Research Article

# To Evaluate the Clinical Efficacy of Palashapushpa Kwatha In Madhumeha W.S.R To DM Type 2

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## I N F O

## A B S T R A C T

Avaranajanya Madhumeha, which has been described in Ayurveda, has similarities with Type-2 Diabetes Mellitus. Globally, the number of diabetic people at present is 366 million, which is further expected to increase to 552 million in 2030. Data reveals the global number of pre-diabetic people is currently around 280 million, it is further expected to increase to 398 million in 2030. India is supposed to be the 'world diabetes capital' because Indians have a genetic predisposition to develop Diabetes mellitus in their genes, which is further precipitated by their lifestyle, etc.

Considering all these facts, there is a need for certain preparations and formulations that are effective, have minimal adverse effects, are easily available, can benefit the community at large. Palashapushpa Kwatha is a single drug formulation containing Palasha Pushpa, its phalashruthi mentions it to be very effective in all types of Prameha, including Madhumeha.

**Keywords:** Avaranajanya Madhumeha, Ayurveda, Prameha, Palashapushpa wath and Madhumeha

## Introduction

Madhumeha described in Indian classical texts has startling similarities in its maximum features with Diabetes Mellitus described in modern books; this will be made much clearer during the conceptual study of the disease. Diabetes mellitus is considered a major public health challenge in this era. Diabetes mellitus is a metabolic syndrome that is characterised by hyperglycemia, which may be either due to an absolute or relative lack of insulin. The global burden of diabetes is mostly contributed by its Type 2 diabetes subtypes, which make up about 80% to 95% of the total diabetic population. Statistical data by the International Diabetes Federation (IDF) reveals that about 285 million adults (20 years to 79 years old) were affected by diabetes in 2010. Without proper control and prevention, its prevalence will Further increase, reaching 438 million in 2030. About 70% of diabetic people live in developing countries; out of that, the largest numbers are in the Indian subcontinent and China. In spite of modern advancements in research in modern medicine, i.e., oral hypoglycemic agents and insulin, they have serious side effects and are unable to prevent long-term complications.[1]

In Shamana Chikitsa of Madhumeha, it is given that the Dravyas having Katu (Bitter), Tikta (pungent), Kashaya (astringent) Rasa, Katu Vipaka, Ushna Veerya, Shoshaka, Chedana properties have to be used. Palashapushpa Kwatha has Madhura (sweet), Katu (bitter), Tikta (astringent), Kashaya (pungent), rasa, Laghu, Ruksha Guna, Sheeta Virya

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(cold potency). Having specific Karmas like Trishnashamaka, Grahi, Kaphahara, Pittahara, Vatahara, Dahaprashamana These properties will remove Kapha Avarana from Vata and pacify the Dushyas like Meda and Kleda. Katakakhadiradi Kashaya has drugs containing Katu, Tikta, Kashaya Rasa, Ruksha and Laghu Guna, Ushna Veerya (hot potency), mostly Kapha Vatahara. It has specific Karmas like Chedana, Lekhana, Medoghna, Pramehahara. And hence helpful in the Samprapti Vighatana of Madhumeha.[2]

Hence, these two formulations were selected for the present study to evaluate their efficacy in the management of Madhumeha. The diagnosis of the disease Madhumeha was confirmed by the presence of signs and symptoms described in the classics along with the laboratory investigation, like blood sugar.

## Aims and Objectives

To evaluate the clinical efficacy of Palashapushpa Kwatha in the treatment of Madhumeha

## Material and Method

### Criteria for Diagnosis

Patients were diagnosed and selected for research on the basis of the classical Indian signs and symptoms of disease, Prameha, as per Ayurvedic texts.

After diagnosis, specific biochemical investigations [F.B.S., P.P.B.S., F.U.S., P.P.U.S.] were carried out. Patients who have a fasting blood sugar level of more than 126mg/dl and a postprandial blood sugar level of more than 200mg/dl were selected for this study. A detailed proforma consisting of signs and Symptoms, a complete history of the disease, Family history, Nidanas of the disease, Dashavidha pariksha, Ashtavidha pariksha was filled out for every patient to support the diagnosis of the disease.

In addition to this, the following laboratory investigations were carried out:

## Urine Routine and Microcsopic

Blood: Hb%, TLC, DLC, ESR

### Exclusion Criteria

Patients with Type 1 DM

Patients with Type 2 diabetes who were insulin dependent.

Patients above the age of 60 years

Patients with F.B.S. more than 300mg/dl and P.P.B.S. more than 400mg/dl Patients with severe diabetic complications like cardiovascular diseases, nephropathy, retinopathy Diabetes due to endocrinopathies, e.g., phaeochromocytoma, acromegaly, Cushing's syndrome, hyperthyroidism, etc.

Patients with certain genetic syndromes that are sometimes associated with diabetes mellitus (e.g., Down's syndrome, Klinefelter's syndrome, Turner's syndrome, etc.)

### Therapeutic Regimen

Selected patients were randomly divided into two groups. Patients receiving Triphaladi Vati were categorised in Group A, while those receiving Shilajitwadi Vati were categorised in Group B. Out of 24 patients, 12 belonged to Group A and 12 to Group B. In those patients who were taking some oral hypoglycemic agents, their blood sugar at that time was considered a basal level, the patients were advised to take the hypoglycemic drug in the same dose. The effect of the study drug was observed in relation to the basal records of symptoms and sugar levels. The study plan can be tabulated as below in Table 1.

### Diet and Exercise

Patients were advised to take the diet indicated for Prameha and to avoid hetu of Prameha. Modification of lifestyle according to 'Pathyavihara' was advised. Patients were encouraged to engage in regular, suitable exercise and advised to avoid 'Apathya' viharas.[3]

### Criteria for Assessment

Effect of the treatment was assessed by assessing- Signs and symptoms before and after treatment. FBS, PPBS and urine sugar levels before and after treatment.

For the assessment of the changes, scoring method was selected. Gradation of signs and symptoms and biochemical parameters was done and their score before treatment and after treatment was observed. Specific symptom score is as follows:

### Prabhuta Mutrata [Polyuria]:

**Table 1.Study Plan**

| Group | No. of patients | Drug | Dose | | Duration | Anupana |
|-------|-----------------|------|------|--|----------|---------|
| Group A | 12 | Triphaladi Vati | 750mg/day | in 3 divided doses | 8 weeks | Lukewarm water |
| Group B | 12 | Shilajitwadi Vati | 750mg/day | in 3 divided doses | 8 weeks | Lukewarm water |

**Table 2.Prabhuta Mutrata**

| Grade | Frequency Day | Frequency Night | Volume |
|-------|---------------|-----------------|--------|
| 0 | 3-5 | Rarely | Normal |

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| 1 | 6-9 | 1-2 | Excessive |
|---|-----|-----|-----------|
| 2 | 10-12 | 3-4 | Excessive |
| 3 | >12 | > 4 | Excessive |

## Avila Mutrata [Turbidity of Urine]

### Table 3.Avila Mutrata

| Grade | Turbidity |
|-------|-----------|
| 0 | Clear urine. |
| 1 | Slight cloudy or smoky (i.e. slight turbidity) |
| 2 | Turbidity clearly presents but news print can be read. |
| 3 | News print can not be read (more turbid). |

## Trishnadhikya [Polydipsia]

### Table 4.Trishnashikya

| Grade | Frequency | Amount of water |
|-------|-----------|-----------------|
| 0 | Normal | 1.5-2 lts |
| 1 | Increased but frequency of drinking can be controlled | 2-3 lts |
| 2 | Increased with frequency, uncontrolled | 3 > 4 lts |
| 3 | Very frequent water intake | > 4 lts |

## Gala-talu-shosha ( Dryness of mouth)

### Table 5.Gala-talu-shosha

| Grade | Shosha |
|-------|--------|
| 0 | No Shosha |
| 1 | Feeling of thirst off and on can be managed by simply a glass of water |
| 2 | Feeling of thirst is severe but can be managed by drinking sufficient amount of water |
| 3 | Severe feeling of thirst remains even after drinking water and very frequent feeling of thirst |

## Kshudhadhikya [Polyphagia]

### Table 6.Kshudhadhikya

| Grade | Main Meals | Light breakfast | Quantity |
|-------|-----------|-----------------|----------|
| 0 | 2 | 1 | Usual |
| 1 | 2 | 2-3 | Increased |
| 2 | 2 | 3-5 | Increased |
| 3 | 3 | 2-3 | Increased |

## Kara-pada-tala-daha (Burning sensation in hand & feet)

### Table 7.Kara-pada-tala-daha

| Grade | Daha |
|-------|------|
| 0 | No Daha |
| 1 | Mild to moderate sensation [occasional] |
| 2 | Moderate to severe [very often and regular activity not hampered] |
| 3 | Very severe [whole day and regular activity hampered] |

## Kara-pada-suptata (Numbness in hand & feet)

### Table 8.Kara-pada-suptata

| Grade | Supti |
|-------|-------|
| 0 | No Supti |
| 1 | Mild to moderate sensation occasional |
| 2 | Moderate to severe [very often and regular activity not hampered] |
| 3 | Very severe [whole day and regular activity hampered] |

## Daurbalya (General debility)

### Table 9.Daurbalya

| Grade | Daurbalya |
|-------|-----------|
| 0 | Can do routine work / exercise |
| 1 | Can do moderate exercise with hesitancy |
| 2 | Can do mild exercise only, with difficulty |
| 3 | Can't do mild exercise either |

## Pindikodweshtana (Cramps)

### Table 10.Pindikodweshtana

| Grade | Cramps |
|-------|--------|
| 0 | No Cramps |
| 1 | Cramps after walking 1 km |
| 2 | Cramps after walking ½-¼ km |
| 3 | Cramps during routine active work |

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## Associated Complaints

### Shithila Gatrata (Lethargy)

**Table 11.Shithila Gatrata**

| Grade | Routine activity | Lethargy |
|-------|------------------|----------|
| 0 | Normal | Without feeling Lethargy |
| 1 | Normal | With feeling Lethargy + |
| 2 | Disturbed | With feeling Lethargy ++ |
| 3 | Bed ridden patient | With feeling Lethargy +++ |

### Klaibya (Libido)

It is sexual desire and is considered only between the age of twenty to fifty six years (i.e., sexually active patient).

**Table 12.Klaibya**

| Grade | Sexual performance |
|-------|--------------------|
| 0 | Normal |
| 1 | Decreased frequency with normal performance |
| 2 | Decreased frequency with inefficiency in performing sex act |
| 3 | No sexual stimulation |

### Atisweda (Perspiration)

**Table 13.Atisweda**

| Grade | Sweda |
|-------|-------|
| 0 | Sweating after heavy work and fast movement or in hot weather |
| 1 | Profuse sweating after moderate work and movement |
| 2 | Sweating after little work and movement (stepping ladder etc.) |
| 3 | Profuse sweating after little work and movement |
| 4 | Sweating even at rest or in cold weather |

## Biochemical Parameters

Blood Sugar Level: Blood sugar level [BSL]- FBS≤125mg/dl and PPBS≤200mg/dl – were considered as base line. Improvement in blood sugar level of each patient was calculated by below mentioned formula-

Improvement in FBS ( %) = Total BT- Total AT × 100

Total BT -125

Improvement in PPBS ( %) = Total BT- Total AT × 100

Total BT - 200

Results obtained from individual patient were categorized according to following gradation pattern as shown in Table No 14 & Table 15.

**Table 14.Gradation Pattern of Blood Sugar Level**

| Grade | Assessment | Criteria |
|-------|------------|----------|
| 0 | No Improvement | Improvement in BSL < 25% or no change in BSL |
| 1 | Mild Improvement | Improvement in BSL ≥ 25% (up to 50%) |
| 2 | Moderate Improvement | Improvement in BSL ≥ 50% (up to 75%) |
| 3 | Marked Improvement | Improvement in BSL ≥ 75% |
| 4 | Control | Blood sugar level within normal range. |

## Urine Sugar

**Table 15.Gradation Pattern of Urine Sugar**

| Grade | Sugar |
|-------|-------|
| 0 | absent or trace |
| 1 | + |
| 2 | ++ |
| 3 | +++ |
| 4 | ++++ |

## Overall Effect of Therapy

Effects of both the therapies were assessed on the basis of two parameters.

Improvement in Signs and Symptoms

Improvement in Blood Sugar Level

### Improvement in Signs and Symptoms

Control: Complete relief in signs and symptoms.

Markedly Improved: ≥ 75% relief in signs and symptoms.

Moderately Improved: ≥ 50% relief in signs and symptoms.

Mildly Improved: Up to 25% relief in signs and symptoms.

No Improvement: < 25% relief in signs and symptoms.

### Improvement in Blood Sugar Level:

Analyzed by above mentioned gradation pattern for Blood Sugar Level.

Results obtained for each patient with the application of

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above mentioned formula indicate efficacy of the drug in reducing the blood sugar level as compared to standard level of BSL [in the form of percentage].

## Statistical Analysis

Clinical data gathered from patients was subjected for statistical analysis. Data was analyzed statistically in terms of Mean score, Percentage of relief, Standard Deviation (S.D.), Standard Error (S.E.) and 't' test. Paired 't' test was carried out at the level of 0.05, 0.01, 0.001 of 'P' value. Results were interpreted as-

$P<0.05$ Improvement

$P<0.01$ Significant improvement

$P<0.001$ Highly significant improvement

## Presentation of Data

Data collected from the patients was tabulated under following two sections.

General observations like age, sex, religion etc.

Results of therapy on the basis of changes in signs-symptoms and disease specific biochemical investigations.

## Observations

Observations of 24 patients are noted here and tabulated in Table 16.

**Table 17.Associated Signs and Symptoms observed in patients**

| Associated Signs and Symptoms | No. of patients A | No. of patients B | Total | Percentage |
|---|---|---|---|---|
| Asyamadhurya | 5 | 3 | 8 | 33.33 |
| Shithila gatrata | 10 | 9 | 19 | 79.16 |
| Tandra | 3 | 3 | 6 | 25.00 |
| Klama | 4 | 4 | 8 | 33.33 |
| Atisweda | 3 | 1 | 4 | 16.66 |
| Visra sharira gandha | 3 | 2 | 5 | 20.83 |
| Sheeta priyata | 5 | 1 | 6 | 25.00 |
| Shvasa | 4 | 3 | 7 | 29.16 |
| Shayyasa na-swapna sukhabhishanga | 8 | 8 | 16 | 66.66 |
| Klaibya | 1 | 1 | 2 | 08.33 |

**Table 16.Signs and Symptoms observed in patients[4,5,6]**

| Main Signs and Symptoms | No. of patients A | No. of patients B | Total | Percentage | Total | Percentage |
|---|---|---|---|---|---|---|
| Prabhuta mutrata | 10 | 10 | 20 | 83.33 | | |
| Avila mutrata | 4 | 6 | 10 | 41.66 | | |
| Kshudhadhikya | 8 | 1 | 9 | 37.5 | | |
| Trishnadhikya | 9 | 6 | 15 | 62.5 | | |
| Gal-talu shosha | 10 | 4 | 14 | 58.33 | | |
| Kara-pada-tala-daha | 5 | 3 | 8 | 33.33 | | |
| Kara-pada-suptata | 6 | 4 | 10 | 41.66 | | |
| Pindikodwesthana | 6 | 8 | 14 | 58.33 | | |
| Nisha mutrata [Nocturia] | 11 | 11 | 22 | 91.66 | | |
| Daurbalya | 9 | 9 | 18 | 75.00 | | |

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Table 16 indicates observations of Main Sign and Symptoms specific to Prameha.

### Table 18.Effect on Prabhuta Mutrata:

| Group | Mean Score | | % Relief | S.D. (±) | S.E. (±) | t | P |
|---|---|---|---|---|---|---|---|
| | B.T. | A.T. | | | | | |
| A (n=10) | 1.2 | 0.3 | 75 | 0.316 | 0.1 | 9.09 | <0.001 |
| B (n=10) | 1.2 | 0.4 | 66.66 | 0.42 | 0.13 | 6.01 | <0.001 |

Table 17 contains associated signs and symptoms observed in patients

## Efficacy of Both the Treatments

Main Signs and Symptoms of Prameha.

**Group A:**

The Table 18 show that mean initial score for Prabhuta mutrata was 1.2, which reduced to 0.3, showing 75% improvement. Statistical analysis shows that the improvement was highly significant at P < 0.001.

**Group B:**

Effect of Shilajitwadi Vati on Prabhuta mutrata reveals that B.T. mean score was 1.2 which reduced to 0.4 with 66.66% relief, giving 't' value of 6.01 which is highly significant at P < 0.001.

### Table 19.Effect on Avila Mutrata

| Group | Mean Score | | % Relief | S.D. (±) | S.E. (±) | t | P |
|---|---|---|---|---|---|---|---|
| | B.T. | A.T. | | | | | |
| A (n=4) | 1.25 | 1.25 | 0 | 0 | 0 | - | - |
| B (n=6) | 1.33 | 0.5 | 62.5 | 0.75 | 0.30 | 2.71 | <0.05 |

**Group A:**

Effect of therapy on Avila mutrata shows no improvement with unchanged mean(1.25).

**Group B:**

In this group, mean score before starting treatment was 1.33 which reduced to 0.5 with relief of 62.5% and calculated 't' value was 2.71 which shows improvement at P < 0.05.

### Table 20.Effect on Kshudhadhikya

| Group | Mean Score | | % Relief | S.D. | S.E. (±) | t | P |
|---|---|---|---|---|---|---|---|
| | (±) | S.E. | | | | | |
| (±) | t | P | 0 | 0 | 0 | - | - |
| | B.T. | A.T. | | | | | |
| A (n=8) | 1.25 | 0.12 | 90 | 0.64 | 0.22 | 4.96 | <0.01 |
| B (n=1) | 1 | 0.00 | 100 | - | - | - | - |

**Group A:**

The mean score for Kshudhadhikya was 1.25 in the beginning, which reduced to 0.12 at the end of treatment, showing 90% improvement. Statistical analysis shows that the improvement was significant giving 't' value 4.96.

**Group B:**

The mean initial score in this group was 1, which reduced to 0, showing 100% improvement.

### Table 21.Effect on Trishnadhikya

| Group | Mean Score | | % Relief | S.D. | S.E. (±) | t | P |
|---|---|---|---|---|---|---|---|
| | (±) | S.E. | | | | | |
| (±) | t | P | 0 | 0 | 0 | - | - |
| | B.T. | A.T | | | | | |
| A (n=8) | 1.75 | 0.62 | 64.28 | 0.35 | 0.12 | 9 | <0.001 |
| B (n=6) | 1.83 | 0.5 | 72.72 | 0.81 | 0.33 | 4 | <0.05 |

**Group A:**

Effect of Triphaladi Vati on Trishnadhikya reveals that B.T. mean score was 1.75 which reduced to 0.62 with 64.28% relief, giving 't' value of 9 which is highly significant at P < 0.001.

**Group B:**

In this group, mean score reduced to 0.5 from initial mean score of 1.83 providing 72.72% relief and giving 't' value of 4 which shows improvement at P<0.05.

### Table 22.Effect on Kara-pada-tala-daha

| Group | Mean Score | | % Relief | S.D. | S.E. (±) | t | P |
|---|---|---|---|---|---|---|---|
| | (±) | S.E. | | | | | |
| (±) | t | P | 0 | 0 | 0 | - | - |
| | B.T. | A.T | | | | | |
| A (n=8) | 1.625 | 0.5 | 69.23 | 0.64 | 0.22 | 4.96 | <0.01 |
| B (n=6) | 1 | 0.5 | 50 | 0.54 | 0.22 | 2.23 | >0.05 |

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**Group A :**

Effect on Kara-pada-tala-daha by this therapy was 69.23%. The initial mean score was 1.62 which decreased to 0.5 after treatment giving 't' value of 4.96 which is significant at P<0.01.

**Group B :**

Here mean scores before and after treatment were 1 and 0.5 respectively. It showed 50% relief with 't' value 2.23 which is insignificant at P>0.05.

**Table 23.Effect on Kara-pada-suptata**

| Group | Mean Score | | % Relief | S.D. | S.E. (±) | t | P |
|---|---|---|---|---|---|---|---|
| | (±) | S.E. | | | | | |
| (±) | t | P | 0 | 0 | 0 | - | - |
| | B.T. | A.T | | | | | |
| A (n=6) | 1.33 | 0.5 | 62.5 | 0.41 | 0.16 | 5 | <0.01 |
| B (n=4) | 1.75 | 0.25 | 85.71 | 0.57 | 0.28 | 5.19 | <0.05 |

**Group A :**

Kara-pada-suptata mean score drop to 0.5 from 1.33 providing 62.5% relief and 't' value of 5 with significant relief at P<0.01.

**Group B:**

Reduction in mean score was 0.25 from 1.75 indicating 85.71% relief in kara-pada-tala-suptata giving 't' value of 5.19 which shows improvement at P<0.05.

**Table 24.Effect on Pindikodweshtana**

| Group | Mean Score | | % Relief | S.D. | S.E. (±) | t | P |
|---|---|---|---|---|---|---|---|
| | (±) | S.E. | | | | | |
| (±) | t | P | 0 | 0 | 0 | - | - |
| | B.T. | A.T | | | | | |
| A (n=6) | 2 | 0.66 | 66.66 | 0.52 | 0.21 | 6.32 | <0.01 |
| B (n=9) | 2.11 | 0.77 | 63.15 | 0.5 | 0.16 | 8 | <0.001 |

**Group A:**

Here mean score drop from 2 to 0.66 post therapeutically with 66.66% relief giving 't' value of 6.32 which is significant at P<0.01.

**Group B:**

Effect on Pindikodweshtana by this therapy was 63.15%. The initial mean score was 2.11 which decreased to 0.77 after

treatment giving 't' value of 8 which is highly significant at P<0.001.

**Table 25.Effect on F.B.S.**

| Group | Mean Score | % Relief | S.D. (±) | S.E. (±) | t | P |
|---|---|---|---|---|---|---|
| A (n=12) | 2.66 | 66.66 | 1.72 | 0.49 | 5.35 | <0.001 |
| B (n=12) | 2.08 | 52.08 | 1.67 | 0.48 | 4.33 | <0.01 |

## Blood Sugar Levels

**Group A :**

Mean score of improvement in F.B.S. in Triphaladi Vati Group, calculated by formula, was 2.66 which shows 66.66% relief giving 't' value of 5.35 which is highly significant ( P<0.001).

**Group B :**

Mean score of improvement in P.P.B.S. in Shilajitwadi Vati Group, calculated by formula, was 2.08 which shows 52.08% relief giving 't' value of 4.33 which is significant ( P<0.01).

**Table 26.Effect on P.P.B.S.**

| Group | Mean Score | % Relief | S.D. (±) | S.E. (±) | t | P |
|---|---|---|---|---|---|---|
| A (n=12) | 2.66 | 66.66 | 1.72 | 0.49 | 5.35 | <0.001 |
| B (n=12) | 2.08 | 52.08 | 1.67 | 0.48 | 4.33 | <0.01 |

**Group A :**

Mean score of improvement in P.P.B.S. in Triphaladi Vati Group, calculated by formula, was 2.66 which shows 66.66% relief giving 't' value of 5.54 which is highly significant ( P<0.001).

**Group B :**

Mean score of improvement in P.P.B.S. in Shilajitwadi Vati Group, calculated by formula, was 1.83 which shows 45.83% relief giving 't' value of 3.52 which is significant ( P<0.01).

## Urine Sugar Levels

**Table 27.Effect on F.U.S.**

| Group | Mean Score | | % Relief | S.D. | S.E. | t | P |
|---|---|---|---|---|---|---|---|
| | B.T. | A.T | | | | | |
| A (n=12) | 1.83 | 0.58 | 68.18 | 1.28 | 0.37 | 3.36 | <0.01 |
| B (n=12) | 1.5 | 0.91 | 38.88 | 0.79 | 0.22 | 2.54 | <0.05 |

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**Group A :**

Initial F.U.S. mean score was 1.83 which decreased to 0.58 providing 68.18% relief with 't' value of 3.36 which is significant at P<0.01.

**Group B :**

Effect of Shilajitwadi Vati on F.U.S. shows that before treatment mean score was 1.5 which reduced to 0.91 with 38.88% relief, giving 't' value of 2.54 which shows improvement at P<0.05.

**Table 28.Effect on P.P.U.S**

| Group | Mean Score | | % Relief | S.D. | S.E. | t | P |
|---|---|---|---|---|---|---|---|
| | B.T. | A.T | | | | | |
| A (n=12) | 3.08 | 1.83 | 40.54 | 1.35 | 0.39 | 3.19 | <0.01 |
| B (n=12) | 2.83 | 2.08 | 26.47 | 0.96 | 0.27 | 2.70 | <0.05 |

**Group A :**

In Triphaladi Vati Group, initial P.P.U.S. mean score of 3.08 which decreased to 1.83 providing 40.54% relief with 't' value of 3.19 which is significant at P<0.01.

**Group B :**

Effect of Shilajitwadi Vati on P.P.U.S. shows that before treatment mean score was 2.83 which reduced to 2.08 with 26.47% relief, giving 't' value of 2.70 which shows improvement at P<0.05.

## Comparative Effect on Main Signs and Symptoms

**Table 29**

| Main Signs & Symptoms | % R | ELIEF |
|---|---|---|
| | GROUP A | GROUP B |
| Prabhuta mutrata | 75.00 | 66.66 |
| Avila mutrata | 0.00 | 62.5 |
| Trishadhikya | 64.28 | 72.72 |
| Gala-talu-shosha | 70.58 | 80.00 |
| Karapadadaha | 67.23 | 50.00 |
| Karapadasupti | 62.5 | 85.71 |
| Pindikodwestan | 66.66 | 63.15 |
| Nisha mutrata (Nocturia) | 52.38 | |

## Overall Effect of Therapy

**Table 30.Overall Effect of Therapy**

| Results | GROU | P A | GROUP B | |
|---|---|---|---|---|
| | Patients | % | Patients | % |
| Controlled | 0 | 0.00 | 1 | 8.33 |
| Marked Improvement | 5 | 41.66 | 1 | 8.33 |
| Moderate Improvement | 5 | 41.66 | 8 | 66.66 |
| Improvement | 2 | 16.66 | 2 | 16.66 |
| Unchanged | 0 | 0.00 | 0 | 0.00 |

**Group A :**

In Triphaladi Vati group, no patient was assessed as controlled. Marked Improvement was seen in 5 patients (41.66%) whereas Moderate Improvement was observed in 5 patients (41.66%). Mild Improvement was seen in 2 patients (16.66%). No patient assessed as unchanged.

**Group B :**

In Shilajitwadi vati group, 1 patient (8.33%) assessed as controlled and 1 patient (8.33%) as Markedly Improved. Moderate Improvement was seen in 8 patients (66.66%) whereas Mild Improvement was observed in 2 patients (16.66%). All patients responded to treatment to some extent and no patient assessed as unchanged.

**Group A :**

In this group, control in F.B.S. and in P.P.B.S. was achieved by 6 patients (50%). In 2 patients (16.66%), Marked Improvement was seen in F.B.S. and in P.P.B.S. Moderate Improvement in F.B.S. was observed in 1 patient (8.33%), no patient showed Moderate Improvement in P.P.B.S. Mild Improvement in P.P.B.S. was seen in 2 patients (16.66%) while no patient obtained this grade in F.B.S.. F.B.S of 3 patients (25%) and P.P.B.S. of 2 patients (16.66%) remained unchanged.

**Group B :**

Control in F.B.S. was achieved by 3 (25%) patients and that of in P.P.B.S. by 4 patients (33.33%). Marked Improvement in F.B.S. was observed in 3 patients (25%) while no patient for P.P.B.S. was categorized under this grade. Moderate Improvement in F.B.S. and in P.P.B.S. was observed in 2 (16.66%) and 3 (25%) patients respectively. No patient assessed as Mildly Improved. F.B.S of 4 patients (33.33%) and P.P.B.S. of 5 patients (41.66%) remained unchanged.

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**Table No 30a.Improvement In Blood Sugar Level**

| Results | GROUP A | | | | GROUP B | | | |
|---|---|---|---|---|---|---|---|---|
| | F.B.S. | | P.P.B.S. | | F.B.S. | | P.P.B.S. | |
| | Patients | % | Patients | % | Patients | % | Patients | % |
| Controlled | 6 | 50.00 | 6 | 50.00 | 3 | 25 | 4 | 33.33 |
| Marked Improvement | 2 | 16.66 | 2 | 16.66 | 3 | 25 | 0 | 0.00 |
| Moderate Improvement | 1 | 8.33 | 0 | 0.00 | 2 | 16.66 | 3 | 25 |
| Improvement | 0 | 0.00 | 2 | 16.66 | 0 | 0.00 | 0 | 0.00 |
| Unchanged | 3 | 25.00 | 2 | 16.66 | 4 | 33.33 | 5 | 41.66 |

## Discussion

In an effort to find out effective remedy which will be helpful to both of these categories of patients, two drugs- Triphaladi Vati and Shilajitwadi Vati were selected for this study. A comparative study of both the drugs was carried out. Both these drugs are indicated for the treatment of Prameha in Ayurvedic classics. Study was carried out in two groups consisting total 24 patients as:

Group A- Triphaladi Vati- 12 patients

Group B- Shilajitwadi Vati- 12 patients

Results of the treatment were assessed over the period of 8 weeks. On the basis of clinical study of observations and, effect of treatment on signs & symptoms, bio-chemical parameters, following discussion is put forth.

**Overall Effect of Therapy :** It is shown via Graph No 01 to Graph No 2.

### Improvement In Signs and Symptoms

In Triphaladi Vati group, 0.00% patients were assessed as Controlled, 41.66% patients provided Marked Improvement, Moderate Improvement was observed in 41.66% of cases, 16.66% cases showed Mild Improvement in diseased condition and 0.00% cases obtained grade-Unchanged.

In Shilajitwadi Vati Group, 8.33% patients obtained Control over diseased condition. Marked Improvement was seen in 8.33% patients. 66.66% of cases presented Moderate Improvement and 16.66% were categorized as Mildly Improved after the treatment. 0.00% patients were under grade Unchanged.

### Improvement In Blood Sugar Level

Assessment of each patient in this study was done by taking in to consideration Blood sugar levels of fastings and post prandial;. values separately as both the values have their own significance.

In Triphaladi Vati group, 50.00% of total cases obtained Control grade in their F.B.S. as well P.P.B.S. values while 16.66% showed Marked Improvement in both values. Moderate Improvement in F.B.S. was observed in 8.33% cases and 0.00% in that of P.P.B.S. Mild Improvement in P.PB.S. was seen in 16.66% cases and 0.00% in F.B.S. In 25.00% and 16.66% cases F.B.S. and P.P.B.S. values remained unchanged.[7]

In Group B, 25% patients obtained Control in F.B.S. value. Marked Improvement in F.B.S. was seen in 25% cases and that of in P.P.B.S. was seen in 0.00% cases. Moderate Improvement in F.B.S. and P.P.B.S. was seen in 16.66% and 25% cases respectively. No patient obtained Mild Improvement grade either in F.B.S. or in P.P.B.S.. F.B.S. of 33.33% patients and P.P.B.S. of 41.66% patients remained unchanged.[8]

Results indicate that the patients of Group A i.e. of Triphaladi Vati group showed better results both, in case of Signs and Symptoms and in Blood Sugar Level, than Shilajitwadi Vati. It is because Triphaladi Vati has better agnideepana and amapachana property than Shilajitwadi Vati. Moreover, it encourages dhatwagni and bhutagni paka better than Shilajitwadi Vati due to presence of higher tikta-katu rasa in it. Triphaladi Vati has better Pittashamaka property than Shilajitwadi Vati. In present study, most of the cases visited hospital after some years of the occurance of disease. At this period, generally Prameha acquires Pittaja dominance in pathology. For this reason, Triphaladi Vati may have shown better results than Triphaladi Vati.

In present study, some patients were taking some oral hypoglycemic agents [OHAs] and still were having high blood sugar level despite of their high dose. This therapy helped to improve their BSL nearer to standard level. In some patients gradual dose reduction of OHA made possible with the help of this therapy.[9]

Many patients were in favor of taking only Ayurvedic treatment and got better results too by this therapy. It was observed that, some patients who were taking OHAs since longer period, had abruptly discontinued them as soon as this treatment was started without informing. In

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such patients, no satisfactory results in sugar level were observed despite of better symptomatic relief.[10]

## Conclusion

Triphaladi Vati and Shilajitwadi Vati both provided fairly good results in improving Signs and Symptoms. Both drugs found to have role in improving levels of F.B.S. and P.P.B.S. and are effective in decreasing their deviation from the normal range. In Triphaladi Vati group better results were obtained as compared to Shilajitwadi Vati.

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