



A CLINICAL STUDY TO EVALUATE THE EFFECT OF *MASURA YUSHA* AS *PATHYA* IN PREDIABETES

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ABSTRACT

Background of the study: Pre-diabetes is an intermediate state of hyperglycemia with glycemic parameters above normal level but below the Diabetes threshold. It is considered to be at risk state, with high chances of developing Diabetes. Following *Pathya* becomes essential in this stage of the disease. *Masura Yusha* has been referred as “*Pramehahara*” in *Yogaratanakara* and *Kaiyyadeva Nighantu*.

Objective: To evaluate the effect of *Masura Yusha* as *Pathya* in Pre-diabetes

Methodology: A minimum of 60 patients fulfilling the inclusion, exclusion and diagnostic criteria of Pre-diabetes were selected and randomly divided into two equal groups, group A and group B. 30 patients of group A were advised with dietary intervention and 30 patients of group B were advised with *Masura Yusha* and dietary intervention for a period of 15 days. The outcome measures were assessed at baseline, on day 15th, 30th, 45th day for Increased thirst, Frequent desire to urinate, FBS and PPBS.

Result: As per the results, the test shows statistically significant results in both the groups (group A and group B) with group B (*Masura yusha* with Dietary Intervention) having better result than group A (Dietary Intervention) in controlling Increased thirst, Frequent desire to urinate, FBS, PPBS.

Conclusion: *Masura Yusha* has better result than Dietary Interventions in Pre-diabetes.

KEY WORDS: Prediabetes, *Masura Yusha*, *Prameha*

INTRODUCTION:

Pre-diabetes is an intermediate state of hyperglycemia with glycemic parameters above normal level but below the Diabetes threshold. It is considered to be at risk state, with high chances of developing Diabetes. According to International Diabetes Federation 2019, worldwide 548.4 million adults are estimated to have IGT (Impaired Glucose Tolerance) in 2045. In India, around 25 million individuals are living with Pre-diabetes and the number is expected to increase to 41 million by 2045.

According to *Acharya Charaka*, the wholesome regimen which does not impair the body system and which is pleasing to the mind is called *Pathya*. *Masura* (*Lens culinaris*) is said to be *Pathya* in *Prameha*. *Masura* has *Kashaya Pradhana Madhura Rasa* (Astringent and Sweet in taste), *Sheeta Veerya* (Cold in potency) *Madhura Vipaka* (Post digestion effect is Sweet) and *Pitta Kapha Shamaka*. *Masura Yusha* has been referred as “*Pramehahara*” in *Yogaratanakara* and *Kaiyyadeva Nighantu*.

An ideal diet plan, which incorporates adequate proteins, high dietary fibers, low fats and calories is important for maintaining blood sugar levels at normal range. In this study patients were made aware of the importance of following a healthy and balanced diet. A common diet chart was made based on Protocol for Prevention and Control of Diabetes through Ayurveda – Ministry of AYUSH. Govt. of India. Here an attempt was made to evaluate the effect of *Masura Yusha* as *Pathya* along with Dietary Interventions in Pre-diabetes owing to its easy administration, availability, cost effectiveness and palatability.

METHODOLOGY:

SAMPLE SOURCE:

Patients diagnosed as Prediabetics were selected from the OPD and IPD of Alva's Ayurveda Medical College and Alva's Hospital, Moodubidire & from other camps and referrals.

METHOD OF COLLECTION OF DATA

A minimum of 60 patients fulfilling the inclusion, exclusion and diagnostic criteria of Pre-diabetes irrespective of gender, religion, occupation, marital status and socio-economic status were selected and randomly divided into two equal groups, group A and group B. The outcome measures were assessed at baseline, on day 15th, 30th, 45th day.

STUDY DESIGN:

A Randomized controlled clinical trial.

DIAGNOSTIC CRITERIA:

Diagnosis was done on the basis of presence of the following features: Fasting Plasma Glucose value between 100mg/dl – 125mg/dl, 2hr Plasma Glucose or OGTT value between 140mg/dl – 199mg/dl, Patients with or without following features of Pre-diabetes, Increased thirst, Frequent desire to urinate.

INCLUSION CRITERIA:

Patients of either gender fulfilling the diagnostic criteria were selected with the age group of 30 – 60 years.

EXCLUSION CRITERIA:

FPG value ≥ 126 mg/dl, OGTT value ≥ 200 mg/dl, Patients with known type 2 Diabetes Mellitus and under Hypoglycemic drugs, Gestational diabetes, Patient with chronic systemic diseases.

INTERVENTION:

GROUP A: 30 patients of group A were advised to follow Dietary Interventions for 15 days.

GROUP B: 30 patients of group B were given with 150ml of *Masura Yusha* once in a day at night time and advised to follow Dietary Interventions for 15 days.

PREPARATION OF YUSHA:

1 *Pala* (48g) of *Masura* was taken in a vessel and 1 *Prastha* (768ml) of water was added and boiled till it was completely cooked and the semisolid consistency was obtained. For this preparation *Ghruta*, followed by *Shunti*, *Pippali* half *Karsha* (6g) and *Saindhava lavana* quantity sufficient was added.

DIETARY INTERVENTIONS: A common Diet chart based on Protocol for Prevention and Control of Diabetes through Ayurveda – Ministry of AYUSH. Govt. of India was advised.

STATISTICAL ANALYSIS: Assessment of the condition was done based on detailed case proforma adopting subjective and objective parameters with scoring method for subjective parameters. The effect of treatment was analysed by using Parametric & non-parametric statistical tests such as Anova Test (One way, Anova on ranks), Mann-Whitney U test, t test, Wilcoxon signed rank test etc.

SUBJECTIVE PARAMETERS:

- 1) Increased thirst
- 2) Frequent desire to urinate

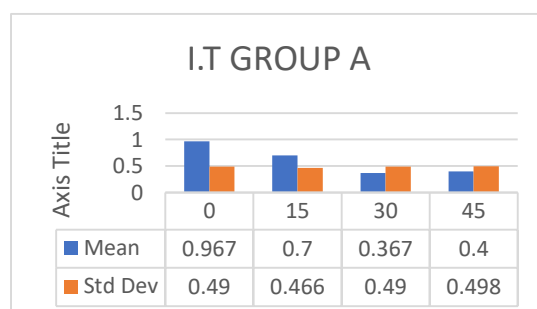
Please refer Table number 1 and 2

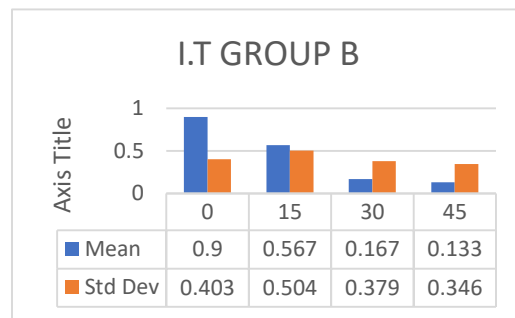
OBJECTIVE PARAMETERS:

- 1) FBS
- 2) PPBS

RESULTS:**1. EFFECT ON INCREASED THIRST:**

Graph no: 1 Effect of diet chart on increased thirst

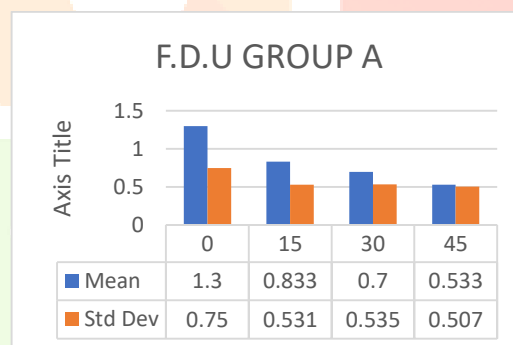
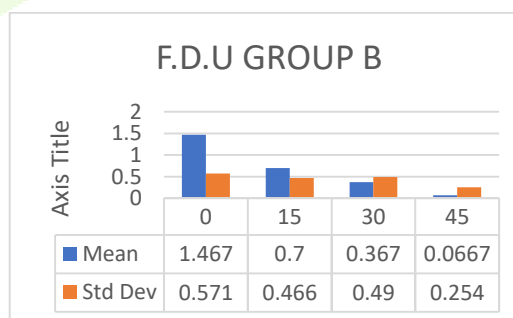


Graph no: 2 Effect of *Masura yusha* with diet chart on increased thirst

There is no statistically significant difference seen on comparing BT and AT in both groups, but there is a statistically significant difference on comparing BT with follow up in both groups. The further decrease during Follow up 2 found in group B, which is significant on comparing with AT suggests that, there is a gradual decrease in thirst seen in both groups with group B showing much reduction during Follow up 2.

EFFECT OF TREATMENT ON INCREASED THIRST BETWEEN GROUP A AND GROUP B

As seen in table no. 3, there is no statistically significant difference noted between Group A and B at all time points.

2. FREQUENT DESIRE TO URINATE**Graph no: 3 Effect of diet chart on frequent desire to urinate in group A****Graph no: 4 effect of *Masura yusha* with diet chart on frequent desire to urinate in group B**

There is a statistically significant difference in within the group analysis of group A and group B on all time points being compared to BT. Further the effect attained during AT is maintained during Follow up in Group A, While there is a significant reduction during Follow up 2 found in group B.

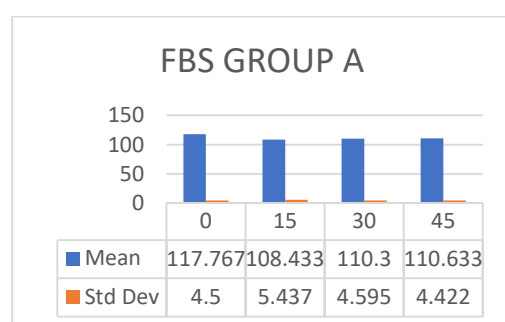
EFFECT OF TREATMENT ON FREQUENT DESIRE TO URINATE BETWEEN GROUP A AND GROUP B

As seen in table no.4, there is a statistically significant difference noted between Group A and B, in frequent desire to urinate when compared with BT. Further on comparing AT with follow up 2 also shows a significant difference. On comparing the medians it can be inferred that group B has better effect on FDU in comparison to Group A, where effect of treatment was maintained till 45th day in group B. ($P < 0.05$)

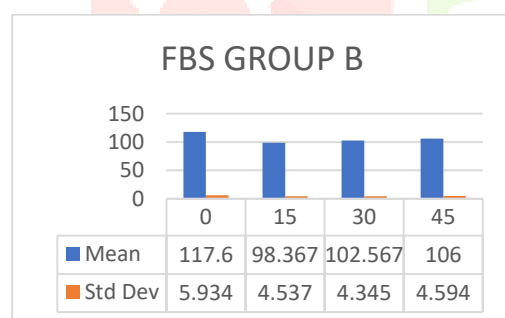
OBJECTIVE PARAMETERS:

1. FBS

Graph no: 5 Effect of diet chart on FBS in group A



Graph no: 6 Effect of *Masura yusha* with diet chart on FBS in group B



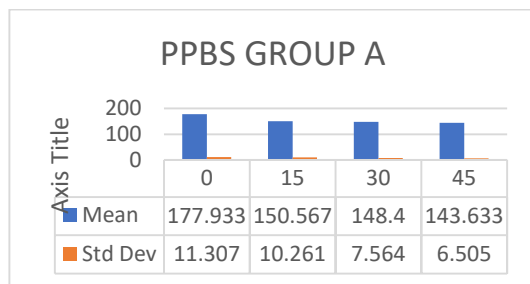
There is a statistically significant difference observed when all time points are compared with BT, with mean FBS being lesser than BT. But the mean FBS being increased on 30th and 45th day, which is statistically significant when compared to 15th day, suggests that diet chart helped to reduce FBS and later during follow up the effect was not maintained. In group B the effect of treatment was maintained when all time points are compared.

EFFECT OF TREATMENT ON FBS BETWEEN GROUP A AND GROUP B

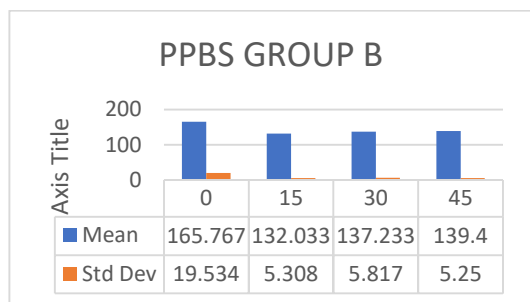
As seen in table no. 5, there is a statistically significant difference noted between Group A and B, in FBS when compared with BT. Further on comparing AT with follow up 1 and follow up 2 also shows a significant difference. On comparing the medians, it can be inferred that group B has better effect on FBS in comparison to Group A which is evident through follow up. ($P < 0.05$).

2. PPBS

Graph no: 7 Effect of diet chart on PPBS in group A



Graph no: 8 Effect of *Masura yusha* with diet chart on PPBS in group B



There is a statistically significant difference in within the group analysis of group A and group B on PPBS, with group B having better effect on PPBS than group A, and the effect was maintained till 30th day.

EFFECT OF TREATMENT ON PPBS BETWEEN GROUP A AND GROUP B

As seen in table no. 6 there is a statistically significant difference noted between Group A and B, in PPBS when compared with BT. Further on comparing AT with follow up 1 and follow up 2 shows a significant difference. On comparing the medians it can be inferred that group B has better effect on PPBS in comparison to Group A which is evident through follow up. ($P < 0.05$).

DISCUSSION:

Pre-diabetes is an alarming sign of upcoming diabetes. Controlling the diet in such conditions would prevent the progression of the disease to later stages. Hence adopting *Pathya Ahara Sevana krama* in Prediabetes becomes important.

To meet the purpose of dietary article which is in day today practice, *Masura* was selected. *Masura Yusha* is easy to prepare, palatable and gives the feeling of satiety. The diabetic potential present in *Masura* helps in controlling the disease from developing into diabetic stage.

DISCUSSION ON INCREASED THIRST:

There is no significant effect of diet chart and *Masura yusha* along with diet chart in reducing the symptom, but group B shows decrease in symptom during second follow up. *Masura yusha* group showing better improvement because of *Madhura vipaka* (Post digestive taste is Sweet) and *Sheeta virya* (Cold in potency) properties.

DISCUSSION ON FREQUENT DESIRE TO URINATE:

Masura yusha has a better effect on reducing the symptom when compared with only diet chart group.

Masura yusha having and *Madhura* (Sweet) in *rasa* and it is *Grahi* (Absorbent) in nature and has a *Kaphahara* property. The *yusha* which has both *Deepana* (Increases digestive power) and *Pachana* (digestion) actions, does *Drava Shoshana* (dries up fluids). *Drava* may be in the form of *Dosha*, *Dhatu* or *Mala*.

Most of the *Dravya* in dietary items suggested to the patients are of *Kashaya Rasa* (Astringent taste) which is having properties of *Shoshana* (dries up fluids), *Kaphaghana* and *Mutra Sangrahaniya* (Anti-diuretic). Also *Dravya* like *Yava* (Barley) is having properties of *Kleda Shoshana* (dries up fluids) and *Rukshana* (Dries up fluids) which probably must have helped in relieving the symptoms.

DISCUSSION ON FBS AND PPBS:

Guna (Property) of *Masura* is *Laghu* (Light) and *Ruksha* (Dry), *Rasa* (Taste) is *Kashaya* (Astringent) and *Madhura* (Sweet), *Madhura vipaka* (Post digestive effect is Sweet), *Sheeta veerya* (Cold in potency), *Doshakarma* (Effect on *Dosha*) is *Kapha hara* (Reduces *Kapha dosha*). *Karma* (Action) is *Bala vardhaka* (Improves body strength), *Graahi* (Absorbent) and *Dhatuvardhaka* (Tissue building). Useful in *Rakta pitta* (Bleeding disorder), *Kapha vikara* (Disease of *Kapha dosha*) and *Madhumeha* (Diabetes Mellitus). *Yusha* is one among *Pathya Kalpana* having properties such as *Rochaka* (Increases taste perception), *Deepaka* (Increases digestive power), *Hrudya* (Conducive to heart) and *Laghu* (Light). *Masura yusha* is *Madhura* in *Rasa*, *Prameha hara*, *Graahi* and it is *Dhatuvardhaka*.

Glycemic index of *Masura* is in between 18 – 38. But when *Masura* is added with water gets cooked to become *Yusha*, the glycemic index reduces to 12.

Masura contains an anti-diabetic potential i.e, α – amylase inhibitory action in it.

Alpha-amylase inhibitory activity is a measure of how well a substance inhibits the activity of alpha-amylase, an enzyme that breaks down carbohydrates. Alpha- amylase is found in the pancreas and saliva, and it helps to start the process of breakdown of the carbohydrates by hydrolyzing starch and related polysaccharides.

The α – amylase inhibitory action of *Masura* helps in reducing the digestion of carbohydrates, which lowers blood glucose levels. The reduced sugar level in blood controls the symptoms such as increased thirst and frequent desire to urinate.

CONCLUSION

As per the results within the group, the test shows statistically significant results in both the groups (group A and group B) for FBS, PPBS and frequent desire to urinate and shows no significant results for increased thirst in both the groups. But there is a gradual decrease in thirst seen in both groups with group B showing much reduction during follow up 2.

Between the group analysis of Increased thirst shows no significant difference. Between the group analysis shows statistically significant difference for frequent desire to urinate, where group B has better effect on FDU in comparison to Group A, and the effect of treatment was maintained till 45th day. Between the group analysis of FBS shows a statistically significant difference and group B has better effect on FBS in comparison to Group A. Between the group analysis of PPBS shows a statistically significant difference with group B having better effect on PPBS in comparison to Group A. Thus, we conclude that null hypothesis H_0 is rejected and the alternate hypothesis H_1 is accepted - H_1 There is a statistically significant difference between Dietary Interventions and *Masura Yusha* with *Masura Yusha* is having better result than Dietary Interventions in Pre-diabetes.

LIST OF TABLES:**Table Number:1 Showing gradings for Increased thirst**

Increased thirst	Assessment Variables	Score
	Feeling of thirst 7 – 9 times/24 hours, either/or Intake of water 5–7 times/24 hours with quantity 1.5 – 2.0 liter/24 hours	0
	Feeling of thirst 9- 11 times/24 hours, either/or Intake of water 7-9 times/24 hours with quantity 2.0 - 2.50 liter/24 hours	1
	Feeling of thirst 11–13 times/24 hours, either/or Intake of water 9 –11 times/24 hours with quantity 2.50 -3.00 liter/24 hours	2
	Feeling of thirst >13 times/24 hours, either/or Intake of water >11 times/24 hours with quantity >3.00 liter/24 hours	3

Table Number:2 Showing gradings for Frequent desire to urinate

Frequent desire to urinate	Assessment Variables	Score
	3–6 times per day, rarely at night	0
	6–9 times per day, 0 – 2 times per night	1
	9–12 times per day, 2- 4 times per night	2
	More than 12 times per day, more than 4 times per night	3

Table no: 3 Effect of treatment on Increased thirst between group**A and group B**

I.T	MEDIAN		MANNWHITHEY TEST		REMARKS
	A	B	T VALUE	P VALUE	
BT – AT	0.000	0.000	885.000	P = 0.662	NS
BT – FU1	1.000	1.000	851.000	P = 0.347	NS
BT – FU2	1.000	1.000	821.500	P = 0.168	NS
AT – FU1	0.000	0.000	880.000	P = 0.609	NS
AT – FU2	0.000	0.000	861.500	P = 0.432	NS

FU1 – FU2	0.000	0.000	886.000	P = 0.671	NS
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Table number: 4 Effect of treatment on Frequent desire to urinate between group A and group B

F.D.U	MEDIAN		MANN WHITHEY TEST	
	A	B	T VALUE	P VALUE
BT – AT	0.000	1.000	780.000	P = 0.046
BT – FU1	1.000	1.000	731.500	P = 0.007
BT – FU2	1.000	1.000	701.500	P = 0.002
AT – FU1	0.000	0.000	830.000	P = 0.210
AT – FU2	0.000	1.000	774.500	P = 0.038
FU1 – FU2	0.000	0.000	855.000	P = 0.377

Table number: 5 Effect of treatment on FBS between group A and group B

Group	Median		T value	P value	Remarks
	A	B			
BT – AT	9.000	20.000	529.500	P = <0.001	Yes
BT – FU1	7.500	13.500	556.000	P = <0.001	Yes
BT – FU2	7.133	11.600	-3.818	P = <0.001	Yes
AT – FU1	-2.500	-4.000	1053.000	P = 0.042	Yes
AT – FU2	-2.200	-7.633	3.927	P = <0.001	Yes
FU1 – FU2	-0.333	-3.433	2.963	P = 0.004	Yes

Table number: 6 Effect of treatment on PPBS between group A and group B

Group	Median		T value	P value	Remarks
	A	B			
BT – AT	26.500	32.500	753.500	P = 0.017	SS
BT – FU1	29.533	28.533	2.250	P = 0.003	SS
BT – FU2	34.300	26.367	2.066	P = 0.043	SS
AT – FU1	3.000	-5.000	1133.500	P = 0.001	SS
AT – FU2	7.000	-8.000	1271.500	P = <0.001	SS
FU1 – FU2	4.767	-2.167	3.909	P = <0.001	SS

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