

Clinical study of add on effect of *Triphaladaruadi Kwatha* (*Vangsenokta*) along with antidiabetic drug in management of *Prameha* (Non-Insulin Dependent Diabetes mellitus- NIDDM)

Research Article

Abhilasha C Lagad^{1,2*}, Vishwas E Gogate³, Almas Y Khan⁴, Pooja S Kombe^{1,2}, Pallavi N Mane^{1,2}, Abhijit Shekhar^{1,3}

1. Ph.D.Scholar, 2. Assistant Professor, 3. Associate Professor, 4. Assistant Professor, Department in Kayachikitsa, Dr.D.Y.Patil College of Ayurved and Research Centre Pimpri, Pune -18 (Maharashtra) India.
Dr. D.Y. Patil Vidyapeeth, Pune (Deemed to be University) Pune. Maharashtra. India.
3. Associate Professor, Department of Kayachikitsa, Government College of Ayurved, Nanded (Maharashtra) India.

Abstract

Prameha (Diabetes mellitus) is an age long disease known from *vedic* period and now it is a leading lifestyle disorder. Diabetes mellitus is a group of metabolic syndromes of fat, protein and carbohydrate which is due to absolute or relative deficiency of insulin. The prevalence of diabetes in India has risen from 7.1% in 2009 to 8.9% in 2019. The estimates in 2019 showed that 77 million individuals had diabetes in India, which is expected to rise to over 134 million by 2045.² In India, it is also 3rd leading cause of death (After heart disease and cancer). The number is projected to be twice by 2030. Type 2 diabetes makes up about 85-90% of all cases. Increase in the overall diabetes prevalence rates largely reflect an increase in risk factors for type 2, notably greater longevity and being overweight or obese. Hence preventive measures are essential and an ideal therapy is still obscure. It remains one of the baffling enigmas for clinical research. This is a randomized single blind standard controlled clinical trial conducted on 66 patients of *Prameha* (Type II DM & who are on antidiabetic treatment) to rule out Add on effect of *Triphaladaruadi kwath* of either gender between age group of 40-60 years and grouped into Group A & Group B. 33 patients in group A were on Antidiabetic drug (Metformin 500mg OD/BD) and 33 patients in Group B are on same antidiabetic drug (Metformin 500mg OD/BD) with additional *Triphaladaruadi kwath* (Decoction) for 3 months. Results obtained in subjective and objective parameters were analyzed for the statistical significance by adapting paired 't' test in the groups, Two-way ANOVA test between the groups, and Wilcoxon rank sum test. The study revealed that Group B was found to be more effective in bringing symptomatic relief and improving biochemical markers in the patients of *Prameha*.

Keywords: *Prameha*, Type 2 Diabetes Mellitus, *Triphaladaruadi Kwath*, Antidiabetic drug, Hypoglycemia.

Introduction

The pathogenesis of *Prameha* is described on the basis of *Dosha-Dhatu-Mala* theory. Early stage of the disease manifests clinically due to the variation of *Kapha* predominantly. *Prameha* is included in the category of '*Maharoga*', which consist of the most fatal conditions that are incurable. The classical texts of Ayurveda-*Charak samhita*, *Sushrut samhita* & *Ashtanghriday Samhita* mention the 20 subtypes of *Prameha* (3). Global access of Diabetes is increasing. Diabetes Mellitus is a metabolic cum vascular syndrome of multiple aetiologies characterized by chronic hyperglycemia with disturbances of carbohydrates, fat and protein metabolism resulting from defects in Insulin

secretion, Insulin action, or both leading to microangiopathy and macroangiopathy (4, 5). Various Oral hypoglycemic agents, Insulin formulations, Life style modification plans, consisting dietary management and exercise, are some of the important efforts towards the management of Diabetes.⁶ In spite of these, world is seeking for a safer and effective remedy. Increased side effects, lack of effective treatment for complications, high cost of new drugs and resistance to the drugs are some reasons for renewed public interest in Ayurvedic medicines. Several diseases of polyuria nature were described in Ayurveda. collectively called *Prameha*. *Prameha* includes an entity called *Madhumeha* (Hyperglycemia). which is equivalent to diabetes mellitus. Reduced insulin production and decreased insulin sensitivity are the contributing factors for Hyperglycaemia. The ayurvedic management of diabetes aims not only to achieve a strict glycemic control but also to treat the root cause of the disease. Many drugs and formulae prescribed for internal and external use in *Ayurveda Samhitas*, one of which is "*Triphaladaruadi kwatha*" (Decoction).

* Corresponding Author:

Abhilasha C Lagad

Assistant Professor and Ph.D.Scholar, Department in Kayachikitsa, Dr.D.Y.Patil College of ayurved and Research Centre Pimpri, Pune -18 (Maharashtra) India. Dr. D.Y. Patil Vidyapeeth, Pune (Deemed to be University) India.
Email Id: lagadabhilasha@gmail.com

Aims and objectives

- To assess add on effect of “Triphaladaruadi kwath” (Decoction) in patients of *Prameha* under treatment of Metformin 500mg OD/BD (antidiabetic drug) between group age of 40-60yr.
- To assess any adverse effect of *Triphaladaruadi Kwatha* (Decoction) in patients of *Prameha* under treatment of Metformin 500mg OD/BD (antidiabetic drug) between group age of 40-60yr.
- To assess the changes in values of BSL Fasting(F) and post prandial (PP) blood sugar levels and HbA1c.

Hypothesis

- **H₀**-Add on effect of *Triphaladaruadi Kwatha* (*Vangsenokta*) along with antidiabetic drug is less effective in Management of *Prameha*.
- **H₁**-Add on effect of *Triphaladaruadi Kwatha* (*Vangsenokta*) along with antidiabetic drug is more effective in Management of *Prameha*.

Materials and Methods

The total 60 patients were enrolled in study on the basis of inclusion criteria and classified into two groups.

Design-This is a randomized single blind standard controlled clinical trial to find add on effect of

Triphaladaruadi kwath (decoction) with Antidiabetic drug Metformin 500mg OD/BD.

Inclusion Criteria

- Age 40-60 yr.
- Patients of NIDDM having symptoms of *Prameha* according to Ayurved.
- Blood Sugar level - Fasting- 121 to 150mg/dl
Postprandial– 151 to 250 mg/dl
- HbA1C- up to 8%.
- Patient following diabetic diet.
- Patients on Metformin 500mg OD/BD.
- Patient of any sex, religion and socioeconomic status.

Exclusion Criteria

- Patients of *Sahaja Madhumeha* (IDDM, Type I).
- Diabetes due to side effect of drugs:
 - a. Diuretics (Thiazide groups)
 - b. Steroids
- Subjects with serum creatinine more than or equal to 2.0 mg/dl or on dialysis.
- Patient not following diabetic diet.
- Gestational diabetes.
- Complicated patient having target organ damage.
- Patients having fasting BSL<120 &>150mg/dl, Post prandial BSL<151 &>250mg
- Age less than 40 yrs. and more than 60 yrs.
- HbA1C > 8%.

Diagnosis

Table 1: Criteria for Assessment (11)

Sr.no	Parameter	Finding	Points
1	<i>Prabhutmootrata</i> (Polyuria)	3 – 6 times per day, rarely at night	0
		6 – 9 times per day, 0 – 2 times per night	1
		9 – 12 times per day, 2 – 4 times per night	2
		More than 12 times per day, more than 4 times per night	3
2	<i>Pipasa</i> (Polydipsia)	1. Feeling of thirst 7 – 9 times/24 hours, either/or Intake of water 5 – 7 times/24 hours with quantity 1.5 – 2.0 liter/24 hours	0
		2. Feeling of thirst 9 - 11 times/24 hours, either/or Intake of water 7 - 9 times/24 hours with quantity 2.0- 2.50 liter/24 hours	1
		3. Feeling of thirst 11 – 13 times/24 hours, either/or Intake of water 9 – 11 times/24 hours with quantity 2.50 -3.00 liter/24 hours	2
		4. Feeling of thirst >13 times/24 hours, either/or Intake of water >11 times/24 hours with quantity >3.00 liter/24 hours	3
3	<i>Kshudha</i> (Appetite)	Normal	0
		Slightly increased (1 – 2 meals)	1
		Moderately increased (3 – 4 meals)	2
		Markedly increased (5 – 6 meals)	3
4	<i>Abhyavaharana Shakti</i> (Hunger)	Person taking food in excessive quantity (More than his or her regular diet) twice in a day or Person taking a small quantity of food but multiple times in a day.	0
		Person taking food in normal quantity (Regular balanced diet) twice in a day	1
		Person taking food in moderate quantity (Slightly more than his or her regular diet) twice in a day	2
		Person taking food in less quantity (Less than his or her usual regular diet) twice in a day.	3
		Person taking food in less quantity once in a day	4
Person not at all taking food	5		
5	<i>Kara-Pada-Tala-Daha/Supti</i> (Neuropathy)	No <i>Daha</i> (Burning sensation)	0
		<i>Kara-pada-tala-daha/Supti</i> is continuous (Burning sensation in palms-sole & Numbness)	1
		<i>Kara-pada-tala-daha</i> (Burning sensation) / <i>Supti</i> (Numbness) continuous but not severe	2
		<i>Kara-pada-tala-daha</i> (Burning sensation)/ <i>Supti</i> (Numbness) continuous and severe	3

6	<i>Avila Mootrata</i> (Turbidity)	Crystal clear fluid Faintly cloudy or smoky (turbidity barely visible) Turbidity clearly present but newsprint easily read through test tube Newsprint not easily read through test tube Newsprint cannot be seen through test tube	0 1 2 3 4
7	<i>Mootramadhurya</i> (Glycosuria)	Absence of Glucose in urine <0.5% Glucose in urine 0.05 - 1.0% of Glucose in urine 1.0 – 2.0% of Glucose in urine >2.0% Glucose in urine	0 1 2 3 4
8	<i>Swedadhikya</i> (Perspiration)	Sweating after heavy work and fast movement or in hot weather Profuse sweating after moderate work and movement Sweating after little work and movement (stepping ladder etc) Profuse sweating after little work and movement Sweating even at rest or in cold weather	0 1 2 3 4
9	<i>Daurbalya</i> (Weakness)	Can do routine exercise/work. (Around 30-45 minutes) Can do moderate exercise (15 minutes more than regular) with hesitancy Can do mild exercise (Around 15-20 minutes) only, with difficulty Cannot do mild (not even a 10-15 minutes) exercise too	0 1 2 3
10	<i>Alasya/Utsahahani</i> (General Debility)	No <i>Alasya</i> (doing satisfactory work with proper vigor and in time) Doing satisfactory work/late initiation, like to stand in comparison to walk Doing unsatisfactory work/late initiation, like to seat in comparison to stand Doing little work very slow, like to lie down in comparison to seat. Don't want to do work/no initiation, like to sleep in comparison to lie down	0 1 2 3 4
11	<i>ShramaShwasa</i> (Dyspnea)	Dyspnea after heavy work Dyspnea after Climbing stairs. Dyspnea even after a walking Dyspnea even at resting condition	0 1 2 3
12	<i>Nidradhikya</i> (Sleep)	Normal sleep, 6 – 8 hours/24 hours Sleep up to 8 hours/24 hours with <i>Angagaurava</i> (Heaviness of body) Sleep up to 8 hours/24 hours with <i>Angagaurava</i> (Heaviness of body) & <i>Jrimbha</i> (Yawning) Sleep up to 10 hours/24 hours with <i>Tandra</i> Sleep up to >10 hours/24 hours with <i>Tandra</i> (Tiredness) & <i>Klama</i> (Weakness)	0 1 2 3 4
13	<i>Jarana Shakti</i> (Digestion)	Presence of all the symptoms like lightness of body, lightness of stomach (<i>Udar laghavata</i>), sensation of appetite, proper digestion of previous taken meal, Erructation (<i>Shuddha Udgarpnachiti</i>) within 4 hours. Presence of all the above-mentioned symptoms within after 4 hours Presence of four or more symptoms after 4 hours Presence of three or more symptoms after 5 hours Presence of two or more symptoms after 6 hours Anyone symptom presence after 6 hours	0 1 2 3 4 5
14	<i>Pindiko-udveshatan</i> (Cramps)	No cramps Cramps after walking more than 1 km Cramps after walking ½ km Inability in walking (Not even a ½ km)	0 1 2 3

Objective Criteria

- BSL (Fasting, Postprandial)
- HbA1c
- Blood urea level
- Serum Creatinine

Samprapti Ghatak (Etiopathogenesis) of Prameha (12)

Dosha: *Kapha* predominant *Tridosha*, Types of *Vata dosha* (*Apan* and *Vyan*)

Dushya: Blood (*Rakta dhatu*), muscle (*Mansa dhatu*), fat (*Meda dhatu*), bone marrow (*Majja dhatu*), lymph (*Lasika*), semen (*Shukra dhatu*), *Oja* (*Essence of all dhatu*)

Agni: *Dhatvagnimandya* (Diminution of digestive fire of all tissues)

Ama: *Aam Annarasa* (Toxic metabolites due to indigestion)

Srotas: *Mutravaha Strotas* (urinary system), *Medovaha strotas* (Channels carrying fat)

Srotodushti: *Sang* (Obstruction)

Adhishta: *Basti* (urinary bladder), *Sarvasharir* (whole body)

Swabhava: *Chirakari* (Chronic illness)

Sadhyasadhyata: *Yapya/ Asadhya* (Irreversible)

Treatment protocols

Table 2: Treatment Protocol

Group- A	Group-B
30 Patients	30 Patients
Metformin 500mg OD or BD	Metformin (500mg OD/BD) + <i>Triphaladaruadi kwath</i> (<i>Decoction</i>)
90 days	90 days

Table 3: Drug Review –Triphaladaruadi Kwatha (Decoction) (13)

Name	Botanical Names/ English Names	Guna	Karma
1. Amalaki (14)	<i>Phyllanthus emblica</i>	<i>Laghu</i> (Light weighted) <i>Ruksha</i> (Dryness) <i>Ras- Lavan varjit panchrasa.</i> (except salty taste all remaining 5 tastes) <i>Virya-Sheet</i> (Cool) <i>Vipak- Madhur</i> (Sweet)	External – <i>Dahaprashamana</i> (decreases burning sensation), <i>Chakshushya</i> (Improves eyesight), <i>Vranshodhana</i> (Cleaning of wound), <i>Vranaropana</i> (Wound healing property), <i>Keshya</i> (Important for hair growth) Internal – <i>Agnideepana</i> (Appetiser), <i>Ruchikara</i> (improves taste), <i>Anulomana</i> (Laxative), <i>Medhya</i> (Improves memory), <i>Balya</i> (Improves strength), <i>Shukravardhana</i> (Improves semen quantity), <i>Vrushya</i> (Improves semen quality), <i>Prajasthapana</i> (Important for fertility), <i>Rasayana</i> (Rejuvenation), <i>Vayasthapana</i> (Prolongs ageing).
2. Haritaki (15)	<i>Terminalia chebula</i>	<i>Laghu</i> (Light weighted) <i>Ruksha</i> (Dryness) <i>Ras- Lavan varjit panchrasa.</i> (Except salty taste all remaining 5 tastes) <i>Virya- Ushna</i> (Hot) <i>Vipak- Madhur</i> (Sweet)	External – <i>Shothahar</i> (Anti-inflammatory), <i>Vedanasthapana</i> (Pain-killer), <i>Vranshodhana</i> (Cleaning of wound), <i>Vranaropana</i> (Wound healing property) Internal – <i>Deepana</i> (Improves appetite), <i>Pachana</i> (Improves digestion), <i>Anulomana</i> (Laxative), <i>Rasayana</i> (Rejuvenation), <i>Krumighna</i> (Deworming).
3. Bibhitaki (14)	<i>Terminalia bellerica</i>	<i>Laghu</i> (Light weighted) <i>Ruksha</i> (Dryness) <i>Ras- Kashay</i> (Pungent, Astringent) <i>Virya- Ushna</i> (Hot) <i>Vipak-Madhur</i> (Sweet)	External – <i>Shothahar</i> (Anti-inflammatory), <i>Vedanasthapana</i> (Pain-killer), <i>Raktastambhana</i> (Blood clotting), <i>Keshya</i> (Important for hair growth) Internal – <i>Deepana</i> (Improves appetite), <i>Pachana</i> (Improves digestion), <i>Anulomana</i> (Laxative), <i>Chhardighna</i> (Anti-emetic), <i>Krumighna</i> (Deworming).
4. Devdaru (16)	<i>Cedrus deodara</i>	<i>Laghu</i> (Light weighted) <i>Snigdha</i> (Oily or Sticky) <i>Ras- Tikta, Katu</i> (Spicy and Bitter) <i>Vipak- Katu</i> (Spicy) <i>Virya- Ushna</i> (Hot)	External – <i>Shothahar</i> (Anti-inflammatory), <i>Vedanasthapana</i> (Pain-killer), <i>Vranshodhana</i> (Cleaning of wound), <i>Vranaropana</i> (Wound healing property) <i>Krumighna</i> (Deworming), <i>Rakshoghna</i> (Protective from invisible power) Internal – <i>Deepana</i> (Improves appetite), <i>Pachana</i> (Improves digestion), <i>Anulomana</i> (Laxative), <i>Krumighna</i> (Deworming).
5. Daruharidra (17)	<i>Berberis aristata</i>	<i>Laghu</i> (Light weighted) <i>Ruksha</i> (Dryness) <i>Ras- Tikta, Kashay</i> (Bitter and Pungent) <i>Virya- Ushna</i> (Hot) <i>Vipak- Katu</i> (Spicy)	External – <i>Vranadhawana</i> (Wound cleaning property), <i>Raktashodhana</i> (Blood purifying property), <i>Raktastambhana</i> (Blood clotting property). Internal – <i>Deepana</i> (Improves appetite), <i>Malsangrahi</i> , <i>Yakrutottejana</i> (Hepatic influencer).
6. Musta (18)	<i>Cyperous rotundus</i>	<i>Laghu</i> (Light weighted) <i>Ruksha</i> (Dryness), <i>Ras- Tikta, Katu</i> (Spicy and Bitter) <i>Vipak- Katu</i> (Spicy) <i>Virya- Sheet</i> (Cool)	External – <i>Twachadoshahar</i> (Important for skin health), <i>Shothaghna</i> (Anti-inflammatory), <i>Lekhana</i> (fat Scrabbing), <i>Anjana</i> (Important for eye) Internal – <i>Deepana</i> (Improves appetite), <i>Pachana</i> (Improves digestion), <i>Grahi</i> , <i>Krumighna</i> (Deworming). <i>Trushnanigrahan</i> (Prevents excessive thirst), <i>Sangrahi</i> .
7. Madhu (19,20) (Used as an anupan) Mediator	<i>Mel depuratum</i>	<i>Ruksha</i> (Dry), <i>Guru</i> (Heavy), <i>Picchila</i> (Sticky), <i>Sukshma</i> (Slipery)	<i>Varnya</i> (Skin tone improver), <i>Swarya</i> (Voice improver), <i>Lekhana</i> (fat Scrabbing), <i>Hridya</i> (Imptrtant for heart health), <i>Vajikarana</i> (Improves Sexual activity), <i>Sandhana</i> (Fermentation), <i>Ropana</i> (Healing), <i>Sangrahi</i> , <i>Chakshushya</i> (Healthy for eyes), <i>Prasadana</i> (Increases freshness), <i>Sukshmamarganusari</i> , <i>Grahi</i> , <i>Yogavahi</i> (Universal Catalyst property) <i>Medoroga</i> (Hyperlipidemia), <i>Hikka</i> (Hiccup), <i>Shwas</i> (Asthama), <i>Kasa</i> (Coughing), <i>Atisara</i> (Diarrhoea), <i>Chardi</i> (Vomitting), <i>Trushna</i> (Excessive Thurst), <i>Krumi</i> (Worms), <i>Vishaprashmana</i> (Poison neutralizer), <i>Sthaulya</i> (Obesity)

Observations and Results

Total 60 patients were enrolled under the study varied from each other in certain aspects. They were categorised into two groups. In control group 36 patients were registered and 35 patients were registered in trial group. 30 patients in each group completed the therapy. 06 patients in control group and 05 patients in

trial group left the treatment against medical advice. So, observations quoted from here onwards include data of 60 patients only, who had completed the entire treatment and follow up period.

In the present study proportion of the patients considering qualitative parameters in the control group having diagnosed as *madhumeha* (Hyperglycemia) got

relief in *Prabhuta Mootrata* (Polyuria) by 56.09%, *Avila Mootrata* (Turbid urine) by 54.83%, *Pipasadhikya* (Excessive thirst) by 32.57%, *Kshudhadhikya* (Excessive appetite) 53.84, *Nidradhikya* (Excessive Sleepiness) by 50%, *Swedadhikya* (Excessive perspiration) by 55.55%, USL(Urine Sugar Level) by 53.84%, *Daurbalya* (General Debility) by 43.75%, *Pindikodweshtan* (Muscle cramping) by 43.75%, *Karapadadaha* (Burning sensation in Palms and soles) by 55.55%, *Purishbaddhata* (Constipation) by 41.17% and hence Total global count reduced by 52.91% .Whereas after adding *Triphaladaruadi Kwatha*

(Decoction) yoga it gave miraculous results as patients got relief in *Prabhuta Mootrata* (Polyuria) by 82.85%, *Avila Mootrata* (Turbid urine) by 68.96%, *Pipasadhikya* (Excessive thrust) by 72.41%, *Kshudhadhikya* (Excessive appetite) by 70%, *Nidradhikya* (Excessive Sleepiness) by 87.5%, *Swedadhikya* (Excessive perspiration) by 57.89%, USL by 50%, *Daurbalya* (General Debility) by 64.7%, *Pindikodweshtan* (Muscle cramping) by 80%, *Karapadadaha* (Burning sensation in Palms and soles) by 57.14%, *Purishbaddhata* (Constipation) by 61.53% and hence Total global count reduced by 70.52%.

Table No. 4: Percentage Relief in Symptoms score in Group A and B

Sr. No.	Effect of Treatment on Symptoms	Group A (30 patients)			Group B (30 patients)		
		No. of Positive difference	No. of Negative difference	% Relief	No. of Positive difference	No. of Negative difference	% Relief
1	Prabhuta Mootrata (Polyuria)	0	21	56.09	0	27	82.85
2	Avila Mootrata (Turbid Urine)	0	17	54.83	0	18	68.96
3	Pipasadhikya (Excess thrust)	0	18	32.57	0	20	72.41
4	Kshudhadhikya (Excess appetite)	0	7	53.84	0	7	70
5	Nidradhikya (Excess sleepiness)	0	15	50	0	11	87.5
6	Swedadhikya (Excess perspiration)	0	7	55.55	0	7	57.89
7	Urine sugar level	0	7	53.84	0	12	50
8	Daurbalya (General debility)	0	7	43.75	0	22	64.7
9	Pindikodweshtan (Muscle cramping)	0	15	43.75	0	16	80
10	Karapadadaha (Burning sensation in Palms & soles)	0	7	55.55	0	8	57.14
11	Purishbaddhata (Constipation)	0	19	41.17	0	30	61.53

Table No. 5: Comparison of statistical observation of BSL Fasting between the groups

			Df	P value	Significance
BSL Fasting	Interaction	27.84	29	0.0340	Yes
	Row factor	37.7	29	0.0024	Yes

Table No. 6: Statistical observations of BSL Fasting before and after treatment in the groups

	No of day	No	Mean	SD	Paired differences		T value	P value	Significance
					Mean	SD			
Control group	D1	30	128.7333	10.1504	4.8333	14.8349	1.785	0.0848	No
	D90	30	133.5667	18.8180					
Trial group	D1	30	132.20	9.2379	-8.9000	8.2393	-5.916	<0.0001	Yes
	D90	30	123.3	12.9858					

Table No. 7: Comparison of statistical observation of BSL Postprandial between the groups

			Df	P value	Significance
BSL Postprandial	Interaction	47.51	29	<0.0001	Yes
	Row factor	29.29	29	<0.0001	Yes

Table No. 8: Statistical observations of BSL Post prandial before and after treatment in the groups

	No of day	No	Mean	SD	Paired differences		T value	P value	Significance
					Mean	SD			
Control group	D1	30	198.1	30.8984	4.4000	16.7406	1.440	0.1607	No
	D90	30	202.5	24.0499					
Trial group	D1	30	202.1000	24.8643	-26.8000	11.6097	-12.644	<0.0001	Yes
	D90	30	175.3000	21.6288					

Table No. 9: Comparison of statistical observation of HbA1c between the groups

HbA1c			Df	P value	Significance
	Interaction		38.06	29	<0.0001
Row factor		41.21	29	<0.0001	Yes

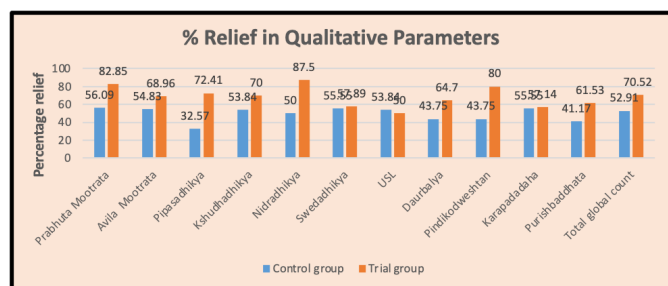
Table No. 10: Statistical observations of HbA1c before and after treatment In the groups

	No of day	No	Mean	SD	Paired differences		T value	P value	Significance
					Mean	SD			
Control group	D1	30	7.1333	0.4138	-0.0167	0.2574	0.355	0.7254	No
	D90	30	7.1167	0.4465					
Trial group	D1	30	6.8833	0.3141	-0.1167	0.0874	-7.309	<0.0001	Yes
	D90	30	6.7667	0.3044					

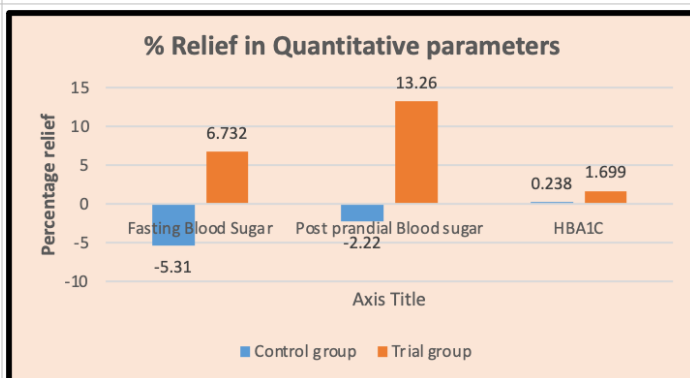
Table No. 11: Combined Observation of BSL F & PP and HbA1c between two groups

No	Symptom	N	Control group Mean			Trial group Mean		
			D0	D90	%Relief	D0	D90	%Relief
1	Blood sugar fasting	30	128.73	133.57	-5.31	132.2	123.3	6.732
2	Blood sugar pp	30	198.1	202.5	-2.22	202.1	175.3	13.26
3	HbA1c	30	7.133	7.116	0.238	6.883	6.766	1.699

Graph no.: 1 Qualitative parameters of Assessment criteria in percentage



Graph no.:2 Quantitative parameters of Lab assessment criteria in percentage



Discussion

Discussion on demographic data

Maximum numbers of patients (56.66%) in this study were above 55 years of age. It was observed that the individuals were more affected by type 2 DM after 55 years of age and it is also seen in earlier age group.

56.66% patients in the study were female, who were the majority. From the study it was observed that after the age of 35-40 years females are at high risk of getting *prameha*, as menopausal age was attained and also due to inactive life style.

70% patients belonged to Hindu community and 20% were from Muslim community. Due to demographic situation pertaining to this region we cannot make any conclusion from this data.

Due to locality of hospital majority of patients were from middle (71.66%) or lower class (20%).

In manifestation of *Prameha* occupation plays an important role. In the present study 20% patients doing sedentary work, 68.33% patients have active work, 11.66% patients having laborious work. In patients who work actively, *Prameha* was seen majorly due to occupational stress.

Majority of patient 43.33% were learned only up to SSC. Hence ignorance about causative factors of *Prameha* may lead aggravation of the disease.

Maximum patients 55% in this study had mixed diet (Vegetarian and non-vegetarian). This causes *medo mamsa dushti* (Vitiation of Fat and muscles) by *samanya vishesh siddhant* and helps the etiological factors to vitiate the dosha and the *Samprapti* (Etiology) of disease.

This study shows that maximum number of patients having *Kaphapitta prakruti* (70%). In the pathogenesis of *Prameha Kapha* plays an important role therefore patients having *kapha* dominance were more prone to *Prameha*.

To avoid complications, newly diagnosed DM patient's maximum up to 2 years were taken in the study.

Maximum number of patients in this study having *Madhyam aharashakti* (Medium Appetite) (71.66%) and 10% patients having *avara aharashakti* (Less Appetite), this shows the Relation of *dhatwagnimandya*, *jatharagnimandya* (Loss of appetite) with the pathogenesis of *Prameha*.

Maximum number of patients in the study were having *Madhyam vyamshakti* (Medium ability to perform exercise) (36.66%) and 53.33% having *avara vyayamshakti* (Lower ability to perform exercise). As *avyayam* (Lack of Exercise) causes *medodushti* (Vitiation of Fat) and in *Prameha medo dhatu* is main *dushya*. In the *samprapti* (Etiology) of *Madhumeha* (Hyperglycemia).

Discussion on observations in the present study

Effect of therapy on quantitative parameters

In this study total 5 quantitative parameters included and effect of therapy on them was studied in control and trial group and also in between groups. As follows –

Fasting blood sugar level

Between the groups

Since the p value 0.0001, considering the Fasting blood sugar level there was significant difference in Trial and Control Groups, hence null hypothesis rejected.

Within group

In Trial group p value 0.0001 and in Control group 0.0840, hence null hypothesis strongly rejected.

Postprandial blood sugar level

Between the groups

Since the p value 0.0001, considering the postprandial blood sugar level there was significant difference in Trial and Control Groups, hence null hypothesis rejected.

Within group

In Trial group p value 0.0001 and in Control group 0.1607, hence null hypothesis strongly rejected.

HbA1C

Between the groups

Since the p value 0.0001, considering the HbA1C blood sugar level there was significant difference in Trial and Control Groups, hence null hypothesis rejected.

Within group

In Trial group p value 0.0001 and in Control group 0.7254, hence null hypothesis strongly rejected.

Conclusion

On the basis of the observations obtained and discussion done in the present study, the following conclusions are drawn

- *Pameha* co-related with Diabetes mellitus as their manifestation and pathogenesis is similar.
- In *Prameha* (Type 2 DM) age group affected 40 or above the age of 40yrs mostly.
- There was no any association of Religion with DM.
- There is an increased occurrence of *Prameha* in females due to their sedentary life style.
- Changing life style, Occupational stress, Lack of exercise causes the formation of *Prameha*.

- The quantitative parameters like Fasting blood sugar, Postprandial blood sugar, HbA1C showed high significance rate statically with *Triphaladaruadi Kwatha* (Decoction) and *anupanana* (Mediator) *madhu* (Honey) as an adjuvant with metformin in the groups and between the groups.
- The qualitative parameters like *Prabhuta Mootrata* (Polyuria), *Avil Mootrata* (Turbid Urine), *Kshudadhikya* (Excess Appetite), *Daurbalya* (General debility), *Karapadadaha* (Burning sensation in Palms & Soles), USL are significantly differing in the groups and between the groups.
- There was evidence that add on effect of *Triphaladaruadi Kwatha* (Decoction) with *anupanana* (Mediator) *madhu* (Honey) along with metformin (Antidiabetic drug) is effective in management of *Prameha*.
- Aims and Objectives of the study are full filled.

Conflict of Interest

The authors declare no conflict of interest.

References

1. India State-Level Disease Burden Initiative Diabetes Collaborators. The increasing burden of diabetes and variations among the states of India: The Global Burden of Disease Study 1990-2016. *Lancet Glob Health*. 2018 Dec;6(12): e1352-e1362. doi: 10.1016/S2214-109X(18)30387-5. Epub 2018 Sep 12. PMID: 30219315; PMCID: PMC6227383.
2. Pradeepa R, Mohan V. Epidemiology of type 2 diabetes in India. *Indian J Ophthalmol*. 2021 Nov; 69(11):2932-2938. doi: 10.4103/ijo.IJO_1627_21. PMID: 34708726; PMCID: PMC8725109.
3. Kushwaha H. S.; Charak Samhita; Chikitsasthan; Chapter 6 Prameha Chikitsa; Chaukambha Orientalia; Varanasi; Reprint 2018; Vol 2; Shlok No 9-11; Page no 185-186.
4. Bloor A., Naik R.; Exam preparatory manual for undergraduates Medicine; 3rd Edition; 2021; Jaypee brother's medical publishers; Page no 94.
5. Sharma Priya, Malik Sujeeta. Knowledge on Management of Diabetes Mellitus among Patients with type II Diabetes Mellitus in a Selected Community Health Centre of Dadra and Nagar Haveli Area. *Asian J. Nursing Education and Research*. 2019; 9(1): 109-112. doi 0.5958/2349-2996.2019.00021.1
6. Gurvishal Sinha. The Pharmaceutical Industry in addition to the physical fitness center an advantage for Indian Diabetic- A Statistical Analysis. *Research J. Pharm. and Tech*. 2019; 12(6): 2970-2972. doi10.5958/0974-360X.2019.00501.8
7. Nirmal Saxena; Vangasena Samhita; Chapter 41 Prameha- Vangasena Chikitsa sarsangraha; Choukamba prakashan; Varanasi; reprint 2004; Vol 1; Shlok no.56; Page no 580.
8. Bloor A., Naik R.; Exam preparatory manual for undergraduates Medicine; 3rd Edition; 2021; Jaypee brother's medical publishers; Page no 106.

9. Bhavana Habib, Jyoti Mittha. Quality Evaluation of Generic Products of Metformin and Vildagliptin Tablets. Asian Journal of Pharmaceutical Analysis. 2021; 11(4): 255-8. doi10.52711/2231-5675.2021.00043.
10. Lizzie Raveendran, Jeyaseelan M. Devadason, Prakash M.Saldanha. Impact of Perceived Self Efficacy on HbA1c among Adolescents with Type 1 Diabetes Mellitus. Int. J. Nur. Edu. and Research 2(4): Oct.- Dec. 2014; Page no 319-323.
11. Gupta A, Agarwal NK, Byadgi PS. Clinical assessment of dietary interventions and lifestyle modifications in Madhumeha (type- 2 Diabetes Mellitus). Ayu. 2014 Oct-Dec;35(4):391-7. doi: 10.4103/0974-8520.158997. PMID: 26195901; PMCID: PMC4492023.ss
12. Kushwaha H. S.; Charak Samhita; Vol 2; Chikitsasthan; Chapter 6 Prameha Chikitsa; Chaukambha Orientalia; Varanasi; Reprint 2018; Shlok No 5-8; Page no 183-185.
13. Sharma G., Dhanwantari Nighantu; Chaukhamba orientalia;2002; Shlok no 211-213, 202-208, 206-210, 75-76, 56-58, 39-41; Page no 55, 53, 54, 29, 26, 23.
14. Sanakousar K. Patel, Arun K Shutter, Ria Patil, Archana Desangi, Vishalakshi Malali, Jyoti Patil, Sumangala Patil, Kusal K. Das, Prachi P. Parvatikar. In-Vitro Antioxidant, Anti-Inflammatory and Cytotoxic effects of different Solvent Extraction Terminalia chebula, Terminalia billerica, Phyllanthus emblica. Research Journal of Pharmacy and Technology. 2022; 15(7):2940-4. doi 10.52711/0974-360X.2022.00490
15. Jiby Elias, Rajesh M.G., Anish N.P., Manu M.S., Iwin C. Varkey. Terminalia chebula Retz. Stem Bark Extract: A Potent Natural Antioxidant. Asian J. Research Chem. 4(3): March 2011; Page no 445-449.
16. Manjula Ramadass, Syed Abdul Hakeem, Aravind Yaswanth Chandran, Gowtham Vadivelu, Padma Thiagarajan. Formulation and Characterization of Cedrus deodara Oil Emulsion and studies on its activity against representative food and plant pathogens. Research J. Pharm. and Tech. 2019; 12(3): 1333-1337. doi10.5958/0974-360X.2019.00223.3
17. Monika Thakur, Kunjan Sharma, Sonia Mehta, Swati Rai, Isha Sharma, Astha Tripathi. Phytochemicals, Antimicrobial and Antioxidant Potential of Methanolic Extract of Berberis aristata roots. Research J. Pharm. and Tech. 2020; 13(12):5763-5767. doi10.5958/0974-360X.2020.01004.5
18. Dominic Amalraj A., Parkavi C., Murugaiah K., Dhanaraj T.S. Hypolipidemic Activity of Cyperous rotundus on CCl4 Induced Dyslipidemia in Rats. Asian J. Pharm. Tech. 2(2): April-June 2012; Page no 51-53.
19. Kunte A. M., Dr. Navare K; Ashtanga Hridaya; Sutasthan; Chapter 5 Dravadravyavignyaneeeyam; Krushnadasa Academy, Varanasi; 2000; Shlok no-51-52, Page no 76.
20. Hisham A. Abbas. Antibacterial, Anti-swarming and Antibiofilm Activities of Local Egyptian Clover Honey Against Proteus Mirabilis Isolated from Diabetic Foot Infection. Asian J. Pharm. Res. 3(3): July-Sept. 2013; Page no 114-117.
