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Comparative Study to determine the efficacy of Triphaladi vati and Mehamudgar vati along with OHA in the management of Prameha patients.

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Abstract:

Ayurveda is the traditional science of medicine included in Indian since centuries. It is the science for longevity which cures the disease as well as teaches how to live healthy & prevents the diseases. Diabetes mellitus (Prameha) is a group of metabolic diseases marked by high level of blood glucose which mainly cause due to defects in insulin production, insulin action or both which ultimately turns in hypoglycaemia. Diabetes may lead to serious complications in multiple organ systems. The present case series is of patients visiting to the Ayurved College with chief complaints of excessive hunger, frequency of micturition, excessive thirst, excessive sweating, and weakness. The treatment plan opted was use of Triphaladi vati & Mehamudgar vati along with modification of diet and lifestyle. Regular follow up at the interval of fifteen days were done for a period of 1 month.

Keywords: Ayurveda and Diabetes, Prameha (Diabetes Mellitus),bHerbal Formulations (Triphaladi Vati, Mehamudgar Vati), Insulin Resistance and Metabolic Disorder.

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INTRODUCTION:

Ayurveda place great emphasis on prevention, cure and maintenance of good health through close attention to balance in once life, diet, right thinking, life style and use of herbal medicines. *Prameha* is included in *mahagada* diseases i.e difficult to treat[1]. It is an *aanushangi vyadhi*[2]. The cardinal symptoms of *prameha* are increased frequency, and quantity of urine along with turbidity of urine[3,4]. Classical text attributes multi-factorial etiology to the causation of *prameha*. The main etiological factors for *prameha* are dietary, excessive eating, life style, hereditary factors *(Jatah-Pramehi),* genetic association *(Beeja Dosha),* sedimentary life, freshly harvested foods and grains *(Navannapana*), consumption of sweet food articles *(Gudavikrita),* intake of certain foods from geographical areas enriched water resources *(Anupadesha)*, and all the factors (food & lifestyle) that aggravate *Kapha Dosha*. Diabetes is a silent killer. Rapidly rising glycemic concentration are seen in population living in developed and developing countries[5].Diabetes mellitus is a group of syndrome characterized by hyperglycemia caused by absolute or relative deficiency of insulin[6]. Diabetes is metabolic disorder in which carbohydrate utilization is reduced & that of lipid and protein increased due to deficiency of insulin which results in hypoglycaemia[7]. The main cause of diabetes is insufficient production of insulin or when the body cannot effectively use the insulin due to its resistance. Various complications which are commonly seen includes kidney damage (nephropathy), retina damage(retinopathy), nerve damage (neuropathy), cardiovascular diseases, foot damage, hearing impartment, skin infection[8]. Increasing prevalence of diabetes mellitus is alarming and globally estimated to be 150 million and figured to be double by 2025[9]. Prevalence of diabetes in India is 8.4%[10]. It is spreading epidemic all over the world. In India has more diabetics than any other country in the world. The disease affects more than 50 million Indians and kills about 1 million people a year.

Aim and Objective:

1) Conceptual and critical studies on *prameha*.
2) To compare the efficacy of *Triphaladi vati* and *Mehamudgar vati* along with OHA in the management of *prameha* patients.

MATERIAL & MATHOD:

Total 47 patients of the type 2 diabetes were randomly selected from the O.P.D. of *Kayachikitsa* of our institute. Case selection was random regardless of sex, age, socioeconomic status, occupation, etc. Informed consent was taken from the participating patients before starting the trial. Out of 47 registered patients only 40 patients turned up to complete follow up. All the 40 patients were divided into two groups randomly.

Group A:- 20 patients treated with *Triphaladi vati* along with OHA

Group B:- 20 patients treated with *Mehamudgar vati* along with OHA

Duration: 30 days.

Dose: 500mg twice day before lunch and dinner.

Anupan: warm water.

Formulation of *Triphaladi vati* – *Choornas* of *Triphaladi vati* are taken in proportion as given in classical text and added in honey and binding agent. Tablets of 500mg will be prepared with help of tablet making machine[11].

Formulation of *Mehamudgar vati* –*Shuddha guggul* dissolved in warm water and *choornas* of *Mehamudgar vati* added in it as per proportion given in classical text. Tablets of 500mg is prepared with tablet making[12].

Inclusion criteria:

1. Patients having signs and symptoms of *Prameha* as mentioned in *Ayurvedic* texts
2. Diagnosed patient with BSF between 125-200 & PPBS 200-280
3. Age of patients - 30-60 year
4. Gender - male and female

Exclusive criteria

1. Patient having DM below age 30 and above age 60
2. Gestational diabetes.
3. Patients having Acute Complications like Coronary Heart Disease, Acute Infective hepatitis, alcoholic hepatitis, HIV
4. Patients having disorders like Carcinoma anywhere in the body
5. Patients having any other major life-threatening disease.

CRITERIA FOR THE ASSESMENT OF PATIENTS

- *Daurbalya*
- *Sweda-Adhikya*
- *Prabhut-Murata*
- *Kara-padatala daha*
- *Kshudha-Adhikya*
- *Pipasa-Adhikya*

Investigations: BSL-fasting, BSL-post prandial

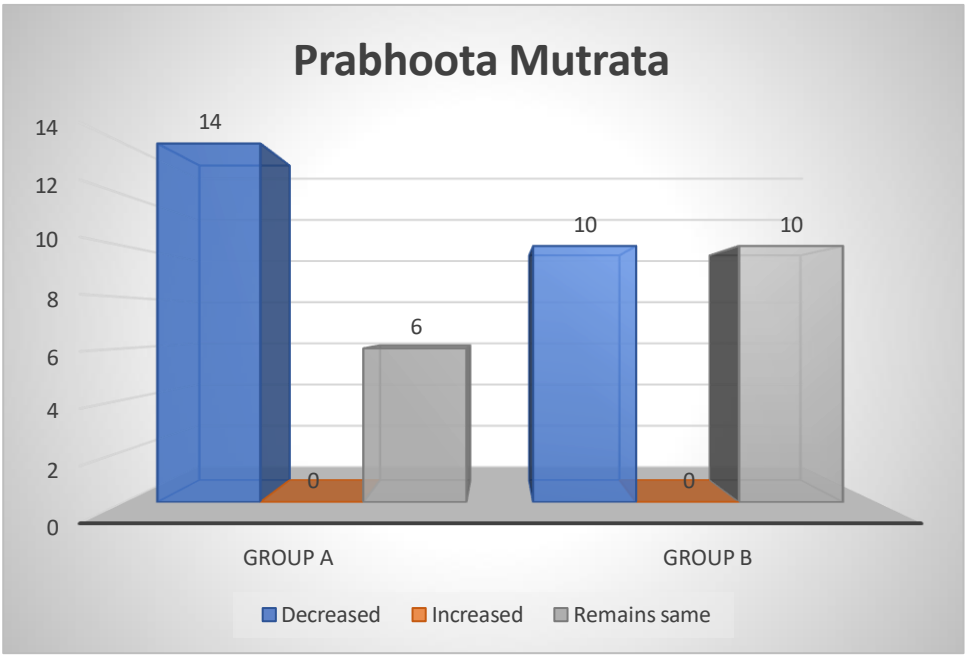
Observations and Results:

Total 47 patients were registered in this study and Random allocation was done to divide patient into two groups. Out of 47, 40 patients were studied and their observations were recorded as follow:

Group A– Triphaladi vati and Group B –Mehamugdar vati.

Results within Group A and Group B

1) **Prabhoota Mutrata:** Result of before and after treatment by Wilcoxon signed rank test as follows

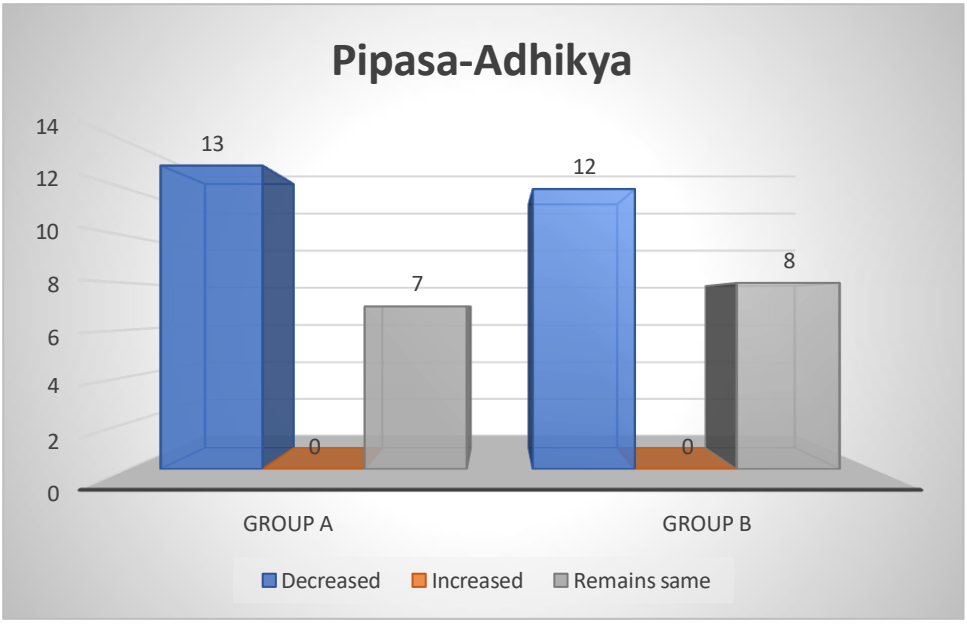


Prabhoota Mutrata	Group A (N)	Group B (N)
Negative Ranks	14	10
Positive Ranks	0	0
Ties	6	10
Total	20	20
Test Statistic	**-3.494**	**-3.162**
P value	**<0.001**	**0.002**

Interpretation: As p value < 0.05, there is significant difference in grades of 'Prabhoota Mutrata' after treatment in both groups. Negative rank indicates it reduces after treatment. Ties indicate it remains same, as in most of the patients of both groups 'Prabhoota Mutrata' is already absent before treatment itself. And in remaining patients, it gets reduced, so the

treatment is effective to reduce grades of 'Prabhoota Mutrata'.
So, groups A and B are effective to reduce grades of 'Prabhoota Mutrata'.

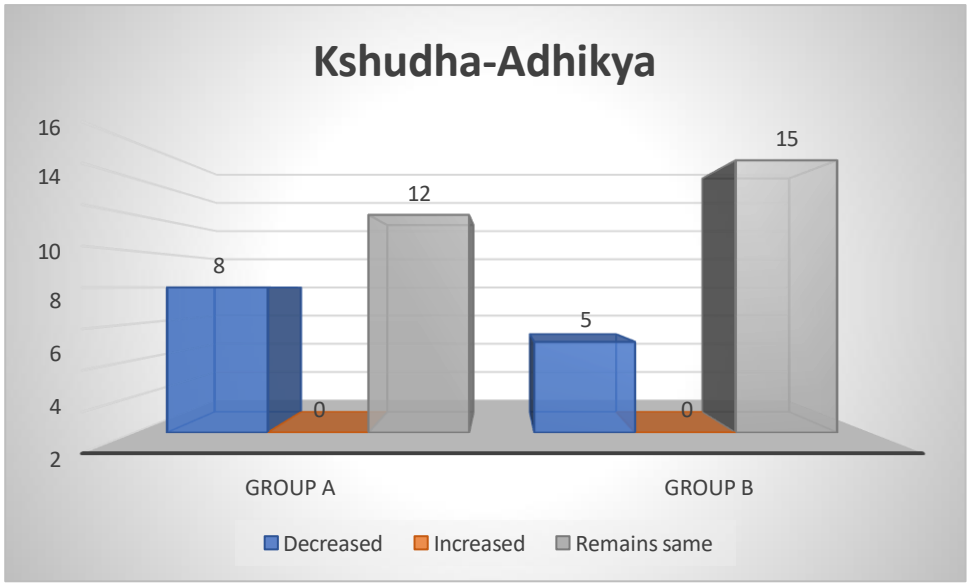
2) **Pipasa-Adhikya:** Result of before and after treatment by **Wilcoxon signed rank test** as follows:



Pipasa-Adhikya	Group A (N)	Group B (N)
Negative Ranks	13	12
Positive Ranks	0	0
Ties	7	8
Total	20	20
Test Statistic	**-3.500**	**-3.464**
P value	**<0.001**	**0.001**

Interpretation: As p value < 0.05, there is significant difference in grades of 'Pipasa-Adhikya' after treatment in both groups. Negative rank indicates it reduces after treatment. Ties indicate it remains same, as in most of the patients of both groups 'Pipasa-Adhikya' is already absent before treatment itself. And in remaining patients, it gets reduced, so the treatment is effective to reduce grades of 'Pipasa-Adhikya'.
So, groups A and B are effective to reduce grades of 'Pipasa-Adhikya'.

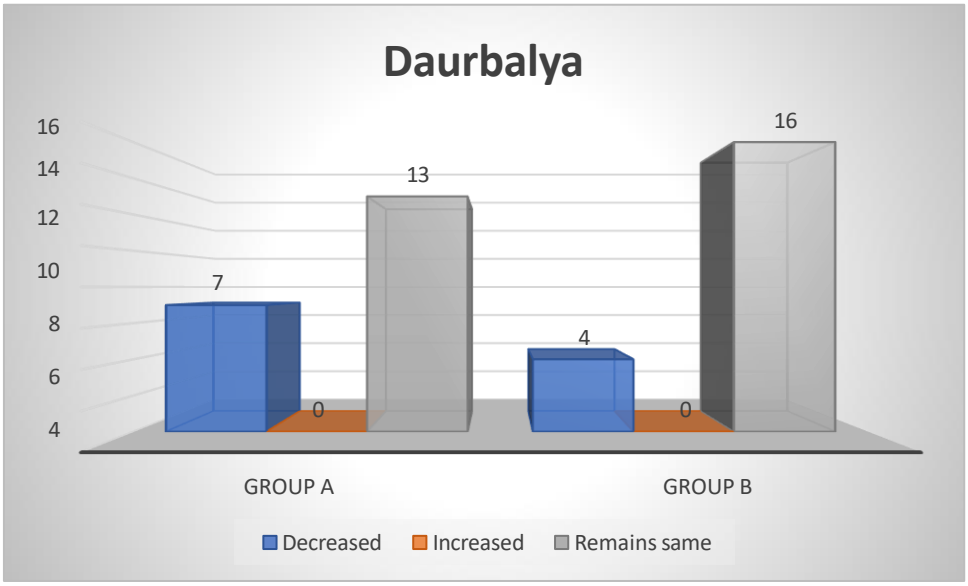
3) **Kshudha-Adhikya:** Result of before and after treatment by **Wilcoxon signed rank test** as follows:



Kshudha-Adhikya	Group A (N)	Group B (N)
Negative Ranks	8	5
Positive Ranks	0	0
Ties	12	15
Total	20	20
Test Statistic	**-2.828**	**-2.236**
P value	**<0.001**	**0.025**

Interpretation: As p value < 0.05, there is significant difference in grades of 'Kshudha-Adhikya' after treatment in both groups. Negative rank indicates it reduces after treatment. Ties indicate it remains same, as in most of the patients of both groups 'Kshudha-Adhikya' is already absent before treatment itself. And in remaining patients, it gets reduced, so the treatment is effective to reduce grades of 'Kshudha-Adhikya'.
So, groups A and B are effective to reduce grades of 'Kshudha-Adhikya'.

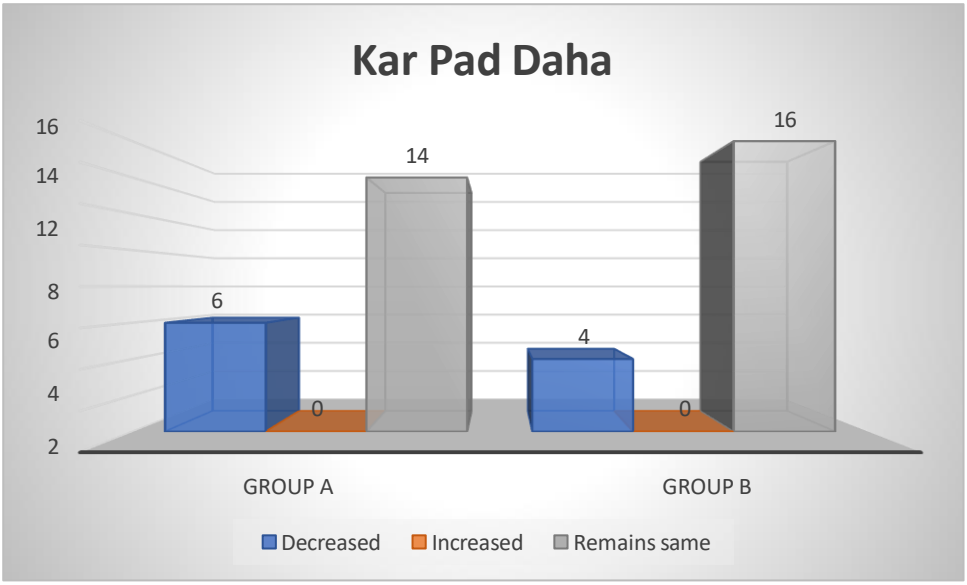
4) **Daurbalya:** Result of before and after treatment by **Wilcoxon signed rank test** as follows:



Daurbalya	Group A (N)	Group B (N)
Negative Ranks	7	4
Positive Ranks	0	0
Ties	13	16
Total	20	20
Test Statistic	**-2.646**	**-2.000**
P value	**0.008**	**0.046**

Interpretation: As p value < 0.05, there is significant difference in grades of 'Daurbalya' after treatment in both groups. Negative rank indicates it reduces after treatment. Ties indicate it remains same, as in most of the patients of both groups 'Daurbalya' is already absent before treatment itself. And in remaining patients, it gets reduced, so the treatment is effective to reduce grades of 'Daurbalya'.So, groups A and B are effective to reduce grades of 'Daurbalya'.

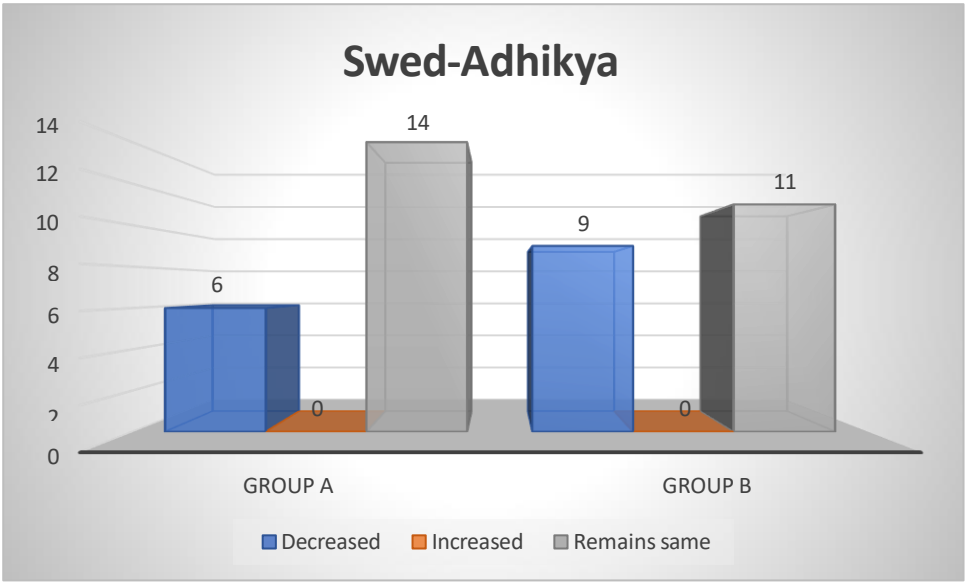
5) **Kar Pad Daha:** Result of before and after treatment by **Wilcoxon signed rank test** as follows:



Kar Pad Daha	Group A (N)	Group B (N)
Negative Ranks	6	4
Positive Ranks	0	0
Ties	14	16
Total	20	20
Test Statistic	**-2.449**	**-2.000**
P value	**0.014**	**0.046**

Interpretation: As p value < 0.05, there is significant difference in grades of 'Kar Pad Daha' after treatment in both groups. Negative rank indicates it reduces after treatment. Ties indicate it remains same, as in most of the patients of both groups 'Kar Pad Daha' is already absent before treatment itself. And in remaining patients, it gets reduced, so the treatment is effective to reduce grades of 'Kar Pad Daha'.So, groups A and B are effective to reduce grades of 'Kar Pad Daha'.

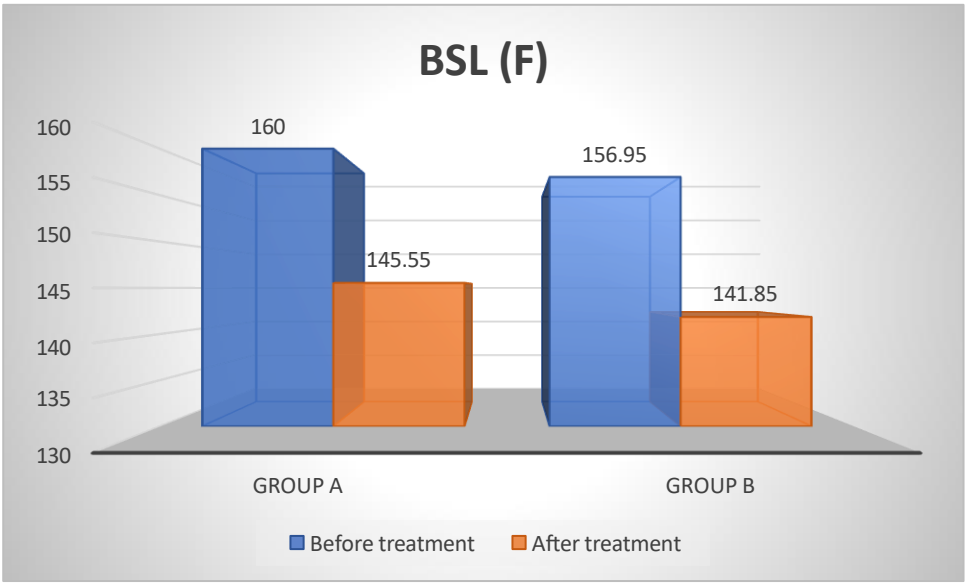
6) **Swed-Adhikya:** Result of before and after treatment by **Wilcoxon signed rank test** as follows:



Swed-Adhikya	Group A (N)	Group B (N)
Negative Ranks	6	9
Positive Ranks	0	0
Ties	14	11
Total	20	20
Test Statistic	**-2.449**	**-3.000**
P value	**0.014**	**0.003**

Interpretation: As p value < 0.05, there is significant difference in grades of 'Swed-Adhikya' after treatment in both groups. Negative rank indicates it reduces after treatment. Ties indicate it remains same, as in most of the patients of both groups 'Swed-Adhikya' is already absent before treatment itself. And in remaining patients, it gets reduced, so the treatment is effective to reduce grades of 'Swed-Adhikya'.So, groups A and B are effective to reduce grades of 'Swed-Adhikya'.

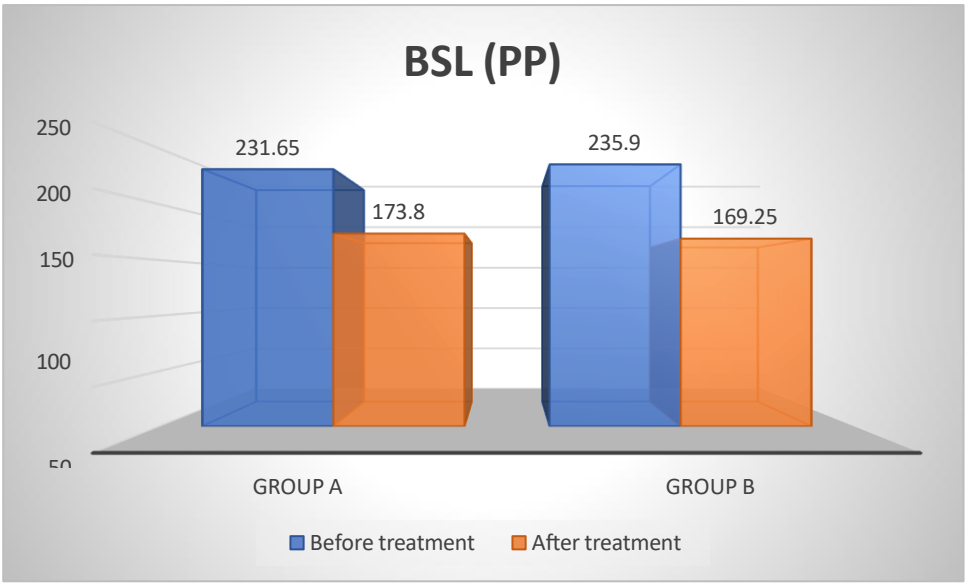
7) **BSL (F):** Result of before and after treatment by **Paired t test** as follows:



BSL (F)	Group A	Group B
Before treatment	160.0	156.95
After treatment	145.55	141.85
Mean difference	14.450	15.100
S.D.	11.601	10.872
Test Statistic	**-5.571**	**-6.212**
P value	**<0.001**	**<0.001**

Interpretation: As p value < 0.05, there is significant difference in averages of 'BSL (F)' after treatment in both groups. In group A, on an average BSL (F) is decreased by 14.450, while in group B it is decreased by 15.100 So, groups A and B are effective to reduce 'BSL (F)'.

8) **BSL (PP):** Result of before and after treatment by **Paired t test** as follows:



BSL (PP)	Group A	Group B
Before treatment	231.65	235.90
After treatment	173.80	169.25
Mean difference	57.850	66.650
S.D.	26.322	10.872
Test Statistic	**9.829**	**10.889**
P value	**<0.001**	**<0.001**

Interpretation: As p value < 0.05, there is significant difference in averages of 'BSL (PP)' after treatment in both groups. In group A, on an average BSL (PP) is decreased by 57.850, while in group B it is decreased by 66.650. So, groups A and B are effective to reduce 'BSL (PP)'.

Comparison between Group A and B

Prabhoota Mutrata: Mean rank of 'Prabhoota Mutrata' is less in group A than that of group B, but as p value > 0.05, there is no significant difference in grades of 'Prabhoota Mutrata' between the groups. So, both groups are equally effective to reduce grades of 'Prabhoota Mutrata'.

Pipasa-Adhikya:

Mean rank of 'Pipasa-Adhikya' is less in group A than that of group B, but as p value > 0.05, there is no significant difference in grades of 'Pipasa-Adhikya' between the groups. So, both groups are equally effective to reduce grades of 'Pipasa-Adhikya'.

Kshudha-Adhikya:

Mean rank of 'Kshudha-Adhikya' is less in group A than that of group B, but as p value > 0.05, there is no significant difference in grades of 'Kshudha-Adhikya' between the groups. So, both

groups are equally effective to reduce grades of 'Kshudha-Adhikya'.

Daurbalya: Mean rank of 'Daurbalya' is less in group B than that of group A, but as p value > 0.05, there is no significant difference in grades of 'Daurbalya' between the groups. So, both groups are equally effective to reduce grades of 'Daurbalya'.

Kar Pad Daha: Mean rank of 'Kar Pad Daha' is less in group B than that of group A, but as p value > 0.05, there is no significant difference in grades of 'Kar Pad Daha' between the groups. So, both groups are equally effective to reduce grades of 'Kar Pad Daha'.

Swed-Adhikya: Mean rank of 'Swed-Adhikya' is less in group B than that of group A, but as p value > 0.05, there is no significant difference in grades of 'Swed-Adhikya' between the groups. So, both groups are equally effective to reduce grades of 'Swed-Adhikya'.

BSL (F): Mean of 'BSL (F)' is less in group B than that of group A, but as p value > 0.05, there is no significant difference in 'BSL (F)' between the groups. So, both groups are equally effective to reduce 'BSL (F)'.

BSL (PP):

Mean of 'BSL (PP)' is less in group B than that of group A, but as p value > 0.05, there is no significant difference in 'BSL (PP)' between the groups. So, both groups are equally effective to reduce 'BSL (PP)'.

Overall Result:

Sr. No.	Parameters	Mean Rank/ Mean		p value	Sig./Not Sig.
		Group A	Group B		
1	Prabhoota Mutrata	17.45	23.55	0.102	Not Significant (A=B)
2	Pipasa-Adhikya	21.28	19.72	0.678	Not Significant (A=B)
3	Kshudha-Adhikya	20.22	20.78	0.883	Not Significant (A=B)
4	Daurbalya	21.85	19.15	0.478	Not Significant (A=B)
5	Kar Pad Daha	24.05	16.95	0.056	Not Significant (A=B)
6	Swed-Adhikya	21.50	19.50	0.602	Not Significant (A=B)
7	BSL (F)	145.55	141.85	0.447	Not Significant (A=B)
8	BSL (PP)	173.80	169.25	0.515	Not Significant (A=B)

A = B means Group A is as effective as group B.

As per above result, both groups are equally effective in all parameters. So, by overall result group A and group B are equally effective.

Overall results in both groups

Group A shows that on Prabhoota Mutrata, Pipasa-Adhikya, Kshudha- Adhikya, Daurbalya, Kar Pad Daha, Swed-Adhikya- 65.4%, 51.9%, 47.1%, 35%, 37.5% and 37.5% relief are observed respectively. On an average group A is 45.7% effective.Group B shows that on Prabhoota Mutrata, Pipasa-Adhikya, Kshudha-Adhikya, Daurbalya, Kar Pad Daha, Swed-Adhikya- 38.5%, 52.2%, 35.7%, 30.8%, 66.7% and 52.9% relief are observed respectively. On an average group B is 46.1% effective.

DISCUSSION:

Prameha is a multifactorial disease caused due to abnormal interaction of three *doshas* and ten *dushyas* predominantly *kapha dosha* and *meda dhatu.* While describing the pathogenesis of *prameha* the *Ayurvedic* texts have explained the involvement of *ama* (oxidative free radicals), *agni* (digestive fire), *meda* (adipose tissue) and *ojas* (immunity), which play a vital role in the development and progression of *prameha* and its complication. *Prameha* is included in *Mutravaha Srotasa* disease in which metabolism is hampered first and then disease evolves gradually. Incidence *prameha* increasing day by day.In this pilot study maximum cases registered were belonging from 4th decade. The study reveals that majority of cases were having siting jobs, services which indicates that persons having minimum physical activity and more stress are much prone to develop type-II diabetes. In present study maximum patients were belonging to urban area. It is well known that urbanization causes lifestyle modification which in turn increases the risk of metabolic disorders like type-II diabetes.

Probable mode of action *Triphaladi Vati* - *Triphaladi Vati* contains *Triphala*, *Haratak*i, *Guduchi*, *Shilajita* and *Lauha Bhasma*. Most of the Drugs contains *tikta-kashaya rasa*, *madhura vipaka* and *ushna veerya*. Drugs containing *Ruksha* and *laghu guna* are more than as compared to the drugs containing *snigdha* and *guru guna*. All of these Drugs are *agnideepana* and *amapachana, balya*, *rasayana* in nature. Many of them act on *kapha-pitaa*, *tridosha* and are able to alleviate them. Thus, formulation possesses *tridoshahara* property but specifically *Kapha-pittahara* property. It can alleviate vitiated *Meda* and *Kleda*. It has capacity to improve tone of *sapta-dhatus*. With the help of *agnideepana-amapachana* properties, *madhura vipaka* and *ushna veerya*, it can cause nourishment of *dhatus*. *Triphaladi Vati* helps to improve metabolism and thus can be effective in lowering signs and symptoms of the disease. *Shilajita* has its action on *Mutravaha Srotasa*. Other Drugs when combined with *Shilajita*, it acts as a vehicle for them to reach to the place of pathology developed in *Mutravaha Srotasa*.

Probable mode of action of *Mehamudgar vati* - *Mehamudgar vati* contains *rasanjana, vidlavan, devdaru, bilvaphala, gokshur, aanardana, chirayta*, *piparamool, trikatu, triphala, nishoth, lauha bhasma, guggul*. Most of the drugs contains *tikita katu kashya rasa*, *ushna veerya, katu vipak* and *laghu ruksha* properties. Due to *ushna veerya, katu vipak, tikshna, laghu guna* it acts as *agnideepan* which help in reliving the *agnimandya*. *Mehamudgar vati* has *ruksha, laghu, tikshna guna* which reduces the *picchilita* and *guruta* of *kapha dosha* and *meda dhatu* and helps in *kapha shaman*. Some of the content of the *mehamudgar vati* like *gokshur, anardana, shunti, haritaki* have *madhur vipak, shet veerya, rasayan* and *vrushya* properties hence plays role in rejuvenation by nourishing the *sapta dahtu* and thus increase the *dhatu bala* and *deha bala*.

CONCLUSION:

Prameha is a multifactorial metabolic disorder primarily involving Kapha dosha and Meda dhatu, often linked to sedentary lifestyle, stress, and urban living. Ayurvedic pathogenesis highlights roles of ama, agni, meda, and ojas in disease development. In the study, most patients were

middle-aged, urban dwellers with sedentary jobs, indicating lifestyle as a key factor in type-II diabetes onset. Triphaladi Vati is significantly effective in the management of prameha.Mehamugdar Vati is significantly effective in the management of prameha.Triphaladi Vati and Mehamugdar Vati are equally effective in the management of prameha.Triphaladi Vati and Mehamudgar Vati, with their agnideepana, amapachana, and tridoshahara properties, help improve metabolism, nourish dhatus, and target Mutravaha Srotasa, showing potential in managing Prameha effectively

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