International Research Journal of Ayurveda & Yoga Vol. 7(1), pp. 21-27, January, 2024
Available online at http://irjay.com
ISSN: 2581-785X
DOI: 10.47223/IRJAY.2024.70104

ORIGINAL RESEARCH ARTICLE

A Comparative Clinicopathological Study on Powder of *Aegle marmelos* Leaf and *Withania coagulans* Flower in the Management of Madhumeha

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ARTICLE INFO

Article history:
Received on: 29-11-2023
Accepted on: 01-01-2024
Published on: 31-01-2024

Key words:
Aegle marmelos leaf,
Avarana Dhatukshaya,
Madhumeha,
Vataja Prameha,
Withania coagulans flower

ABSTRACT

Background: In view of *Ayurveda,* abnormal and profuse excretion of urine in general is called as *Prameha*. If we do not treat the *Prameha*, it leads to *Madhumeha.* There are many herbs mentioned in *Ayurveda* that have *Madhumehahara* property. Hence, to control *Madhumeha* two effective Ayurvedic drugs, namely, "*Aegle marmelos*" and "*Withania coagulans*" were selected for the present study. The study aimed to study the efficacy of *A. marmelos* leaf and *W. coagulans* flower powder in the management of *Madhumeha.*

Materials and Methods: For the present study, 40 patients of *Madhumeha* were randomly selected according to the Inclusion criteria. The prepared medicine was trailed in two groups (Groups A and B) each having 20 Patients. The assessment was in every 10 days of intervals.

Discussion and Conclusion: Statistically, *A. marmelos* leaf powder provided no significant results and *W. coagulans* flower powder provided significant results in improving subjective and objective signs and symptoms of *Madhumeha*.

1. INTRODUCTION

Madhumeha is a type of *Vataja Prameha*.[1] In this, patient voids urine having similarity with honey (Madhu) either in its color, taste, or smell. In Allopathy, we can compare with Diabetes Mellitus. According to etiology, it is of two types,[2] one due to *Dhatukshaya*, another due to *Avarana*. In both types, *Vata* gets aggravated.

Diabetes mellitus is a group of metabolic disorders sharing the common features of chronic hyperglycemia with disturbances of carbohydrate, fat, and protein metabolism. Hyperglycemia in diabetes results from defects in insulin secretion and abnormal insulin function or both. It has been seen that there is no organ or system spared from diabetic complications.

The current study was proposed to establish the effect of *Aegle Marmelos* leaf and *Withania Coagulans* flower in the form of powder for the treatment of *Madhumeha.*

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1.1. Aim

The aim of the study was to study the efficacy of *A. marmelos* leaf and *W. coagulans* flower powder in the management of *Madhumeha.*

2. MATERIALS AND METHODS

2.1. Ethical Clearance

The study was approved by the Institutional Ethics Committee, Government Ayurvedic College and Hospital, Balangir vide Letter No: 1082/G.A.C and H of dated May 26, 2021 and registered in Clinical Trial Registry of India (CTRI; www.ctri.nic.in) vide Registration No: CTRI/2022/12/048589 on dated October 29, 2022. The study has been conducted among the patients registered for the purpose. Written consent was obtained from each patient who participated in the study with prior proper information.

2.2. Source of Patient

Forty patients were selected from the OPD and IPD of Government Ayurvedic College and Hospital, Balangir, and Sharadeswari Govt.

Ayurvedic Hospital, Balangir, and were enrolled for the clinical study.

2.3. Study Design and Grouping

2.3.1. Method of collection of patients

Forty patients suffering from *Madhumeha* were taken for the present study. They were screened by a special proforma which includes details history taking, physical signs and symptoms, and pathological investigations mentioned in classics and modern science.

2.4. Methodology

Clinicopathological study (Single-blind study).

2.4.1. Group-A (trial group)

Twenty patients treated with *A. marmelos* leaf powder 5 g twice daily, in empty stomach for 30 days.

2.4.2. Group-B (trial group)

Twenty patients treated with *W. coagulans* flower powder 5 g twice daily, in an empty stomach for 30 days.

2.5. Duration

The duration of the study was 30 days.

Comparison was one within two groups to find out the effectiveness of the mentioned medicines.

2.6. Diagnostic Criteria

The patient was diagnosed based on multiple parameters (*Trividha*, *Sadvidha*, *Astabidha*, *Dashavidha* parikhya). Clinical sign symptoms as described in classical text were considered for the diagnosis of *Madhumeha,* for example,

i. *Prabhutamutrata* (Frequent urination), Ati Ksudha (excessive appetite), *Atitrishna* (increased thirst), *Dourbalya* (Weakness), Kar-pada daha (burning sensation in hand and feet), Kar-pada suptata (numbness in hand and feet), and *Mukhamadhurya* (sweetness in mouth)
ii. Fasting blood sugar >126 mg/dL and <250 mg/dL.
iii. Postprandial blood sugar >200 mg/dL and <300 mg/dL.
iv. HbA_1C: –6.5–8.5%.

2.7. Inclusion Criteria

The following criteria were included in the study:

i. Patients with age between 25 and 60 years
ii. Both sexes (male and female)
iii. Patient not taking medication of another system
iv. Newly diagnosed patient
v. Patients who fulfill the diagnostic criteria
vi. Fasting blood sugar >126 mg/dL and <250 mg/dL
vii. Postprandial blood sugar >200 mg/dL and <300 mg/dL
viii. HbA1C: –6.5–8.5%
ix. Patients having symptoms of *Prabhutamutrata* (Frequent urination), *Ati Ksudha* (excessive appetite), *Atitrishna* (increased thirst), *Dourbalya* (Weakness), *Kar-pada daha* (burning sensation in hand and feet), *Kar-pada suptata* (numbness in hand and feet), and *Mukhamadhurya* (sweetness in mouth)
x. Subject willing to follow the procedure as per the study protocol and voluntarily sign informed consent form.

2.8. Exclusion Criteria

The following criteria were excluded from the study

i. Patient age <25 years and >60 years
ii. Patient having fasting blood sugar >250 mg/dL
iii. Postprandial blood sugar >300 mg/dL
iv. Patient with more than HbA_1C 8.5%
v. Insulin-dependent patients
vi. Patient having complications of diabetes like ketoacidosis, nephropathy, neuropathy, retinopathy, and diabetic wounds
vii. Patient having chronic, contagious infection diseases such as active tuberculosis, hepatitis A, B and C, or HIV
viii. Patient associated with other fatal diseases like heart diseases, hypertension, and chronic kidney diseases.

2.9. Assessment Criteria

For assessment of result, severity of the sign and symptom was graded as 0,1,2,3 grade for normal (0), mild (+), moderate (++), and severe (+++) accordingly mentioned in Table 1.

The detail pathogenesis of clinical study was carried out based on *Trividha*, Sadvidha, Astavidha, and Dashavidha parikshya as per Ayurvedic classics.

2.10. Dose and Administration Procedure

i. Dose of *A. marmelos* leaf powder: 5 g twice daily in empty stomach for 30 days.
   Anupana: Ushnajala.

ii. Dose of W. coagulans flower powder: 5 g twice daily in empty stomach for 30 days.
   Anupana: Ushnajala.

iii. Dietic Regimen
   a. Ahara: Patients were advised to take a normal diet, green vegetables except carbohydrates, sugar-containing food, spicy food, junk food, and non-vegetarian food.
   b. Vihara: Practice exercise and yoga in a regular basis.

2.11. Follow-up

Follow-up were done in every 10 days gap, that is, 10^{th}, 20^{th}, and 30^{th} day of the clinical trial. During follow-up, both subjective and objective parameters of assessment were done to assess the result.

2.12. Assessment for Results

The degree of severity as per above gradation criteria and data collected from pathological investigations after 10 days AT_1, 20 days AT_2, and 30 days AT_3 of treatment were assessed. The assessment has been done in two stages as follows-

2.12.1. Clinical assessment

The average percentage improvement in the severity of different clinical sign and symptoms was calculated. The overall clinical assessment has been done considering the sign and symptoms as follows-

- Marked Improvement: 76–100% relief in sign and symptoms in trial period.
- Moderate Improvement: 51–75% relief in sign and symptoms.
- Mild Improvement: 26–50% relief in sign and symptoms.
- Unsatisfactory: below 25% relief in sign and symptoms.

2.13. Statistical Analysis

The subjective and objective data, like the signs and symptoms, FBS, PPBS, and HbA1C, gathered from the patients were subjected for statistical analysis. Data were analyzed statistically in terms of mean, standard deviation, standard error, *t*-value, and *P*-value. The statistical analysis after 30 days of treatment has been done. For the effectiveness of the trial drug and control drug, paired "*t*" test and unpaired *t*-test have been used. The effectiveness of trial drugs and control drugs has been assessed through the *P*-value.

The *P*-value was interpreted as:

- >0.05 statistically insignificant at 5% level.
- <0.05 significant at 5% level.
- <0.01 significant at 1% level.
- <0.005 significant at 0.5% level.
- <0.001 highly significant at 0.1% level.

2.14. Presentation of Data

Data collected from the patients were tabulated under the following two sections:

a. General observations such as age, sex, religion, occupation, educations status, socioeconomics status, marital status, dietary habit, habit/addiction, history of past illness, family history, sleeping habit, urination, bowel habit, and vyayama.
b. Result of therapy based on changes in sign-symptoms and disease specific-biochemical-investigation.

3. RESULTS

It has been observed 23 numbers of patients were registered in Group-A and 22 numbers of patients were registered in Group-B. There were five number of patients drop out from the study. Twenty patients in both groups have completed the study.

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy in Group A and Group B. We can observe that *P*-value for Group A and Group B is <0.05. Hence, we can conclude that effect observed in Group A and Group B is significant.

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed-rank Test to test efficacy in Group A and Group B. We can observe that *P*-value for Group A and Group B is <0.05. Hence, we can conclude that effect observed in Group A and Group B is significant.

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Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed-rank Test to test efficacy in Group A and Group B. We can observe that *P*-value for Group A and Group B is <0.05. Hence, we can conclude that effect observed in Group A and Group B is significant.

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed-rank Test to test efficacy in Group A and Group B. From the above table 2, we can observe that *P*-value for Group A and Group B is <0.05. Hence, we can conclude that effect observed in Group A and Group B is significant.

Mann–Whitney U Test is carried out for comparison between Group A and Group B. From the above table 3, we can observe that *P*-value for almost parameters is <0.05. Hence, we can conclude that there is a significant difference between Group A and Group B.

Further, we can observe that mean rank for Group B is greater than Group A. Hence, we can conclude that effect observed in Group B is better than Group A [Table 4].

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed-rank Test to test efficacy in Group A and Group B. From the above table 5, we can observe that *P*-value for Group A and Group B is <0.05. Hence, we can conclude that effect observed in Group A and Group B is significant.

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed-rank Test to test efficacy in Group A and Group B. From the above table 6, we can observe that *P*-value for Group A and Group B is <0.05. Hence, we can conclude that effect observed in Group A and Group B is significant.

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed-rank Test to test efficacy in Group A and Group B. From the above table 7, we can observe that *P*-value for Group A and Group B is <0.05. Hence, we can conclude that effect observed in Group A and Group B is significant.

Mann–Whitney U Test is carried out for comparison between Group A and Group B. From the above table 8, we can observe that *P*-value for almost parameters is <0.05. Hence, we can conclude that there is a significant difference between Group A and Group B.

Further, we can observe that mean rank for Group B is greater than Group A. Hence, we can conclude that effect observed in Group B is better than Group A [Table 9].

4. DISCUSSION

4.1. Trial Drug-1 *A. marmelos* Leave Powder

Bilwa Patra has Tikta Rasa which alleviates Abaddha *Meda*[3] and Abaddha *Kapha* as Tikta rasa reduces the extra fats of the body. Furthermore, it has Kashaya Rasa which reduces the excessive *Kleda* and *Lasika*[4] in the body for which the frequency of micturition decreases. It has Ushna Virya, which pacifies both Vata and *Kapha Dosha*. It enhances the Agni which reduces Amajirna,[5] helps in proper formation of *Meda* and other dhatu. By Rukshya Guna pacifies excessive *Snigdhata* of *Kapha Dosha* and *Meda* Dhatu[6] so *Snigdhangatwa* reduces. Due to Katu Vipaka, it Pacifies excessive *Madhurattva* of *Kapha Dosha* and opens the Srotas. By Grahi, it absorbs the extra *Kleda* and *Lasika* of the body. Methanolic extract from Leaves of Bilwa reduces blood sugar levels.

4.2. Trial Drug-2 *W. coagulans* Flower Powder

It has Tikta Rasa and Katu Rasa which pacifies *Kapha Dosha* and Madhura Ras which pacifies Vata *Dosha*. Tikta Ras alleviates Abadha *Meda* and Abadha *Kapha*[7] as tikta rasa reduces the extra fats in the body. It has Ushna Virya, which pacifies Sheeta Guna of both Vata and *Kapha Dosha*.[8] Katu Rasa clears all the Srotas and cleans up the outh. Due to Laghu Guna, it acts on Guru Guna of *Kapha Dosha* and Snigdha.[9] It pacifies Rukshata of Vata *Dosha*. It has Rasayan and Balya properties which reduces weakness in patients. It has Hydroxywithnanolide K, Coagulin-L, Coagulanolide, and Withanolide which promote the secretion of Insulin, inhibit glucose absorption, and restore pancreatic endocrinal tissue. By this, it lowers the sugar levels in the body.

5. CONCLUSION

Statistically, *A. marmelos* leaf powder provided less significant results and *W. coagulans* flower powder provided significant results in improving subjective and objective signs and symptoms of *Madhumeha*. Better clinical improvement was seen in patients in Group B with *W. coagulans* flower powder, Than in Group A with *A. marmelos* leaf powder. Hence, both are proven to be efficient antidiabetic drugs.

6. ACKNOWLEDGMENTS

None.

7. AUTHORS' CONTRIBUTIONS

All the authors contributed equally in design and execution of the article.

8. FUNDING

Nil

9. ETHICAL APPROVALS

Letter No: 1082/G.A.C and H of dated May 26, 2021 and registered in (CTRI; www.ctri.nic.in) vide Registration No: CTRI/2022/12/048589 on dated October 29, 2022

10. CONFLICTS OF INTEREST

Nil.

11. DATA AVAILABILITY

This is an original manuscript and all data are available for only research purposes from principal investigators.

12. PUBLISHERS NOTE

This journal remains neutral with regard to jurisdictional claims in published institutional affiliation.

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How to cite this article:
Swain SK, Nayak U, Panda PK. A Comparative Clinicopathological Study on Powder of *Aegle marmelos* Leaf and *Withania coagulans* Flower in the Management of Madhumeha. IRJAY. [online] 2024;7(1);21-27.
Available from: https://irjay.com
DOI link- https://doi.org/10.47223/IRJAY.2024.70104

Table 1: Grading-(subjective parameters)

Illness	Severity	Grade
Prabhutamutrata (Frequent urination)	Quantity-0.5–2.5 l/day	0
	2.5–3.5 l/day	1
	3.5–4.5 l/day	2
	More than 4.5 l/day	3
	Frequency-3–5 times/day, rare at night	0
	5–7 times/day, 1–2 times at night	1
	7–10 times/day 3–4 times at night	2
	10–12 times/day more than 3–4 times at night	3
Ati Ksudha (excessive appetite)	Main meal-2 times, snacks-2 times	0
	Main meal-2 times, snacks-2–3 times	1
	Main meal-2 times, snacks-3–5 times	2
	Main meal-3 times, snacks->5 times	3
Atitrishna (increased thirst)	Intake of water/ liquid-1.5–2.5 l/day	0
	Intake of water/ liquid-2.5–3.0 l/day	1
	Intake of water/ liquid-3.0–3.5 l/day	2
	Intake of water/liquid-More than 3.5 l/day	3
Dourbalya (Weakness)	Absent	0
	Mild	1
	Moderate	2
	Severe	3
Kar-pada daha (burning sensation in hand and feet)	No daha present	0
	Feeling of daha (burning sensation)	1
	Feeling of daha (burning sensation) most of the time	2
	Always feeling of daha (burning sensation)	3
Kar-pada suptata (numbness in hand and feet)	No suptata	0
	Suptata present seldomly	1
	Most of the time feeling of Suptata	2
	Always feeling of Suptata	3
Mukhamadhurya (sweetness in mouth)	Absent	0
	Mild	1
	Moderate	2
	Severe	3

(Contd...)

Table 1: *(Continued)*

Illness	Severity	Grade
Pathological investigation (Objective Parameters)		
Fasting blood sugar	**Range**	**Grade**
	70–100 mg/dL	0
	101–125 mg/dL	1
	126–150 mg/dL	2
	>150 mg/dL	3
Post prandial blood sugar	<140 mg/dL	0
	141–200 mg/dL	1
	201–260 mg/dL	2
	>260 mg/dL	3
HbA1c	<5.7%	0
	5.8–6.5%	1
	6.6–8%	2
	>8%	3

Table 2: Subjective parameters before and after treatment in Group A and Group B (*n*=40)

Variable	Group	N	Mean Rank	Sum of Ranks	Mann–Whitney U	*P*-value
Prabhutamutrata	Group A	20	14.00	280.00	76.000	0.000103
	Group B	20	25.00	500.00		
	Total	40				
Prabhutamutrata	Group A	20	14.00	280.00	76.000	0.000103
	Group B	20	25.00	500.00		
	Total	40				
Atikshudha	Group A	20	15.34	306.84	101.500	0.008546
	Group B	20	23.66	473.16		
	Total	40				
Atitrishna	Group A	20	16.24	324.74	118.500	0.028650
	Group B	20	22.76	455.26		
	Total	40				
Dourbalya	Group A	20	17.05	341.05	134.000	0.110563
	Group B	20	21.95	438.95		
	Total	40				
Karapadadaha	Group A	20	17.00	340.00	133.000	0.107470
	Group B	20	22.00	440.00		
	Total	40				
Karapadasuptata	Group A	20	16.79	335.79	129.000	0.085648
	Group B	20	22.21	444.21		
	Total	40				
Mukhamadhurya	Group A	20	16.05	321.05	115.000	0.033998
	Group B	20	22.95	458.95		
	Total	40				

Table 3: FBS before and after treatment in Group A and Group B (*n*=40)

FBS	Mean	Median	Standard Deviation	SE	Wilcoxon W	*P*-value	% Effect	Result
Group A								
BT	2.55	3.00	0.51	0.11	−3.606[b]	0.000311	25.49	Sig
AT	1.90	2.00	0.85	0.19				
Group B								
BT	2.70	3.00	0.47	0.11	−3.817[b]	0.000135	53.70	Sig
AT	1.25	1.50	0.97	0.22				

Table 4: Intergroup comparison showing the FBS

FBS	Mean		Standard deviation		% Effect	
	Group A	Group B	Group A	Group B	Group A	Group B
BT	2.55	2.70	0.51	0.47	-	-
AT1	2.40	2.45	0.60	0.51	5.88	9.26
AT2	2.25	1.95	0.72	0.83	11.76	27.78
AT3	1.90	1.25	0.85	0.97	25.49	53.70

Table 5: PPBS before and after treatment in Group A and Group B (*n*=40)

PPBS	Mean	Median	Standard deviation	SE	Wilcoxon W	*P*-value	% Effect	Result
Group A								
BT	2.40	2.00	0.50	0.11	−3.464[b]	0.000532	25.00	Sig
AT	1.80	2.00	0.62	0.14				
Group B								
BT	2.45	2.50	0.60	0.14	−4.025[b]	0.000057	38.78	Sig
AT	1.50	1.50	0.69	0.15				

Table 6: Intergroup comparisons showing the PPBS

PPBS	Mean		Standard Deviation		% Effect	
	Group A	Group B	Group A	Group B	Group A	Group B
BT	2.40	2.45	0.50	0.60	-	-
AT1	2.35	2.20	0.49	0.62	2.08	10.20
AT2	2.00	1.85	0.56	0.81	16.67	24.49
AT3	1.80	1.50	0.62	0.69	25.00	38.78

Table 7: $HbA1_c$ before and after treatment in Group A and Group B (*n* = 40)

$HbA1_c$	Mean	Median	Standard deviation	SE	Wilcoxon W	*P*-value	% Effect	Result
Group A								
BT	1.40	1.50	0.94	0.21	-2.449[b]	0.014306	17.86	Sig
AT	1.15	1.00	1.09	0.24				
Group B								
BT	1.60	2.00	0.88	0.20	-2.449[b]	0.014306	18.75	Sig
AT	1.30	1.00	0.92	0.21				

Table 8: Objective parameters before and after treatment in Group A and Group B (*n*=40)

Variable	Group	N	Mean rank	Sum of Ranks	Mann-whitney U	*P*-value
FBS	Group A	20	13.92	278.42	74.500	0.000502
	Group B	20	25.08	501.58		
	Total	40				
PPBS	Group A	20	16.68	333.68	127.000	0.041494
	Group B	20	22.32	446.32		
	Total	40				
HbA1C	Group A	20	19.50	390.00	180.500	1.000000
	Group B	20	19.50	390.00		
	Total	40				

Table 9: Overall effect of the therapy

Overall Effect	Group A		Group B	
	n	%	*n*	%
Marked Improvement	0	0.00	0	0.00
Moderate Improvement	3	15.00	9	45.00
Mild Improvement	5	25.00	11	55.00
No Improvement	12	60.00	0	0.00
Total	20	100.00	20	100.00