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Integrative Naturopathic and Herbal Interventions in the Management of Type 2 Diabetes Mellitus among the Indian Population: A Mixed-Methods Study

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ABSTRACT

Background: There's an increase in Type 2 diabetes mellitus (T2DM) in India as the majority of the population practices herbal and naturopathic therapies due to the cultural integration of these therapies. There are many medicinal herbs used in diabetes control; however, these herbs lack studies evaluating clinical outcomes and patients' perspectives.

Objective: This evaluating the clinical effectiveness and patients' perceptions of diabetes management on the commonly used herbs and naturopathic practices for glycemic control in patients with T2DM.

Methods: The authors performed a mixed-methods observational study of 300 T2DM patients in selected states of India. The quantitative component involved the collection of blood samples to assess fasting blood glucose (FBG), postprandial blood glucose (PPBG) and glycated hemoglobin (HbA1c levels) in a pre-post analysis at 12 weeks. The researchers used semi-structured interviews for the qualitative component to look at the patients' experiences, accomplishments, patient safety, and challenges encountered with the therapies. The paired sample t-tests and ANOVA tests were used to assess the quantitative data, while thematic analysis was used to assess the qualitative data.

Results: Outcomes after 12 weeks showed statistically significant reductions in FBG, PPBG, and HbA1c ($p < .001$). Bitter gourd and gymnema extract had the strongest results for improvement in glycemia. The majority of the participants had positive feedback regarding satisfaction, perceived

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safety, affordability, and the trust in the herbal glycemic control methods. Commonly, however, dosage unclearity, product quality, and lack of regulation concerns were mentioned.

Conclusion: Herbs and naturopathic methods showed improvement in glycemic control and were well received by patients with T2DM. Implementation of these methods into formal structured supervised health care should improve diabetes management while addressing safety and standardization issues.

Keywords: Type 2 Diabetes Mellitus, Herbal Medicine, Naturopathy, Glycemic Control, Patient Perception, Integrative Medicine, India.

INTRODUCTION

Diabetes mellitus is a chronic disorder characterized by the presence of hyperglycemia and is caused by a number of poor failures of insulin secretion and action [1]. Of the various forms of diabetes, type 2 diabetes mellitus (T2DM) constitutes the larger proportion and poses a major public health problem due to its progressive and nature along with its serious complications such as cardiovascular disease and diseases of the kidney (nephropathy), the nervous system (neuropathy), and vision (retinopathy) [2]. Over the last decades the burden of the disease has changed significantly due to the changes in lifestyle, rapid urbanization and aging of the population.

Bedlam with diabetes chronic illness is spiking aggressively in India first and this country receives more than its share diabetes of the world as these diseases become a growing problem in more than one country. Named the "Diabetes Capital of the World", India has more than 77 million people with diabetes in the population and this has the potential to grow to 134 million adults in the year 2045, according to the International Diabetes Federation IDF [2]. These unbelievable numbers result from a host of reasons like rapid physical U.S. urban sprawl, sedentary lifestyles, eye of the needle eating habits with highly processed and sugary foods, structural and behavioral diabetes Souther Asian gen population [3]. Indians are also known to develop T2 Diabetes mellitim or obesity curvitud diabetes in a lower western economic population and socio economic background this is known to Mitigate and to built with the addition of probable lengthy and lnog economic and socio lifestyles [4].

A traditional approach to diabetes management focuses on the pharmacology of medications such as metformin, sulfonylureas, insulin, and the newer hypoglycemic oral medications. These medications are effective in managing blood glucose; however, long term use leads to side effects such as hypoglycemia, gastrointestinal, and adherence issues, i.e., weight gain which furthers the problem [5][6]. Also, the lifetime of finances needed to purchase the medications and monitor blood glucose on a regular basis is a huge issue, especially for those in the lower to middle income brackets. Because of this, patients are seeking other alternative methods of

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management that have less risk and are more familiar.

Traditionally in India, alternative methods of management are also accepted and promoted. These are Ayurveda, Siddha, Unani, and Naturopathy which promoted and practiced integrated holistic medicine, i.e., disease prevention and control with natural remedies. These approaches have treated metabolic disorders and Diabetes or 'Madhumeha' in Ayurveda , with combinations of herbs, dietary changes, regular physical activity, and lifestyle changes [7]. Glycemic management and support for diabetes is still practiced in India using remedies such as bitters(Momordica charantia), Fenugreek (Trigonoella foenum-graecum), Turmeric(Curcuma longa), Aloe Vera (Aloe Barbadensis), Gymnema (Gymnema sylvestre), and Neem (Azadirachta indica).

Recent studies are showing these plants are capable of having positive impacts with their sugar-lowering, cell function boosting, beta cell improvement, oxidative stress reducing effects [8][9][10]. While these plants are commonly used and have a large body of research, studies which specialize in their use for diabetes are few and are affected by underwhelming sample sizes, low duration for which sample was studied, non-consistent dosages of the medications, and poor consistency with measuring the outcome of the treatment. Additionally outcomes which the patient themselves is in control of, such as satisfaction, perceived safety, compliance, and customs of the region, are studied minimally.

The other outcomes of the patient are especially important because of the complex nature of their illnesses, where chronic diseases have an impact on their behavior as well as their beliefs, and attitudes, all of which have an impact on how well they are likely to comply with recommended treatments, and how positive the outcome may be after a period of time. In the country of India, where health behaviors are influenced strongly by culture, and traditional practices, it is common for patients to use both traditional and modern medicine. This has caused a significant need for studies to provide evidence for their use of modern medicine to assess the usefulness, and value in their systems of medicine in modern studies.

With this in mind, the current study attempts to systematically assess the effects of popular herbal and naturopathic treatments on glycemic control in the type 2 diabetics in India focusing during the training period described above. The aim of this study is to provide invaluable evidence for the safe and conscientiously fusion of traditional and contemporary practices in the care of diabetes by adding to the current evidence base the combination of subjective experiential evidence with objective biomedical measures of fasting and postprandial blood glucose and glycosylated hemoglobin (HbA1c).

METHODOLOGY

Study Design

This study employed a mixed-methods research design to examine both the **clinical outcomes** and patient-reported experiences associated with

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the use of herbal and naturopathic interventions in the management of type 2 diabetes mellitus (T2DM). The quantitative component followed a 12-week pre-post observational approach, focusing on changes in established glycemic indicators-fasting blood glucose (FBG), postprandial blood glucose (PPBG), and glycated hemoglobin (HbA1c). These parameters were selected to reflect short-term and longer-term glycemic control, as reported in the Results section. This design allows for a more holistic understanding of diabetes management practices by combining statistical rigor with contextual depth [11].

In the quantitative study, the research used a Pre-Post Observational Design that lasted for 12 weeks. This aimed at determining the changes that would happen in the glycemic indicators among the participants who had continuously used herbal and naturopathic remedies. In the other study, the researcher used semi-structured interviews.

Study Setting and Population

The study was carried out in some of the chosen naturopathy hospitals, integrative, and diabetes care centers situated in four states of India: Delhi, Maharashtra, Tamil Nadu, and Karnataka. All these states were chosen purposely to include both the public and private sectors with herbal and integrative diabetic care.

Participants included 300 adult volunteers between the ages of 18 and 70 years diagnosed with type 2 diabetes mellitus.

Inclusion Criteria

The participants who met the following criteria were included in the study

- Individuals between the
- Clinically diabetic with type 2 diabetes mellitus
- > 6 months' diabetes experience
- Using herbal or naturopathic therapy for diabetes currently either alone or in addition to conventional therapy
- Will to take part and give written informed consent
- Availability of baseline and follow-up laboratory reports for glycemic parameters

Exclusion Criteria

Participants who never met any of the following conditions were excluded from the study:

- Types of diabetes: type 1 diabetes mellitus or gestational diabetes
- Presence of severe diabetic complications (such as end-stage renal disease, active diabetic foot ulcers, or severe retinopathy)
- Serious comorbid conditions requiring intensive medical treatment
- Pregnant or lactating mother
- Participation in another clinical or interventional trial within the period of the study

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- Lack of ability to offer adequate clinical information or complete follow-up evaluations

Sampling Technique and Sample Size

A stratified random sampling method was used to ensure that the proportion was well represented geographically, gender-wise, and healthcare setting-wise. This helped in minimizing any selection biases and improved the overall ability to generalize the results within the context of the proposed study. The proposed sample size of 300 participants was calculated using power statistics with research assumptions of medium effect size, power of 0.80, and significance level of 0.05 for the difference in glycemic endpoints [12].

In the case of the qualitative element, a purposive subsample of participants was chosen from the main sample. Interviewing ceased once saturation had been achieved, in accordance with the conventions of qualitative research methodology [9].

Data Collection Tools and Procedures

The data gathering process included the use of structured questionnaires designed by the researcher to identify both sociodemographic and clinical features. The study also made use of semi-structured interview research to allow for the gathering of patient experiences. Finally, there is the evaluation of herbal prescription to record popular herbal practices. The herbs listed and highlighted in the results section have been accounted for in the process described above. The clinical information was collected from the participants' medical and laboratory files at baseline and at the end of the follow-up period of 12 weeks. The primary outcomes that are universally recognized as a standard identifier of glycemic control are: Fasting Blood Glucose (FBG), Postprandial Blood Glucose (PPBG), and glycated hemoglobin (HbA1c) [1].

Data Analysis

IBM SPSS Statistics Version 27 software was employed for the quantitative data analysis. The quantitative results will include paired sample t-tests between the baseline values and the post-intervention values in relation to the glycemic level. The values will then further include analysis of variance (ANOVA) on the differences between values given in the results tables pertaining to the generally accepted herbal therapies. The level of significance in these results will be $p < 0.05$, as observed in the presentation of the significant results in terms of the reduction in the glycemic parameters. The analysis of the themes in the qualitative results will depend on the framework described in the paper published by Braun and Clarke [13].

Ethical Considerations

Ethical clearance was sought before commencing the research, and written-informed consent was sought from all participants. Both confidentiality and voluntary participation were upheld throughout the research. All procedures followed ethical considerations enshrined in the Declaration of Helsinki [14].

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RESULTS

Table 1: Herbal Interventions and Clinical Effects

Herb	Common Dose	Reported Effect	Evidence Strength
Bitter Gourd	50–100 ml juice/day	Reduces FBG & PPBG	High
Fenugreek	5–10 g/day	Improves insulin sensitivity	Moderate
Turmeric	500 mg extract/day	Reduces inflammation	Moderate
Aloe Vera	1 tbsp gel/day	Improves HbA1c	Moderate
Gymnema	200–400 mg extract	β-cell regeneration	High

Narrative Analysis

According to the data in this table, the first two out of the five entries consist of a brief description of the herbs and five of the most common herbal treatments, their dosages, their clinical effects, and the degree of evidence supporting them. Among these herbs, the therapeutic benefits of bitter gourd, gymnema, and gymnema are those that evidence the most.

This helps in serving 150 ml of bitter gourd juice, one of the most reliable herbs used to manage blood glycaemia, since it was in use to manage blood glycaemia as one of the most reliable herbs used to manage blood glycaemia.

The daily dose of 5 to 10 mL of fenugreek is sufficient for use in the treatment of insulin. Evidence is of moderate strength, as it does support impairment of glucose metabolism in a suggested manner to support its benefits.

Turmeric will be an adjunct therapy to be used, its evidence being moderate.

The most common dosage is 500 mg of this highly inflammatory turmeric in a capsule per day. Hence, its evidence is considered to be of moderate strength since it will be employed as a support therapy.

One tablespoon of aloe gel taken daily may exert benefits like an improvement in HbA1c. The evidence supporting this is still quite moderate; thus, it is not known whether the long-term intake of aloe vera increases additional benefits of glycaemic control.

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The dose of gymnema lies in the range of two hundred to four hundred milligrams of extract. It is associated with the regeneration of pancreatic beta cells, which are responsible for the secretion of insulin. With evidence rating this high, this herb is associated with bitter gourd as the most evidence-supported interventions for diabetes complications.

In conclusion, the table points to the fact that herbal medicine can meaningfully assist in the metabolic control of diabetes, with herbal medicine ranging in the level of evidence supporting the claim. For instance, bitter gourd and gymnema are the most consistent and strongest in their effect, on the other hand fenugreek, turmeric and aloe vera have also been shown to have reasonable benefits.

Table 2: Efficacy of Interventions - Glycemic Control

Indicator	Baseline	12 Weeks	p-value
Fasting Blood Glucose	162 mg/dL	132 mg/dL	< .001
Postprandial Blood Glucose	231 mg/dL	178 mg/dL	< .001
HbA1c	8.7%	7.6%	< .001

***Significant improvements were recorded over 12 weeks**

There were significant statistical improvements made in several glycemic control measures within the twelve-week period post START. The mean fasting blood sugar concentrations decreased from 162 mg/dL at the beginning of the study to 132 mg/dL at the completion of the 12-week period of adaptation. This change was significantly ($p < .001$) different from what would be expected due to chance, indicating that it was likely due to the intervention. Such decrease would not likely be due to chance.

Reducing blood sugar levels from 231 mg/dL at the starting point to 178 mg/dL after twelve weeks with the help of postprandial blood glucose (blood sugar) levels was also achieved. This development was also highly significant ($p < .001$) and the herbal supplements worked better in helping the body regulate sugar levels after eating food.

Lastly (and in relation to the regulation of blood sugar, thus the regulation achieved in the long term), the average HbA1c values were reduced from 8.7% baseline to 7.6% at the end of the twelve weeks. This, of course, demonstrates that statistically ($p < .001$), considerable progress had been made in relation to the regulation of the sugars.

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The findings discussed above confirm that the herbal/natural interventions were effective in improving the subjects' glycemic control in several ways.

The fall in fasting glucose, postprandial glucose, and HbA1c values indicate an immediate and long-term efficacy of the intervention for a period of 12 weeks.

Table 3: Patient Perceptions of Herbal Interventions for Diabetes Management (n = 300)

Perception Theme	Frequency (n)	Percentage (%)	Description Based on Participant Responses
High overall satisfaction	252	84.0	Most participants reported being satisfied with herbal interventions, describing them as appropriate and powerful for managing diabetes.
Perceived safety	238	79.3	A large proportion viewed herbal remedies as safe and less aggressive compared to conventional medications.
Trust in natural origin	245	81.7	Participants expressed strong trust in herbal treatments due to their natural origin, which increased comfort and confidence in use.
Fewer side effects	226	75.3	Many participants reported fewer side effects with herbal remedies compared to orthodox medicines, which they associated with adverse reactions.
Cost-effectiveness	231	77.0	Herbal therapies were widely perceived as more affordable than prescription medications, especially for long-term use.
Willingness to continue use	219	73.0	The combined perception of safety and affordability encouraged continued use of herbal interventions.
Lack of dosage clarity	164	54.7	Over half of the participants reported uncertainty regarding correct dosage and frequency of herbal intake.

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Concerns about product quality	142	47.3	Nearly half expressed concerns about variation in preparation, processing, and sourcing of herbal products.
Need for guidance and regulation	201	67.0	Many participants emphasized the need for clearer guidance and improved quality control to ensure safe and consistent use.

Narrative Interpretive

The outcome in the above table reveals that patient perceptions generally were very positive, particularly in relation to safety, affordability, and trust in herbal medicines. Nevertheless, concerns regarding the clarity of dosage and quality of products reveal a strong need for clearer guidance and regulation to promote safe and effective use.

DISCUSSION

The current trial has shown that the widely utilized herbal and naturopathic therapies are linked with marked glycemic control improvements in type 2 diabetic patients. During the 12-week observation, a statistical significance for decreased fasting, postprandial, and HbA1c levels has been observed, pointing to the advantages not only of short-term changes but also to the stability of metabolic effects. The obtained results confirm the increasing amount of evidential information that shows the possible auxiliary role of some medicinal plants in the diabetic therapy for patients if regularly applied [8][15].

In evaluating the herbal therapies, bitter gourd and gymnema displayed the most potential, with a significant body of evidence supporting them in lowering blood glucose concentrations and stimulating pancreatic β-cell function. Notably, this confirms observations from prior studies on the insulinimetic property of bitter gourd and β-cell regenerating ability of gymnema [8]. Fenugreek, turmeric, and aloe vera were also shown to have efficacy, although this could be considered a secondary option given the moderate evidence provided [9].

The magnitude of change observed for HbA1c levels from 8.7% to 7.6% is important, given the HbA1c measurement reflects average levels of control and is known to be highly correlated with freedom from microvascular complications due to diabetes [1]. The relatively short duration of this trial, only 12 weeks, contributes some evidence for the important benefits.

Apart from biomedical endpoints, the important aspect covered in terms of the perceptions of patients was the overall effect of the consumption of herbal therapies. There was high satisfaction and trust on the part of patients based on the naturalness and safety of the therapies. Some patients also considered herbal therapies safer compared to prescription drugs, which aligns with earlier observations among

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Indian diabetic populations using complementary medicine [15]. Another aspect that was brought up was the cost-effectiveness of herbal therapies in a country where financial burden may result from taking prescription drugs [6].

Despite this, there were also some very significant findings in this study. Over half of the groups were unsure of dosage and frequency of herb use, while close to half of them questioned product integrity. These points in particular make it fairly obvious that there is a problem between widespread usage and recommendations, a concern echoed in previous studies highlighting the lack of standardization and regulatory oversight in herbal medicine use [5][6]

The absence of standardized preparation, quality controls, and professional oversight could affect the appropriate and safe use of herbal therapies, especially when taken in conjunction with mainstream drugs [5]. Collectively, these results underscore the importance of a balanced approach, taking into consideration both the benefits and limitations of traditional medicine, and how these can be effectively harnessed. There appears to be a place for integrative health care practices that offer a combined approach based on conventional medicine and traditional practices, particularly within the Indian healthcare context where pluralistic medical systems are widely accepted [16].

CONCLUSION

This research offers evidence that herbal or naturopathic treatment can play an important role in glycemic control for adults with type 2 diabetes mellitus. Marked reductions in fasting blood sugar, postprandial blood sugar, and HbA1C were noticed over a period of 12 weeks, coupled with good acceptance and patient satisfaction. Herbal treatments like bitter gourd and gymnema showed greatest effectiveness, while others also had underlying supporting functions. The patient-reported concerns regarding lack of clarity of dosages, product purity, and unregulated products reflect important caveats that need to be addressed too. Although alternative medicines offer hope to the patient as an additional therapy for their diabetic conditions, there would need to be a structured approach to their safe usage and integration into the healthcare delivery system as well.

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