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CLINICAL EVALUATION OF THE EFFICACY OF SHILAJATHU WITH SALASARADI GANA KASHAYA & KHADIRA KASHAYA IN THE MANAGEMENT OF MADHUMEHA (DIABETES MELLITUS 2)

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ABSTRACT

Diabetes, according to sir Jerold M Olefsky, is not a single disease process, but instead represents a heterogenous constellation of the disease syndrome all leading to a final common pathway – hyperglycemia**.** The objective of this study was to corroborate the efficacy of Shilajathu with salasaradi gana kashaya & khadira kashaya in the management of Madhumeha (Diabetes mellitus- 2). Subjects presenting with classical symptoms & FBS >110 mg/dl & <250mg/dl were selected randomly. Total 40 subjects were randomly distributed into two groups i.e. 20 each. The subjective parameter before & after treatment were recorded. Group A patients after virechana were given shilajathu 1 gm bid with salasaradi gana kashaya 1 pala Bid as anupan for 3 months. The subjects in group B after virechana were administerd shilajathu 1 gm bid with khadira kashaya 1 pala bid for 3 months. The variation in observational data were recorded & statistically analysed to determine the significance of the treatment. It was concluded as-: In group A treatment has succeeded in reducing the signs, symptoms FBS & PPBS effectively within a period of 3 months. Whereas in group B, the treatment results were mediocre in subjective & objective parameters.

KEYWORDS: Madhumeha, Diabetes mellitus-2, Shilajathu, Salasaradi gana kashaya, Khadira kashaya.

INTRODUCTION

The scope of medical practice changes as diseases, therapies and prognosis are constantly shifting. One major source of change in the field of health care is in the treatment of global

burden vis-à-vis diabetes mellitus, a baffling enigma in clinical research. It's considered as a sweet disorder with bitter mortality rate & multiple complications with a myriad of disorders associated with it. The world is facing a growing diabetic epidemic of potentially devastating proportions. Its repercussions will be felt most severely in developing countries like India. It's time for "**diabetes action now**" in order to prevent and manage diabetes along with its complications, so as to ensure a quality life to the suffering population.

AETIOLOGY

Madhumeha is a disease known to mankind since Vedic period. It's one of the ashta mahagadas.[1] The disease in which the excreted urine is having quality concordant with madhu in its colour, taste, smell and consistency is called Madhumeha. Madhumeha is a variety of vataja prameha.[2] Basically, in Vataja prameha, nidana is due to the vata prakopa, apatarpana eventuates, apatarpana eventuates & leads to krisha madumehi. In sthoola madhumehi, the pathogenesis is due to avarana caused by vitiation of kapha dosha. Nidana mentioned for sthoulya are also kapha vardaka. Therefore, we can say that increased kapha medas and muthra can be considered as nidana of Madhumeha in sthoola. While mentioning sadhyasadhyatva of prameha in chikitsa sthana, charaka has mentioned about beeja dosha[3] which also plays a role in the aetiology of Prameha. Aetiology of diabetes mellitus revolves around insulin secretory defects, relative insulin deficiency and insulin resistance.[4] It is generally agreed that type 2 diabetes has strong genetic and environmental (acquired) components. Most DM patients are obese; obesity especially is also under genetic control.

CLINICAL FEATURES

Symptomatology of Madhumeha are those which are ascribed to Prameha, they are i) Prabhoota mootrata:[5] The increase in quantity and frequency is known as prabhoota mootrata. It is manifested due to increase of shareera kleda. ii) Avila mootrata:[6] Mootra avilata is nothing but the turbidity of mootra, which is manifested due to drava and guru guna vriddhi of kapha and medhas. Polyurea, Polydipsia, polyphagia, weight loss and delayed healing of wounds are the marked clinical features of Diabetes Mellitus.

CLASSIFICATION

Clinicopathological status of a disease has an invariable relation with physical constitution of the body in Madhumeha & hence classified as Sthoola Pramehi & Krisha Prameha.[7] The Etiologic classification of diabetes mellitus is as follows under Primary Diabetes I) Type I: - Beta-cell destruction, usually leading to absolute insulin Primary deficiency II) Type II

diabetes (may range from predominantly insulin resistance with relative deficiency to a predominantly secretary defect with insulin resistance).[8] Secondary classification is included under Genetic defects, diseases of exocrine pancreas, endocrinopathies, infections and gestational diabetes.

PATHOLOGY

Samprapthi of Madhumeha sails through the Kshaya of Gambhira and Sarabhuta Dhatus like, Majja, Vasa, Oja and Lasika leads to Vata Prakopa. Vata Dosha gets vitiated leading to Ksharana of Sarabhuta Dhatus through Mutra Pravritti in such a quantity that this Ksharana of Sarabhuta Dhatus itself acts as etiological factor again for Vata Prakopa hence this vicious circle goes on. But due to Ashukaritva of Vata all the stages of Samprapti proceeds so fast that, it leads to Asadhya stage of the disease very quickly.[9]

In Kapha-Avarana janya, Guru Snigdhadi Ahara, Avyayamadi Vihara etc, leads to provocation of Kapha and Pitta Dosha which inturn increases in quantity of Meda and Mamsa. All these increased factors obstruct the Gati of Vata leading to provocation of Vata. This provocated Vata withdraws Oja from the body and takes it towards Basti and leads to Madhumeha, which is Krichhrasadya for treatment due to its origin from Kapha and Pitta Doshas. The Vata, Pitta a and Kapha Doshas starts manifesting their symptoms intermittently depending on their extent of Dushti. Subsequently Pitta and Kapha attain Kshayavastha compared to Vata; due to Kshaya of Dhatus. Three factors namely insulin resistance, β cell dysfunction and Hepatic Glucose Output underline the pathologic defects which constitute the endocrine and metabolic profile subjects with NIDDM and Auto Immune Beta cell destruction constitutes the major defect in IDDM.

TREATMENT

While mentioning the Chikitsa sootra two varieties of Pramehis are mentioned. They are Sthoola -balavan and krusha-durbala. Two different lines of treatment have been explained for these two varieties of Pramehi.

1) Stoola pramehi: Patients who are Sthoola, balvan and having bahudosha for such patients Samshodhan therapy[10] has been advised depending on the doshic Predominance & accordingly the procedures vamana, virechana, basti is decided. Swedana should be avoided, being contraindicated in prameha. Basti is contraindicated in Madhumeha but patients presenting symptoms of burning sensation are advised Nyagrodadi kashaya basti by Susruta.

2) Krushapramehi: Patients who are krusha, durbala, for such patient's samshamana and santharpana Chikitsa are advised.[11] Here the ahara, oushada which will increase dhatus, impart strength to the body. Depending on the symptoms and predominance of the doshas, sneha should be administered.

In modern system of medicine treatment constitutes five classes of oral glucose-lowering drugs: two that treat insulin deficiency, two that treat insulin resistance and one that delays carbohydrate absorption. These drugs are selected based on the primary defect that lead to hyper glycemia. Insulin Dependent subjects are treated with Insulin therapy.

MATERIALS AND METHODS

Method of Research design

The clinical study is based on the classical explanations with scientific well designed research protocol. This trial is Simple Random sampling technique clinical study. In this Patients were taken in randomized selection.

DRUG CONTRIVE

Criteria for selecting drugs

1. The medicines of first group Shilajathu & Salasaradi gana kashaya[12] are selected from the sushruta Samhita madhumehadhikara 13th.[13]
2. The medicines of second group shilajathu & khadira kashaya is selected from ashtanga hridaya prameha adhikara.[14]
3. The pharmacological actions of the individual drugs are Pramehahara.
4. The said combination is hypothetically effective in reversal of Samprapti or the patho-physiological normalcy induction in madhumeha.

Posology of Trial drug

1. 2gm / 24hrs in divided two equal doses of Shilajathu in the form of capsules.
2. 1pala bid of Salasaradi & khadira kashaya as anupana for Shilajathu in two groups respectively.
3. Agni kumara rasa[15] for Ama pachana 1 TDS with ushna jala as anupana until nirama laxanas are attained.
4. Vatashani taila[16] for snehapana in arohana karma according to agnibala of the patient till alpa snigdha laxanas.
5. Trivrith lehya for Virechana 30gms approx.

Anupana of Trial drug: Salasaradi gana kashaya & khadira kashaya is undertaken as it is stipulated for the medicines by acharyas.

Study duration of Trial drug: Simple Random sampling technique clinical study was conducted for 3 months. The medicine was dispensed for one month to all patients and advised to report after every 1 month interval; noted the variation of the symptoms & laboratory investigations during their visits.

Follow up of Trial drug: Follow ups will be once in a month during the course of treatment. The effect of yoga was analyzed according to clinical and functional response before and after the treatment & is compared.

PATIENTS CONTRIVE

Source of data of Trial drug: The data was collected from the patients suffering from Madhumeha in the OPD, IPD & special camp conducted in Ashwini Ayurveda medical college & hospital, Davanagere.

Sample size: Total of twenty patients is selected in each group ie group A & group B.

Selection of the patient: Patients of Madhumeha fulfilling the criteria of diagnosis were selected in the Present study. Patients were excluded, as they are discontinuous at the treatment or unable to fulfill the study design.

Inclusion Criteria: Patients with symptoms of Madhumeha are included with classical symptoms enumerated at the classical texts under the lime light of contemporary medical context along with criteria of inclusion like.

1. Patients diagnosed as Madhumeha rogi.
2. Patients falling in the age Group 35- 65 years.
3. Patients with FBS value > 110 mg / dl and < 250mg/ dl

Exclusion Criteria:

1. Patients suffering from other systemic disorder.
2. Patients with complications of this disease will be excluded.
3. Patients unfit for virechana will be excluded.

PLAN OF STUDY

In this study the patient were divided into two groups and treatment were given to two groups as follows.

Table 1: Showing Plan of Study.

GROUP A	GROUP B
▪ Ama pachana with Agni kumara rasa 1tds with ushna jala before food for 1 week.	▪ Ama pachana with Agni kumara rasa 1tds with ushna jala before food for 1 week.
▪ Snehapana with vatashani taila in arohana krama untill snigdha laxanas.	▪ Snehapana with vatashani taila in arohana krama untill snigdha laxanas.
▪ Virechana with trivrith lehya. Samsarjana krama followed. (20-30 gms)	▪ Virechana with trivrith lehya. Samsarjana krama followed.(20-30 gms)
▪ Followed by intake of shalasaradi gana Kashaya bhavita shilajathu with shalasaradi gana kashaya as anupana. (1 pala bid) for 3 month	▪ Followed by intake of Khadira Kashaya bhavita shilajathu with Khadira Kashaya as anupana.(1 pala bid) for 3 month

Group A: The 20 patients of madhumeha were included in this group & given following treatment as mentioned in table.

Group B: The 20 patients of madumeha were included in this group & treatment were done as mentioned in table.

CRITERIA FOR DIAGNOSIS

Subjective parameter

Signs & symptoms of madhumeha

1. Prabhoota mootra
2. Kshud adhikya
3. Pippasa adhikya
4. Dourbalya
5. Mukha talu shosha
6. Kara pada daha
7. Kara pada suptata
8. Shareera bhara hani
9. Shitilangata

Objective Parameter

It includes estimation of blood sugar level & urine sugar level, before, during & at the end of therapy on objective parameters i.e FBS, PPBS, FUS, PPUS.

Criteria for assessment

After completion of therapy result were on the basis of following criteria.

1. By observing the clinical the clinical improvement in sign & symptoms of the diseases were noted & taken for assessment.
2. Biochemical parameters FBS, PPBS, FUS, PPUS.

Subjective criteria assessment

Table No 2: Showing Grading of Prabhoota Mutrata.

Grade	Frequency in day	Frequency in night	Volume
0	3-4	0-1	normal
1	5-7	1-2	Slightly increased
2	8-10	2-3	Moderately increased
3	>10	3-4	Excessive

Table No 3: Showing Grading of Kshudh Adikya.

Grade	Main meals	Quantity
0	2	Normal
1	2-3	Slightly increased
2	2-3	Moderately increased
3	3-4	Markedly increased

Table No 4: Showing Gradings of Pippasa Adhikya.

Grade	Feeling of thirst	Water intake
0	Normal	1.5-2 litres
1	Increased but frequencies of drinking can be controlled	2.0- 2.5 litres
2	Increased with increased frequency	2.5- 3 litres
3	Very much increased with very frequent intake	>3 litres

Table No 5: Showing Gradings of Dourbalya.

Grade 0	**No Dourbalya**
Grade 1	Occasionally noticed
Grade 2	Periodically noticed
Grade 3	Continuously noticed

Table no. 6: showing grading of mukha talu shosha.

Grade 0	No mukha talukanta sosham
Grade 1	Occasionally dryness of oral cavity & disappear just after taking simple water
Grade 2	Persistence of dryness of mouth & subsides after taking more quantity of water
Grade 3	Continous dryness of mouth & does not subsides even after taking more quantity of water.

Table No. 7: Showing Gradings Kara Pada Daha.

Grade 0	**No kara pada daha**
Grade 1	Occasionally daha either in hand or feet & disappear shortly
Grade 2	Continous kara pada daha in both limbs
Grade 3	Continous kara pada daha in both limbs & cannot be tolerated.

Table No 8: Showing Gradings of Kara Pada Suptata.

Grade 0	**No kara pada suptata**
Grade 1	Occasionally suptata either in hand or feet & disappear shortly
Grade 2	Continous kara pada suptata in both limbs
Grade 3	Continous kara pada suptata in both limbs & not tolerated.

Table No 9: Showing Gradings Shareera Bhaarahani

Grade 0	**No Bhaarahani**
Grade 1	occasionally noticed
Grade 2	periodically noticed
Grade 3	regularly noticed

Table No 10: Showing Gradings Of Shitilangata.

Grade 0	**No weakness**
Grade 1	occasionally noticed
Grade 2	periodically noticed
Grade 3	regularly noticed

Table No 11: (A) Objective Parameter With Assessment Criteria.

It includes estimation of blood sugar level & urine sugar level

	FBS	**PPBS**	**Urine Sugar**
Normal	70-110 mgs	126-180 mgs	Nil
Mild	110-170 mgs	181-230 mgs	0.5%
Moderate	171-220 mgs	231-280 mgs	1-1.5%
Severe	221 mgs above	281 mgs – above	2% and above

Overall effect of therapies: Each patient was assessed on basis of signs & symptoms & blood sugar levels. On basis of scoring pattern as well as percentage reduction, patients were classified as follows.

1. Improvement: patients having fasting & postprandial blood sugar level within normal limit & 100% relief in sign & symptoms.
2. Marked improvement: blood sugar level 20- 30 % above the normal level & more than 75 %relief in signs & symptoms.
3. Moderate improvement: Blood sugar level 30-40% above the normal level & 51-75 % relief in sign & symptoms.

4. Mild improvement: some reduction in blood sugar level & 25 – 50 % relief in signs & symptoms.
5. No improvement: no reduction in blood sugar & less than 25 % relief in signs & symptom.

RESULTS

Group A subjects exhibited significant results in subjective parameters such as prabhoota mootrata (91%), kshud adikya (90%), pippasa adikya (95%), dourbalya (81%), mukha talu shosha (80%), kara pada daha (82%) kara suptata (86%) shitilangata (100%) & in objective parameters like FBS (60%), PPBS 56%), FUS (79%), PPUS (77%). In group B results were not significant in subjective parameters such as prabhoota mootrata(55%) kshud adikya(53%), pippasa adikya(52%), dourbalya (50%), mukha talu shosha(69%), kara pada daha(55%), kara pada suptata(53%), sharira bhara hani (56%), shitilangata (60%) & in objective para meters such as FBS (51%), PPBS (50%), FUS (51%), PPUS(51%).

DISCUSSION

Most of these drugs are having tikta, kashayarasa, laghu, rooksha guna and katuvipaka. These are said to be kaphagna, mehagna, medogna and mootrasangrahaneeya. Tikta, kashayarasa, laghu, rooksha guna produces rookshana effect and they are having opposite qualities to that of kapha and medas. Hence they act as mehagna and kaphagna. So, these drug may have been effective on kapha and pitta and also on vata. This tridoshashamaka property of some drugs helped to correct the dhatudushti and srotodushti leading to their normal functioning. Bahudravata will be present in Madhumeha. These tikta rasa and kashaya rasa drugs posses the kaphahara, Meda, Kleda Upashoshana properties. Bahudravata will be reduced by the absorption of excessive fluid from the body. When bahudravata reaching basthi reduces then prabhoothamootrata pratyatma lakshana of Prameha also reduces. Pipasa which is dependent on prabhoothamootrata also subsides. Further Madhumeha is a metabolic disease, dhatvagni mandhya janita vyadhi. This metabolic disease demands medho dhatvagni vriddhi. When any agni is not proper, dhatus are not produced properly. Drugs having deepana & pachana drugs and katu rasa, ushna virya in the formulation encounters dhatvagnimandya & potentiates the dhatvagnimandhya and help in ama-pachana thereby alleviates aparipakwa and ama. That in turn helps to form the dhatus in proper proportion with good qualities. There by it ensures sarvadhatuposhana and pacifies Daurbalya. Pramehahara property of the ingredients of trial drug helps in alleviating the hyperglycemia.

Shilajathu

- Nutritive Tonic: The effect of Shilajathu was investigated on the body weight of young rats for a period of one month. The body weight of the rats was found to be significantly greater in the rats taking Shilajathu compared with a control group. Researchers suggests a better utilization of food as a cause of the weight gain which in terms can be taken of proper dhatu poshana & showing its rasayana action.[17]
- Counteracts Diabetes and regulates the blood sugar level as Shilajathu is tiktha rasa pradhana.
- Reduces fat as it is having chedana & lekhana action, thus increasing insulin sensitivity.

CONCLUSION

The parameters both subjective and objective showed good significance rate statistically in group A with Shilajathu and Salasaradi gana kashaya & non significance in group B with Shilajathu with Khadira Kashaya.

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