



Research Article

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A CLINICAL STUDY TO EVALUATE THE EFFECT OF SALSARADI CHURNA AND VIJAYSAR KWATHA IN THE MANAGEMENT OF MADHUMEHA WITH SPECIAL REFERENCE TO TYPE-II DIABETES MELLITUS

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ABSTRACT

The present era is full of chaos, stress and strain due to lifestyle modifications and change in dietary habits, urbanization and industrialization. This has led in the upsurge of many diseases and one of them is Madhumeha with special reference to Type-II DM. Currently, a number of anti-diabetic agents are available to control hyperglycemia but due to long term or lifelong application, their use is restricted because of the risk profile. Ayurveda is a rich treasure of safe and traditional materia medica which provides a promising field of drug research. Objective of the study was to evaluate the effect of Salsaradi Churna and Vijaysar Kwatha in the management of Madhumeha with special reference to Type-II Diabetes mellitus. Design: Open randomized single group clinical study. Group: Single group trial was conducted for 60 days on 15 subjects in whom 14 subjects completed the study. Main outcome measures: Subjective parameters- Prabhuta Mutrata, Avilmutrata, Pipasa, Kshudha, Klama, Karapada Suptaata, Karapada Daha, Galtalushosha, Atisweda, Daurbalya, Shithilangta and Madhurasaya. Objective parameters- FBS and PPBS. Results: The drugs were found effective in Madhumeha Roga as evidenced by reduction in the mean score of various subjective and objective parameters.

Keywords: Madhumeha, Diabetes mellitus Type-II, Salsaradi Churna, Vijaysar Kwatha.

INTRODUCTION

The worldwide prevalence of Diabetes mellitus has risen dramatically over the past two decades, from an estimated 30 million cases in 1985 to 177 million in 2000¹. Globally, an estimated 422 million adults are living with diabetes mellitus, according to latest data from the W.H.O.². Diabetes has emerged as a major healthcare problem in India. It is estimated that every fifth person with diabetes will be an Indian. The real burden of the disease is however due to its associated complications, which leads to increased morbidity and mortality. Heart disease and stroke in this estimate is linked with diabetes.³

Diabetes mellitus is a metabolic disorder of carbohydrate, fat and protein characterized by hyperglycemia with or without glycosuria. It is associated with long term potentially catastrophic effects on almost all systems of the body. These can manifest as minor annoyances at first but then insidiously destroy the cellular components of a given body part, organ or entire system. Diabetes mellitus is aggressively progressive, and the prognosis is poor unless definite measures will be taken to control the disease.⁴

The management of Madhumeha is described in classical texts according to the peculiarities of Dosha and Dushya etc. The main initiating factor or Dosha described in Madhumeha pathogenesis is "Bahu Drava Shleshma."⁵ Madhumeha is described under Vataja Prameha as incurable vyadhi. The reason mentioned in texts is Vishama Kriya (opposite treatment lines of Dosha and Dushya) & Mahatyaya (fast progression into severe form) as

limitations of availability of the drugs which are capable of pacifying aggravated Kapha and Vata simultaneously.⁶

Currently, a number of anti-diabetic agents are available to control hyperglycemia but due to long term or lifelong application, their use is restricted because of the risk profile.⁷ Therefore, there is a need of satisfactory therapeutic modalities free from side effects. In Ayurveda several plant-based drugs have been advocated to manage hyperglycemia. There are many plants showing potential anti-diabetic properties, but the present trial Salsaradi Churna and Vijaysar Kwatha is a humble attempt to see the response of drugs to reduce blood sugar level.⁸

AIMS AND OBJECTIVES

- To study the efficacy of Salsaradi Churna with Vijaysar Kwatha in the management of Madhumeha w.s.r. to Type-II Diabetes mellitus.
- To study the other associated effect of the trial drug if any.

MATERIALS AND METHODS

It was an open clinical trial with randomized sampling. The trial drugs Salsaradi Churna and Vijaysar Kwatha were selected on the basis of classical references as well as modern knowledge of drugs. Salsaradi Churna is a formulation of two herbs which was administered in capsule form and Vijaysar Kwatha in Yavkuta form. [Table 1]

Ethical Clearance- The proposed clinical study was presented in the form of a synopsis in front of the Institutional Ethical Committee of Rajiv Gandhi Govt. P.G. Ayurvedic College, Paprola, Distt. Kangra, Himachal Pradesh. The trial was started after the approval from the Chairman of Ethical Committee vide letter no. IEC/2015/1016 dated 16-06-2016.

Method of collection of data- A special pro forma was prepared incorporating demographic data of patients, detailed clinical history, and all the clinical manifestation and assessment criteria of Madhumeha including laboratory investigations.

Selection of Patients- In this study the total 15 patients were selected from O.P.D. and I.P.D. of Kayachikitsa Department, Rajiv Gandhi Govt. P.G. Ayurvedic College, Paprola, Distt. Kangra, Himachal Pradesh, irrespective of socio-economic status. A written and informed consent of patients was taken before trial.

Inclusion criteria

- Patients who fulfill the diagnostic criteria.
- Patients age between 20-60 years.
- Patients with Fasting Blood Sugar between 126 mg/dl to 200 mg/dl.
- Only uncomplicated case of Type-II Diabetes mellitus.

Exclusion criteria

- Patients unwilling to participate in the trial.
- Patient below 20 and above 60 years.
- Patients presenting with complications like severe renal disease, retinopathy, ischemic heart disease, severe hypertension etc.
- Fasting Blood Sugar <126 mg/dl and >200 mg/dl.
- Type-I Diabetes mellitus.
- Patients associated with major medical disease like cancer, concurrent infection like tuberculosis etc.
- Any other patient considered not fit for trial.

Laboratory investigations

- Fasting Blood Sugar [FBS]
- Postprandial Blood Sugar [PPBS]

Intervention- A total number of 15 patients willing for the trial and fulfilling the criteria for trial were selected for this study. They were registered in a single group. In which 14 patients completed the trial and 1 patient left the treatment in between. These patients were treated with Cap. Salsaradi Churna 1 gm. with Vijaysara Kwatha 50 ml. (25 gm.) thrice a day for duration of 60 days.

Criteria of assessment- To observe the effect of therapy, patients were thoroughly assessed for improvement in subjective and objective criteria, on the basis of grading and scoring system. Adopted criteria were-

Subjective criteria- Prabhuta Mutrata (polyuria), Avilamutrata (discolored urine), Pipasadhikya (polydipsia), Klam (laziness) Kshudhadhikya (polyphagia), Karapadadaha (burning sensation in hands and feet), Swedadhikya (excess sweating), Galatalu sosh (dryness in oral cavity), Dourbalya (weakness), Madhurasya (sweetness in mouth), Tandra (drowsiness), Shithilangata (laziness) and Karapada Suptata (numbness in hands and feet).

Objective criteria- Fasting Blood Sugar and Postprandial Blood Sugar.

Statistical analysis- The score of criteria of assessment were analyzed statistically in the form of Mean, Standard Deviation ($\pm SD$) and Standard Error ($\pm SE$). Student's Paired 't' Test was applied to observe the significance of result. The results obtained were interpreted as table-2.

OBSERVATIONS

Among 15 patients registered for the clinical study, 47% patients were in the age group of 51-60 years, 60% patients were male, and all the patients were Hindu. 73% patients belonged to middle class family, 80% patients resided in rural area and maximum patients i.e. 93% were married. 60% patients in this study were consuming Madhura Rasa predominant food, a large number of patients i.e. 47% were taking Guru Ahara, 73% patients were having Adhyashna dietary habit and 87% were found addict to tea. All patients were complained of increased thirst and appetite with 73% patients told about their Pravara Ahara Shakti (Jarana and Abhyaharana). Around 53% patients were having regular bowel habit and the majority of patients i.e. 87% were experiencing polyurea. 93% patients were involved in only routine work, without indulging in any strenuous workout. 53% patients were of Vata-Kaphaja Prakriti and 60% were of Rajsika Prakriti. All the patients were executing Madhyama Samhanana with Medo Sara predominance in 53%. Utmost patients (73%) were having BMI between 18.6-25. 67% patients were having normal sleep pattern and family history of Madhumeha.

According to the data, symptoms of Madhumeha, among the registered patients were as follows. All the patients were suffering from Madhurasya, Kshudhadhikya, Pipasadhikya, and Gala Talu Shosa. 13 among the 14 patients were suffering from Klam, and 12 of them were suffering from Swedadhikya, Dourbalya, Kara Pada Daha, Prabhuta Mutrata. 11 out of 14 were suffering from Tandra and Shithilangata. The nine patients were suffering from Avila Mutrata and 7 patients were complaining of Kara Pada Suptata.

RESULTS

Pipasadhikya has shown statistically highly significant improvement with 45.72 % of change. The symptoms like Prabhuta Mutrata, Avila Mutrata, Kshudhadhikya, Karapada Daha and Madhurasya were improved by 37.90%, 38.64%, 32.15%, 34.62% and 34.81% respectively which was significant statistically. Galatalu Shosha, Swedadhikya, Dourbalya and Tandra also improved markedly with 34.47%, 21.45%, 42.32% and 40.03% improvement respectively which were statistically significant change. Karapada Suptata, Klam, and Shithilangata were improved by 9.94%, 20.82% and 19.06% respectively which showed insignificant change according to statistics. Highly significant results were obtained in PPBS (<0.001) and FBS (<0.001) with the change of 35.87% and 31.48% respectively. (Interpretation of data in table 3)

Table 1: Ingredients of Salsaradi Kwatha

Name	Botanical Name	Part Used	Ratio
Sala	<i>Shoria robusta</i>	Heart Wood	1 Part
Khadir	<i>Acacia catechu</i>	Heart Wood	1 Part

Table 2: Effect of therapy

Parameters	Mean Score		% relief	'p' value
	BT	AT		
Subjective Parameters				
Prabhuta Mutrata (polyuria)	2.07	1.28	37.90	0.003
Avila Mutrata (turbid urine)	0.92	0.57	38.64	0.019
Pipasadhikya (polydipsia)	2.50	1.35	45.72	<0.001
Karapada Suptata (numbness of limbs)	0.71	0.64	9.943	0.671
Kshudhadhikya (polyphagia)	2.00	1.35	32.15	0.022
Shithilangata (lethargy)	1.50	1.21	19.066	0.218
Kara Pada Daha (burning sensation over palm and sole)	1.85	1.21	34.62	0.007
Swedadhikya (excessive sweating)	2.00	1.57	21.45	0.028
Gala Talu Sosha (dryness of oral cavity)	2.07	1.35	34.47	0.019
Dourbalya (weakness)	1.85	1.07	42.32	<0.001
Klama (tiredness without doing any physical work)	1.71	1.35	20.82	0.136
Madhurasya (sweetness of mouth)	1.64	1.07	34.81	0.001
Tandra (drowsiness)	1.78	1.07	40.03	0.006
Objective Parameters				
FBS (mg/dl)	175.42	112.50	35.87	<0.001
FBS (mg/dl)	261.78	179.35	31.487	<0.001

BT: Before treatment, AT: After treatment, FBS: Fasting Blood Sugar, PPBS: Postprandial Blood Sugar

Table 3: Interpretation of statistical values

'p' Value	Result
p>0.05	Insignificant
P<0.05	Significant improvement
P<0.001	Highly significant

DISCUSSION

This clinical study was conducted to evaluate the efficacy of Salsaradi Churna and Vijaysar Kwatha in the management of Madhumeha with special reference to Type-II Diabetes mellitus. Thus, Saalasaradi Churna and Vijayasara Kwatha were found effective in most of the subjective and objective criteria selected for evaluation of the clinical efficacy. These drugs were prepared in Charak Govt. Ayurvedic Pharmacy, Paprola, Distt. Kangra, Himachal Pradesh.

The vitiated Kapha due to the etiological factors spreads all over the body and further vitiates Meda, Mamsa and Kleda of the body. They come to Basti area where Kha Vaigunya occurs at the opening of Mutravaha Srotas; here it is obstructed by vitiated Meda and Kleda. Vitiated Kleda too forms urine. By the Sroto Sanga, Vata gets vitiated and if a person continues the use of etiological factors, Vata gets more and more vitiated. The vitiated

Vata due to its Ruksha Guna with the association of Kashaya Rasa pulls Oja Dhatus towards Mutrashaya. All these leads to Madhumeha.⁹

Ayurvedic herbal drugs for diabetes are selected on the principles of Rasa (taste), Guna (physico-chemical properties), Veerya (potency), Vipaka (post-digestive effect) & Prabhava (unique action) each of these principles is felt to have specific effects on the Doshas and functions of the body which is how they exert their therapeutic effect. In Sushruta Samhita, guidelines have been given to select drugs for management of Madhumeha, according to which the drugs possess Tikta (bitter), Katu (pungent), Kashaya (astringent), Sara (mobility) properties with Katu-Vipaka, Ushna Virya, Shoshaka and Chedana actions.

Fortunately, the drugs Salsaradi Churna and Vijaysara Kwatha fulfilled all these requirements. They helped in Samprapti Vighatan of Madhumeha either by their Rasa, Guna, Virya, Vipaka or Karma by acting at different levels i.e. Dosha, Dushya, Agni, Srotas and pacify the symptoms of Madhumeha.

PROBABLE MODE OF ACTION OF DRUG

In this present study Saalasara Niryasa, Khadira and Vijaysaar were used.¹⁰

Drug	Rasa	Guna	Vipaka	Veerya	Doshaghnata	Pharmacological Action
Sala Niryas	Kashaya, Madhura	Ruksha	Katu	Sheeta	Pitta-Kaphashamaka	anti-neuralgic, Anti-bacterial, Anti-obesity
Khadir	Tikta, Kashaya	Laghu, Ruksha	Katu	Sheeta	Kapha-Pittashamaka	Anti-diabetic, Anti-septic, Tonic, Anti-inflammatory
Vijaysar	Kashaya , Tikta	Laghu, Ruksha	Katu	Ushna	Kapha-Pittashamaka	Anti-diabetic, Rejuvenating Urinary Astringent, Anti-inflammatory,

Majority of drugs have Kashaya Rasa and it helps in decreasing the sugar level in blood by reducing the absorption of carbohydrates in intestine.¹¹ Tikta Rasa and Laghu, Ruksha Guna, Ushna Veerya and Katu Vipaka, of the drugs are effective on main Dosha i.e. Kapha and Vata and on Dushya i.e. Abadha Meda. Majority of Dravya's have Agnidheepan (appetizer), Amapachana, Rasayana (rejuvenative), Vrushya (aphrodisiac), Anuloman, Trishna Nigrasha (anti-thirst drug), Lekhana (scrapping) and Medohara (lepyolytic) Properties.¹²

Almost all the Dravyas have Deepan Pachan properties mainly, reduces the Ama present in the body. It helps to improve disturbed metabolism. Therefore, it mainly acts on Dhatvagnimandya and has been proved effective in signs and symptoms like

Shithilangta, Aalasya, Trishnanigrahana, Tandra and Gala-Talu Shosha.¹³ These are probably also effective at the Dhatwagni (metabolic) level by enhancing the action of insulin.¹⁴ Rasayana properties help in Uttarottar Dhatupusti and reducing Daurbalya, Klama, Hasts-Pada Daha and Kara-Pada Suptata.¹⁵

All these drugs have different types of chemical constituents i.e. pterostilbene, marsupinol, sesquiterpene, non-glucosidal tannin, catechutannic acid, aldobiose, flavonoid, glucopyranoside etc. which can rejuvenate & protective action of beta cells in pancreas, decrease blood glucose, insulin resistance, inflammation, triglycerides, weight & obesity and consist of antibiotic & healing properties.¹⁶

CONCLUSION

Hence it can be concluded that Saalasaradi Churna and Vijaysara Kwatha is effective in the patients of Madhumeha in terms of efficacy and subjective parameters as well as on biochemical profile. It showed highly significant improvement in fasting blood sugar and postprandial blood sugar.

As the sample size was small hence one cannot establish the definite conclusion. It requires further study in large scale to establish the results. It is hoped that this research will go long way in providing relief to the patients suffering from diabetes mellitus.

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