iJRASET
International Journal For Research in Applied Science and Engineering Technology

INTERNATIONAL JOURNAL FOR RESEARCH

IN APPLIED SCIENCE & ENGINEERING TECHNOLOGY

Volume: 11 **Issue:** X **Month of publication:** October 2023

DOI: https://doi.org/10.22214/ijraset.2023.56114

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International Journal for Research in Applied Science & Engineering Technology (IJRASET)
ISSN: 2321-9653; IC Value: 45.98; SJ Impact Factor: 7.538
Volume 11 Issue X Oct 2023- Available at www.ijraset.com

A Clinical Study of Nisha Amalaki Churna in Prameha Purvarupa (Pre-Diabetic State)

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Abstract: Introduction- The incidence of Prameha is increasing rapidly because of changes in dietetic habits and lifestyle. If the Prameha Purvarupa (Pre-diabetic) clinical features are treated by formulation Nisha-amalaki Churna is recommended in Ayurvedic Classics, Proven efficacious and widely practiced in the management of Prameha (Diabetes).
Materials and methods- 30 patients from OPD and IPD of Govt. Ayurvedic College & Hospital, Balangir, fulfilling the Subjective and Objective Parameters were registered for clinical trial. After diagnosis they were under trial with Ayurvedic formulation Nisha-amalaki Churna treated in a dose of 3gm twice daily empty stomach, for a period of 30 days with Ushna Jala. 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 the trial by statistical paired 't' test.
Observation and results- The average percentage of improvement in subjective parameter Prabhuta mutrata (quantity) 90.91%, Prabhuta mutrata (frequency) 83.33%, Pipasa (increased thirst) 71.67%, Kshudha (excessive appetite) 87.04%, Kara-pada Daha (burning sensation in hand and feet) 91.67%, Kara-pada Suptata (numbness of hand and feet) 85.71%, Sweda Pravritti (excessive sweating) 77.78%, Mukha Shosha (dry mouth) 70%, Mukha Madhurya (sweetness in mouth) 80.95%, Sheeta Priyata (liking for cold things) 86.67% and Madhura Shukla Mutrata (sweetness in urine) 100% and in objective Parameter fasting plasma glucose 88.89%, post prandial glucose 96.67%, HbA1c 87.78%. It has been observed that the trial drug patients is highly significant (p<0.001) to reduce both Subjective and Objective parameter after 30 days of treatment.
Discussion and Conclusion- Prameha is a Kapha Pradhana Tridoshaja Vyadhi in which Meda is a Pradhana Dushya. The drug showed potent Pramehahar effect which is evident from the reduction in Subjective Parameter of Prameha and objective parameter of the levels of FBS, PPBS and HbA1c in patients. No side effect was noticed during clinical study of Nisha-amalaki Churna.
Keywords: Prameha, Diabetes, Nisha-Amalaki Churna.

I. INTRODUCTION

Prameha is a syndrome described in the ancient Ayurvedic texts that includes clinical conditions involved in obesity, prediabetes, diabetes mellitus and metabolic syndrome[1]. In *Ayurveda, Prameha* is described as a set of complex clinical disorders characterized with excessive urination (both in frequency and quantity), and turbidity[2].
The nature of the turbidity may vary depending upon the body reaction with the doshas[3]. Now a days the disease *Prameha* has evolved as a life complicating disorder. *Prameha* is a *Tridoshajanya Vikara* due to the simultaneous vitiation of all the three *Doshas*[4]. *Ayurveda* describes 20 types of *Prameha* as different clinico-pathological conditions produced out of specific *Doshas* and *Dushyas*, showing gross urinary characteristics and clinical manifestations. The fractional changes in *Dushyas* namely *Meda, Mamsa, Kleda, Shukara, Shonita, Vasa, Majja, Lasika, Rasa* and *Oja,* in association with three morbid *Doshas* manifests different subtypes of *Prameha*[5]. *Nisha-amalaki Churna* is one such drug the use of which has been advocated for *Prameha* in ancient texts[6]. So for better and safety treatment *Ayurvedic* preparation *Nisha-amalaki Churna* are selected for present research protocol in *Prameha.*

II. AIM AND OBJECTIVE OF THE STUDY

1) To study the efficacy *Nisha-amalaki Churna* in the management of *Prameha.*
2) To find out a suitable herbal drug for the treatment of *Prameha.*
3) To correlate *Prameha* in modern parlence.

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III. MATERIALS AND METHODS

A. *Selection of Patients*

The total 30 patients 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 Saradeshweri Govt. Ayurvedic Hospital Balangir*. The consent of patients were also taken before clinical trial.

B. *Inclusion Criteria*

Patients age between 30-65 years of both sexes. 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). Patients having FBS (100-125mg%), PPBS (140-200mg%) and HbA1c (5.7-6.4mg/dl) were selected for this study.

C. *Exclusion Criteria*

Patients age <30 years and >65 years, fasting plasma glucose > 125mg, oral glucose tolerance > 200mg%**,** HbA1c 6.5% or more, having complications of diabetes like ketoacidosis, nephropathy, neuropathy, retinopathy, and diabetic wounds, chronic, contagious infection disease such as active tuberculosis, hepatits B or C, or HIV**,** Pregnant and lactating females, active metabolic or gastrointestinal disease that may interfere with nutrient absorption, metabolism, excretion, excluding diabetes, Type-1 diabetes mellitus and Type-2 diabetes mellitus.

D. *Criteria for Investigations*

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

E. *Selection of Drug*

Nisha-amalaki Churna had been taken for clinical trial. The drug was 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.*

F. *Method of Preparation of Nisha-amalaki Churna*

Good quality and given proportion of Dried raw ingredients (*kastha Ausadhis*) were taken in specific quantity and powdered separately. The powder was obtained and passed through sieve to obtain fine powder. Both the powder in equal quantity was mixed thoroughly by grinder to obtain homogenous mixture. The fine powder was packed in air tight packets.

G. *Administration of Drug*

The trial drug *Nisha-amalaki Churna* was given by oral route in the dose of **3gms**/day twice daily empty stomach, for a period of 30 days with *Ushna Jala*.

Table No.-1; Showing the pharmacodynamics of drug of Nisha-amalaki Churna

Name	Rasa	Guna	Veerya	Vipaka	Doshakarmata	Quantity
Nisha (Haridra)	*Tikta, Katu*	*Laghu, Rukshya*	*Ushna*	*Katu*	*Kaphapittashamaka*	1.75kg
Amalaki	*Amlapradhana Lavana Varjita Pancharasa*	*Guru, Laghu, Sheeta*	*Sheeta*	*Madhura*	*Tridoshashamaka*	1.75kg

H. 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.

IV. OBSERVATION AND RESULT

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	53.33%	40-50 years
Sex	53.33%	Male
Religion	100%	Hindu
Education status	73.33%	Literate
Occupation	53.33%	Service
Socio- Economical status	73.33%	Middle class
Marital status	100%	Married
Dietary habit	80%	Mixed diet
Habit / Addiction	70%	Taking tea
Mode of onset	100%	Gradual
History of past illness	60%	No past history
Family history	60%	Absent
Sleeping habit	66.66%	Less 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%	*Vatakapha*
Vikriti	50%	*Madhyama- vastha*
Sara	63.33%	*Madhyama-sara*
Samhanan	53.33%	*Madhyama*
Pramana	86.67%	*Madhyama sharira*
Satwa	50%	*Madhyama*
Satmya	53.33%	*Madhyama*
Ahara Shakti	70%	*Madhyama Ahara Shakti*
Vyayama Shakti	63.33%	*Hinabala Vyayama Shakti*
Vaya	60%	*Madhyamavastha*

The Subjective and Objective Parameters of research patients 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 and percentage of Improvement (n=30) (f-Frequency, %-Percentage)

Symptoms	Frequency	Percentage	Percentage of Improvement
Subjective Parameter			
Prabhuta Mutrata (Quantity)	11	73.33	90.91
Prabhuta Mutrata (Frequency)	11	73.33	83.33
Pipasa (Increased thirst)	10	66.67	71.67
Kshudha (Excessive appetite)	9	60	87.04
Kar-pada Daha (Burning sensation in hand and feet)	6	40	91.67
Kar-pada Suptata (Numbness in hand and feet)	7	46.67	85.71
Sweda Pravriti (Excessive Sweating)	9	60	77.78
Mukha Shosha (Dry mouth)	5	33.33	70
Mukha Madhurya (Sweetness in mouth)	7	46.67	80.95
Sheeta Priyata (Liking for cold things)	5	33.33	86.67
Madhura Shukla Mutrata (Sweetness and whitish in urine)	3	20	100
Objective Parameter			
FBS	30	100	88.89
PPBS	30	100	96.67
HbA1c	30	100	87.78

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)

Symptoms	Mean ± SD		t-value	p-value
	Before treatment	After treatment		
Subjective parameter				
PrabhutaMutrata (Quantity)	1.91 ± 0.7	0.09 ± 0.30	6.90	<0.001
Prabhuta Mutrata (Frequency)	2.00 ± 0.77	0.36 ± 0.50	6.71	< 0.001
Pipasa	2.30 ± 0.67	0.70 ± 0.48	9.80	< 0.001
Kshudha	2.22 ± 0.83	0.33 ± 0.50	7.25	< 0.001
Kara-pada Daha	1.50 ± 0.55	0.17 ± 0.41	6.32	< 0.001
Kar-pada Suptata	1.57 ± 0.79	0.14 ± 0.38	3.87	< 0.01
Sweda Pravriti	1.67 ± 0.71	0.33 ± 0.50	4.62	< 0.005
Mukha Shosha	1.80 ± 0.45	0.40 ± 0.55	3.50	< 0.05
Mukha Madhurya	1.86 ± 0.69	0.43 ± 0.53	7.07	< 0.001
Sheeta Priyata	2.40 ± 0.89	0.40 ± 0.55	6.32	< 0.005
Madhura ShuklaMutrata	1.67 ± 0.58	0.0 ± 0.0	5.00	<0.05
Objective Parameters				
FBS	2.67 ± 0.62	0.33 ± 0.49	14.64	< 0.001
PPBS	1.93 ± 0.59	1.93 ± 0.59	11.30	< 0.001
HbA1c	1.87 ± 0.74	0.27 ± 0.46	8.41	< 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

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V. DISCUSSION

The present study was undertaken to interpret the efficacy of *Nisha-amalaki Churna* in the management of *Prameha Purvarupa.*

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

Individual *Dashavidha- Pariksha* was covered and observed that (Table No.-03) *the Vata- kapha* patients having *Madhyama – Sara- Samhanan- Pramana- Satwa- Satmya- Ahara Shakti and Hinabala Vyayama Shakti* were manifested with *Prameha Purvarupa.*

The effect of therapy was assessed on the basis of observations of subjective and objective parameters which was significant ($p<0.05$) statistically after 30 days. (Table No.-04 and 05)

The outcome of the study showed ample evidence of *Nisha-amalaki Churna* acting as *Pramehahar* and showed significant result in reducing the symptoms. *Nisha* have *Tikta* and *Katu Rasa, Katu Vipaka, Ushna Virya,* and *Kaphapittashamka* properties. Amalaki have Pancharasa, *Madhura Vipaka, Sheeta Virya* and *Tridoshashamka* properties. This helps in reducing *Kapha*, *Meda* and *Kleda* and due to their *Tridosha Shamaka* property they can alleviate all the three *Doshas* in the body. The selected drug showed better improvement on subjective and objective parameter. 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*. *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. Many research works had been carried out on *Nisha (Curcuma longa), Amalaki (Emblica officinalis Gaertn),* their extracts and chemical ingredients in these two drugs for their effects on *Prameha, Madhumeha,* Diabetes Mellitus, complications of Diabetes and Antihyperglycemic effects on Blood glucose regulation. Research works show that *Nisha-Amalaki Churna* best suits for Diabetes management, which affects multisystem, multifunction and multiple organs. *Nisha-Amalaki Churna* possesses Antihyperglycemic, Antidiabetic, Insulinomimetic, α-Amylase inhibitory and β-glucosidase inhibitory, antioxidant properties. It improves insulin sensitivity and increases glucose uptake by skeletal muscles and is beneficial in the management of *Prameha Purvarupa* or Pre diabetes. **(**Table No.-1)

VI. CONCLUSION

In the present study *Nisha-amalaki Churna* was evaluated for its efficacy in *Prameha Purvarupa (Pre-diabetic Condition).* The drug showed potent *Pramehahar* effect which is evident from the reduction in fasting and post prandial blood glucose levels, glycosylated haemoglobin and improvement in subjective parameter including the quality of life, psychological and social well-being. So, the study revealed that *Nisha-amalaki Churna* can be used as a drug in the management of *Prameha Purvarupa*. Present study 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.

VII. ACKNOWLEDGEMENT

I am very much grateful and thankful to Principal Prof. (Dr.) Arun Kumar Das, Dr. G.B. Acharya, H.O.D Dravyaguna, Dr. S.B. Behera, H.O.D Rasashastra & Bhaisajya Kalpana, Prof. (Dr.) Pradeep Kumar Panda, Dean, Sri Sri College of Ayurveda Science and Research Hospital, Dr. M.R Sahu, Lecturer, RNVV for their grateful blessings. I am also thankful to all my P.G. Scholars friends, Hospital Staff and other Staff of RNVV dept. for their constant helping attitude to complete the research work with a full satisfaction and belief.

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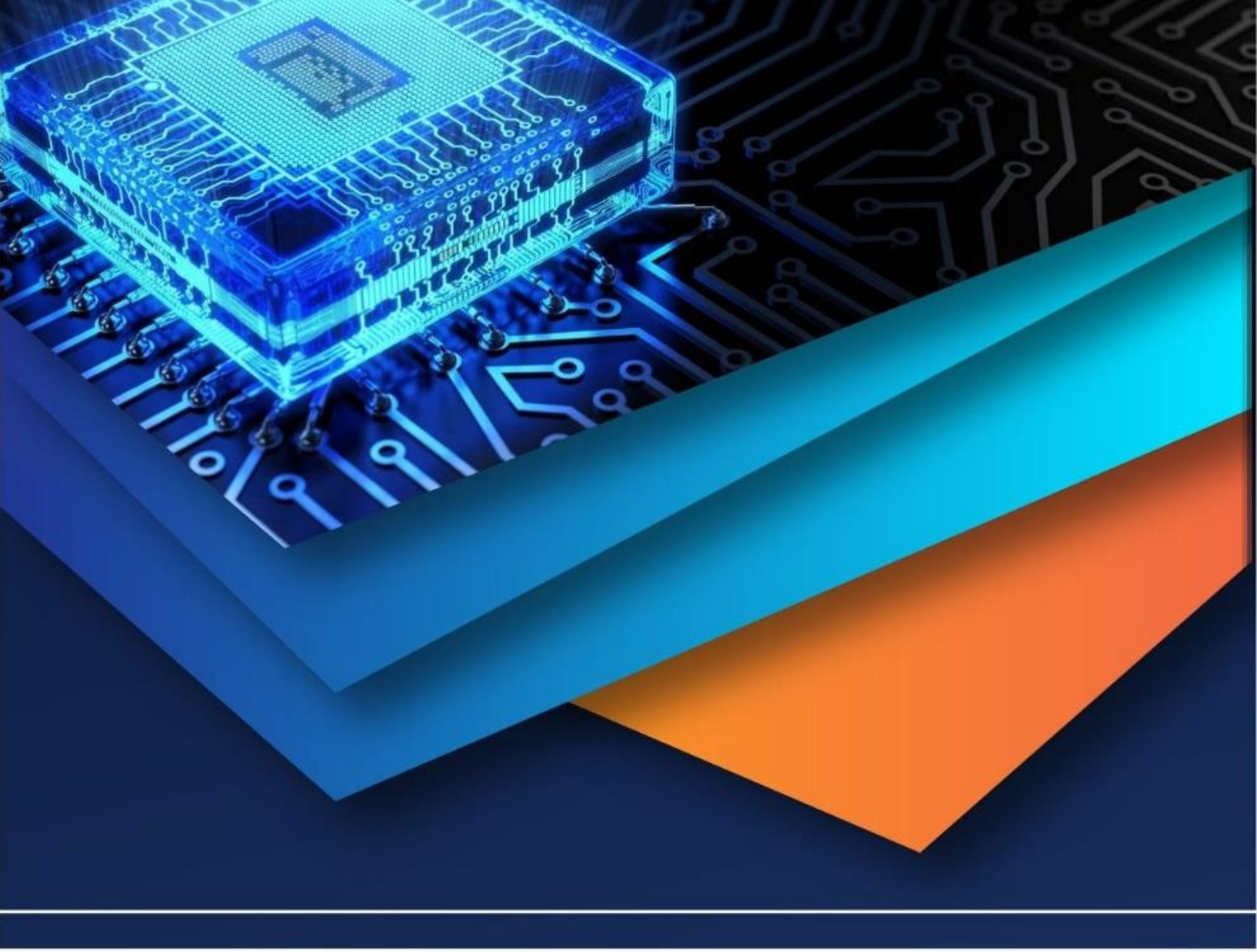

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