



ISSN 2456-3110

Vol 5 · Issue 5

Sept-Oct 2020

Journal of **Ayurveda and Integrated Medical Sciences**

www.jaims.in

JAIMS

An International Journal for Researches in Ayurveda and Allied Sciences



Charaka
Publications

Indexed

Open randomised clinical study of *Arjuna* (*Terminalia arjuna roxb.*) *Kaand Twak Churna* on *Madhumeha*: A Pilot Study

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ABSTRACT

A clinical study was conducted on patients of *Madhumeha* resembling condition with Diabetes Mellitus, to evaluate the efficacy of *Arjuna* (*Terminalia arjuna* Roxb.) *Kaand Twak Churna* which is mentioned in traditional *Bhavaprakash Nighantu* as *Madhumehahar*. The present study was designed on newly diagnosed cases of Type II Diabetes Mellitus. The Aim and Objective of this study was to evaluate the efficacy of *Arjuna* (*Terminalia arjuna* Roxb.) *Kaand Twak Churna* on *Madhumeha*. This study was planned on 40 newly diagnosed cases of Diabetes Mellitus who were orally administered with *Arjuna* (*Terminalia arjuna* Roxb.) *Kaand Twak Churna*. Result obtained from study revealed that *Kaand Twak Churna* of *Arjuna* (*Terminalia arjuna* Roxb.) shows good effect in relieving the subjective criteria's viz, *Prabhutamutrata*, *Pippasa Vridhhi*, *Avila Mutrata*, *Swedaadhikya*, *Nidradhikya*. It has also shown significant result in Objective criteria viz. FBS, PPBS, HBA_{1C}.

Key words: *Arjuna*, *Kaand Twak Churna*, *Madhumeha*, *Diabetes Mellitus*.

INTRODUCTION

Madhumeha has emerged as a global health hazard having tremendous socio-economic impact to the individual as well as society as a whole. In spite of tremendous advances in modern medical sciences, today *Madhumeha* (Diabetes Mellitus) is one of the most common non-communicable diseases.^[1] Diabetes Mellitus is the most severe metabolic pandemic of the 21st century, affecting essential biochemical activities in almost every cell in the body

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Submission Date: 26/09/2020 Accepted Date: 22/10/2020

Access this article online

Quick Response Code



Website: www.jaims.in

Published by Maharshi Charaka Ayurveda Organization, Vijayapur, Karnataka (Regd) under the license CC-by-NC-SA

and increasing the risk of cardiac problems. It is estimated that in the year 2000, 171 million people had diabetes and this is expected to double by the year 2030.^[2] Though there are variety of Hypoglycaemic drugs available along with the use of insulin, there is an increase in demand of natural drugs producing hypoglycaemic effect.^[3] Few researches have analysed the efficacy of various *Dravyas* mentioned in Ayurvedic classics for *Madhumeha*. Here an attempt was made to analyse the effect of "*Arjuna Kaand Twak Choorna* (Bark powder) of *Terminalia arjuna* Roxb." which is used by many traditional practitioners as *Hrudya Dravya*. There is reference of use of *Arjuna* in *Madhumeha* in *Bhavaprakash Nighantu*.^[4]

The analysis of *Arjuna Kaand Twak Choorna* indicated the presence of tannins, cardenolide, triterpenoid saponins (arjunic acid, arjunolic acid, arjungenin, glycosides), flavonoids, gallic acid, ellagic acid, phytosterols, calcium, magnesium, zinc, and copper. The present article here by is done to show the efficacy of *Arjuna Kaand Twak Choorna* in *Madhumeha*.^[5]

AIMS AND OBJECTIVES

To evaluate the efficacy of *Arjuna Kaand Twak Choorna* (*Terminalia arjuna* Roxb.) in the management of *Madhumeha*.

MATERIALS AND METHODS

Source of Data

Botanically identified *Arjuna* (*Terminalia arjuna* Roxb.) belonging to Combretaceae^[6] family was procured from Smt. K. G. Mittal Ayurveda Mahavidyalaya, Garden, Kalina, Santacruz, and identified by Department of Dravyaguna Smt. K. G. Mittal Ayurveda Mahavidyalaya, Charni road, Mumbai, India. Authenticated and Standardised by Alarsin Pharmaceuticals, Andheri, Mumbai, India. Finger printing analysis (HPTLC) was done at NFB, Khalsa College, Mumbai, India.

Source of the Patients

Patients were selected after subjecting them through clinical examination from OPD of Dravyaguna Department of Smt. K. G. Mittal Ayurveda Mahavidyalaya, Charni road, Mumbai, India.

Preparation of Medicine

A well identified bark of *Arjuna* was procured, the bark was cut in flat sawn, washed in running tap water then powdered and filtered in #60-85 (*Putra Churna*) sieve mesh. The sieve powder was stored in air tight container till further clinical use.

Shelf life of *Churna Kalpana* is- 2-3 month.^[7]

Place of Work

Medicine was prepared at Rasashatra Department of Smt. K. G. Mittal Ayurveda Mahavidyalaya, Charni road, Mumbai, India. Clinical trial was conducted at Dravyaguna Department of Smt. K. G. Mittal Ayurveda Mahavidyalaya, Charni road, Mumbai, India.

Method of Collection of Data

Written and informed consent was taken of the enrolled patients based on the classical signs and symptoms of *Madhumeha*, the patients screening for inclusive criteria irrespective of sexes between the

age group 18-60 years were selected from the OPD of Dravyaguna Department of Smt. K. G. Mittal Ayurveda Mahavidyalaya, Charni road, Mumbai, India. Totally 40 patients were randomly selected for study according to inclusion and exclusion criteria.

Drug Administration Details

1)	Drug	<i>Arjuna Kanda Twak</i>
2)	Kalpana	<i>Churna</i>
3)	Dose	6 gm for 3 month
4)	<i>Sevan Kaal</i>	<i>Pragbhakta</i>
5)	<i>Anupana</i>	<i>Koshna Jala</i>
6)	Mode of Administration	Oral

Pathyapathya

Without proper diet and lifestyle any medicine will not cure the disease.^[8] Patient were advised to take standard diabetic diet according to Ayurvedic texts and modern medical science.^[9]

Clinical study based on inclusion and exclusion criteria

Inclusion criteria

1. Age- 18 to 60yrs
2. Sex- Either
3. Race- No Barrier
4. Religion- No Barrier
5. Economic Status- No Barrier
6. If yes in any of the 2-
 - a) Blood Sugar Level- Fasting >126 & =<200mg/dL or Post Prandial >200mg/dL & <=300mg/dL or
 - b) Glycated Hb > 7% & < 10%

Exclusion criteria

1. Patient below 18yrs and above 60yrs
2. Malignant and accelerated hypertensive

3. Pregnant women or planning to be pregnant within 6month
4. Lactating Mother
5. Diabetes with known complications

Follow-up

1. Patient will be accessed clinically before and after 15 days of the clinical study trial
2. BSL will be accessed after 45 days before and after study.
3. HbA1C will be accessed before and after study.

Withdrawal criteria

1. Patient not on regular follow-up.
2. Aggravation of Symptoms
3. Development of complications due to presenting illness or otherwise
4. Any adverse drug effects.

Assessment Criteria

Subjective Parameters

Gradation of symptoms^[10]

To access the change in the subjective symptoms of *Madhumeha* the clinical symptomology was graded into four (0-3).

Study of changes in gradation of each symptom was done between, before and after treatment. Gradation done according to Clinical Research Protocol for Traditional Health Science. (Table 1)

SN	Criteria	Detail	Score
1.	<i>Pippasa</i> (Polydipsia)	Daily normal quantity of water to quench thirst (<=2lit) With no <i>Mukhasushkata</i>	0
		Requires additional water more than normal (2- 2.5lit) Still <i>Mukhasushkata</i> .	1
		Requires additional water than normal (2.5 – 3lit) Still <i>Mukhasushkata</i> .	2

		Requires additional water > 3lit. than normal Still <i>Mukhasushkata</i> .	3
2.	<i>Prabhut Mutrata</i> (polyuria)	3 to 6 times per day, rarely at night.	0
		6 to 9 times per day, 0 to 2 times at night.	1
		9 to 12 times per day, 2 to 4 times at night.	2
		More than 12 times per day, more than 4 times per night.	3
3.	<i>Avila Mutrata</i> (turbidity)	Crystal clear fluid.	0
		Faintly cloudy, smoky or hazy with turbidity barely visible.	1
		Turbidity clearly visible but newsprint easily read through test tube.	2
		newsprint cannot be read through test tube.	3
4.	<i>Nidradhikya</i> (sleep)	Normal sleep, 6-8hours/24hours.	0
		Sleep upto 8hours/24hours with Angagaurava.	1
		Sleep upto 8hours/24hours with Angagaurava and Jhrimba.	2
		Sleep upto 10 hours/24hours with Tandra	3
		Sleep upto>10hours/24hours with tandra and klama.	4
5.	<i>Swedadhikya</i> (perspiration)	Sweating after heavy work and fast movement or in hot Weather.	0
		Profuse sweating after moderate work and movement.	1
		Sweating after little work and movement.	2
		Profuse sweating after little work and movement.	3

	Sweating even at rest and/or in cold weather.	4
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Statistical evaluation of treatment and result

Clinical data obtained from patients was analysed statistically in terms of Mean score, Percentage of relief, Standard Deviation (S.D.), Standard Error (S.E.) by following tests.^[11]

1. Wilcoxon matched pairs signed ranks test:

Comparison of symptoms grade score before and after treatment within Group is a qualitative data, so Wilcoxon matched pairs signed ranks test was applied for assessment of effect of treatment on symptom grade within Trial group and within Control group.

2. Paired 't' test: For assessment of effect of treatment on objective parameters before and after treatment within Group is a quantitative data, 'Paired 't' test' was applied.

Results were interpreted as;

P<0.05 - Improvement, Significant

Table 2: Subjective Criteria.

Variable	Treatment	Mean	S.D.	Wilcoxon matched pair Sign Rank	P-Value
<i>Pipasa Vriddhi</i>	BT	1.85	0.975	561.00	< 0.0001
	AT	0.7	0.563		
	Diff (BT-AT)	1.15	0.412		
<i>Prabhuta Mutrata</i>	BT	2.125	0.882	630.00	< 0.0001
	AT	1	0.784		
	Diff (BT-AT)	1.125	0.098		

<i>Avila Mutrata</i>	BT	0.9	0.871	210.00	< 0.0001
	AT	0.275	0.452		
	Diff (BT-AT)	0.625	0.419		
<i>Nidradhikya</i>	BT	1.475	0.933	480.00	< 0.0001
	AT	0.55	0.597		
	Diff (BT-AT)	0.925	0.336		
<i>Swedadhikya</i>	BT	1.35	0.863	406.00	< 0.0001
	AT	0.525	0.505		
	Diff (BT-AT)	0.825	0.358		

There was significant difference found in all symptoms. The P value is <0.05 which means the Trial drug in *Madhumeha* was effective with respect to above symptoms.

Table 3: Objective Criteria.

Variable	Treatment	Mean	S.D.	Paired t Test t value	P-Value
BSL – F	BT	141.45	10.028	19.36	< 0.0001
	AT	115.175	5.324		
	Diff (BT-AT)	26.3	8.584		
BSL – PP	BT	229.3	19.252	11.473	< 0.0001
	AT	189.125	13.156		
	Diff (BT-AT)	40.175	6.096		

HbA ₁ C	BT	7.475	0.274	15.452	< 0.0001
	AT	6.41	0.403		
	Diff (BT-AT)	1.065	0.435		

Statistical Analysis of the effect of therapy on Objective parameters of 40 patients of Madhumeha by paired 't' test:

- BSL - Fasting Mean of difference was 26.3± 8.584, paired t was 19.36; P < 0.05 significant, which suggests that difference of mean exhibited by Trial Drug was significant.
- BSL - Post Prandial Mean of difference was 40.175±6.096, paired t was 11.473; P < 0.05 significant, which suggests that difference of mean exhibited by Trial Drug was significant.
- HbA₁C Mean of difference was 1.065± 0.0435, paired t was 15.452; P < 0.05 significant, which suggests that difference of mean exhibited by Trial Drug was significant.

Comparison of Numerical Data before and After Within the groups was statistically evaluated by "paired-t test". The value of 't' is 19.36, 11.47, and 15.45, while P-value is less than 0.05, which was statistically significant suggestive of significant difference with respect to effect of therapy on Objective Criteria. Hence null hypothesis is rejected.

Total effects of treatment

In the present study, 40 patients of Madhumeha were registered and treated with Trial Drug i.e. Arjuna Kaand Twak Churna.

Table 4: Showing effect on symptoms score of 40 patients of Madhumeha.

SN	Subjective Parameter	Total Score - BT	Total Score - AT	Difference	Percentage Relief
1.	Pipasa-Vridhhi	74	28	46	62.16%
2.	Prabhuta-	85	40	45	52.94%

	Mutrata				
3.	Avila-Mutrata	36	11	25	69.44%
4.	Nidradhikya	59	22	37	62.71%
5.	Swedadhikya	54	21	33	61.11%

Effect of therapy on symptom score

It was observed that overall percentage of relief was more by Trial drug (60.38%). The symptoms such as Pipasa-vridhhi, Prabhuta-Mutrata, Avila-Mutrata, Nidradhikya, and Swedadhikya were studied in this trial as described here before in table. Percentage of relief for all the symptoms is more by Trial Drug.

Table 5: Showing effect on Objective Parameters of 40 Patients of Madhumeha.

SN	Objective Parameter	Total Score - BT	Total Score - AT	Difference	Percentage Relief
1.	BSL- F	141.45	115.175	26.275	18.691%
2.	BSL- PP	229.3	189.125	40.175	17.52%
3.	HbA ₁ C	7.475	6.41	1.065	14.745%

Effect of therapy on Objective parameters

It was observed that overall percentage of relief was more by Trial drug i.e. 18.69%(BSL-F), 17.52%(BSL-PP), and 14.74% (HbA₁C). Percentage of relief for all the Objectiveness is more by Trial Drug.

DISCUSSION

Selection of Problem

Diet and lifestyle are major factors to influence susceptibility to many diseases. Man has adapted himself to the fast-paced life by modifying dietary and lifestyle preferences to suit this modern era. This has resulted in a state of discrepancy between the external environment and internal mechanism causing many diseases which are popularly referred as 'lifestyle-diseases' and "Diabetes" is one of them.

Plan of study

After the permission from Ethical Committee approved by University, we randomly selected 40 patients of *Madhumeha* having their written consent and were administered *Arjuna Kaand Twak Churna* 6gms twice a day *Pragbhakta* (before meal) because any Disease that has affects *Vrukka*, the Drug is given in *Apaan Kaal*^[12] for 14 weeks. All the patients were strictly examined according to the criteria of diagnosis and included in the study. Blood Sugar level (Fasting and Post Prandial) was done before treatment and at an interval of 4th, 8th weeks as well as HbA1C was done before and after treatment to observe the effects. For the purpose of symptomatic improvement, a follow-up of two weeks was kept. All concerned symptoms and investigations, detailed history and *Rugna-Pariksha* were recorded in the CRF.

Discussion on mode of action of Arjuna

As Ayurveda *Samprapti* and *Samprapti Bhanga* both depends on *Panchbhuta Sanghatana*. i.e. *Dosha*, *Dushya*, *Strotasa*, *Agni*, *Ama*. So, hereby put forth the probable mode of action.

Samprapti Bhanga of Madhumeha by Arjuna^[13-15]

Rasa - Kashaya - Kleda, Meda Shoshak; Lekhana, Shoshana

Virya - Sheeta

Vipaka - Katu, Ruksha, Laghu (Reduces Meda)

Guna - Laghu- Kaphaghna, Lekhana, Ruksha- Meda Shoshana

Karma - Medohara- Kleda, Medahara

Discussion on total effect of therapy

Effect of therapy on symptom score

It was observed that overall percentage of relief was more by Trial drug (61.67%). The symptoms such as *Pipasa-vridhi*, *Prabhuta-Mutrata*, *Avila-Mutrata*, *Nidradhikya*, and *Swedadhikya* were studied in this trial as described here before in table. Percentage of relief for all the symptoms is more by Trial Drug.

Effect of therapy on Objective parameters

It was observed that overall percentage of relief was more by Trial drug i.e. 18.69% (BSL-F), 17.52%(BSL-PP), and 14.74% (HbA_{1C}). Percentage of relief for all the Objectives is more by Trial Drug.

Adverse drug effect

Amongst 40 patients, it was observed that 3 patients had symptom of Sore throat. Age limit of these 3 patients was 45-55years and *Prakriti Vata-Kaphaja*.

CONCLUSION

Madhumeha known as silent killer needs to be treated as early as possible to stop onset of further Diabetic complication. *Arjuna (Terminalia arjuna Roxb.)* a very easily available drug can be used to heal *Madhumeha*. *Arjuna* has improved quality of life to all the patients who have undergone clinical trial. *Ekal Dravya* (Single drug) treatment like *Arjuna Kaand Twak Churna* can prove boon to the world wide. Majority of Population suffering from Diabetes mellitus comprising of sedentary lifestyle. The change in their lifestyle i.e. *Pathyakara Ahara-Vihara* followed by regular practice of *Yogasanas* will help in treatment of *Madhumeha*. This pilot study proves that *Arjuna Kaand Twak Choorna* is an efficient as well as an ideal drug for its *Madhumehahara* property.

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How to cite this article: Vd. Balaji S. Sawant, Vd. Shivangi J. Mishra. Open randomised clinical study of Arjuna (Terminalia arjuna roxb.) Kaand Twak Churna on Madhumeha: A Pilot Study. J Ayurveda Integr Med Sci 2020;5:597-603.

Source of Support: Nil, **Conflict of Interest:** None declared.
