

AN EXTENDED CLINICAL TRIAL ON EFFICACY OF ‘NISHA TRIPHALA YOGA’ IN THE MANAGEMENT OF MADHUMEHA W.S.R TO DIABETES MELLITUS TYPE 2

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ABSTRACT

Diverse lifestyle related disease like Diabetes, Hypertension and Obesity etc. are dramatically increasing these days. Diabetes Mellitus (DM) is one of the lifestyles related and non- communicable disease. Diabetes Mellitus is a growing health risk in developing countries. As a psychosomatic disease and due to most dangerous complications, DM has grabbed the attention of health community all over the world. DM From ancient past *Ayurveda* serving as the oldest medical science ever since in the world. The main objective of *Ayurveda* is restoration, promotion and maintenance of positive health. The 21st century is the age of science, technology, computer and atomic energy. The Improper unbalanced diet and sedentary lifestyle are showing upward trend in India. This has led to emergence of several health problems, among

that Diabetes mellitus is a giant disease considered as one of the arch enemies of mankind. Diabetes and its complications pose a significant challenge to potential worldwide public health services. Diabetes does not come alone; it brings with itself the various metabolic complications of hyperglycaemia both acute and chronic affecting every organ from head to toe. India is the world's leader, with the most diabetic subjects' distinction to be named the

“capital of the world for diabetes”. the current research topic has been selected. As an extended research on clinical trials with significant outcomes/results is the need of hour, so that more affirmed conclusions can be drawn from the research trial. Therefore, the present study entitled “An Extended Clinical Trial on *Efficacy of ‘Nisha Triphala Yoga’ in the Management of Madhumeha W.S.R Diabetes Mellitus Type 2*” is an effort to establish the efficacy of *Nisha Triphala Yoga* on Diabetes Mellitus Type 2 (*Madhumeha*) with following.

Aims and Objectives: 1. Conceptual study (Aetiopathogenesis) of *Madhumeha* in relation to Diabetes Mellitus. 2. To evaluate the efficacy of “*Nisha Triphala Yoga*” in the management of a series of patients of *Madhumeha* in relation with Type-2 Diabetes Mellitus. **Material and Methods:** The study will be conducted on 60 clinically diagnosed and confirmed patients of *Madhumeha* (DM type-2). The selections of patients will be made from OPD/IPD wing of P.G. Department of *Kayachikitsa* in DSRRAU, Jodhpur. **Results:** Statistically Significant result was observed in various subjective & objective parameters of Diabetes Mellitus type 2. **Conclusion:** The conclusion is made that *Nisha Triphala Yoga* are effective in management of *Madhumeha* when used with therapeutic lifestyle changes. It definitely reduces all of the symptoms of *Madhumeha*. The trial drugs were effective in reducing Fasting Blood Sugar, Post Prandial Blood Sugar. It can be used safely in patients of *Madhumeha* (Diabetes Mellitus) with success.

KEYWORDS: Diabetes Mellitus, Insulin, *Nisha Triphala Yoga*, Sedentary life.

INTRODUCTION

Diabetes Mellitus (DM) is a clinical condition with hyperglycemia characterized by an absolute or relative deficiency of insulin.^[1] A dynamic combination of genetics and environmental factors induces many distinct forms of Diabetes Mellitus. Factors contributing to hyperglycemia include reduced insulin secretion, decreased glucose utilization, and increase glucose production. Diabetes Mellitus can be classified into 2 broad categories: Type-1 DM and Type- 2 DM. Type-1 DM is a result of an absolute deficiency of insulin while Type-2 is a heterogeneous group of disorders characterized by variable insulin resistance, impaired insulin secretion, and increased glucose production.^[2]

The 21st century is the age of science, technology, computer, and atomic energy. Improper unbalanced diet and sedentary lifestyles are showing an upward trend in India. This has led to the emergence of several health problems, among that Diabetes mellitus is a giant disease considered as one of the arch enemies of mankind.

In *Ayurvedic* texts, the given characteristic features of *Madhumeha* show marked similarity with the syndrome of Type 2 Diabetes. It is *Tridoshaj* in origin with the predominance of *Kapha*. According to *Charak* major causative factor (*Nidana*) of *Madhumeha* are *Madhura*, *Amla*, *Lavana Rasa* dominant diet mentioned as '*Gramya Udaka Aanupa Rasa Payansi Dadhini*,^[3] and lifestyle such as '*Aasya Sukham Swapna Sukham*,^[4] is similar to the causes quoted as overeating, eating of a large amount of carbohydrates mainly sugar-rich substances, dairy products, practicing sedentary lifestyle, overweight in the modern medical literature.

According to the Diabetes Atlas 2015 published by the International Diabetes Federation, the number of individuals 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. The so-called "Asian Indian Phenotype" refers to certain unique clinical and biochemical abnormalities in Indians which include enhanced insulin resistance, greater abdominal adiposity i.e., higher waist circumference despite lower body mass index, lower Adiponectin and quite delicate C-reactive protein levels. This phenotype makes Asian Indians more prone to diabetes and premature coronary artery disease. At least a part of this is due to genetic factors.^[5,6]

Need of study

Encouraged with the significant clinical effects observed in the previous clinical trial on the previous trial (*Saini Sanju, soni Anamika*: The clinical evaluation of the role of *Nisha Triphala yoga* and *Panchatikta Panchprasrttika Niruha Basti* in the management of *Madhumeha* w.s.r Diabetes Mellitus type 2, PG department of *kaya Chikitsa*, University college of Ayurveda, Dr SR RAU Jodhpur, Year 2014) the current research topic has been selected. As extended research on clinical trials with significant outcomes/results is the need of hour, so that more affirmed conclusions can be drawn from the research trial.

AIIMS AND OBJECTIVES

Present research work has been undertaken with the following main objectives:

1. Conceptual study (Aetiopathogenesis) of *Madhumeha* in relation to Diabetes Mellitus.
2. To evaluate the efficacy of "*Nisha Triphala Yoga*" in the management of a series of patients of *Madhumeha* in relation with Type-2 Diabetes Mellitus.

Literary review

The word *Prameha* is derived from "*Pra*"- means excess, *Meha*- "*ksharne*"-passing of urine. So *Prameha* is passing excessive and turbid urine (*prabhootha avil mootrata*).

Madhumeha is a clinical entity in which patient passes large quantity of urine similar to *madhu* having *kshaya* and *Madhur* taste, *ruksha* texture and honey like colour and thus body attains sweetness. On the other hand the word “diabetes mellitus” consists of two words diabetes and mellitus. Diabetes means “excessive discharge of urine” and mellitus mean “honey”. So it shows that word diabetes mellitus and *Madhumeha* have same literal meaning.

Acharya charaka has classified the “Pramehi” in to two types i.e.^[7]

- *Sthula Pramehi & Krishna Pramehi*
- *Santarpan janya & Aptarpan janya Prameha*

Acharya sushruta has classified *madhumeha* as^[8]

- *Kulaja Madhumeha* (Hereditary) and *Apathyanimittija Madhumeha* (because of faulty life style).

Acharya vagbhata classified *prameha* as^[9]

- *Dhatukshaya janya Madhumeha* and *Avarana janya Madhumeha*.

Mordern review^[10]

1. Type diabetes: (Beta-cell destruction, usually leading to absolute insulin deficiency).

Beta cell destruction may be of two types:

- A. Immune mediated
- B. Idiopathic.

2. Type diabetes: (may range from predominantly insulin resistance with insulin deficiency to a predominantly insulin secretory defect with insulin resistance). International Diabetes Federation data reveal that India has more diabetes than the United States. Although the prevalence of both type I & II Diabetes is Mellitus is expected to rise more rapidly in future because of increasing obesity and sedentary life style.

MATERIALS AND METHODS

Study design

- Single centre
- Open Label
- Randomized
- Interventional

1. Selection of cases

The study will be conducted on 60 clinically diagnosed and confirmed patients of *Madhumeha* (DM type-2). The selections of patients will be made from OPD/IPD wing of P.G. Department of *Kayachikitsa* in DSRRAU, Jodhpur.

(a) Inclusion criteria

- Diagnosed and confirmed cases of Diabetes Mellitus type-2, on the basis of the
- laboratory investigations.
- Patients between the age group of 18-70 year of either sex.
- Patients willing to sign the consent form.

(b) Exclusion criteria: Following patients excluded from clinical trial–

- Patients having type-1 DM (IDDM)
- Age below 18 and above 70 years.
- Patient of type-2 DM who are on insulin therapy.
- DM with complications
- Uncontrolled DM
- Diabetes insipidus
- Drug induced DM
- FBS (>250mg/dl)
- PPBS (>300mg/dl)
- DM with coronary artery disease.

1. **Clinical trial:** 60 clinically diagnosed patients will be randomly selected.

2. **Trial drug-** “*Nisha Triphala Yoga*”

2. **Administration of Drug:** 60 clinically diagnosed patients will be randomly selected.

Criteria are for Assessment

The effect of the trial drug will be assessed in terms of:

- Subjective Assessment
- Laboratory parameters

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

1. *Prabhuta Mutrata* (polyuria) Frequency of urine.

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

2. *Pipasa* (polydipsia) feeling of thirst.

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

3. *Kshudha* (Appetite).

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

4. *Avila mutrata* (Turbid 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 in the following situation to doze off or fall asleep, as opposed to only feeling tiered?

This refers to your recent habitual way of life. 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

2 = moderate chance of dozing

1 = slight 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 an alcohol-free lunch	0	1	2	3
8.	In a car, while stopped for a few minutes in traffic	0	1	2	3

Scoring

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

6. *Kara-pada-Tala-Daha/Supti* (burning sensation/numbness in palm and soles).

No <i>Daha</i>	0
<i>Kara-Pada-tala-daha/Supti</i> incontinuous	1
<i>Kara-Pada-tala-daha/Supti</i> continuous but not severe	2
<i>Kara-Pada-tala-daha/Supti</i> continuous and severe	3

7. *Alasya/Utsahani* (General Debility).

No <i>Alasya</i> (doing satisfactory work with proper vigor and in time)	0
Normal capacity of doing work/late initiation	1
Less capacity of doing work/ late initiation	2
No initiation of doing work	3

8. *Panduvarna mutra* (yellowish-white urine).

Normal Pale-yellow urine	0
Mild pale urine	1
Pale urine	2
Colourless or watery coloured urine	3

9. *Pindiko-udveshtan* (cramps).

No Cramps	0
Cramps after walking more than 1 km.	1
Cramps after walking ½ km.	2
Inability in walking even ½ km.	3

10. Mutramadhurya (glycosuria).

Absence of Glucose in urine	0
<0.5% Glucose in urine	1
0.5-1.0% of Glucose in urine	2
-2.0% of Glucose in urine	3
>2.0% Glucose in urine	

(A) Laboratory parameters

- Blood sugar level
- Fasting blood sugar (F.B.S)
- Post prandial blood sugar (P.P.B.S)
- HbA1c
- L.F.T
- R.F.T
- Urine test: - routine & microscopic examination for assessment of improvement in clinical manifestations following grading developed by Dr. Pramod kumar Mishra et.al will be used.

S.no.	Observation	Grading	%
1.	No relief	0	0%
2.	Mild relief	1	1-25%
3.	Moderate relief	2	26-50%
4.	Significant relief	3	51-75%
5.	Excellent	4	76-100%

3. Selection of trial drugs

Nisha triphala yog:- Nisha Triphala Yog was taken for the clinical trial which includes following drugs:

Contents of nisha triphala yoga

S. no.	Constituents	Latin name	Rasa	Guna	Vipaka	Veerya
1.	<i>Haridra</i>	Curcuma longa	<i>Katu, Tikta</i>	<i>Ruksha, Laghu</i>	<i>Katu</i>	<i>Ushna</i>
2.	<i>Daruharidra</i>	Berberis Aristata	<i>Tikta, Kashaya</i>	<i>Laghu, Ruksha</i>	<i>Katu</i>	<i>Ushna</i>
3.	<i>Amalki</i>	Emblica officinalis	<i>Madhura, Amla, katu, Tikta, kashay</i>	<i>Guru, Ruksha, sheeta</i>	<i>Madhura</i>	<i>Sheeta</i>
4.	<i>Vibhitaki</i>	Terminalia bellirica	<i>Kashaya</i>	<i>Ruksha, Laghu</i>	<i>Madhura</i>	<i>Ushna</i>
5.	<i>Haritaki</i>	Terminalia Chebula	<i>Madhura, Amla, Katu, Tikta, Kashaya</i>	<i>Ruksha, Laghu</i>	<i>Madhura</i>	<i>Ushna</i>

Method of preparation of drug

Following process adopted for the preparation of trial drug – The coarse powder (*Yavkutta churna*) form of all the drugs as mentioned 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 so formed is then filtered, continuously boiled till Ghana (semisolid form) is obtained. Ghana is then air-dried and filled in capsules with the help of a capsule filling machine. The trial drug will be prepared in the pharmacy of University college of Ayurveda, DSRRAU, Jodhpur.

Mode of administration: Orally 500 mg capsule twice a day in empty stomach for 90 days.

Duration of the Trial: The clinical trial was continued for 90 days with each patient with follow up on 15 days.

OBSERVATIONS

- ❖ Total 66 patients were registered for the study in which 60 patients were completed and 6 patients left treatment against medical advice.
- ❖ Maximum no. of patients 19 (32%) were observed in 6th decade (51-60 yrs.) followed by, 16 (27%) were in 5th (41-50 yrs.), 13 (22%) patients were observed in 7th decade (61-70 yrs.) and 10 (16%) were in 4th decade (31-40 yrs.), 2 (3%) patients were observed in 3rd decade (18-30 yrs.). Thus, showing peak incidence of type 2 diabetes in elderly adults.
- ❖ Maximum no. of patients 22 (37%) were from semi-urban areas. 20 (33%) from Rural areas and 18 (30%) patients were from urban areas.
- ❖ Most of the patients 20 (33%) in this study were primary educated followed by 16 (27%) were graduate & 15 (25%) were secondary educated, while 9 (15%) were illiterate.
- ❖ Clinical trial most of the patients 40 (67%) revealed positive family history while 20 (33%) revealed negative family history.
- ❖ Maximum no. of patients 35 (59%) had taken Allopathic treatment while 12 (20%) had not taken any treatment and 11 (18%) had taken Ayurvedic treatment and only 2 (3%) patient had taken homeopathic treatment.
- ❖ Maximum 27 (45%) were having *Vata-kaphaja prakriti* followed by, 17 (28%) patients were having were having *Vata-Pittaja Prakriti* while 16 (27%) were having *Pitta- kaphaj prakriti*.
- ❖ *The Manasika prakriti* of patients was observed that majority of patients 30 (50%) were *Tamasika* while 21 (35%) patient were *Rajasika* and 9 (15%) was of *Satvika prakriti*.

- ❖ Maximum no. of patients 22 (37%) each were of *Avara satva*, followed by 20 (33%) of *Madhyam Sara* and 18 (30%) each patient was of *Pravara Satva*.
- ❖ Maximum patient 23 (38%) were having *Avara Aahara Shakti*, followed by 19 (32%) were having *Madhyam* and 18 (30%) were having *Pravara Aahara Shakti*.
- ❖ *The majority of patients were having:*
 - *Prabhoota mutrata* (polyuria) in 60 (100%) cases.
 - *Pipasaadhikya* (polydipsia), *Kara-pada-tala-daha/supti* (burning sensation of hands and feet) and *Pindiko-udveshatan* in 59 (98.33%) cases.
 - *Avila Mutrata* and *Kshudhadhika* in 45 (75%) cases.
 - *Tandra* (Drowsiness) and *Pandurvarna Mutrata* in 39 (65%) cases.
 - *Alasya* (Lassitude) in 44 (73.33%) cases.
 - *Mukha-Madhurya* in 32 (53.33%) cases.

RESULTS

All the Results have been calculated by using software: In Stat Graph Pad 3.

- ❖ For Nonparametric Data Wilcoxon matched-pairs signed ranks test was used while for parametric Data Paired 't' test was used and results calculated.
- ❖ Among 60 patients registered for present clinical trial (n=60).

Below Table Showing effect of therapeutic trial on clinical symptomatology in 60 patients of *Madhumeha* (Diabetes Mellitus) (Wilcoxon matched-pairs signed ranks test)

Variable (n=60)	Mean		Mean Diff.	% Relief	SD±	SE±	P	S
	BT	AT						
<i>Prabhuta Mutrata</i> (frequency of Urine)	1.800	0.7500	1.050	58.333%	0.5945	0.07675	<0.0001	E.S.
<i>Pipasa Adhika</i> (polydipsia)	1.667	0.7000	0.9667	57.990%	0.6369	0.08222	<0.0001	E.S.
<i>Kshudha</i> (Appetite)	1.267	0.7500	0.5167	40.78%	1.228	0.1585	0.0010	V.S.
<i>Avil Mutrata</i> (turbidity in urine)	1.300	0.7833	0.5167	39.746%	1.242	0.1603	0.0011	V.S.
<i>Tandra</i> (Drowsiness/ sleepiness)	1.183	0.9667	0.2167	18.31%	1.379	0.1780	0.1124	N.S.
<i>Kara-pada- tala-Daha/ Suptata</i> (Numbness in hands and feet)	1.533	0.6833	0.8500	55.44%	0.5771	0.07450	<0.0001	E.S.
<i>Alasya/ Utsahahani</i> (General Debility)	1.317	1.083	0.2333	17.71%	1.370	0.1769	0.1075	N.S.
<i>Pandurvarna Mutrata</i> (yellowish white urine)	1.133	0.7333	0.4000	35.304%	1.330	0.1717	0.0107	S
<i>Pindiko- udveshatan</i> (cramps)	1.433	0.6000	0.8333	58.150%	0.6930	0.08946	<.0001	E.S.

(Note – BT: Before Treatment; AT: After Treatment; %: Percentage; SD: Standard Deviation; SE: Standard Error; *p*: P value; E.S.-Extremely Significant; V.S.-Very Significant, N.S.-Not Significant.

Below Table Showing effect of therapeutic trial on lab parameters in 60 patients on *Madhumeha* (Diabetes Mellitus) (paired ‘t’ test).

Variables n=60)	Mean		Mean Diff.	% relief	SD±	SE±	P value	t value	S
	BT	AT							
Fasting Blood Sugar (mg/dl)	156.11	110.18	45.937	29.42%	18.892	2.439	<0.0001	18.835	E.S.
Post Prandial Blood Sugar (mg/dl)	203.61	155.92	47.697	23.42%	18.308	2.364	<0.0001	20.183	E.S.
Blood Hb.	11.861	12.004	-0.1423	1.199%	0.7288	0.09409	.0678	1.513	NQS
HbA1c	7.685	7.350	0.3350	4.359%	0.3579	0.04620	<0.0001	7.251	E.S.
Blood urea	28.703	27.998	0.7042	2.453%	4.244	0.5480	0.1019	1.285	N.S.
S. Creatinine	0.7977	0.7837	0.01400	1.7550%	0.1677	0.02164	0.2601	0.6468	N.S.
S. Bilirubin	0.6342	0.6243	0.009833	1.5504%	0.05896	0.007612	0.1007	1.292	N.S.
SGPT	26.854	26.642	0.2123	0.79057%	1.379	0.1780	0.1188	1.193	N.S.
SGOT	28.156	27.935	0.2203	0.7824%	1.376	0.1776	0.1098	1.241	N.S.

DISSUSSION AND SUMMARY

Any research work without any explanation of its existence, usefulness and value shall be considered incomplete. Discussion is helpful to establish the entire research by clinical findings and observation.

Discussion regarding probable mode of action of Nisha-triphala yoga

The contents of *Nisha Triphala Yoga* are *Ushna Virya* except *Amalki (Sheeta Virya)*. *Haridra* and *Daruharidra* have *Katu Vipaka* and rests have *Mahura Vipaka*. *Nisha Triphala Yoga* has predominance of *Katu, Tikta and Kashaya Rasa*. *Katu* rasa stimulates *Pachakagni* desiccants the food removes obstruction and dilates the passages and allays *Kapha Doshas*. Its main pharmacological action is *Amapachana* and make *Ama* stable (it obstructs the processing of product of digestive impairment i.e. *Ama*) which helps in glucose uptake in insulin sensitive tissues like as muscle, fats etc. by enhancing activity of insulin receptor (*Aavaraganana* effects). The *Tikta Rasa* has potency to improve the basic cellular metabolism due to their *Shodhana* properties. *Tikta Rasa* with its *Lekhana* and *Shoshana* properties, it cleans *Srotasa*, it helps in the *Shoshana* of *Bahu Mutrata*, and *Shodhana* of *Mutra vaha srotasa*. *Tikta Rasa* has a property of *Shoshana* for *Sharira Kleda, Meda, Majja, Lasika, Mootra and Kapha*. The *Kasaya Rasa* acts as a controller of excessive urination, *Dhatu Kshaya* and *Oja Kshaya* through

urine by their *Stambhana* properties. It absorbs *Kleda*, *Meda*, *Vasa* and *Kapha Dosha*. *Kasaya rasa* not only reduces the peripheral resistance as well as clinical manifestation of the disease.

Probable mode of action of *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, *Emblica 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 arturmerone 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.

CONCLUSION

In the current project entitled “*An Extended Clinical Trial on Efficacy of ‘Nisha Triphala Yoga’ in the Management of Madhumeha W.S.R Diabetes Mellitus Type 2*” following Conclusion can be made:

- 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 types of *Vataja Prameha*. Literary evidence proves its modern correlation with Diabetes Mellitus.
- *Madhumeha* can be interpreted as Type 2 diabetes with dominancy of *Kapha* among the *Doshas*, *Meda* among the *Dooshyas*. It can be concluded that description of aetiology, pathogenesis, signs and symptoms, complications and prognosis appear to be similar in both Ayurveda as well as modern medicine in respect to *Madhumeha* (Type 2 diabetes). The treatment prescribed in Ayurvedic texts can be used to manage the condition of Type 2 diabetes.
- The clinical study of 60 registered patients establishes that excessive consumption of *Guru*, *Madhura*, *Snigdha* type of diet along with lack of exercise, day sleep and chronic

stress play a significant role in causation of the disease. They increase mainly *Kapha & Meda*, the main *Dosha* and *Dooshya* of the disease which play key role in the etiopathogenesis of the disease.

- *Nisha Triphala Yoga* is effective in management of *Madhumeha* when used alone; reduce all the symptoms of *Madhumeha* (Diabetes Mellitus) that include *Prabhootamutrata* (Polyuria), *Pipasaadhikya* (Polydipsia), *Kshudha* (Appetite), *Avila Mutrata* (turbidity in urine), *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 calves), *Mutramadhurya* (Glycosuria). These improvements in symptoms is brought about by *Samprapti Vighatana* of the disease. It proves that the trial drugs possess hypoglycaemic effects.
- The trial drugs were effective in reducing Fasting Blood Sugar, Post Prandial Blood Sugar and Urine 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* exhibit significant hypoglycaemic activity individually but more effective when both are used in combination and can be used safely in patients of *Madhumeha* (Diabetes Mellitus) with success.

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