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EFFECTS OF *NISHA TRIPHALA YOGA* ON *STHOOLA* AND *KRISHA PRAMEHI* W.S.R. TO DIABETES MELLITUS

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ABSTRACT

Prameha is a group of disorders, which bear a resemblance to the modern understanding of Diabetes Mellitus. Prameha is further classified into Sthoola Pramehi (associated with obesity) and Krisha Pramehi (associated with leanness)5. According to Ayurveda2, Sthoola Pramehi results from the imbalance of Kapha and Meda (fat tissue) and the obstruction of normal body channels (Srotas) leading to insulin resistance, Krisha Pramehi 1(Lean Diabetic) on the other hand, is observed in individuals with a lean body constitution. This condition is associated with the imbalance of Vata and depletion of Dhatus (body tissues), leading to frequent urination, emaciation, and general weakness. Hence, to control those abnormalities an ayurvedic formulation, namely, "Nisha Triphala Yoga" 6was selected for the management of Sthoola Pramehi and Krisha Pramehi. Materials and Methods: For the present study, 30 patients of Prameha (15 Sthoola and 15 Krisha) were randomly selected according to the Inclusion criteria. The prepared medicine was trialed in two groups i.e. Groups A (Sthoola Pramehi) and Group B (Krisha Pramehi) each having 15 Patients. The assessment was in every 15 days of intervals for one month. Discussion and Conclusion: Statistically, Nisha Triphala Yoga provided more significant results in Group A than Group B by improving subjective and objective signs and symptoms of Prameha

KEYWORDS: - *Ayurveda, Prameha, Sthoola Pramehi, Krisha Pramehi, Diabetes Mellitus, Meda Dhatu, Insulin Resistance, Metabolic Disorders, Nisha Triphala Yoga.*

1. INTRODUCTION

Diabetes mellitus is a long-term metabolic disorder defined by raised blood glucose levels due to deficiencies in the action or secretion of insulin, or both. The prevalence of diabetes is rising globally, making it a major public health concern. *Ayurveda*, the traditional Indian system of medicine, offers a unique perspective on diabetes through the concept of *Prameha*. *Prameha*[5] encompasses a group of urinary disorders, which include conditions that closely resemble the symptoms and pathophysiology of Diabetes Mellitus. Among the various types of *Prameha*, *Sthoola Pramehi* and *Krisha Pramehi* are subtype of this told by *Acharya Charak*. This article explores the *Ayurvedic* classification, pathophysiology, and management of *Sthoola* and *Krisha Pramehi*, providing insights into their relevance in contemporary diabetes care.

1.2. Aim

The aim of the study was to study the efficacy of *Nisha Triphala* powder in the management of *Sthoola Pramehi and Krisha Pramehi.*

MATERIALS AND METHODS

2.1. Ethical Clearance

The study was approved by the Institutional Ethics Committee, Government Ayurvedic College and Hospital, Balangir vide Letter No: 1800/G.A.C and H of dated August 29, 2022 and registered in Clinical Trial Registry of India (CTRI; www.ctri.nic.in) vide Registration No: CTRI/2023/06/054549. The study has been conducted among the patients registered for the purpose. Written consent was obtained from each patient who participated in the study with prior proper information.

2.2. Source of Patient

Thirty patients were selected from the OPD and IPD of Government Ayurvedic Hospital, Balangir, and were enrolled for the clinical study.

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2.3. Study Design and Grouping

2.3.1. Method of collection of patients

Thirty patients suffering from *Prameha (*15 *Sthoola* and 15 *Krisha Pramehi*) were taken for the present study. They were screened by a special proforma which includes details history taking, physical signs and symptoms, and pathological investigations mentioned in classics and modern science.

2.4. Methodology

Clinicopathological study (Single-blind study).

2.4.1. Group-A *(Sthoola Pramehi)*

15 patients of *Sthoola Pramehi* treated with *Nisha Triphala Yoga* powder 5 gm twice daily, in empty stomach i.e. morning and Evening for 30 days.

2.4.2. Group-B *(Krisha Pramehi)*

15 patients of *Krisha Pramehi* treated with *Nisha Triphala Yoga* powder 5 gm twice daily, in an empty stomach i.e. morning and Evening for 30 days.

2.5. Duration

The duration of the study was 30 days.

Comparison was one within two groups to find out the effectiveness of the mentioned medicines.

2.6. Diagnostic Criteria[7,3]

The patient was diagnosed based on multiple parameters (*Trividha*, *Sadvidha*, *Astabidha*, *Dashavidha Parikhya)*. Clinical sign symptoms as described in classical text were considered for the diagnosis of *Prameha*

- For *Sthoola Pramehi*-B.M.I.- >25kg/m^2
  W.H.R.-0.96 to 1 for male and 0.81 to 0.85 for female
- For *Krisha Pramehi*-B.M.I.-<18kg/m^2
  W.H.R.-0.96 or less for male and 0.80 or Less for female **O** Fasting blood sugar >126mg/dl and <200mg/dl.
- Post prandial blood sugar >200mg/dl and<300mg/dl.
- HbA_1C: – 6.5 % - 8.5 %.
- Blood- Blood urea, Serum creatinine if required
- Urine- Routine and Microscopic

2.7. Inclusion Criteria[7,3]

The following criteria were included in the study:

- Patients with age between 25–65Yrs.
- Sex: – Both male and female.
- Patients not dependent upon insulin therapy.
- Patients suffer from only type 2 Diabetes Mellitus
- For *Sthoola Pramehi*-B.M.I.- >25kg/m^2
  Krisha Pramehi-B.M.I.- <18kg/m^2

Patients who fulfil the above diagnostic criteria, along with patients having symptoms of *Prabhutamutrata* (Frequent urination), *Atiksudha* (excessive appetite), *Trishnadhikya* (increased thirst), *Dourbalya (Weakness), Kar-pada daha (burning sensation in hand and feet)* were included under inclusion criteria. Subject willing to follow the procedure as per the study protocol and voluntarily sign this consent form.

2.8. Exclusion Criteria[7,3]

The following criteria were excluded from the study.

- Patient age < 25Yrs and >65Yrs.
- Patient having fasting blood sugar >200mg/dl
- Postprandial blood sugar >300mg/dl
- Patient with HbA_1C more than 8.5 %.
- Insulin dependent patients (Type-1).
- Patient having complication of diabetic neuropathy, Nephropathy, Retinopathy, ketoacidosis.
- Patient having chronic, contagious infection disease such as active tuberculosis, hepatitis A, B & C.
- Patients having association with other endocrinal disorder.

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- Patients taking corticosteroids, antidepressant medication or medication for weight loss or weight gain

2.9. Assessment Criteria

For assessment of result, severity of the sign and symptom was graded as 0,1,2,3 grade for normal (0), mild (+), moderate (++), and severe (+++) accordingly mentioned in Table 1.

The detail pathogenesis of clinical study was carried out based on *Trividha*, *Sadvidha, Astavidha*, and *Dashavidha Parikshya* as per *Ayurvedic* classics.

2.10. Dose and Administration Procedure

i. Dose of *Nisha Triphala Yoga* powder: 5 gm twice daily in empty stomach i.e morning and Evening for 30 days with Madhu.
ii. Dietic Regimen
Ahara: Patients were advised to take a normal diet, green vegetables except carbohydrates, sugar-containing food, spicy food, junk food, and non-vegetarian food.
Vihara: Practice exercise and yoga in a regular basis.

2.11. Follow-up

Follow-up were done in every 15 days gap, that is, 15th, and 30th day of the clinical trial. During follow-up, both subjective and objective parameters of assessment were done to assess the result.

2.12. Assessment for Results

The degree of severity as per above gradation criteria and data collected from pathological investigations after 15 days AT_1 and 30 days AT_2 of treatment were assessed. The assessment has been done in two stages as follows-

2.12.1. Clinical assessment

The average percentage improvement in the severity of different clinical sign and symptoms was calculated. The overall clinical assessment has been done considering the sign and symptoms as follows-

- Unsatisfactory: below 25% relief in sign and symptoms.
- Mild Improvement: 26–50% relief in sign and symptoms.
- Moderate Improvement: 51–75% relief in sign and symptoms.
- Marked Improvement: 76–100% relief in sign and symptoms in trial period.

2.13. STATISTIACAL ANALYSIS The subjective and objective data, like the sign & symptoms, FBS, PPBS & HbA1c, gathered from the patients were subjected for statistical analysis. Data were analyzed statistically in terms of Mean, Standard Deviation (SD), Standard Error (S.E), t- value and p- value. The statistical analysis after 30 days of treatment has been done. For the effectiveness of trial drug and control drug paired 't' test and unpaired t- test has been used. The effectiveness of trial drug and control drug has been assessed through the P Value.

The p- Value was interpreted as:

- > 0.05 statistically insignificant at 5% level.
- < 0.05 significant at 5% level.
- < 0.01 significant at 1% level.
- < 0.005 significant at 0.5 % level.
- < 0.001 highly significant at 0.1% level.

2.14. Presentation of Data

Data collected from the patients were tabulated under the following two sections:

a. General observations such as age, sex, religion, occupation, educations status, socioeconomic status, marital status, dietary habit, habit/addiction, history of past illness, family history, sleeping habit, urination, bowel habit, and *Vyayama*.
b. Result of therapy based on changes in sign-symptoms and disease specific-biochemicalinvestigation.

3. OBSERVATION AND RESULTS

It has been observed 17 numbers of patients were registered in Group-A and 16 numbers of patients were registered in Group-B. There were three number of patients drop out from the study.

Fifteen patients in both groups have completed the study.

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Table 1: GRADING- (Subjective Parameters)

ILLNESS	SEVERITY	GRADE
Prabhutamutrata (Frequent Urination)	**Quantity**- 0.5 to 2.5 lit/day	0
	2.5 to 3.5 lit/day	1
	3.5 to 4.5 lit/day	2
	More than 4.5 lit/day	3
	Frequency- 3 to 5 times/ day, rare at night	0
	5 to 7 times/day, 1-2 times at night	1
	7 to 10 times/day 3-4 times at night	2
	More than 10 times/day and 4 times/night	3
Atikshudha (Excessive Appetite)	Normal quantity	0
	Slightly more quantity	1
	Moderately increased quantity	2
	Always feeling hungry	3
Trishnadhikya (increased thirst)	Intake of water / liquid - 1.5 to 2.5 lit/day	0
	Intake of water / liquid - 2.5 to 3.0 lit/day	1
	Moderately feeling Thirsty	2
	Always feeling thirsty	3
Swedadhikya (Excessive Sweating)	Normal sweating after exercise and hot Temperature	0
	Increased of sweating after exercise	1
	Increased of sweating after exercise and hot weather	2
	Always feeling of sweating and sweating in cold also	3
Kar-Padadaha (burning sensation in hand and feet)	No Daha present	0
	Slight feeling of Daha (burning sensation)	1
	Moderate feeling of Daha (burning sensation) most of the time	2
	Could not fall asleep due to Daha	3
Mukhamadhurya (Feeling Of sweet taste)	Absent	0
	Mild feeling of sweetness	1
	Moderate feeling of sweetness	2
	Always feeling of Sweetness in mouth, Sticky in nature	3

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Pathological investigation (Objective Parameters)

Fasting blood sugar	**RANGE**	**GRADE**
	< 126mg/dl	0
	126-140mg/dl	1
	141-180mg/dl	2
	181-200mg/dl	3
Post prandial blood sugar	<140 mg/ dl	0
	141- 200 mg/ dl	1
	201 – 260 mg/ dl	2
	>260mg/ dl	3
HbA1c	< 5.7 %	0
	5.8 – 6.5 %	1
	6.6 – 8 %	2
	>8 %	3

Since observations are done under grading of subjective and objective parameters of table1.

Table 2: Showing the subjective Parameters before and after treatment in Patients (N = 30)

Variable	Group	N	Mean Rank	Sum of Ranks	Mann-Whitney U	P-Value	Result
Prabhutamutrata (Quantity)	Group A	15	18.00	270.00	90.000	0.024	Sig
	Group B	15	13.00	195.00			
	Total	30					
Prabhutamutrata (Frequency)	Group A	15	19.00	285.00	75.000	0.005	Sig
	Group B	15	12.00	180.00			
	Total	30					
Atikshudha	Group A	15	16.97	254.50	105.500	0.040	Sig
	Group B	15	14.03	210.50			
	Total	30					
Trishnadhikya	Group A	15	17.00	255.00	105.000	0.017	Sig
	Group B	15	14.00	210.00			
	Total	30					
Swedadhikya	Group A	15	17.30	259.50	100.500	0.046	Sig
	Group B	15	13.70	205.50			
	Total	30					
Karapadadaha	Group A	15	18.17	272.50	87.500	0.026	Sig
	Group B	15	12.83	192.50			
	Total	30					

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed-rank Test to test efficacy in Group A and Group B. From the above table 2, we can observe that *P*-value for Group A and Group B is <0.05. Hence, we can conclude that effect observed in Group A and Group B is significant.

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Table 3: Showing the FBS before and after treatment in Patients (N = 30)

FBS		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Group A	BT	1.87	2.00	0.92	0.24	-2.725[b]	0.006423	50.00	Sig
	AT	0.93	1.00	0.46	0.12				
Group B	BT	2.33	2.00	0.62	0.16	-3.500[b]	0.000465	40.00	Sig
	AT	1.40	1.00	0.51	0.13				

Mann–Whitney U Test is carried out for comparison between Group A and Group B. From the above table 3, we can observe that *P*-value for almost parameters is <0.05. Hence, we can conclude that there is a significant difference between Group A and Group B.

Table 4: Intergroup comparison showing the FBS

FBS	Mean		SD		% Change	
	Group A	Group B	Group A	Group B	Group A	Group B
BT	1.87	2.33	0.92	0.62	-	-
AT1	1.67	1.80	0.62	0.56	10.71	22.86
AT2	0.93	1.40	0.46	0.51	50.00	40.00

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed-rank Test to test efficacy in Group A and Group B. From the above table 4 , we can observe that *P*-value for Group A and Group B is <0.05. Hence, we can conclude that effect observed in Group A and Group B is significant.

Table 5: Showing the PPBS before and after treatment in Patients (N = 30)

PPBS		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Group A	BT	2.47	2.00	0.52	0.13	-3.286[b]	0.001017	48.65	Sig
	AT	1.27	1.00	0.59	0.15				
Group B	BT	2.53	3.00	0.64	0.17	-3.419[b]	0.000629	39.47	Sig
	AT	1.53	2.00	0.52	0.13				

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed-rank Test to test efficacy in Group A and Group B. From the above table 5, we can observe that *P*-value for Group A and Group B is <0.05. Hence, we can conclude that effect observed in Group A and Group B is significant.

Table 6: Intergroup comparison showing the PPBS

PPBS	Mean		SD		% Change	
	Group A	Group B	Group A	Group B	Group A	Group B
BT	2.47	2.53	0.52	0.64	-	-
AT1	1.87	1.80	0.74	0.77	24.32	28.95
AT2	1.27	1.53	0.59	0.52	48.65	39.47

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed-rank Test to test efficacy in Group A and Group B. From the above table 6, we can observe that *P*-value for Group A and Group B is <0.05. Hence, we can conclude that effect observed in Group A and Group B is significant.

Table 7: Showing the HbA1c before and after treatment in Patients (N = 30)

HbA1c		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Group A	BT	2.60	3.00	0.51	0.13	-2.449[b]	0.014306	15.38	Sig
	AT	2.20	2.00	0.56	0.14				
Group B	BT	2.60	3.00	0.51	0.13	-1.000[b]	0.031731	12.82	Sig
	AT	2.27	2.00	0.80	0.21				

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed-rank Test to test efficacy in Group A and Group B. From the above table 7, we can observe that *P*-value for Group A and Group B is <0.05. Hence, we can conclude that effect observed in Group A and Group B is significant.

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Table 8: Showing the Objective Parameters before and after treatment in Patients (N = 30)

Variable	Group	N	Mean Rank	Sum of Ranks	Mann-Whitney U	P-Value	Result
FBS	Group A	15	17.20	258.00	102.000	0.036	Sig
	Group B	15	13.80	207.00			
	Total	30					
PPBS	Group A	15	17.80	267.00	93.000	0.034	Sig
	Group B	15	13.20	198.00			
	Total	30					
HbA1c	Group A	15	19.00	285.00	75.000	0.003	Sig
	Group B	15	12.00	180.00			
	Total	30					

Mann–Whitney U Test is carried out for comparison between Group A and Group B. From the above table 8, we can observe that *P*-value for almost parameters is <0.05. Hence, we can conclude that there is a significant difference between Group A and Group B.

Table 9: Showing the overall effect between both groups

Overall Effect	Group A		Group B	
	N	%	N	%
Marked Improvement	12	80.00%	6	40.00%
Moderate Improvement	3	20.00%	9	60.00%
Mild Improvement	0	0.00%	0	0.00%
No Improvement	0	0.00%	0	0.00%
TOTAL	15	100.00%	15	100.00%

Further, we can observe that mean rank for Group A is greater than Group B. Hence, we can conclude that effect observed in Group A is better than Group B [Table 9].

4. DISCUSSION

Trial Drug- *Nisha Triphala Yoga*[4]:

Nisha Triphala Yoga [8,9]combining *Nisha* (Turmeric/Curcuma longa), *Daruharidra* and *Triphala (Amalaki, Bibhitaki, Haritaki)* acts on the body by its mode of action through its *Rasa, Guna, Veerya*, and *Vipaka*. Sugar in blood as well as in urine is the result of deranged metabolism, lowered urinary threshold point, production of *Ama Dosha*, or due to their cumulative effect. The aforesaid trial drug has capacity to improve deranged metabolism, increasing urinary threshold points and having the *Amapachana-Agnideepana* property. *Nisha Triphala Yoga* having *Tikta-Katu Rasa* which plays a better role in *Dhatwagni* and *Bhutagni Paka*. As *Sthoola Pramehi* is primarily a *Kapha*-dominant disorder with *Pitta* and *Vata* imbalances. It is characterized by excess fat (*Medas*), leading to obesity and related metabolic disturbances, including Type 2 Diabetes. The accumulation of *Kapha* and *Ama* (toxins) leads to heaviness, slow metabolism, and increased blood sugar levels. Here *Nisha Triphala's* action[10,11] by Pacification *Kapha* and *Pitta* while supporting *Vata*, addressing the root causes of metabolic imbalances. In *Krisha Pramehi, Nisha Triphala's* action is more focused on balancing *Vata* and *Pitta*, while supporting *Kapha* through nourishment and tissue restoration. It prevents excessive tissue depletion, supports healthy digestion, and maintains a balance between all three *Doshas*, especially addressing the *Vata* dominance characteristic of this condition.

To understand how *Nisha Triphala Yoga* acts at the *Dosha* level (balancing *Kapha, Pitta,* and *Vata Doshas*), we can analyse its effects on each *Dosha*.

5. CONCLUSION

Statistically, *Nisha Triphala Yoga* powder provided more significant results in improving subjective and objective signs and symptoms of *Group A (Sthoola Pramehi)* than *Group B (Krisha Pramehi)* is proven to be efficient antidiabetic drug.

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