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AN OPEN LABEL SINGLE ARM CLINICAL STUDY TO EVALUATE THE EFFICACY OF DARVYADI CHURNA PRAYOGA IN THE MANAGEMENT OF PRAMEHA (TYPE 2 DIABETES MELLITUS)

Dr. Anjan Saloi[1]*, Dr. Bhagyesha K.[2] and Dr. Anush N.[3]

[1]Post Graduate Scholar, Department of Kayachikitsa, KVG Ayurvedic Medical College and Hospital, Sullya-574239.
[2]Professor and HOD, Department of Kayachikitsa, KVG Ayurvedic Medical College and Hospital, Sullya-574239.
[3]Post Graduate Scholar, Department of Kayachikitsa, Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Hassan-573201.

***Corresponding Author: Dr. Anjan Saloi**

Post Graduate Scholar, Department of Kayachikitsa, KVG Ayurvedic Medical College and Hospital, Sullya-574239.

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ABSTRACT

Background: The prevalence of diabetes has surged dramatically since the early 2000s, primarily due to rising obesity rates and sedentary lifestyles. According to the latest 2021 data from the IDF Diabetes Atlas (10th edition), approximately 537 million adults are currently affected by diabetes, with projections estimating this number will increase to 643 million by 2030 and 783 million by 2045. India is expected to have around 109 million individuals with diabetes mellitus (DM) by 2035, with type 2 diabetes (DM2) constituting nearly 90% of all cases. Thus, Darvyadi Churna with warm water for 30 days was selected for the study. **Objective:** To study the efficacy of Darvyadi Churna in the management of Prameha (Type 2 DM) **Methodology:** Among the 35 registered subjects 30 completed the course of treatment. They were administered with Darvyadi Churna 3gms once a day in morning on empty stomach with warm water for a period of 30 days. Subjective Parameters were analysed using paired sample t test. **Result:** Among 35 registered subjects, 30 completed the trial. After 30 days of intervention, significant improvements were observed in fasting blood sugar (FBS) (34.9% reduction, $p<0.0001$) and postprandial blood sugar (PPBS) (31.7% reduction, $p<0.0001$). The results suggest that Darvyadi Churna is an effective Ayurvedic intervention for managing Prameha and its associated symptoms. **Conclusion:** Darvyadi Churna is effective in the management of Prameha (Type 2 DM).

KEYWORDS: Prameha, Type 2 DM, Darvyadi Churna.

INTRODUCTION

Type 2 diabetes is a chronic metabolic disorder resulting from disruptions in glucose, fat, and protein metabolism. Its growing prevalence is linked to factors such as aging, genetic predisposition, obesity, urbanization, lower socioeconomic status, high-calorie diets, and inadequate physical activity. The worldwide rise in Type 2 diabetes has become a major public health concern. Clinically, it presents with symptoms such as frequent urination, excessive thirst, increased appetite, tingling sensations, unexplained weight loss, and fatigue, often accompanied by glucose in the urine. The causes and clinical features of diabetes mellitus closely resemble those of *Madhumeha*. Since the early 2000s, the prevalence of diabetes has increased significantly, largely due to rising obesity rates and increasingly sedentary lifestyles. According to the latest 2021 data from the IDF Diabetes Atlas (10th edition), an estimated 537 million adults worldwide are affected by diabetes. This number is projected to rise to 643 million by 2030 and 783 million by 2045. In India alone, approximately 109 million people are expected to have diabetes mellitus (DM) by 2035, with type 2 diabetes (DM2) accounting for nearly 90% of all cases.[1]

Darvyadi Churna, when combined with *Gomutra*, is traditionally used in the management of *Prameha*. This formulation consists of six key ingredients: *Daruharidra*, *Kalinga*, *Katuka*, *Ativisha*, *Chitrakamula*, and *Patha*. These herbs predominantly possess *Katu-Tikta rasa* (pungent and bitter taste), *Ushna veerya* (hot potency, except for *Katuka*), and *Katu vipaka* (pungent metabolic transformation), making them highly effective in reducing *Kapha dosha*.

Since Prameha is primarily a *Kapha-dominant* disorder, these properties help in breaking down its *samprapti* (pathogenesis) by restoring the balance of doshas. Their deepana (digestive stimulant), pachana (carminative), and medohara (fat-reducing) actions contribute to

managing Prameha by improving metabolism, reducing excess meda (fat), and promoting proper digestion and elimination of toxins. Hence, Darvyadi Churna, along with Gomutra, plays a significant role in both the prevention and treatment of Prameha.

Method of collection of data: Data was collected using specially prepared case report form.

a) Screening of the patient: A screening form was prepared with all the aspects of history, signs, and symptoms of *Prameha* (Type 2 DM)

b) Diagnostic criteria

- Diagnosis will be made on the basis of classical *Lakshanas* of *Prameha* mentioned in Ayurveda classics.

c) Inclusion criteria

- Subjects exhibiting classical signs and symptoms of *Prameha* as described in Ayurvedic texts.
- Subjects aged between **30 to 70 years**, irrespective of gender.
- Those with stable systemic functions, without severe cardiac, hepatic, or renal impairment.
- Subjects willing to comply with the study protocol and follow-up assessments.

d) Exclusion criteria

- Subjects with *Prameha* accompanied by *Pidaka* and other complications as described in classical texts.
- Any systemic disease with impaired cardiac, hepatic and renal functions that may interfere with the course of treatment.
- Subjects who are dependent on insulin and other hypoglycemic drugs.

Sampling Technique: Convenient Sampling
Sample Size: 30
Statistical Tests: Paired Sample t Test for subjective parameters.

Ethical Clearance: The ethics clearance certificate from the Institutional Ethics Committee of KVG Ayurvedic Medical College and Hospital, Sullya was obtained.

INTERVENTION

Darvyadi Churna

SR.NO.	*SANSKRIT NAME*	BOTANICAL NAME	PROPORTION
01	*Daruharidra*	Berberis aristata	1 part
02	*Kalinga*	Caesalpinia bonducella	1 part
03	*Katuka*	Picorrhiza kurroa	1 part
04	*Ativisha*	Aconitum heterophyllum	1 part
05	*Chitrakamula*	Plumbago zeylanica	1 part
06	*Patha*	Cyclea peltata	1 part
07	*Gomutra*	Cows's urine	Q.S

- Dose –3gm
- Anupana- Ushna Jala
- Time of administration – Abhaktam (Morning on empty stomach)
- Duration of intervention – 30 days.
- Follow up period – 7 days.
- Total duration of study – 37 days

Source of medicine and authentication: Raw drug was procured from the vendor and authenticated at *Dravya Guna* department at KVG Ayurvedic Medical college and Hospital, Sullya.

Assessment Criteria

Clinical Parameters

1) Prabhoota mutrata

Frequency (Day time)	Frequency (Night time)	
3-5 times/day	0-1 times/day	0
6-8 times/day	2-3 times/day	1
9-11times/day	4-5times/day	2
>11times/day	>5times	3

2) Avila mutrata

Crystal clear fluid	0
Faintly cloudy/hazy with slight turbidity	1
Turbidity clearly present but news print readable with difficulty through the tube	2
Turbidity clearly present & news print is not readable	3

3) Kara pada Daha

Absent	0
Occasionally mildly present	1
Constantly mildly present	2
Severely present	3

4) Kara pada suptata

Absent	0
Occasionally mildly present	1
Constantly mildly present	2
Severely present	3

5) Kshudhadikya

Feels hunger for next annakala only	0
Feels hunger for once in between annakala	1
Feels hunger twice in between annakala	2
Feels hunger always	3

6) Pipasaadhikya

Feeling of thirst 7-9 times/24hrs or 1-2 ltrs	0
9-11 times/24hrs or 2-4 ltrs	1
11-13 times/24hrs or 3-4ltrs	2
>13 times or >4ltrs	3

7) Angasaada

Can do normal work	0
Can do normal with difficulty	1
Can do only mild work	2
Can do mild work with difficulty	3
Unable to do even mild work	4

8) Atinidra

6-7 hrs sleep/day& night and performs work with normal enthusiasm	0
6-7 hrs sleep/day & night-feels drowsiness and lazy to do normal work	1
8-9 hrs sleep/day & night-feels drowsiness and lazy to do normal work	2
>10 hrs sleep/day & night-feels drowsiness and lazy to do normal work	3

9) Urine Sugar

Blue Colour	0
Green Colour	1
Brown colour	2
Yellow Orange	3
Brick Red	4

Showing Assessment Of Total Effect

Total Effect	Relief in %
Gunaalaba (Unchanged)	≤25% or no relief
KinchithShamana (Mild Improvement)	25 to 50%
AnshikaShamana (Moderate Improvement)	50 to 75 %
PrayikaShamana (Marked Improvement)	≥75%
Shamana (Complete Remission)	100%

OBSERVATIONS

Distributions of patients according to sex

SEX	NO. OF PATIENTS	% OF PATIENTS
MALE	16	53.33%
FEMALE	14	46.66%

Showing distribution of 30 patients of *Prameha* according to Age

AGE GROUP (YEARS)	NO. OF PATIENTS	% OF TOTAL PATIENTS
31-40	11	36.66%
41-50	6	20%
51-60	4	13.33%
61-70	9	30%

Showing distribution of 30 patients of *Prameha* based on chronicity

CHRONICITY	NO. OF PATIENTS	% OF PATIENTS
LESS THAN 6 MONTHS	3	10%
6 MONTHS TO 1 YEAR	6	20%
MORE THAN 1 YEAR	21	70%

Showing distribution of 30 patients of *Prameha* based on *Prakruthi*

PRAKRUTHI	NO. OF PATIENTS	% OF PATIENTS
VATAKAPHA	5	16.67%
VATAPITTA	2	6.66%
PITTAVATA	2	6.66%
PITTAKAPHA	6	20%
KAPHAVATA	9	30%
KAPHAPITTA	4	13.33%

Showing distribution of 30 patients of Prameha based on Doshadhikatya

DOSHADHIKYA	NO. OF PATIENTS	% OF PATIENTS
KAPHAADHIKATYA	19	63.33%
VATADHIKYA	4	13.33%
PITTADHIKYA	7	23%

RESULTS

Showing effect of *Darvyadi choorna* on *Prabhoota mutrata*

Roopa	MEAN SCORES					%	S.D (±)	S.E (±)	t VALUE	p VALUE
	BT									
Prabhoota Mutrata	1.17	**AT**	0.57	**BT-AT**	0.60	51.8%	0.50	0.09	6.5955	< 0.0001
		AF	0.51	**BT-AF**	0.70	59.8%	0.51	0.10	8.2260	< 0.0001

Showing effect of *Darvyadi choorna* on *Avila mutrata*

Roopa	MEAN SCORES					%	S.D (±)	S.E (±)	t VALUE	p VALUE
	BT									
Avila	1.27	**AT**	0.63	**BT-AT**	0.63	49.6%	0.49	0.09	6.238	< 0.0001
Mutrata		**AF**	0.50	**BT-AF**	0.77	60.6%	0.51	0.09	7.388	< 0.0001

Showing effect of *Darvyadi choorna* on *Kara Pada Daha*

Roopa	MEAN SCORES					%	S.D (±)	S.E (±)	t VALUE	p VALUE
	BT									
Karapada	0.90	**AT**	0.53	**BT-AT**	0.37	41.1%	0.571	0.10	4.0975	< 0.0001
Daha		**AF**	0.37	**BT-AF**	0.53	58.8%	0.561	0.10	5.7570	< 0.0001

Showing effect of *Darvyadi choorna* on *Kara Pada Suptata*

Roopa	MEAN SCORES					%	S.D (±)	S.E (±)	t VALUE	p VALUE
	BT									
Karapada	0.87	**AT**	0.33	**BT-AT**	0.53	60.9%	0.55	0.10	5.1128	< 0.0001
Suptata		**AF**	0.30	**BT-AF**	0.57	65.5%	0.47	0.09	5.4613	< 0.0001

Showing effect of *Darvyadi choorna* on *Kshudhadhikya*

Roopa	MEAN SCORES					%	S.D (±)	S.E (±)	t VALUE	p VALUE
	BT									
Kshudhadhikya	2.03	**AT**	1.33	**BT-AT**	0.70	34.9%	0.61	0.11	7.1667	< 0.0001
		AF	1.17	**BT-AF**	0.86	42.36%	0.59	0.11	7.7088	< 0.0001

Showing effect of *Darvyadi choorna* on *Pipasaadhikya*

Roopa	MEAN SCORES					%	S.D (±)	S.E (±)	t VALUE	p VALUE
	BT									
Pipasa Adhikya	1.57	AT	0.90	BT-AT	0.67	42.6%	0.55	0.10	5.5251	< 0.0001
		AF	0.77	BT-AF	0.80	50.9%	0.57	0.10	5.757	< 0.0001

Showing effect of *Darvyadi choorna* on *Angasaada*

Roopa	MEAN SCORES					%	S.D (±)	S.E (±)	t VALUE	p VALUE
	BT									
Angasada	1.67	AT	0.97	BT-AT	0.70	42.6%	0.76	0.14	5.8872	< 0.0001
		AF	0.83	BT-AF	0.83	49.7%	0.70	0.13	6.1132	< 0.0001

Showing effect of *Darvyadi choorna* on *Atinidra*

Roopa	MEAN SCORES					%	S.D (±)	S.E (±)	t VALUE	p VALUE
	BT									
Atinidra	1.80	AT	1.10	BT-AT	0.70	38.8%	0.58	0.11	6.4334	< 0.0001
		AF	1.07	BT-AF	0.73	42.6%	0.63	0.13	8.5105	< 0.0001

Showing effect of *Darvyadi choorna* on FBS

Roopa	MEAN SCORES					%	S.D (±)	S.E (±)	t VALUE	p VALUE
	BT									
FBS	217.29	AT	144	BT-AT	73.2	33.7%	42.2	7.72	12.343	< 0.0001
		AF	141	BT-AF	75.8	34.9%	36.6	6.69	11.270	< 0.0001

Showing effect of *Darvyadi choorna* on PPBS

Roopa	MEAN SCORES					%	S.D (±)	S.E (±)	t VALUE	p VALUE
	BT									
PPBS	296.3	AT	205	BT-AT	90.6	30.7%	48.7	8.91	13.216	< 0.0001
		AF	202	BT-AF	94.3	31.7%	48.6	8.88	13.341	< 0.0001

Showing effect of *Darvyadi choorna* on Urine sugar

Roopa	MEAN SCORES					%	S.D (±)	S.E (±)	t VALUE	p VALUE
	BT									
Urine Sugar	1.37	AT	0.93	BT-AT	0.43	31.3%	0.37	0.07	4.1763	< 0.0001
		AF	0.90	BT-AF	0.47	34.3%	0.40	0.07	4.4737	< 0.0001

DISCUSSION

A clinical study on 30 patients with *Prameha* evaluated the effects of treatment on various symptoms (*Lakshanas*) using statistical analysis. The results showed significant improvements across all parameters ($P < 0.0001$).

- **Prabhoota Mutrata (Excessive Urination):** Improved by **59.8%** after follow-up.
- **Avila Mutrata (Turbid Urine):** Improved by **60.6%** after follow-up.
- **Kara Pada Daha (Burning Sensation in Hands & Feet):** Improved by **58.8%** after follow-up.
- **Kara Pada Suptata (Numbness in Hands & Feet):** Improved by **65.5%** after follow-up.
- **Kshudhadhikya (Excessive Hunger):** Improved by **42.36%** after follow-up.
- **Pipasaadhikya (Excessive Thirst):** Improved by **50.9%** after follow-up.
- **Angasaada (Body Fatigue & Weakness):** Improved by **49.7%** after follow-up.
- **Atinidra (Excessive Sleepiness):** Improved by **42.6%** after follow-up.
- **FBS (Fasting Blood Sugar):** Reduced from **217.29** to **141**, showing **34.9%** improvement.
- **PPBS (Postprandial Blood Sugar):** Reduced from **296.3** to **202**, showing **31.7%** improvement.
- **Urine Sugar Levels:** Reduced from **1.37** to **0.90**, showing **34.3%** improvement.

The study demonstrated highly significant reductions in diabetic symptoms and biomarkers, indicating the effectiveness of the treatment.

PROBABLE MODE OF ACTION

In Ayurveda, the mode of action of a single drug can be explained based on its *Rasa* (taste), *Guna* (qualities), *Veerya* (potency), and *Vipaka* (post-digestive effect). However, understanding the precise mechanism of a compound formulation (*Yoga*) through these parameters is more complex. As Chakrapani states, only highly knowledgeable sages can fully elucidate the specific actions of such formulations. The fundamental goal of any treatment is to disrupt the *Samprapti* (pathogenesis) and restore balance between *Dosha* and *Dushya*. In this

context, a sincere effort is made to comprehend the probable mode of action of *Darvyadi Churna*.

- All the ingredients of *Darvyadi Churna* primarily exhibit *Katu-Tikta Rasa* (pungent and bitter taste), *Ushna Veerya* (hot potency, except Katuka), *Katu Vipaka* (pungent metabolic effect), and *Kaphahara* (Kapha-reducing) properties.[2]
- The *Katu* (pungent) and *Tikta* (bitter) *Rasa* act as *Kleda Soshana* (moisture absorbents), *Mutra Sangrahi* (urine regulators), and contribute to *Kapha-Meda Soshana* (reduction of Kapha and fat).[3]
- The *Laghu* (light) and *Ruksha* (dry) qualities facilitate the elimination of excess *Kleda* (moisture) and counteract the *Madhura-Snigdhata* (sweetness and unctuousness) associated with *Madhumeha* (diabetes).[4,5]
- *Katu Vipaka* aids in reducing *Kapha* and promoting *Meda Soshana* (fat metabolism).
- The *Deepana* (digestive stimulant), *Pachana* (carminative), and *Kapha-Meda Hara* (Kapha and fat-reducing) properties enhance *Jatharagni* (digestive fire) and *Meda Dhatvagni* (fat metabolism), preventing the formation of *Ama* (toxins) and abnormal *Dhatus* (tissues).[6,7]
- **Daruharidra** contains *berberine*, which helps lower blood sugar levels by mimicking insulin, improving insulin sensitivity, and reducing insulin resistance. It also has antioxidant and anti-inflammatory properties, which may help prevent diabetic complications.[8]
- **Katuka (Picrorhiza kurroa)** contains *picroside-I (P-I)* and *picroside-II (P-II)*, glycosides that inhibit *α-amylase enzyme* activity, reducing carbohydrate breakdown and postprandial glucose levels.[9]
- **Chitrak (Plumbago zeylanica) root** supports diabetes management by lowering blood glucose levels and enhancing insulin secretion due to its anti-diabetic and antioxidant properties.[10]
- **Ativisha (Aconitum heterophyllum)** contains active compounds such as *aconitine*, *heteratisine*, and *atisine*, which have anti-inflammatory and analgesic properties, potentially supporting diabetes treatment.[11]
- **Cyclea peltata root** possesses antidiabetic properties due to alkaloids such as *tetrandrine*, *fangchinoline*, and *cycleanorine*, which contribute to its pharmacological benefits.
- **Gomutra (Cow urine)** contains *urea* and *creatinine*, which may aid metabolic processes and improve insulin sensitivity. Additionally, it provides essential minerals like *potassium* and *calcium*, which support overall metabolic health.
- Collectively, all these ingredients contribute to lowering blood sugar levels and enhancing insulin sensitivity.

Thus, *Darvyadi Churna* plays a significant role in *Samprapti Vighatana* (disrupting the pathogenesis) of *Prameha*, making it an effective formulation for its management.

CONCLUSION

Darvyadi Churna, with its *Katu-Tikta Rasa*, *Ushna Veerya*, and *Kaphahara* properties, plays a vital role in disrupting the *Samprapti* of *Prameha*. Its ingredients enhance *Agni*, regulate metabolism, reduce *Kapha* and *Meda*, and improve insulin sensitivity. The bioactive compounds in its herbs exhibit antidiabetic, anti-inflammatory, and antioxidant effects, making it an effective formulation for managing *Prameha* (Type 2 Diabetes Mellitus) and preventing its complications.

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