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Research Article

A COMPARATIVE CLINICAL EVALUATION OF THE EFFICACY OF *MADHUMEHA NASHINI GUTIKA* & *DARVYADI KWATH* IN *MADHUMEHA* W.S.R. TO DIABETES MELLITUS

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ABSTRACT

Diabetes has become a dreadful disease in this era. It is also described in Ayurvedic texts in terms of *Madhumeha*. Diabetes Mellitus is disease known from the dawn of civilization. Sedentary life style, lack of exercise, faulty dietary habits, improper medication & urbanization precipitate the disease. It is estimated that the total number of people with diabetes will rise from 171 million in 2000 to 366 million by 2030. As per WHO report, currently half a billion people (12% of the world's population) are considered obese. As obesity is the one of the root cause of the disease. Observing the current status of prevalence and morbidity of the disease proper medication for the disease is mandatory. In the present study, *Madhumeha Nashini Gutika* a herbomineral preparation and *Darvyadi Kwath* (both mentioned in *Ayurvedic* texts) were selected for clinical trial. The study comprised of a series of 60 patients of *Madhumeha*. The patients were selected from OPD and IPD of *Kayachikitsa* of Rishikul Government Ayurvedic P.G. College & Hospital. After evaluating the total effect of therapies it was observed that the *Madhumeha Nashinh Gutika & Darvyadi Kwath* (Combined therapy) provided better relief to the patients of *Madhumeha* in comparison to single group therapy.

KEYWORDS: *Madhumeha,* Obesity, *Madhumeha Nashinh Gutika, Darvyadi Kwath.*

INTRODUCTION

Each year about 17 million people die prematurely as the result of the global epidemic of largerly preventable diseases or life style diseases. According to WHO, world deaths from life style diseases will double by 2015 unless all out efforts are taken to combat them.

According to International Diabetes Federation 61.3 million people in India have diabetes in 2011 that figure is projected to rise to 101.2 million by 2030. IDF revealed that India has more diabetes than the US. India has rank second in the world in diabetes prevalence, just behind China.

India has more than 40 million diabetic patients, more than any other country in the world. 20 % of diabetic patients live in India. Type 1 DM is relatively rare in our country and less than 2% of the diabetics in India are having Type 1 DM, whereas more than 96% of the diabetics have Type 2 DM. Prevalence of Type 2 DM which was about 2% in early seventies has sharply risen to more than 8% in late nineties in urban areas in our country.[1]

Diabetes mellitus (DM) is not a single disease but a group of metabolic disorders, characterized by hyperglycaemia, and finally resulting in the appearance of various complications (macro and micro angiopathy). Blood glucose levels are controlled by a complex interaction of multiple chemicals and hormones in the body, including the hormone insulin made in the beta cells of the pancreas. Diabetes mellitus refers to the group of diseases that lead to high blood glucose levels due to defects in either insulin secretion or insulin action.

Diabetes develops due to a diminished production of insulin (in type 1) or resistance to its effects (in type 2 and gestational). Both lead to hyperglycemia, which largely causes the acute signs of diabetes: excessive urine production, resulting compensatory thirst and increased fluid intake, blurred vision, unexplained weight loss, lethargy, and changes in energy metabolism. Monogenic forms, e.g. MODY, constitute 1-5 % of all cases.

Diabetes mellitus is classified as,[2]

1) Type 1 DM
2) Type 2 DM
3) Other specific type of diabetes mellitus (genetic defects of beta cell function and insulin action, disease of exocrine pancreas, endocrinopathies, drug induced etc.)
4) Gestational diabetes mellitus.

Among lifestyle diseases, Diabetes is on increasing trends to the tune of lifestyle epidemics globally, but largely in Asian sub continent. The centric point in the causation of the disease is derangement of *Agni* (Metabolic fire) and *Dhatuposhan* (Altered cells homoeostasis). Severe lifestyle related risk factors are needed to be modified along with the invention of few potent Ayurvedic medicines and herbs to prevent at primary as well as secondary level and for treatment of the disease concerned.

In Ayurveda *Madhumeha* (diabetes mellitus) is described among the 20 sub types of *Prameha* and is predominantly a *Vatika* disease. Ayurveda believes that it occurs mainly due to *Medodusti*. This *Medodusti* vitiate *Mansa, Rakta, Kleda* and *Ojas*. All the *Dhatus* and *Malas* & all three *Doshas* are involved in the disease procedure. In sutra 17, '*Kiyantahshirsia Adhyay*' charak says that the disease leads due to *Ojodusti,* when a person eats a rich diet with lack of exercise, it leads to vitiation of *Ojo,* which *Avrits* the *Mutravaha srotas* precipitating to *Prameha*.[3] It seems to be the description of autoimmune diabetes mellitus. In Nidan 4, *'Prameh Nidan Adhyay'* and Chikitsa 6 *'Prameh Chikitsa Adhyay'* the pathogenesis starts with vitiation of *Medas*. According to Charak the *Manasdoshas - Rajas* and *Tamas* have a very great adverse effect on the body and three *Doshas* also.[4]

In Ayurvedic literature the disease has been classified as under:

- **Etiological classification**
  - *Apathyanimittaja Prameha*– Non-Insulin Dependent Diabetes Mellitus (NIDDM) -Due to over eating and lack of exercise.
  - *Sahaja Prameha* -Insulin Dependent Diabetes Mellitus (IDDM) – It highlights the genetic pre-disposition of disease.
- **Clinico-pathological classification (*Doshic*)**
  - *Kaphaja Prameha* (Early diabetes)
  - *Pittaja Prameha* (Acute diabetes)
  - *Vataja Prameha* (Chronic diabetes)
- **Therapeutic classification (Based on body constitution)**
  - *Sthula Pramehi* (Obese diabetics)
  - *Krisha Pramehi* (Asthenic diabetics)
- **Prognostic classification (Based on *Sadhya sadhyata*)**
  - Easily *manageable – Apathyanimittaja, sthula, kaphaja*
  - Palliative – *Pittaja prameha*
  - Unmanageable – *Sahaja, krisha, vataja*

Though, the discovery of Insulin and other hypoglycemic drugs has a great achievement of modern medical science, but the hazardous side effects of hypoglycemics after long term used are incurable and hence an ideal therapy is still obscure. The Ayurvedic management of Diabetes aims not only to achieve a strict glycemic control but also to treat the root cause of the disease. For it various modalities of treatment are developed which depends upon the underline pathology.

Thus it is the demand of today's era to explore the better treatment options from the most time tested system of medicine. Ayurveda advocates healthy life style both to prevent and manage the life style diseases. "*Swathasya swathya rakshanama aaturasya vikara prashamanam*".

It also prescribes the dietary and other life style modifications in terms of exercise etc, besides recommending drugs for the same. Ayurvedic medications as proved repeatedly have multi-factorial effects (*Deepana*, *Pachana*, *Rasayana* etc). Besides countering the raised glucose levels in the blood they also nourishes the body tissues, have rejuvenative effect on the brain tissue of chronic diabetic state. They ensure better sustainability to the tissues of the body because of their *Rasayana* (anti-oxidant action) property as there is no such action reported from the conventional system of medicine. As faulty dietary habits are one of the most important reasons for type-2 diabetes, Ayurvedic dietary recommendations ensures no further worsening of diabetic state.

To further support the above said facts and to explore a new combination of Ayurvedic herbs in modern era of ever growing diabetes mellitus, the study was planned to evaluate the efficacy of Ayurvedic herbal drug combination.

In the present study, a *'Madhumeha Nashini Gutika'*[5] herbomineral preparation and *'Darvyadi Kwath'* [6] are selected for clinical trial.

Aims and objectives of the study are to study the etiopathogenesis of *Madhumeha* to compare the effect of *Madhumeha Nashini Gutika* & *Darvyadi Kwath* and to identify the best, effective and safe treatment in Ayurveda for *Madhumeha*.

MATERIAL AND METHODS

Selection of the patients

The study comprised of a series of 60 patients of Type 2 DM. The patients were selected from OPD and IPD of *Kayachikitsa* of Rishikul Government Ayurvedic P.G. College. These patients are randomly divided in 3 groups 20 patients in each, on the basis of inclusion and exclusion criteria depending upon Fasting & PP Blood Sugar with detailed clinical history, physical examination and other necessary / desired investigation. Some cases were hospitalized for investigation and some were taken as OPD patients. The cases were recorded with help of a special proforma prepared for this purpose.

Selection of drug

1. *Madhumeha Nashini Gutika (Rasamrit)* 500mg TDS with luke warm water after meal.

2. *Darvyadi Kwath (Charak chi. 6/26)* 40ml BD after meal.

Ingredients of *'Madhumeh Nashini Gutika' (Rasamrit)*

1. *Trivanga Bhasma (Nag, Vanga & Yashad bhasma)*
2. Leaf of *Gudmar (Gymnema Sylvestre)*
3. Leaf of *Nimb (Azardichata Indica)*
4. *Shilajeet*

The powder forms of these drugs are taken in the ratio of 1:3:3:6 and mixed with each other, then tablet of 500mg is made and let it to dry.

Properties of the contents

Contents	Sanskrit Name	Latin Name	*Rasa*	*Veerya*	*Vipak*	*Doshaghnta*	*Rogaghnta*
1.(Trivanga Bhasm) - Nag	*Nag*	Plumbum	*Tikt, Katu Madhur, Lavan*	*Ushana*	*Katu*	*Kaphvatanashak*	*Pramehnashak, Aamvatnashak, Panduhar* etc.
Vanga	*Vanga*	Stannum	*Tikt, katu, kashay, aml*	*Ushana*	*Katu*	*Kaphpittahar*	*Pramehhar, Krimihar, Panduhar* etc.
Yashad	*Yashad*	Zincum	*Tikt, katu, kashay*	*Sheet*	*Katu*	*Kapha -pitta nashak, Vatahar*	*Pramehhar, Panduhar, Kas-shwashar*
2.Gudmar	*Meshshringi*	*Gymnema Sylvestre*	*Tikta, kashay*	*Ushana*	*Katu*	*Kaph-vata nashak*	*Pramehhar, Kushthar* etc.
3. Nimb	*Nimb*	*Azardichata Indica*	*Tikt, Kashay*	*Sheeta*	*Katu*	*Kapha - Pitta nashak*	*Kushthagn, Kandughn* etc.
4.Shilajeet	*Shilajatu*	*Asphaltum Punjabinum*	*Tikt, lavan*	*Sheet*	*Katu*	*Tridoshshamak*	*Mutrarognashak, Medonashak* etc.

Ingredients of *Darvyadi Kwath*

Name of drug	Latin name	Chemical constitutes	*Ras*	*Veerya*	*vipak*	*Doshaghnta*
Daruharidra	*Berberis aristata*	Berberin	*Tikta*	*Ushana*	*Katu*	*Kapha pitta nashak*
Devadaru	*Cedrus deodara*	Terpenoids, Flavonoids and Glycosides	*Tikta, Katu*	*Ushana*	*Katu*	*Kapha pitta nashak*
Haritki	*Terminalia chebula*	Tannins, anthraquinones and polyphenolic compounds	*Pancaras* except *Lavan*	*Ushana*	*Madhur*	*Tridoshahar*
Bibhitki	*Terminalia bellirica*	Gallic acid, tannic acid and glycosides	*Kashaya*	*Ushana*	*Madhur*	*Kapha shamak*
Amalki	*Emblica officinalis*	Ascorbic acid tannins, gallic acid.	*Pancharasa,* except *Lavana*	*Sheeta*	*Madhura*	*Tridoshhar*
Musta	*Cyperus rotundus*	Volatile Oil	*Tikta, Katu, Kashay*	*Sheeta*	*Katu*	*Pitta shamak*

Drug Dosages

1. *Madhumeha Nashini Gutika (Rasamrit)*

Every tablet of *'Madhumeha Nashini Gutika'* is consist of 500mg wt. Patients are asked to take *'Madhumeha Nashini Gutika'* 1.5gm/day in divided dose, i.e. 3 times in a day with Luke warm water for 3 months.

2. *Darvyadi Kwath (Charak chi. 6/26)*

Patients are dispensed *Darvyadhi Kwath* in raw form and asked to prepare it by following method: 5gm of raw *Kwath* is taken and make it boil with 4 cup of water (about 160 ml). After some time when 1 cup of water (about 40 ml) is remaining then after filtering it should be used after meal.

Duration of study – 90 days, Follow up **–** 15 days.

Groups for drug trial

GROUP I - *Madhumeha Nashini Gutika*
GROUP II - *Darvyadi Kwath*
GROUP III - *Madhumeha Nashini Gutika & Darvyadi Kwath*

Inclusion criteria

- Diagnosed patients without any complication are included.
- Age between 16-60 years.
- BSF – upto 200 mg/dl
- BSPP – upto 300 mg/dl

Exclusion criteria

- Patient having DM type 1
- Patient having complication of diabetes
- Any other serious medical & surgical ill patients are excluded.

Investigations

- Hb%, TLC, DLC, ESR
- Urine – Routine & Microscopic
- Lipid profile
- HbA1C
- X ray chest

These investigations were done in all the patients before and after completion of treatment to rule out any other pathological condition.

- BS- F & PP
- It will be carried out before trial and after each follow up i.e. 15 days.

Parameter of assessment

1. Subjective assessment
2. Objective assessment

1. Subjective parameter of assessment

The assessment of the drug trial is done the basis of improvement in the symtoms during and after trial. The symptoms are graded as per their severity. The detail assessment of clinical signs and symptoms are discussed below:

(1) Polyuria

3-6 times/day, rarely at night	0
6-9 times/day, 0-2 times at night	1
9-12 times/day, 2-4 times at night	2
>12 times/day, >4 times at night	3

(2) Polydipsia

Feeling of thirst 7- 9 times/24 hrs	0
Feeling of thirst 9-11 times /24hrs	1
Feeling of thirst 11-13 times/24hrs	2
Feeling of thirst>13 times/24 hrs	3

(3) Polyphagia

Regular (usual diet schedule)	0
Slightly increased (1-2 meals)	1
Moderately increased (3-6 meals)	2
Markedly increased (>6 meals)	3

(4) Weakness

Can do routine exercise/work	0
Can do moderate exercise with hesitancy	1
Can do mild exercise only, with difficulty	2
Cannot do mild exercise too	3

(5) Muscles cramps

No cramps	0
Cramps after walking 2 km	1
Cramps after walking 1&1/2 Km	2
Cramps after walking 1 Km	3
Unable to walk even ½ km	4

(6)Libido

Normal	0
Decreased frequency with normal performance	1
Decrease frequency with insufficiency	2
No sexual stimulation at all	3

(7) Joint pain

No pain	0
Pain in joint, routine movements normal	1
Pain in joint, slight limitations of movements	2
Pain in joint, limitations of movements with much reduced activity	3

(8) *Panduvaranmutrata*

Crystal clear fluid	0
Faintly cloudy or hazy with slight turbidity	1
Turbidity clearly present and newsprint easily read through test tube	2
Newsprint not easily read through test tube	3

2. Objective parameter of assessment

The assessment will be done on the basis of change in Blood Sugar F & PP in each follow up and at the end of trial.

Statistical analysis Mean, percentage relief, S.D, 't' and 'p' values were calculated. Paired 't' test was used for calculating the 't' value in the paired data.

Assessment of overall effect of the therapy

First percentage improvement of individual patient was calculated as shown below:

All the B.T. score of the above mentioned symptoms & biochemical parameters of the patient were added. All the A.T. score of the above mentioned symptoms & biochemical parameters of the patient were added. Overall percentage improvement of each patient was calculated by the following formula:

$$\frac{\text{Total BT-Total AT}}{\text{Total BT}} \times 100$$

The result thus obtained from individual patient was categorized according to the following grades:

Control of the disease 100% relief, Marked improvement ≥75% relief

Moderate improvement ≥50% upto 74% relief, Mild improvement ≥25% upto 49% relief

No improvement ≤25% relief

Results and Discussion

Table 1: Distribution of signs and symptoms in 60 patients of Diabetes Mellitus

Symptoms	No. of patients in Group-I	No. of patients in Group-II	No. of patients in Group-III	Total	Percentage
Polyuria	12	10	8	28	46.7%
Polydipsia	9	8	8	25	41.7%
Polyphagia	12	7	5	24	40%
Panduvaran mutrata	4	4	5	13	21.7%
Weakness	17	12	16	45	75%
Joint pain	11	14	8	33	55%
Muscles cramp	11	10	14	35	58.3%
Libido	4	3	6	13	21.7%

Table 2: Assessment of result in symptoms of diabetic patients in GROUP – I

Symptoms	BT	FU_1	FU_2	FU3(AT)	% relief	't'	P
Polyuria	2.05±1.81	1.6±.68	0.9±.97	0.9 ± 1.07	56	4.38	<.001H.S
Polydipsia	1.6±1.87	1.1±0.90	0.65±1.26	0.5 ± 1.41	68.7	3.49	<.01
Polyphagia	1.5±1.74	1.6±1.74	.85±.94	.55 ± 1.15	63.3	3.68	<.01
Weakness	2.75±1.41	1.85±1.12	1.1±1.17	0.9 ± 1.14	67.2	7.19	<.001H.S
Muscles Cramps	1.6±1.57	1.25±.58	0.75±.89	0.4 ± 1.13	75	4.53	<.001H.S
Libido	0.4±.83	0.2±0.53	0.15±.65	0.15 ± .67	62	2.33	<.05
Joint pain	1.9±1.86	1.45±.83	0.95±1.25	0.8 ± 1.14	57.8	4.27	<.001H.S
Panduvarn mutrata	0.45±.82	0.2±.31	0.1±.31	0.1 ± 0.73	77	2.134	<.05

BT-Before Treatment, AT- After Treatment, FU- Follow up, Mean±SD

Table 3: Assessment of result in blood sugar fasting and post prandial cases in GROUP – I

	B.T.	FU_1	FU_2	FU_3 (AT)	% relief	't'	P
BSF	149.06±46.68	127.58± 12.86	115.7±16.75	106.24 ± 36.49	28.7	4.02	<.001H.S
BSPP	220.68±78.99	196.35±23.90	180±30.48	174.37 ± 51.50	20.9	4.01	<.001H.S

Table 4: Assessment of results in symptoms of diabetic patients in Group- II

Symptoms	BT	FU_1	FU_2	FU3(AT)	% relief	't'	P
Polyuria	0.95± 1.03	0.50±.91	0.35±.68	0.15± .84	84.2%	2.39	<.05
Polydipsia	0.95±1.35	0.6±0.56	0.5±.61	0.25±.95	73.6%	3.27	<.01
Polyphagia	1.25±1.58	0.85±.59	0.5±.93	0.3±1.26	76%	3.35	<.01
Weakness	1.75±1.84	.85±1.12	0.65±1.10	0.15±1.64	71.4%	4.36	<.001H.S
Cramps on walking	1.45±1.79	0.9 ±.60	0.65±.1.10	0.3±1.31	79.3%	3.90	<.001H.S
Libido	0.5±.88	0.3±0.78	0.25±.89	0.05± .84	90%	2.39	<.05
Joint pain	1.85±1.22	1.2±1.01	0.15±.68	0.05±.84	97.2%	4.09	<.001H.S
Panduvarn mutrata	.85±.1.34	0.7±.37	0.5± .47	0.25±1.07	70.5%	2.50	<.05

Table 5: Assessment of result in blood sugar fasting and post prandial cases in GROUP – II

	B.T.	FU_1	FU_2	FU_3 (AT)	% relief	't'	P
BSF	158.05±20.42	150± 3.80	148.35±7.05	140.15 ± 6.78	11.3%	4.64	<.001H.S
BSPP	215.45±33.24	211.85±6.71	211.6±4.86	210.45 ± 3.6	2.3%	3.86	<.01

Table 6: Assessment of result in symptoms of diabetic patients in GROUP – III

Symptoms	BT	FU_1	FU_2	FU3(AT)	% relief	't'	P
Polyuria	1.9 ±1.83	1.3±.607	0.8±1.14	0.3± 1.64	84.2%	4.36	<.001H.S
Polydipsia	1.6±1.87	1.0±0.83	0.75±1.16	0.35±1.59	78.1%	3.50	<.01
Polyphagia	1.35±1.75	0.9±.84	0.6±1.09	0.25±1.55	81.4%	3.15	<.01
Weakness	2.45±1.76	1.8±1.12	1.2±1.04	0.35±1.64	85.7%	5.71	<.001H.S
Cramps on walking	2.75±1.71	1.80±.91	0.9±.1.52	0.4± 1.63	85.4%	6.39	<.001H.S
Libido	0.4±.88	0.35±0.53	0.25±.37	0.15 ± .36	62.5%	2.79	<.05
Joint pain	1.85±1.92	1.2±1.01	0.45±1.67	0.2 ± 1.80	89.1%	4.09	<.001H.S
Panduvarn mutrata	1.0±.1.6	0.65±.67	0.3±.1.24	0.15± 1.43	85%	2.64	<.02

Table 7: Assessment of result in blood sugar fasting and post prandial cases in GROUP – III

	B.T.	FU_1	FU_2	FU_3 (AT)	% relief	't'	P
BSF	172.04±42.32	153.8± 17.94	140.1±17.86	124.85 ± 27.67	27.4%	7.62	<.001H.S.
BSPP	268.4±64.73	237.4±25.96	217.2±33.57	191.5± 45.14	28.6%	7.61	<.001H.S

Table 8: Effect of drug trial on other biochemical values in Group III

Biochemical values (mg/dl)	B.T	A.T	S.D	't'	P
S.Cholesterol	209.65	208.15	1.97	3.35	<.01S
S.Triglycerides	171.7	169.2	2.97	3.08	<.01S
S.HDL	42.35	41.45	1.28	3.12	<.01S
S.LDL	154.35	153.15	1.56	3.42	<.01S
S.VLDL	39.25	38.3	1.31	3.24	<.01S
S.Creatinine	1.04	1.01	1.06	2.78	<.02S
Blood urea	37.35	36.45	1.10	3.65	<.01S

Table 9: Comparative assessment of % relief on various symptoms

Symptoms	% Relief in Group I	% Relief in Group II	% Relief in Group III
Polyuria	56%	84.2%	84.2%
Polydipsia	68.7%	73.6%	78.1%
Polyphagia	63.3%	76%	81.4%
Weakness	67.2%	71.4%	85.7%
Cramps on walking	75%	79.3%	85.4%
Libido	62%	90%	62.5%
Joint pain	57.8%	97.2%	89.1%
Panduvarnmutrata	77%	70.5%	85%

Table 10: Comparative improvement of symptoms in various Groups

	GROUP – I			GROUP – II			GROUP – III		
Symptoms	Marked	Moderate	Mild	Marked	Moderate	Mild	Marked	Moderate	Mild
Polyuria	-	56%	-	84.2%	-	-	84.2%	-	-
Polydipsia	-	68.7%	-	-	73.6%	-	78.1%	-	-
Polyphagia	-	63.3%	-	76%	-	-	81.4%	-	-
Weakness	-	67.2%	-	-	71.4%	-	85.7%	-	-
Muscles Cramps	75%	-	-	79.3%	-	-	85.4%	-	-
Libido	-	62%	-	90%	-	-	62.5%	-	-
Joint pain	-	57.8%	-	97.2%	-	-	89.1%	-	-
Panduvarn mutrata	77%	-	-	-	70.5%	-	85%	-	-

DISCUSSION

In view of Ayurveda, indulgence in faulty life style creates a number of diseases where along with the medical interventions; modifications in life style, dietary stuffs & habits plays important role in managing or reversing the diseases process. *Apathyanimittajja prameha* mentioned in the Ayurvedic

texts has much similarity to the type-2 diabetes mellitus in terms of its etiology, etiopathpogenesis, and presentation of the disease. Thus the study was planned to study etiopathogenesis of the disease, and explore the better and safer treatment options for the management of this disease through Ayurvedic management. *Madhumeha* is a disease in which the patient voids excessive quantity of urine having concordance with *Madhu* i.e. of *Kashaya* and *Madhura* taste, *Ruksha* texture and honey like color. In *Madhumeha,* mainly the *Vata* and *Kapha* are predominant though the disease is *Tridoshaj.* The *Vata* may be provoked either directly by its etiological factors or by the *Avarana* of its path by *Kapha, Pitta* or other *Dushyas*. So, *Vagbhata* has classified the *Madhumeha* into two categories i.e. *Dhatukshanajanya Madhumeha* and *Avarnajanya Madhumeha.* Type I Diabetes mellitus is nearer to *Dhatuakshanajanya Madhumeha* while type II Diabetes mellitus resembles to *Avaranajanya Madhumeha.*

Among the 60 cases of diabetes mellitus the symptomatic distribution of weakness was 75%, i.e. highest, muscle cramps was 58.3% and joint pain was 55%. In statistical data follow up of 1 month duration has been shown in table, so there are total 3 follow FU1, FU2 and last FU3 is AT i.e. is after treatment due to enlargement of data in 6 follow up. In subjective assessment of Group I (*Madhumeha Nashini Gutika*) symptomatically the result was highly significant (p>.001) in Polyuria, Weakness, Muscles cramps and joint pain. While it was significant in Polydipsia (p<.01), Polyphagia (<.01), Libido (p<.05) and *Paduvarnmurata* (p<.05). In objective assessment of Group I (*Madhumeha Nashini Gutika*) results based on laboratory investigations was highly significant (p<.001) in both BSF & BSPP. In subjective assessment of Group II (*Darvyadi Kwath*) symptomatically the result was highly significant (p>.001) in Weakness, Muscles cramps and joint pain. While it was significant in Polyuria (p<.05) Polydipsia (p<.01), Polyphagia (<.01), Libido (p<.05) and *Paduvarnmurata* (p<.05). In objective assessment of Group II (*Darvyadi Kwath*) results based on laboratory investigations was highly significant (p<.001) in BSF, while it was significant (p<.01) in case of BSPP. In subjective assessment of Group III (*Madhumeha Nashini Gutika & Darvyadi Kwath*) symptomatically the result was highly significant (p>.001) in Polyuria, Weakness, Muscles cramps and joint pain. While it was significant in Polydipsia (p<.01), Polyphagia (<.01), Libido (p<.05) and *Paduvarn murata* (p<.02). In objective assessment of Group III (*Madhumeha Nashini Gutika & Darvyadi Kwath*) results based on laboratory investigations was highly significant (p<.001) in both BSF & BSPP. While observing other biochemical parameters, (e.g. lipid profile, B. urea and S. Creatinine) significant reduction is found at the end of the trial. Not any kind of side effect was detected after the end of the trial of 90 days.

Comparative assessment of improvement is also observed in all three groups. In Group I (*Madhumeha Nashini Gutika*) Marked Improvement was found in symptoms of muscles cramps and *Panduvaran mutrata*. In Group II (*Darvyadi Kwath*) Marked Improvement was found in symptoms of Polyuria, Polyphagia, Muscles cramps, joint pain and *Panduvaran mutrata*. In Group III (*Madhumeha Nashini Gutika & Darvyadi Kwath*) was found in all symptoms viz. Polyuria, Polyphagia, Polydipsia, Muscles cramps, Joint pain, weakness and *Panduvaran mutrata*.

Probable mode of action of selected drugs

The first trial drug *'Madhumeh Nashini Gutika'* is a herbo-mineral formulation; the constituents are *Shilajeet, Trivang Bhasma (Naag, Vang* and *Yasad*), *Nimba* and *Gudmar.* All the ingredients have documented hypoglycaemic activity and have been extensively studied in diabetic patients. *'Trivang Bhasma'* is *Kapha-Medohar*, and contains the *Tikta-Kashaya ras* by which it corrects vitiation of *Kapha & Pitta.* These three metals of *Trivang bhasma* also reduces the general weakness of body. The second constituent is *'Gudmar'*, which is *Kapha-vatahar* and contains *Tikta Kashay ras*. It contains alkaloids like gymnemagenin, gypenosies etc. Its dried leaf powder increased circulating insulin level and exhibited hypoglycaemic activity. The third constituent is *'Nimba'*, which is *Kapha-Pittahar* and contains *Tikt-Kashay ras.* Its leaves have chemicals like Azadirachtin, Azadirone, Nimbolide etc. Which effectively decrease blood sugar level and prevent hyperglycaemia. The fourth constitute is *'Shilajeet'*. It is a phytocomplex that contains over 85 minerals in their ionic form and triterpenes, selenium, phospholipids, humic acid and fulvic acid. These compounds have strong antioxidant properties which reduces degenerative changes in beta cells of pancreas, while the minerals help give *Shilajeet* an energy-enhancing effect. Most *Shilajeet* compounds contain between 60-80% fulvic acid, and the greater the content of fulvic acid, the more anti-aging properties the compound contains. It reduces *Kapha* due to *Tikta ras, Katu vipak, Ushan virya, Shoshak* and *Chedaka* properties and then it checks *Mandagni* and reduces *Meda,* which is the major factor (i.e. *Medodushti*) in pathogenesis of *Madhumeh*. Due to its *Chedan* property it expels the *Kaphadi doshas* from the *Srotas* with the force due to *Prabhava* of the drug. *Chedana* drugs are usually belonging to *Amla, Katu rasa* and *Teekshna guna*. On the other hand *Chedana* serves two fold functions. 1. *Amla* helps in *vilayana* of obstructive materials. 2. *Katu & Tikta* expels the vitiated material from the *Srotas.* With the above diathesis the obstructive *Kapha* and other material have been cleared out from the *Srotas*. *Shilajeet* is having the properties of *Katu, Ushna virya, Ushna* and *Laghu* so it acts *Deepana*. *Katu rasa* of *Shilajeet* stimulate the function of the *Vyana*. So the normalized functions of the stomach also help in digestion of *Aam.*

In this way the properties of all four contains of drug help in *Samprapti Vighatan* of the disease.

The second trial drug is *'Darvyadi Kwath'* consisting *Devdaru, Daruhridra, Triphala* and *Musta.* These drugs basically are *Kashaya* and *Tikta Rasa pradhan*, *Ushna Veerya* and *Laghu Ruksha Guna*, this formulation helps in eliminating vitiated *kapha.* It also corrects the vitiated both *Medas* and *Kapha* being the main entity of the *Samprapti,* thus by breaking the *Samprapti* (correcting the vitiation of *Medas* and *Kapha*) treats the disease. As the drug is *Ushna* it also increased improving the *Dhatvagni,* (as Ayurveda believes that the disease is *Amajanya*).

CONCLUSIONS

It can be concluded that *Avaranjanya Madhumeha* can be correlated with Diabetes mellitus type-II. An etiological factor vitiates mainly *Kapha, Pitta* and *Meda* causes excessive accumulation of morbid matter inside the body and obstructs the path of *Vata*. Due to *Avarana* aggravated *Vata* causes depletion of Vital *Dhatu* like *Oja, Majja* and *Vasa* and affect the normal physiology. Sedentary life, Lack of exercise, Faulty food habits and improper medication precipitate the disease. Treatment modalities based upon the consideration of vitiated *Kapha, Meda* and *Vata* having properties like *Shleshamamedohara, Pramehaghna* and *Kapha-Vatahara.*. After evaluating the total effect of therapies it was observed that the *'Madhumeha Nashinh Gutika' & Darvyadi Kwath* (Combined therapy) provided better relief in the patients of *Madhumeha* in comparison to single group therapy. No any side effects were observed during treatment Though Diabetes is irreversible if established once. The complication of Diabetes mellitus and side effects can be controlled on prevented with the best use of Ayurvedic medicine. Thus we are very happy indeed to declare our highly encouraging results regarding the successfully treated cases. we sincerely hope and wish that the presented study shall always be pioneers an ideal research work for the coming generation.

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