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A Clinico-Pathological Study On *Prameha Purvarupa* (Pre- Diabetic Condition) And Its Management With *Nisha-Amalaki Churna* And *Shilajeet Vati*

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ABSTRACT: -

Introduction- *Purvarupa* (Prodromal symptoms) of *Prameha* (Diabetes) helps in early diagnosis as well as prevention of the disease as compared to *Rupa* of *Prameha*. *Purvarupa Avastha* of *Prameha* is a condition in which the patients have high blood glucose but not up to the mark that can be defined as Diabetes Mellitus or *Madhumeha*.

Materials and methods- 30 patients of Group A- (15 patients) and Group B- (15 patients) were registered from OPD and IPD of Govt. Ayurvedic College & Hospital, Balangir, presented with Subjective Parameter as *Prabhuta mutrata* (frequency of micturition), *Pipasa* (increased thirst), *Kshudha* (excessive appetite), *Kara-pada Daha* (burning sensation in hand and feet), *Kara-pada Suptata* (numbness of hand and feet), *Sweda Pravritti* (excessive sweating), *Mukha Shosha* (dry mouth), *Mukha Madhurya* (sweetness in mouth), *Sheeta Priyata* (liking for cold things) and *Madhura Shukla Mutrata* (sweetness in urine) and Objective Parameter as fasting plasma glucose 100-125 mg%, oral glucose tolerance 140-200mg%, HbA1c 5.7%-6.4%. After diagnosis they were under trial with *Ayurvedic* formulations of *Nisha-Amalaki Churna* given 3gm twice daily empty stomach in Group A and *Shilajeet Vati* given 1 vati (500mg) twice daily empty stomach, for a period of 30 days with *Ushna Jala* respectively. The assessment of subjective and objective parameters were evaluated in 10th, 20th and 30th day from the day of initiation of trial up to 30 days in order to find the efficacy of both the trials by statistical paired 't' test.

Observation and results:- It has been observed that both the trial drugs revealed good result but drug of Group-A patients was highly significant (p<0.001) to reduce both Subjective and Objective parameter as compared to Group-B patients after 30 days of treatment.

Discussion and Conclusion- *Prameha* (Diabetes) is a **Kapha Pradhana Tridoshaja vyadhi** in which *Meda* (Fat) is a *Pradhan Dushya.* Both the drugs had improved by reducing *Prameha Purvarupa* and the levels of FBS, PPBS and HbA1c in patients but *Nisha-Amalaki Churna* inferred better result as compare to *Shilajeet Vati*. No side effect was noticed during clinical study of *Nisha-Amalaki Churna* and *Shilajeet Vati*.

Keywords - *Prameha*, Pre-diabetes, *Purvarupa Avastha, Nisha-Amalaki Churna, Shilajeet Vati*.

INTRODUCTION

Acharaya Charaka, Sushruta, and Vagbhata have described *Prameha* (Diabetes) as one of the *Ashtamahagada vikara* (eight major diseases)[1]. Now a days the disease Diabetes Mellitus has evolved as a life complicating disorder. *Prameha* is a *Tridoshajanya Vikara* due to the simultaneous vitiation of all the three *doshas*[2]. In view of *Ayurveda* "*Prabhutavilamutrata*"[3] the morbid secretion of urine in general is called *Prameha i.e.*profuse urination along with copious and turbid urine. Pre-diabetes is a condition where a person's blood sugar levels are higher than normal, but not high enough to be diagnosed as Diabetes Mellitus. According to American Diabetes association in Pre-diabetes FPG is 100-125 mg/dl, GTT is 140-199 mg/dl and HbA1c is 5.7%-6.4%[3]. If pre-diabetic condition is not treated properly, prevention is not taken and *Nidana Parivarjana* (avoid the cause) is not done then it may turn into diabetic state. So for better and safety treatment *Ayurvedic* herbal preparations *Nisha-Amalaki Churna*[4] and *Shilajeet Vati*[5] are selected for present comparative research protocol in *Prameha Purvarupa*[6] (Pre-diabetic condition).

AIM AND OBJECTIVE OF THE STUDY

1. To study the efficacy of *Nisha-amalaki Churna* and *Shilajeet vati* in the management of *Prameha Purvarupa.*

2. To find out a suitable herbal drug for the treatment of *Prameha Purvarupa.*

3. To correlate *Purvarupa* of *Prameha* in modern parlance.

MATERIALS AND METHODS

Selection of Patients:

The total 30 patients (Group A- 15, Group B- 15) had been selected by a special proforma covering demography along with both Subjective and Objective parameters from OPD and IPD of Govt. *Ayurvedic College and Hospital, Balangir and Saradeshwari Govt. Ayurvedic Hospital Balangir.* The consent of patients were also taken before clinical trial.

Inclusion Criteria:

1. Patients age between 30-65 years of both sexes.

2. Patients having symptoms of *Prabhuta Mutrata* (frequency of micturition), *Pipasa* (increased thirst), *Kshudha* (excessive appetite), *Kara-pada Daha* (burning sensation in hand and feet), *Kara-pada Suptata* (numbness of handand feet), *Sweda Pravritti* (excessive sweating), *Mukha Shosha* (dry mouth), *Mukha Madhurya* (sweetness in mouth), *Sheeta Priyata* (liking for cold things) *Madhura Shukla Mutrata* (sweetness in urine).

3. Patients having FBS (100-125mg%), PPBS (140-200mg%) and HbA1c (5.7-6.4mg/dl) were selected for this study.

Exclusion Criteria:

1. Patients age <30 years and >65 years.

2. Patients having fasting plasma glucose > 125mg, oral glucose tolerance > 200mg%, HbA1c more than 6.5%.

3. Patients having complications of diabetes like ketoacidosis, nephropathy, neuropathy, retinopathy, and diabetic wounds.
4. Chronic, contagious infection disease such as active tuberculosis, hepatitis B or C, or HIV.
5. Pregnant and lactating females.
6. Active metabolic or gastrointestinal disease that may interfere with nutrient absorption, metabolism, excretion.
7. Excluding Type-1 diabetes mellitus and Type-2 diabetes mellitus.

Criteria for Investigations

Hb%, TLC, DLC, Urine (Routine and Microscopic) examination, Fasting blood sugar (FBS), Post prandial blood sugar (PPBS), HbA1c were investigated initially and follow up periods.

Selection of drug

Two medicines *Nisha-Amalaki Churna*[7] (*Nisha* and *Amalaki* equal part) and *Shilajeet Vati*[8] had been taken for clinical trial. The drugs of both medicines were identified by the experts of Dept. of *Dravyaguna and Rasashastra and Bhisajya Kalpana* which were approved by DRC and IEC of College and Sambalpur University. Medicines were prepared as per GMP certified method in Mini Pharmacy of College under the supervision of expert of *Rasashastra and Bhisajya Kalpana.* The sample of research medicines were sent to Quality control Laboratories of ALN Rao Memorial Ayurvedic Medical College and PG centre Koppa, Distt. Chikmagalur, Karnatka for Analytical study.

Table No.-01; Showing the pharmacodynamics of drugs of *Nisha-Amalaki Churna*[9] and *Shilajeet Vati*

Name	Rasa (Essence)	Guna (Quality)	Veerya (Potency)	Vipaka (Post digestive effect)	Doshakarmata	Quantity Taken
		Nisha-Amalaki Churna				
Nisha(Turmeric)	*Tikta, Katu*	*Laghu Rukshya*	*Ushna*	*Katu*	*Kaphapittashamaka*	1 Part
Amalaki (Indian gooseberry)	*Amlapradhana LavanaVarjita Pancharasa*	*Rukshya Guru Sheeta*	*Sheeta*	*Madhura*	*Tridoshashamaka*	1 Part
		Shilajeet Vati[10]				
Shilajeet (Asphaltum)	*Tikta Lavana*	*Sheeta Guru Snigdha*	*Sheeta*	*Katu*	*Tridoshashamaka*	950 gm

Dose – *Nisha-Amalaki Churna* 3 gm twice daily empty stomach *and Shilajeet Vati* 1*Vati* (500mg) twice daily empty stomach with *Ushna Jala* (hot water) in Group A and Group B respectively.

Assessment Criteria:

The Subjective parameters and Objective parameters as per Inclusion Criteria were assessed by the grading score from 0 to 3 according to the severity of disease and favorable shift to back. Both parameter follow-up was taken on 10th, 20th and 30th day of medication. The overall assessments were done considering the percentage relief of both parameters and statistical evaluation.

OBSERVATION AND RESULT

The clinical study period of 30 patients were from 11-05-2020 to 06-03-2021.

Within the aforesaid period the demography (Table No.-02) based on Age-Sex-Religion etc. along with incidence of *Dashvidha Pariksha* (Table No.-03) were observed and assessed.

Table no. 02; Demography Incidence of Registered Patients. (n=30)

Criteria	Maximum Percentage	Category
Age	36.67%	30-40 years
Sex	50%	Both Male & Female
Religion	96.67%	Hindu
Education status	73.33%	Literate
Occupation	23.33%, 46.67%	Service, Housewife
Socio- Economical status	73.33%	Middle class
Marital status	100%	Married
Dietary habit	80%	Non-vegetarian
Habit / Addiction	70%	Taking tea
Mode of onset	100%	Gradual
History of past illness	86.67%	No past history
Family history	60%	Absent
Sleeping habit	66.67%	Normal sleep
Urination	60%	More
Bowel habit	53.33%	Normal

Table no. 03; Incidence of *Dashavidha- Pariksha* of Registered Patients. (n=30)

Criteria	Maximum Percentage	Category
Prakriti	43.33%	*Vatapitta*
Vikriti	50%	*Madhyama- vastha*
Sara	63.33%	*Madhyama-sara*
Samhanan	53.33%	*Madhyama*
Pramana	86.67%	*Madhyama sharira*
Satwa	50%	*Madhyama*
Satmya	43.33%	*Madhyama*
Ahara Shakti	60%	*Madhyama Ahara Shakti*
Vyayama Shakti	63.33%	*Hinabala Vyayama Shakti*
Vaya	60%	*Madhyamavastha*

The Subjective and Objective Parameters of both Group-A and Group-B were observed during clinical study. The percentage of improvement were also observed and assessed after clinical trial. (Table No.-04)

Table No. 04; Showing the observation of total patients as per disease ad percentage of Improvement in Group-A and Group-B. (n=30) (f-Frequency,%- Percentage)

Sign/ Symptom	Group-A		Group-B		Group-A	Group-B
	f	%	F	%	%age of improve.	%age of improve.
Subjective Parameter						
Prabhuta Mutrata (Quantity)	11	73.33	7	46.67	90.91	71.43
Prabhuta Mutrata (Frequency)	11	73.33	6	40	83.33	77.78
Pipasa (Increased thirst)	10	66.67	11	73.33	71.67	72.73
Kshudha (Excessive appetite)	9	60	9	60	87.04	72.22
Kar-pada Daha (Burning sensation in hand and feet)	6	40	7	46.67	91.67	73.81
Kar-pada Suptata (Numbness in hand and feet)	7	46.67	4	26.67	85.71	100
Sweda Pravriti (Excessive Sweating)	9	60	7	46.67	77.78	83.33
Mukha Shosha (Dry mouth)	5	33.33	8	53.33	70	79.17
Mukha Madhurya (Sweetness in mouth)	7	46.67	6	40	80.95	77.78
Sheeta Priyata (Liking for cold things)	5	33.33	5	33.33	86.67	80
Madhura Shukla Mutrata (Sweetness and whitish in urine)	3	20	3	20	100	100
Objective Parameter						
FBS	15	100	15	100	88.89	68.89
PPBS	15	100	15	100	96.67	81.11
HbA1c	15	100	15	100	87.78	73.33

After observation of subjective and Objective Parameters, the statistical analysis of parameter were assessed with help of statistical method. (Table No.-05)

Table No. 05; Showing the Statistical Analysis of Subjective Parameter and ObjectiveParameter. (n=30)

Sign/ symptoms	Mean ± SD				Group-A		Group-B	
	Before Treatment Group-A	After Treatment Group-A	Before Treatment Group-B	After Treatment Group-B	t-value	p-value	t-value	p-value
Subjective parameter								
Prabhuta Mutrata (Quantity)	1.91 ± 0.7	0.09 ± 0.30	2.14 ± 0.69	0.71 ± 0.76	6.90	<0.001	7.07	<0.001
Prabhuta Mutrata (Frequency)	2.00 ± 0.77	0.36 ± 0.50	2.50 ± 0.84	0.67 ± 0.82	6.71	<0.001	5.97	< 0.005
Pipasa	2.30 ± 0.67	0.70 ± 0.48	2.09 ± 0.70	0.55 ± 0.52	9.80	< 0.001	7.46	< 0.001
Kshudha	2.22 ± 0.83	0.33 ± 0.50	2.11 ± 0.78	0.67 ± 0.71	7.25	< 0.001	5.96	< 0.001
Kara-pada Daha	1.50 ± 0.55	0.17 ± 0.41	1.86 ± 0.69	0.57 ± 0.53	6.32	< 0.001	6.97	< 0.001
Kar-pada Suptata	1.57 ± 0.79	0.14 ± 0.38	1.50 ± 0.58	0 ± 0.00	3.87	< 0.01	5.20	< 0.05
Sweda Pravriti	1.67 ± 0.71	0.33 ± 0.50	1.86 ± 0.69	0.43 ± 0.79	4.62	< 0.005	7.07	< 0.001
Mukha Shosha	1.80 ± 0.45	0.40 ± 0.55	2.00 ± 0.76	0.50 ± 0.53	3.50	< 0.05	7.94	< 0.001
Mukha Madhurya	1.86 ± 0.69	0.43 ± 0.53	1.83 ± 0.75	0.33 ± 0.52	7.07	< 0.001	4.39	< 0.01
Sheeta Priyata	2.40 ± 0.89	0.40 ± 0.55	1.60 ± 0.55	0.40 ± 0.55	6.32	< 0.005	6.00	< 0.005
Madhura Shukla Mutrata	1.67 ± 0.58	0.0 ± 0.0	1.33 ± 0.58	0.0 ± 0.0	5.00	< 0.05	4.00	<0.05
Objective Parameters								
FBS	2.67 ± 0.62	0.33 ± 0.49	2.87 ± 0.35	0.93 ± 0.70	14.64	< 0.001	12.61	< 0.001
PPBS	1.93 ± 0.59	0.07 ± 0.26	2.20 ± 0.68	0.47 ± 0.64	11.30	< 0.001	9.54	< 0.001
HbA1c	1.87 ± 0.74	0.27 ± 0.46	1.80 ± 0.68	0.60 ± 0.74	8.41	< 0.001	8.29	< 0.001

S.D= standard deviation,t= test of significance, p=probability; <0.05= significant at 5% level, <0.01 =significant at 1% level, <0.005= significant at 0.5%, <0.001 = Highly significant at 0.1% level

DISCUSSION

Purvarupa Avastha of *Prameha* (Prodromal symptoms of DM) can be considered as Pre-diabetes which is a condition where a person's blood sugar levels are higher than normal, but not high enough that mark to be diagnosed as diabetes[11]. Pre- diabetes does not have to result in diabetes if lifestyle changes are made. If pre-diabetic phase is not treated properly, with *Nidana Parivarjana* (Avoiding the cause) and appropriate *Pathyapathya* (wholesome -unwholesome)then it may turn into diabetic phase[12]. In this study *Purvarupa* of *Prameha* (Prodromal symptoms of DM) were taken into consideration. If the clinical features of *Prameha Purvarupa* are minimized by the administration of *Ayurvedic* drugs which are cost effective, easily available and palatable, the condition may not be aggravated and reverse to normal.

The literary reviews were discussed with *Nidana* (aetiology), *Samprapti* (Pathogenesis), Classifications and its probable modern co-related diseases narrated in modern classics. Here all the disease associated with *Kapha* and transformed into *Bahu Drava Sleshma* which in turn hampers the *Visarga Karma* of *Kapha.* This could be correlated as the soluble glucose abundantly found in blood in case of impaired glucose metabolism leading to hyperglycaemia[13].

Regarding demographic incidence it has been observed that (Table No.-02) both male and female of middle age group, educated residing in urban areas, middle class, married, mixed diet, addiction of taking tea and having more urination were prone to pre-diabetes.

Individual *Dashavidha- Pariksha* (10 fold examination) was covered and observed that (Table No.-03) the *Vata- Pittaja* patients having *Madhyama – Sara- Samhanan- Pramana- Satwa-Satmya- Ahara Shakti* and *Hinabala Vyayama Shakti* were manifested with pre-diabetic condition.

In Group-A better improvement was seen in *Prabhuta Mutrata* (quantity, frequency), *Kshudha*, *Kar-pada Daha*, *Mukha Madhurya* and *Sheeta Priyata* compared to in Group B. In Group B better improvement was seen in *Kar-pada Suptata*, *Sweda Pravritti*, *Mukha shosha* compared to in Group A. Similar results were also obtained in both the group's in *Pipasa* and *Madhura Shukla Mutrata* after 30 days. So it is revealed that the clinical sign and symptoms of both Group A and B patients were improved in treatment but better result was observed in Group-A patients which was statistically significant. Among the Objective Parameter the FBS, PPBS and HbA1c decreased in Group-A and Group-B but statistically significant in both groups. (Table No.-04 and 05)

The drugs of *Nisha-Amalaki Churna* were the predominance of *Katu, Tikta Rasa* and *Ruksha Guna* helps in reducing *Kapha, Meda* and *Kleda* and due to *Tridosha Shamaka* property they can alleviate all the three *Doshas* in the body. Amalaki contains the chromium mineral that regulate carbohydrate metabolism and also act as powerful antioxidant which reverse the oxidative stress and Nisha has Curcuminone which has Anti-diabetic effects According to Ayurveda literature both *Nisha* and *Amalaki* have many benefits in healthy and diseased state and are mentioned to possess rejuvenating property *(Rasayana).* This helps in proper body nourishment in each and every *Dhatu* level. *Amalaki* is recommended as dietary intervention for treatment of *Prameha*. (Table No.-1)

Shilajeet have *Tikta, Katu,* and *Kashaya Rasa, Katu Vipaka, Ushna Virya*, *Rechaka*, *Shoshana* and *Chedana* properties. It has *Rasayana, Vrishya* and *Pramehaghna* properties also. Due to *Lavana Rasa* Shilajeet acts on *Agni* and maintains the excellent status of *Agni*[14]. Due to *Katu Vipaka* and *Ushna Virya* acts on *Srotas* and removes the blockage of microchannels leading to better perfusion of tissue. It reduces the quantity of *Kapha, Meda* and Kleda by its properties which are the *Dushyas* in *Prameha. Rasayana* property of *Shilajeet*

nourishes the body, helps to keep the body tissue in healthy state and improves the metabolism at each and every level of *Dhatu.* It can also function as an antioxidant to improve body's

immunity and memory, anti-inflammatory, an energy booster. Due to *Rechaka* property it act as diuretic to remove excess fluid from the body. (Table No.-1)

Table No.06; Showing clinical assessment of Result in Group-A and Group-B

Clinical Assessment	After Treatment			
	Group-A		Group-B	
	No. of Patients	%age	No. of Patients	%age
Marked Improvement (76-100%)	01	6.66	00	00
Moderate Improvement (51-75%)	11	73.33	10	66.66
Mild Improvement (26-50%)	02	13.33	03	20.00
Unsatisfactory (below 25%)	01	6.66	02	13.33

Chart No.-01 Showing clinical assessment of Result in Group-A and Group-B After Treatment
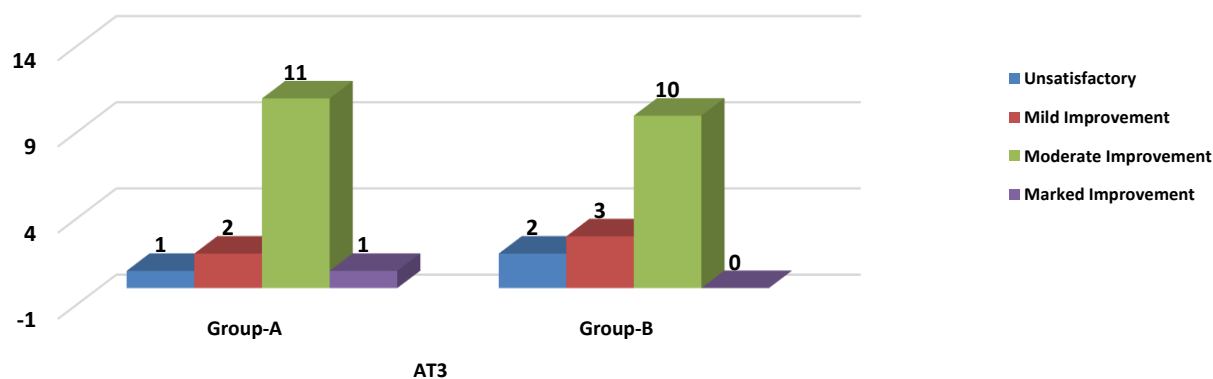
It has been observed that as per after treatment procedures of both Groups, 01 patient from Group-A got marked improvement, 11 patients got moderate improvement, 2 patients got mild improvement and 1 patient got unsatisfactory result. On the other hand, in Group-B 10 patients got moderate improvement and 03

patients got mild improvement and 2 patients got unsatisfactory result. (Table No.-06 & Chart No.-01)

CONCLUSION

Both *Nisha-Amalaki Churna* and *Shilajeet Vati* were provided significant result in improving signs & symptoms and decreased the levels of FBS, PPBS & HbA1c in patients. But *Nisha Amalaki Churna* shows faster and better response in Group A than *Shilajeet Vati* in Group B. Both the drugs are effective in controlling the sign and symptoms of *Prameha Purvarupa* (Prodromal symptoms of DM). Hence, these drugs were proved to be efficient anti-hyperglycemic medicines. Presentstudy was carried out with certain limitations like fewer samples. Forth coming researchers may pursue further study in a large sample size over a period of longer duration. No side effect was noticed during clinical trial.

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REFERENCES

1. Pandit Kashinatha Panday Charaka Samhita, "Vidyotinitika" vol-1, Edition- Reprint-2016, Chapter-09, Indryasthana, Chaukhamba Bharati Academy. PageNo-1004

2. Pandit Kashinatha Panday Charaka Samhita, "Vidyotinitika" vol-1, Edition-Reprint-2016, Chapter-06, Chikitsasthana, Chaukhamba Bharati Academy.Page No.-229

3. Kaviraja Dr. Ambikadutt Shastri Sushruta Samhita, "Ayurveda Tatwa Sandeepika", vol-1, Edition- Reprint-2014, Chapter-06, Nidanasthana Chaukhamba Bharati Academy. Page No.-326,327,

4. WWW.webmd.com/Diabetes.

5. Acharya Kaviraja Atrideva Gupta Astangahrdayam, edited with "Vidyotini" Hindi commentary, Edition- Reprint- 2016, Chapter-40, Uttarsthana, Chaukhamba Sanskrit pratisthana Page No.-832

6. Kaviraja Dr. Ambikadutt Shastri Sushruta Samhita, "Ayurveda Tatwa Sandeepika" i , vol-1, Edition- Reprint-2014, Chapter-13,vol-1 Chikitsasthana Chaukhamba Bharati Academy. Page No.-81-85

7. Priyavrat Sharma Dravya Guna Vigyana, vol-2 , Chaukhamba Bharati Academy Page No.-758,162

8. Dr.Devanath Singh Gautam Rasatarangini; Tarangini Hindi Commentary, 22th Tarang, Page No.-558-567

9. Shrigulraja Sharma Ayurveda Prakasha Chaukhamba Bharati Academy, Chapter-04 Page No.-427-434

10. Ravindra Angadi A text book of Rasasastra Chaukhamba Bharati Academy, Chapter-15, Page No-203-211

11. Harrison's Principle of Internal Medicine, 19th edition, Page No.-2407-2408

12. Diabetes mellitus (Madhumeha) and Ayurveda, Prof. Ajay Ku Sharma; page 231-235

13. Walmiki, D. P., Kumar, D. P., Iqbal Chowdhury, D. N. M., & Kumar Godatwar, P. P. (2019). Madhumeha(Diabetes Mellitus): An Ayurved a Review. International Research Journal of Ayurveda & Yoga, 2(3), 60-73.

14. J.L.N Sastry & Dr. Tanuja M. Nesari A text book of Dravya Guna Vijana, Chaukhamba Bharati Academy, Chapter-01, Page No.-8-11/114-118