

THE CLINICAL EVALUATION OF THE ROLE OF 'NISHA TRIPHALA YOGA' & 'PANCHATIKA PANCHAPRASRTTIKA NIRUHA BASTI' IN THE MANAGEMENT OF MADHUMEHA (DIABETES MELLITUS)**Kumar Sanju*¹ Soni Anamika² and Sharma Brahmanand³**¹MD Scholar, PG Department of Kayachikitsa, University College of Ayurved, Dr. S. R. Rajasthan Ayurved University, Jodhpur, Rajasthan, India.²MD (Ay.) Assistant Professor, PG Department of Kayachikitsa, University College of Ayurved, Dr. S. R. Rajasthan Ayurved University, Jodhpur, Rajasthan, India.³MD, Ph.D. (Ay) Assistant Professor PG Department of Kayachikitsa, University College of Ayurved, Dr. S. R. Rajasthan Ayurved University, Jodhpur, Rajasthan, India.***Corresponding Author: Dr. Kumar Sanju**

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ABSTRACT

Diabetes is a chronic disease that occurs when the body cannot produce enough insulin or cannot use insulin effectively. Insulin is a hormone produced in the pancreas that allows glucose from food to enter the body's cells where it is converted into energy needed by muscles and tissues to function. Keeping in view the increasing incidence of this problem a study was conducted with following **Aims and Objectives-** To Conceptual study (Aetiopathogenesis) of *Madhumeha* in relation with Diabetes Mellitus. To evaluate efficacy and safety of '*Nisha Triphala Yoga*' and '*Panchatikta Panchaprasrttika Niruha Basti*' in the management of a series of patients of *Madhumeha* in relation with Type-2 Diabetes Mellitus. **Materials and Methods-** 45 clinically diagnosed patients will be randomly divided into 3 Groups of 15 each as below: In **Group A** - 15 patients will be administered '*Nisha Triphala Yoga*' in the dose of Two Capsule of 500 mg each twice a day in empty stomach for 30 days. In **Group B** - 15 patients will be administered '*Panchatikta Panchaprasrttika Niruha Basti*' (350 - 400 ml/day) for 30 days. In **Group C** - 15 patients will be administered '*Nisha Triphala Yoga*' in the dose of Two Capsule of 500 mg each twice a day in empty stomach and '*Panchatikta Panchaprasrttika Niruha Basti*' (350 - 400 ml /day) both for 30 days. **Results-** Statistically highly significant result was observed in both Groups. **Conclusion-** It can be concluded that in current research work the proposed medicines *Nisha Triphala Yoga* & *Panchatikta Panchaprasrttika Niruha Basti* exhibit significant hypoglycemic activity individually but more effective when both are used in combination and can be used safely in patients of *Madhumeha* (Diabetes Mellitus) with success.

KEYWORDS: Diabetes Mellitus, *Madhumeha*, *Nisha Triphala Yoga*, *Panchatikta Panchaprasrttika Niruha Basti*.**INTRODUCTION**

Diabetes is a disease known from the dawn of civilization. Sedentary life style, Lack of exercise, Faulty food habits and improper medication and Urbanization precipitate the disease. Diabetes mellitus is a syndrome with disordered metabolism and inappropriate hyperglycemia due to either a deficiency of insulin secretion or to a combination of insulin resistance and inadequate insulin secretion to compensate for the resistance.^[1]

In *Ayurveda*, *Madhumeha* is one of the twenty type of *Prameha* described in *Ayurvedic* literature, In *Madhumeha* the patient passes urine which is sweet and astringent in taste, whitish pale in color & unctuous.^[2] *Madhumeha* is related primarily with *Mutravaha* and *Medovaha Srotasa* but along with these many other

Srotasa are also involves. So it is multisystem disorder as it involves ten *Dushya* and *Tridosha*, According to etiological factors, Clinical features and pathogenesis, *Madhumeha* can be correlated with DM which is most common endocrine & metabolic disorder marked by high level of blood glucose resulting from defects in insulin secretion, glucose production & utilization.

Some 415 million people worldwide, or 8.8% of adults, are estimated to have diabetes. About 75% live in low- and middle-income countries. If these trends continue, by 2040, some 642 million people, or one adult in 10, will have diabetes.^[3] According to the Diabetes Atlas 2015 published by the International Diabetes Federation, the number of people with diabetes in India currently around 69.2 million is expected to rise to 123.3 million by 2040 unless urgent preventive steps are taken.^[4]

AIMS AND OBJECTIVES

1. Conceptual study (Aetiopathogenesis) of *Madhumeha* in relation with Diabetes Mellitus.
2. To evaluate efficacy and safety of '*Nisha Triphala Yoga*' and '*Panchatikta Panchaprasrttika Niruha Basti*' in the management of a series of patients of *Madhumeha* in relation with Type-2 Diabetes Mellitus.

MATERIALS AND METHODS

- 1) **Study Design-** Multi centre, Open label, Randomized, Standard, Controlled, Clinical Interventional type.
- 2) **Selection of Cases:** The study will be conducted on 45 clinically diagnosed and confirmed patients of *Madhumeha* [DM type-2]. The selection of patients will be made from OPD/IPD wing of P.G. Department of *Kayachikitsa* in DrSRRAU, Jodhpur.
- 3) **Inclusion Criteria**
 - Diagnosed and confirmed cases of Diabetes Mellitus type II, on the basis of the laboratory investigations.
 - Patients between the age group of 18-60 years of either sex.
 - Patients willing to sign the consent form.
- 4) **Exclusion Criteria:** Following patients excluded from clinical trial-
 - Patients having Type - DM I [IDDM]
 - Age below 18 and above 60 years.
 - Patient of type II DM who are on Insulin therapy.
 - DM with complications.
 - Uncontrolled DM
 - Diabetes insipidus.
 - Drug induced DM.
 - FBS [>250 mg/dl]
 - PPBS [>300 mg/dl]
 - DM with coronary artery diseases.
- 5) **Grouping and Administration of Drug:** 45 clinically diagnosed patients will be randomly divided into 3 Groups of 15 each as below:

Group A - 15 patients will be administered '*Nisha Triphala Yoga*' in the dose of Two Capsule of 500 mg each twice a day in empty stomach for 30 days.

Group B - 15 patients will be administered '*Panchatikta Panchaprasrttika Niruha Basti*' (350 - 400 ml/day) for 30 days.

Group C - 15 patients will be administered '*Nisha Triphala Yoga*' in the dose of Two Capsule of 500 mg each twice a day in empty stomach and '*Panchatikta Panchaprasrttika Niruha Basti*' (350 - 400 ml /day) both for 30 days.

6) Criteria for Assessment

(A) **Subjective assessment-** All the patients registered for clinical trial will be asked for any changes in their clinical manifestations.

Scoring criteria

1) *Prabhuta Mutrata* (Polyuria): Frequency of urine

- 0- 3 – 5 times per day, no or rarely at night.
- 1- 6 – 8 times per day, 1 – 2 times per night.
- 2- 9 – 11 times per day, 3 – 4 times per night.
- 3- > 11 times per day, > 4 times per night.

2) *Pipasaadhikya* (Polydipsia)

- 0- 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.
- 1- 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.
- 2- 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/24hours.
- 3- Feeling of thirst >13 times/24 hours, either/or Intake of water >11 times/24 hours with quantity >3.00 liter/24 hours.

3) *Kshudha* (Appetite)

- 0- 2 main meals + 1 breakfast
- 1- Feeling of hunger after 6 hours of food
- 2- Feeling of hunger after 4 hours of food
- 3- Feeling of hunger after 2 hours of food.

4) *Avila Mutrata* (Turbidity in urine).

Sp. Gravity	Urine Sugar	Alb.	Total score
1020-1025 (0)	Nil (0)	Nil (0)	0
1026-1030 (1)	+ (1)	+ (1)	1-3
1031-1035 (2)	++(2)	++(2)	2-6
1036-1040 (3)	+++ (3)	+++ (3)	3-9
1041-1045 (4)	++++ (4)	++++ (4)	4-12

5) *Tandra* (Drowsiness/sleepiness) (Scoring by using The Epworth sleepiness scale).

How likely are you to doze off or fall asleep in the following situation, in contrast to just feeling tired?

This refers to your usual way of life in recent times. Even if you have not done some of this thing recently, try to work out how they would have, affected you. Use the following scale to choose the most appropriate number for each situation:

0 = would never doze

1 = slight chance of dozing

2 = moderate chance of dozing

3 = high chance of dozing.

1.	Sitting and reading	0	1	2	3
2.	Watching television	0	1	2	3
3.	Sitting, inactive, in a public space	0	1	2	3
4.	As a passenger in a car for 1 hour	0	1	2	3
5.	Lying down in the afternoon	0	1	2	3
6.	Sitting and talking to some one	0	1	2	3
7.	Sitting quietly after a lunch without alcohol	0	1	2	3
8.	In a car, while stopped for a few minute in traffic	0	1	2	3

Scoring

- 0- 0 to 6
 1- 7 to 12
 2- 13 to 18
 3- 19 to 24

6) Kara-Pada-Tala- Daha/ Supti (Burning sensation/ numbness in palm and soles)

- 0- No Daha
 1- Kara-pada-tala-daha/Supti incontinuous
 2- Kara-pada-tala-daha/Supti continuous but not severe
 3- Kara-pada-tala-daha/Supti continuous and severe

(7) Alasya/Utsahani (General Debility)

- 0- No Alasya (doing satisfactory work with proper vigour and in time)
 1- Doing satisfactory work/late initiation, like to stand in comparison to walk

- 2- Doing unsatisfactory work/late initiation, like to sit in comparison to stand
 3- Doing little work very slow, like to lie down in comparison to sit
 4- Don't want to do work/no initiation, like to sleep in comparison to lie down

8) Pandurvarna mutrata (Yellowish white urine)

- 0- Colorless (normal)
 1- Light yellow
 2- Lemon yellow
 3- Dark yellow
 4- Dark yellow with orange tinge

9) Pindiko-udveshatan (Cramps)

- 0- No cramps
 1- Cramps after walking more than 1 km
 2- Cramps after walking
 3- Cramps after walking ½ km
 4- Inability in walking even ½ km

(B) Laboratory Parameters

1. Blood Sugar level
 (i) Fasting Blood Sugar (F.B.S.)
 (ii) Post Prandial Blood Sugar (P.P.B.S.)
 2. Serum Creatinine
 3. Blood Urea
 4. LFT (SGOT, SGPT)
 5. RFT
 6. HbA1c

TRIAL DRUGS**1. Nisha Triphala Yoga^[5]****Table 1: Quantity of ingredients taken for preparation of Nisha Triphala Yoga.**

S. No.	Constituents	Botanical Name/ Latin name	Part Used	Ratio
1	Haridra	Curcuma longa	Rhizome	1 Part
2	Daruharidra	Berberis aristata	Rhizome	1 Part
3	Amalki	Amblika officinalis	Fruit	1 Part
4	Vibhitaki	Terminalia bellirica	Fruit	1 Part
5	Haritaki	Terminalia chebula	Fruit	1 Part

Preparation of Nisha Triphala Yoga

The coarse powder (*Yavkuttachurna*) form of all the drugs as described above in the table are taken in equal quantity. Now, the eight times of water is added to it and boiled on medium flame till it reduces to one fourth in the quantity. The decoction (*Kwatha*) so formed is then

filtered, continuously boiled till *Ghana* (semisolid form) is obtained. The *Ghana* is then air dried and filled in capsules with the help of capsule filling machine. The trial drug will be prepared in Pharmacy of University College of Ayurved, DSRRAU, Jodhpur.

2. Panchatikta Panchprasrtika Niruha Basti.^[6]**Table 2: Quantity of ingredients taken for preparation of Panchatikta Panchprasrtika Niruha Basti.**

S. No.	Name of drug	Botanical Name/ Latin name	Part Used	Ratio
1.	Patola	Trichosanthus dioica	Leaves	1 Part
2.	Nimba	Azadirachta indica	Bark	1 Part
3.	Bhunimba (Chirayita)	Swertia chirayita	Bark	1 Part
4.	Rasana	Pluchea lanceolata	Bark	1 Part
5.	Saptaparna	Alstonia scholaris	Bark	1 Part
6.	Goghrita (Cow ghee)	---	--	2 Part
7.	Sarshapa	Brassica campestris	Seeds	1 Part

Preparation of Basti Drava- The contents 1 to 5 of 'Panchatikta Panchaprasrtika Niruha Basti' as described in above table are taken in equal quantity to prepare a decoction. Then, for the preparation of *Basti Drava*, first of all *Goghrita* is mixed with the *Sarshapa Kalka* (past of mustard seeds) thoroughly then the prepared decoction is added to this mixture & churned properly.

Follow-up Study- Clinical & physiological assessment will be done before treatment, on day 1 then 7th, 15th, 21st, 28th (every week/ weekly) day of treatment and after the completion of treatment. The patient will be regularly follow up once in a week for next one month.

OBSERVATION

Maximum number of the patients that is 17 (38%) belonged to 41 to 50 years (5th decade) age group, Maximum patients were Male 30 (67%) and Most of the patients were Hindus 40 (89%) and Married 43 (96%). Most of the patients were Secondary class educated 16

(36%), Most of the patients were from rural habitat 21 (47%), Maximum No. of patients 18 (40%) were from middle class, Maximum patients i.e. 14 (31%) were having the occupation related with housewives. Most of the patients were having positive family history 30 (67%), Most of the patients 26 (58%) were mixed dietary habits, Maximum no. of patients 25 (55%) were having addiction of tea/coffee. Most of the patient 23 (51%) had not taken any treatment, Most of the patients 17 (38%) were having *Mandagni*, 24 (53%) patients were *Madhyama Koshtha*. Most of the patients 20 (44%) were having *Vata-kaphaja Sharirika Prakriti*, 23 (51%) of patients were having *Tamasika Manasika Prakriti*, 20 (45%) patients were of *Avara sara*, 28 (62%) patients were of *Madhyama Samahanana*, 25 (56%) patients were having *Sarva rasa Satmya* and 28 (62%) patients were having *Madhyama Satva. Madhyama Ahara Abhyavaharana Shakti* was found in 23 (51%) patients and *Avara Vyayama Shakti* was found in 24 (53%) patients.

RESULTS

Table no. 3: Showing effect of therapy on subjective parameters (wilcoxon matched-pairs signed-ranks test).

Variable	Gr	Mean		Mean Diff.	% Relief	SD±	SE±	P	S
		BT	AT						
<i>Prabhuta Mutrata</i> (Frequency of Urine)	A	2.067	0.800	1.267	61.29	0.8837	0.2282	0.0006	HS
	B	1.867	0.666	1.200	64.27	1.146	0.2960	0.0034	HS
	C	2.000	0.333	1.667	83.35	0.9759	0.2520	0.0003	HS
<i>Pipasa Adhika</i> (Polydipsia)	A	1.933	0.666	1.267	65.54	1.100	0.2840	0.0017	HS
	B	1.667	0.533	1.133	67.96	0.9904	0.2557	0.0026	HS
	C	2.000	0.600	1.400	70	1.183	0.3055	0.0015	HS
<i>Kshudha</i> (Appetite)	A	1.800	0.733	1.067	59.27	1.387	0.3581	0.0166	S
	B	2.200	0.866	1.333	60.59	0.8997	0.2323	0.0006	HS
	C	2.067	0.600	1.467	70.97	1.356	0.3501	0.0012	HS
<i>Avil Mutrata</i> (Turbidity in Urine)	A	1.533	0.666	0.866	56.49	1.302	0.3362	0.0273	S
	B	1.667	0.733	0.933	55.98	1.163	0.3003	0.0039	HS
	C	1.467	0.466	1.000	68.16	1.309	0.3381	0.0137	S
<i>Tandra</i> (Drowsiness/ Sleepiness)	A	1.400	1.000	0.400	28.57	0.7368	0.1902	0.1055	NS
	B	1.800	0.933	0.866	48.11	1.060	0.2737	0.0122	S
	C	1.267	0.600	0.666	52.56	0.8165	0.2108	0.0137	S
6. <i>Kara-Pada-Tala-Daha /Suptata</i> (Numbness in hands and Feet)	A	1.867	0.800	1.067	57.15	1.280	0.3305	0.0134	S
	B	1.533	0.400	1.133	73.90	1.246	0.3217	0.0049	HS
	C	1.600	0.400	1.200	75	1.014	0.2619	0.0010	HS
7. <i>Alasya/ Utsahani</i> (General Debility)	A	1.933	1.400	0.533	27.57	1.125	0.2906	0.1272	NS
	B	1.600	1.133	0.466	29.12	0.9904	0.2557	0.1230	NS
	C	2.000	1.133	0.866	43.33	1.187	0.3065	0.0156	S
8. <i>Pandurvarna Mutrata</i> (Yellowish white urine)	A	1.733	1.267	0.466	26.88	0.9904	0.2557	0.1230	NS
	B	1.067	0.400	0.666	62.41	0.9759	0.2520	0.0313	S
	C	1.533	0.533	1.000	65.23	1.414	0.3651	0.0195	S
9. <i>Pindiko-udveshatan</i> (Cramps)	A	1.867	0.800	1.067	57.15	1.223	0.3157	0.0105	S
	B	2.000	0.733	1.267	63.35	1.163	0.3003	0.0052	HS
	C	1.800	0.600	1.200	66.66	1.082	0.2795	0.0024	HS

(HS: Highly Significant, S: Significant, NS: Non Significant)

➤ The results of therapeutic trial reveal that **patients of group-A** showed statistically **highly significant** changes in the symptoms of *Prabhuta Mutrata*

($P < 0.001$) and *Pipasa Adhikaya* ($P < 0.01$). Statistically **Significant** result were seen in symptoms of *Kshudha* ($P < 0.05$), *Avil Mutrata*

($P < 0.05$), *Kara-Pada-Tala-Daha/ Suptata* ($P < 0.05$), *Pindiko-udveshatan* ($P < 0.05$). While statistically **no significant** was found in rest other parameters.

- **In patients of group B** statistically **highly significant** changes in *Prabhuta Mutrata* ($P < 0.01$), *Pipasa Adhikaya* ($P < 0.01$), *Kshudha* ($P < 0.001$), *Avil Mutrata* ($P < 0.01$), *Kara-Pada-Tala-Daha/Suptata* ($P < 0.01$) and *Pindiko-udveshatan* ($P < 0.01$). Statistically **significant** changes are found in *Tandra* ($P < 0.05$), *Pandurvarna Mutrata* ($P < 0.05$). While

statistically **no significant** was found in rest other parameters

- **In patients of group C**, showed statistically **highly significant** changes in symptoms of *Prabhuta Mutrata* ($P < 0.001$), *Pipasa Adhikaya* ($P < 0.01$), *Kshudha* ($P < 0.01$), *Kara-Pada-Tala-Daha/Suptata* ($P < 0.01$) and *Pindiko-udveshatan* ($P < 0.01$). Statistically **significant** changes was found in *Avil Mutrata* ($P < 0.05$), *Tandra* ($P < 0.05$), *Alasya/ Utsahahani* ($P < 0.05$) and *Pandurvarna Mutrata* ($P < 0.05$).

Table No. 4: Intergroup comparison in subjective parameters of group A, B and C (Kruskal-wallis stastic test).

S. No.	Parameter	Kruskal-wallis stastic	P-Value	Significance
1.	<i>Prabhuta Mutrata</i> (Frequency of Urine)	3.618	0.1638	NS
2.	<i>Pipasa Adhika</i> (Polydipsia)	1.147	0.5635	NS
3	<i>Kshudha</i> (Appetite)	2.648	0.2661	NS
4	<i>Avil Mutrata</i> (Turbidity in Urine)	1.298	0.5225	NS
5	<i>Tandra</i> (Drowsiness/ Sleepiness)	3.593	0.1659	NS
6	<i>Kara-Pada-Tala-Daha/suptata</i> (Numbness in hands and Feet)	0.9262	0.6293	NS
7	<i>Alasya/ Utsahahani</i> (General Debility)	1.799	0.4068	NS
8	<i>Pandurvarna Mutrata</i> (Yellowish white urine)	1.667	0.4346	NS
9	<i>Pindiko-udveshatan</i> (Cramps)	0.7325	0.6933	NS

- **In inter-group** comparison *Prabhuta Mutrata* (Frequency of Urine) ($P > 0.05$), *Pipasa Adhika* (Polydipsia) ($P > 0.05$), *Kshudha* (Appetite) ($P > 0.05$), *Avil Mutrata* (Turbidity in Urine) ($P > 0.05$), *Tandra* (Drowsiness/ Sleepiness) ($P > 0.05$), *Kara-Pada-*

Tala-Daha/ suptata (Numbness in hands and Feet) ($P > 0.05$), *Alasya/ Utsahahani* (General Debility) ($P > 0.05$), *Pandurvarna Mutrata* (Yellowish white urine) ($P > 0.05$) and *Pindiko-udveshatan* (Cramps) ($P > 0.05$) all are shows **no significant** results.

Table No. 5: Showing effect of therapy on laboratory parameters (objective parameters): (Paired 'T' Test).

Variable	Gr	Mean		Mean Diff.	% Relief	S.D. ±	S.E.±	P	Paired t-test	S
		BT	AT							
Fasting Blood Sugar (mg/dl)	A	172.01	157.49	14.527	8.44	20.097	5.189	0.0142	2.800	S
	B	181.01	160.67	20.347	11.24	22.532	5.818	0.0036	3.497	HS
	C	183.07	143.73	39.333	21.48	32.177	8.308	0.0003	4.734	HS
Post Prandial Blood Sugar (mg/dl)	A	199.15	182.45	16.705	8.38	21.793	5.627	0.0102	2.969	S
	B	225.20	200.67	24.533	10.89	23.673	6.112	0.0013	4.014	HS
	C	193.73	165.93	27.800	14.34	22.482	5.805	0.0003	4.789	HS
S. Bilirubin Total	A	0.8253	0.7553	0.0700	8.48	0.1637	0.0422	0.1199	1.657	NS
	B	0.7733	0.7367	0.0366	4.73	0.0947	0.0244	0.1562	1.498	NS
	C	0.8120	0.7640	0.0480	5.91	0.0818	0.0211	0.0395	2.271	S
S. Bilirubin Direct	A	0.2387	0.2273	0.0113	4.73	0.0906	0.0234	0.6356	0.4844	NS
	B	0.3453	0.3127	0.0326	9.44	0.0811	0.0209	0.1411	1.560	NS
	C	0.3087	0.2760	0.0326	10.56	0.0558	0.0144	0.0399	2.265	S
SGOT	A	29.823	26.181	3.642	12.21	8.517	21.99	0.1199	1.656	NS
	B	24.393	23.500	0.8933	3.66	5.678	1.466	0.5521	0.6093	NS
	C	27.040	24.980	2.060	7.61	4.677	1.208	0.1101	1.706	NS
SGPT	A	24.016	24.449	0.4327	1.80	11.980	3.093	0.8908	0.1399	NS
	B	36.187	30.753	5.433	15.01	12.130	3.132	0.1047	1.735	NS
	C	27.040	26.120	0.9200	3.40	2.455	0.6337	0.1686	0.5963	NS
Blood Urea	A	25.037	24.717	0.3193	1.27	3.787	0.9779	0.7488	0.3265	NS
	B	25.553	24.673	0.8800	3.44	2.027	0.5234	0.1149	0.1681	NS
	C	26.293	25.180	1.113	4.23	2.576	0.6651	0.1163	1.674	NS
Sr. Creatinine	A	1.001	0.9127	0.0886	8.85	0.2257	0.0582	0.1504	1.522	NS
	B	0.9220	0.8673	0.0546	5.92	0.1568	0.0405	0.1985	1.350	NS
	C	0.8400	0.7973	0.0426	5.07	0.09384	0.02423	0.1001	1.761	NS

GHb. %	A	6.700	6.050	0.6510	9.71	0.7990	0.2527	0.2971	2.573	NS
	B	6.550	6.380	0.1730	2.64	0.3234	0.1023	0.1178	1.663	NS
	C	7.023	6.878	0.1450	2.06	0.2180	0.07280	0.0373	2.135	S

➤ The results of therapeutic trial on lab parameters reveal that the **patients of group-A** showed statistically **significant** change (decrease) in FBS and PPBS. In **patients of group B** statistically **highly significant** changes (decrease) in FBS and

PPBS. In **patients of group C**, showed statistically **highly significant** changes in Fasting blood sugar and Post Prandial blood sugar. While statistically significant changes in S. Bilirubin Total and S. Bilirubin Direct and GHb.

Table No. 6: Intergroup comparison in lab investigation (objectives parameters) of group A, B and C: (Tukey's Multiple Comparison Test).

Parameter	P Value	Significance	Tukey's Multiple Comparison Test
Fasting Blood Sugar (mg/dl)	0.0032	HS	A Vs B – NS A Vs C - HS B Vs C – HS
Post Prandial Blood Sugar (mg/dl)	0.0310	S	A Vs B – NS A Vs C – S B Vs C - NS
S. Bilirubin Total	0.1442	NS	
S. Bilirubin Direct	0.7147	NS	
SGOT	0.0028	HS	A Vs B – HS A Vs C – S B Vs C - NS
SGPT	0.0023	HS	A Vs B – NS A Vs C – HS B Vs C - S
Blood Urea	0.1060	NS	
Sr. Creatinine	0.2456	NS	
GHb %	P>0.05	NS	

➤ For **intergroup comparison** ANOVA test was used which revealed that **highly significant** difference was found in Fasting Blood Sugar, SGOT and SGPT. While **statistically significant** difference was found in Post Prandial Blood Sugar.

DISCUSSION

PROBABLE MODES OF ACTIONS OF THE DRUG

1. Nisha-Triphala Yoga

Haridra, Daruharidra, Amalaki, Haritaki, Bhibhitaki due to their *Laghu-Ruksha* properties reduces *Kleda* in the body that in turn corrects the *Dhatushaithilya*. Most of the drugs in the formulation are having *Tikta-Kashaya* Rasa which reduces *Madhurya* in the *Rasa, Rakta* and other *Jaliya Dhatu*. In modern parlance *Nisha Triphala Yoga* appears to enhance endogenous insulin, possibly by regeneration/ revitalization of the residual beta cells in insulin-dependent diabetes mellitus. Moreover, *Embllica officinalis* exhibits anti-diabetic activity on virtue of improvement in peripheral glucose utilization, increased insulin sensitivity, or anti-oxidant property. It is a well known *Rasayana* drug which might have affected the β -cell destruction. *Triphala* is a combination that is found to have a hypoglycaemic effect. Curcumin, demethoxycurcumin, bisdemethoxycurcumin, and ar-turmerone mainly contribute to the hypoglycemic effects of *Haridra* via human peroxisome proliferator-activated

receptor (PPAR)- gamma ligand-binding activity. *Berberis aristata* inhibits hepatic gluconeogenesis in terms of prevention of proteolysis and lipolysis thus enhances the antihyperglycemic effect.

2. Panchatikta Panchaprasrttika Niruha Basti

The drug of *Panchatikta Panchaprasrttika Niruha Basti* are dominated by *Tikta, Madhura Rasa, Laghu, Ushna Guna* and *Bramhana Karma* which directly regulate the glucose metabolism and nourishes at cellular level.

Basti cleanses the *Koshtha* and correct the functioning of intestine which in turn regulates the proper the absorption of glucose. *Basti* eliminates the accumulated *Dosha Malarupi Abadha Meda* form *Srotas* all over the body in turn regulates movement of *Vata Dosha* which will regulate the functioning of *Agni* regulate glucose metabolism and increase glucose absorption in cell. *Basti* is best to correct *Vata Dosha* to remove the *Avarana* of *Vata* and *Panchatikta Panchaprasrttika Niruha Basti* is specially advised for *Prameha* the drugs of *Panchatikta Panchaprasrttika Niruha Basti* are *Lekhana* in nature their by reduces *Meda* and *Kleda* which are the basic factor in *Prameha*.

In pathogenesis of *Madhumeha*, *Vata Dosha* is predominant factor. For controlling of *Vata Dosha*, the *Nisha Triphala Yoga* has contents of *Laghu* and *Ruksha*

which balance with *Snigdha Guna*, *Guru Guna*. *Laghu Guna* is *Kaphaghna*, promotes *Vata Dosha* and depletes the quantum of *Dhatu*s in the body. *Ruksha Guna* also promotes *Vata Dosha* and pacifies *Kapha* and *Meda Dhatu*s. All of these processes are balance with *Madhura Rasa*, *Rasayana* and *Yogvahi* properties of drug.

Total Drug effects by which the trial drugs is effective in *Madhumeha* is because of its various qualities like *Ojovardhaka*, *Rasayana* and *Yogvahi* which pacify the *Vata Dosha* and minimize the chances of the complication of DM where as the other properties of the trial drug like *Kasaya-Tikta Rasa*, *Katu Vipaka* may act synergistically to produce beneficial effects on the disease by virtue of its *Ojovardhaka*, *Rasayana*, *Yogvahi*, *Tridoshashamaka Doshakarma* and are *Grahi*, *Deepana* and *Amapachana* as well as *Pramehaghna* effects. These effects may be helpful in *Samprapti Vighatana* of *Madhumeha*.

CONCLUSION

- The disease *Madhumeha* is well documented in all perennial sources of *Ayurvedic* wisdom/ classics. *Madhumeha* has been discussed in *Prameha roga* as one of the type of *Vataja Prameha*. Literary evidence proves its modern correlation with Diabetes Mellitus.
- *Nisha Triphala Yoga* and *Panchatikta Panchaprasrttika Niruha Basti* are effective in management of *Madhumeha* when used alone or in combination. Both of them definitely reduce all the symptoms of *Madhumeha* (Diabetes Mellitus) that include *Prabhootamutrata* (Polyuria), *Pipasaadhikya* (Polydipsia), *Kshudha* (Appetite), *Avila Mutrata*, *Tandra* (Drowsiness), *Kara-Pada-Tala-Daha/ Supti* (Burning sensation/ Numbness in palm and soles), *Alasaya/ Utsahahani* (General Debility), *Panduvarna Mutra* (Yellowish-white urine), *Pindiko-udveshtan* (Cramps in claws). These improvements in symptoms are brought about by *Samprapti Vighatana* of the disease. It proves that the trial drugs posses' hypoglycemic effects.
- The trial drugs were effective in reducing Fasting Blood Sugar, Post Prandial Blood Sugar.
- Therapy was well tolerated by all the patients and no toxic or unwanted effects were noticed in any patient, suggesting that the drugs selected for current clinical trial are absolutely safe for internal use.
- It can be concluded that in current research work the proposed medicines *Nisha Triphala Yoga* & *Panchatikta Panchaprasrttika Niruha Basti* exhibit significant hypoglycemic activity individually but more effective when both are used in combination and can be used safely in patients of *Madhumeha* (Diabetes Mellitus) with success.
- **Thus, finally we can conclude that 'Nisha Triphala Yoga' and 'Panchatikta Panchaprasrttika Niruha Basti' are safe, cost effective and free from any side effects in the management of**

***Madhumeha* [Diabetes mellitus]". It also prevents the relapse considerably.**

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