

Title: **Effect of Extended Release Gymna Leaf Extract Alone or In Combination With Oral Hypoglycemics or Insulin Regimens for Type 1 and Type 2 Diabetes.**

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Abstract:

Introduction

Gymna is an Indian herb used Ayurveda, the ancient Hindi medicine system of India. Also referred to as mesahasringis in Sanskrit, it is a woody climbing plant that grows in the tropical forests of central and southern India. The leaves are used in herbal medicine preparations, which, when chewed, interfere with the ability to taste sweetness, which explains the Hindi name—"destroyer of sugar." Gymna's primary application was for adult-onset diabetes (NIDDM), a condition for which it continues to be recommended today in India. The leaves were also used for stomach ailments, constipation, water retention, and liver disease.

Ayurvedic treatments employ physician monitored fasting and medication, internal cleansing, and then personalized treatments based upon a well-developed body typing system. Therapies typically include diet, exercise, meditation and herbal supplements.

The gradual hypoglycemic action of Gymna leaves, first documented in the 1930, differs from the rapid effect of many prescription hypoglycemic drugs.

1. Gymna leaves raise insulin levels, according to research in healthy volunteers
2. possible due to regeneration of the b-cells in the pancreas.
3. The leaves are also noted for lowering serum cholesterol and triglycerides.
4. A water-soluble acidic fraction of the leaves provides hypoglycemic actions, possibly Gymna acid.
5. Its action in the reduction of intestinal glucose uptake has also been noted.
6. In OTC - Market it is sold under brands name "apimanu Diabgymna ayurveda[®]". The product promote healthy glucose

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levels and pancreas function. As a supplement, Gymna is also used to help diminish sugar intake.

Gymna is generally safe and devoid of side effects although it should be avoided during pregnancy. Administration is recommended under the clinical supervision of a healthcare professional. Gymna cannot be used in place of insulin to control blood sugar by persons with IDDM or NIDDM.

Trial Design

100 patients with type 1 or type 2 diabetes were started on the Gymna product and 65 completed the study. Males or non-pregnant females with a hemoglobin A1c > 7.8% were chosen for the study. An HbA1c was taken at the beginning and at the conclusion of the study. Fasting blood glucose and postprandial blood glucose was measured during the trial. A minimum of 1 fasting blood glucose and 1 postprandial blood glucose was taken daily for at least 5 of 7 days. At the end of each 30 day period, the readings were added and divided by the number of days and reported back as an average fasting and postprandial blood glucose. Treatment was added for a period of three months, 1 x 400mg tablet, twice daily. At the end of that period, we obtained another HbA1c.

Efficacy Variables

1. Hemoglobin A1c
2. Fasting Blood Glucose
3. Postprandial Blood Glucose

OBJECTIVE:

The prevalence of diabetes has increased dramatically in recent years

1. Gymna is an Indian herb used in Ayurveda, the ancient Hindi medicine system of India. Its primary application was for adult-onset diabetes (NIDDM), a condition for which it continues to be recommended today in India. The gradual hypoglycemic action of Gymna leaves, first documented in the 1930s, differs from the rapid effect of many prescription hypoglycemic drugs.

2. Gymna leaves raise insulin levels, according to research in healthy volunteers² possibly due to regeneration of the b-cells in the pancreas.

3. The leaves are also noted for lowering serum cholesterol and triglycerides.

2 due to law & restrictions of the EU health authorities for medical consultant only

4. A water-soluble acidic fraction of the leaves provides hypoglycemic actions, possibly Gymna acid.

5. Its action in the reduction of intestinal glucose uptake has also been noted.

6. The purpose of this work was to investigate the acute effects of supplementing the diet with Gymna in regards to its glucose lowering thereby reducing the HbA1c and therefore the complications from diabetes.

7. By reducing the HbA1c (Average Blood Glucose) 1%, the DCCT7 study showed Type 1 diabetics could reduce the complications of Retinopathy by 38%, Nephropathy by 28% Neuropathy by 35%. The UKPDS8 showed that reducing the HbA1c in Type 2 diabetics by 0.9% could reduce any diabetic end point by 12%, reduce any Microvascular end point by 25%, reduce MI by 16%, reduce Retinopathy by 21% and reduce microalbuminuria at 12 years by 34%.

8. The UKPDS also showed that Postprandial (blood glucose 1-2 hours after eating) glucose is a better indicator of glycemic control than fasting glucose levels

9. Treatment of postprandial hyperglycemia is critical to achieving optimal outcomes in type 2 diabetes.

METHODS:

Sixty-five (65) patients (37male/28 female) completed the study. 7.6%(5) of the patients were insulin dependent. Their pre-study average fasting glucose (163 mg/dl) and postprandial blood glucose (212 mg/dl), and a base HbA1c (8.8) were taken. Patients were instructed to take two (2) tablets per day, one in AM, one in PM for 90 days. They continued to monitor fasting and postprandial blood glucose through the study period. At the conclusion of the 90-day period, their levels were measured.

RESULTS:

Sixty five percent of the participants completed the study. After the 90 days of the Gymna supplementation, mean daily preprandial plasma glucose concentrations were 11 percent lower (161 vs. 144 mg/dl). The Gymna supplementation also lowered the 2-hour postprandial plasma glucose concentrations, by 13 percent (207 vs. 180mg/dl). The Gymna supplementation lowered HbA1c from 8.8% to 8.2% (0.6% decrease).

In the sub set of participants whose pre-study HbA1c was 9% or above the results were more profound. Mean daily preprandial plasma glucose concentrations were 15 percent lower (191 vs. 161 mg/dl). The Gymna supplementation also lowered the 2-hour postprandial plasma glucose

concentrations, by 21 percent (250 vs. 199 mg/dl). The Gymna supplementation lowered HbA1c from 10.1% to 9.3% (0.8% decrease).

In the poorest controlled patients, those with a starting HbA1c of 10% or greater, mean daily preprandial plasma glucose concentrations were 18 percent lower (216 vs. 178 mg/dl). The Gymna supplementation also lowered the 2-hour postprandial plasma glucose concentrations by 28 percent (295 vs. 212 mg/dl). The Gymna supplementation lowered HbA1c from 11.1% to 9.9% (1.2% decrease).

In addition 11 patients (16%) had a decrease in prescription medicine intake.

CONCLUSIONS:

As can be seen from the data above, the use of Gymna supplementation in all patients with diabetes has a positive result. In addition the use of Gymna supplementation in patients with the poorest control is even more critical. It appears that the largest effect occurs from decrease of postprandial glucose levels, which is consistent with the mechanisms of action stated. Gymna supplementation appears to improve glycemic control in patients with type 2 diabetes. Reducing postprandial blood glucose significantly caused a decrease of HbA1c, therefore reducing the complications from diabetes. 7,8,9,10

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