Original Article

Effect of Ayurveda intervention, lifestyle modification and *Yoga* in prediabetic and type 2 diabetes under the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS)–AYUSH integration project

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Abstract

Background: Type 2 diabetes is a lifestyle-related disorder that affects around 422 million individuals in India. Integration of AYUSH (Ayurveda) with the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) was conceived on pilot basis at Gaya, Bihar, to provide integrative treatment for non-communicable disease patients and to manage the burden of non-communicable diseases in India. **Objectives:** The objective of this study was to analyze the effect of Ayurveda intervention, lifestyle modification and *Yoga* in the management of type 2 diabetes under NPCDCS-AYUSH integration project. **Materials and Methods**: A multi-centric, open-labeled, prospective, comparative clinical study was conducted at 17 community health centers and 1 district hospital. Population over 30 years of age was screened and prediabetic or type 2 diabetic individuals were enrolled in two cohorts, i.e., pre-diabetic (Cohort A) and type 2 diabetic (Cohort B). Each cohort was further divided into two groups: Group A1 was advised for lifestyle modification and *Yoga* and group A2 was given Ayurveda medication in addition to lifestyle modification and *Yoga*. Similarly, group B1 was advised for lifestyle modification and Yoga along with allopathic medication and group B2 was given Ayurveda medication, i.e., *Mamajjaka*, *Amalaki* and *Guduchi* powder in addition to lifestyle modification and *Yoga* along with allopathic medication. Treatment was given for 6 months. Data were analyzed through paired *t*-test. **Results:** A significant reduction was observed in fasting blood sugar level in groups A2 and B2 ($P = 0.001$) and also in the postprandial blood sugar level in Groups A2 and B2 ($P = 0.001$). Further, improvement in subjective symptoms such as polyuria, polydipsia, polyphagia, blurred vision and weakness was found in all the groups, while non-healing ulcer does not show any improvement. **Conclusion:** The study reveals that Ayurveda intervention, i.e., *Mamajjaka Churna* (1 g), *Amalaki Churna* (3 g) and *Guduchi Churna* (3 g) two times a day effectively controls blood sugar level in pre-diabetic and type 2 diabetic patients and improves the disease management with lifestyle modification and *Yogasana* as well as with allopathic treatment.

Keywords: Ayurveda, *Madhumeha*, Noninsulin-dependent diabetes mellitus, *Prameha*, type 2 diabetes

Introduction

Non-communicable diseases (NCDs) kill 41 million people each year, equivalent to 71% of all deaths globally.[1] According to the ICMR India State-Level Disease Burden Study report "India: Health of the Nation's States," the estimated proportion of all deaths due to NCDs has increased from 37.09% in 1990 to 61.8% in 2016.[2] The number of people with diabetes has risen from 108 million in 1980 to 422 million in 2014. The

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global prevalence of diabetes among adults over 18 years of age has risen from 4.7% in 1980 to 8.55% in 2014. Almost half of all deaths were attributable to high blood glucose and occurred before the age of 70 years.[3] Physical inactivity, faulty diet, sedentary lifestyle habits and stress are the major risk factors of noninsulin-dependent diabetes. The main aim of the management of diabetes is to lower the blood glucose level either by intervention of medicine or by improving behavior of diet and lifestyle.

Ayurveda emphasized on the management of *Prameha* through diet and lifestyle modification (which can be correlated to diabetes).[4] Studies have also shown the effectiveness of Ayurveda intervention in the management of type 2 diabetes.[5]

Global report on diabetes (2016) by the WHO[6] and the National Health Policy (2017)[7] emphasized on the integrated management of NCDs. Keeping in view the strength of AYUSH systems for the prevention and management of NCDs by promoting healthy lifestyle, a project aimed for "Integration of AYUSH (Ayurveda) with National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS)" was conceived in 2015 by the Ministry of AYUSH and Central Council for Research in Ayurvedic Sciences (CCRAS) in collaboration with Directorate General of Health Services, Ministry of Health and Family Welfare (MoHFW), for imparting health services on pilot basis in the three districts of three states, namely Bhilwara (Rajasthan), Gaya (Bihar) and Surendranagar (Gujarat).[8] The present article reports interim analysis of the patient outcome through integrated management of diabetes (from April 2016 to December 2017) at 17 community health centers (CHCs) and 1 district hospital (DH) of Gaya district.

Objectives

The objective of this study was to analyze the effect of Ayurveda intervention, lifestyle modification and Yoga in the management of type 2 diabetes under NPCDCS-AYUSH integration project.

Materials and Methods

A multicenter, open-labeled study was conducted at 17 CHCs and 1 DH in Gaya district of Bihar. A total number of 1,04,627 individuals were screened for type 2 diabetes at 17 CHCs and 1 DH between April 2016 and December 2017 and out of them, a total of 7735 participants were enrolled as prediabetic and type 2 diabetic patients for integrated management between April 2016 and December 2017. The data of all those patients who completed the management of 6 months, i.e. 3044 patients were included in the analysis. Dropped out cases were 2049 and the rest of 2642 patients were at different phases of management as it is a ongoing project.

Enrolled patients were distributed in two cohorts: pre-diabetic, i.e., Cohort A and type 2 diabetic, i.e. Cohort B. Each cohort was further divided into two groups, i.e. A1 and A2 and B1 and B2 as follows:

1. Group A1 was advised for lifestyle modification and *Yoga*
2. Group A2 was given Ayurveda medication, lifestyle modification and *Yoga*
3. Group B1 was advised for lifestyle modification and *Yoga* along with allopathic medication
4. Group B2 was given Ayurveda medication, lifestyle modification and *Yoga* along with allopathic medication.

Ethical clearance

The study protocol was approved by the Institutional Ethical Committee (15-1/IMR/RARIID/Patna/17-18/835 dated on June 10, 2017) and written informed consent was also taken before enrollment for intervention.

The case record forms (CRFs) and electronic format (E-format) were designed for recording the data of registered patients. The schematic diagram of the project is depicted in Figure 1.

Diagnostic criteria

- Cohort A: The Indian Diabetic Risk Score (IDRS)[9] 30–60 and adults with impaired fasting glucose as per the American Diabetes Association (ADA)[10] criteria (fasting plasma glucose [FPG] level between 100 and 125 mg/dL).
- Cohort B: IDRS >60, adults with FPG ≥126 mg/dl (7.0 mmol/l), or patients with classical symptoms of hyperglycemia or hyperglycemic crisis having random plasma glucose ≥200 mg/dl (11.1 mmol/l) as per the ADA[10] criteria and patients of type 2 diabetes with or without complications on standard care of treatment.

Inclusion criteria

Cohorts A and B: Patients of either sex aged between 30 and 60 years and those who are willing to give written informed consent were included.

Exclusion criteria

Cohorts A and B: Known cases of HIV positive; type 1 diabetic individuals; patients having a history of cardiovascular diseases such as bundle branch block, transient ischemic attack, uncontrolled hypertension and stroke; patients who have undergone recent or significant abdominal surgery (e.g., gastrectomy) during the past 6 months; patients on corticosteroids and hormonal treatment; pregnant and lactating mothers and patients having any major systemic illness were excluded.

The registered patients were provided the treatment as per their study cohort for 6 months as shown in Figure 2. The laboratory investigations such as fasting blood sugar (FBS), postprandial blood sugar (PPBS) and hemoglobin A_1C (HbA_1C) were conducted (as per the availability of investigations facilities with state health authorities) at baseline and at the end of 6th month.

Withdrawal criteria

- Patients with irregularity in follow-up or missing consecutive three follow-ups
- Noncompliance of treatment protocol
- Developed any serious side effect.

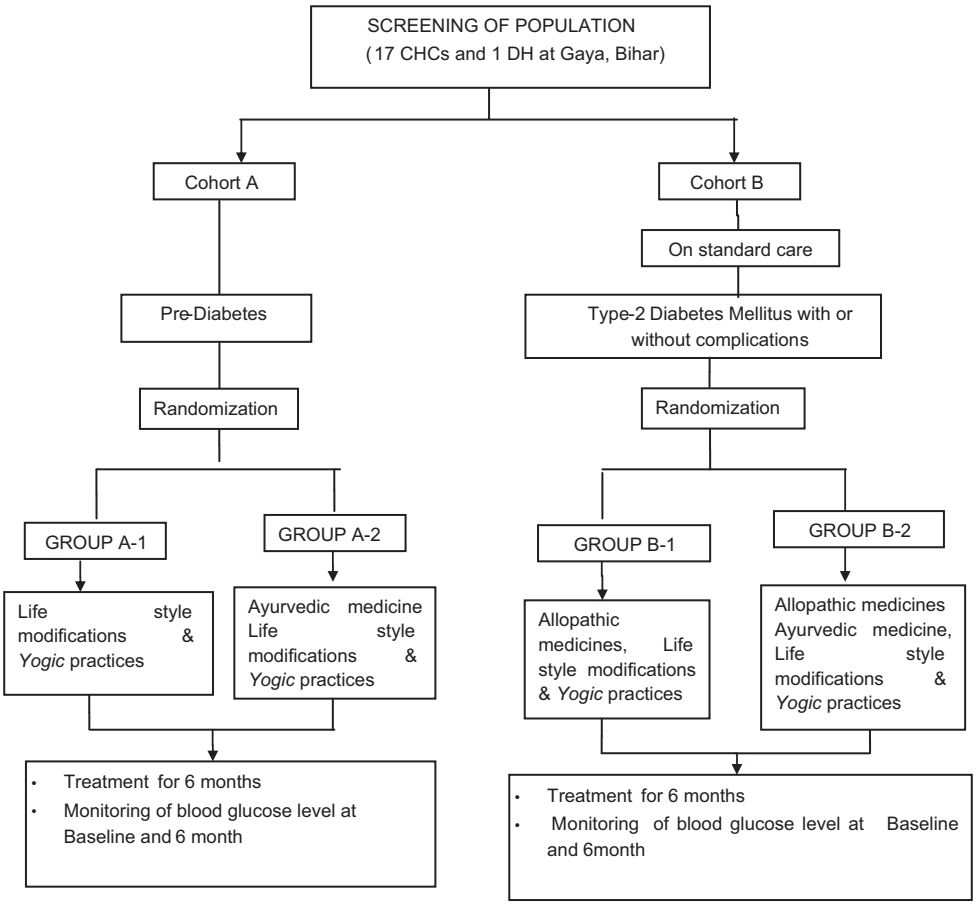


Figure 1: Scheme of categorization of patients

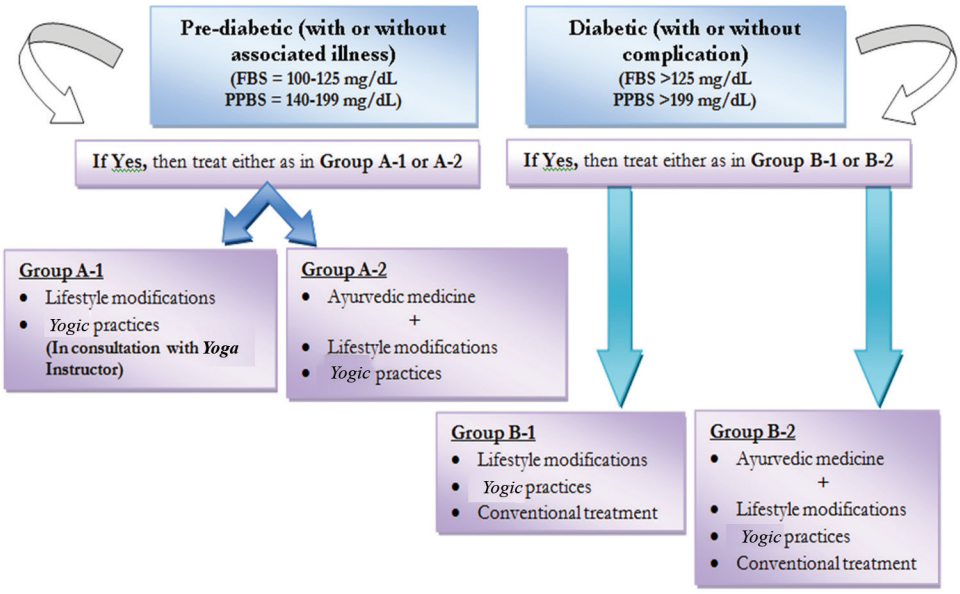


Figure 2: Methodology for enrollment of patients

Pharmacological interventions

Keeping in view of classical texts and various research studies, the *Mamajjaka* capsule (powdered dried whole plant of *Enicostemma littorale* Blume) 1 g, *Amalaki Churna* (powdered dried fruit of *Emblica officinalis* Gaertn.) 3 g and *Guduchi Churna* (powdered dried stem of *Tinospora cordifolia* (Willd.) Miers.) 3 g twice a day after meals with lukewarm water were administered for the management of type 2 diabetes. The medicines were

procured from Good Manufacturing Practices (GMP) certified Ayurvedic pharmaceutical companies as per pharmacopoeial standards. The medicines were prescribed for 6 months.

The list of common allopathic medications prescribed by the allopathic physicians for type 2 diabetic patients in the study contains chlorpropamide, tolbutamide, glibenclamide, glibornuride, tolazamide, glipizide, gliclazide and metformin.

Diet and lifestyle modification

The details of the advocacy on diet and lifestyles on diabetes are shown in Table 1.

Yogasana intervention for prediabetic and type 2 diabetes

A list of selected *Asana*/*Kriya*/*Pranayama* was advocated under the supervision of *Yoga* experts for practice by enrolled patients depending on the age and severity of disease, as mentioned in Table 2.

Assessment criteria

1. Blood sugar level: As per ADA, the fasting and PPBS levels were measured at baseline and the 6th month
2. Subjective symptoms of type 2 diabetes such as polyuria, polydipsia, polyphagia, weakness, non-healing ulcer and blurred vision of the individual patients were measured on following scoring:
   a. Absent: 0 Mild: 1 Moderate: 2 Severe: 3
3. Changes in subjective symptoms after treatment:
   a. Static: No change in subjective symptoms at 6th month from baseline
   b. Improved: Improvement in subjective symptoms at 6th month from baseline
   c. Worse: Increase in severity of subjective symptoms at 6th month from baseline.

Statistical analysis

The demographic variables and chief complaints have been presented in percentage. The continuous data for blood glucose level within the group related to outcome variables were subjected to paired *t*-test. $P < 0.05$ has been considered as statistically significant.

Results and Observations

Study cohort

A total of 7735 participants (56 in group A1, 1565 in group A2, 43 in group B1 and 6071 in group B2) were enrolled as prediabetic and type 2 diabetic patients for the integrated management during April 2016 to December 2017. The data of patients who had completed the management of 6 months, i.e., 3044 patients (15 in group A1, 487 in group A2, 13 in group B1 and 2529 in group B2) were included in the analysis. Dropped out cases were 2049 (13 in group A1, 546 in group A2, 7 in group B1 and 1483 in group B2) and the rest of 2642 patients (28 in group A1, 532 in group A2, 23 in group B1 and 2058 in group B2) were at different phases of management as it is a continuous running project. Figure 3 shows the outflow of patients in the study from April 2016 to December 31, 2017.

The study revealed that maximum patients (68.4%) were male in gender and the mean age of all the patients was between 45 and 54 years. About 25.4% of patients were illiterate, followed by 19.6% of patients who were educated above senior secondary. Almost 32.2% were homemakers. The baseline demographic data of the patients are summarized in Table 3.

Effect of management of type 2 diabetes on subjective symptoms

Changes in subjective symptoms after treatment were assessed with following criteria:

a. Static: No change in subjective symptoms at 6th month from baseline
b. Improved: Improvement in subjective symptoms at 6th month from baseline
c. Worse: Increase in severity of subjective symptoms at 6th month from baseline.

The effect of management of type 2 diabetes on subjective symptoms is depicted in Graphs 1-6 and Table 4.

Grading of the symptoms of type 2 diabetes, i.e., polyuria, polydipsia, polyphagia, weakness, blurred vision and

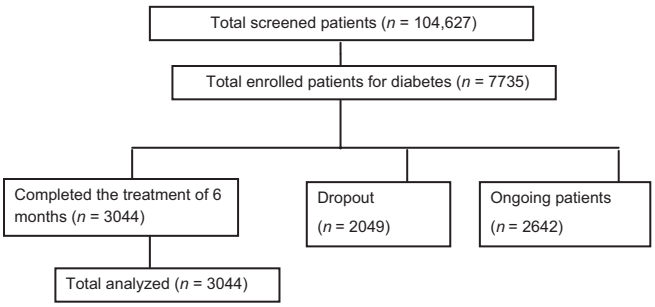


Figure 3: Outflow of the patients in the study

Table 1: Details of advocacy on diet and lifestyles for pre-diabetic and type 2 diabetes patients

Do's	Dont's
Intake of old harvested cereals, barley (*Yava*), sorghum (*Jwar*), whole wheat atta, bitter gourd (*Karela*), green leafy vegetables, garlic (*Rasona*), turmeric (*Haridra*), *Aloe vera* (*Kumari*) in vegetables (leafy) and fruits such as guava, oranges and Indian blackberry (*Jammbu Phala*)	Sugarcane juice, jaggery, sugar, milk products
Timely intake of diet	Reduce intake of rice, food rich in carbohydrate and fried, or processed food
Regular exercise, especially walking	Sedentary lifestyle
Regular practice of *Yoga*, meditation, etc., under the supervision of *Yoga* specialist is suggested	Sleeping in the daytime and excessive sleeping
	Alcohol consumption
	Staying too long on empty stomach
	Cold drinks, ice cream, burger-pizza and other fast foods.

Table 2: Details of *Asana*/*Kriya*/*Pranayama* advocated

Yogasana	*Pranayama*	*Kriya*
Surya Namaskar, Tadasana, Katichakrasana, Sarvangasana, Halasana, Matsyasana, Ushtrasana, Gomukhasana, Ardha Matsyendrasana, Mandukasana, Paschimottanasana, Pawanmuktaasana, Bhujangasana, Shalabhasana, Dhanurasana, Vajrasana, Shavasana	*Nadi Shodhana, Suryabhedi, Bhastrika*	*Kunjal, Kapalabhati, Agnisara*

Table 3: Baseline characteristics of the study participants (*n*=3044) (Demographics)

Variables	*n* (%)
Mean age (year)	45-54
Gender	
Male	64.8
Female	35.2
Education	
Illiterate	25.4
Up to primary	14.7
Up to middle	21.7
Up to senior secondary	18.5
College and above	19.6
Occupation	
Desk work	14.7
Field work	28.6
Homemaker	32.2
Others	24.5

non-healing ulcer was done at baseline and the 6th month and recorded in CRFs.

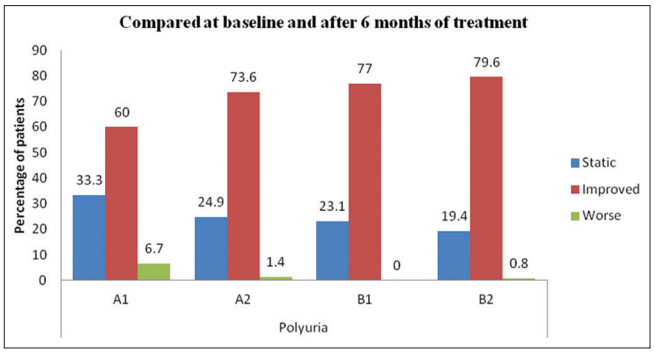
Effect of integrative management

The effect of integrative management in blood sugar level is shown in Table 5 and Graphs 7, 8. A significant reduction in the FBS level was observed from baseline to 6 months after intervention of integrative management in groups A2, B1 and B2, whereas non-significant reduction in the FBS level was observed in group A1. It was also observed that there was a significant reduction in the PPBS level from baseline to 6 months in groups A2, B1 and B2, whereas non-significant reduction in the FBS level was observed in group A1.

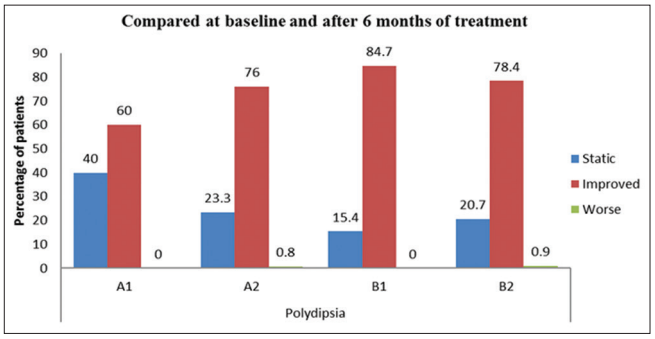
Discussion

The trial drugs, i.e., *Mamajjaka*, *Amalaki* and *Guduchi* were found effective in controlling FBS and PPBS levels in type 2 diabetic individuals. *Mamajjaka* is a folklore drug which has been practiced since long time for the management of *Prameha* in India. Various studies have documented the potential role of *Mamajjaka* in controlling blood sugar levels.[11] It possesses *Bitter Taste (Tikta Rasa)*[12] which is known to help in stimulating metabolism.

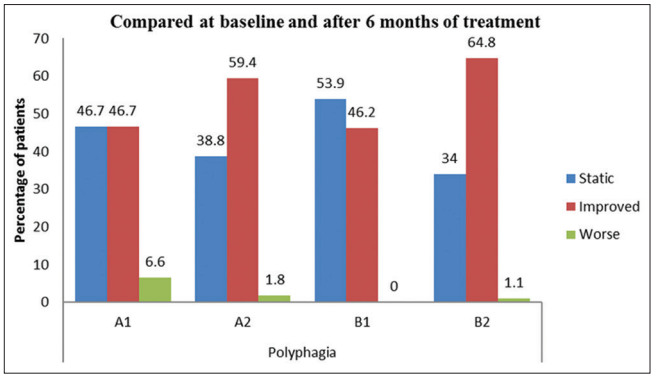
Amalaki and *Guduchi* are documented in the Ayurvedic Pharmacopoeia of India to possess anti-diabetic activity.[13,14]



Graph 1: The effect of intervention on the symptom of polyuria, *n*=3044



Graph 2: The effect of intervention on the symptom of polydipsia, *n*=3044



Graph 3: The effect of intervention on the symptom of polyphagia, *n*=3044

Further, *Amalaki* and *Guduchi* impart rejuvenating (*Rasayana*) effect that causes improvement in digestive functions and metabolism, thus enhancing glucose uptake by the cells. *Amalaki* is a rich source of Vitamin C and amino acids[15] and possesses immune-modulatory effect[16] and antioxidant activity.[17] Studies reported that *Guduchi* enhances glucose tolerance and lowers the blood glucose level.[18] It possesses antioxidant activity.[19]

Lifestyle modification contributes to the effect of Ayurveda medications as proper diet, abstinence of substance abuses such as tobacco and alcohol and management of daily routines will remove the causative factors of disease and help in preventing progression of disease.

Yoga has been practiced since ancient times to manage the physiology of the body. This not only improves the flexibility

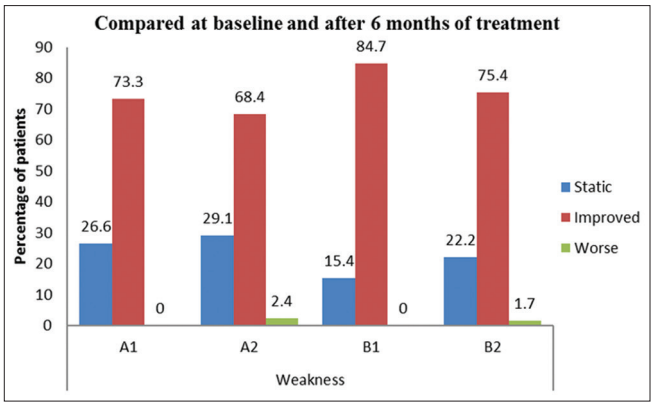
Table 4: The effect of management of type 2 diabetes on subjective symptoms and signs

Complaint	Group	Static (%)	Improved (%)	Worsened (%)
Polyuria	A1	33.3	60.0	6.7
	A2	24.9	73.6	1.4
	B1	23.1	77.0	0.0
	B2	19.4	79.6	0.8
Polydipsia	A1	40.0	60.0	0.0
	A2	23.3	76.0	0.8
	B1	15.4	84.7	0.0
	B2	20.7	78.4	0.9
Polyphagia	A1	46.7	46.7	6.6
	A2	38.8	59.4	1.8
	B1	53.9	46.2	0.0
	B2	34.0	64.8	1.1
Weakness	A1	26.6	73.3	0.0
	A2	29.1	68.4	2.4
	B1	15.4	84.7	0.0
	B2	22.2	75.4	1.7
Blurred vision	A1	46.7	46.7	6.6
	A2	64.1	33.5	2.5
	B1	53.9	46.2	0.0
	B2	57.6	39.5	2.8
Nonhealing ulcer (if any)	A1	100.0	-	-
	A2	96.9	2.3	0.8
	B1	100.0	-	
	B2	95.8	3.2	1.0

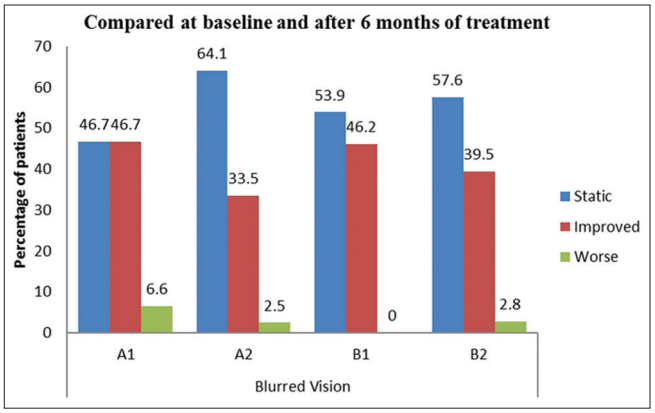
but also improves the function of both endocrines and exocrine glands of the body. Various studies have reported that *Yoga* has a positive impact in the management of type 2 diabetes. Different *Asanas* such as *Surya Namaskara* and *Tadasana* help in insulin production and improve digestive fire. Cleansing process in *Yoga Kriya* like *Kapalnbhati* and *Agnisara* stimulates pancreatic cells and improves their efficiency.[20]

Subjective symptoms of type 2 diabetes, i.e. polyuria, polydipsia, polyphagia, blurred vision, and weakness showed improvement in all the groups. This was possibly due to elimination of causative factors through lifestyle modification and improvement in physiology through *Yogic* practices. Further, pharmacological intervention controls the blood sugar levels and thus, relief in subjective symptoms was observed. Few patients felt improvement in vision which may be due to retinopathy changes which are nonreversible. Fewer people perceived an improvement in non-healing ulcer. This is possibly because of requirement of localized treatment of the ulcer tissue.

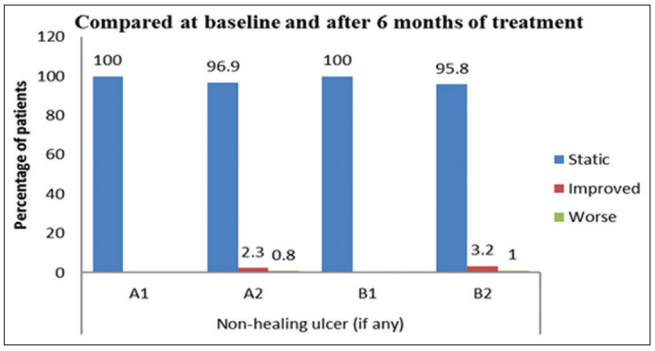
On comparing the *P* values of the four groups in FBS, it was observed that though lifestyle and *Yoga* have a positive impact over the disease management, the groups having medical intervention in the form of Ayurveda or allopathic medicine, i.e. groups A2, B1 and B2 performed better than group A1. This implies that lifestyle and *Yoga* can prevent disease progression through removal of causative and aggravating factors, but



Graph 4: The effect of intervention on the symptom of weakness



Graph 5: The effect of intervention on the symptom of blurred vision



Graph 6: The effect of intervention on the symptom of non-healing ulcer

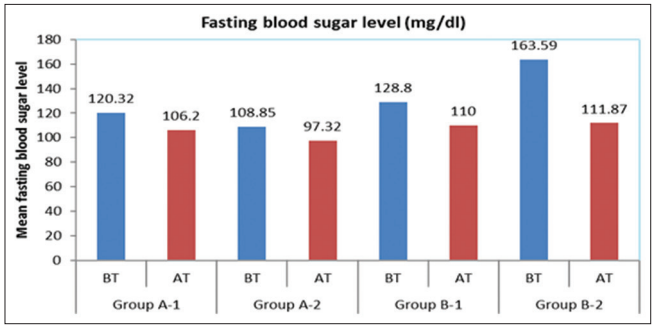
pharmacological intervention is required to manage the disease. *Yoga* regulates eating pattern and leads to medication adherence.[20] Diet plays an important role in the management of every disease as medicine is effective only in the presence of proper diet.[21]

Similarly, groups having Ayurveda medication, i.e., groups A2 and B2 showed better treatment outcome than group B1 which is having allopathic medicine along with lifestyle and *Yoga* in diseased cases. This signifies that type 2 diabetic patients responded better to Ayurveda medications, i.e., *Mamajjaka*, *Amalaki* and *Guduchi* in the current study. The reasons for better response may be multi-modal action of Ayurveda

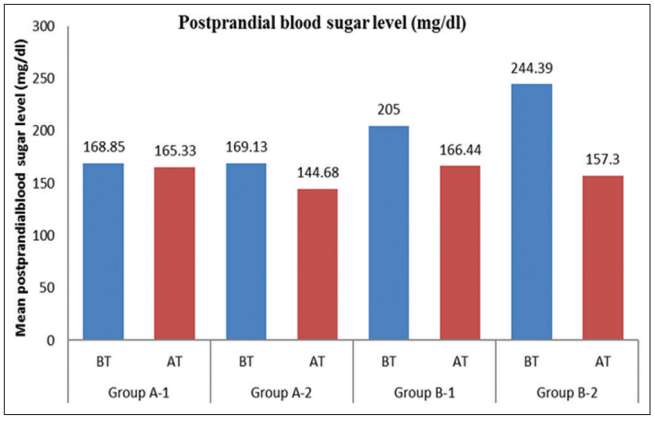
Table 5: Effect on fasting blood sugar and postprandial blood sugar

Parameters	Groups	0 day (BT)-after 6 months (AT)	Paired differences					*t*	*P*
			Mean	SD	SEM	95% CI of the difference			
						Lower	Upper		
Blood sugar fasting (mg/dl)	Group A1	BT	120.32	6.117	2.735	−11.435	39.675	1.534	0.200
		AT	106.20	21.534	9.630				
	Group A2	BT	108.85	10.894	1.168	8.076	14.990	6.663	<0.001
		AT	97.32	12.402	1.330				
	Group B1	BT	128.80	28.940	9.152	2.915	34.685	2.677	0.025
		AT	110.00	13.367	4.227				
	Group B2	BT	163.59	56.190	1.620	48.692	54.758	33.456	<0.001
		AT	111.87	24.098	0.695				
Blood sugar postprandial (mg/dl)	Group A1	BT	168.85	43.091	17.592	−47.952	54.985	0.176	0.867
		AT	165.33	33.720	13.766				
	Group A2	BT	169.13	21.598	1.619	19.918	28.974	10.653	<0.001
		AT	144.68	24.345	1.8525				
	Group B1	BT	205.00	42.834	14.278	12.494	64.617	3.412	0.009
		AT	166.44	33.313	11.104				
	Group B2	BT	244.39	76.309	2.036	83.097	91.084	42.780	<0.001
		AT	157.30	35.789	0.955				

CI: Confidence interval, SD: Standard deviation, SEM: Standard error of mean, AT: After Treatment, BT: Before Treatment, *n*=3044



Graph 7: The effect of integrative management on fasting blood sugar level



Graph 8: The effect of integrative management on postprandial blood sugar level

medications which not only relieve the symptoms but also stimulate the glands, rejuvenate the cells, and improve the uptake of glucose in the body and may probably increase insulin sensitivity. Similar observations were also observed during analysis of PPBS levels.

This highlights the importance of management of type 2 diabetes through integrative approach with Ayurveda medications that help to correct the vitiated *Dosha* and help in improving metabolism as reflected through the laboratory parameters and subjective parameters. Thus, Ayurveda intervention exhibits potential for integrative management along with lifestyle modifications, *Yoga* and allopathic anti-diabetic agents.

The acceptance of Ayurveda intervention was overwhelming among population as depicted by large proportion of participants in groups A2 and B2, where Ayurveda medication was prescribed. Further, a number of participants in the groups without Ayurveda medications were very less. The reason may be the inclination of individuals for pharmacological treatment of type 2 diabetes mellitus.

Limitations of the study

The laboratory investigations such as serum insulin HbA_1C, fasting and PPBS are the key factors in diagnosis and analysis of the result of the study, but there was restricted availability of in-house and outsourced laboratory facilities at every CHCs well in time.

Conclusion

The study reveals that Ayurveda intervention, i.e. *Mamajjaka Churna* (1 g), *Amalaki Churna* (3 g) and *Guduchi Churna* (3 g) two times/day effectively controls blood sugar level in pre-diabetic and type 2 diabetic patients and improves the disease management with lifestyle modification and *Yogasana* as well as with allopathic treatment.

Way forward

1. Further studies should be carried out for the assessment of quality of life during integrative management
2. The present study shows an increased flow of participants in groups having medical intervention. This implies a psychological aspect of taking some medication along with lifestyle modification and *Yoga* for the treatment of type 2 diabetes. Hence, to get comparable number of participants in each group, further studies may be planned with a placebo in those groups where only lifestyle modification and Yoga had been prescribed.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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