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EFFICACY OF GOKSHURADI GUTI IN THE MANAGEMENT OF TYPE 2 DIABETES-A CLINICAL STUDY

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ABSTRACT

Diabetes mellitus poses a significant global health challenge due to its escalating prevalence and associated complications. Ayurveda, with its holistic approach, offers potential alternatives to conventional management strategies. This study aimed to evaluate the efficacy of Gokshuradi Guti, a traditional Ayurvedic formulation, in the management of Type 2 Diabetes Mellitus (DM). A single-arm interventional clinical trial was conducted at Government Ayurvedic College and Hospital, Ghy-14, involving 30 participants. The primary objective was to assess the impact of Gokshuradi Guti on fasting blood glucose, postprandial blood glucose, and HbA1c levels over a 3-month period. The study included comprehensive data collection and analysis using standard statistical methods. The findings suggest promising outcomes that warrant further investigation into the therapeutic potential of Gokshuradi Guti in diabetes management.

KEYWORDS: Ayurveda, Gokshuradi Guti, Type 2 Diabetes Mellitus, clinical trial.

INTRODUCTION

Diabetes mellitus, a global disease impacting millions of people, presents a tremendous challenge to modern healthcare due to its numerous consequences and rising prevalence. Diabetes, which is characterised by persistent *hyperglycemia*, predisposes people to microvascular damage such as *retinopathy*, *nephropathy* and *neuropathy*, as well as an increased risk of macrovascular disorders such as *ischemic heart disease* and *stroke*. These

variables, taken together, reduce both the life expectancy and the quality of life for those afflicted.

The *Diabetes Atlas 2019*[1] data shows concerning trends that highlight the burden of diabetes: *one in eleven persons* worldwide between the ages of 20 and 79 have diabetes, with half of those cases going undiagnosed.[2] Diabetes now affects 77 million people in India alone; by 2045, that figure is predicted to rise to 134.2 million.[3] The increasing frequency highlights the pressing requirement for efficient management approaches, particularly in the field of complementary and alternative medicine.

Ayurveda, while recognised for its ability to fit with current medical norms, confronts obstacles due to a lack of documentation and scientific confirmation of its therapies. As a result, many parts of Ayurvedic practice remain veiled. The purpose of this study is to discover and describe new insights into the treatment of *Madhumeha* (Type II Diabetes mellitus) with *Gokshuradi Guti*. By assessing the efficacy of this traditional combination, we want to close the gap between old wisdom and modern medical expectations. This study aims to give useful empirical data by providing light on the therapeutic potential of Ayurvedic therapies in addressing a common and complicated global health concern such as diabetes mellitus.

AIM AND OBJECTIVE OF THE STUDY

To study the efficacy of Gokshuradi Guti on fasting blood glucose, post parandial blood glucose and HbA1c levels.

MATERIALS AND METHODS

a) Study Setting and Selection of the patients

A single-arm interventional clinical trial was conducted at Government Ayurvedic College and Hospital, Ghy-14, involving 30 patients. Comprehensive data on patients, including demographic and clinical profiles, were meticulously recorded and analyzed for the study.

b) Selection of the drug

The mentioned drug Gokshuradi Guti [4] is taken from Yogaratnakar Prameha adhikar.

Ingredients of gokshuradi guti

Table 1: Showing ingredients of the trial drug.

Sl. No.	Ingredients	Botanical Name	Family	Part Used	Quantity
1	Haritaki	*Terminalia chebula Retz.*	Combretaceae	Fruit	1 part
2	Bibhitaki	*Terminalia bellirica Roxb*	Combretaceae	Fruit	1part
3	Amalaki	*Emblica officinalis Gaertn.*	Euphorbiaceae	Fruit	1 part
4	Sunthi	*Zinziber officinale Rose*	Scitaminae	Rhizome	1 part
5	Pippali	*Piper longum*	Piperaceae	Fruit, Root	1 part
6	Maricha	*Piper Nigrum*	Piperaceae	Fruit	1 part
7	Guggulu	*Commiphora mukul*	Burseraceae	Resin, Gum	6 parts
8	Gokshura	*Tribulus terrestris*	Zygophyllaceae	Fruit, Root	1 part

Dose: 1000 mg (2 tabs) thrice daily after food [5]

Duration of treatment: 3 months and follow up after 30th, 60th and 90th day.

Intervention

Patients who reported pain, medication sensitivities, or health problems were excluded from the trial. Follow-up evaluations were scheduled at 30, 60 and 90 days after treatment. Participants were encouraged to avoid sugar and sweets while maintaining a healthy lifestyle that included at least 30 minutes of activity five days a week.

Preparation of the trial drug

The drug was prepared at the Rasashala of Government Ayurvedic College and Hospital, Ghy.200 grams of Gokshur powder was mixed with 3200 ml of water in a stainless-steel container and gently heated until the volume reduced to 400 ml. Finely powdered Triphala and Trikatu, along with dried pieces of Guggulu, were added to this mixture. After grinding for 4-5 hours, the mixture was left to sit overnight.

The following day, 150 grams of fresh Gokshur was crushed and boiled with 2400 ml of water until reduced to 300 ml. This Gokshur Kwath was then added to the dried material, and the grinding process was repeated daily for 4-5 hours.

After complete drying, the material was shaped into a bolus, coated with clarified butter (ghee), and dried in an oven at 50°C for 6-7 hours. This drying process was repeated the subsequent day. Once dried thoroughly, the bolus was finely powdered and combined with

Gum acacia, starch, magnesium stearate, and sodium benzoate to produce 500 mg tablets of Gokshuradi guti. These tablets were carefully packed into airtight containers.

Inclusion criteria

1. Patients of both sex and age between 30 to 70 years.
2. Naive patients or newly diagnosed patients of Type II Diabetes Mellitus taking oral hypoglycaemic drugs for ≤ 6 weeks.
3. Patients having Glycosylated haemoglobin (HbA1c) > 6.5%.
4. Patients recently diagnosed for uncomplicated NIDDM (type 2 diabetes) and having Fasting blood sugar level ≥126 mg/dl & ≤250 mg/dl & Post meal blood sugar level ≥200 mg/dl.
5. Cases of type-2 DM not taking any other hypoglycaemic drugs.
6. Diabetic Patients suffering from Controlled Hypertension (Blood Pressure not more than ≥140 mm hg or an average Diastolic Blood Pressure not more than ≥90 mm hg).
7. Patients willing to give informed consent and able to participate for 12 weeks.

Exclusion criteria

1. Patients already diagnosed and suffering from the complications of Diabetes Mellitus.
2. Patients suffering from brittle diabetes mellitus.
3. Patients who have a past history of IHD, MI, Stroke etc. within the last 6 months.
4. Patient with poorly controlled Hypertension (≥160 / 100 mm Hg)
5. Patients with concurrent serious Hepatic Dysfunction, Renal Dysfunction, uncontrolled Pulmonary Dysfunction or other concurrent severe disease or malignancy.
6. Pregnant / Lactating women.
7. Patient on steroids, oral contraceptive pills or estrogen replacement therapy.
8. Alcoholics and/or drug abusers.
9. Patients suffering from major systemic illness necessitating long term drug treatment
10. H/o hypersensitivity to any of the trial drugs or their ingredients.

Investigations

1. Fasting plasma glucose (FBS)
2. 2 hour post prandial glucose (PPBS)
3. HbA1c (checked before and after at the end of the treatment. i.e.90 days)
4. Sr.creatinine
5. Urine R/E

Assessment parameters

Objective parameters

1) Fasting plasma glucose
2) 2 hour post prandial glucose
3) HbA1c

Data analysis

The data obtained were organised and then analysed using the arithmetic mean, standard deviation and paired t-test to compare the results before and after treatment.

RESULT

Table 2: Effect of Gokshuradi guti on blood glucose parameters (n=30).

Sl. No	Observations	Mean±SD				t_{29}-value			p-value
		BT	FU1	FU2	AT	BT-FU1	BT-FU2	BT-AT	
1	FBS	202.7± 36.4	179.3± 38.6	165.4± 42.5	150.5± 40.2	4.4	6.1	7.3	<0.001
2	PPBS	252.6± 42.5	225.3± 41.9	220.6± 41.3	201± 47.5	4.2	5.6	8	<0.001
3	HbA1c	8.3±0.9	-	-	7.6±1.1	6.3			<0.001

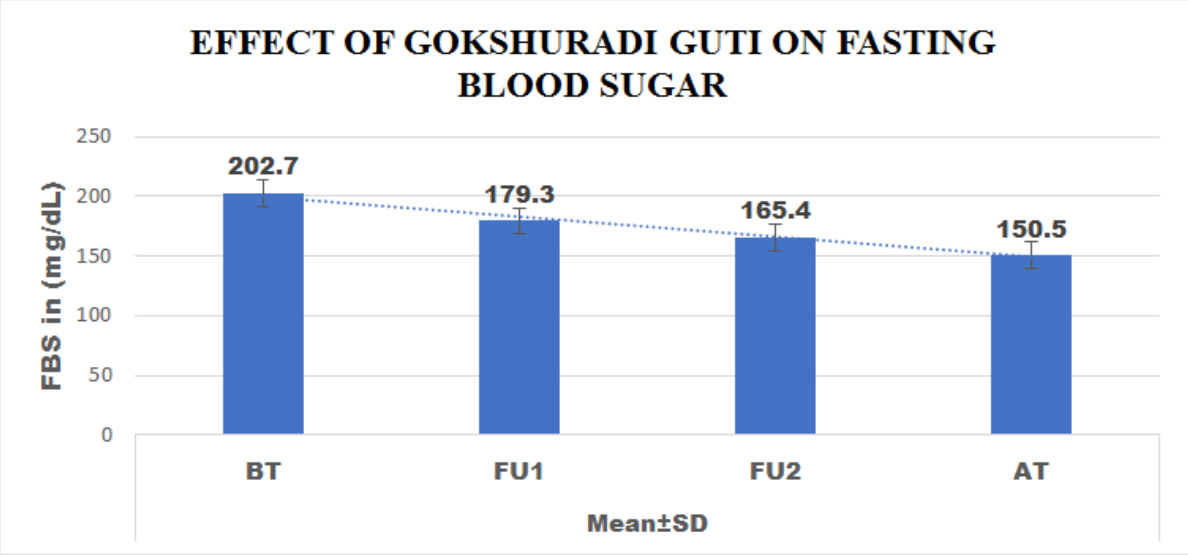

Figure 1: Distribution of Fasting Blood Glucose level observed in 30 patients before treatment along with 2 consecutive follow ups and after treatment.

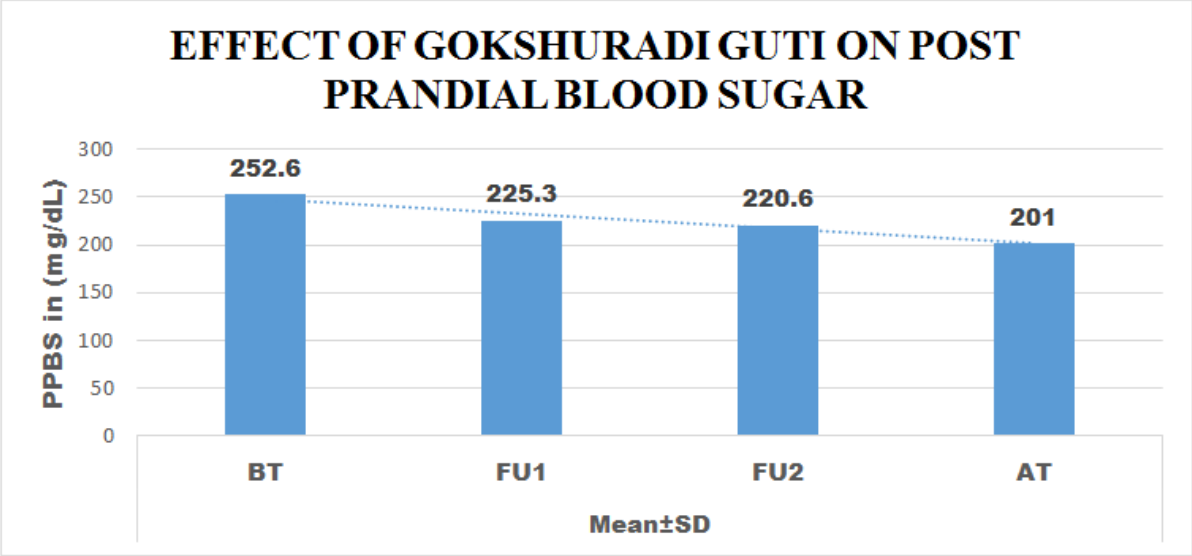

Figure 2: Distribution of Post Prandial Blood Glucose level observed in 30 patients before treatment along with 2 consecutive follow ups and after treatment.

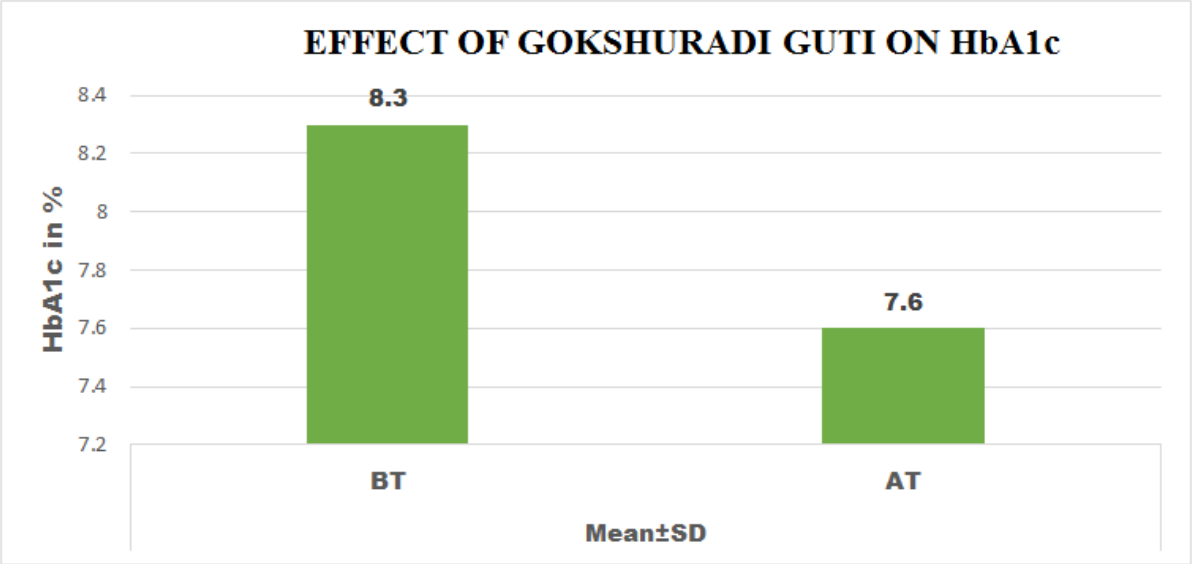

Figure 3: Distribution of HbA1c level observed in 30 patients before and after treatment.

Interpretation of the results

Fasting blood sugar

Treatment with Gokshuradi Guti significantly reduced fasting blood glucose levels in the study population. The observed decrease in mean fasting blood glucose levels from 202.7±36.4 before treatment to 150.5±40.2 after treatment was statistically significant, with a p-value <0.001. These findings suggest that Gokshuradi Guti is effective in lowering fasting blood glucose levels.

Post prandial blood sugar

Treatment with Gokshuradi Guti significantly post prandial blood glucose levels in the study population. The observed decrease in mean post prandial blood glucose levels from 252.6±42.5 before treatment to 201±47.5 after treatment was statistically significant, with a p-value <0.001. These findings suggest that Gokshuradi Guti is effective in lowering PP blood glucose levels.

HbA1c

Treatment with Gokshuradi Guti significantly reduced HbA1c levels in the study population. The observed decrease in mean HbA1c levels from 8.3% to 7.6% is clinically significant as it indicates improved long-term glucose control with a p-value <0.001. These findings suggest that Gokshuradi Guti is effective in improving long-term glucose control.

DISCUSSION

The study titled "*Efficacy of Gokshuradi Guti in the Management of Type 2 DM-a clinical study*" presents compelling findings suggesting that Gokshuradi Guti, an herbal formulation, offers significant benefits in managing type 2 diabetes mellitus (DM). This discussion examines the study's methodology, the probable mode of action of the ingredients of the drugs involved and the results of the study.

Study Design and Methodology

The research utilized a randomized clinical study design involving 30 patients diagnosed with type 2 diabetes mellitus. The primary objective was to evaluate the impact of Gokshuradi Guti on various blood glucose parameters, including fasting blood glucose levels, postprandial blood sugar levels (PPBS), and HbA1c levels. The study reported statistically significant reductions in all these parameters post-treatment, with a notable decrease in mean values supported by a p-value<0.001.

Probable mode of action of the drug

The efficacy of Gokshuradi Guti can be attributed to the synergistic actions of its key ingredients:

- **Triphala:** Comprising Haritaki, Amalaki, and Bibhitaki, Triphala offers hypoglycemic, antihyperglycemic, and antioxidant properties. It balances Tridosha and helps in reducing Kapha and Kleda, thereby improving glucose metabolism.

- **Trikatu:** A combination of Sunthi, Marich, and Pippali, Trikatu aids in digestion (Agnideepana) and eliminates excess Kapha and Meda, crucial in managing conditions like diabetes.
- **Guggulu:** Known for its lipid-lowering (Medohar) and metabolic enhancing properties, Guggulu helps in reducing Kapha and Meda, which are associated with diabetes and obesity.
- **Gokshura:** This herb possesses diuretic and hypoglycemic properties, aiding in the elimination of excess Kleda and Meda, thereby improving metabolic function and reducing symptoms of diabetes.

Key findings of the study

The study on Gokshuradi Guti revealed promising outcomes across various parameters related to glucose metabolism in patients with type 2 diabetes mellitus (DM). Significant reductions were observed in fasting blood glucose levels, indicating the formulation's potential to enhance fasting glucose control. Furthermore, Gokshuradi Guti demonstrated efficacy in lowering postprandial blood sugar levels over different follow-up periods (FU1 and FU2), suggesting consistent improvements throughout the day in regulating glucose metabolism. Moreover, the formulation led to a notable decrease in HbA1c levels, highlighting its role in long-term glycemic management. These findings collectively underscore Gokshuradi Guti's therapeutic potential in managing type 2 DM by addressing both short-term and long-term aspects of glucose regulation.

Limitations and Directions

While the study presents promising results, it is crucial to acknowledge its limitations, including the small sample size and the need for larger, multicenter studies to validate these findings across diverse populations. Additionally, further research could explore the specific mechanisms through which Gokshuradi Guti exerts its effects on glucose metabolism and insulin sensitivity.

CONCLUSION

The clinical study on Gokshuradi Guti underscores its potential as an effective herbal remedy for managing type 2 diabetes mellitus. By significantly improving various blood glucose parameters, the formulation offers hope for enhancing the quality of life and health outcomes of individuals with diabetes, pending further robust clinical validation.

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