



**International Journal of Biology, Pharmacy
and Allied Sciences (IJBPAS)**

'A Bridge Between Laboratory and Reader'

www.jibpas.com

INTEGRATED AYURVEDIC MANAGEMENT PROTOCOL IN GLYCEMIC CONTROL PARAMETERS IN PREDIABETES - A RANDOMIZED CONTROLLED CLINICAL STUDY

KEERTAN MS¹, TUBAKI BR^{2*} AND SHETE H³

- 1:** Associate Professor, Department of Roga Nidana, KAHER'S Shri B M Kankanawadi
Ayurveda Mahavidhyalaya, Shahapur, Belagavi, Karnataka
- 2:** Professor and HOD ,Dept. of Kayachikitsa, KAHER's Shri B M K Ayurved Mahavidyalaya,
Shahpur, Belagavi, Karnataka, 590003, India
- 3:** Assistant Professor, Department of Roga Nidana, KAHER's Shri B M K Ayurved
Mahavidyalaya, Shahpur, Belagavi, Karnataka, 590003, India

***Corresponding Author: Dr. Basavaraj R Tubaki: E Mail: ayurbasavaraj@gmail.com**

Received 24th July 2024; Revised 25th Aug. 2024; Accepted 17th Sept. 2024; Available online 1st Dec. 2024

<https://doi.org/10.31032/IJBPAS/2024/13.12.9667>

ABSTRACT

Background: Prediabetes, characterized by elevated blood glucose levels and a risk of progressing to diabetes, is linked to various health problems and worsened by sedentary lifestyles and poor diet. This study assesses the effectiveness of an integrated Ayurvedic approach, including herbal remedies, diet, and Yoga, in managing glycemic control and enhancing quality of life compared to standard treatments over a 90-day period. **Objective:** To evaluate the efficacy of the Integrated Ayurvedic Management Protocol in participants with prediabetes. **Materials and Methods:** The study involved 180 prediabetic patients (HbA1c levels between 5.7% and 6.4%). The control group (Group A) received standard prediabetes care, while the treatment group (Group B) followed an Integrated Ayurvedic protocol that included Madhumeahari Kashaya, a personalized diet, and a 30-minute daily Yoga regimen. Fasting blood sugar (FBS), post-prandial blood sugar (PPBS), and quality of life (DQoI) were measured at baseline, and on days 30, 60, and 90, with HbA1c and fasting insulin assessed at baseline and day 90. **Results:** Both the Integrated Ayurvedic Management (IAM) protocol (HbA1c pre 6.11±0.31 and post 5.13±0.33) and the standard

prediabetes care (HbA1c pre 6.28 ± 0.33 and post 5.8 ± 0.26) effectively managed prediabetes. However, IAM showed significantly superior results in improving glycemic control compared to standard nutrition and lifestyle management alone. **Conclusion:** Although standard nutrition and lifestyle management was effective, the study's small sample size and short duration limit the applicability of the findings, highlighting the need for larger, long-term studies.

Keywords: Blood glucose level, HbA1c, Integrative management, Diet, Yoga

INTRODUCTION:

The American diabetes association defined “prediabetes” as a condition wherein the blood glucose level is above the normal level but below the threshold value of diabetes [1]. However, prediabetes is a complex multifactorial metabolic disorder that extends beyond glucose dysregulation. Once thought of as an innocuous condition, current studies have found that it is associated with various micro & macro vascular disorders, cognitive dysfunction, blood pressure changes, fatty liver disease, cancer and many more [2].

Increase in sedentary lifestyle, consumption of calorie dense diet and less or no physical activity are the main reasons for this alarming rise in the prediabetic individuals [3].

The ICMR-INDIAB survey estimated that the prevalence of prediabetes in India is 136 million which is much higher than the figures predicted in the earlier studies. Moreover, the progression of prediabetes to diabetes is also faster in Asian Indians because they tend to develop diabetes at lower levels of Obesity [4].

Several studies conducted so far on Prediabetic individuals for prevention of progression to diabetes are use of metformin, lifestyle modification (LSM) and various other medicines. The reported major adverse reactions of the drugs and failure to maintain continuity in the lifestyle modifications posed a major challenge in the long-term sustainability of these treatment modalities [5]. Therefore there is an increasing interest towards safe and effective remedies for prevention of the progression of prediabetes to diabetes, which we believe an Integrative approach with Ayurvedic medication, diet and Yoga can provide.

Ayurveda herbal drugs like *Jambu* [6], *Madhunashini*, *Triphala* [7], *Vijayasara*, *Tamala* [8] *patra daruharidra*, *haridra* [9], *guduchi* [10] have properties of increasing insulin sensitivity, anti hyperglycemic, anti hyper lipidemic, antioxidant properties etc. have beneficial effect in Type 2 DM. The above drugs have been combined in the ayurvedic formulation *Madhumehahari Kashaya* for effective glycemic control in

Diabetes mellitus. Ayurveda dietetics has shown to have a positive outcome in T2DM management [11]. Yoga, being lifestyle intervention, has been reported to be a successful complementary treatment for Type 2 DM [12].

We have therefore designed an Integrated Ayurveda Management protocol for assessing its efficacy in glycemic control by evaluating biochemical parameters of Prediabetes (HbA1c, FBS, PPBS and Fasting Insulin) and compare it with Standard treatment regimen intervention on quality of life in Prediabetes (DQoL) over a period of 90 days.

MATERIALS & METHODS:

This study was a randomized control clinical study conducted at the KLE Ayurveda Hospital, Belagavi, between the time periods of July 2022– March 2023. The study was conducted in accordance with provisions of the Declaration of Helsinki and the Guidelines of Good Clinical Practice. The data was analyzed and interpreted by the investigators in collaboration with all authors. All the authors contributed to the drafting and review of the manuscript.

Ethics approval:

The trial protocol was approved by the Institutional Ethics Committee ((KAHER/EC/21-21/012) and was registered

in the Clinical Trial Registry of India (REF/2021/12/049921).

Screening methods:

Each participant was included in the study after obtaining their informed written consent in the prescribed format. The participants were given full information about the study as well as description of any foreseeable risks and discomforts. Participants were also informed of their right to opt out of the study at any time without giving any reasons.

After receiving the written consent, the patient registered; was screened for study related examinations i.e. physical examination and laboratory screening procedures. Those participants who fulfilled the eligibility criteria were recruited in the study.

Study participants:

The participants were screened based on the eligibility criteria and those who fulfilled the same were recruited in the study. The inclusion criteria were: Participants of either sex, in between 18 and 70 years of age who were pre-diabetics with HbA1c ranging between 5.7-6.4%, FBS <126mg/dl and those willing to give a written informed consent were included in the study.

The exclusion criteria were : Patients with Known Cases of DM, both type I and II, Past history of gestational diabetes, uncontrolled

Hypertensives (with or without medication > 140/90 mmHg), Pregnant and lactating women, alcoholics and/or drug abusers, patients suffering from major systemic illness necessitating long term drug treatment rheumatoid arthritis, psycho-neuroendocrinal disorders, etc.) and any other medical illness like Coronary Artery disease, Stroke etc were excluded from the study.

Also, patients who have completed participation in any other clinical trial during the past six (06) months were excluded from the study.

Sample size and randomization:

As this is a proof of concept, study aimed to evaluate Integrated Ayurveda Management Protocol in Prediabetes, a sample size 'n' of 90 participants (with 10% Attrition) in each group has been considered as adequate. Descriptive statistics (% , mean, SD etc), Chi square test, one way analysis of variance and Z test. Statistical significance will be taken at 5% level ($p < 0.05$).

Enrollment and intervention

Selected participants were enrolled into two groups with control and treatment group. The participants in the control group (Group A) received the standard prediabetic care (nutritional and lifestyle management counseling) and the treatment group (Group B) received Integrated Ayurvedic protocol with oral medication Madhumehahari Kashaya 35ml twice daily orally after food with luke warm water along with diet (meal plans as per calorie requirement of the individuals were suggested) and a Yoga protocol including Suryanamaskar along with Trikonasana, Virabhadrasana, Padahastana, Vakrasana and Gomukhasana were advised for a span of 30 minutes per day.

The fasting blood sugar (FBS), post-prandial blood sugar (PPBS) and DQol were measured at baseline and Day 30, 60 and 90 days. HbA1C and Fasting Insulin were measured at baseline and at the end of the study on 90th day.

Table 1: Ingredients for Madhumehahari Kashaya

Sl. No	Drug	Latin name	Part
1	Vijaya sara	<i>Pterocarpus marsupium</i>	Heart wood
2	Jambu	<i>Syzygium cumini</i>	Seeds
3	Amalaki	<i>Emblica Officiale</i>	Fruit
4	Hareetaki	<i>Terminalia Chebula</i>	Fruit
5	Vibheetaki	<i>Terminalia Bellirica</i>	Fruit
6	Haridra	<i>Curcuma longa</i>	Rhizome
7	Guduchi	<i>Tinospora cardifolia</i>	Stem
8	Tamala Patra	<i>Cinnamom tamala</i>	Leaves
9	Daruharidra	<i>Berberis aristata</i>	Rhizome
10	Madhunashini	<i>Gymnema sylvestre</i>	Leaves

Criteria of assessments:**Primary outcome measure:**

The primary end points of the study were changes in HbA1c level from baseline (day 0) and end of the study period (Day 90) for evaluating glycemetic control.

Secondary outcome measure:

The secondary outcome such as changes in fasting insulin level was evaluated from baseline and at 90 days. Changes in fasting and post prandial blood sugar were measured from baseline and at 30, 60 and 90 days. Changes in Quality of Life (DQoL) were evaluated at baseline and at 30, 60 and 90 days.

RESULTS:

The demographic data is presented in Table II. The patient's demographic and baseline data were evaluated, and the results indicated that there was no significant difference in the patients age, gender, socioeconomic status, educational status, religion; marital status and occupation in both the groups and they were comparable.

The comparison of different treatment time points of various parameters in Group A and Group B were tested by Wilcoxon matched pairs and Friedman's ANOVA test, while comparison of Group A and Group B for different parameters at different time

points were tested by using Mann-Whitney U test. The results have been tabulated below.

Subject characteristics (Table 2)

1. Age Group: There were 180 patients, among them 88 were from the age group of 20-40 years old, 84 were from 40 – 60 years old, 08 were from above 60 years old.
2. Gender: There were 180 patients, among them 94 were male, 86 were female.
3. Socio economic status: There were 180 patients, among them 76 were Middle class, 10 were Upper class and 94 were Lower class.
4. Marital status: There were 180 patients, among them 175 were married and 05 were unmarried.

Quality of Life scale and Basic blood glucose levels at different intervals

The effect of interventions on various parameters of glycemetic control assessed at baseline and on Day 30, 60 and 90 expressed as mean and standard deviations (SD) (Table 3).

Glycemic Index Parameters Before and After Trail.

Effect of intervention on parameters to assess glycemetic regulation at baseline and Day 90 expressed as Mean and standard deviations (SD) (Table 4).

The effect of interventions on various parameters of glycemetic control

The effect of interventions on various parameters of glycemetic control assessed at

baseline and on Day 30, 60 and 90 expressed as mean and standard deviations (SD) in between group A and Group B (Table 5).

Table 2: Demographic data of Prediabetic Subjects

S. No	Category		Group A	Group B
1	Age-group	20-30	9	7
		30-40	42	30
		40-50	22	34
		50-60	14	14
		60+	3	5
2	Gender	Male	43	51
		Female	47	39
3	Socio-economic status	Upper	5	5
		Middle	38	38
		Lower	47	47
4	Marital status	Married	87	88
		Unmarried	3	2

Table 3: Quality of Life scale and Basic blood glucose levels at different intervals

Variable	Baseline	Day 30	Day 60	Day 90	P value
FBS					
Group A	98.88 ± 9.08	96.11±5.63	95.56±6.61	94.11±7.16	<0.001
Group B	98.88±10.02	92.91±8.07	93.07±8.40	89.92± 7.79	<0.001
PPBS					
Group A	135.33±2.91	130.41±5.32	124.92±5.53	116.26±6.57	<0.001
Group B	144.87±3.35	135.1± 2.99	128.1±4.58	113.85±4.80	<0.001
WHO-QOL-Bref					
Group A	83.74±3.03	84.21±2.35	84.78±2.76	86.51± 3.31	<0.001
Group B	83.62±2.90	83.82±2.13	85.0±2.65	87.18±3.32	<0.001

The parameter of glycemetic control, FBS and PPBS were found to be statistically significant ($p<0.001$) in Group A and Group B individually. WHO-QOL-Bref was also found to be statistically significant in both groups. ($p<0.001$)

Table 4: Glycemetic Index Parameters Before and After Trail

Variable	Day 0	Day 90	P value
HbA1c			
Group A	6.28±0.33	5.80± 0.26	<0.001
Group B	6.11±0.31	5.13±0.33	<0.001
Fasting Insulin			
Group A	13.46±1.67	14.63±1.71	<0.001
Group B	13.70±2.10	15.48±2.66	<0.001

The parameter of glycemetic control, HbA1c and fasting insulin were found to be statistically significant ($p<0.001$) within Group A and Group B individually

Table 5: The effect of interventions on various parameters of glycemetic control

Study Variable	Groups	DAY 0	DAY 90	P value
Fasting insulin	A	13.46±1.67	14.63±1.71	<0.01
	B	13.70±2.10	15.48±2.66	
HbA1C	A	6.28±0.33	5.8±0.26	<0.001
	B	6.11±0.31	5.13±0.33	

The parameter of glycemetic control, fasting insulin was found to be statistically significant ($p<0.01$) in between both Group A and Group B, while HbA1c was also found to be statistically significant in between both Groups ($p<0.001$)

DISCUSSION:

In this study, the efficacy of Integrated Ayurvedic Management protocol was assessed in prediabetes against a controlled group with standard prediabetes protocol (nutrition and lifestyle management counseling). It was found that, both the standard prediabetes protocol and the Integrated Ayurveda Management (IAM) protocol were found to be efficient therapies in prediabetes individually. There was also a significant difference between Group A (the standard prediabetes protocol) and Group B (IAM protocol).

The standard prediabetes protocol included nutrition and lifestyle practices to combat prediabetic conditions; while the Integrated Ayurvedic management protocol included a combination of oral medication *Madhumehahari Kashaya* 35ml twice daily orally after food with luke warm water along with diet (meal plans as per calorie requirement of the individuals were suggested) and a Yoga protocol including *Suryanamaskar* along with *Trikonasana*, *Virabhadrasana*, *Padahastanasana*, *Vakrasana* and *Gomukhasana* were advised for a span of 30 minutes per day. The individuals were given a training session in the hospital yoga hall before the commencement of the study

and were then advised to follow the same daily.

The ingredients of the *Madhumehahari Kashaya* [6-10] have individually shown to possess properties of increasing insulin sensitivity and are reported to be anti-hyperglycemic in patients of Type 2 Diabetes Mellitus [13, 14]. Therefore, it was studied to evaluate its effect in gaining glycemic control in prediabetic individuals and accordingly was found to be effective in reducing the glycemic parameters.

The yoga intervention included *Suryanamaskar* along with asanas such as *Trikonasana*, *Virabhadrasana*, *Padahastanasana*, *Vakrasana* and *Gomukhasana*.

Various studies conducted on the effect of *Suryanamaskar* in Diabetes mellitus report that it improves sensitivity of β -cells to the glucose signal thereby improving insulin sensitivity and glucose uptake. *Suryanamaskar* being a combination of *Yogasana* and breathing combined together; imparts a massaging effect on the pancreas and promotes proper secretion of Insulin [15].

The similar principle of systematic muscle contraction and relaxation while performing asanas stimulates the pancreas and the pancreatic cells, thus increasing insulin secretion and regulation which is evident

significantly in the fasting insulin levels of the patients [16].

It is reported that lifestyle changes along with improved nutrition and physical activity are the first line of treatment for prevention of transition from prediabetes to diabetes [17]. Accordingly the integrated Ayurvedic management protocol comprising of medication, diet and physical activity is found to be effective in all parameters of glycemic control.

The control group comprising of nutrition and lifestyle management counseling was found to be effective as well for effective management of glycemic indices.

However, there is significant difference between the two groups when compared to each other.

Limitations of the study

The present study was conducted in a smaller sample size over a period of 90 days. However, the study may require a larger sample size to be monitored over a greater period to arrive at a definitive strategy for prevention of transition from prediabetes to diabetes.

ABBREVIATIONS

IAM - Integrated Ayurveda Management, FBS - Fasting blood sugar, PPBS - post-prandial blood sugar, DQol – Diabetes Quality

of life, LSM - Lifestyle modification, SD – Standard deviation.

Acknowledgement

We thank Dr Suhaskumar Shetty for his unconditional support to carry out clinical trial providing timely requirements and guidance during the study.

Conflict of Interest

The authors declare that there is no conflict of interest

REFERENCES:

- [1] K. S. A, Subramanian M, C. P. Prevalence of pre-diabetes and its associated risk factors among people in rural field practice area of Vydehi Institute of Medical Sciences and Research Centre, Bangalore. *Int J Community Med Public Health* [Internet]. 2024 Mar. 30 [cited 2024 Aug. 20];11(4):1675-80.
- [2] Tabák AG, Herder C, Rathmann W, Brunner EJ, Kivimäki M. Prediabetes: a high-risk state for diabetes development. *Lancet*. 2012 Jun 16;379(9833):2279-90. doi: 10.1016/S0140-6736(12)60283-9.
- [3] Chandrupatla SG, Khalid I, Muthuluri T, Dantala S, Tavares M. Diabetes and prediabetes prevalence among young and middle-aged adults in India, with an analysis of geographic differences:

- findings from the National Family Health Survey. *Epidemiol Health*. 2020;42:e2020065. doi: 10.4178/epih.e2020065.
- [4] Anjana RM, Unnikrishnan R, Deepa M, Pradeepa R, Tandon N, Das AK, Joshi S, Bajaj S, Jabbar PK, Das HK, Kumar A, Dhandhanika VK, Bhansali A, Rao PV, Desai A, Kalra S, Gupta A, Lakshmy R, Madhu SV, Elangovan N, Chowdhury S, Venkatesan U, Subashini R, Kaur T, Dhaliwal RS, Mohan V; ICMR-INDIAB Collaborative Study Group. Metabolic non-communicable disease health report of India: the ICMR-INDIAB national cross-sectional study (ICMR-INDIAB-17). *Lancet Diabetes Endocrinol*. 2023 Jul;11(7):474-489. doi: 10.1016/S2213-8587(23)00119-5. Epub 2023 Jun 7. PMID: 37301218.
- [5] Nakanekar A, Kohli K, Tatke P. Ayurvedic polyherbal combination (PDBT) for prediabetes: A randomized double blind placebo controlled study. *J Ayurveda Integr Med*. 2019 Oct-Dec; 10(4):284-289.
- [6] Sidana S, Singh V, Meena B, Beniwal S, Singh K, Kumar D, *et al*. Effect of *Syzygium cumini* (jamun) seed powder on glycemic control: A double-blind randomized controlled trial. *Journal of Medical Society*. 2017;31(3):185.
- [7] Christine Tara Peterson, Kate Denniston, Deepak Chopra. Therapeutic Uses of Triphala in Ayurvedic Medicine, *J Altern Complement Med*. 2017 Aug 1; 23(8): 607–614. Published online 2017 Aug 1. doi: 10.1089/acm.2017.0083, PMID : 28696777)
- [8] Shradha Bisht, S.S. Sisodia, Assessment of antidiabetic potential of *Cinnamomum tamala* leaves extract in streptozotocin induced diabetic rats, www.ijp-online.com Quick Response Code:DOI: 10.4103/0253-7613.84977,)
- [9] Menon VP, Sudheer AR. Antioxidant and anti-inflammatory properties of curcumin. *Adv Exp Med Biol*. 2007;595:105-25. doi: 10.1007/978-0-387-46401-5_3. PMID: 17569207.
- [10] V. Sivakumar and M. S. Dhana Rajan, Antioxidant Effect of *Tinospora cordifolia* Extract in Alloxan-induced Diabetic Rats, *Indian J Pharm Sci*. 2010 Nov-Dec; 72(6): 795–798. doi: 10.4103/0250-474X.84600, PMID: 21969757

- [11] Gupta A, Agarwal NK, Byadgi PS. Clinical assessment of dietary interventions and lifestyle modifications in Madhumeha (type-2 Diabetes Mellitus). *Ayu*. 2014 Oct-Dec;35(4):391-7. doi: 10.4103/0974-8520.158997. PMID: 26195901; PMCID: PMC4492023.
- [12] Hongasandra Ramarao, Effect of a Residential Integrated Yoga Program on Blood Glucose Levels, Physiological Variables, and Anti-Diabetic Medication Score of Patients with Type 2 Diabetes Mellitus: A Retrospective Study, *Integr Med Int* 2017;4:181–186, DOI: 10.1159/000487947, karger open access, April 4, 2018.
- [13] Aggarwal N, Shishu. A Review of Recent Investigations on Medicinal Herbs Possessing Anti-Diabetic Properties. *Journal of Nutritional Disorders & Therapy*. 2011;01(01).
- [14] Rizvi SI, Mishra N. Traditional Indian medicines used for the management of diabetes mellitus. *J Diabetes Res*. 2013;2013:712092. doi: 10.1155/2013/712092.
- [15] Moogi R, Galatage V. Suryanamaskar: A Lifestyle Modification in Prediabetes. *NJRAS* [Internet]. 2021Jan.8 [cited 2024Aug.20];9(01).
- [16] Gordon L. Effect of yoga and traditional physical exercise on hormones and percentage insulin binding receptor in patients with type 2 diabetes. *Am J Biotechnol Biochem*. 2008; 4:35–42.
- [17] Alvarez S, Coffey R, Mathias PM, *et al*. Prediabetes. [Updated 2023 Jul 17]. In: *StatPearls* [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK459332/>