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SINGLE ARM CLINICAL TRIAL TO ASSESS THE EFFICACY AND SAFETY OF SAPTARANGI BHAVIT VACHADI GANA IN DIABETES MELLITUS TYPE 2 ASSOCIATED WITH METABOLIC SYNDROME

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ABSTRACT

Madhumeha involves ten *dushyas*– 1. *Abadh medha dhatu*, 2. *Mamsa* 3. *Kleda*(*jala*), 4. *Shukra* 5. *Shonita* 6. *Vasa* 7. *Majja* 8. *Lasika* 9. *Rasa* 10. *Oja*. *Acharya Charak* described that *Kapha* in liquid state is main (*Vishesha*) *dushya* of *Madhumeha*. *Vachadi gana mentioned* in *Ashtang Hridya Sutra Sthan* have properties of *Kapha Medhohar*. *Saptarangi* is also well known drug for its antidiabetic property. It is mentioned in *Nishakattakadi Kashaya* by the name of *Eknayakam* in *Sahastrayogam*. As mentioned above that *Vachadi gana* has properties of *kapha medhohar*, which are main *dushyas* of *Prameha* and *Saptrangi* is drug of choice for diabetes. Therefore, it has been decided to consider *Vachadi ghana* with *Saptarangi kwath Bhawana* in Diabetes mellitus type 2/ *Madhumeha* associated with metabolic syndrome. First of all cytotoxicity of the drug was studied by performing MTT assay. Which was found non toxic. So it can be used for further clinical trials. Saptarangi bhavit vachadi gana was found to have a notable impact on all symptoms associated with Madhumeha. Most of the ingredients in the formulation are characterized by tikta, katu, kashaya taste and ushna potency. These properties contribute to its effects, including agni deepana, aampachana, medovishoshana,

lekhana, srotosodhana, mutra (urinary detoxification) and vata anulomana. Statistical analysis indicates that the overall effectiveness of the therapy is approximately 30.7%.

KEYWORDS: Diabetes mellitus, MTT assay, vachadi gana, Prameha, saptarangi, metabolic syndrome.

INTRODUCTION

In the modern era, many people are grappling with lifestyle-related health challenges. Sedentary behaviours, poor dietary habits, stress and environmental factors have contributed to a surge in metabolic disorders. Metabolic syndrome—a cluster of conditions including obesity, hypertension, dyslipidaemia and insulin resistance—has become increasingly prevalent, raising concerns about its long-term health implications.

In Ayurveda, *Acharya Charak*[1] mentioned in *Sutra Sthana* in special *Samprapti* of *Prameha*; *Shleshma, Pitta* and *Mamsa* increases and blocks the channels of *Vayu,* so it get vitiated and goes to urinary bladder along with *Ojas* giving rise to *Madhumeha* disease in our body.[2] *Madhumeha* involves ten *dushyas*– 1. *Abadh medha dhatu*, 2. *Mamsa* 3. *Kleda*(*jala*), 4. *Shukra* 5. *Shonita* 6. *Vasa* 7. *Majja* 8. *Lasika* 9. *Rasa* 10. *Oja*.[3] These all *dushyas* are quite similar with *Kapha dosha* and further in *Nidanasathana*, *Acharya Charak* described that *Kapha* in liquid state is main (*Vishesha*) *dushya* of *Madhumeha.*[4]

Drugs like *Vacha, Jaladh, Devdaaru, Nagar, Ativisha* and *Haritaki* combinedly mentioned under *Vachadi gana* in *Ashtang Hridya Sutra Sthan* have properties of *Kapha Medhohar*.[5] *Saptarangi* is also well known drug for its antidiabetic property. It is mentioned in *Nishakattakadi Kashaya* by the name of *Eknayakam* in *Sahastrayogam*.[6] *Saptarangi* (Salacia) roots have been used in Ayurvedic medicine for Diabetes and Obesity since antiquity specifically in southern part of India and have been extensively consumed in Japan, United States and other countries as a food supplement which prevents them from obesity and diabetes. As mentioned above that *Vachadi gana* has properties of *kapha medhohar*, which are main *dushyas* of *Prameha* and *Saptrangi* is drug of choice for diabetes. Therefore, it has been decided to consider *Vachadi ghana* with *Saptarangi kwath Bhawana* in Diabetes mellitus type 2/ *Madhumeha* associated with metabolic syndrome.

The integration of these Ayurvedic principles and herbal remedies hold promise for addressing the growing challenge of diabetes and metabolic syndrome. As modern medicine continues to

evolve, the need for complementary approaches that consider lifestyle modifications, dietary changes, and herbal treatments becomes increasingly relevant. This study aims to delve deeper into the antidiabetic properties of the Vachadi gana, combined with Saptarangi by giving its bhawna, and evaluate their effectiveness in managing Type 2 Diabetes Mellitus associated with metabolic syndrome. By bridging the wisdom of ancient practices with contemporary health challenges, this research aspires to contribute to the ongoing discourse on diabetes management, offering holistic solutions for patients and healthcare practitioners alike.

MATERIALS AND METHODS

Material:- Sources of Data

- **Literacy source**: The literature related to Diabetes mellitus and these 7 drugs were explored and discussed from *Ayurvedic* classical text, modern literature, research journals & published articles.

Drugs:- Vachadi gana with saptrangi bhawna.

Table 1: Description of Drugs In Vachadi Ghana and Saptarangi.

Sr. No.	Constituents	Botanical Name	Family	Part Used	Picture
1	*Vacha*	*Acorus calamus*	*Araceae*	*Kandha*	
2	*Jalad*	*Cyprus rotundus*	*Cyperaceae*	*Kandha*	
3	*Naagar*	*Zingiber officinalis*	*Zingiberacae*	*Kandha*	
4	*Ativisha*	*Aconitum heterophyllum*	*Ranunculaceae*	*Moola*	
5	*Abhaya*	*Terminialia chebula*	*Combritaceae*	*Phala*	
6	*Devdaaru*	*Cedrus deodara*	*Pinaceae*	*Kashtha*	

7	*Saptrangi*	*Salacia reticulata*	*Celasteraceae*	*Root*	

Safety study of drug:- Cytotoxicity of the drug was studied throught MTT assay from progen biology lab, Acme progen Biotech Private Limited Tamil Nadu, India.

Clinical Source: 30 patients were randomly selected from OPD of *Dravyaguna vigyan* and *Kayachikitsa* department of IAS & R Hospital and college formely known as Shri Krishna Govt. Ayurvedic College and Hospital, Kurukshetra.

Clinical Study- Total 30 patients were enrolled for clinical trial after providing informed consent.

Study Design- Open clinical trial.

Sample Size- Maximum 30 patients were selected, and Saptarangi bhavit vachadi gana in the form of tablet were given for 45 days.

Study Duration: Duration of trial: 45days.

Number of visits:- 8 visits and after every seven days patient visited for follow up. 0^{st} day, 7^{th} day, 14^{th} day, 21^{st} day, 28^{th} day, 35^{th} day, 42^{th} day, 45^{th} day).

Criteria for Selection of Patients- Total 30 patients of either sex of age group 30-60 years were selected randomly for study from OPD of *Dravyaguna* and *Kayachikitsa* Department of Shri Krishna Govt. Ayurvedic College and Hospital, Kurukshetra, Haryana after taking informed consent. Ethical Clearance was also obtained from Institutional Ethical Committee.

Ethical Committee Clearance: Institutional Ethical Committee (IEC) approval was taken prior to initiation of research with letter No. IEC Code: SKAU/Acad/2022/6725, Dated on 2/11/2022.

CTRI Registration No.: Study was registered in Clinical Trial Registry of India with No. CTRI/2023/07/055334 (Registered dated on 18/07/2023).

Inclusion Criteria

Patients possessing sign and symptoms of *Prameha* (Diabetes mellitus)

Patient fulfilling the diagnostic criteria for Diabetes Mellitus framed by AMERICAN DIABETES ASSOCIATION.

FBS<126 to 200mg /dl; PPBS<150 to 300mg/dl HbA1c <6.5%

Patient with age between 30 to 60 years of either sex.

Patient willing for clinical trials and ready to give written consent.

Exclusion Criteria

Patients not fulfilling the inclusion criteria

Patients of *Sahaj Prameha* and IDDM (type 1 diabetes mellitus). Pregnancy and lactating mothers, Gestational diabetes.

Patient with diabetic complications such as impaired renal functions. Patient suffering from Secondary Diabetes.

Patients suffering from any serious systemic disorders such as uncontrolled hypertension, tuberculosis, carcinoma and HIV.

Patient below 30 years & above 60 years of age

Discontinuation criteria

Any acute or severe illness.

Patient not willing to continue the treatment.

Laboratory Investigations

For the purpose of diagnosing and assessing the patients of *Madhumeha* (type 2 Diabetes mellitus), the following investigations may be performed before and after the completion of trial:

Blood and serological tests:-

Blood sugar levels - Fasting and Postprandial HbA1c

Route of administration and dose: 2 tablets(1000mg) were given orally before food(निरअन्नि) in morning and evening twice in a day.

Preparation of the Trial Drug:- *Vati* of 500 mg were prepared by *churana* of six drugs mentioned in *Vachadi Gana* in equal ratio after giving the *bhawna* of *Saptarangi kwatha* from GMP certified pharmacy named as Chachan Pharmaceuticals, Ellenabad-125102.

Pictures showing tablets prepared by vachadi gana after giving saptarani bhawna

Criteria for Assessment of Overall Effect of Therapy: Assessment was done on the basis of subjective and objective parameters. For this purpose, symptoms were graded according to their severity.

Subjective Criteria

1. *Shya-asana*, 2. Turbid-urine (*Avilmutrata*), 3. Obesity (*Sthoolta*), 4. Incresed appetite (*bahuashi)*, 5. Unctuous body (*Gandh),* 6. Polyuria, 7. *Kandu,* 8. Prolonged wound healing, 9. *karpadatala daha.*

Objective Criteria (Investigation)

For the purpose of diagnosing and assessing the patients of Madhumeha (type 2 diabetesmellitus), the following investigations may be performed before and after the completion of trial:

- Blood and serological tests:-
  - Blood sugar levels - Fasting and Postprandial
  - HbA1c

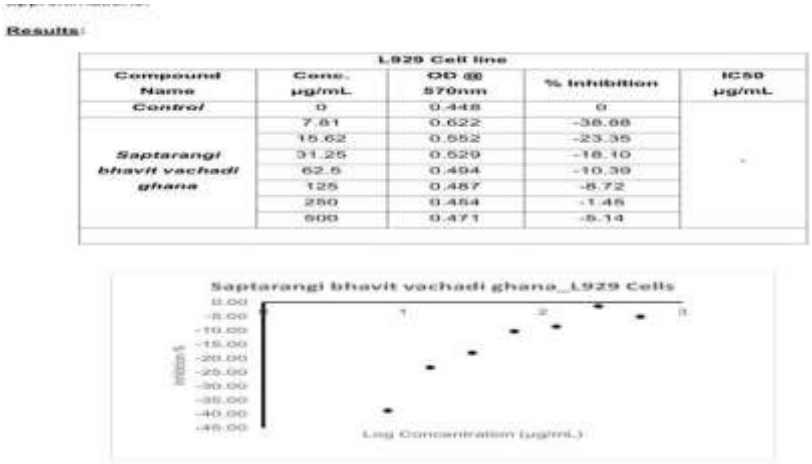
Overall Effect of Therapy: Considering the improvement in symptoms of Madhumeha, the subjects were divided into following groups

1. Complete Remission- 100 % relief in symptoms.
2. Marked Improvement- 75 % to < 100 % relief in symptoms.
3. Moderately Improved- 50 % to < 75 % relief in symptoms.
4. Mild Improvement- 25 % to < 50 % relief in symptoms.
5. Unchanged- Below 25 % relief in symptoms.

OBSERVATIONS AND RESULTS

Safety study of drug:- Cytotoxicity of the drug was studied throught MTT assay from progen biology lab, Acme progen Biotech Private Limited Tamil Nadu, India. Which were found non toxic against against L929 cell line.

Figure below showing results obtained in MTT assay



Results:

L929 Cell line

Compound Name	Conc. µg/mL	OD @ 570nm	% Inhibition	IC50 µg/mL
Control	0	0.448	0	
Saptarangi bhavit vachadi ghana	7.81	0.622	-38.88	
	15.62	0.552	-23.35	
	31.25	0.520	-16.10	
	62.5	0.494	-10.39	
	125	0.487	-8.72	
	250	0.454	-1.46	
	500	0.471	-5.14	

Clinical results:- The following section presents the findings of the study, offering a detailed analysis of the data collected in relation to the research questions/hypotheses.

Wilcoxon Signed Rank test was applied on the Subjective parameters and Paired T-test was applied on the Objective parameters.

Table 2: Results obtained by Wilcoxon signed Rank test on subjective criteria.

Variables	Opts	BEFOR	AFTER	Wilcoxon test	P Value	Result
Shaya Asana	No	0	8	-4.237	<0.001	Highly Significant
	Mild	10	14			
	Moderate	11	7			
	High	9	1			
Turbid Urine	No	7	12	-4.264	<0.001	Highly Significant
	Mild	6	13			
	Moderate	13	4			
	High	4	1			
Obesity(By BMI)	No	0	0	-3.9	<0.001	Highly Significant
	Mild	4	12			
	Moderate	11	12			
	High	15	6			
	No	3	17	4.148	<0.001	
Bahuashi	Mild	7	4			Highly

Increased appetite	Moderate	14	8			Significant
	High	6	1			
Unctuous body(Gandh)	No	0	9	4.486	<0.001	Highly Significant
	Mild	7	15			
	Moderate	14	6			
	High	9	0			
Kar-pada daha	No	3	11	4.234	<0.001	Highly Significant
	Mild	8	8			
	Moderate	12	11			
	High	7	0			
Polyurea	No	3	8	4.613	<0.001	Highly Significant
	Mild	5	11			
	Moderate	9	10			
	High	13	1			
Kandu	No	17	23	2.81	<0.001	Highly Significant
	Mild	8	6			
	Moderate	4	1			
	High	1	0			
Prolonged wound healing	No	26	29	1.732	0.083	Not Significant
	Mild	3	0			
	Moderate	1	1			
	High	0	0			
	6.6-8 %	11	10			
	8.1-10%	17	14			
	>10 %	0	0			
Variable	**Subjective parameters**					
MEAN	14.4	7.7				
MEAN DIFFERENCE	6.3					
CHANGE %	45.0%					

Paired T-Test Analysis of objective Parameter

The paired t-test analysis reveals significant improvements in key health indicators post-intervention:

Fasting Blood Sugar (FBS): Mean score decreased from 170.52 to 147.87, with a significant t-value of 10.165 ($p < 0.001$).

Postprandial Blood Sugar (PPBS): Mean score decreased from 218.48 to 179.64, with a significant t-value of 7.871 ($p < 0.001$).

HbA1c: Mean score decreased from 8.32 to 6.80, with a significant t-value of 5.786 ($p < 0.001$).

Total effect of therapy including objective and subjective criteria

Table No. 3: Percentage of relief.

Sr no	Parameters	% of relief
1.	Subjective	45%
2.	Objective parameters	16.4%
Over all effect		30.7%

Total effect of therapy		
Sr. No.	**Improvement**	**Total Relief**
1	Good Improvement (75%-100%)	.
2	Moderate improvemnet (51%-75%)	
3	Mild Improvement (26%-50%)	30.7%
4	No Improvement (0-25%)	

Statistical analysis reveals that the overall effectiveness of the therapy was approximately 30.7%. Specifically, subjective parameters showed a notable treatment effect of 45%, indicating significant improvements from the patient's perspective. In contrast, objective parameters exhibited a more modest relief of 16.4%. When examining these results in detail, it is evident that the therapy provided mild relief across both subjective and objective measures.

Adverse Drug Reaction

No adverse drug reactions were reported for the trial drug during the study or follow-up period, given the prescribed dosage and duration.

DISCUSSION

Probable Mode of Action of *Vachadi Gana* and *Saptarangi* in Managing *Prameha*

Effects of Vachadi Gana on the followings

Kleda (Jala) and Kapha Dosha: Vachadi Gana, drugs possess rasa tikta, katu, Kashaya and Ushna virya which acts as Kaphaghna properties, helps balance the excess.

Medha Dhatu: Due to ushna virya of drugs mentioned in vachadi gana has Deepana (digestive stimulant) and Pachana (digestive aid) properties enhance digestive fire (Agni), which helps in the proper assimilation and transformation of nutrients, thereby addressing disruptions in Medha Dhatu and aiding overall metabolic balance.

Ama and Metabolism: Their katu and kashaya ras with ushna virya and katu vipaka do Aampachana (ama-cleansing) which helps to eliminate toxins (ama) that can exacerbate the condition, thereby reducing the systemic burden and improving metabolic functions.

Mamsa Dhatu, Shukra and Vasa: By promoting better digestion and metabolism, Vachadi Gana indirectly supports the balance of Mamsa Dhatu (muscle tissue), Shukra (reproductive tissue), and Vasa (fat), which are critical in Prameha management.

Saptarangi: Pitta and Kapha Balancing: The Laghu, Ruksha, Tikshna, Gunas and Tikta-Kashaya (bitter-astringent) Rasa of Saptachakra help balance both Pitta and Kapha doshas. This balance is crucial for addressing the Pitta and Kapha imbalances often seen in Prameha.

Its Ruksha (dry) and Tikshna (sharp) properties assist in reducing excess Kleda (fluid) and Vasa (fat), which are integral to managing Prameha.

Support for Amenorrhea and Genito-Urinary Health: Saptachakra's effectiveness in treating amenorrhea and genito-urinary issues provides additional support for reproductive and urinary health, which can be affected in Prameha.

Table 4: Karma of drugs.

Drugs	*Karma* of Drug[180-186]
Vacha[7]	Vachadi possesses rasa tikta, katu, Kashaya and Ushna virya possess *Deepana, Kaphaghna, Vataghna*
Nagarmotha[8]	*Deepana, Kaphaghna, Vataghna properties*
Devdaru[9]	*Deepana, Pachana, Kaphanissaraka, Shleshmaputihara, Lekhana, Vatahara, Kaphahara, Dushtavrana Shodhaka*
Shunthi[10]	*Katu,Usna rasa works as Kapha har, Aamhar, Deepana, Pachana, Anulomana, Hridyottejaka, Raktprasadana, Kaphanissaraka, Shleshmaputihara, Lekhana. Vatahara, Kaphahara, Dushtavrana Shodhaka*
Ativisha[11]	*Tikta, Katu rasa, Anusna, Kapha har, Aamhar Deepana, Pachana and Sarav doshahar*
Haritaki[12]	*Deepana, Rasayana, Sarvadoshaprashmana.*
Saptarangi[13]	*Laghu, Ruksha, Tikshan guna And Tikta-Kashya rasa*

Discussion about result in Subjective parameters

The Wilcoxon signed-rank test results across all subjective parameters indicate statistically significant changes, The data presents the analysis of several clinical parameters before and after treatment, focusing on their mean values, mean differences (BT-AT), and statistical significance. The analysis revealed several significant associations between various variables and the outcomes. Shaya Asana showed a strong impact, with a reduction in mild and moderate effects and a notable decrease in high effects ($W= -4.237$, $p < 0.001$). Turbid urine also demonstrated a significant change with a decrease in moderate and high turbidity, and an increase in mild turbidity ($W = -4.264$, $p <0.001$). Obesity was significantly associated with a

shift from moderate and high categories to mild (W = -3.9, p < 0.001). Increased appetite showed a marked improvement, with high appetite issues declining and mild and moderate issues less frequent (W= 4.148, p < 0.001). Unctuous body symptoms decreased significantly, particularly in severe cases (W= 4.486, p <0.000). Kar-pada Daha saw a reduction in high symptoms, with mild symptoms becoming more prevalent (W= 4.234, p < 0.001). Polyuria also significantly improved, with high cases decreasing and mild cases increasing (W = 4.861, p < 0.002) and Kandu (W = 2.81, p <0.001) also shows significant improvement.

However, no significant associations were found for prolonged wound healing (W = 1.732, p= 0.083).

Discussion about result of objective Parameters

In paired t-test analysis, most objective parameters show statistically significant changes post-intervention, The data presents the statistical analysis of several objective clinical parameters before and after treatment, using metrics such as mean difference, standard deviation, t-value, and P-value to determine the significance of changes. The results demonstrate significant improvements in key measures of glycaemic control. The mean Fasting Blood Sugar (FBS) level decreased notably from 170.52 to 147.87, with a significant t-value of 10.165 (p < 0.001). Similarly, the mean Postprandial Blood Sugar (PPBS) level dropped from 218.48 to 179.64, reflecting a significant change with a t-value of 7.871 (p < 0.001). HbA1c also showed a substantial reduction, from 8.32 to 7.80, supported by a significant t-value of 5.786 (p < 0.001). These findings highlight the effectiveness of the intervention in improving overall glycemic control in patients.

Discussion about overall result

Statistical analysis reveals that the therapy's overall effectiveness is approximately 30.7%. Subjective parameters, reflecting patients' personal experiences, showed a significant improvement of 45%, while objective parameters, which are measurable and clinical, exhibited a more modest relief of 16.4%. This indicates that the therapy provided mild overall relief, with a particularly strong impact from the patient's perspective.

CONCLUSION AND RECOMMENDATIONS

- Saptarangi bhavit vachadi gana was in the form of tablet was found non-toxic in MTT assay.So it can be used for further clinical trials
- Saptarangi bhavit vachadi gana was found to have a notable impact on all symptoms

associated with Madhumeha. Most of the ingredients in the formulation are characterized by tikta, katu, kashaya taste and ushna potency. These properties contribute to its effects, including agni deepana, aampachana, medovishoshana, lekhana, srotosodhana, mutra (urinary detoxification) and vata anulomana.

- Statistical analysis indicates that the overall effectiveness of the therapy is approximately 30.7%. Specifically, subjective parameters, which reflect the patient's personal experience, showed a substantial improvement of 45%. Conversely, objective parameters, which are measurable and clinical, demonstrated a more modest relief of 16.4%. This suggests that while the therapy provided mild relief overall, it was particularly effective from the patient's perspective.
- The results support the alternate hypothesis, confirming the significant efficacy of Saptarangi Bhavit Vachadi Gana in managing type 2 DM, especially when associated with metabolic syndrome.
- The null hypothesis, which posited no significant effect of the therapy, is rejected based on the evidence provided.

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