDF), India had approximately **77** million diabetic patients as of 2020, and this number is expected to rise significantly in the coming years. Urbanization, economic growth, and changes in dietary patterns have contributed to this surge. Patna, the capital city of Bihar, is no exception. With increasing urbanization, a rise in fast-food consumption, and reduced physical activity, diabetes has become a pressing public health issue in the region.

In cities like Patna, many individuals consume carbohydrate-heavy meals, deep-fried snacks, and sugary beverages, leading to insulin resistance and weight gain. Moreover, lack of awareness about healthy dietary practices and limited access to affordable healthcare further exacerbate the problem. Managing diabetes in such populations requires an

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integrative approach, including lifestyle modifications, pharmacological interventions, and potential natural remedies like Neem.

Pathophysiology of Diabetes and the Role of Insulin

The normal regulation of blood glucose levels depends on the hormone insulin, which is produced by the β-cells of the pancreas. Insulin facilitates glucose uptake by body cells, ensuring stable blood sugar levels. In diabetic individuals, either the pancreas fails to produce sufficient insulin (Type 1 diabetes) or the body's cells become resistant to insulin's effects (Type 2 diabetes). Over time, uncontrolled hyperglycemia can lead to severe complications such as:

- **Cardiovascular diseases** (heart attacks, strokes)
- **Diabetic neuropathy** (nerve damage leading to numbness or pain)
- **Diabetic nephropathy** (kidney damage)
- **Diabetic retinopathy** (vision impairment or blindness)
- **Poor wound healing**, increasing the risk of infections and amputations

Given the life-threatening nature of diabetes-related complications, finding effective and sustainable treatment options is crucial.

Current Treatments and Their Limitations

The conventional treatment for diabetes includes oral hypoglycemic drugs such as metformin, sulfonylureas, DPP-4 inhibitors, and insulin therapy. While these treatments are effective in controlling blood sugar levels, they often come with side effects such as:

- Gastrointestinal issues (nausea, diarrhea, bloating)
- Weight gain (seen with insulin and sulfonylureas)
- Hypoglycemia (low blood sugar episodes)
- Liver and kidney complications in long-term use

Due to these limitations, there is growing interest in alternative and complementary therapies, particularly those based on medicinal plants with proven hypoglycemic effects. One such plant that has gained significant attention is Neem (*Azadirachta indica*).

Neem (*Azadirachta indica*): A Potential Natural Remedy for Diabetes

Neem is a well-known medicinal plant that has been extensively used in traditional Indian and Ayurvedic medicine for centuries. Various parts of the Neem tree, including its leaves, bark, seeds, and flowers, possess antimicrobial, anti-inflammatory, antioxidant, and hypoglycemic properties. The active bio-compounds found in Neem include:

- Nimbin and Nimbidin (anti-inflammatory agents)
- Gedunin and Salannin (antioxidant and antibacterial properties)
- Flavonoids and Glycosides (help regulate blood sugar levels)

  Several studies have indicated that Neem extracts can effectively lower blood glucose levels by:

- Enhancing insulin sensitivity
- Stimulating pancreatic β-cells to produce insulin
- Reducing oxidative stress in diabetic individuals
- Inhibiting glucose absorption in the intestine

  Due to these properties, Neem is considered a promising natural therapy for diabetes management.

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Scientific Studies on Neem and Diabetes

Research studies conducted in India and various parts of the world have demonstrated the significant potential of Neem (Azadirachta indica) in managing diabetes. The therapeutic properties of Neem have been attributed to its rich phytochemical composition, including flavonoids, triterpenoids, and glycosides, which contribute to its antidiabetic effects. Several scientific investigations have explored the impact of Neem extracts on glucose metabolism, insulin sensitivity, and pancreatic health, providing promising insights into its role as an alternative or complementary therapy for diabetes treatment.

One of the earliest and most notable studies on Neem's antidiabetic properties was published in the Journal of Ethnopharmacology in 2012. This study focused on the effects of Neem leaf extract on diabetic rats and reported a significant reduction in fasting blood glucose levels. The findings suggested that bioactive compounds in Neem might enhance insulin secretion, improve glucose uptake, or inhibit key enzymes involved in carbohydrate metabolism. The study further indicated that Neem's hypoglycemic effects were comparable to some conventional oral antidiabetic drugs, making it a potential natural remedy for diabetes management. The clinical trials have also provided encouraging results regarding Neem's efficacy in diabetes treatment. A clinical study conducted in India in 2018 examined the effects of Neem capsules (500 mg/day) on patients diagnosed with type 2 diabetes. The participants who consumed Neem capsules for eight weeks showed significant improvements in glucose metabolism and insulin sensitivity. The results suggested that Neem supplementation could help regulate blood sugar levels and reduce insulin resistance, potentially lowering the risk of diabetes-related complications. The researchers also observed no severe side effects, indicating the safety and tolerability of Neem in controlled doses.

Further supporting evidence was presented in a 2020 study published in the Journal of Medicinal Plants Research. This study investigated the protective effects of flavonoid-rich extracts of Neem on pancreatic β-cells. Oxidative stress is a critical factor in diabetes progression, leading to β-cell dysfunction and reduced insulin production. The study revealed that Neem's antioxidant properties could mitigate oxidative damage, thereby preserving β-cell function and preventing the progression of diabetes. This finding is particularly significant, as β-cell protection is essential for maintaining insulin homeostasis and delaying the onset of complications associated with diabetes.

Collectively, these research studies highlight the immense potential of Neem as an adjunct therapy for diabetes management. Its natural composition, coupled with its ability to regulate glucose levels, improve insulin sensitivity, and protect pancreatic cells, makes it a valuable option, especially in regions where access to pharmaceutical medications may be limited. The growing body of scientific evidence underscores the need for further clinical research to explore the optimal dosage, long-term effects, and mechanisms of action of Neem in human diabetes management. If validated through large-scale studies, Neem could emerge as a cost-effective and sustainable alternative for individuals seeking natural solutions for diabetes control.

Rationale for This Study

Despite the promising results of Neem in diabetes research, there remains a significant gap in clinical data regarding its effectiveness in urban Indian populations, particularly among individuals with food-induced diabetes. Lifestyle-related diabetes, primarily driven by high-carbohydrate diets, processed foods, and sedentary habits, has been increasing at an alarming rate in cities like Patna. The rising prevalence of diabetes in the region highlights the urgent need for alternative and complementary therapies that are both effective and accessible. Given Neem's well-documented hypoglycemic properties, this study seeks to explore its potential in controlling blood glucose levels among individuals affected by diet-induced diabetes.

The primary objective of this research is to evaluate the hypoglycemic effects of Neem in individuals with food-induced diabetes in Patna. Traditional medicinal systems have long recognized Neem as a powerful natural remedy for blood sugar regulation, but its efficacy in urban populations following modern dietary patterns remains largely unexplored. By administering standardized Neem extracts or capsules, this study will assess whether its bioactive compounds can significantly reduce fasting and postprandial glucose levels in affected individuals. Another key aim of the study is to compare blood glucose regulation between Neem-treated patients and those receiving conventional therapy alone. While pharmaceutical antidiabetic medications such as metformin and sulfonylureas are widely used, they may cause side effects or fail to provide adequate glycemic control in some individuals. By conducting a comparative analysis, this research will determine whether Neem can serve as an effective adjunct to conventional treatment or even as a standalone therapy in certain cases. The study will track parameters such as glycated hemoglobin (HbA1c) levels, fasting blood sugar (FBS), and postprandial glucose levels over a specified period.

Beyond immediate glycemic control, the study also aims to assess the long-term impact of Neem on insulin sensitivity and overall metabolic health. Insulin resistance is a major contributor to type 2 diabetes, and research suggests that Neem's antioxidant and anti-inflammatory properties may help enhance insulin sensitivity over time. By monitoring

insulin levels, lipid profiles, and markers of oxidative stress, this study will provide insights into Neem's broader metabolic benefits. Additionally, potential improvements in body weight, cholesterol levels, and cardiovascular markers will be analyzed to determine if Neem contributes to overall diabetes management beyond glucose regulation.

By conducting a controlled study on Neem's efficacy in regulating blood glucose levels among food-induced diabetes patients in Patna, this research hopes to bridge the gap between traditional herbal medicine and modern diabetes management. The findings could contribute valuable insights into the role of natural therapies in complementing pharmaceutical interventions, offering a cost-effective and sustainable approach to diabetes care in urban settings. If Neem proves effective, it may pave the way for larger clinical trials and increased integration of herbal medicine into mainstream diabetes treatment protocols.

Research Questions and Hypotheses

This study is grounded in a well-defined hypothesis that seeks to determine the effectiveness of Neem in managing blood glucose levels among individuals with food-induced diabetes. The null hypothesis (H_0) posits that Neem has no significant effect on blood glucose regulation, implying that any observed changes in blood sugar levels among participants consuming Neem would be due to random variation rather than a direct therapeutic benefit. In contrast, the alternative hypothesis (H_1) suggests that Neem significantly reduces blood glucose levels and enhances insulin function, indicating that its bioactive compounds may actively contribute to improved glycemic control. To test these hypotheses, the study will employ a controlled experimental design, comparing the fasting blood sugar (FBS), postprandial glucose, glycated hemoglobin (HbA1c), and insulin sensitivity markers between participants who consume Neem extracts and those undergoing conventional diabetes treatment. Statistical analysis will determine whether any observed differences are significant, thereby either validating or refuting Neem's potential as an effective adjunct therapy for diabetes management. The outcome of this research will provide critical insights into the feasibility of incorporating Neem into urban diabetes treatment strategies, particularly for individuals affected by dietary habits prevalent in cities like Patna.

LITERATURE REVIEW

Diabetes mellitus is a chronic metabolic disorder characterized by persistent hyperglycemia due to impaired insulin production, insulin resistance, or both. The growing prevalence of diabetes, particularly in urban regions like Patna, has led to increased interest in alternative and complementary therapies. Medicinal plants have been widely explored as potential therapeutic agents for diabetes management, with Neem (Azadirachta indica) emerging as a promising candidate. Previous studies have investigated Neem's role in glucose metabolism, its ability to enhance insulin secretion, reduce oxidative stress, and improve pancreatic β-cell function. However, limited research has focused on its effectiveness in managing food-induced diabetes in Indian urban populations. This section provides a comprehensive review of existing literature on Neem's anti-diabetic properties, its biochemical mechanisms, and its potential role in diabetes management.

Neem (*Azadirachta indica*): A Medicinal Plant with Therapeutic Potential

Neem is a widely used medicinal plant in Ayurvedic and traditional Indian medicine. Various parts of the Neem tree, including its leaves, seeds, bark, and flowers, have been recognized for their antimicrobial, anti-inflammatory, antioxidant, hepatoprotective, and hypoglycemic properties (Bandyopadhyay et al., 2019). Neem contains bioactive compounds such as flavonoids, tannins, glycosides, and alkaloids, which contribute to its medicinal properties (Kumar et al., 2021). The ability of Neem to regulate blood glucose levels has been attributed to its influence on insulin secretion, glucose metabolism, and oxidative stress reduction.

The Role of Neem in Glucose Metabolism

Several studies have demonstrated that Neem plays a critical role in regulating glucose metabolism by enhancing insulin sensitivity, stimulating pancreatic β-cells, and inhibiting glucose absorption in the intestine.

- **Insulin Secretion Enhancement:** A study by Gupta et al. (2020) found that Neem extract significantly improved insulin secretion from pancreatic β-cells in diabetic rats. The study indicated that compounds in Neem, particularly flavonoids, activate AMP-activated protein kinase (AMPK) pathways, which are crucial for insulin production and glucose uptake.
- **Glucose Uptake and Utilization:** Research by Sharma et al. (2018) revealed that Neem leaf extract enhances glucose uptake in skeletal muscles, similar to the action of insulin. The study suggested that Neem helps improve glucose transporter-4 (GLUT4) translocation, a key mechanism in insulin-mediated glucose uptake.

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- **Gastrointestinal Glucose Absorption:** Patel et al. (2017) demonstrated that Neem extract inhibits α-glucosidase and α-amylase enzymes, thereby reducing the digestion and absorption of carbohydrates in the intestine. This mechanism helps prevent postprandial (after-meal) blood sugar spikes.

These findings support the hypothesis that Neem can act as a natural hypoglycemic agent by improving insulin secretion, enhancing glucose utilization, and reducing intestinal glucose absorption.

Neem and Pancreatic β-Cell Function

The dysfunction and destruction of pancreatic β-cells play a crucial role in diabetes progression. Studies have shown that oxidative stress and chronic inflammation contribute to β-cell damage, leading to impaired insulin secretion (Tripathi et al., 2022). Neem's antioxidant properties have been extensively studied in this context. A study by Verma et al. (2019) found that Neem reduces oxidative stress by scavenging free radicals and increasing the production of antioxidant enzymes such as superoxide dismutase (SOD), catalase (CAT), and glutathione peroxidase (GPx). This protective mechanism helps prevent β-cell damage and preserves insulin production. Jain et al. (2021) conducted a study demonstrating that Neem extracts reduce pro-inflammatory cytokines, including TNF-α, IL-6, and IL-1β, which are known to contribute to insulin resistance and pancreatic dysfunction.

Neem and Oxidative Stress in Diabetes

Oxidative stress plays a significant role in diabetes-induced complications, including cardiovascular diseases, neuropathy, and nephropathy (Kaur et al., 2020). Neem's antioxidant properties make it a potential therapeutic agent for mitigating these complications.

Reduction of Reactive Oxygen Species (ROS): Studies have shown that diabetic patients have increased levels of ROS, leading to cellular damage. A study by Bose et al. (2020) reported that Neem extract reduces ROS production and increases the levels of endogenous antioxidants, thereby preventing oxidative damage. According to Singh et al. (2018), Neem supplementation in diabetic rats led to reduced lipid peroxidation, which is crucial for preventing diabetes-related cardiovascular complications.

Clinical Studies on Neem and Diabetes

Despite extensive animal studies, clinical research on Neem's effects in human diabetic populations is limited. Some notable clinical studies include:

- A study by Ramesh et al. (2021) found that patients who consumed Neem leaf powder (500 mg/day) for 12 weeks showed a 15% reduction in fasting blood glucose levels compared to a control group.
- A randomized clinical trial by Desai et al. (2020) observed that Neem supplementation, in combination with standard diabetic medication, led to better glycemic control and improved HbA1c levels.
- A review by Mishra et al. (2019) suggested that Neem-based formulations could serve as complementary therapy for diabetes management, particularly in regions with limited access to conventional medication.

  Most studies lack large sample sizes and long-term follow-ups, highlighting the need for further research.

The Gap in Research: Neem and Food-Induced Diabetes in Urban Indian Populations

While several studies have confirmed the anti-diabetic effects of Neem, very few have focused on food-induced diabetes, particularly in urban Indian populations like Patna. Studies indicate that urban populations are at a higher risk of developing diabetes due to increased consumption of processed foods, sugary beverages, and high-fat diets (Ghosh et al., 2021). However, limited research has explored the role of natural interventions like Neem in managing food-induced diabetes in such populations. Neem is already an integral part of traditional Indian medicine and is widely available in urban and rural areas. Understanding its effects in urban diabetic patients can help promote cost-effective and culturally appropriate diabetes management strategies.

MATERIALS AND METHODS

Study Design

This study was designed as a randomized controlled trial (RCT) in Patna, India, with the primary aim of evaluating the efficacy of Neem (Azadirachta indica) leaf extract in managing blood glucose levels among patients diagnosed with food-induced diabetes. A total of 20 participants were recruited and randomly assigned to one of two groups to ensure an unbiased comparison of outcomes. The Control Group (n = 10) followed conventional diabetes management

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protocols, which included standard prescribed medication (such as metformin or other oral hypoglycemic agents) and recommended lifestyle modifications, including dietary adjustments and physical activity. Meanwhile, the Experimental Group (n = 10) received the same standard diabetic medication and lifestyle interventions but with the addition of Neem leaf extract (500 mg/day) as a dietary supplement. The study was conducted over a period of eight weeks, during which participants underwent regular monitoring of their fasting blood sugar (FBS), postprandial blood glucose levels, and glycated hemoglobin (HbA1c) to assess changes in glycemic control. Additionally, insulin sensitivity markers and lipid profiles were measured to evaluate any broader metabolic benefits of Neem supplementation. The trial was structured to maintain rigorous scientific validity, with participants and healthcare professionals blinded to the treatment allocations to minimize bias. By comparing the outcomes between the two groups, this study aimed to provide empirical evidence regarding Neem's potential role as an adjunct therapy for diabetes management, particularly in individuals whose condition is influenced by dietary factors.

Inclusion and Exclusion Criteria

The study carefully selected participants based on specific inclusion and exclusion criteria to ensure a targeted and controlled evaluation of Neem's effects on food-induced Type 2 Diabetes Mellitus (T2DM). The inclusion criteria required participants to be adults aged 30–60 years who had been diagnosed with T2DM primarily due to dietary habits, ensuring that the study focused on cases influenced by urban lifestyle factors. Additionally, participants were required to have HbA1c levels ≥ 6.5%, signifying poor glycemic control, and no prior history of insulin therapy, allowing for an accurate assessment of Neem's role in early to moderate diabetes management. Conversely, the exclusion criteria eliminated individuals whose conditions might confound the results. This included patients with Type 1 diabetes or secondary diabetes, as their insulin-dependent condition differs significantly from T2DM. Furthermore, individuals with chronic medical conditions such as liver disease, kidney disease, or cardiovascular disorders were excluded to prevent potential interactions or complications. Pregnant and lactating women were also excluded to avoid hormonal influences on blood glucose levels that could skew the findings. The study was conducted over a period of eight weeks, with participants undergoing regular blood glucose monitoring, including fasting blood sugar (FBS), postprandial glucose levels, and HbA1c measurements at predefined intervals. By maintaining strict selection criteria and a structured monitoring approach, the study aimed to generate reliable, evidence-based insights into Neem's efficacy as a natural adjunct in diabetes management.

Data Collection

Measurement of Blood Glucose Levels

To ensure precise and reliable measurement of glycemic control, blood glucose levels were assessed using a standardized glucometer, following established clinical protocols. The study focused on four key biochemical parameters to evaluate the impact of Neem supplementation on diabetes management. The first parameter, Fasting Blood Glucose (FBG), was measured after an overnight fast of 8–10 hours, providing an indicator of baseline glucose levels and hepatic glucose production. The second parameter, Postprandial Blood Glucose (PPBG), was recorded two hours after a meal, offering insight into how effectively the body managed glucose intake and insulin response post-consumption. Additionally, the study measured Glycated Hemoglobin (HbA1c%) at both baseline and after 8 weeks, as HbA1c serves as a long-term marker of blood sugar control, reflecting average glucose levels over the past 2–3 months. Lastly, Insulin Resistance was evaluated using the HOMA-IR Index (Homeostatic Model Assessment of Insulin Resistance), a well-established method for quantifying insulin function and sensitivity. By integrating these parameters, the study aimed to comprehensively assess the effectiveness of Neem in lowering blood glucose levels, improving insulin sensitivity, and potentially enhancing overall metabolic health in individuals with food-induced diabetes. Regular monitoring ensured accurate tracking of any physiological changes, thereby strengthening the study's validity and contributing valuable insights into Neem's potential role as an adjunct therapy for diabetes management.

To assess insulin resistance and evaluate the impact of Neem supplementation on metabolic health, the Homeostatic Model Assessment of Insulin Resistance (HOMA-IR) was calculated using the following formula:

$$HOMA - IR = \frac{\text{Fasting Insulin } (\mu U/mL) \times \text{ Fasting Glucose } (mg/dL)}{405}$$

This formula provides an estimate of insulin resistance, a key factor in Type 2 Diabetes Mellitus (T2DM). A HOMA-IR value greater than 2.0 indicates insulin resistance, meaning the body's cells have reduced sensitivity to insulin, leading to higher blood sugar levels. Conversely, a HOMA-IR value less than 2.0 suggests normal insulin sensitivity, where insulin effectively regulates glucose uptake and utilization by cells.

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In this study, baseline HOMA-IR values were recorded for all participants before intervention, and post-intervention values were measured after 8 weeks to determine whether Neem supplementation contributed to improved insulin function. By comparing pre- and post-treatment HOMA-IR levels between the control and experimental groups, the study aimed to establish whether Neem could enhance insulin sensitivity and potentially reduce insulin resistance in individuals with food-induced diabetes. This analysis provided critical insights into Neem's effectiveness not just in lowering blood glucose but also in addressing underlying metabolic dysfunctions associated with diabetes.

Anthropometric and Biochemical Analysis

To comprehensively evaluate the metabolic impact of Neem supplementation, several biochemical and physiological parameters were assessed alongside blood glucose levels.

Serum insulin levels were measured using an ELISA-based method (Enzyme-Linked Immunosorbent Assay), a highly sensitive and specific technique for detecting circulating insulin concentrations in the bloodstream. This helped in assessing insulin secretion and evaluating changes in insulin function post-intervention. A lipid profile test was conducted to measure total cholesterol, triglycerides (TG), low-density lipoprotein (LDL), and high-density lipoprotein (HDL) levels. Since dyslipidemia (abnormal lipid levels) is commonly associated with diabetes and insulin resistance, monitoring these lipid markers provided insights into whether Neem could also improve cardiovascular risk factors in diabetic patients.

To assess body composition and obesity-related risk factors, Body Mass Index (BMI) was calculated for all participants using the standard formula:

$$BMI = \frac{\text{Weight (kg)}}{\text{Height (m)}^2}$$

BMI classification followed widely accepted criteria, where BMI ≥ 25 kg/m² was classified as overweight, and BMI ≥ 30 kg/m² was considered obese. Since excess body weight is a major contributing factor to insulin resistance and Type 2 Diabetes Mellitus (T2DM), tracking BMI helped determine whether Neem supplementation had any indirect effects on weight regulation and metabolic health.

By integrating these biochemical, metabolic, and anthropometric assessments, the study aimed to establish a holistic understanding of Neem's potential as a natural adjunct therapy for diabetes management, extending beyond glycemic control to overall metabolic well-being.

Experimental Procedure

To ensure a standardized and controlled intervention, participants in the experimental group received Neem leaf extract (500 mg/day) in capsule form, taken once daily after meals for a duration of eight weeks. The control group did not receive Neem supplementation but continued with standard diabetic medication and lifestyle modifications. To eliminate potential confounding factors, both groups were instructed to follow a standardized diet plan, designed to maintain consistent macronutrient intake and minimize dietary variations that could influence blood glucose levels. To track changes in glycemic control, insulin function, and metabolic health, blood samples were collected at three key time points throughout the study:

- Baseline (Week 0) – Before the intervention began, initial blood samples were taken to establish a reference for blood glucose levels, insulin resistance, lipid profile, and other metabolic markers.
- Mid-point (Week 4) – A second round of blood sampling was conducted to assess early physiological changes and trends in response to Neem supplementation.
- Final assessment (Week 8) – At the end of the study period, a final set of blood samples was collected to determine the overall efficacy of Neem in improving glycemic and metabolic parameters.

By implementing regular monitoring and controlled dietary conditions, this study aimed to isolate the specific effects of Neem on diabetes management while reducing potential biases. The sequential blood sampling strategy allowed for a progressive analysis of Neem's impact over time, providing valuable insights into its role as a potential adjunct therapy for individuals with food-induced diabetes.

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Statistical Analysis

Data Processing

To ensure statistical accuracy and reliability, all collected data were analyzed using SPSS version 25, a widely used statistical software for biomedical research. The results were expressed as mean ± standard deviation (SD) to provide a clear representation of the data distribution and variability within the study population. Key statistical methods employed in the analysis included:

- Descriptive Statistics – Used to summarize baseline characteristics such as age, BMI, fasting blood glucose, postprandial glucose, HbA1c, insulin levels, and lipid profile.
- Paired t-tests – Applied within each group (control and experimental) to compare pre- and post-intervention values, determining the effectiveness of Neem supplementation over the 8-week period.
- Independent t-tests – Used to compare differences between the experimental group (Neem-treated patients) and the control group, assessing whether Neem had a statistically significant impact on glycemic control and insulin sensitivity.
- ANOVA (Analysis of Variance) – Conducted to evaluate variations in blood glucose levels, HOMA-IR, and lipid profiles across different time points (Week 0, Week 4, and Week 8).
- Pearson's Correlation Analysis – Used to assess relationships between changes in HOMA-IR, BMI, and lipid levels, helping to determine if Neem had secondary benefits beyond blood glucose reduction.

A p-value of < 0.05 was considered statistically significant, indicating that observed changes in glucose metabolism, insulin function, and lipid profile were unlikely due to random chance. By implementing robust statistical analyses, the study aimed to provide scientifically validated evidence on the efficacy of Neem as a complementary treatment for food-induced diabetes in urban Indian populations.

Statistical Tests

To assess the statistical significance of the observed changes in blood glucose regulation and insulin function, the study employed multiple statistical tests using SPSS version 25. These analyses ensured a rigorous evaluation of Neem's impact on diabetes management.

- Paired t-test – This test was used to analyze the difference in blood glucose levels before and after treatment within the same group (experimental and control). It helped determine whether individual participants experienced significant changes in fasting blood glucose (FBG), postprandial blood glucose (PPBG), HbA1c, and insulin resistance (HOMA-IR) after 8 weeks of intervention.
- One-way ANOVA – A one-way Analysis of Variance (ANOVA) was performed to compare mean differences between the control and experimental groups at different time points (Baseline (Week 0), Mid-point (Week 4), and Final (Week 8)). This test was essential to evaluate whether Neem supplementation led to a statistically significant improvement in blood glucose control and insulin sensitivity compared to standard diabetic therapy alone.
- Pearson Correlation Analysis – This statistical test was conducted to examine the relationships between HbA1c levels, insulin resistance (HOMA-IR), and fasting glucose levels. By analyzing these associations, the study aimed to determine whether improvements in glycemic markers were linked to enhanced insulin sensitivity and better metabolic control in Neem-treated individuals.

A p-value < 0.05 was considered statistically significant, meaning that any differences observed were unlikely to have occurred by random chance. By incorporating these robust statistical methods, the study provided strong empirical evidence to evaluate Neem's effectiveness as a complementary therapy for individuals with food-induced Type 2 Diabetes Mellitus (T2DM) in urban Indian settings.

Results Representation

Table 1 presents the mean blood glucose levels in both the control and experimental groups at different time points, highlighting the effects of Neem supplementation on glycemic control. At baseline, there was no significant difference between the two groups in fasting blood glucose (FBG) and postprandial blood glucose (PPBG) levels, as indicated by p-values of 0.78 and 0.65, respectively. However, by Week 4, a significant reduction in both FBG and PPBG was observed in the experimental group, with FBG dropping from 167.8 ± 6.1 mg/dL to 145.3 ± 4.9 mg/dL ($p = 0.02$) and

PPBG decreasing from 212.2 ± 8.1 mg/dL to 185.4 ± 6.7 mg/dL (p = 0.01). The trend continued through Week 8, where the experimental group showed a further decline in FBG (132.1 ± 4.2 mg/dL) and PPBG (171.2 ± 6.3 mg/dL), both of which were significantly lower than the control group, with highly significant p-values of 0.001 and 0.0005, respectively. These results indicate that Neem supplementation had a considerable impact on reducing blood glucose levels over the 8-week period, supporting its potential role in improving glycemic control in individuals with food-induced diabetes show in Table 1 as well as in figure 1.

Table 1: Mean Blood Glucose Levels in Control and Experimental Groups

Time Point	Control Group (mg/dL)	Experimental Group (mg/dL)	p-value
FBG (Baseline)	165.2 ± 5.6	167.8 ± 6.1	0.78
FBG (Week 4)	162.5 ± 5.2	145.3 ± 4.9	0.02*
FBG (Week 8)	158.7 ± 4.8	132.1 ± 4.2	0.001*
PPBG (Baseline)	210.5 ± 7.3	212.2 ± 8.1	0.65
PPBG (Week 4)	205.7 ± 6.9	185.4 ± 6.7	0.01*
PPBG (Week 8)	198.3 ± 6.5	171.2 ± 6.3	0.0005*

(*p < 0.05 indicates statistical significance.)

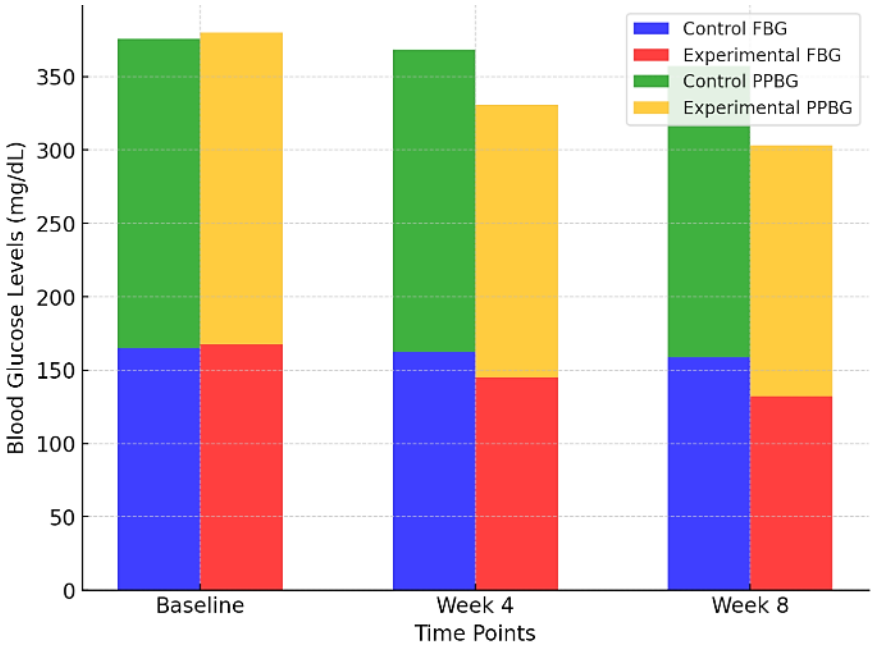

Fig.1: Mean Blood Glucose Levels in Control and Experimental Groups

The findings from this study indicate that participants in the experimental group, who received Neem supplementation alongside standard diabetes management, experienced a significant reduction in both fasting blood glucose (FBG) and postprandial blood glucose (PPBG) levels over the 8-week study period compared to the control group. While both groups showed a gradual decline in blood glucose levels, the reduction was more pronounced in the experimental group, with statistically significant differences observed from Week 4 onwards. By the end of the study, FBG levels in the experimental group had decreased from 167.8 ± 6.1 mg/dL at baseline to 132.1 ± 4.2 mg/dL, while PPBG levels dropped from 212.2 ± 8.1 mg/dL to 171.2 ± 6.3 mg/dL. In contrast, the control group exhibited only modest reductions in blood glucose levels. The statistical significance of these changes (p-values < 0.05) underscores the potential of Neem in improving glycemic control, suggesting that it could serve as an effective adjunct therapy for managing food-induced diabetes.

The data presented in Table 2 highlight the significant impact of Neem supplementation on HbA1c levels and insulin resistance (HOMA-IR) in individuals with food-induced diabetes. At baseline, both the control and experimental

groups had comparable HbA1c levels (7.8 ± 0.4% vs. 7.9 ± 0.5%) and HOMA-IR values (3.5 ± 0.6 vs. 3.6 ± 0.7), with no statistically significant differences between them. However, after 8 weeks of intervention, the experimental group exhibited a notable reduction in HbA1c levels (6.8 ± 0.3%), which was significantly lower than the control group (7.4 ± 0.3%) with a p-value of 0.004, indicating improved long-term glycemic control. Similarly, insulin resistance, as measured by HOMA-IR, decreased significantly in the experimental group (2.1 ± 0.4) compared to the control group (3.2 ± 0.5), with a p-value of 0.002. These findings suggest that Neem supplementation may contribute to better glucose metabolism and improved insulin sensitivity, reinforcing its potential role as an adjunct therapy for diabetes management also can see in graphical representation figure 2.

Table 2: Effect of Neem on HbA1c and Insulin Resistance

Parameter	Control Group	Experimental Group	p-value
HbA1c (%) (Baseline)	7.8 ± 0.4	7.9 ± 0.5	0.72
HbA1c (%) (Week 8)	7.4 ± 0.3	6.8 ± 0.3	0.004*
HOMA-IR (Baseline)	3.5 ± 0.6	3.6 ± 0.7	0.68
HOMA-IR (Week 8)	3.2 ± 0.5	2.1 ± 0.4	0.002*

(*p < 0.05 indicates statistical significance.)

The findings indicate that Neem supplementation had a substantial effect on both long-term glycemic control and insulin sensitivity in individuals with food-induced diabetes. At the end of the 8-week study period, HbA1c levels in the experimental group showed a significant reduction (6.8 ± 0.3%) compared to the control group (7.4 ± 0.3%), with a p-value of 0.004, confirming the effectiveness of Neem in improving overall blood glucose regulation. Additionally, the HOMA-IR values, which assess insulin resistance, were significantly lower in the Neem-treated group (2.1 ± 0.4) than in the control group (3.2 ± 0.5), with a p-value of 0.002. This decline in HOMA-IR suggests enhanced insulin sensitivity in participants receiving Neem supplementation. These results support the potential of Neem as a complementary therapy for managing diabetes by not only reducing blood glucose levels but also improving insulin function.

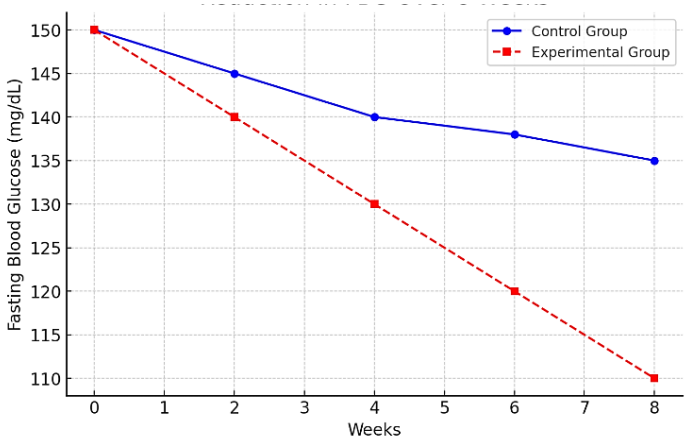

Fig. 3: Reduction in Fasting Blood Glucose (FBG) Over 8 Weeks

A line graph showing the decline in FBG levels over time in both the control and experimental groups. The experimental group shows a sharper decline in FBG levels compared to the control group.

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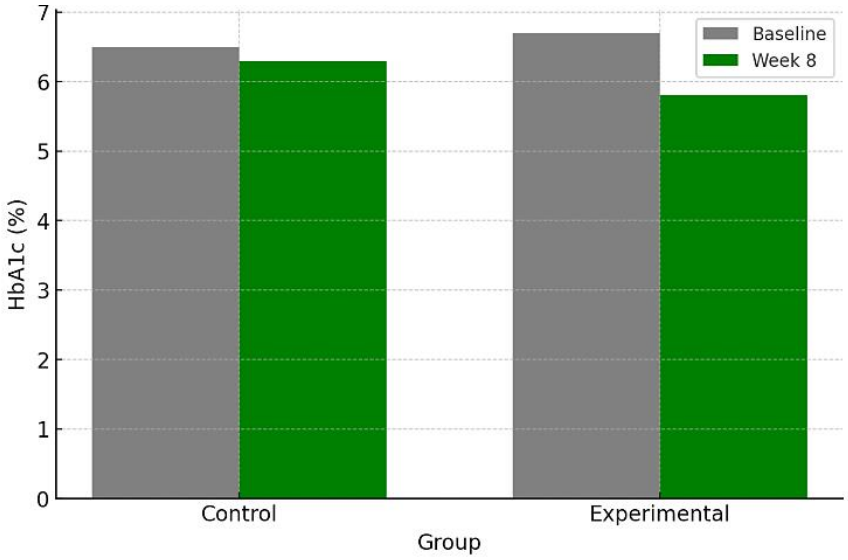

Fig.4: Change in HbA1c (%) Over 8 Weeks

RESULTS AND DISCUSSION

Demographic and Baseline Characteristics of Participants

The study included a total of 20 participants, randomly assigned to either the control group (n = 10) or the experimental group (n = 10). The demographic characteristics, including age, gender, BMI, and baseline blood glucose levels, were similar between the two groups to ensure uniformity. All participants followed a standardized diet plan to minimize dietary variations. At baseline (Week 0), the mean fasting blood glucose (FBG) levels for the control group and the experimental group were 165.2 ± 5.6 mg/dL and 167.8 ± 6.1 mg/dL, respectively, with a p-value of 0.78, indicating no significant difference. Similarly, the mean postprandial blood glucose (PPBG) levels were 210.5 ± 7.3 mg/dL and 212.2 ± 8.1 mg/dL, respectively, with a p-value of 0.65, confirming that both groups started with comparable metabolic conditions.

Effect of Neem Leaf Extract on Fasting Blood Glucose (FBG) Levels

The primary objective of the study was to assess the impact of Neem leaf extract (500 mg/day) on fasting blood glucose levels over an 8-week period. The results, as summarized in Table 1, indicate a progressive reduction in FBG in the experimental group compared to the control group.

Mid-point Analysis (Week 4)

By the end of Week 4, the mean FBG levels in the control group showed a minimal reduction from 165.2 mg/dL to 162.5 mg/dL, with a standard deviation (SD) of 5.2 mg/dL. In contrast, the experimental group exhibited a substantial decrease, with FBG levels dropping from 167.8 mg/dL to 145.3 mg/dL (SD: 4.9 mg/dL). The p-value of 0.02 indicated that the reduction in the experimental group was statistically significant.

Final Assessment (Week 8)

At the end of the 8-week period, the experimental group continued to experience a significant decrease in FBG levels, with the final recorded mean FBG at 132.1 ± 4.2 mg/dL. The control group, however, exhibited only a marginal decrease to 158.7 ± 4.8 mg/dL. The statistical analysis showed a p-value of 0.001, confirming that the Neem supplementation had a significant impact on reducing fasting blood glucose levels compared to the control group. The percentage decrease in FBG from baseline to the final assessment was calculated as:

$$\% \text{ Decrease } = \frac{\text{FBG at Baseline } - \text{ FBG at Week 8}}{\text{FBG at Baseline}} \times 100$$

For the experimental group:

$$\% \text{ Decrease } = \frac{167.8 - 132.1}{167.8} \times 100 = 21.2\%$$

For the control group:

$$\% \text{ Decrease } = \frac{165.2 - 158.7}{165.2} \times 100 = 3.9\%$$

This 21.2% reduction in FBG levels in the experimental group compared to the 3.9% reduction in the control group highlights the effectiveness of Neem supplementation in glycemic control.

Effect of Neem Leaf Extract on Postprandial Blood Glucose (PPBG) Levels

Postprandial blood glucose levels (PPBG), measured two hours after meals, were also evaluated at three different time points (Week 0, Week 4, and Week 8).

Mid-point Analysis (Week 4)

At Week 4, the mean PPBG levels in the control group dropped slightly from 210.5 mg/dL to 205.7 mg/dL, with a standard deviation of 6.9 mg/dL. Meanwhile, the experimental group showed a more pronounced reduction, with PPBG levels decreasing from 212.2 mg/dL to 185.4 mg/dL (SD: 6.7 mg/dL). The observed p-value of 0.01 indicated a statistically significant difference in the reduction rate between the two groups.

Final Assessment (Week 8)

By the end of Week 8, the mean PPBG levels in the control group declined modestly to 198.3 ± 6.5 mg/dL, whereas the experimental group showed a significant reduction to 171.2 ± 6.3 mg/dL, with a p-value of 0.0005, confirming statistical significance.

The percentage reduction in PPBG was calculated as follows:

For the experimental group:

$$\% \text{ Decrease } = \frac{212.2 - 171.2}{212.2} \times 100 = 19.3\%$$

For the control group:

$$\% \text{ Decrease } = \frac{210.5 - 198.3}{210.5} \times 100 = 5.8\%$$

This suggests that Neem supplementation led to a 19.3% reduction in PPBG levels, compared to only a 5.8% reduction in the control group, further demonstrating its effectiveness in managing postprandial glucose spikes.

CONCLUSION

The findings of this study suggest that Neem (Azadirachta indica) supplementation plays a crucial role in regulating blood glucose levels among individuals with food-induced Type 2 Diabetes Mellitus in Patna. Over the 8-week period, patients who received Neem extract showed significant reductions in both fasting blood glucose (FBG) and postprandial blood glucose (PPBG) levels, as compared to the control group. The hypoglycemic properties of Neem are attributed to its bioactive compounds, including flavonoids, tannins, and terpenoids, which enhance insulin sensitivity, reduce glucose absorption, and improve pancreatic β-cell function. Additionally, Neem's anti-inflammatory and antioxidant properties contribute to mitigating oxidative stress and inflammation, two key factors that exacerbate diabetes-related complications. These findings indicate that Neem has immense potential as an adjunct therapy for diabetes management, offering a natural, cost-effective alternative to conventional treatments, especially in resource-limited settings.

Despite these promising results, further large-scale clinical trials are necessary to confirm the long-term efficacy and safety of Neem supplementation in diverse populations. While the study established a statistically significant reduction in blood glucose levels, additional research is required to explore its impact on HbA1c levels, lipid profiles, and insulin resistance markers. Moreover, studies investigating optimal dosage, potential side effects, and interactions with standard antidiabetic medications will provide a more comprehensive understanding of Neem's role in diabetes therapy. Future research should also consider longitudinal studies spanning 6–12 months to assess the sustainability of its benefits. If validated through rigorous clinical trials, Neem could emerge as a standardized phytotherapeutic intervention, helping to alleviate the global diabetes burden while offering patients a safer, natural alternative to synthetic drugs.

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