INTERNATIONAL
AYURVEDIC MEDICAL
JOURNAL

IAMJ

International Ayurvedic Medical Journal, (*ISSN: 2320 5091)* (September, 2017) 5(9)

A CLINICAL STUDY TO EVALUATE THE EFFICACY OF PALASHAPUSHPAKWATHA IN MADHUMEHA W.S.R TO TYPE-2 DM

Roopa Rani Halder[1], K.N Rajashekhar[2]

Post Graduate student[1], Professor[2]
Department of Kayachikitsa, Alva's Ayurveda Medical College, Moodbidri-574227,
Dakshina Kannada (Dist), Karnataka, India

Email: roopahalder13@gmail.com

ABSTRACT

Madhumeha which is a variety of *Vataja Prameha* is one among the *Ashtamahagadas* and it is caused basically due to the vitiation of *vatakaphapradhana Tridosha* associated with *Medas* and other *Dushyas* along with *Ojas* and leads to *Mutravaha Srotodushti* and manifests various *lakshanas. Avaranajanya Madhumeha* which has been described in *Ayurveda* has similarity with Type-2 Diabetes Mellitus. **Objective:** To evaluate the efficacy of *Palashapushpa Kwatha* in the treatment of *Madhumeha* w.s.r to Type-2 DM., **Methods:** 20 patients fulfilling the diagnostic and inclusion criteria belonging to either sex were selected for this Single Group clinical study, *Palashapushpa Kwatha* was given 30 ml twice before food with *Sukhoshnajala* as *Anupana* for 30 days and Patients were assessed clinically before treatment, on 10th day, 20th day during treatment and 31st day (next day after stopping the treatment) by adopting a suitable scoring method. **Results:** The statistical analysis over the effect of *Palashapushpa Kwatha* after 10, 20 and 30 days of treatment period was calculated using Paired Student 't' test. *Palashapushpa Kwatha* showed significant reduction in 6 out of 7 *Lakshanas* (clinical parameters) and not much difference was seen in FBS and PPBS values statistically. The test of significance showed that the group has significant effect statistically in relieving the clinical symptoms but has insignificant results in reducing blood glucose levels. **Conclusion:** The impact of treatment in every trial patient was analyzed carefully and the overall result obtained is presented in terms of the degree of response of the disease. It can be concluded that *Palashapushpa Kwatha* has significant effect in reducing Clinical symptoms of *Madhumeha* but is statistically insignificant in bringing glycemic control.

Keywords: *Madhumeha*, Diabetes Mellitus, *Palashapushpa Kwatha.*

INTRODUCTION

Madhumeha is one of the *'Ashta Mahagada'* and involves maximum number of *Srotas* and vitiates almost all the *Dhatus* and also *Ojas*. Acharya Vagbhata classifies *Madhumeha* into two categories i.e. *Dhathukshayajanya* and *Avaranajanya*. In *AvaranajanyaPrameha, Kapha* is the predominant *Dosha* while the important *Dushyas* are *Meda* and *Kleda*. The vitiated *Kapha* and *Pitta* obstruct the path of *Vata* causing its aggravation. Acharya Charaka has classified *Prameha* into two types i.e *Sthula Prameha* and *Krusha Prameha* which can be correlated to *Avaranajanya* and *Dhatukshayajanya* respectively. Present study is emphasizing more on *Avaranajanya Madhumeha.* It becomes *Asadhya* as the disease attains chronicity. Therefore, timely intervention with *Oushadha, Pathya* and *Vyayama* is highly essential for a better quality of life.

The description of *Madhumeha* has startling similarities with Diabetes Mellitus in almost all the aspects. Diabetes mellitus is a major public health challenge of the twenty-first century. Diabetes mellitus is a clinical syndrome characterized by hyperglycemia either due to absolute or relative lack of insulin. The global burden due to diabetes is mostly contributed by Type-2 diabetes which constitutes 80% to 95% of the total diabetic population. The estimate is by the International Diabetes Federation (IDF) shows that 285 million adults (20 years to 79 years) were affected by the disorder in 2010. Epidemiological trends indicate that without proper control and prevention, its prevalence will increase further to 438 million in 2030. Nearly 70% of the people with diabetes live in developing countries; the largest numbers are in Indian subcontinent and China. In spite of tremendous advancement of modern medicine i.e. oral hypoglycemic agents and insulin, they are not free from serious side effects and are unable to prevent long term complications.

Taking all these facts into consideration, there is a need for certain preparations and formulations which are effective, have minimal adverse effects, easily available and which can benefit the community at large. This study focuses on assessing the effect of *Palashapushpa kwatha* in *Madhumeha* w.s.r to Type-2 DM. *Palashapushpa Kwatha* is a single drug formulation containing *Palashapushpa* and its *phalashruthi* mentions it to be very effective in all types of *Prameha* including *Madhumeha.* Hence this formulation was selected for the clinical study and an attempt is made to evaluate its efficacy in the management of *Madhumeha*.

MATERIALS AND METHODS

Formulation used for the study: *Palashapushpa Kwatha*

- ***PalashapushpaKwatha***

Ingredients:

1. *Palashapushpa* - 5 Kg, 2. *Jala*-40 litres

Method of Medicine preparation:

The *Kwatha* was made in two batches. The dried flowers of *Palasha* measuring 5 Kg was taken to which 40 litres of water was added and was heated on *Mandagni* i.e mild fire. It was then subjected to fire until it reduced to 1/4th of the total quantity. The *kwatha* thus prepared was filtered using a cloth and was collected in a clean sterile container. After cooling, it was preserved by adding Sodium Benzoate powder and the *Kwatha* was filled in bottles of 400 ml and sealed.

Study Design: Single Group clinical study

Photograph: Preparation of Kashaya

SOURCE OF DATA:

1. Pharmaceutical Source:

The formulation *Palashapushpa Kwatha* was prepared in the *Rasa Shastra* and *Bhaishajya-Kalpana* Laboratory of Alva's Ayurveda Medical College.

2. Clinical Source: Patients were diagnosed and selected from Kayachikitsa OPD of Alva's Ayurveda medical college &hospital, *Moodbidri*.

1. Patients diagnosed as *Madhumeha* according to classical signs and symptoms.
2. Patients fulfilling the diagnostic and inclusion criteria irrespective of sex, religion, caste, educational status and socio-economic status were selected for the study.
3. Patients willing to participate were selected after explaining them the intention of the study in detail.

Diagnostic criteria: The patients were diagnosed based on :

- The *Pratyatma lakshana* of *madhumeha* mentioned in the classical literature.
- *Tanu Madhuryata*- with (FBS) and (PPBS) mild and moderate value.

Inclusion criteria:

- Patient aged above 20 years, of both the genders fulfilling the diagnostic criteria with the *lakshanas* of *Madhumeha* were selected for the study.
- Mild and Moderate Type-2 Diabetes Mellitus cases were selected for the study

Exclusion criteria:

- Patients with severe grade blood glucose levels.
- Patients with complications of Diabetes mellitus were excluded from the study.
- Gestational diabetics and patients with Insulin Dependent Diabetes Mellitus (Type 1) were excluded from the study.
- Diabetics with any other endocrinal disorders were excluded from the study.
- Patients suffering from any other systemic disorders, which may interfere with the study, were excluded.

Intervention:

The intervention of clinical study was carried according to individual group as mentioned below. This group is assigned as 'A' treated with *Palashapushpa Kwatha.*

Table 1: Intervention

	Group A
Sample Size	20 patients
Drug	*Palashapushpa Kwatha*
Dose	30 ml twice before food
Anupana	*Sukhoshnajala*
Duration	30 days

Treatment period: Patients were assessed clinically before treatment, on 10th day, 20th day during treatment and 31st day (next day after stopping the treatment).

Investigation: Following investigation was carried out before treatment and after treatment to assess the general status of improvement.

- Biochemical examination: FBS and PPBS.

Assessment of Variables: The grading was assigned for the severity of individual symptoms from 0-3.The grading of variables is given along with clinical proforma especially formatted for the study on *Madhumeha*. The severity of each variable ranging from

0-Normal 1-Mild 2-Moderate 3-Severe

Assessment Criteria:

The details of the assessment criteria are as follows:

Table 2: Assessment Criteria and Grading of the Results

1.	*Prabhuta Mutrata* (Polyuria)		
	Frequency in Day time	Frequency at Night	Grade
A	3-5 times	0-1 times	0
B	6-8 times	2-3 times	1
C	9-11 times	4-5 times	2
D	>11times	> 5 times	3
2.	*Aavila Mutrata* (Turbidity)		
A	Crystal clear fluid		0
B	Faintly cloudy/smoky/hazy with slight turbidity		1
C	Turbidity clearly present but news print readable with difficulty through the tube		2
D	Turbidity clearly present & news print is not readable		3
3.	*Kshudhaadhikya* (Polyphagia)		
A	Experiences hunger at next *Annakala* only		0
B	Experiences hunger once in between the *Annakala*		1
C	Experiences hunger twice in between *Annakala*		2
D	Experiences hunger always		3
4.	*Trishnaadhikya* (Polydipsia) Quantity of water intake per day		
A	Experiences thirst 7-9 times/24hours or 1-2 liters		0
B	Experiences thirst 9-11 times /24 hours or 2 liters		1
C	Experiences thirst 11-13 times/24 hours or 3-4 liters		2
D	Experiences thirst >13 times/24 hours or >4 liters		3

5.	*Karapada TalaDaha* (Burning sensation in palms and soles)	
A	Absent	0
B	Not continuous and Occasionally present	1
C	Moderate and Constantly present	2
D	Severe and hampers daily activities	3
6.	*Karapada Suptata* (Numbness in palms and soles)	
A	Absent	0
B	Not continuous and Occasionally present	1
C	Moderate and Constantly present	2
D	Severe and hampers daily activities	3
7.	*Daurbalya* (Debility)	
A	Can do routine work/exercise.	0
B	Can do moderate exercise/routine work.	1
C	Can do mild exercise/less work with difficulty.	2
D	Cannot do even mild exercise/slight work.	3

Table 3: LABORATORY PARAMETERS

1.	Fasting Blood Sugar	Grade
A	<110	0
B	110-126	1
C	127-170	2
D	171-220	3
2.	Post Prandial Blood Sugar	Grade
A	<180	0
B	181-230	1
C	231-280	2
D	281-300	3

OVERALL ASSESSMENT CRITERIA

The Overall effect of treatment in 20 *Madhumeha* patients was assessed considering both clinical parameters and laboratory parameters (FBS and PPBS) in terms of complete remission, marked improvement, moderate improvement, mild improvement, minimal improvement and no improvement by adopting the following criteria and calculated by taking mean percentage of relief in self assessed scoring.

STATISTICAL ANALYSIS:

- Statistical analysis was done using Sigma Stat Version 3.1
- Completed 20 patients were taken for statistical analysis excluding the drop outs. Descriptive Statistical Data which includes Mean, Standard Deviation, Standard Error, t value and P value were calculated for all the variables.
- Paired t test was done for analyzing the significance of each clinical parameters and laboratory parameters (Within the group).

- The obtained results were interpreted in the statistical terms as, *Significant (S)*:P <0.05 *Highly Significant (HS):* P <0.001

RESULTS& DISCUSSION

The statistical analysis over the effect of *Palashapushpa Kwatha* after 10, 20 and 30 days of treatment period was calculated using Paired 't' test. The statistical analysis reports are as follows:

1. EFFECT ON PRABHUTA MUTRATA

Table 4:

Prabhuta mutrata	Mean score				%	S.D	S.E	t value	p value
	BT	DT		BT-AT					
	1.650	DT1	1.6	0.05	3.030	0.681	0.152	1.000	0.330
		DT2	1.55	0.1	6.06	0.686	0.153	1.453	0.163
		AT	1.25	0.4	24.24	0.550	0.123	3.559	=0.002

Statistical analysis of *Palashapushpa Kwatha's* effect on *Prabhuta mutrata* showed insignificant effect (p=0.330) after 10 days of treatment with 3.030% minimal improvement, insignificant effect (p=0.163) after 20 days with 6.06% and significant effect (p=0.002) after 30 days of treatment with 24.24% improvement.

PrabhutaMutrata is due to increase of *Shareera Kleda* and due to *Draveekarana* of all *Dushyas*. The reduction in the symptom by *Palashapushpa Kwatha* is because of its *Grahi* property which does *shoshana* of excessive *kleda* present in the body causing reduction in frequency of micturition.

2. EFFECT ON AAVILA MUTRATA

Table 5:

Aavila Mutrata	Mean score				%	S.D	S.E	t value	p value
	BT	DT		BT-AT					
	0.800	DT1	0.800	0	0	0.616	0.138	0.000	1.000
		DT2	0.800	0	0	0.616	0.138	0.000	1.000
		AT	0.500	0.300	37.5	0.607	0.136	2.854	=0.010

Statistical analysis of *Palashapushpa Kwatha's* effect on *Aavila mutrata* showed insignificant effect (p=1.000) after 10 days of treatment with 0% improvement, insignificant effect (p=1.000) after 20 days with no improvement and significant effect (p=0.010) after 30 days of treatment with 37.5% improvement.

3. EFFECT ON KSHUDHAADHIKYA

Table 6:

Kshudha aadhikya	Mean score				%	S.D	S.E	t value	p value
	BT	DT		BT-AT					
	0.900	DT1	0.900	0	0	0.788	0.176	0.000	1.000
		DT2	0.750	0.150	16.66	0.750	0.176	1.831	0.083
		AT	0.400	0.500	55.55	0.503	0.112	4.359	=<0.001

Statistical analysis of *Palashapushpa Kwatha's* effect on *Kshudhaadhikya* showed insignificant effect (p=1.000) after 10 days of treatment with 0% improvement, insignificant effect (p=0.083) after 20 days with 16.66% improvement and significant effect (p=<0.001) after 30 days of treatment with 55.55% improvement.

Palashapushpa is having *Madhura Rasa, Sheeta Virya* and *Madhura Vipaka* and is *Pittashamaka* by nature. These properties pacify *Teekshna, Ushnagunataha vriddhi* of *Pitta* leading to reduction in *Kshudha.*

4. EFFECT ON TRISHNAADHIKYA

Table 7:

Trishna aadhikya	Mean score				%	S.D	S.E	t value	p value
	BT	DT		BT-AT					
	1.300	DT1	1.300	0	0	0.657	0.147	0.000	1.000
		DT2	1.250	0.0500	3.846	0.639	0.143	1.000	0.330
		AT	0.550	0.750	57.69	0.510	0.114	7.550	=<0.001

Statistical analysis of *Palashapushpa Kwatha's* effect on *Trishnaadhikya* showed insignificant effect (p=1.000) after 10 days of treatment with 0% improvement, insignificant effect (p=0.330) after 20 days with 3.846% improvement and significant effect (p=<0.001) after 30 days of treatment with 57.69% improvement.

Trishnaadhikya is due to *Pitta Vriddhi* leading to *UdakaKshaya*. The reduction in the symptom by *Palashapushpa Kwatha* is due to properties of *Palashapushpa* like *Madhura Rasa, Sheeta virya, Pittahara* and *Trishnashamaka Karma* which pacifies *Pitta*.

5. EFFECT ON DAURBALYA

Table 8:

Daurbalya	Mean score				%	S.D	S.E	t value	p value
	BT	DT		BT-AT					
	1.500	DT1	1.500	0	0	0.761	0.170	0.000	1.000
		DT2	1.400	0.1	6.67	0.681	0.152	1.453	0.163
		AT	0.750	0.750	50	0.639	0.143	7.550	=<0.001

Statistical analysis of *Palashapushpa Kwatha's* effect on *Daurbalya* showed insignificant effect (p=1.000) after 10 days of treatment with 0% improvement, insignificant effect (p=0.163) after 20 days with 6.67% improvement and significant effect (p=<0.001) after 30 days of treatment with 50% improvement. *Palashapushpa* has *Madhura Rasa, Sheeta Virya* and *Madhura Vipaka* which helps in the replenishment of *Ojas* which becomes depleted with disease progression owing to continued exposure of body to vitiated *vata.*

6. EFFECT ON KARA PADATALA DAHA

Table 9:

Kara pada Tala Daha	Mean score				%	S.D	S.E	t value	p value
	BT	DT		BT-AT					
	0.450	DT1	0.450	0	0	0.510	0.114	0.000	1.000
		DT2	0.450	0	0	0.510	0.114	0.000	1.000
		AT	0.350	0.1000	22.22	0.489	0.109	1.453	=0.163

Statistical analysis of *Palashapushpa Kwatha's* effect on *Kara pada tala Daha* showed insignificant effect (p=1.000) after 10 days of treatment with 0% improvement, insignificant effect (p=1.000) after 20 days with 0% improvement and insignificant effect (p=0.163) after 30 days of treatment with 22.22% improvement.

7. EFFECT ON KARA PADATALA SUPTATA

Table 10:

Kara pada Tala Suptata	Mean score				%	S.D	S.E	t value	p value
	BT	DT		BT-AT					
	0.800	DT1	0.800	0	0	0.523	0.117	0.000	1.000
		DT2	0.650	0.150	18.75	0.489	0.109	1.831	0.083
		AT	0.300	0.500	62.5	0.470	0.105	4.359	=<0.001

Statistical analysis of *PalashapushpaKwatha's* effect on *Kara padasuptata* showed insignificant effect (p=1.000) after 10 days of treatment with 0% improvement, insignificant effect (p=0.083) after 20 days with 18.75% improvement and significant effect (p=<0.001) after 30 days of treatment with 62.5% improvement. *PalashapushpaKwatha* has *Vatahara* action which might have resulted in reducing *KarapadaSuptata.*

8. A) EFFECT ON TANU MADHURYATA-FBS

Table 11:

Tanu Madhuryata (FBS)	Mean score			%	S.D	S.E	t value	p value
	BT	AT	BT-AT					
	155.785	145.895	9.890	6.348	0.620	0.125	1.37	>0.05

Tanu Madhuryata (PPBS)	Mean score			%	S.D	S.E	t value	p value
	BT	AT	BT-AT					
	231.525	221.865	9.660	4.172	0.738	0.143	1.000	>0.05

Statistical analysis of *Palashapushpa Kwatha's* effect on *Tanu Madhuryata*-FBS showed insignificant effect (p=0.073) after 30 days of treatment with 6.348% improvement whereas on-PPBS, it showed insignificant effect (p=0.052) after 30 days of treatment with 4.172% improvement. This little reduction in blood glucose level may be because of the improvement in the insulin mediated suppression of hepatic gluconeogenesis and also the main ingredient of the formulation *Palashapushpa* has significant effect in improving glucose tolerance and causing reduction in blood glucose level.

OVERALL ASSESSMENT OF CLINICAL PARAMETERS

Table No 13:

Improvement	Group A	%
No relief (=0%)	0	0
Minimal relief (1-25%)	2	10
Mild relief (26-50%)	15	75
Moderate relief (51-75%)	2	10
Marked relief (76-99%)	1	5
Complete Remission(=100%)	0	0

After 30 days of Treatment Period, Mild improvement was seen in the condition of 15 patients (75%), Moderate relief was seen in 2 patients (10%), marked relief was found in 1 patients (5%) and Minimal relief was found in 2 patients (10%) and complete remission was not observed in any patients. After considering Overall assessment, it can be inferred that *Palashapushpa Kwatha* has significant effect in reducing the clinical symptoms.

DISCUSSION ON PROBABLE MODE OF ACTION:

Palshapushpa Kwatha- It is a single drug formulation which has *Palshapushpa* as the main ingredient. *Madhumeha* is a *Kaphavatapradhana Tridoshaja Vyadhi. Palshapushpa* has *Kaphahara, Pittahara* and *Vatahara* action. So, it has effect on all the *Doshas* and the symptoms manifested as a result of these vitiated *Tridoshas*. It also has attributes like *Trishnashamaka, Grahi* and *Dahaprashamana* and has *Laghu, Rukshagunas* which acts on various symptoms manifested due to the impairment of *doshas, dhatus* and *malas* in individuals suffering with *Madhumeha.* Obstruction of *Vata* by *Kapha* and *Medas* occurs in the *Samprapti* as *Kapha* is the *aarambhaka dosha* and *Vata* is *preraka dosha*. *Laghu* and *Ruksha guna* by virtue of their *Kaphaghna* and *Medoghnaprabhava* helps in reducing tissue weight.

CONCLUSION

Literary contrive reveals that major etiological factors are *Kapha, Meda, MutraVardhaka Ahara* and *Vihara*. Tendency towards sedentary life style and faulty dietary habits leads to vitiation of *Kapha* and *Meda* leading to *Madhumeha*.

The mode of treatment for *Apathyanimittaja Madhumeha* should be *Kaphahara, Medohara, Apatharpanakaraka* and *Kleda Nashaka*. *Palashapushpa Kwatha* has *Madhura, Katu, Tikta, Kashaya rasa. Laghu, Rukshaguna* and *Sheeta Virya*. Having specific *Karma*s like *Trishnashamaka, Grahi, Kaphahara, Pittahara, Vatahara, Dahaprashamana.* These properties help in the removal of *Kapha Avarana* of *vata* and pacify the *Dushyas* like *Meda* and *Kleda*. Hence helpful in the *Samprapti Vighatana* of *Madhumeha*.

PalashapushpaKwatha showed significant reduction in 6 out of 7 *Lakshanas* (clinical parameters) and no much difference in FBS and PPBS values statistically. Significant results found in the *lakshanas* like- *PrabhutaMutrata, Aavila Mutrata, Kshudhaadhikyata, Trishnaadhikyata, Karapada Suptata, Daurbalya.* Insignificant results found in the *lakshanas* like- *Karapada tala Daha.*

Though *Palashapushpa Kwatha* had no significant effect in bringing Glycemic control

but it was found in the study that it was very effective in reducing the clinical symptoms of *Madhumeha*. This study was an attempt to evaluate an effective single drug formulation for *Madhumeha* which could benefit the mankind.

REFERENCES

1. Munjal YP. API Text book of medicine. 10th ed. New Delhi: Jaypee brothers medical publishers (p) Ltd; 2015.Vol.1 P..458.
2. Acharya JadavjiTrikamji, editor, (1st ed.). Commentary Ayurveda Dipika of Chakrapanidatta on Charaka Samhita of Agnivesa, Nidanasthana; PramehaNidana: Chapter 4, Shloka 44. Varanasi: Chaukhambha Publications, 2014; P.215.
3. Yoga ratnakara, first edition,Uttaraardha Volume-2, Published by ChowkhambaOrientalia, Varanasi, Shloka 72, 2008; P.792.
4. Virendra KS. Diabetes mellitus in Indian medicine. 1st ed. Varanasi: Chowkhambhaorientalia; 2009.P.31
5. www.who.int/
6. Acharya JadavjiTrikamji, editor, (1st ed.). Commentary Ayurveda Dipika of Chakrapanidatta on Charaka Samhita of Agnivesa, Chikitsasthana; PramehaChikitsaadhyaya: Chapter 6, Varanasi: Chaukhambha Publications, 2014;P. 445.
7. www.ejpmr.com/admin/assets/article_issue/1490957726
8. Paradakara HS, editor, (1st ed.). Commentary SarvangaSundara of Arunadatta on AstangaHrdayam of Vagbhata, Nidanasthana; PramehaNidana: Chapter 10, Shloka 1-3. Varanasi; ChaukhambhaSurbharatiPrakashan, 2010; P.502.
9. The Ayurvedic Pharmacopoeia of India, Department of Ayush, Government of India, Volume 4, Part 1, P. 88-89.
10. Acharya JadavjiTrikamji, editor, (1st ed.). Commentary Nibandhasangraha of Dalhana on Sushruta Samhita of Sushruta, Nidanasthana; PramehaNidana: Chapter 6. Varanasi: Chaukhambha Sanskrit Samsthana, 2010; P.290

Source of Support: Nil
Conflict Of Interest: None Declared

How to cite this URL: Roopa Rani Halder & K.N Rajashekhar: A Clinical Study To Evaluate The Efficacy Of Palashapushpa Kwatha In Madhumeha W.S.R To Type-2 Dm. International Ayurvedic Medical Journal {online} 2017 {cited September, 2017} Available from: http://www.iamj.in/posts/images/upload/3330_3339.pdf