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CLINICAL EVALUATION OF *DIABECARE YOGA (KALPITA YOGA)* IN THE MANAGEMENT OF *AHITAAHARAJA APATHYANIMITTAJA PRAMEHA* W.S.R. TO TYPE-2 DIABETES MELLITUS AS A *NAIMITTIKA RASAYANA*

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ABSTRACT

Type-2 diabetes mellitus is a persistent health problem that requires innovative strategies to improve health and needs a multifactorial approach for the treatment. ***Diabecare Yoga***, a new formulated Ayurvedic compound consists of four herbs with anti-diabetic potential i.e. ***Jambu*** *(Syzygium Cumini*), ***Udumbara*** (*Ficus golmerata*), ***Haridra*** (*Curcuma longa*) ***and Amalaki*** (*Emblica officinalis*). In a total of 33 patients, 16 patients were of newly detected type-2 diabetes mellitus and 17 patients were of chronic type-2 diabetes mellitus and they were divided into Group A and group B respectively. Group A consisted newly detected subjects of type-2 diabetes and were not taking any regular medication and group B consisted of chronic cases of type-2 diabetes mellitus, who were taking modern ant-diabetic medication, but their blood-glucose level was not controlled to desired level. Patients in group A were administered *Diabecare yoga* in *Choorna* form with *Triphala Kwath* as an *Anupana* (5 gms *Diabecare yoga* with *Triphala Kwath* of 50 ml in divided doses of two-times a day before breakfast and dinner. Patients in group B were administered *Diabecare yoga* in *Choorna* form with *Triphala Kwath* as an *Anupana* in the same dose in addition to the concomitant anti-diabetic (Allopathic) medication. Glycosylated hemoglobin (serum HbA1c) evaluated in eight patients of group B showed statistically significant reduction. There was also statistically significant reduction in the fasting and post prandial blood sugar parameters in newly detected cases as well as chronic cases of type-2 diabetes mellitus.
Keywords: Anti-diabetic, Glycosylated hemoglobin, *Diabecare yoga*, *Triphala Kwath,* type-2 diabetes mellitus

INTRODUCTION

Nowhere is the diabetes epidemic more pronounced than in India, as World Health Organization (WHO) report shows that 32 million people had diabetes in the year 2000.[1] Type-2 diabetes is the result of a progressive impairment of pancreatic β-cell function in the setting of worsening insulin resistance. Studies in high-risk populations have demonstrated that during progression to diabetes, β-cells have declining function and lose the first phase of insulin secretion, resulting in less than adequate suppression of hepatic glucose production following meals. In addition, oscillations of insulin secretion become unmatched from their normal coupling with glucose. Several mechanisms are thought to be responsible for impaired β-cell function, including glucose toxicity and lipotoxicity and potentially contribute to β-cell loss.

Type-2 diabetes mellitus is one of the most prevalent life style disorders in today's era.[2] Ayurveda, the science of life mentions *Apathyanimittaja Prameha* which resembles type-2 diabetes mellitus in terms of etiology, pathogenesis and presentation of the disease. Therefore, the treatment regime prescribed in Ayurveda for *Apathyanimittaja Prameha* has been adopted in the present study, aiming to counteract the complex metabolic derangement of type-2 diabetes mellitus and to explore the potential of a new Ayurvedic compound drug formulation to provide safe and cost effective treatment for type-2 diabetes mellitus.

Aims and objectives:

- ❖ Critical and Conceptual and clinical analysis of *Madhumeha* in relation with Type 2 Diabetes mellitus.
- ❖ To assess the efficacy of the ***Diabecare Yoga*** in newly detected cases of type-2 diabetes mellitus and in chronic uncontrolled cases of type-2 diabetes mellitus, whose blood glucose levels are not controlled up to the desirable limits with modern drugs with ***"Triphala Kwath"*** as an *Anupana.*

Materials and Methods: The study will be conducted on 30 clinically and pathologically diagnosed patients of *Madhumeha* [DM type-2]. The selection of patients will be made from OPD/IPD of Arogyashala, National Institute of Ayurveda and SSBH, Jaipur (Raj.).

Inclusion Criteria:

- ➢ Type II DM- patients
- ➢ Patients having hyperglycemia confirmed by Laboratory Investigation.
- ➢ Age group between 30-70 yrs of either sex.

Exclusion Criteria:

- ➢ Patients having Type - DM I [IDDM]
- ➢ Age below 30 and above 70 years.
- ➢ Patient of type II DM who are on Insulin therapy.
- ➢ DM associated with any type of Malignancy.
- ➢ DM with complications.
- ➢ Diabetes insipidus.
- ➢ Patient having any serious illness.
- ➢ Drug induced DM.
- ➢ FBS [>250mg/dl]
- ➢ PPBS [>300mg/dl]
- ➢ DM with coronary artery diseases.

Parameters of evaluation: Subjective parameters:

1) *Prabhoot Mutrata* (Polyurea)

A. **Quantity of urine**
B. **Frequency of urine**
2) *Pipasa - Adhika* (Polydipsia)
3) *Avila Mutrata* (Turbidity in urine)
4) *Kshudha Adhika* (Polyphagia)
5) *Kara-Pada Suptata* (numbness in hand and feet)
6) *Kar Pada Daha (*Burning sensation in hands & feet
7) S*wedadhikya* (Perspiration)
8) *Daurbalya* (Weakness)
9) *Shula* (Joint Pain)
10) *ShramaSwasa* (Dyspnoea) {ATS scale}
11) *Nidradhikya* (Sleep)
12) *Purishabadhdhata* (Constipation)
13) *Mathunavaraisaya* (Libido)
14) P*indikodveshtana* (Cramps)
15) Objective Parameters: Assessment of B.M.I. (weight in kg/height in meter^2)
16) **Laboratory Parameters**

- Hemoglobin, Total Leucocyte Count (TLC), differential leucocyte count, Erythrocyte Sedimentation Rate (ESR), CBC
- Urine for routine and microscopic examination.
- Biochemical investigations: FBS, PPBS, lipid profile, and Serum Glycosylated Hemoglobin (S. HbA1c).

Treatment protocol:

- Group A: Patients with newly diagnosed type-2 diabetes mellitus, not taking any medication were administered *Diabecare yoga* with *Triphala Kwath* as an *Anupana*.(5 gms *Diabecare yoga* with *Triphala Kwath* of 50 ml in divided doses of two-times a day before breakfast and dinner).
- Group B: Patients with concomitant anti-diabetic (Allopathic) medication, whose blood glucose is not well under control. These patients were administered the test drug *Diabecare yoga* with *Triphala Kwath* as an *Anupana* in the same dose in addition to the concomitant anti-diabetic (Allopathic) medication.

Drug, Dose and Duration:

1. Drug: *Diabecare yoga.*
2. Dose: 5 gms *Diabecare yoga* in *choorna* form with *Triphala Kwath* of 50 ml in twice a day before breakfast and dinner).
3. *Anupana*: *Triphala Kwath* of 50 ml.
4. Duration: 2 months (for both groups).

The patients under both the groups were provided a proper diet chart planned according to the classics and keeping glycemic index of the dietary substances and calorie requirement of the patients. Simultaneously they were asked to maintain a routine of 30 min walk in the morning and in the evening hours, ***Pranayama*** a daily of 30 min in morning hours, 7 days a week. There was Fortnight (15 day) of follow-up, after completion of 2 months of the treatment

Statistical analysis: Evaluation of the data through statistical estimation within the group and comparison between the groups BT (Before Treatment) and AT (After Treatment) were assessed using paired and unpaired Student's *t* test, respectively. The statistical estimations particularly sample means; SD (Standard Deviation), SEM (Standard Error of Mean), calculated *t* value and *P* (Probability) values were obtained by applying the standard formulae. For comparison of the subjective parameters, **Mann Whitney test** was used and for comparison of the objective parameters, **Unpair t test with Welch correction** was used. $P < 0.05$ was considered as statistically significant,

P>0.05 was considered as statistically non significant.

Results and Observation: A total of 33 patients, consisting of 17 patients newly detected and 16 chronic cases of type-2 diabetes mellitus were registered in group A and group B, respectively. In group A, 15 and in group B, 15 patients completed the study. In the clinical study maximum number (33%) of patients belonged to the age group of 40-49 years and 70% were males. Majority of them belonged to Hindu religion (70%), married (97%), urban area (70%), govt. employees (36%) and educated (84%), non vegetarian (55.5%) and were from middle class (52%) of the society. Positive family history for type-2 diabetes was found in 42% of the patients. Majority of them have to H/o allopathic treatment (70%), (49%) had addicted tea and coffee, (51.5%) had urgency of urine.

The present study revealed that (96.96 %) were having *Ati Madhura Guru Aahara* while *(84.84%)* patients having *Aasyasukham Nidana,* and *Ati Dadhi Sevana* and *Swapnasukham* had equal incidence of (78.78%). The majority of patients were having *Aalasya* constituting (84.84 %) while *Trishna* was present in (81.81%) patients followed by *Shayyaasan swapna sukhratishcha* in (66.66%), *Mukha Talu Shosa* and *Hasta Padtal Daha in* (63.63%) as a *Purvarupa.* The majority of patients were having *Prabhoot mutrata* (Polyurea) and Daurbalya (Weakness) (81.81%)*, Pipasadhikya* (Polydipsia) (75.75%) and *Kshudhadikya* (Polydipsia) in (78.78 %) cases, *Nidradhikya* (sleep) *in* (69.69%) cases.

Mean FBS and PPBS values were 121 mg/dl and 171.46 mg/dl in group A, respectively. In group B, mean FBS and PPBS values were 172.66 mg/dl and 235.7 mg/dl, respectively, before the commencement of the treatment. In group A, mean serum cholesterol and serum triglyceride values were 187.33 mg/dl and 148.53 mg/dl, respectively. In group B, S. cholesterol and S. triglyceride were having mean values of 213.73 mg/dl and 171.33 mg/dl, respectively. In group A, mean serum LDL and serum VLDL values were 107.56 mg/dl and 29.45 mg/dl, respectively. In group B, S. LDL and S. VLDL were having mean values of 124.53 mg/dl and 35.21 mg/dl, respectively. In group A, mean value of S. HDL (Serum High Density Lipoprotein) was 49.13 mg/dl and in group B mean value for S. HDL was 51.33 mg/dl. Mean S. HbA1c value in eight patients of group B was 7.22 %. In group A, 2+ urine sugar was present in 13.33 % of the patients and 1+ in 18.75 % patients. In group B, 4+ urine sugar was found in 11.76 % of the patients, followed by 3+ in 17.64 %, 2+ in 23.52 %, and 1+ urine sugar in 29.4 % of the patients.

Effect of the therapies on subjective parameters: There was statistically highly significant ($P < 0.001$) reduction of 43.75 % and 43.33 % in quantity of urine in group A and group B, respectively. There was statistically highly significant ($P < 0.001$) reduction of 59.09 % in group A and statistically significant ($P < 0.05$) reduction of 41.66 % in group B in frequency of urine (Prabhoot Mutrata). In *Daurbalya (*Weakness*),* there was statistically highly ($P < 0.001$) significant reduction of 57.14 % and 54.54% in group A and group B, respectively. In *Nidradhikya* (Excessive sleep), there was statistically highly ($P < 0.001$) significant re-

duction of 70.58 % and 69.56 % in group A and group B, respectively. In *Purisha-badhdhata* (Constipation), there was statistically highly ($P < 0.001$) significant reduction of 65.21 % and 55.55 % in group A and group B, respectively. There was statistically significant ($P < 0.05$) reduction of 42.85% in group A and statistically highly significant ($P < 0.001$) reduction of 48.14 % in group B in *Pipasadhikya* (Polydipsia). There was statistically significant ($P < 0.05$) reduction of 50 % in group A and statistically highly significant ($P < 0.001$) reduction of 43.33 % in group B in *Avila Mutrata* (Turbidity in urine). There was statistically significant ($P < 0.05$) reduction of 54.54 % in group A and statistically highly significant ($P < 0.001$) reduction of 58.33 % in group B in *Karpada suptata* (Burning sensation in hand and feet). In *Kshudhadikya* (Polyphagia), there was statistically non significant ($P > 0.05$) reduction of 19.04 % in group A and statistically significant reduction ($P < 0.05$) of 28.57 % in group B. In *Karpada Daha* (Numbness in hand and feet), there was statistically non significant ($P > 0.05$) reduction of 45.45 % in group A and statistically significant reduction ($P < 0.05$) of 43.75 % in group B. In *ShramaSwasa* (Dyspnoea), there was statistically non significant ($P > 0.05$) reduction of 17.64 % in group A and statistically significant reduction ($P < 0.05$) of 31.25 % in group B. In *Sandhi Shula* (pain in joints), there was statistically significant ($P <0.05$) reduction of 43.75 % in group A and statistically non significant reduction ($P >0.05$) of 11.11 % in group B. *Swedadhikya* (Excessive perspiration), *Mathuna Varyasaya* (Libido) and *Pindikodveshtana* (Cramps) were statistically non significant reduction ($P >0.05$) in both groups. **[Table No.1&2]**

Effect of the therapies on Objective parameters: In Fasting blood sugar values (FBS), there was statistically high significant ($P < 0.001$) reduction of 13.88 % in group A and 14.98 % in group B, respectively. In Post Prandial blood sugar (PPBS), there was statistically highly significant ($P < 0.001$) reduction of 11.93 % in group A and 10.76 % in group B, respectively. In urine sugar fasting, there was statistically non significant ($P > 0.05$) reduction of 40 % in group A and statistically highly significant reduction ($P < 0.001$) of 58.33 % in group B. In S. cholesterol, there was statistically significant ($P < 0.05$) reduction of 6.93 % in group A and statistically highly significant reduction ($P < 0.001$) of 13.06 % in group B. In S. triglyceride, there was statistically non significant ($P > 0.05$) reduction of 12.74 % in group A and statistically significant reduction ($P < 0.05$) of 12.52 % in group B. In S. HDL, there was statistically significant increase ($P < 0.05$) of 4.34 % in group A and statistically non significant increase ($P > 0.05$) of 3.89 % in group B. In S. LDL, there was statistically non significant ($P > 0.05$) reduction of 4.12 % in group A and statistically highly significant reduction ($P < 0.001$) of 14.73 % in group B. In S. VLDL, there was statistically non significant ($P > 0.05$) reduction of 4.25 % in group A and statistically significant reduction ($P < 0.05$) of 17.03 % in group B. **[Table No. 3&4].** In BMI, there was statistically non significant ($P > 0.05$) reduction of 27.27 % in group A and statistically significant reduction ($P < 0.05$) of 27.27 % in group B. **[Table No. 5&6].** There was insignificant increase in S.

creatinine and S. urea in group A and group B. **[Table No. 7].** There was statistically highly significant ($P < 0.001$) reduction of 7.78 % in S. HbA1c. **[Table No. 8].**

In intergroup comparison, subjective symptoms ***Kar-Pada Suptata, ShramaSwasa*** shows good relief in group B than group A and Laboratory parameters **Fasting Blood Sugar, LDL** shows good relief in group B than group A. **[Table No. 9,10,11]**

Discussion: Type-2 diabetes mellitus and *Apathyanimittaja Prameha* have a similarity in terms of etiology, etiopathogenesis as well as presentation of the disease. The cardinal symptoms mentioned in the Ayurvedic texts such as *Prabhoot Mutrata* (polyurea), *Avila Mutrata* (turbid urine or the urine with high specific gravity) are also invariably found in almost all the diagnosed cases of type-2 diabetes mellitus. Secondly, Ayurvedic texts mention *Prameha* as one of the first disease as a manifestation of obesity, which is the most prominent predisposing factor in the incident of type-2 diabetes mellitus. Life style and diet style factors such as sedentary habits, high sugar content food articles such as simple carbohydrates, milk products, and sweets, which make an individual prone for the incidence of type-2 diabetes mellitus, are also mentioned in Ayurvedic texts as predisposing factors for *Apathyanimittaja Prameha*. Thus in this study, the treatment regime both in the form of lifestyle modifications as well as pharmacological intervention using the Ayurvedic herbs mentioned for their *Medohara*, *Prameha hara*, *Rasayana* actions were selected.

A total of 33 patients, consisting of 17 patients newly detected and 16 chronic cases of type-2 diabetes mellitus were registered in this study and were kept in group A and group B, respectively. A total of 30 patients completed the treatment, 15 in group A and 15 in group B.

Probable Modes of Action of *Diabecare Yoga:* *Madhumeha* is the disease of *Agnivikriti* and *Dhatuvikriti*. Formation of *Ama Dosha* at different levels is the main *Samprapti* responsible for the disease. So for the *Samprapti Vighatana* of the disease, the drug should remove *Ama Dosha* at various levels, correct the *Agni* and cleanses the *Srotasa.* In this formulation, *Diabecare Yoga* has a maximum of *Kashaya Rasa* followed by *Tikta Rasa, Madhura Rasa* and *Katu Rasa. Triphala Kwath* also having *Kashaya Rasa* followed by *Tikta Rasa. Kasaya Rasa* acts as a controller of excessive urination, *Dhatu kasaya* and *Oja Ksaya* through urine by their *Stambhana* properties. It absorbs *Kleda*, *Meda*, *Vasa* and *Kapha Dosha*. The *Rasa* like *Tikta* has also potency to improve the basic cellular metabolism due to their *Shodhana* properties while *Kasaya Rasa* not only reduces the peripheral resistance as well as clinical manifestation of the disease. *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 (*Aavaranagana* effects). *Madhura Rasa* being habituated since birth produces greater strength in *Srotasa*, *Dhatus* (tissues) and improves the strength of *Oja* due to their *Ojovardhaka*, *Rasayana* and

Yogvahi properties which play an important role in pathogenesis of *Madhumeha.*

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 *Tikta*, *Kasaya 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*

Diabecare Yoga provided significant relief in almost all the cardinal symptoms. On comparison, both the groups were equally significant in all the symptoms except, ***Kara pada Suptata, Shrama Swasa, Nidradhikya*** in which group B showed better effect then group A. This can be because of the combined effects of modern and Ayurvedic medicines have synergistic effect. So Diabecare yoga has properties of maintain blood sugar when used in alone and in combination with modern medicine. Reduction of fasting blood glucose can be attributed β-cell protective and regenerative effect of the drugs like ***Haridra*** [3] ***Udumbara*** [4] and ***Amalaki*** [5] in the combination which might have improved the basal insulin secretion and thus, might have reduced the hepatic gluconeogenesis also. In PPBS and Urine sugar showed statistically significant in both groups. It can be attributed insulin secretagogues effects and increase the glucose uptake in insulin sensitive tissues such as muscles and fat, also such drugs like ***Haridra, Jambu*** [6] ***,and Triphala*** [7] ***Triphala*** proves an antibacterial, antiviral antioxidant, maintain GIT motility, and have Lipid Lowering and Antiatherosclerotic Effects. There was statistically highly significant reduction ($P < 0.001$) in S. HbA1c levels carried out in a selected number (n =8) of the patients in group B. This reduction can be attributed to the multifactorial, i.e., *Pramehaghna* (*Jambu, Amalaki, Haridra*[8] *Triphala* etc.), *Medohara* (*Haridra, Udumbara, Triphala*[9] *Amalaki* etc.), *Rasayana* (*Triphala*, *Amalaki, Haridra*, etc.) effect of the ingredients of the combination. Significant reduction in S.HbA1c levels shows good glycemic control for the long term as well as significant improvement in the lipid profile besides reduction in oxidative stress related to hyperglycemia. After 2 months of the treatment, insignificant increases in the S. urea and S. creatinine indicate that there is no harmful in the renal functions and thus *Diabecare yoga* does not cause any renal impairment.

CONCLUSION

The treatment regime mentioned for *Apathyanimittaja Prameha* can be a worth for the management of the type-2 diabetes by countering its complex pathology. The *Pramehaghna* (Antidiabetic), *Medohara* (Anti-hyperlipidemic), and *Rasayana* (Anti-oxidant and rejuvenate action) property of the Ayurvedic drugs not only ensures good glycemic control when supported by *Pathya* and *Apathya* mentioned for *Prameha* but also will delay its complications

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Table 1: Table showing Effect of therapeutic trial on clinical symptomatology in 15 patients of *Madhumeha* (DM) based on (Wilcoxan matched pairs signed ranks t-test). Group A

Variable	Mean		Mean Diff.	S.D. ±	S.E. ±	Paired t-test	P-value	% Relief	Sign
	BT	AT							

1.*Prabhoot Mutrata* (polyurea) a)Quantity of urine	2.13	1.2	0.93	0.25	0.06	14	<0.001	43.75	**H.S.**
b) Frequency of urine	1.46	0.6	0.86	0.35	0.09	9.53	<0.001	59.09	**H.S.**
2.*Pipasaadhikya* (Polydipsia)	1.4	0.8	0.6	0.50	0.13	4.58	<0.05	42.85	**S.**
***3.Avila mutrata* (Turbidity in urine)**	1.33	0.66	0.66	0.48	0.12	5.29	<0.05	50	**S.**
4. *Kshudhadikya* (Polyphagia)	1.4	1.13	0.26	0.70	0.18	1.46	>0.05	19.04	**N.S.**
5.*Kar-Pada Suptata* (Numbness in hand and feet)	0.73	0.33	0.4	0.50	0.13	3.05	<0.05	54.54	**S.**
6.*KarPada Daha* (Burning in hand and feets	0.73	0.4	0.33	0.48	0.12	2.64	>0.05	45.45	**N.S.**
***7.Swedadhikya* (Perspiration)**	1	0.66	0.33	0.81	0.21	1.58	>0.05	33.33	**N.S.**
8.*Daurbalya* (weakness)	**1.4**	**0.6**	**0.8**	**0.41**	**0.10**	**0.02**	**<0.001**	**57.14**	**H.S.**
9. *Sandhi Shula* (Pain in joints)	1.06	0.6	0.46	0.63	0.16	2.82	<0.05	43.75	**S.**
10.*shramaSwasa* (dyspnoea)	1.13	0.93	0.2	0.67	0.17	1.14	>0.05	17.64	**N.S.**
11.*Nidradhikya* (Sleep)	1.13	0.33	0.8	0.41	0.10	7.48	<0.001	70.58	**H.S.**
12.*Purisha-badhdhata* (Con-stipation)	1.53	0.53	1	0.65	0.16	5.91	<0.001	65.21	**H.S.**
13.*Mathuna Va-ryasaya* (loss of libido)	1.2	0.93	0.26	0.59	0.15	1.73	>0.05	22.22	**N.S.**
14.*Pindikodvesh-tana* (Cramps)	0.93	0.6	0.33	0.72	0.18	1.78	>0.05	35.71	**N.S.**

Table 2: Table showing Effect of therapeutic trial on clinical symptomatology in 15 patients of *Madhumeha* (DM) based on (Wilcoxan matched pairs signed ranks t-test). Group B

Variable	Mean		Mean Diff.	S.D. ±	S.E. ±	Paired t-test	P-value	% Re-lief	Sign.
	BT	AT							
1.*Prabhoot Mutrata* (polyurea) a)Quantity of urine	2	1.13	0.86	0.51	0.13	6.5	<0.001	43.33	**H.S.**
b) Frequency of urine	1.6	0.93	0.66	0.48	0.12	5.29	<0.05	41.66	**S.**
2.*Pipasaadhikya* (Polydipsia)	1.8	0.93	0.86	0.35	0.09	9.53	<0.001	48.14	**H.S.**

3.Avila mutrata **(Turbidity in urine)**	2	1.13	0.86	0.35	0.09	9.53	<0.001	43.33	**H. S.**
4. *Kshudhadikya* **(Polyphagia)**	1.8	1.33	0.53	0.63	0.16	3.22	<0.05	28.57	**S.**
5.*Kar-Pada Suptata* **(Numbness in hand and feet)**	1.6	0.66	0.93	0.25	0.06	14	<0.001	58.33	**H. S.**
6.*KarPada Daha* **(Burning in hand and feets**	1.06	0.6	0.46	0.51	0.13	3.5	<0.05	43.75	**S.**
7.Swedadhikya **(Perspiration)**	1.13	1	0.13	0.83	0.21	0.61	>0.05	11.76	**N. S.**
8.*Daurbalya* **(weakness)**	**1.46**	**0.66**	**0.8**	**0.56**	**0.14**	**5.52**	**<0.001**	**54.54**	**H.S.**
9. *Sandhi Shula* **(Pain in joints)**	1.2	1.06	0.13	0.74	0.19	0.69	>0.05	11.11	**N.S.**
10.*shramaSwasa* **(dyspnoea)**	2.13	1.46	0.66	0.61	0.15	4.18	<0.05	31.25	**S.**
11.*Nidradhikya* **(Sleep)**	1.53	0.46	1.06	0.25	0.06	16	<0.001	69.56	**H.S.**
12.*Purishabadhdhata* **(Constipation)**	1.8	0.8	1	0.53	0.13	7.24	<0.001	55.55	**H.S.**
13.*Mathuna Varyasaya* **(Libido)**	1.4	1.06	0.33	0.72	0.18	1.78	>0.05	23.80	**N.S.**
14.*Pindikodveshtana* **(Cramps)**	1.13	0.73	0.4	0.63	0.16	2.44	>0.05	35.29	**N.S.**

Table 3: Table showing Effect of therapeutic trial on Laboratory parameters in 15 patients of *Madhumeha* (DM) based on (Wilcoxan matched pairs signed ranks t-test). Group A

Variable	Mean		Mean Diff.	S.D. ±	S.E. ±	Paired t-test	P-value	% Relief	Sign.
	BT	AT							
Fasting Blood Sugar (mg/dl)	121	104.2	16.8	7.58	1.95	8.57	<0.001	13.8	**H.S.**
Post Prandial Blood Sugar (mg/dl)	171.4	151	20.4	11.38	2.94	6.96	<0.001	11.93	**H.S.**
Urine Sugar(fasting)	0.33	0.2	0.13	0.51	0.13	1	>0.05	40	**N.S.**
S. Cholesterol mg/dl	187.3	174.3	13	17.3	4.47	2.9	<0.05	6.93	**S.**
S. Triglycerides mg/dl	148.5	129.6	18.93	37.55	9.69	1.95	>0.05	12.74	**N.S.**
HDL mg/dl	49.13	51.2	2.13	2.16	0.55	3.81	<0.05	4.34	**S.**

LDL mg/dl	107.5	103.1	4.43	18.3	4.72	0.93	>0.05	4.12	**N.S.**
VLDL mg/dl	29.45	28.2	1.25	8.96	2.31	0.54	>0.05	4.25	**N.S.**

Table 4: Table showing Effect of therapeutic trial on Laboratory parameters in 15 patients of *Madhumeha* (DM) based on (Wilcoxan matched pairs signed ranks t-test). Group B

Variable	Mean		Mean Diff.	S.D. ±	S.E. ±	Paired t-test	P-value	% Relief	Sign.
	BT	AT							
Fasting Blood Sugar (mg/dl)	172.6	146.8	25.86	15.66	4.04	6.39	<0.001	14.98	**H.S.**
Post Prandial Blood Sugar (mg/dl)	235.7	210.	25.36	21.95	5.66	4.47	<0.001	10.76	**H .S.**
Urine Sugar(fasting)	1.6	0.66	0.93	0.593	0.15	6.08	<0.001	58.33	**H.S.**
S. Cholesterol mg/dl	213.7	185.8	27.93	23.0	5.93	4.70	<0.001	13.06	**H.S.**
S. Triglycerides mg/dl	171.3	149.8	21.46	30.31	7.82	2.74	<0.05	12.52	**S.**
HDL mg/dl	51.3	53.33	2	6.40	1.65	1.65	>0.05	3.89	**N.S.**
LDL mg/dl	124.5	106.1	18.34	8.90	2.29	0.24	<0.001	14.73	**H.S.**
VLDL mg/dl	35.2	29.21	6	6.34	1.63	0.24	<0.05	17.03	**S.**

Table 5: Table showing Effect of therapeutic trial on objective parameters in 15 patients of *Madhumeha* (DM) based on (Wilcoxan matched pairs signed ranks t-test). Group A

Variable	Mean		Mean Diff.	S.D. ±	S.E. ±	Paired t-test	P-value	% Re-lief	Sign.
	BT	AT							
1.Weight (Kg)	67.46	65.73	1.73	2.43	0.62	2.75	<0.05	2.56	**S.**
2. BMI (Kg/m2)	0.73	0.53	0.2	0.41	0.10	1.87	>0.05	27.27	**N.S.**

Table 6: Table showing Effect of therapeutic trial on objective parameters in 15 patients of *Madhumeha* (DM) based on (Wilcoxan matched pairs signed ranks t-test). Group B

Variable	Mean		Mean Diff.	S.D. ±	S.E. ±	Paired t-test	P-value	% Re-lief	Sign.
	BT	AT							

1.Weight (Kg)	72	69.2	2.8	4.95	1.28	2.18	<0.05	3.88	**S.**
2. BMI (Kg/m2)	1.2	0.86	0.33	0.48	0.12	2.64	<0.05	27.77	**S.**

Table 7: Table showing Effect of therapeutic trial on S. Creatinine and S. Uric acid in 8 patients of *Madhumeha* (Diabetes Mellitus) based on (pairs t-test). (n=8).

Variable	Mean		Mean Diff.	S.D. ±	S.E. ±	Paired t-test	P-value	% Relief	Sign.
	BT	AT							
1.S.Creatinine mg/dl	5.56	5.7	0.13	0.26	0.092	0.122	>0.05	2.47	**N.S.**
2. S. Uric acid mg/dl	1.03	1.11	0.07	0.23	0.081	0.122	>0.05	7.22	**N.S.**

Table 8: Table showing Effect of therapeutic trial on Glycosylated Hemoglobin (Hb1Ac) in 8 patients of *Madhumeha* (Diabetes Mellitus) based on (pairs t-test). (n=8).

Variable	Mean		Mean Diff.	S.D. ±	S.E. ±	Paired t-test	P-value	% Relief	Sign.
	BT	AT							
1. Hb1Ac	7.22	6.66	0.56	0.25	0.08	6.35	<0.001	7.78	**H.S.**

Table no. 9: Intergroup comparison in subjective symptoms (Group A and Group B) Mann Whitney test (unpair t test).

Variable	Mann Whitney U value	P-value	Sign.
1.*Prabhoot Mutrata* (polyurea) a)Quantity of urine	104.50	0.63	**N.S.**
b) Frequency of urine	90	0.21	**N.S.**
2.*Pipasaadhikya* (Polydipsia)	82.5	0.11	**N.S.**
***3.Avila mutrata* (Turbidity in urine)**	90	0.21	**N.S.**
4. *Kshudhadikya* (Polyphagia)	88.5	0.21	**N.S.**
5.*Kar-Pada Suptata* (Numbness in hand and feet)	52.5	0.002	**S.**
6.*KarPada Daha* (Burning in hand and feets	97.5	0.47	**N.S.**
***7.Swedadhikya* (Perspiration)**	97	0.50	**N.S.**
8.*Daurbalya* (weakness)	**111**	**0.95**	**N.S.**
9. *Sandhi Shula* (Pain in joints)	84.5	0.21	**N.S.**
10.*ShramaSwasa* (dyspnoea)	68.5	0.04	**S.**
11.*Nidradhikya* (Sleep)	84	0.04	**S.**

12.*Purishabadhdhata* (Constipation)	107	0.77	**N.S.**
13.*Mathuna Varyasaya* (Libido)	103.50	0.69	**N.S.**
14.*Pindikodveshtana* (Cramps)	108.50	0.87	**N.S.**

Table no. 10: Intergroup comparison in objective symptoms (Group A and Group B) Unpair t test with Welch correction:

Table no. 11: Intergroup comparison in Laboratory parameters (Group A and Group B), Unpair t test with Welch correction:

Variable	t value	P value	Sign.
1.Weight (Kg)	0.74	0.46	**N.S.**
2. BMI (Kg/m2)	0.80	0.42	**N.S.**
Hb gm%	**1.825**	**0.082**	**N.S.**
TLC / cumm	0.1448	0.88	**N.S.**
TRBC /mill/µL	0.4693	0.64	**N.S.**
TPLC/ lac/µL	0.00	0.9	**N.S.**
ESR(mm/h)	0.8541	0.40	**N.S.**
Fasting Blood Sugar (mg/dl)	2.017	0.05	**N.S.**
PP Blood Sugar (mg/dl)	0.7672	0.45	**N.S.**
Urine Sugar(fasting)	3.938	0.0005	**H.S.**
S. Cholesterol mg/dl	2.008	0.055	**N.S.**
S. Triglycerides mg/dl	0.2033	0.840	**N.S.**
HDL mg/dl	0.076	0.940	**N.S.**
LDL mg/dl	2.647	0.015	**S.**
VLDL mg/dl	1.674	0.106	**N.S.**

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