

A Clinical Study to Evaluate the Preventive Aspect of Amalaki Swarasa and Haridra Churna with Madhu in Pre-diabetes (Borderline Type2 DM)

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ABSTRACT

Diabetes mellitus is rising to an alarming epidemic level. Pre-diabetes (intermediate hyperglycemia) is a high-risk state for diabetes that is defined by glycemic variables that are higher than normal, but lower than diabetes thresholds. It stems up in persons who are physically inactive, obese, takes more kaphakara medokara abhishyandi ahara. Diabetes if not treated can cause a severe burden on society. The rising prevalence is closely associated with urbanization because of increasing obesity and inclination towards fast food.

For pre-diabetic individuals, lifestyle modification is the cornerstone of diabetes prevention. Physical activity and decreased calorie intake can reduce the occurrence of Diabetes. So an attempt was made to find out the efficacy of Amalaki swarasa and haridra churna with madhu in pre-diabetes (borderline diabetes)

Keywords: Pre-Diabetes, Amalaki, Haridra, Madhu, Borderline Diabetes Mellitus

INTRODUCTION

Diabetes mellitus is a chronic metabolic disorder characterized by hyperglycemia with or without glycosuria, resulting from an absolute or relative deficiency of insulin.¹

Diabetes is a chronic disease that affects millions of people worldwide. It is a fast growing global problem with huge social, health and economic consequences. The proportion of people with type-2 diabetes is increasing in most countries. 79% of adults with diabetes were living in low and middle income countries. And it is not a great thing to know that 1 in 2 (212 million) people with diabetes were undiagnosed. 352 million people were at risk of developing type-2 diabetes.²

In most cases, blood glucose levels in persons with diabetes increase with age, leading to heart disease, stroke, chronic kidney failure, foot ulcers, damage to the

eyes. Such high glucose levels are associated with frequent urination and increased thirst and hunger.³

There are many factors associated with the onset of diabetes, some of which are modifiable. Modifiable factors in persons, who are pre-diabetic, regardless of their age, are a diet high in fat and low in fresh fruits vegetables and whole grains. Foods containing low levels of sugar may also prevent and/or delays diabetes onset. In addition, the maintenance of normal cholesterol and blood pressure levels may also reduce pre-diabetes symptoms and diabetes onset.⁴

Pre-diabetes is a health condition that means blood sugar level is higher than normal, but not yet high enough to be diagnosed with diabetes. Pre-diabetes usually has no symptoms, but it almost always shows up before it is diagnosed. About 86 million people in US over age 20

have pre-diabetes. Although most people with pre-diabetes have no symptoms but one might notice feeling of thirsty, increasing frequency of micturition, fatigue, blurry vision.

Risk factors and cause of pre-diabetes are persons with gestational diabetes, PCOS, over-weight /obese especially around the middle (belly fat) have high cholesterol, high LDL cholesterol, lack of exercise and age above 40 years.⁵

India would have the certainty of becoming the capital of 3 major diseases by 2030, viz., Diabetes, TB and AIDS. The gravity of the problem is understood by the fact that every 5th patient visiting a physician is diabetic and every 5th diabetic in the world is Indian⁶.

In classics, various pathya dravyas are explained in the context of prameha. Among those, amalaki, haridra and madhu are famous for its anti-diabetic effects. These are cost effective and easily available. Usage of Amalaki (*Emblica officinalis*), commonly known as Indian gooseberry possess anti-diabetic effects through their anti oxidant and free radical scavenging properties.

Haridra (*curcuma longa*. rhizomes) with the most active component curcumin is a potential therapeutic agent in diabetes because of its effect in reducing glycemia. Anti diabetic drugs in combination with honey improve glycemic control, enhance anti oxidant defences and reduce oxidative damage. These effects are believed to be mediated partly via antioxidant mechanism of honey.⁷ Hence a hypothesis is made to evaluate the effect of amalaki swarasa with haridra and madhu as preventive measure in management of borderline DM (Pre-diabetic condition).

Therefore keeping the above points in view the present clinical study is planned, to evaluate the “A clinical study to evaluate

the preventive aspect of Amalaki swarasa and haridra churna with Madhu in Pre-diabetic condition (borderline type-2 DM)” Amalaki, haridra and madhu are said to be best pathya dravyas in prameha . It was proposed to take the persons having FBS between 100-120 mg/dl which are designated as pre-diabetic who if not managed properly will turn into TYPE 2 Diabetics. This study helps to evaluate the effect of Amalaki swarasa and haridra churna with madhu in controlling the pre -diabetes and preventing diabetes.

In present study 15 subjects of Pre-diabetes were administered Amalaki swarasa with haridra and madhu in the early morning, empty stomach for two months. After completing the study the procured statistical data was tested with different statistical methods, which shown statistically significant results in all criteria. Over all Amalaki swarasa and haridra churna with madhu has shown Mild improvement in patients of Pre-diabetes.

MATERIALS AND METHODS

OBJECTIVES OF THE STUDY

- 1) To study the effect of Amalaki swarasa and haridra churna with madhu in patients of pre- diabetes stage.
- 2) To observe if there is any benefits after the use of this combination.

SOURCE OF DATA

Patients from OPD, IPD and camps were selected for this study.

METHOD OF COLLECTION OF DATA

30 patients who were fulfilling the criteria for diagnosis and inclusion were Selected irrespective of sex, occupation, religion etc for the present clinical study.

DIAGNOSTIC CRITERIA:

Diagnosis were established on the basis of symptoms seen in the Patients, history and laboratory investigations.

Table No. 1 Grading Table for symptoms

	Grade '0'	Grade '1'	Grade '2'	Grade '3'
INCREASED HUNGER	Normal	Mildly Increased	Moderately increased	Severely increased
URINATION	3-5 Times in a day 0-1 Time at night	5-7 Times in a day 2-3 Time at night	7- 10 Times in a day 3-5 Time at night	More than 10 Times in a day More than 5 Times at night
FATIGUE	Absent	Mild	Moderate	Severe
INCREASED THIRST	Absent	Mild	Moderate	Severe

LABORATORY INVESTIGATIONS:

1) FASTING PLASMA GLUCOSE TEST (FPG)

- Normal - Less than 100 mg/dl
- Pre-diabetes - Between 100 and 125 mg/dl
- Diabetes - Greater than 126

2) Random value

- 200 mg/dl (11.1mmol/L) or more
- In a symptomatic patient DM

INCLUSION CRITERIA

- Subjects were selected respective sex
- Subjects aged 40 to 60 years of age
- Subjects with family history of type2 DM and high bp
- Subjects with sedentary lifestyle
- Obese (BMI more than 30)
- Clinical signs and symptoms fulfilling the criteria of pre diabetes
- Patients having impaired fasting glucose(IFG-100mg/dl-125 mg/dl)

EXCLUSION CRITERIA

- subjects with other systemic disease (HTN/IHD) etc
- Subjects aged less than 40 and more than 60 years
- Subjects suffering from type 1 DM
- Subjects suffering from type 2 DM
- Patients on steroids or oral hypoglycemic drugs

STUDY GROUPS:

It was a clinical study with two groups, each group comprising of 15 patients.

GROUP A - Patients were advised to take amalaki swarasa and haridra churna with madhu once a day for 60 days

GROUP B - Patients were not advised anything and kept under observation for 60 days.

Assessment was done after 2 months.

Blood investigation and symptoms were noted for every 15 days.

ADMINISTRATION OF MEDICINE

Amalaki was made into swarasa (fresh juice) and haridra was crushed and made into powder manually. Amalaki (25ml), Haridra(2gm) and Madhu (10gm) was consumed in an empty stomach, once a day.

Statistical Analysis:

All the observation made on various parameters of both the groups were noted

And the data was analyzed by Friedman's test, Wilcoxon signed rank test, unpaired 't' test to calculate data between two groups and the result of Statistical analysis was interpreted in terms of mean (x) S.D., S.E and P value.

The obtained results were interpreted in the statistically terms as

- Significant: $P < 0.05$ / $P < 0.01$
- Highly Significant: $P < 0.001$

ASSESSMENT CRITERIA:

A Self formulated scoring scale was used to assess the symptoms.

- Subjective criteria
- Increased thirst
 - a. Normal hunger & also satiety achieved - 0
 - b. Hunger is more, mild satiety -1
 - c. Severe hunger, moderate satiety, nibbling present - 2
 - d. Very severe hunger, reach to satiety too late, extensive eating seen -3
- Increased hunger
 - a) Normal thirst - 0
 - b) Upto 2 litres of excess intake of fluids - 1
 - c) Upto 2-3 litres of excess intake of fluids - 2
 - d) More than 3 litres of excess intake of fluids -3
- Fatigue
 - a) No fatigue, performs work normally - 0
 - b) Mild Fatigue but can perform work - 1
 - c) Moderate fatigue which impairs work occasionally -2

- d) Severe fatigue and Cant perform any work – 3
- Frequent urination
 - a) 3-5 Times in a day and 0-1 Times at night
 - b) 5-7 Times in a day and 2-3 Times at night
- c) 7- 10 Times in a day and 3-5 Times at night
- d) More than 10 Times in a day and More than 5 Times at night
- Objective criteria
 - i. RBS
 - ii. FBS
 - iii. PPBS

EVALUATION TABLE FOR THE TREATMENT

Table No. 2 Subjective Parameters of Group A / Group B

VARIABLES	BEFORE TREATMENT	ON 15 TH DAY	ON 30 TH DAY	ON 45 TH DAY	ON 60 TH DAY
INCREASED APPETITE					
FREQUENT URINATION					
FATIGUE					
INCREASED THIRST					

Table No. 3 Objective Parameters of Group A / Group B

VARIABLES	BEFORE TREATMENT	ON 15 TH DAY	ON 30 TH DAY	ON 45 TH DAY	ON 60 TH DAY
FBS					
PPBS					
RBS					

FOLLOW UP STUDY:

The patients were advised to report for the follow up twice in a month (every 15 days) for two months.

Statistical analysis

Statistical results of in Group A patients (administered with medicine) and Group B patients in (without any medical intervention) before and after treatment

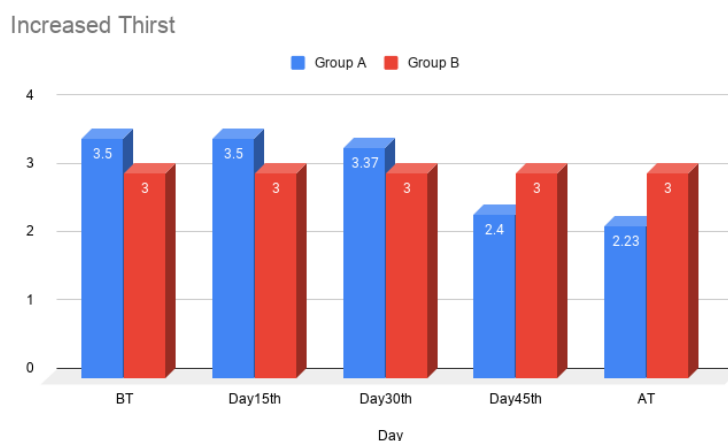
Total 30 patients were registered in this study. Out of that all 30 patients were studied in this project. 15 patients were in group A while 15 were in B group. Each patient was observed thoroughly and noted

neatly. The observations are recorded and necessary charts and graphs were made

OBSERVATION & RESULTS

Results on subjective parameters

In this work of 15 patients studied with Group-A Increased Thirst revealed are given in detail in Table No.4. Statistical analysis showed that the mean score which was 3.5 before the treatment was reduced to 2.23 after the treatment with 36.28% improvement and there is a statistically significant. (P<0.05) results are graphically represented in graph no.17



Graph No.1: Effect of Group A & Group B on Increased thirst of Type2 DM

In this work of 15 patients studied with Group-B Increased Thirst revealed are given in detail in Table No.4. Statistical analysis showed that the mean score which was 3 before the treatment and has remained same 3 after the treatment with 0% improvement. Results are graphically represented in Graph no. 1

Table No. 4 Mean of Increased thirst

Increased Thirst		
Day	Group A	Group B
BT	3.5	3
Day15th	3.5	3
Day30th	3.37	3
Day45th	2.4	3
AT	2.23	3

Increased Hunger: Results on subjective parameters for increased hunger

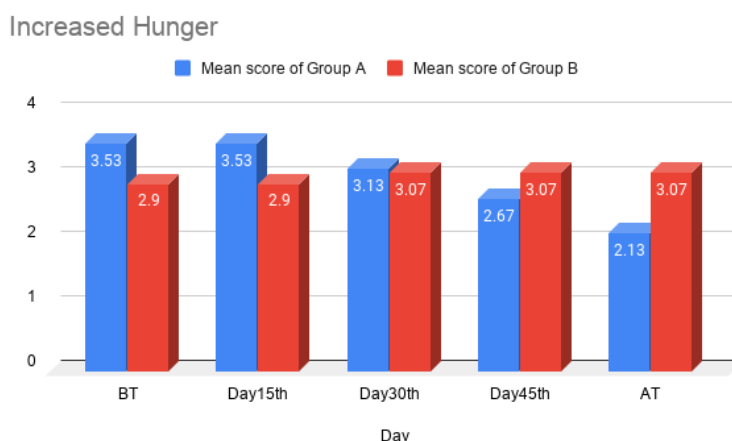
In this work of 15 patients studied with Group-A Increased Hunger revealed are given in detail in Table No.4. Statistical

analysis showed that the mean score which was 3.53 before the treatment was reduced to 2.13 after the treatment with 39.66% improvement and there is a statistically significant. (P<0.05) results are graphically represented in graph no 2:

In this work of 15 patients studied with Group-B Increased Hunger revealed are given in detail in Table No.4. Statistical analysis showed that the mean score which was 2.9 before the treatment and has increased to 3.07 after the treatment with 5.86% decrement. Results are graphically represented in graph no 2:

Table No.5 Mean of Increased hunger

Increased Hunger		
Day	Mean score of Group A	Mean score of Group B
BT	3.53	2.9
Day15th	3.53	2.9
Day30th	3.13	3.07
Day45th	2.67	3.07
AT	2.13	3.07



Graph No.2: Effect of Group A & Group B on Increased Hunger of Type2 DM

Results of subjective parameters on fatigue

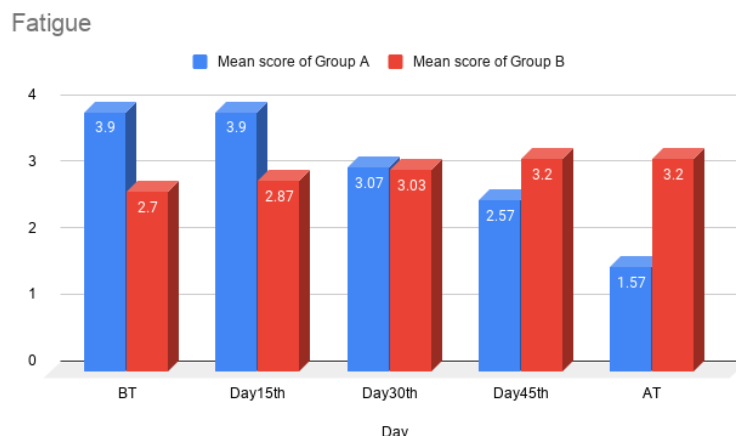
In this work of 15 patients studied with Group-A Fatigue revealed are given in detail in Table No.6. Statistical analysis showed that the mean score which was 3.9 before the treatment was reduced to 1.57 after the treatment with 59.74% improvement and there is a statistically significant. (P<0.05) results are graphically represented in graph no 19:

In this work of 15 patients studied with Group-B Fatigue revealed are given in

detail in Table No.6. Statistical analysis showed that the mean score which was 2.7 before the treatment and has increased to 3.2 after the treatment with 18.5% decrement. Results are graphically represented in graph no 3:

Table No.6: Mean For fatigue

Fatigue		
Day	Mean score of Group A	Mean score of Group B
BT	3.9	2.7
Day15th	3.9	2.87
Day30th	3.07	3.03
Day45th	2.57	3.2
AT	1.57	3.2



Graph No.3: Effect of Group A and Group B on fatigue of Type2 DM

Results of Subjective Parameters for Frequency of urination

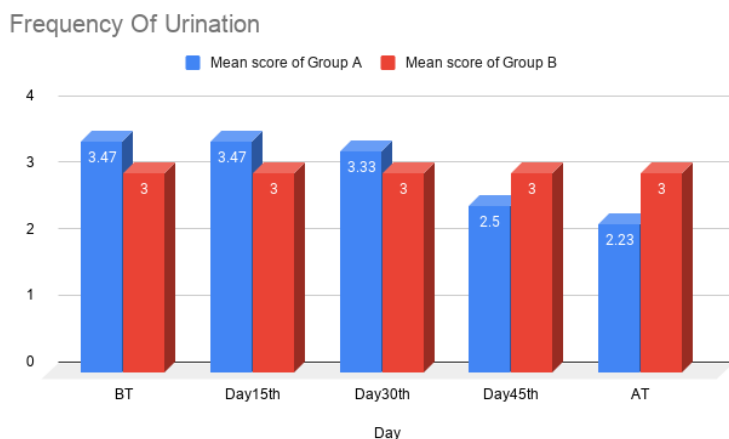
In this work of 15 patients studied with Group-A Frequency Of Urination revealed are given in detail in Table No.7. Statistical analysis showed that the mean score which was 3.47 before the treatment was reduced to 2.23 after the treatment with 35.73% improvement and it is statistically significant. ($P < 0.05$) results are graphically represented in graph no 20:

In this work of 15 patients studied with Group-B Increased Thirst revealed are

given in detail in Table No.7. Statistical analysis showed that the mean score which was 3 before the treatment and has remained same 3 after the treatment with 0% improvement. Results are graphically represented in graph no 4:

Table No.7 Mean for Frequency of Urination

Frequency Of Urination		
Day	Mean score of Group A	Mean score of Group B
BT	3.47	3
Day15th	3.47	3
Day30th	3.33	3
Day45th	2.5	3
AT	2.23	3



Graph No.4: Effect of Group A and Group B on frequency of urination of Type2 DM

Effect of Group-A and B on FBS

Table No 8 Group Statistics FBS

Group Statistics FBS					
	Group	N	Mean	Std. Deviation	Std. Error Mean
BT	Group A	15	122.2	12.852	3.318
	Group B	15	122.93	7.146	1.845
Day15th	Group A	15	121.4	12.397	3.201
	Group B	15	124	6.866	1.773
Day30th	Group A	15	119.2	10.995	2.839
	Group B	15	124.13	7.511	1.939

Table 8 continued...

Day45th	Group A	15	117.33	10.887	2.811
	Group B	15	123.67	7.724	1.994
AT	Group A	15	114.2	9.966	2.573
	Group B	15	123.93	6.85	1.769

Effect on FBS

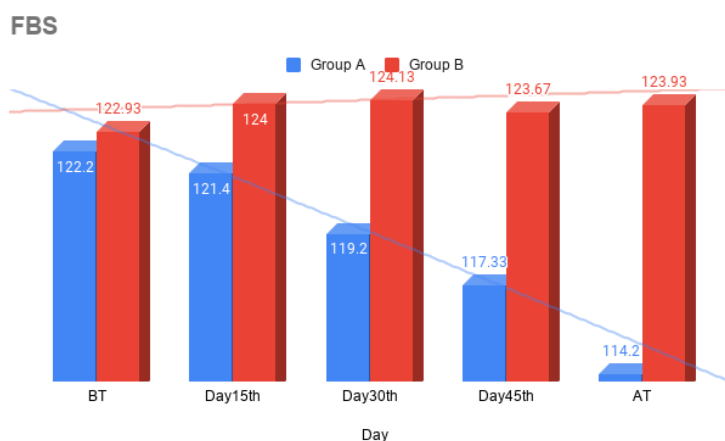
In this work of 15 patients studied with Group-A FBS revealed are given in detail in Table No.8. Statistical analysis showed that the mean score which was 122.2 before the treatment was reduced to 114.2 after the treatment with 6.5% changes and there is statistically significant. (P<0.05) results are graphically represented in graph no 21:

In this work of 15 patients studied with Group-B FBS revealed are given in detail in Table No.8. Statistical analysis showed that the mean score which was

122.93 before the treatment was reduced to 123.93 after the treatment with decrement of 0.81% and results are graphically represented in graph no 21:

Table No. 9 Percentage change in FBS

FBS				
Day	Group A	Group B	Percentage Change in FBS BT and AT in Group A	Percentage Change in FBS BT and AT in Group B
BT	122.2	122.93	6.55	-0.81
Day15th	121.4	124		
Day30th	119.2	124.13		
Day45th	117.33	123.67		
AT	114.2	123.93		



Graph 5: Effect of Group A & Group B on FBS

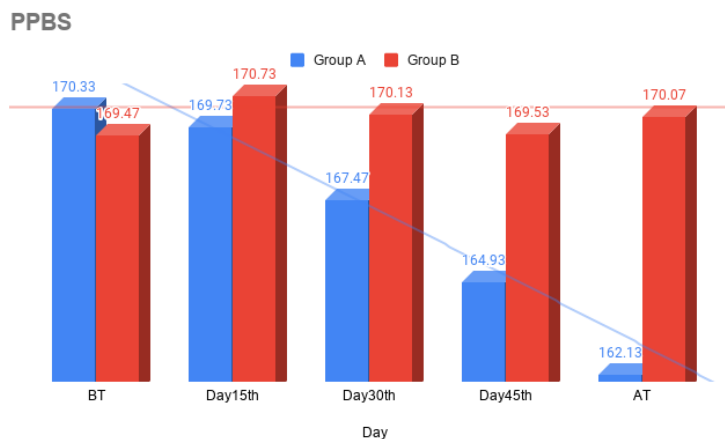
Effect on PPBS

Table No. 10 Group Statistics PPBS

Group Statistics PPBS					
	Group	N	Mean	Std. Deviation	Std. Error Mean
BT	Group A	15	170.33	10.111	2.611
	Group B	15	169.47	7.954	2.054
Day15th	Group A	15	169.73	9.362	2.417
	Group B	15	170.73	7.869	2.032
Day30th	Group A	15	167.47	8.114	2.095
	Group B	15	170.13	7.745	2
Day45th	Group A	15	164.93	7.815	2.018
	Group B	15	169.53	7.864	2.03
AT	Group A	15	162.13	7.708	1.99
	Group B	15	170.07	7.62	1.968

Table 11: Percentage Change in PPBS

PPBS				
Day	Group A	Group B	Percentage Change in PPBS BT and AT in Group A	Percentage Change in PPBS BT and AT in Group B
BT	170.33	169.47	4.81	-0.35
Day15th	169.73	170.73		
Day30th	167.47	170.13		
Day45th	164.93	169.53		
AT	162.13	170.07		



Graph No.6: Effect of Group A and Group B on PPBS of Type2 DM

Effect on PPBS

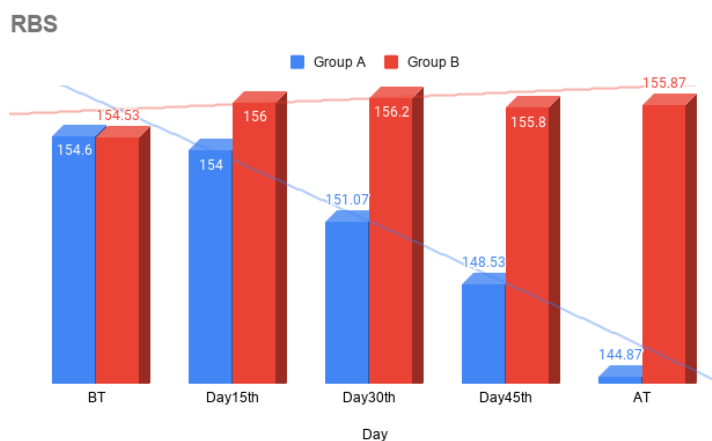
In this work of 15 patients studied with Group-PPBS revealed are given in detail in Table No.11. Statistical analysis showed that the mean score which was 177.33 before the treatment was reduced to 162.13 after the treatment with 4.81% changes and there is statistically significant. (P<0.05) results are graphically represented in graph no 22:

In this work of 15 patients studied in with Group-B PPBS revealed are given in detail in Table No.11. Statistical analysis showed that the mean score which was 169.47 before the treatment was increased to 170.07 after the treatment with decrement of 0.35% and results are graphically represented in graph no 6.

Effect on RBS

Table No. 12 Reading on RBS

Group Statistics RBS					
Day Of Treatment	Group	N	Mean	Std. Deviation	Std. Error Mean
BT	Group A	15	154.6	17.05	4.402
	Group B	15	154.53	14.956	3.862
Day15th	Group A	15	154	16.553	4.274
	Group B	15	156	14.745	3.807
Day30th	Group A	15	151.07	14.24	3.677
	Group B	15	156.2	15.162	3.915
Day45th	Group A	15	148.53	12.58	3.248
	Group B	15	155.8	15.753	4.068
AT	Group A	15	144.87	11.338	2.927
	Group B	15	155.87	15.454	3.99



Graph No.7: Effect of Group A and Group B on RBS of Type2 DM

Table No. 13 Percentage Change in RBS

RBS				
Day	Group A	Group B	Percentage Change in RBS BT and AT in Group A	Percentage Change in RBS BT and AT in Group B
BT	154.6	154.53	6.29	-0.87
Day15th	154	156		
Day30th	151.07	156.2		
Day45th	148.53	155.8		
AT	144.87	155.87		

In this work of 15 patients studied with Group-A RBS revealed are given in detail in Table No.13. Statistical analysis showed that the mean score which was 154.6 before the treatment was reduced to 144.87 after the treatment with 6.29% changes and there is statistically significant. (P<0.05) results are graphically represented in graph no 23:

In this work of 15 patients studied with Group-B RBS revealed are given in detail in Table No.13. Statistical analysis showed that the mean score which was 154.53 before the treatment was increased to 155.87 after the treatment with decrement of 0.87% and results are graphically represented in graph no 7:

Table No. 14 Percentage Change and Overall Improvement in Group A w.r.t Symptoms:

Symptoms	BT/AT	Mean Score of Group A	Percentage Change
Increased Hunger	BT	3.5	36.28
	AT	2.23	
Increased Thirst	BT	3.53	39.66
	AT	2.13	
Fatigue	BT	3.9	59.8
	AT	1.57	
Frequency of Urination	BT	3.47	35.73
	AT	2.23	

The percentage of improvement for Increased Hunger in Group A is 36.28%, for Increased Thirst is 39.66%, for Fatigue is 59.8%, for Frequency of Urination is 35.73.

Table No. 15 Percentage Change and Overall Improvement in Group A w.r.t Investigations

Investigations	BT/AT	Mean Score of Group A	Percentage Change
FBS	BT	122.2	6.55
	AT	114.2	
PPBS	BT	170.33	4.81
	AT	162.13	
RBS	BT	154.53	6.25
	AT	144.87	

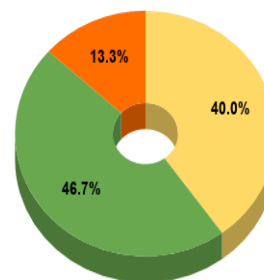
The percentage of improvement for FBS in Group A is 6.55%, for PPBS is 4.81%, for RBS is 6.25%.

Table No.16 Overall Improvement in Patients

Overall Improvements			
Class	Improvement Levels	Number Of Patients	Percentage
0-25%	No Improvement	0	0
25-50%	Mild Improvement	6	40
50-75%	Moderate Improvement	7	46.7
75-100%	Marked Improvement	2	13.3

Overall Improvement

● Mild Improvement ● Moderate Improvement ● Marked Improvement



Graph No.8: Overall improvement

DISCUSSION

Ayurveda doesn't stand simply for the cure of certain disease in individuals. It aims at prevention and promotion of physical and mental health and disease. And preventing diabetes can reduce a lot of burden on society. The combination of Amalaki, haridra along with madhu is said to cure all kinds of prameha. Individual agents are found to be effective in preventing various complications of diabetes. *Curcuma longum* has been studied for renoprotective, cataract preventing antioxidant, anti-inflammatory, antimicrobial, and anti-carcinogenic activities and *Embilica officinalis* is renoprotective, causes insulin release hepatoprotective, gastroprotective, immunomodulator. Different studies demonstrate the hypoglycemic effect of

honey. Research studies explain to a large extent many medicinal effects of honey such as antioxidant, hepatoprotective, cardio protective, antibacterial, anti-inflammatory, or antitumor.

The present trends of health consciousness, preference of healthy lifestyle and inclination towards usage of herbal medicine, considering simple and cost effective formulation of Amalaki swarasa and haridra churna with madhu can benefit and help in prevention of diabetes.

It is said that nidana parivar-janameva pradhana chikitsa, accordingly the pathya included both dietary and life style modifications which are to be practiced to manage the disease. In dietary pathya, diet rich in fibre content and also qualities opposite to the disease and its components.

Lifestyle modifications include regular exercise to maintain ideal weight. As mentioned in the benefits of vyayama, agnivridhi, sthaurya, doshakshaya can be attained. Beside regular exercise, manual labour and long distance walking of 100 yojana 100 days i.e., 1 yojana per day, vyayama, niyuddha, kreedha, gajacharya, turagacharya, rathacharya and padacharya explained. contemporary medicine also suggests to exercise regularly and maintain the ideal weight.

In Madhumeha, apakwa vata and pitta combines with kapha and medas as does dooshana of mootravahi srotas and further does dooshana of basti. Hence produces madhu rasa and madhu varna yukta mootra. It is a santarpana janya vyadhi. Hence the mode of the treatment here should be kaphahara, Medohara, Apatharpanakaraka and Kleda Nashaka.

The combination contains Amalaki, Haridra and Madhu. Amalaki is having Lavana varjita pancha rasa, sheeta virya, Laghu Ruksha guna and Tridosahara. Haridra is having Katu, Tikta rasa, Laghu Ruksha guna, Ushna virya and Tridosahara. Madhu is having Katu, Tikta rasa, Laghu Ruksha guna, Ushna virya and mainly kaphahara, lekhanakarma.

All the drugs are predominantly of tikta rasa and has laghu ruksha guna. Haridra acts as mutrasangrahaniya, medorogahara and pramehaghna. Amalaki not only acts as pramehghna but also as rasayana in madhumeha rogi. It also has the ability to stimulate the islets of langerhans and helps them to secrete their own natural insulin. Thus in diabetic it reduces the blood sugar, imparts a feeling of well being by treating other symptoms further preventing the complications. Madhu with its lekhanika guna is beneficial in santarpana janya vikara like madhumeha. It also acts as a very good anupana. It serves good amounts of antioxidants, useful to fight minor infections and hence very useful in diabetes.

Increased hunger

In Group-A, increased hunger after statistical analysis showed that the mean score which was 3.53 before treatment was reduced to 2.13 after treatment with 39.66% improvement and there is a statistically significant. As the symptom is due to medasavruta agni, the drugs included in the formulation has got medohara properties as well as lekhanika properties.

In Group-B increased appetite showed that the mean score which was 2.9 increased to 3.07 on last follow up with 5.86% decrement and there is a statistically significant ($P < 0.05$). This indicates that without any medication the severity of the symptoms goes on increasing.

Increased Thirst

In Group-A statistical analysis on thirst showed that the mean score of which was 3.5 before treatment was reduced to 2.23 after treatment with 36.29% improvement and there is statistically significant ($P > 0.05$). The drugs used especially madhu has got thrishnahara and dahaprashamana properties and tikta rasa has got trushnahara properties.

In Group-B increased thirst showed that the mean score which was 3 before treatment remained same after follow up with 0% improvement. as they have not

been given with any medication there is no improvement.

Fatigue

In Group-A fatigue showed that the mean score of which was 3.9 before treatment was reduced to 1.57 after treatment with 59.74% improvement and there is a statistically significant ($P < 0.05$). The medicine had good effect on this symptom. This medicine gives a nutritional support which reduces the common symptoms like fatigue, weakness etc.

In Group-B fatigue showed that the mean score if which was 2.7 on 1st follow up was increased to 3.2 on last follow up with 18.52% decrement.

Frequent urination

In Group-A frequent urination showed that the mean score which was 3.47 before treatment was reduced to 2.23 after treatment with 35.73% improvement and there is a statistically significant ($P < 0.05$). it is due to the drugs have got mooltra-sangrahaniya properties.

In Group-B frequent urination showed that the mean score which was 3 before remained the same on the last day of follow-up with 0% improvement.

FBS- Fasting blood sugar

In Group-A FBS showed that the mean score which was 122.2 before the treatment was reduced to 114.2 after the treatment with 6.55% changes and there is statistically significant ($P < 0.05$). The drugs contain potential therapeutic agent which reduces glycemia. Anti-diabetic drugs in combination with honey improve glycemic control further preventing oxidative damage.

In Group-B FBS showed that the mean score which was 122.93 before was increased to 123.93 a with 0.81% decrement.

PPBS- Post prandial blood sugar

In Group-A PPBS showed that the mean score which was 177.33 before the

treatment was reduced to 162.13 after the treatment with 4.81% changes and there is statistically significant ($P < 0.05$). the drugs in the formulation possess anti-diabetic effects through their anti-oxidant and free radical scavenging properties.

In group-B PPBS statistical analysis showed that the mean score which was 169.47 before was increased to 170.07 with 0.35% decrement.

RBS- Random blood sugar

In Group-A RBS showed that the mean score which was 154.6 before the treatment was reduced to 144.87 after the treatment with 6.29% changes and there is statistically significant ($P < 0.05$). The medicine has given a hypo-glycemic action, thus helping in lowering the fasting blood sugar levels.

In Group-B RBS showed that the mean score which was 154.53 before it was increased to 155.87 with 0.87% changes and there is statistically significant ($P < 0.05$)

CONCLUSION

Diabetes mellitus is one of the oldest diseases recognized since antiquity. It is a silently killing disease that has affected millions. Recently, the concept of pre-diabetes has been co-related by the modern science for the purpose of prevention. Many research works are carried out on Diabetes Mellitus but very less on Pre-diabetes. People with pre-diabetes have an increased risk of getting Type-2 Diabetes Mellitus. Pre-diabetes is now recognized as a reversible condition with certain dietary and lifestyle modifications.

The lakshanas told in classics and the symptoms told in recently co-related pre-diabetes is almost same. Pathya is the base for treating Diabetes Mellitus. Pathya should be emphasized when dealing with the management of Diabetes Mellitus. In present study, Pathya dravyas like Amalaki, Haridra and Madhu were selected and it provided significant results.

The formulation helped in overcoming the symptoms of pre-diabetes

especially fatigue, increased thirst and hunger. The group which was not administered with any medicine did not have any improvements and there is a definite chance of developing diabetes mellitus. They also showed signs of developing diabetes mellitus. So the Pathya dravyas Haridra, Amalaki and Madhu intake should be practiced regularly to prevent diabetes.

The present study was conducted with limited time, limited facilities and limited number of patients. A study of larger group may help to comprehend the mode of action of the trial drug.

A further study with strict dietary intervention and specific lifestyle modifications is recommended. In the future, additional studies may be performed to take the present issue further in a proper perspective and future possibilities of reduction of modern drug requirement or relaxation of dietary restriction.

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